

DBMS Consulting Overview,
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 TMS Dictionary Updating issues.
- Present an overview of functionality for Generic TMS Dictionary Updater Tool.
- Briefly 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.



Overview DBMS Consulting (2)

- Core group of consultants and part-time specialists in several technical areas, about 12 members total for both Oracle ERP/CRM and OPA.
- Started in May 1997 with a customised software development project for SF-36 data.
- Headquartered in New York, with an office in Southern CA.
- All full-time staff travel extensively to client sites and are usually on-call 24-hours.



Overview DBMS Consulting (3)

- DBMS Consulting currently maintains a long-term presence in several companies.
- Additionally, remote support 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 and Medical Device Companies.



Overview DBMS Consulting (4)

- 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)

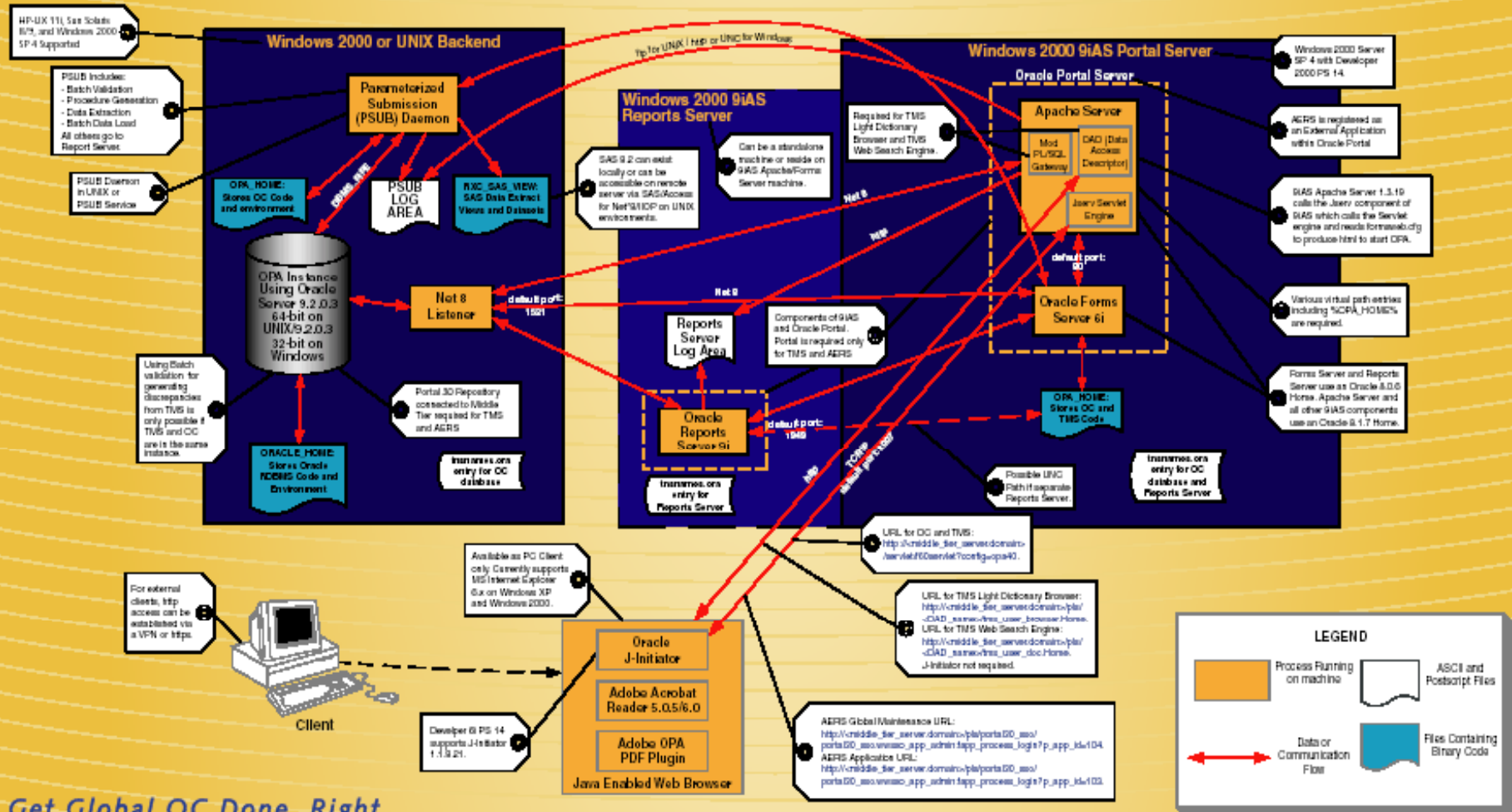
- Tremendous technical expertise in Oracle, with most members of DBMS having an Oracle DBA or Development background in either the Pharmaceutical or Financial sector.
- Typically, we are called to solve the most difficult technical issues or to offer strategic implementation advise.
- Created a series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



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Oracle Pharmaceutical Applications 4.5 3-Tier Configuration



Get Global OC Done. Right.



Other OPA-Related Products and Services

- Developing an automated testing tool for the OPA, called OPA-Tester.
- Working with Torsten Adam and PharmaSOL to develop and market the Generic TMS Dictionary Updater.
- 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.
- Full set of Validation test cases for Oracle AERS
- Custom development and integration with other 3rd party tools.
- Flat-rate customized functional and technical OPA training.
- Technical recruiting for Oracle-related requirements
- SF-36 tool for Cardiac Rehabilitation centers in the US.



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 Virtual Dictionary Creation and the update to the base dictionary need to occur on the same calendar day.



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



Updating a TMS dictionary using the TMS Dictionary Updater

- Identify the new source data for an update (such as MedDRA 6.1 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.



Test case example with MedDRA 6.0 to MedDRA 6.1 data

- Using a subset of the MedDRA 6.1 update from 6.0, we have created a set of walk-through screen shots of a MedDRA update using the Generic TMS Dictionary Updater
 - New LLTs
 - Conjunctival Swelling (LLT 10060702) linked to PT Conjunctival Oedema (PT 10010726)
 - Telangiosis (LLT 10060714) linked to PT Capillary Disorder NOS (10007190)
 - LLTs which become Non-Current
 - Colour Vision Deficiencies (LLT 10010054)
 - Raised Liver Enzymes (LLT 10037823)



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OPA (Op Apps - OP5\$OPAPP5 at OPA40 on 06-SEP-2003)

Action Move Clear Data Query Special Workflow Help Window



INITIAL LOG-IN AND FIRST-PASS ENTRY (Study: QASTUDY1)

Doc#	S28329	Status	COMPLETE		
Patient	1111	DCI Name	MEDUPD	MEDUPD	
DCI Date	06-09-2003				
Event	BASELINE 1	Visit#	1	Sub #	0
Site	QASITE1	Investigator	QAINV1		
Comment					Blank?
1	of 1	DCM	MEDU	Subset	AE
				Layout	1
				Blank?	N
				Status	COMPLETE

Page 1 of 1, Repeat 2 of 4.

LLT Term	LLT Code	PT Code	HLT Term	HLGT
COLOUR VISION DEFICIENCIES				
RAISED LIVER ENZYMES				
CONJUNCTIVAL SWELLING				
TELANGLOSIS				



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OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003)

Action Move Clear Data Query Special Workflow Help Window

BROWSE (Study: QASTUDY1)

Doc# S28329 Status PASS 2 COMPLETE

Patient 1111 DCI Name MEDUPD MEDUPD

DCI Date 06-09-2003

Event BASELINE 1 Visit# 1 Sub # 0

Site QASITE1 Investigator QAINV1 DCI Book Page#

Comment Blank?

1 of 1 DCM MEDU Subset AE Layout 1 Blank? N Status PASS 2 COMPLETE

Page 1 of 1, Repeat 1 of 4.

LLT Term	LLT Code	PT Code	HLT Term	HLGT
COLOUR VISION DEFICIENCIES	10010054	COLOUR BLINDNESS NOS	OCULAR DISORDERS CONGENITAL NEC	EYE DISORDERS CONGENITAL
RAISED LIVER ENZYMES	10037823	LIVER FUNCTION TEST ABNORMAL	LIVER FUNCTION ANALYSES	HEPATOBIILIARY INVESTIGATIONS
CONJUNCTIVAL SWELLING				
TELANGLOSIS				



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Classify VT Omissions (MEDDRA_DOM - MedDRA)

Distinct Verbatim Term Omissions | All Verbatim Term Omissions

Verbatim Term	Search	DictionaryTerm
CONJUNCTIVAL SWELLING		Swelling
TELANGLOSIS		

Filter All Systems

Classifications | Actions

Global? VTA SubType: Accepted Comment:

Classify VT

Query: Standard Search Type: Open Query Dictionary Term: Level:

Term	Id	Level	Code	Alt Code	Appr?
Swelling	59854	LLT	10042674	6.0	<input checked="" type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>



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OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003) ORACLE

Action Move Clear Data Query Special Workflow Help Window

BROWSE (Study: OASTUDY1)

Doc# S28329 Status PASS 2 COMPLETE

Patient 1111 DCI Name MEDUPD MEDUPD

DCI Date 06-09-2003

Event BASELINE 1 Visit# 1 Sub # 0

Site QASITE1 Investigator QAINV1 DCI Book Page#

Comment Blank?

1 of 1 DCM MEDU Subset AE Layout 1 Blank? N Status PASS 2 COMPLETE







Page 1 of 1, Repeat 1 of 4.

LLT Term	LLT Code	PT Code	HLT Term	HLGT	SOC Te
COLOUR VISION DEFICIENCIES	10010054	COLOUR BLINDNESS NOS	OCULAR DISORDERS CONGENITAL NEC	EYE DISORDERS CONGENITAL	CONGE
RAISED LIVER ENZYMES	10037823	LIVER FUNCTION TEST ABNORMAL	LIVER FUNCTION ANALYSES	HEPATOBIILIARY INVESTIGATIONS	INVEST
CONJUNCTIVAL SWELLING	10042674	SWELLING NOS	SOFT TISSUE DISORDERS NEC	MUSCULOSKELETAL AND CONNECTIVE TIS	MUSCLU
TELANGLOSIS					

Record: 1/1 ... <OSC>



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Name ▲	Size	Type
 psi_dictupg_addterms.rep	216 KB	REP File
 psi_dictupg_declassify.rep	180 KB	REP File
 psi_dictupg_tmspool.plb	95 KB	PLB File
 psi_dictupg_tmspool.pls	7 KB	PLS File
 psi_setup.sql	1 KB	SQL File
 PSIDICT.fmx	111 KB	FMX File



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pharmasol.de Generic TMS Dictionary Updater v0.9

Page 1: Prepare PREDICT tables

Predict Group then... Dictionary

Choose Options...

Update ALL DICT_CONTENT_ALT_CODE

...with PREDICT value

Display optional Report...

Display Unapproved Terms in Reports

 1/2

Log

Log file: c:\tmp

This computer program is protected by copyright law and international treaties

Record: 1/1



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psi_dictupg_addterms: Previewer

File View Help



Dictionary Upgrade Added Terms

Listed Dictionary: MEDDRA

(Migrating from version 6.0 to 6.1)

List Unapproved Terms: No

<u>New term</u>	<u>New code</u>	<u>New Level</u>
Conjunctival Swelling	10060702	LLT
Telangiosis	10060714	LLT



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psi_dictupg_addterms: Previewer

File View Help

Page: 1

pharma) SOL solutions for the pharmaceutical industry

Dictionary Upgrade Added Terms

Listed Dictionary: MEDDRA
(Migrating from version 6.0 to 6.1)
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
CONJUNCTIVAL SWELLING	MEDDRA_DOM	Conjunctival Swelling	10060702	Swelling	10042674



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pharmasol.de **Generic TMS Dictionary Updater v0.9**

Page 1: Prepare PREDICT tables

Predict Group then... Dictionary

Choose Options...

Update ALL DICT_CONTENT_ALT_CODE

...with PREDICT value


Display optional Report...

Display Unapproved Terms in Reports

 1/2

Log

Question

 Do you really want to run this job?

Log file: C:\dbms\meddra\meddra61_update_subset\load

This computer program is protected by copyright law and international treaties

Record: 1/1



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Dictionary Maintenance in Progress

Executing...

	Job Status	Progress
Updating IDs	STARTED	5.61 %
Insert DELETES into CONTENTS	WAITING	0.00 %
Insert DELETES into RELATIONS	WAITING	0.00 %
Delete redundant CONTENTS	WAITING	0.00 %
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

Dictionary Updater v0.9

Dictionary: MEDDRA

Show optional Report...

List ALL new verbatim terms

List new Automatches for VTAs

Unapproved Terms in Reports

Prepare PREDICT

Log

```
Upgrading Dictionary MEDDRA from version 6.0 to version 6.1.  
PREDICT processing started at 06-SEP-2003 16:56  
STEP10 entered with Job ID 30  
STEP10 started at 06-SEP-2003 16:56:41
```

Log file: C:\dbms\meddra\meddra61_update_subset\load\upd_MEDDRA

Change Location



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Please visit the webpage <http://www.pharmasol.de> for further information

Window: Dictionary Maintenance in Progress

Executing...

	Job Status	Progress
Updating IDs	COMPLETED	100.00 %
Insert DELETES into CONTENTS	COMPLETED	100.00 %
Insert DELETES into RELATIONS	STARTED	100.00 %
Delete redundant CONTENTS	WAITING	0.00 %
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

STEP10 completed at 06-SEP-2003 17:58:24
PREDICT IDs successfully updated! 0 PREDICT Records processed.
STEP20 entered with Job ID 60
STEP20 started at 06-SEP-2003 17:59:14
STEP20 completed at 06-SEP-2003 17:59:19
DEL statements successfully inserted into PREDICT_CONTENTS! 0 PREDICT Records processed.

Log file: C:\dbms\meddra\meddra61_update_subset\load\upd_MEDDRA Change Location

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Window: Dictionary Maintenance in Progress

Executing...

	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

STEP10 completed at 06-SEP-2003 17:58:24
PREDICT IDs successfully updated! 0 PREDICT Records processed.
STEP20 entered with Job ID 60
STEP20 started at 06-SEP-2003 17:59:14
STEP20 completed at 06-SEP-2003 17:59:19
DEL statements successfully inserted into PREDICT_CONTENTS! 0 PREDICT Records processed.

Log file: C:\dbms\meddra\meddra61_update_subset\load\upd_MEDDRA Change Location

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Window: Dictionary Maintenance in Progress

Executing...

	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	COMPLETED	100.00 %
Delete redundant RELATIONS	COMPLETED	100.00 %
Identify UPDATES	COMPLETED	100.00 %
Run Declassification Report	ENTERED	0.00 %
Update dict. version in prod. tables.	WAITING	0.00 %

Cancel

Log file: C:\dbms\meddra\meddra61_update_subset\load\upd_MEDDRA

Change Location

STEP10 completed at 06-SEP-2003 17:58:24
PREDICT IDs successfully updated! 0 PREDICT Records processed.
STEP20 entered with Job ID 60
STEP20 started at 06-SEP-2003 17:59:14
STEP20 completed at 06-SEP-2003 17:59:19
DEL statements successfully inserted into PREDICT_CONTENTS! 0 PREDICT Records processed.

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psi_dictupg_declassify: Previewer

File View Help

Page: 1

pharma)SOL
solutions for the
pharmaceutical industry

Dict. Upgrade VTA Declassifications

Dictionary: MEDDRA
Migrating from version 6.0 to 6.1

Declassified Verbatim Terms	Domain	Declass. Reason
COLOUR VISION DEFICIENCIES	MEDDRA_DOM	TERM DELETED
CONJUNCTIVAL SWELLING	MEDDRA_DOM	NEW AUTOMATCH
RAISED LIVER ENZYMES	MEDDRA_DOM	TERM DELETED



OCUG Chicago 2003: DBMS Consulting Demo with Generic TMS Dictionary Updater Tool

The screenshot shows a 'Dictionary Maintenance in Progress' dialog box with a progress table. Below the table is a 'Cancel' button. A 'Question' message box is overlaid on top, stating 'PREDICT tables processing completed. Check log file for error messages.' with an 'OK' button. The background application window shows various buttons like 'Log file', 'Change Location', and 'PREDICT'.

	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	COMPLETED	100.00 %
Delete redundant RELATIONS	COMPLETED	100.00 %
Identify UPDATES	COMPLETED	100.00 %
Run Declassification Report	COMPLETED	100.00 %
Update dict. version in prod. tables.	WAITING	0.00 %

Log file: C:\dbms\meddra\meddra61_update_subset\load\upd_MEDDRA

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```
upd_MEDDRAPP2_200309061954.log - Notepad
File Edit Search Help
Upgrading Dictionary MEDDRAPP2 from version 60 to version 60.
PREDICT processing started at 06-SEP-2003 19:54
STEP10 entered with Job ID 830
STEP10 started at 06-SEP-2003 19:55:34
STEP10 completed at 06-SEP-2003 20:40:59
PREDICT IDs successfully updated! 58571 PREDICT Records processed.
STEP20 entered with Job ID 840
STEP20 started at 06-SEP-2003 20:42:01
STEP20 completed at 06-SEP-2003 20:42:51
DEL statements successfully inserted into PREDICT_CONTENTS! 555 PREDICT Records processed.
STEP30 entered with Job ID 850
STEP30 started at 06-SEP-2003 20:44:08
STEP30 completed at 06-SEP-2003 20:46:29
DEL statements successfully inserted into PREDICT_RELATIONS! 3857 PREDICT Records processed.
STEP40 entered with Job ID 860
STEP40 started at 06-SEP-2003 20:47:00
STEP40 completed at 06-SEP-2003 20:58:58
58311 redundant records in PREDICT_CONTENTS successfully deleted! CREATED_BY statement set
to pharmaSol.
STEP50 entered with Job ID 870
STEP50 started at 06-SEP-2003 20:59:11
STEP50 completed at 06-SEP-2003 21:15:38
110090 redundant records in PREDICT_RELATIONS successfully deleted! CREATED_BY statement set
to pharmaSol.
STEP60 entered with Job ID 880
STEP60 started at 06-SEP-2003 21:15:55
STEP60 completed at 06-SEP-2003 21:15:58
166 UPD statements in PREDICT CONTENTS successfully updated!
STEP70 entered with Job ID 890
STEP70 started at 06-SEP-2003 21:16:06
STEP70 completed at 06-SEP-2003 21:16:43
Declassification Report execution completed.
PREDICT processing completed successfully.
STEP80 entered with Job ID 900
```



OCUG Chicago 2003: DBMS Consulting Demo with Generic TMS Dictionary Updater Tool

pharmasol.de Generic TMS Dictionary Updater v0.9

Page 2: Activate Terms

Predict Group then... Dictionary

Press the button 'Activate' if you want to run the activation job to move the data from the PREDICT tables into the productive DICT tables.
Choose with the following tick box whether you want to run a testactivation first.

Run Activation in TEST mode?

Display optional Report...

Display Unapproved Terms in Reports

 2/2

Log

```
0 redundant records in PREDICT_RELATIONS successfully deleted! CREATED_BY
statement set to pharmasol.
STEP60 entered with Job ID 170
STEP60 completed at 06-SEP-2003 18:37:32
2 UPD statements in PREDICT_CONTENTS successfully updated!
STEP70 entered with Job ID 180
STEP70 started at 06-SEP-2003 18:37:54
STEP70 completed at 06-SEP-2003 18:40:14
Declassification Report execution completed.
PREDICT processing completed successfully.
```

Record: 1/1



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pharmasol.de Generic TMS Dictionary Updater v0.9

Page 2: Activate Terms

Predict Group then... Dictionary

Press the button 'Activate' if you want to run the activation job to move the data from the PREDICT tables into the productive DICT tables.
Choose with the following tick box whether you want to run a testactivation first.

Run Activation in TEST mode?

Display optional Report...

Display Unapproved Terms in Reports

 2/2

Log

```
0 redundant records in PREDICT_RELATIONS successfully deleted! CREATED_BY
statement set to pharmasol.
STEP60 entered with Job ID 170
STEP60 completed at 06-SEP-2003 18:37:32
2 UPD statements in PREDICT CONTENTS successfully updated!
STEP70 entered with Job ID 180
STEP70 started at 06-SEP-2003 18:37:54
STEP70 completed at 06-SEP-2003 18:40:14
Declassification Report execution completed.
PREDICT processing completed successfully.
```

Record: 1/1

Click Help Topics on the Help Menu.



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OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003) ORACLE

Action Move Clear Data Query Special Workflow Help Window

BROWSE (Study: QASTUDY1)

Doc# S28329 Status PASS 2 COMPLETE

Patient 1111 DCI Name MEDUPD MEDUPD

DCI Date 06-09-2003

Event BASELINE 1 Visit# 1 Sub # 0

Site QASITE1 Investigator QAINV1 DCI Book Page#

Comment Blank?

1 of 1 DCM MEDU Subset AE Layout 1 Blank? N Status PASS 2 COMPLETE

Page 1 of 1, Repeat 1 of 4. <Univ>

LLT Term	LLT Code	PT Code	HLT Term	HLGT	SOC Tr
COLOUR VISION DEFICIENCIES					
RAISED LIVER ENZYMES					
CONJUNCTIVAL SWELLING	10060702	CONJUNCTIVAL OEDEMA	CONJUNCTIVAL INFECTIONS, IRRITATIONS	OCULAR INFECTIONS, IRRITATIONS AND INF	EYE D
TELANGIOSIS	10060714	CAPILLARY DISORDER NOS	NON-SITE SPECIFIC VASCULAR DISORDERS	VASCULAR DISORDERS NEC	VASC

Record: 1/1 ... <OSC>



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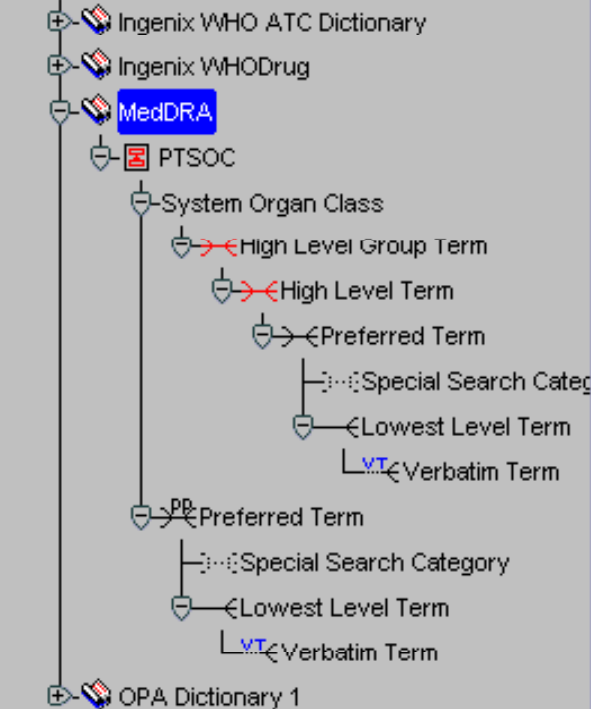
OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003)

File Edit Query Navigate Record Window Help



Define Dictionaries

Dictionaries



Base Dictionary

Virtual Dictionary

Dictionary Link

Informative Notes

Short Name

Name

Description

Status

Cut-off Date

Audit Information

Created By Creation Time

Modified By Modification Time



OCUG Chicago 2003: DBMS Consulting Demo with Generic TMS Dictionary Updater Tool

OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003)

Action Move Clear Data Query Help Window

Maintain Domain Elements

TMS Domain Elements

Project Domain Elements

TMS Domain Elements for Study - QASTUDY1

Global			Local	
TMS Dictionary Short Name	TMS Domain	Coding Dictionary?	TMS Dictionary Short Name	TMS Domain
OPADIC1	OPADOM1	<input checked="" type="checkbox"/>		
MEDDRA60	MEDDRA60	<input checked="" type="checkbox"/>		
		<input type="checkbox"/>		
		<input type="checkbox"/>		
		<input type="checkbox"/>		
		<input type="checkbox"/>		
		<input type="checkbox"/>		
		<input type="checkbox"/>		

Back Save

Elements assigned to project QAPROJ1

TMS Dictionary Short Name	TMS Domain

- Repository Maintenance
- VTA Maintenance
- Omission Management



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OPA (Op Apps - OPS\$OPAPPS at OPA40 on 06-SEP-2003) ORACLE

Action Move Clear Data Query Special Workflow Help Window

BROWSE (Study: QASTUDY1)

Doc# S28329 Status PASS 2 COMPLETE

Patient 1111 DCI Name MEDUPD MEDUPD

DCI Date 06-09-2003

Event BASELINE 1 Visit# 1 Sub # 0

Site QASITE1 Investigator QAINV1 DCI Book Page#

Comment Blank?

1 of 1 DCM MEDU Subset AE Layout 1 Blank? N Status PASS 2 COMPLETE

Page 1 of 1, Repeat 1 of 4.

LLT Term	LLT Code	PT Code	HLT Term	HLGT	SC
COLOUR VISION DEFICIENCIES	10010054	COLOUR BLINDNESS NOS	OCULAR DISORDERS CONGENITAL NEC	EYE DISORDERS CONGENITAL	CC
RAISED LIVER ENZYMES	10037823	LIVER FUNCTION TEST ABNORMAL	LIVER FUNCTION ANALYSES	HEPATOBIILIARY INVESTIGATIONS	INV
CONJUNCTIVAL SWELLING	10042674	SWELLING NOS	SOFT TISSUE DISORDERS NEC	MUSCULOSKELETAL AND CONNECTIVE TIS	MU
TELANGLOSIS					

Record: 1/1 <OSC>



Validation

- Developing a Validation Document Set
 - Requirements Specification
 - Functional Test Protocol
 - 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.



Ongoing enhancements

- Web Enabled version
- Use of user-defined External Search Objects for automatic VTA reclassification
- Patient information on reports
- Global VTA propagation to Virtual Dictionary Domains
- Automatic viewing of job log files
- Browse button for Log directory settings



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 migrating to the Type C structure from a Type B format on 9-Sep-2003 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 in Development

- 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.
- Tested and certified update scripts for WHODrug 1Q 2003 for new (Vigibase) TMS structures



Overview of Future Development

- 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 Booth 3 with any additional questions and more detailed demos, and also for:
 - Free Flashlight
 - More Brochures, posters and cards

