OC, TMS and RDC Administration: An Application Overview

Presented by Sunil G. Singh of DBMS Consulting.

Acknowledgements

- Thanks to the OCUG for this opportunity to present this tutorial
- Thanks to the audience members for attending.
- Thanks to Paul Clarkson for his invitation and request for presenting this tutorial.
- Many thanks to the OCUG Presentation committee and Lori Venable for their patience with the completion of these presentations.

Goals and Agenda

- Examine the Administrative menu options of OC and RDC, starting with the perspective of user creation in OC.
- Relate these menu options to back-end architecture and components where relevant or time permits or questions are asked.
- Not every administrative option can be covered due to time constraints, will not cover many options but handouts can serve as a reference

OC Administrative Functions

- User accounts
  - Creation
  - Study access
  - Menu privileges
- Configuring Printers in OC
- Report Server configuration
- Directory Mappings
- Batch Jobs functionality, execution and monitoring
- GLIB Access
  - User
  - Study
- EDMS Profile Access

OC Administrative Functions (2)

- Data Entry Configuration
  - System
  - Study
  - User

TMS Administrative Functions

- Menu Roles for TMS
- User Accounts for TMS Lite Browser
- Scheduled Jobs

RDC Administrative Functions

- User account roles
- Study Security
- Site Security
- News Configuration
- Links Configuration
- RDC Configurator

OC User Account Concepts

- Several levels of access are required to use Oracle Clinical
  - Database (RDBMS) Access
  - Database Server Operating System Access
  - Access to Menu Paths
  - Access to Studies
  - Access to GLIB Domains
  - Access to EDMS Profiles (if using EDMS)
- The OC Account is used to control access to all of these components of Oracle Clinical
- The administration of users is therefore a key part of Oracle Clinical administration and touches upon many parts of the system

OC Users Account Concepts (2)

- Oracle Clinical uses Pro*C/C complied code on the Database RDBMS Server to execute batch jobs.
- Every Oracle Clinical User is also a bona-fide Oracle RDBMS User, unlike other systems such as Documentum
- Therefore, at least two base accounts are required for Oracle Clinical:
  - Operating System Account (Windows or Unix)
  - Oracle Database Account
- A Windows Domain account is recommended for the Middle Tier, since the Middle Tier must run on Windows.
  - This Domain account is required in a Windows RDBMS Server and Windows Middle Tier configuration where the output of the PSUB jobs is redirected to the Middle Tier.

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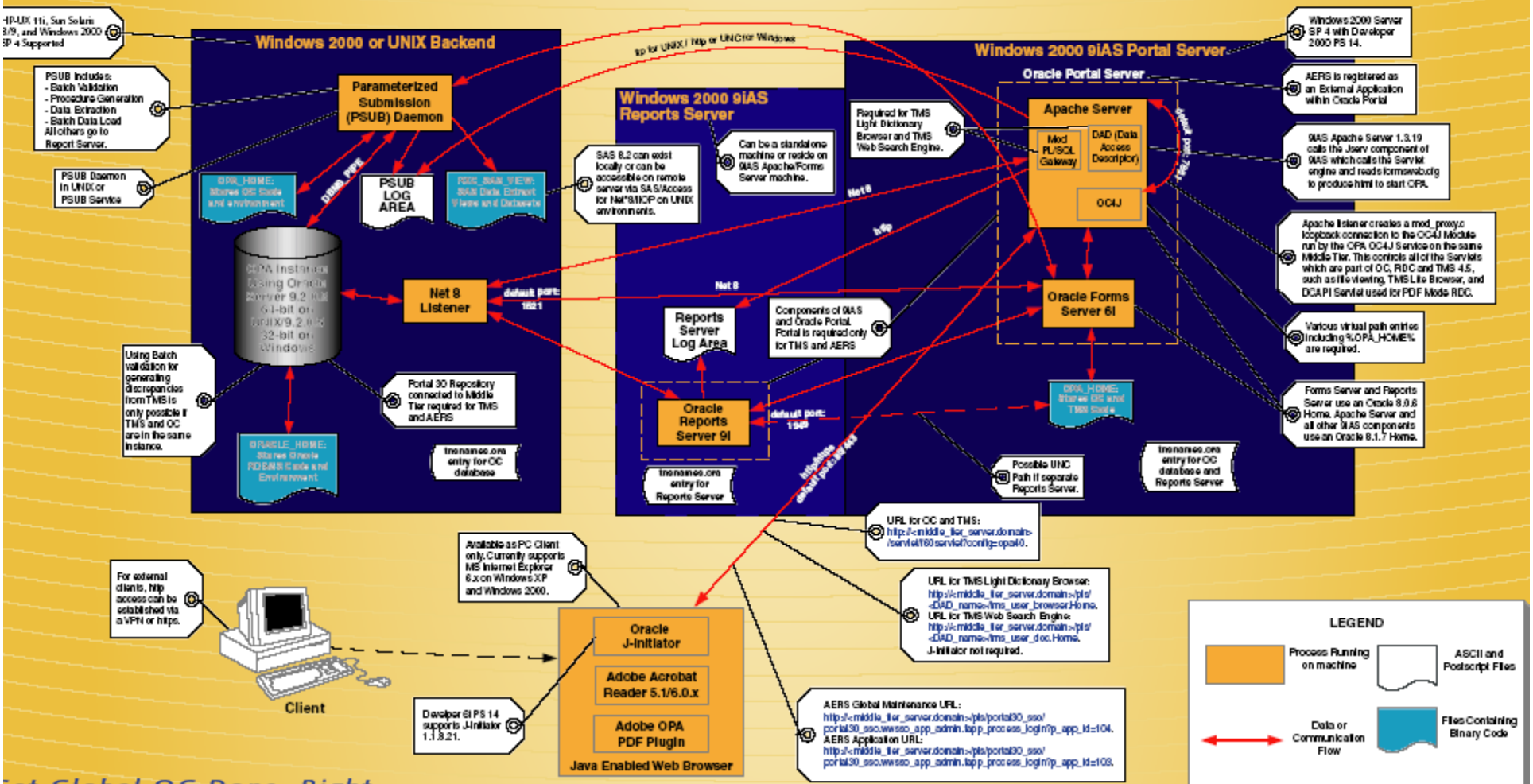
Oracle Pharmaceutical Applications 4.5 3-Tier Configuration



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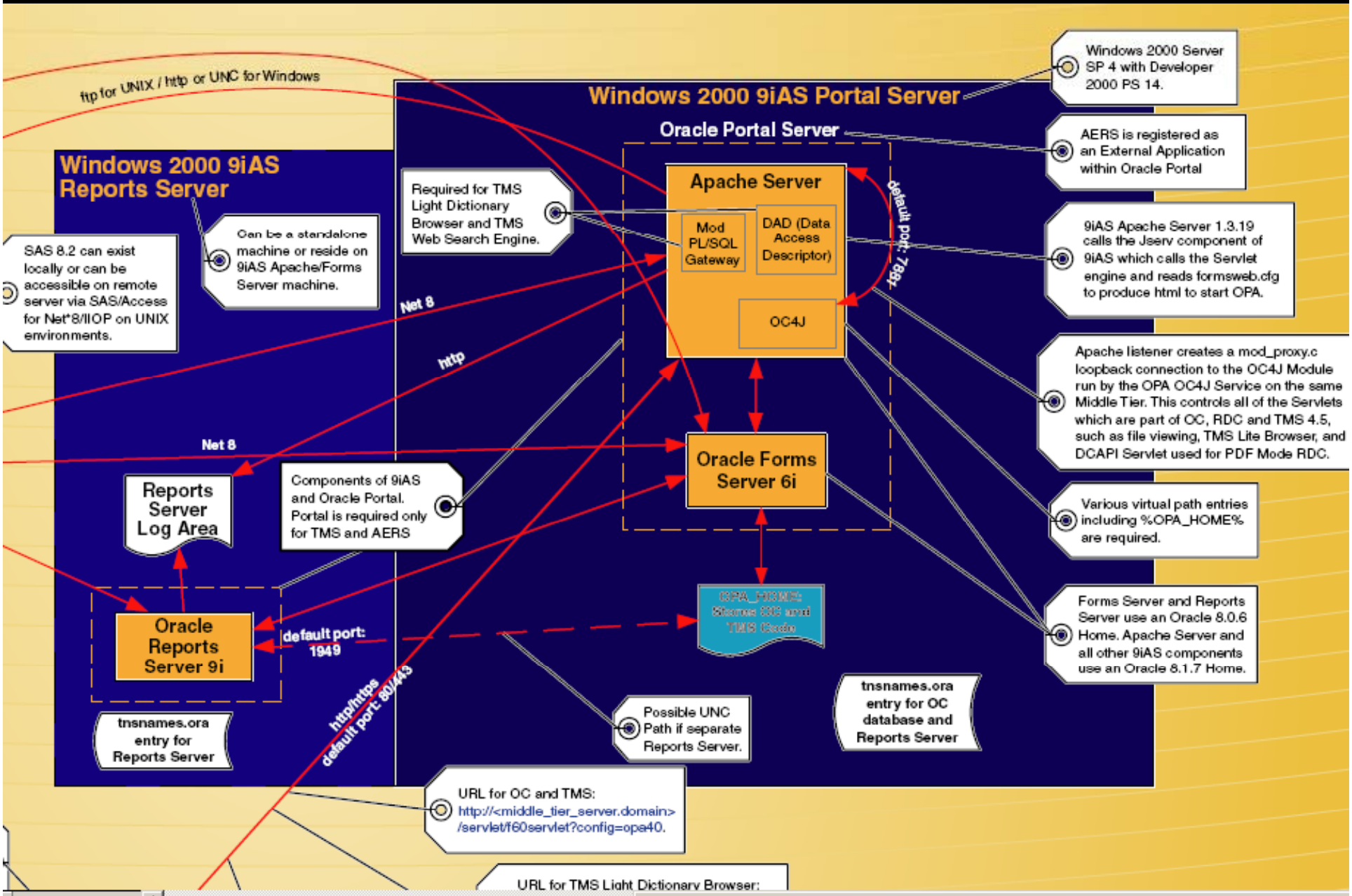
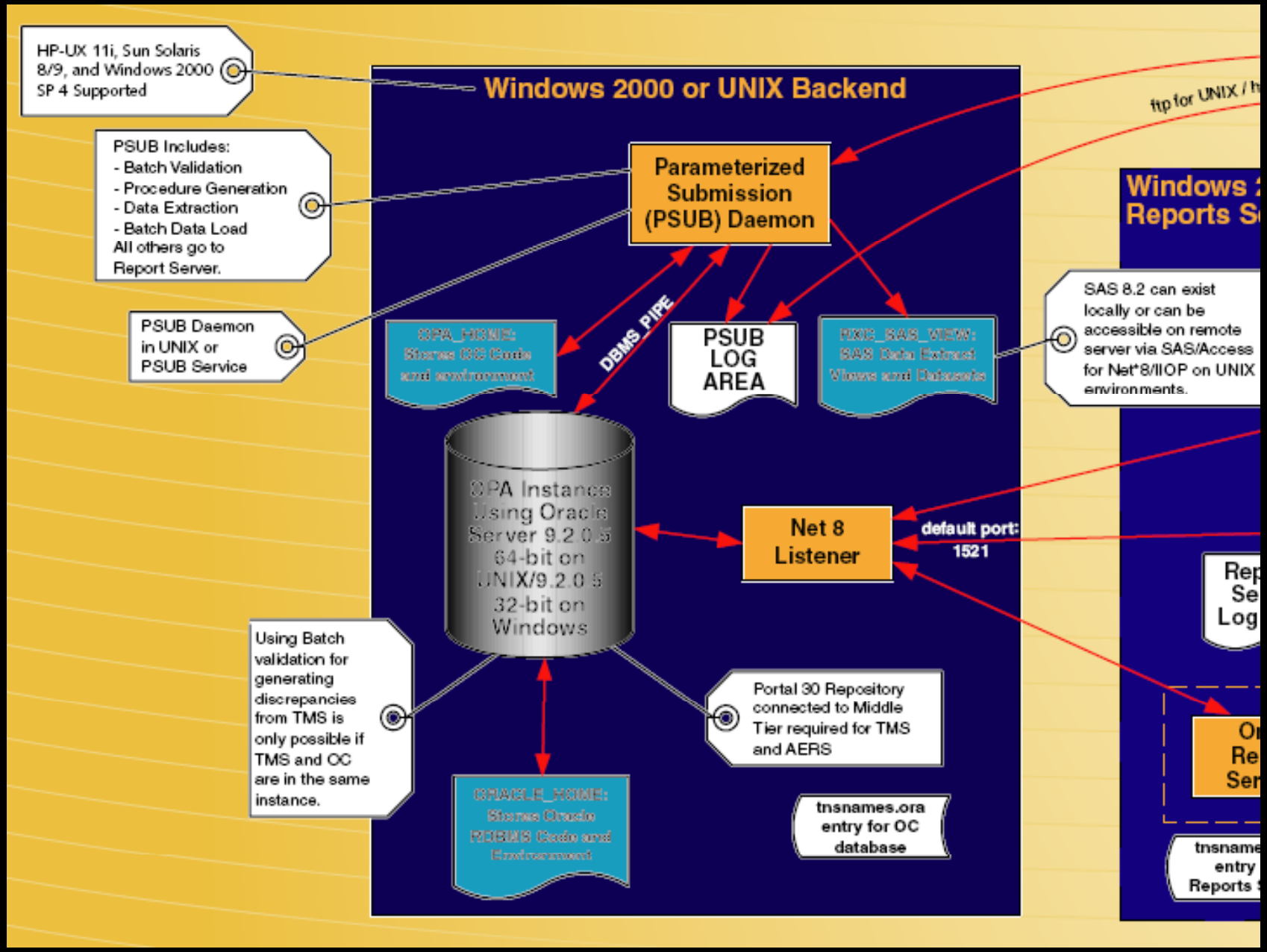
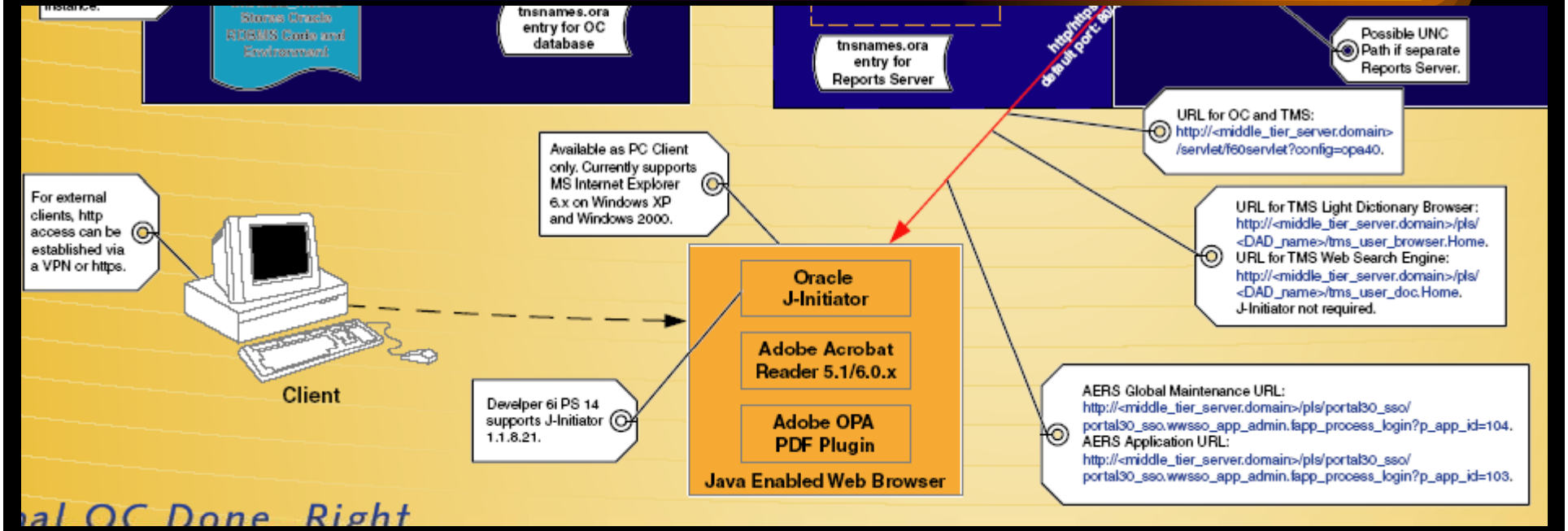

ftp for UNIX / http or UNC for Windows
Windows 2000 9iAS Portal Server
Oracle Portal Server
Windows 2000 9iAS Reports Server
Windows 2000 Server SP 4 with Developer 2000 PS 14.
AERS is registered as an External Application within Oracle Portal
Required for TMS Light Dictionary Browser and TMS Web Search Engine.
Apache Server
Mod PL/SQL Gateway
DAD (Data Access Descriptor)
OC4J
default port: 7894
9iAS Apache Server 1.3.19 calls the Jserv component of 9iAS which calls the Servlet engine and reads formsweb.cfg to produce html to start OPA.
SAS 8.2 can exist locally or can be accessible on remote server via SAS/Access for Net*8/IIOP on UNIX environments.
Can be a standalone machine or reside on 9iAS Apache/Forms Server machine.
Net 8
http
Apache listener creates a mod_proxy.c loopback connection to the OC4J Module run by the OPA OC4J Service on the same Middle Tier. This controls all of the Servlets which are part of OC, RDC and TMS 4.5, such as file viewing, TMS Lite Browser, and DCAPI Servlet used for PDF Mode RDC.
Net 8
Reports Server Log Area
Components of 9iAS and Oracle Portal. Portal is required only for TMS and AERS
Oracle Forms Server 6i
Various virtual path entries including %OPA_HOME% are required.
OPA_HOME: Stores OC and TMS Code
Oracle Reports Server 9i
default port: 1949
http/https default port: 80/443
Forms Server and Reports Server use an Oracle 8.0.6 Home. Apache Server and all other 9iAS components use an Oracle 8.1.7 Home.
tnsnames.ora entry for Reports Server
Possible UNC Path if separate Reports Server.
tnsnames.ora entry for OC database and Reports Server
URL for OC and TMS: http://<middle_tier_server.domain>/servlet/f60servlet?config=opa40.
URL for TMS Light Dictionary Browser:


HP-UX 11i, Sun Solaris 8/9, and Windows 2000 SP 4 Supported
Windows 2000 or UNIX Backend
PSUB Includes:
- Batch Validation
- Procedure Generation
- Data Extraction
- Batch Data Load
All others go to Report Server.
Parameterized Submission (PSUB) Daemon
PSUB Daemon in UNIX or PSUB Service
DBMS_PIPE
PSUB LOG AREA
SAS 8.2 can exist locally or can be accessible on remote server via SAS/Access for Net*8/IIOP on UNIX environments.
OPA Instance Using Oracle Server 9.2.0.5 64-bit on UNIX/9.2.0.5 32-bit on Windows
Net 8 Listener
default port: 1521
Using Batch validation for generating discrepancies from TMS is only possible if TMS and OC are in the same instance.
Portal 30 Repository connected to Middle Tier required for TMS and AERS
tnsnames.ora entry for OC database
ftp for UNIX / h
Windows 2 Reports S
Rep Se Log
O Re Ser
tnsname entry Reports

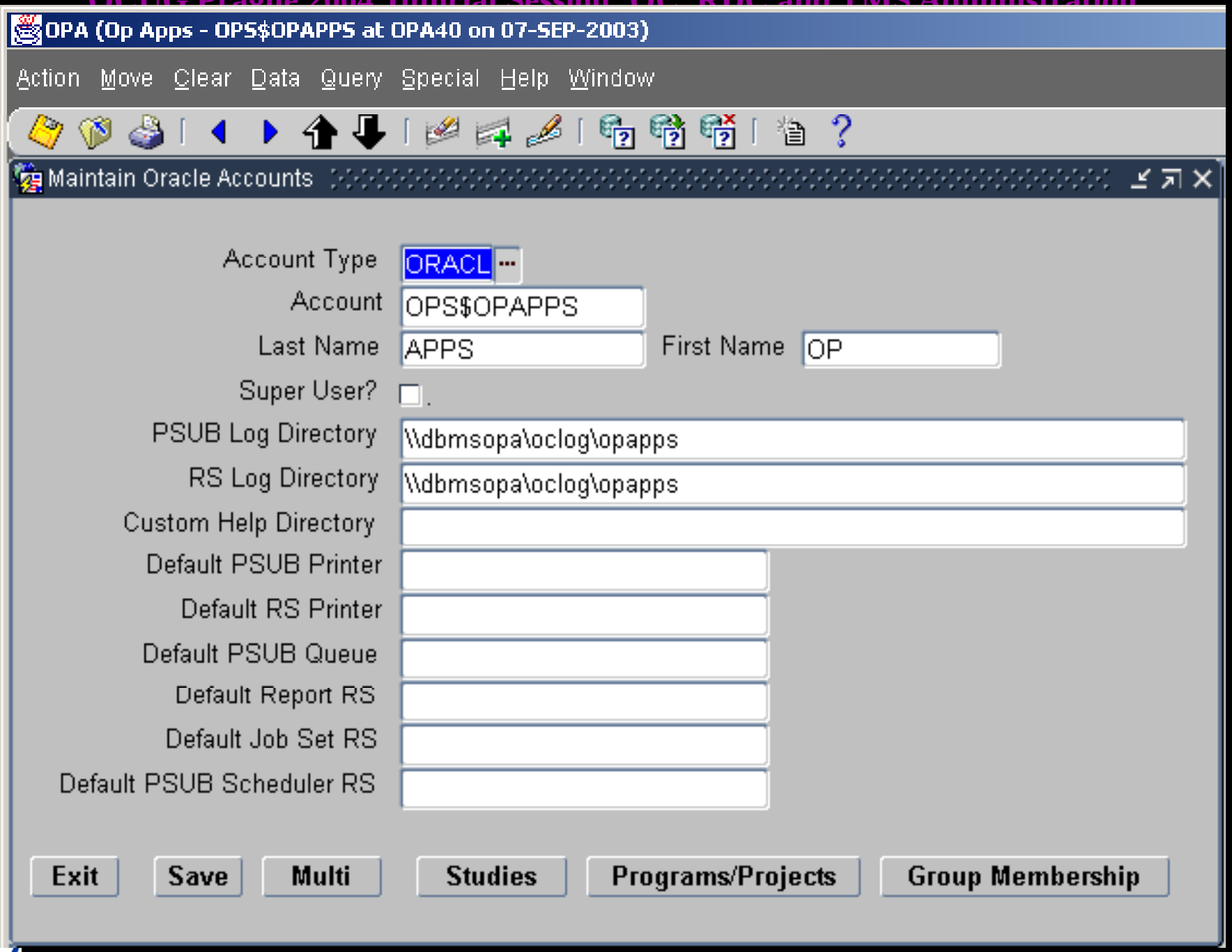

tnsnames.ora entry for OC database
tnsnames.ora entry for Reports Server
Possible UNC Path if separate Reports Server.
URL for OC and TMS: http://<middle_tier_server.domain>/servlet/f60servlet?config=opa40.
Available as PC Client only. Currently supports MS Internet Explorer 6.x on Windows XP and Windows 2000.
For external clients, http access can be established via a VPN or https.
URL for TMS Light Dictionary Browser: http://<middle_tier_server.domain>/pls/<DAD_name>/tms_user_browser.Home.
URL for TMS Web Search Engine: http://<middle_tier_server.domain>/pls/<DAD_name>/tms_user_doc.Home.
J-Initiator not required.
Client
Oracle J-Initiator
Adobe Acrobat Reader 5.1/6.0.x
Adobe OPA PDF Plugin
Java Enabled Web Browser
Develper 6i PS 14 supports J-Initiator 1.1.8.21.
AERS Global Maintenance URL: http://<middle_tier_server.domain>/pls/portal30_sso/portal30_sso.wwsso_app_admin.fapp_process_login?p_app_id=104.
AERS Application URL: http://<middle_tier_server.domain>/pls/portal30_sso/portal30_sso.wwsso_app_admin.fapp_process_login?p_app_id=103.

OC Users Accounts Concepts (3)

- Additionally, an entry into the ORACLE_ACCOUNTS table is required for each Oracle RDBMS account accessing Oracle Clinical. The menu path Admin=>Users=>Oracle Accounts populates this table.
- The Oracle_Account_Name column must match the actual Oracle RDBMS account name.
- Every user in OC also has two log directories
  - Report Server or Middle Tier log directory
  - RDBMS Server PSUB Log Directory

OC Users Accounts Concepts (4)

- These Log directories are also stored in the ORACLE_ACCOUNTS table for each user
- The synchronization of external operating system components with their references inside of the OC database is a key concept in administering Oracle Clinical
- The $RXC_TOOLS/ocl_add_user.sql is useful since it creates the RDBMS account and populates the ORACLE_ACCOUNTS table.


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Maintain Oracle Accounts
Account Type
ORACL
Account
OPS$OPAPPS
Last Name
APPS
First Name
OP
Super User?
PSUB Log Directory
\\dbmsopa\oclog\opapps
RS Log Directory
\\dbmsopa\oclog\opapps
Custom Help Directory
Default PSUB Printer
Default RS Printer
Default PSUB Queue
Default Report RS
Default Job Set RS
Default PSUB Scheduler RS
Exit
Save
Multi
Studies
Programs/Projects
Group Membership

Reference Codelists

- Reference Codelists exist to configure many, many aspects of Oracle Clinical. They are divided into
  - Local
  - Installation
  - Design
  - System
- There are over 400 reference codelist altogether. Mastering the meaning of each of these codelists is difficult, but learning some of them is key to administering OC and TMS

Thematic Concepts in OC

- Many configurations are possible at the System, Study and User level. In general, the System configuration only takes effect when there is no equivalent Study or User level configuration. If there is a Study level configuration, it gets the next highest precedence. If there is a user Level configuration, it gets the highest precedence within OC.

Operating System Accounts

- Create an Operating System Account on the Oracle RDBMS Server machine. If this is HP-UX or Sun Solaris, then a UNIX account is required on the database server machine. If the Oracle RDBMS Server machine is Windows, then a local Windows account is required
- The OS account should have the path of the opa_settings or opa_settings.bat file in its environment. For UNIX, instead of setting a path variable in each users .cshrc (C-Shell or tcsh) or .profile (Bourne Shell or ksh), set the path in the system-level environment files /etc/.login (csh and tcsh) or /etc/profile (Bourne shell or ksh).
- For Windows OS accounts, add the path to the SYSTEM environment variable PATH which contains the opa_settings.bat file.

Operating System Accounts (2)

- On the Oracle RDBMS Server machine, define a log area for all OC Users if one does not already exist. Under this log area, create a directory named for the OC user. In UNIX, set the owner to the username and the group to oclsascr.
- On the OC Windows Middle Tier, define a log area for all OC users. This log area may not necessarily be on this specific middle tier, but could be on another middle tier or a file-server. Be sure to check that a Universal Naming Convention (UNC) path is defined for this log area. In this log area, create a directory named for this user.
- For the Middle Tier log area, it must be accessible by the user running the Oracle Reports Server service (usually opareps or opareports). If the Oracle RDBMS Server is a Windows machine, then it is possible to establish a single UNC path for both the PSUB log files and the Middle Tier log files

Using ocl_add_user.sql

- Once the UNIX or Windows OS account is created, execute the $RXC_TOOLS/ocl_add_user.sql script. The script prompts for the username, which should be ops$<OS_account_name>. It then prompts for a password and the Log file directories for the Report Server output and the PSUB job output for this user. The log files specified are the paths on the Middle Tier and Oracle RDBMS Server, not on the local machine.
- The script prompts for whether the user is a Super User (access to all studies) and whether or not the role RXC_SUPER (access to all menu paths in OC) should be granted to the user (more explanation to follow)
- Also, the RDC_ACCESS role is granted if Y is chosen for access to RDC
- However, no type of TMS access is granted through this script
- The other parameters are optional.

```
$ setenv TERM vt100
$ copa_setup OPA45 45dev
Found line in oratab file for database "OPA45".


ORACLE_SID      =OPA45
TWO_TASK        =Undefined
ORACLE_HOME     =/oracle/app/oracle_dev/product/9.2.0
RXC_ROOT        =/opt/opapps/opappsdev/oc/45
PRODUCT_INSTANCE=OPA45
PRODUCT_CODE_ENV=45dev
$ echo $RXC_TOOLS
/opt/opapps/opappsdev/oc/45/tools

$ sqlplus /

SQL*Plus: Release 9.2.0.5.0 - Production on Fri Sep 10 10:51:29 2004

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Connected to:
Oracle9i Enterprise Edition Release 9.2.0.5.0 - 64bit Production
With the Partitioning, OLAP and Oracle Data Mining options
JServer Release 9.2.0.5.0 - Production

SQL> @$RXC_TOOLS/ocl_add_user
running OCL_ADD_USER.SQL

Account Details - General

User ID, starting with OPS$ : ops$singhs
Password : singhs
Last Name : Singh
First Name : Sunil
PSUB Log Directory : /<UNIX_Server>/<log_directory>/singhs
Report Server Log Directory : \\<ReportServer>\<log_share_name>\singhs
Grant RXC_SUPER menu role (Y/N) : Y
Grant Super-User status to access all studies (Y/N) : Y
Does user require access to RDC (Y/N) : Y
Custom Documentation Directory (optional) :

Account Details - PSUB (optional)

Printer for PSUB :
Queue :

Account Details - Report Server (optional)

Printer for Report Server :
Report Server :
Job Set Report Server :
PSUB Scheduler Report Server :
```
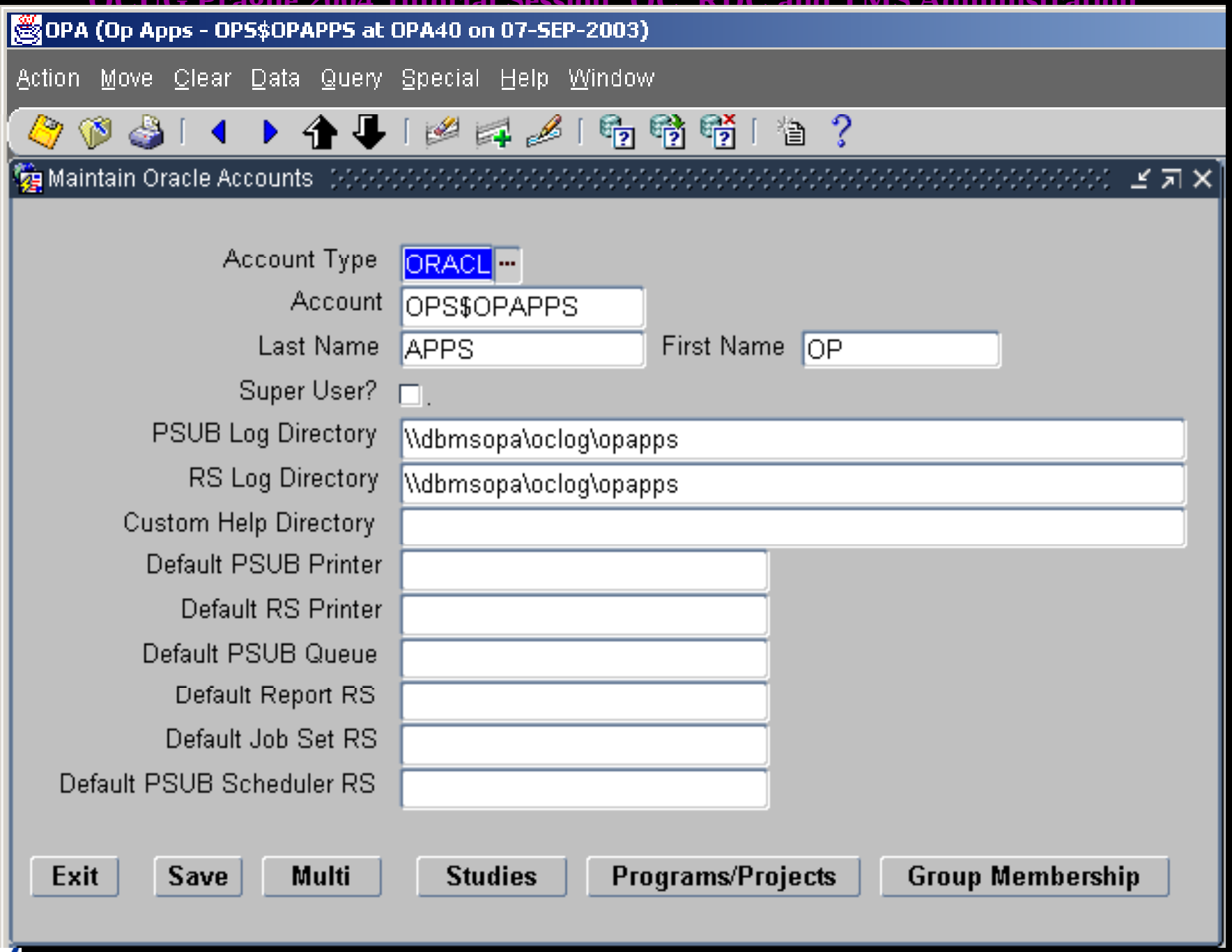

OC Study Access

- Once an account has been created with ocl_add_user.sql, an entry for this account will appear in Admin => Users => Oracle Accounts (oracle_accounts table)
- The existence of this entry does not necessarily provide study access.
- An OC account can access studies in five ways:
  - Super User? flag checked (all_study_access_flag)
  - Access granted to specific studies via the Studies button
  - Account can be part of group(s). These groups can have access to specific studies
  - Accounts can have access to a Program/Project combination which contains the study via the Programs/Projects button
  - Groups can also have access to Project/Program combinations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Account Type
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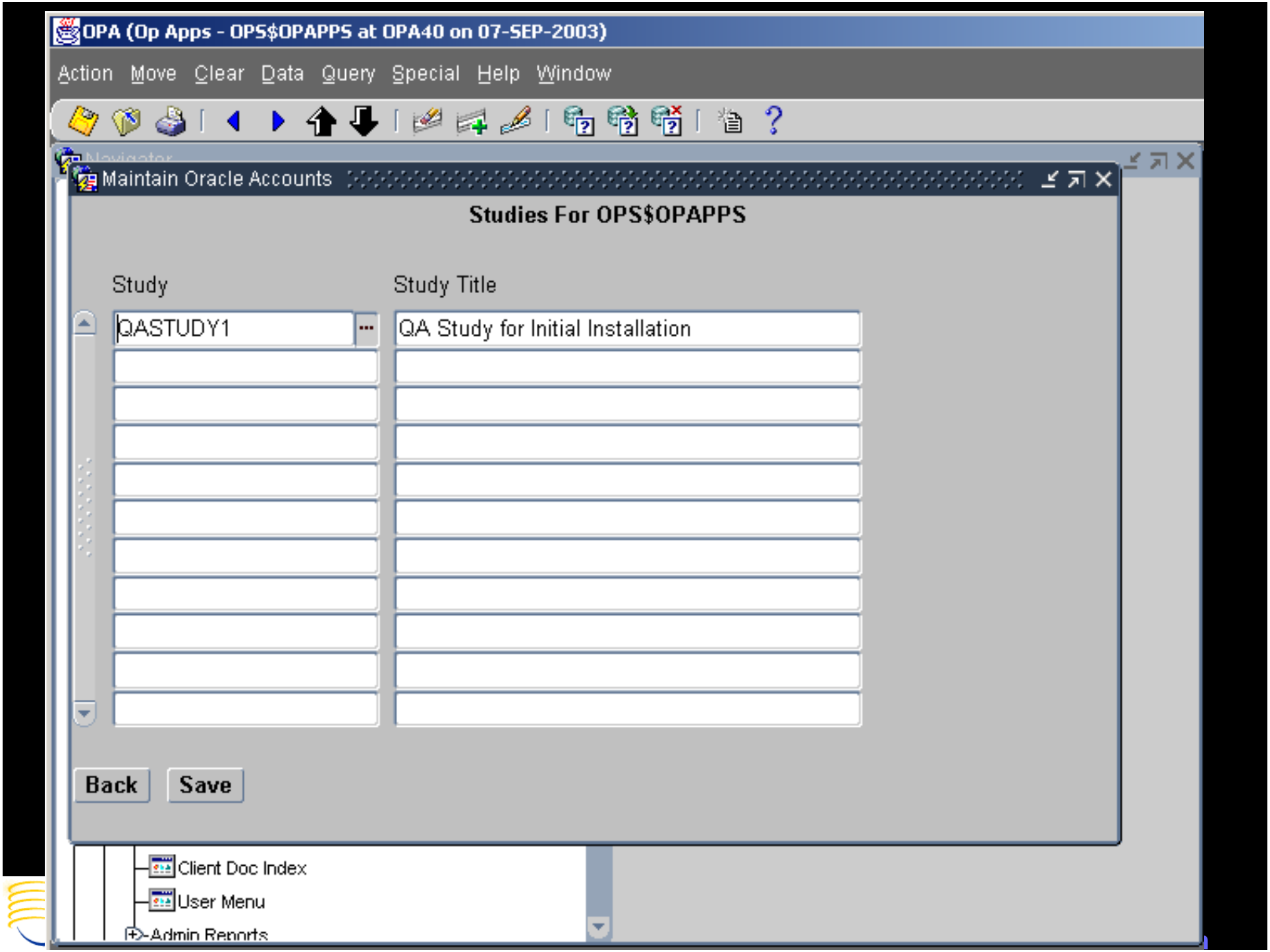
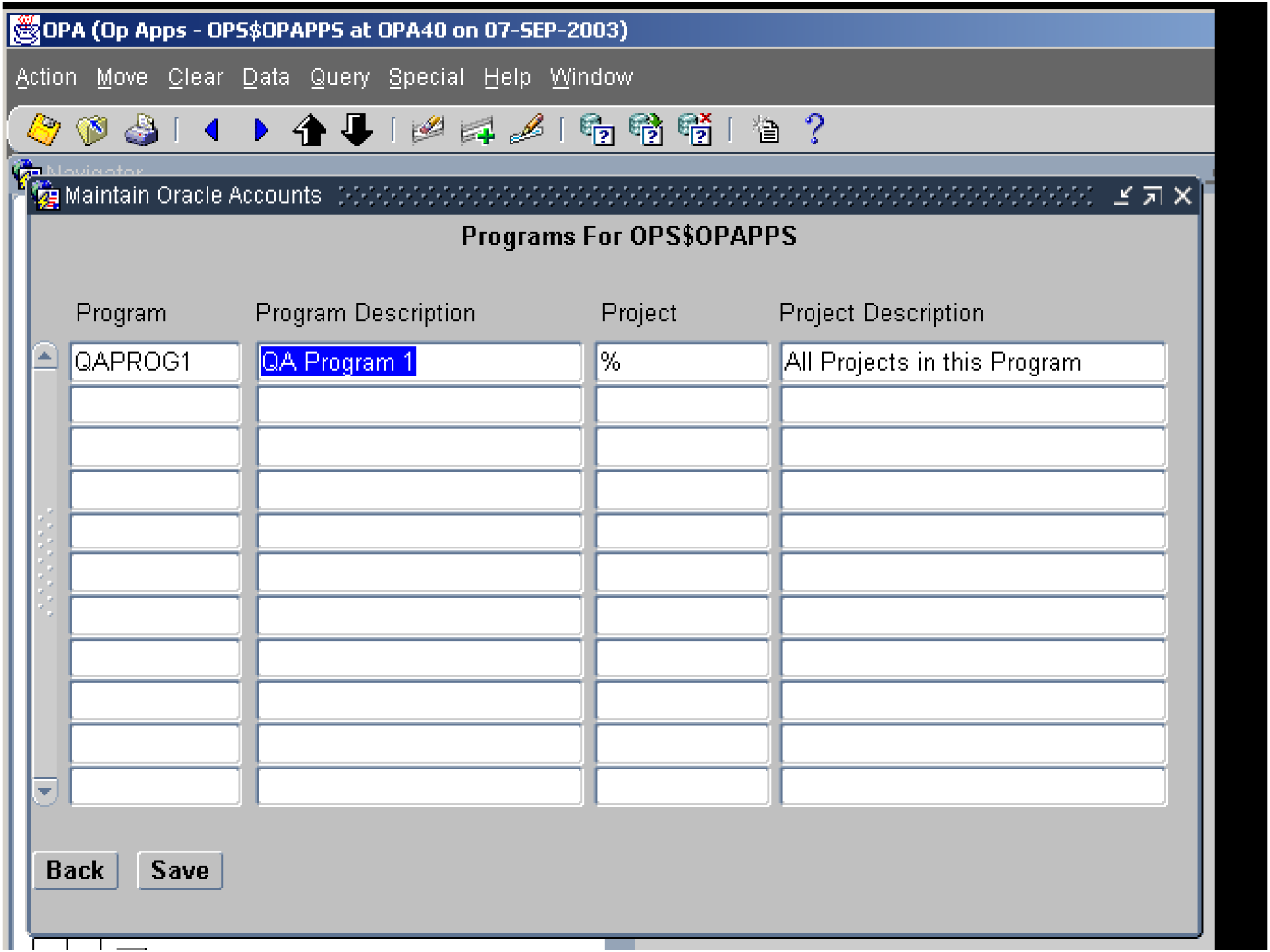
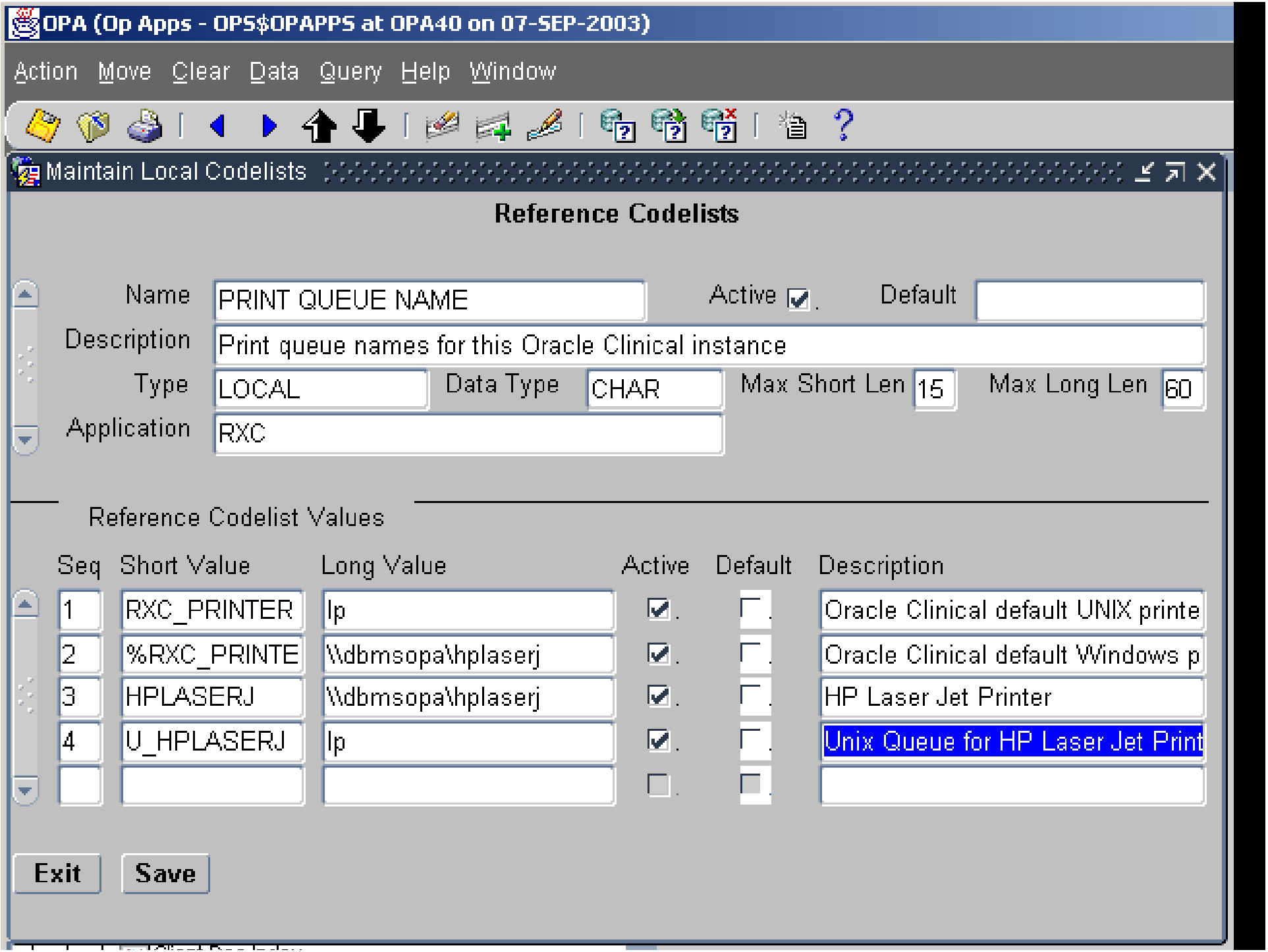
Account
OPS$OPAPPS
Last Name
APPS
First Name
OP
Super User?
PSUB Log Directory
\\dbmsopa\oclog\opapps
RS Log Directory
\\dbmsopa\oclog\opapps
Custom Help Directory
Default PSUB Printer
Default RS Printer
Default PSUB Queue
Default Report RS
Default Job Set RS
Default PSUB Scheduler RS
Exit
Save
Multi
Studies
Programs/Projects
Group Membership

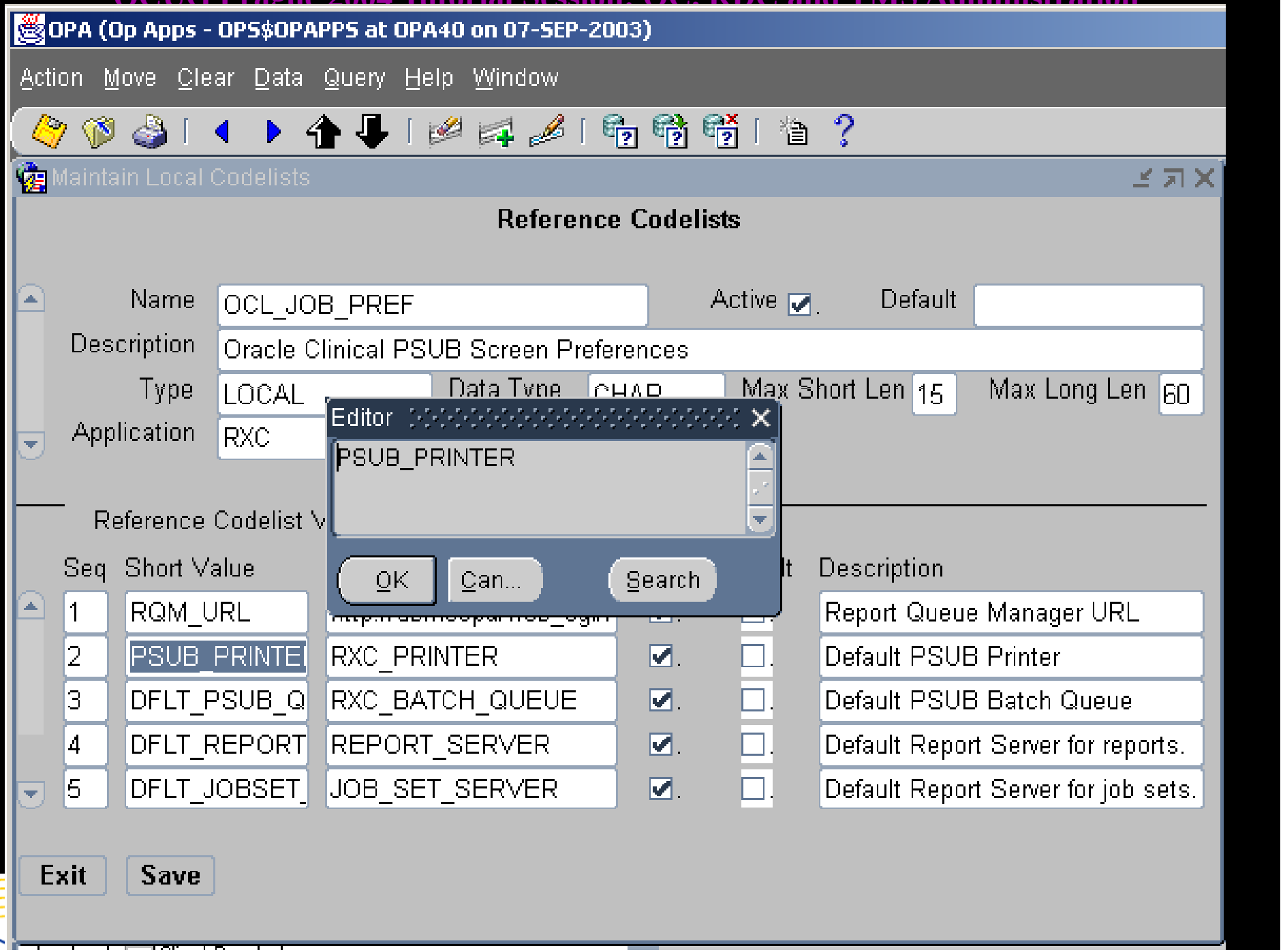

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Maintain Oracle Accounts
Studies For OPS$OPAPPS
Study
Study Title
QASTUDY1
QA Study for Initial Installation
Back
Save
Client Doc Index
User Menu
Admin Reports

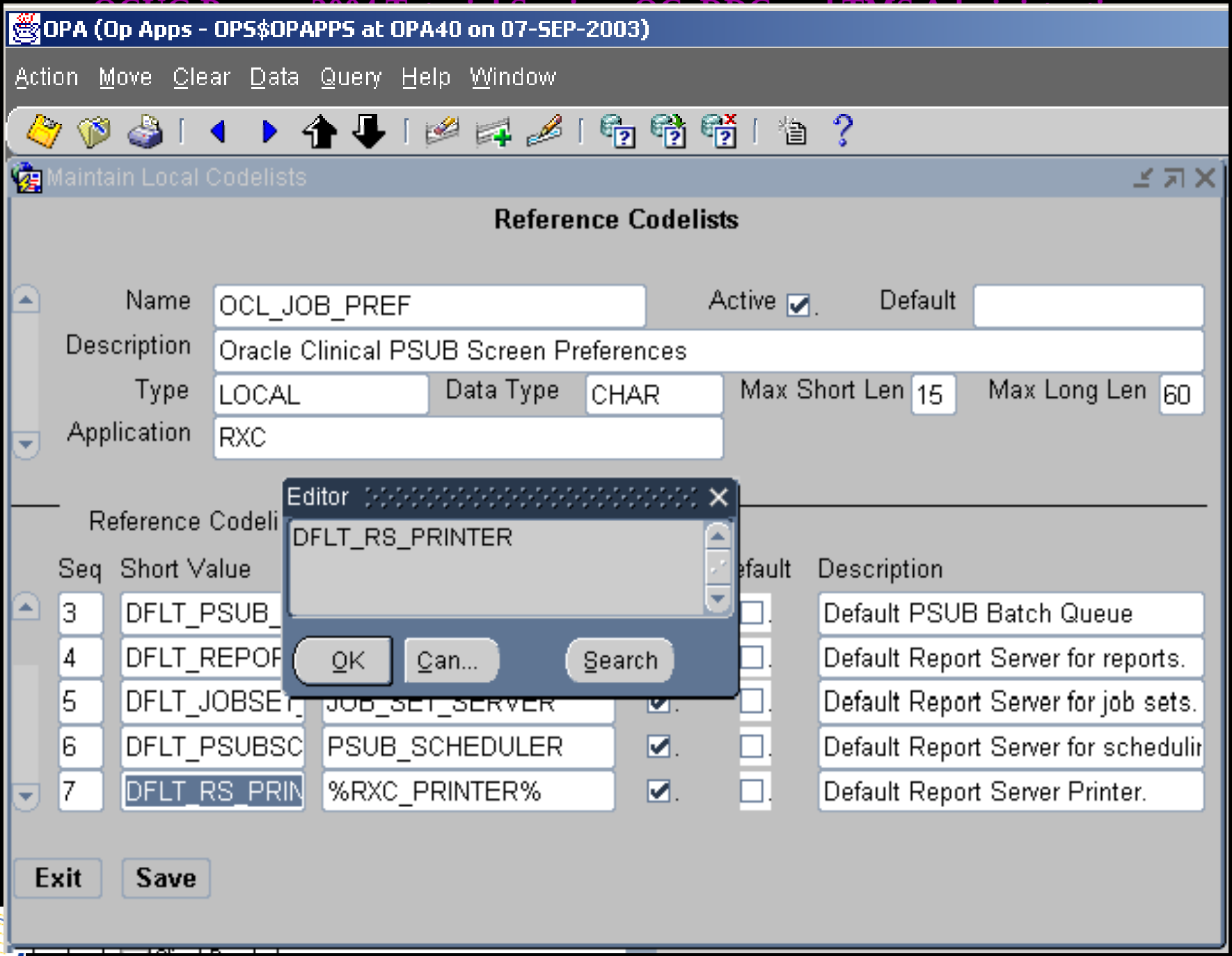

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Maintain Oracle Accounts
Programs For OPS$OPAPPS
Program
Program Description
Project
Project Description
QAPROG1
QA Program 1
%
All Projects in this Program
Back
Save

OC Printers

- The master set of printers are defined in Admin => Reference Codelists => Local Codelists: PRINT QUEUE NAME
- Two default printers should be defined if the database server is an UNIX server:
  - One default printer for the UNIX environment (RXC_PRINTER)
  - One default printer for the WINDOWS middle-tier (%RXC_PRINTER%)
- These defaults are set in Local Reference Codelist: OCL_JOB_PREFS
  - DFLT_RS_PRINTER (define to %RXC_PRINTER%)
  - PSUB_PRINTER (define to RXC_PRINTER)
- These defaults are then set for every job which defaults to a printer. Server-based jobs can therefore default to a different printer than Middle-Tier based jobs


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Local Codelists
Reference Codelists
Name PRINT QUEUE NAME
Active
Default
Description Print queue names for this Oracle Clinical instance
Type LOCAL
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Reference Codelist Values
Seq Short Value Long Value Active Default Description
1 RXC_PRINTER lp Oracle Clinical default UNIX printe
2 %RXC_PRINTE \\dbmsopa\hplaserj Oracle Clinical default Windows p
3 HPLASERJ \\dbmsopa\hplaserj HP Laser Jet Printer
4 U_HPLASERJ lp Unix Queue for HP Laser Jet Print
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Local Codelists
Reference Codelists
Name OCL_JOB_PREF
Active
Default
Description Oracle Clinical PSUB Screen Preferences
Type LOCAL
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Editor
PSUB_PRINTER
OK
Can...
Search
Reference Codelist V
Seq Short Value
Description
1 RQM_URL Report Queue Manager URL
2 PSUB_PRINTE RXC_PRINTER Default PSUB Printer
3 DFLT_PSUB_Q RXC_BATCH_QUEUE Default PSUB Batch Queue
4 DFLT_REPORT REPORT_SERVER Default Report Server for reports.
5 DFLT_JOBSET_ JOB_SET_SERVER Default Report Server for job sets.
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Local Codelists
Reference Codelists
Name OCL_JOB_PREF
Active
Default
Description Oracle Clinical PSUB Screen Preferences
Type LOCAL
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Editor
DFLT_RS_PRINTER
OK
Can...
Search
Reference Codeli
Seq
Short Value
Description
3 DFLT_PSUB_ Default PSUB Batch Queue
4 DFLT_REPOR Default Report Server for reports.
5 DFLT_JOBSET Default Report Server for job sets.
6 DFLT_PSUBSC PSUB_SCHEDULER Default Report Server for schedulir
7 DFLT_RS_PRIN %RXC_PRINTER% Default Report Server Printer.
Exit
Save

OC Printers (Middle-Tier and Windows Database Server)

- The short value of the PRINT QUEUE NAME Local Reference Codelist contains an alias used within OC to refer to this printer
- The long value contains either the UNC name (\\printserver\printer) or the DNS or TCP/IP name of the printer. Since the Middle-Tier of OC is a Windows machine, it likes to refer to printers on a print server by their UNC naming. This is also true for Log directories on the Middle Tier.

OC Printers (Unix Database Server only)

- The short value contains an alias used within OC to refer to this printer. A convention should be established to separate the aliases of UNIX printers from Windows printers (Ex. U_)
- The long value of these printers should be the name of any valid UNIX print queue accessible from the database server
- A UNIX printer must be selected if the output of any server-based batch job is set to printer, even though the selection of any Printer is possible

OC Report Servers

- One or more Report Servers can be defined in a single environment for Oracle Clinical. At the very minimum at least one Report Server must be defined for the Windows Middle Tier running OC.
- Every Report Server must have an entry defining the Report Server in the Windows Middle Tier tnsnames.ora file. If there are multiple Middle Tiers used in the same environment, e.g., multiple Middle Tiers used for load balancing or dedicated to different groups of users, then each middle tier must have a reference to ALL Report Servers being used in the environment.
- The Local Reference codelist REPORT_SERVER must contain the references to all of the Report Servers that can be used by an OC Instance.

OC Report Servers (2)

- The Report Server itself is now installed in the Oracle 9iDS Home, since the OPA Reports now run under Oracle 9i Reports.
- The default behavior for the 9i Reports Server is to accept requests for report processing though web URLs only and integration with Apache. However, Oracle Clinical is installed in the Oracle 8.0.6 Home, and currently does have the ability to generate URL-based report requests.
- This means that in order for connectivity from Oracle Forms in the Oracle 8.0.6 Home to exist, the compatibility of the 9i Reports Server must be set to accept Reports 6i request, which are made via SQL*Net/Net*8.

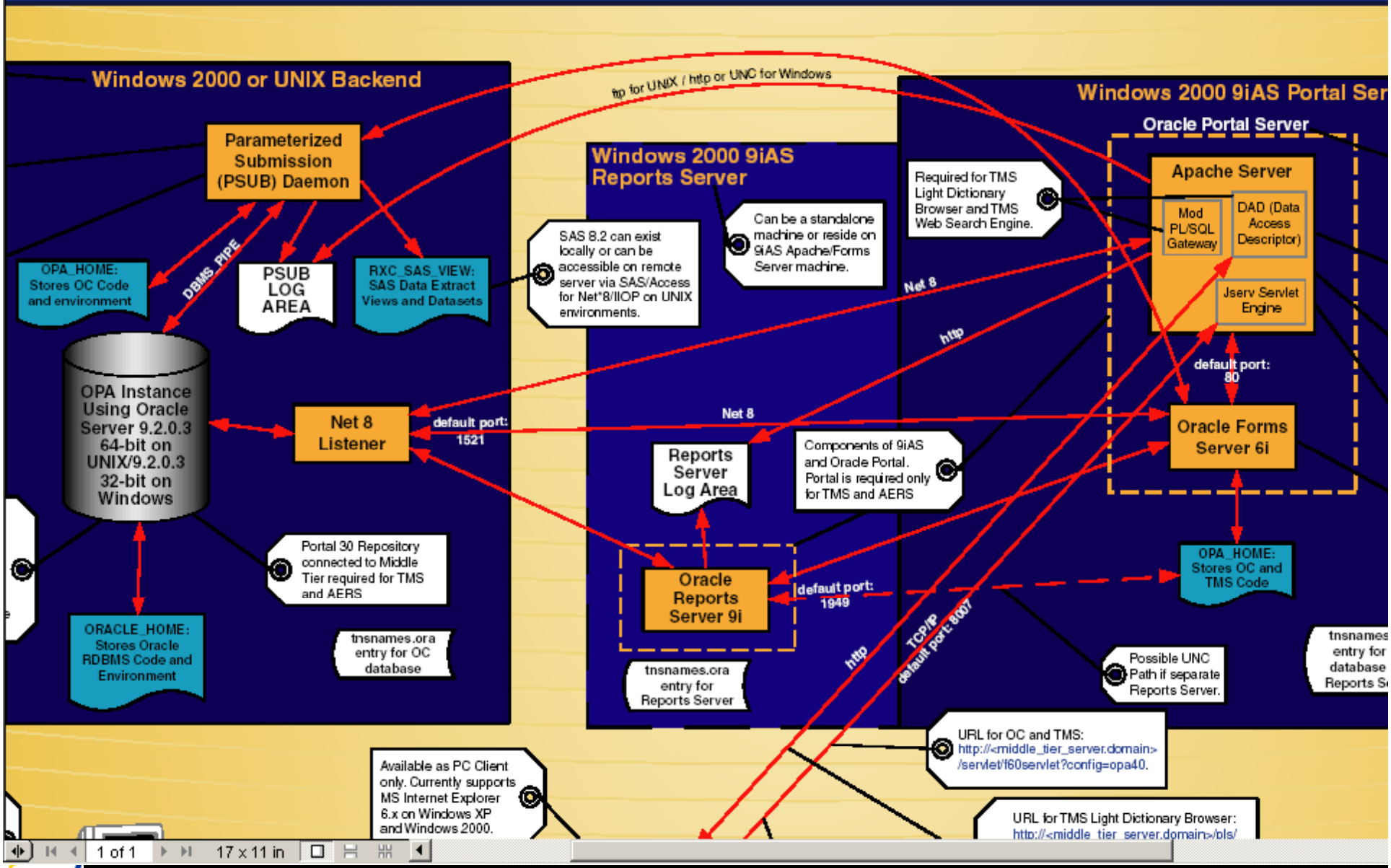
OC Report Servers (3)

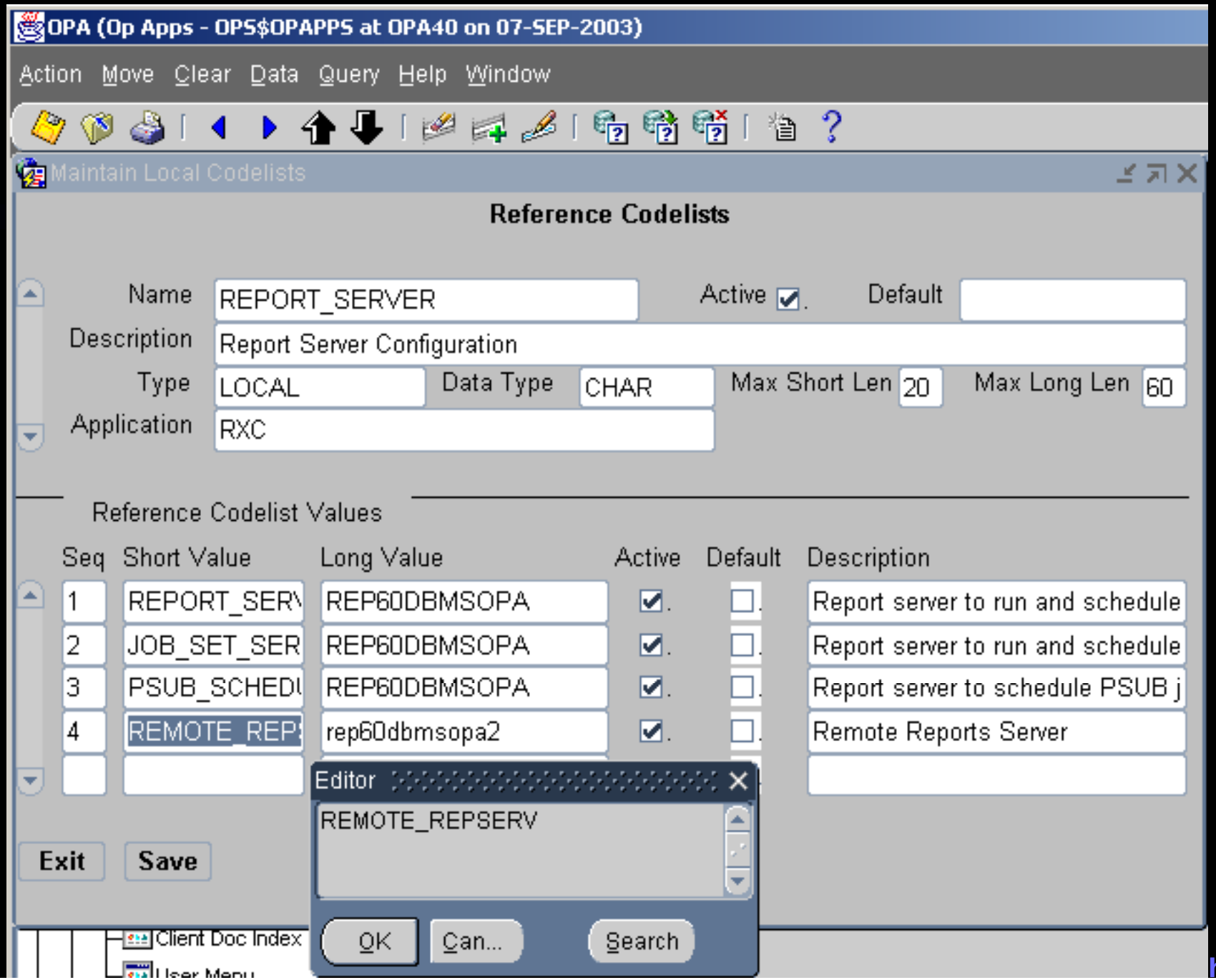
- This compatibility is set by enabling the following line in the %ORACLE_9iDS_HOME%\reports\conf\rep90<Reports_Server>.conf file name. Note that this line is disabled by default if a Report Server is installed manually.
  - <compatible version="6i"/>
- However, a master template is created at OC Client Code install time on the Middle Tier. This master template contains the compatible setting as well as other settings, such as CLASSPATH, which are required for OC. This template should be used by the Reports Server even if the Report Server is created manually.

OC Report Servers (4)

- The Short Value for the Report Server is an alias used to refer to the Report Server within Oracle Clinical. There are three short values which are required:
  - REPORT_SERVER: Used for submitting Report Jobs
  - JOB_SET_SERVER: Used for submitting Job Sets
  - PSUB_SCHEDULER: Used for scheduling all jobs, including PSUB Batch Jobs
- It is typical for all of these three short values to default to the same Report Server, but not required
- The Long Value for the Report Server must be the tnsnames.ora entry in the 8.0.6 ORACLE_HOME on the Middle Tier(s) used to connect to this OC Instance.
- Note that for connectivity from the Oracle 8.0.6 Home to the
- Additional entries must be defined for Report Servers which are Stand-Alone or Remote Report Servers

Oracle Pharmaceutical Applications 4.5 3-Tier C




OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Local Codelists
Reference Codelists
Name REPORT_SERVER
Active
Default
Description Report Server Configuration
Type LOCAL
Data Type CHAR
Max Short Len 20
Max Long Len 60
Application RXC
Reference Codelist Values
Seq Short Value Long Value Active Default Description
1 REPORT_SERV REP60DBMSOPA Report server to run and schedule
2 JOB_SET_SER REP60DBMSOPA Report server to run and schedule
3 PSUB_SCHEDU REP60DBMSOPA Report server to schedule PSUB j
4 REMOTE_REP rep60dbmsopa2 Remote Reports Server
Editor
REMOTE_REPSERV
OK
Can...
Search
Exit
Save
Client Doc Index

Select C:\WINNT\System32\cmd.exe

```
Microsoft Windows 2000 [Version 5.00.2195]
(C) Copyright 1985-2000 Microsoft Corp.

C:\>cd oracle\806\net80\admin

C:\Oracle\806\NET80\ADMIN>dir
 Volume in drive C has no label.
 Volume Serial Number is A078-054C

 Directory of C:\Oracle\806\NET80\ADMIN

03/19/2003  02:02a      <DIR>          .
03/19/2003  02:02a      <DIR>          ..
12/18/1997  05:10p                   191 Copy of SQLNET.ORA
03/19/2003  01:52a                 1,813 Copy of tnsnames.ora
03/19/2003  12:41a      <DIR>          SAMPLE
03/19/2003  02:04a                   258 SQLNET.ORA
07/13/2003  11:14a                   271 tnsnames.ora
               4 File(s)          2,533 bytes
               3 Dir(s)  15,347,694,080 bytes free

C:\Oracle\806\NET80\ADMIN>notepad tnsnames.ora

C:\Oracle\806\NET80\ADMIN>type tnsnames.ora
OPA40.DBMS =
  (DESCRIPTION =
    (ADDRESS_LIST =
      (ADDRESS = (PROTOCOL = TCP)(HOST = DBMSOPA)(PORT = 1521))
    )
    (CONNECT_DATA =
      (SERVICE_NAME = opa40)
    )
  )
Rep60DBMSOPA.dbms=(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp)(HOST=DBMSOPA)(PORT=1949))
)
Rep60DBMSOPA2.dbms=(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp)(HOST=DBMSOPA2)(PORT=1949
)))

C:\Oracle\806\NET80\ADMIN>
```

OC Menu Path Access

- Once users' accounts have been created and study-level access has been provided, the users' access to the various menu paths in Oracle Clinical must be administered and controlled
- OC uses a concept of Menu Role access, that is, if a user has a particular database role, the user is allowed to access certain accounts
- The Oracle database role RXC_SUPER allows access to all menu paths within Oracle Clinical. Typically, this role is not given to many users, usually only Application Administrators and DBAs

OC Menu Path Access (2)

- A complete list of the Database Roles and the Menu Paths which they provide access to is available from the report Developer's Toolkit => Menu Roles. However, to access this report, the OC account must have the special role DTK_ADMIN.
- Run this job with OPA Application Codes set to OCL. Setting to any other OPA Application Code will only return values for OCL (Oracle Clinical) even though other application types are available (TMS, DTK, etc).
- Every organization must make an internal job function to OC menu role mapping. When a new OC user is created, the appropriate Database roles based on the users' job function in OC must be granted. Since every organizations' internal job functions can be different within OC, the default OC database role to menu role association is frequently customized.

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Menu Roles for OCL version 4.5.0.24

	ADM	ANY	BIO	CRA	DE	DE2	DER	DES	DMG	DQA	DX	EDA	GLA	GLF	GLP	KLL	LNK	LRA	LO	MC	MCT	MEA
Admin		*																				
PSUB/Report Jobs		*																				
Resubmit Scheduled Jobs																						
Reference Codelists		*																				
DE Admin	*																					
Glib Admin	*												*	*								
Discrepancy Mgmt Admin																						
User Group Administration	*																					
Layout Definitions	*																					
Users		*																				
Study Security	*																					
Query Study Security		*																				
Site Security	*																					
Query Site Security		*																				
Directory Mappings		*																				
Directory Mappings	*																					
Query Directory Mappings		*																				
Replication	*													*				*				
User Menu		*																				
DCI Form Local Database Settings	*																					
Admin Reports		*																				
Plan		*																				
Design		*																				
Studies		*																				
Investigators and Sites		*																				
Treatments		*																				
Strata		*																				
Schedule		*																				
Randomization							*															
Version Randomization																						
Strata Randomization																						
Version Blocked Randomization																						
Strata Blocked Randomization																						
Randomization Batch Load																						
Randomization Maintenance							*															
Patient Positions		*																				
Test a Study Design		*																				
DCI Form Local Study Settings			*					*														
Design Reports		*																				
Glib		*																				
Questions		*																				
Question Groups		*																				

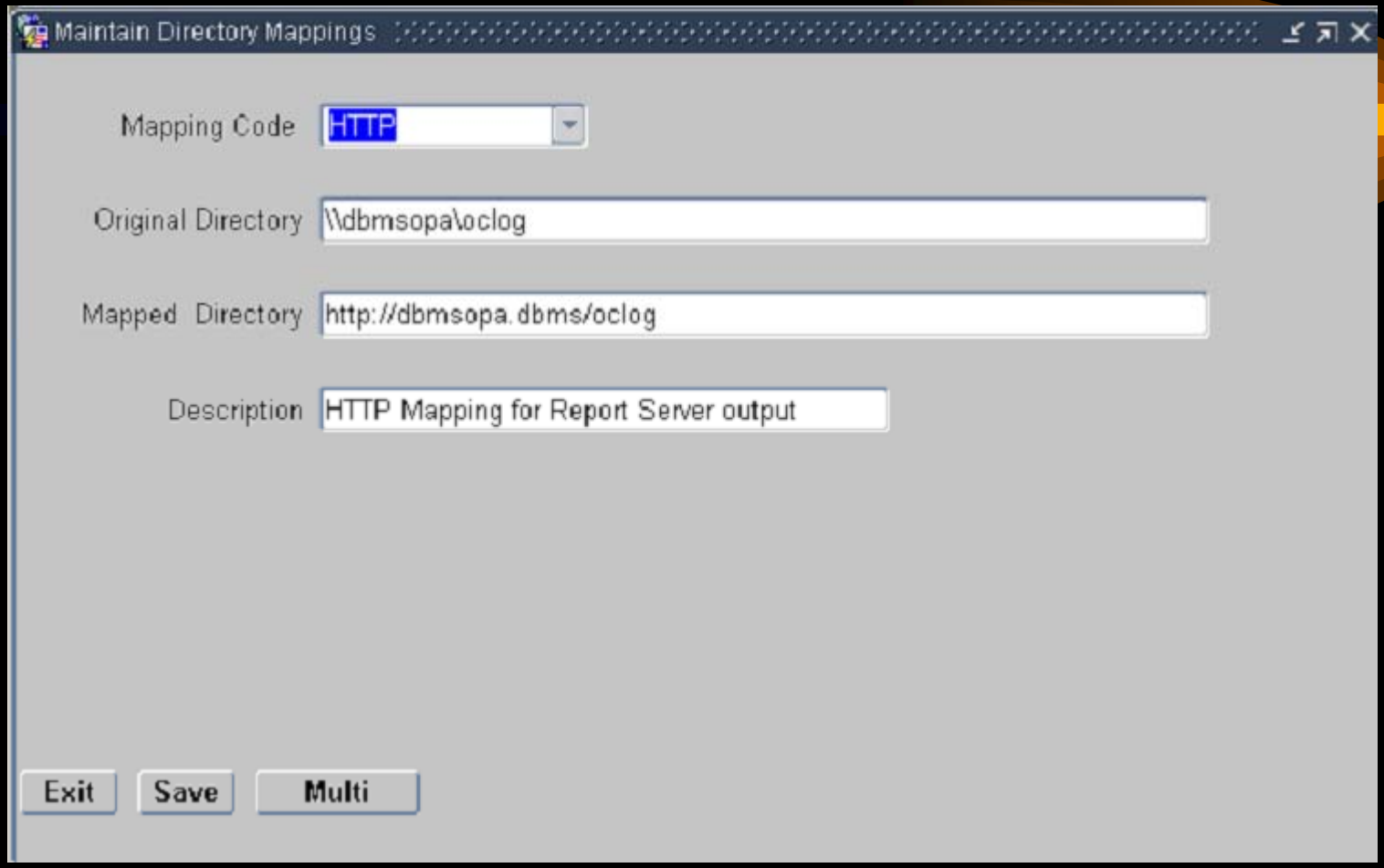
2 of 9 11 x 8.5 in

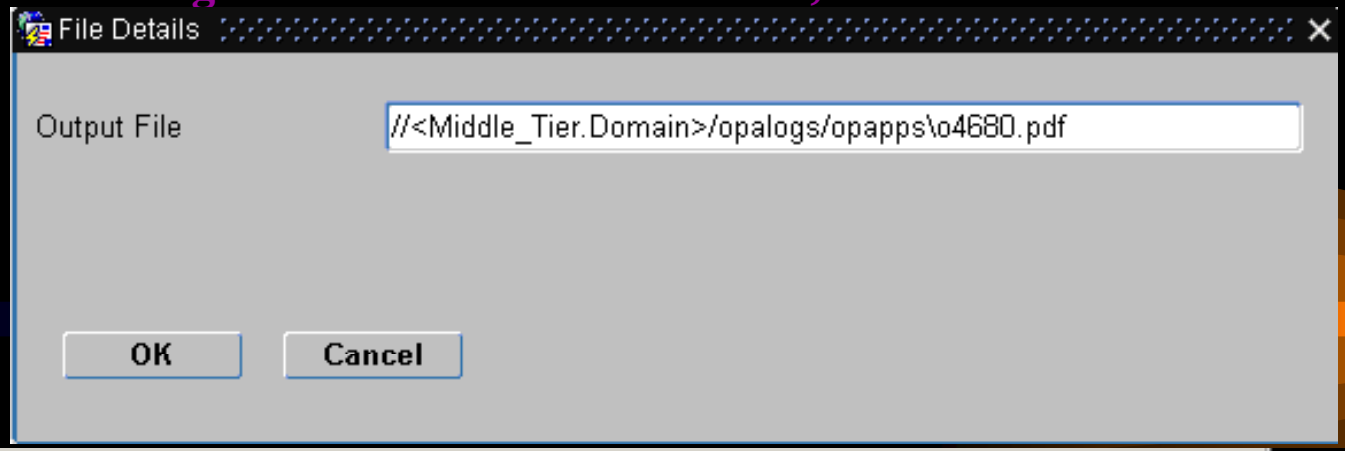
OC Directory Mappings

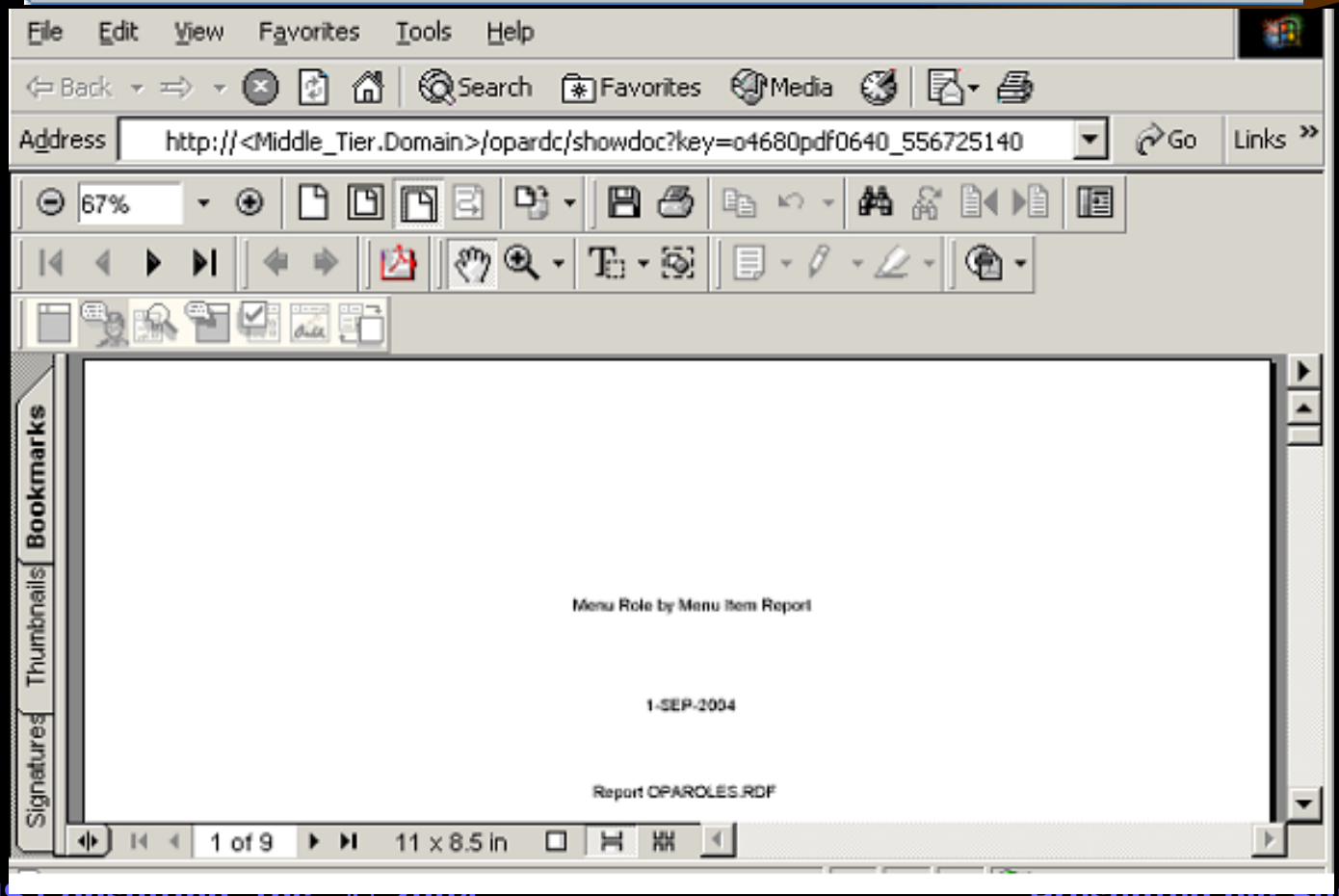
- In order for a user to see the output of the PSUB Batch Jobs or the Reports Server jobs, directory mappings are sometimes required in Admin => Directory Mappings => Directory Mappings
- For the Report Server output, it is almost always necessary to make an HTTP association with the UNC output path for a log or output file directory on the Reports Server.
- However, it is not necessary to create a corresponding alias in httpd.conf to view these files. In fact, doing so opens an additional security risk where any user knowledgeable of the http alias mapping could see any users output on the Middle Tier server.
- When a request is made to the Apache to show a Report Server output file, it is translated into a call to http://<Middle_Tier.Domain>/opardc/showdoc?key=<output_file_name_without_a_dot><key_number>

OC Directory Mappings (2)

- This key= portion of the URL represents a file name which is temporarily generated on the Middle Tier server in a temporary directory
- The OC directory mapping is used to populate the UNC path of the file requested for retrieval in this key file.
- Apache retrieves the file path specified in the key file and returns it to the requesting client. The key file is subsequently deleted. This accomplishes two things:
  - It protects the physical path of the file from the external world and the requesting user
  - It prevents ad-hoc URL requests for a Report Server output/log directory


Maintain Directory Mappings
Mapping Code
HTTP
Original Directory
\\dbmsopa\oclog
Mapped Directory
http://dbmsopa.dbms/oclog
Description
HTTP Mapping for Report Server output
Exit
Save
Multi


File Details
Output File
//<Middle_Tier.Domain>/opalogs/opapps\o4680.pdf
OK
Cancel


File Edit View Favorites Tools Help
Back Search Favorites Media
Address http://<Middle_Tier.Domain>/opardc/showdoc?key=o4680pdf0640_556725140
Go Links
67%
Bookmarks
Thumbnails
Signatures
Menu Role by Menu Item Report
1-SEP-2004
Report OPAROLES.RDF
1 of 9
11 x 8.5 in

OC Directory Mappings (3)

- In order for this to work, a mapping is made in the %OPA_HOME%\config\opa45_httpd.conf. This file is called from %ORACLE_iSuites_HOME%\Apache\Apache\conf\httpd.conf
- In this opa45_httpd.conf file, a special module of Apache is called, mod_proxy.c. This redirects all requests from Apache from http://<Middle_Tier.Domain>/opardc to port 7881, or the OPA OC4J Service.
- In a UNIX Database Server environment, no entry should be required for Directory Mappings to view PSUB Batch Job output and log files.
- **However, ftp is currently required and http viewing of output files from a UNIX Server is no longer supported. Support for http viewing of UNIX Server output files returns in OC 4.5.1**

```
# 2262004_24407PM : Configuration for OPA 4.5.0 products
alias /opa45/ "E:\opapps45/html/"
#alias /opa_repout/ "E:\opapps45/html/repout/"

# 2262004_24349PM : Configuration for RDC 4.5.0 products

        <IfModule mod_proxy.c>
          ProxyRequests On
          ProxyPass         /opardc/ http://<Middle_Tier_Server.Domain>:7881/opardc/

          ProxyPassReverse  /opardc/ http://<Middle_Tier_Server.Domain>:7881/opardc/

        </IfModule>

# 2262004_45838PM : Configuration for TMS 4.5.0 products

        <IfModule mod_proxy.c>
          ProxyRequests On
          ProxyPass         /tms/ http://<Middle_Tier_Server.Domain>:7881/tms/
          ProxyPassReverse  /tms/ http://<Middle_Tier_Server.Domain>:7881/tms/
        </IfModule>

        <IfModule mod_proxy.c>
          ProxyRequests On
          ProxyPass         /xhelp/ http://<Middle_Tier_Server.Domain>:7881/xhelp/
          ProxyPassReverse  /xhelp/ http://<Middle_Tier_Server.Domain>:7881/xhelp/
        </IfModule>
```

OPA 4.5 and use of Servlets

- From the changes in File Viewing output, it is clear that the redirection to the OPA OC4J Server service on Port 7881 is required for the /opardc/showdoc key file translation to work.
- This is because a set of Servlets, or Java and code, have been introduced in OPA 4.5.
- A list of these servlet components and their corresponding URLs can be found from the magical web.xml file, which is located deep under the %OPA_HOME% directory in %OPA_HOME%\j2ee\home\applications\opardc\opardcweb\WEB-INF\web.xml
- RDC 4.5, OPA File Viewing, TMS Lite Browser all use servlets, and therefore, are all dependent on the configurations in their respective web.xml files.

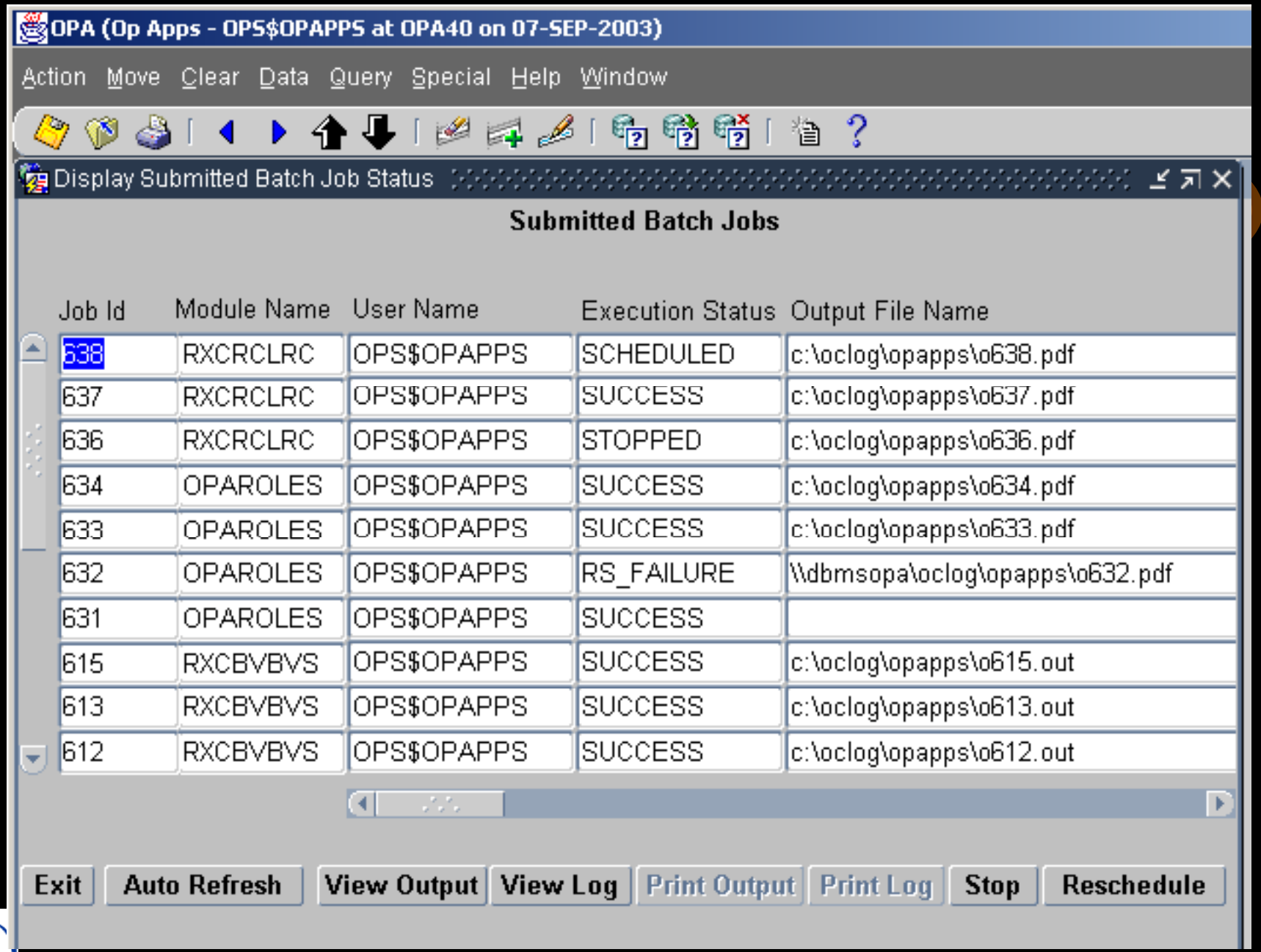
```
<servlet>
  <servlet-name>DCIDataServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.DCIDataServlet</servlet-class>
  <init-param>
    <param-name>donotdeletedatafile</param-name>
    <param-value>0</param-value>
  </init-param>
</servlet>
<servlet>
  <servlet-name>DCIFormServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.DCIFormServlet</servlet-class>
</servlet>
<servlet>
  <servlet-name>FieldDataServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.FieldDataServlet</servlet-class>
</servlet>
<servlet>
  <servlet-name>CleanURLServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.CleanURLServlet</servlet-class>
</servlet>
<servlet>
  <servlet-name>RDCHelpServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.RDCHelpServlet</servlet-class>
</servlet>
<servlet>
  <servlet-name>OclnLoadServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.OclnLoadServlet</servlet-class>
</servlet>
<servlet>
  <servlet-name>RDCServletSessionManager</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.RDCServletSessionManager</servlet-class>
  <init-param>
    <param-name>debugenabled</param-name>
    <param-value>0</param-value>
  </init-param>
  <init-param>
    <param-name>debugfolder</param-name>
    <param-value>[Replace_with_debug_folder_path]</param-value>
  </init-param>
  <load-on-startup>0</load-on-startup>
</servlet>
<servlet>
  <servlet-name>ShowDocServlet</servlet-name>
  <servlet-class>oracle.pharma.rdc.servlet.ShowDocServlet</servlet-class>
  <init-param>
    <param-name>keyfolderlocation</param-name>
    <param-value>E:\opapps45\temp</param-value>
  </init-param>
  <init-param>
    <param-name>donotdeletekeyfile</param-name>
    <param-value>0</param-value>
  </init-param>
  <load-on-startup>0</load-on-startup>
```

OC Scheduled Jobs

- Any user can schedule a job from the Job Details button => Schedule button for any submitted job.
- Submitting a Scheduled jobs causes two things to happen:
  - An entry is made into the BATCH_JOBS table with Execution_Status = SCHEDULED
  - A entry is made into the Reports Queue Manager for the scheduled job.
- The Scheduled job status can be viewed by Admin => PSUB/Report Jobs => Batch Jobs and querying for an Execution_Status = SCHEDULED as the user who has scheduled the job.
- The Scheduled job can also be seen in Admin => PSUB/Report Jobs => Report Queue Manager, and selecting the Report Server to which the job was scheduled

OC Scheduled Jobs (2)

- Stopping the scheduled job also deletes the entry from the Report Queue Manager
- However, changing the Oracle Database password of the user who has submitted the scheduled job will also cause the scheduled job to continuously fail.
- However, patch OC 4.5.0.18 provides some other ways to deal with this problem.
- Sometimes, it is difficult to find the user who has scheduled a job, log into OC as that user, and stop their scheduled job (suppose the user has left the company and their OC account no longer exists)
- In these cases, the Scheduled job must be killed from the Reports Queue Manager. Sometimes, the Reports Queue Manager tool should be invoked from the Report Server or Middle Tier to actually see and kill the scheduled jobs. (Start => Programs => Oracle 9i Developer Suite => Reports Developer => Oracle 9iAS Reports Services => Reports Queue Manager)


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Display Submitted Batch Job Status
Submitted Batch Jobs
Job Id | Module Name | User Name | Execution Status | Output File Name
638 | RXCRCLRC | OPS$OPAPPS | SCHEDULED | c:\oclog\opapps\o638.pdf
637 | RXCRCLRC | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o637.pdf
636 | RXCRCLRC | OPS$OPAPPS | STOPPED | c:\oclog\opapps\o636.pdf
634 | OPAROLES | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o634.pdf
633 | OPAROLES | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o633.pdf
632 | OPAROLES | OPS$OPAPPS | RS_FAILURE | \\dbmsopa\oclog\opapps\o632.pdf
631 | OPAROLES | OPS$OPAPPS | SUCCESS |
615 | RXCBVBVS | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o615.out
613 | RXCBVBVS | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o613.out
612 | RXCBVBVS | OPS$OPAPPS | SUCCESS | c:\oclog\opapps\o612.out
Exit
Auto Refresh
View Output
View Log
Print Output
Print Log
Stop
Reschedule

Reports Server Queue Status

Queue on server REP60DBMSOPA, on September, 07 2003, 08:06:18

To **kill** a current (enqueued or scheduled) job, or to **get a cached output** of a successfully finished past job, click on the Job Status hyperlink of that job (if available).

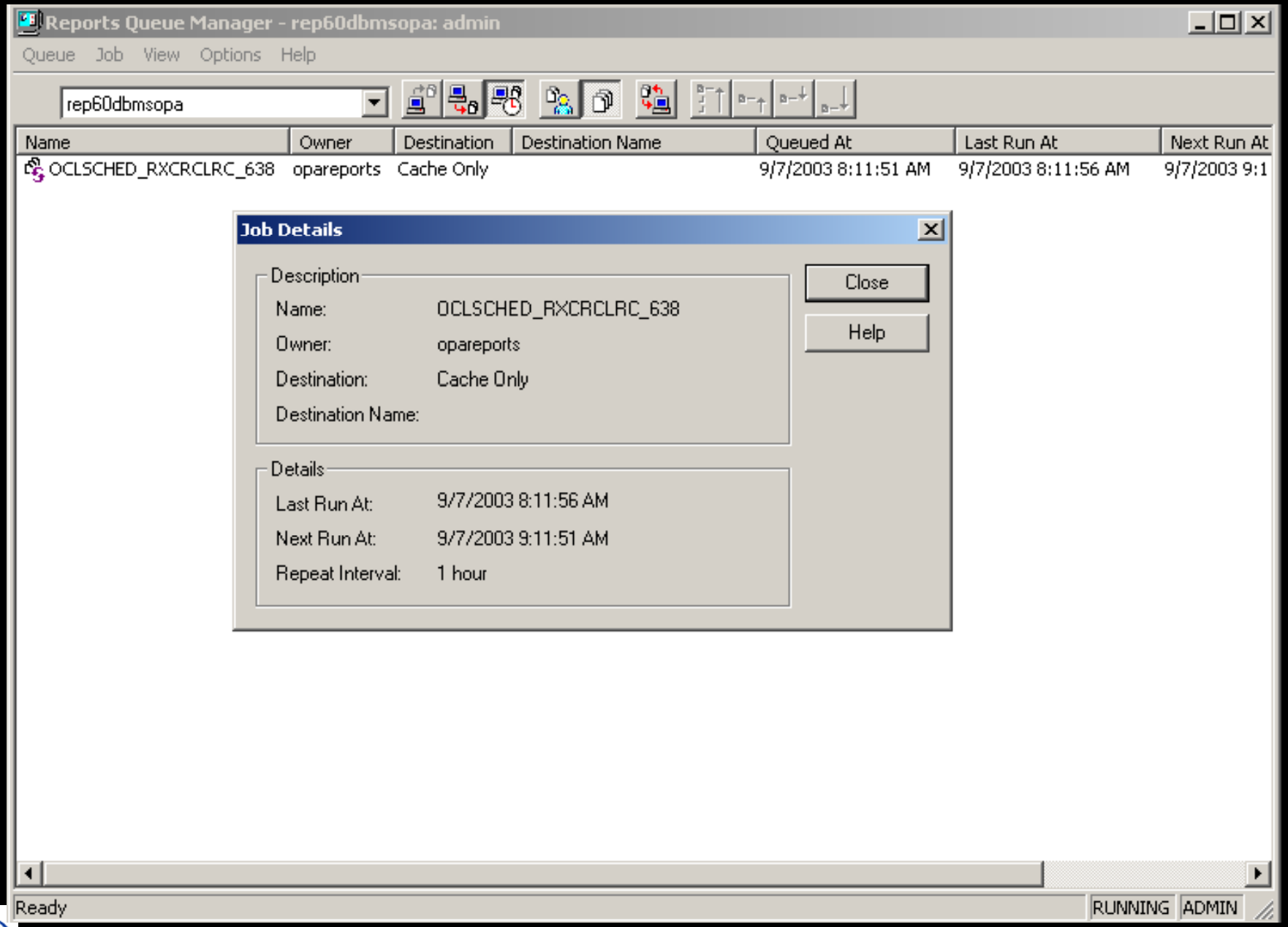
1. **Current Jobs** : **None**

2. **Past Jobs** :

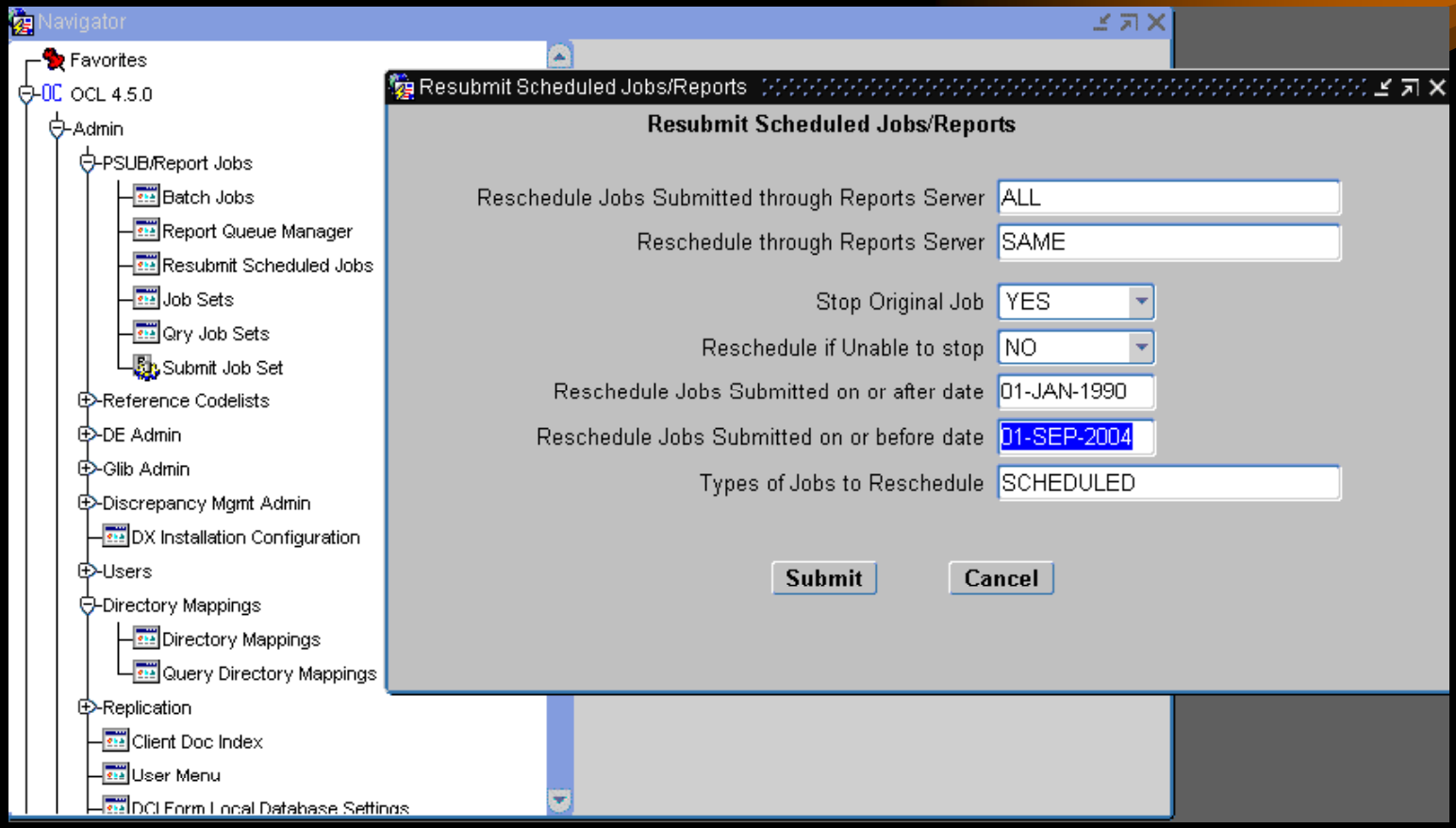
Job ID	Job Name	Job Status	Job Owner	Output Type	Output Name	Server Name	Queued At	Started At	Finished At
6	OCLSCHED_RXCRCLRC_636	Finished	opareports	Cache		Rep60DBMSOPA	09/07/03, 08:02:29	09/07/03, 08:02:29	09/07/03, 08:02:34
4	OCL_OPAROLES_634	Finished	opareports	Cache		Rep60DBMSOPA	09/07/03, 07:33:48	09/07/03, 07:33:48	09/07/03, 07:34:43
3	OCL_OPAROLES_633	Finished	opareports	Cache		Rep60DBMSOPA	09/07/03, 07:29:34	09/07/03, 07:29:34	09/07/03, 07:30:33
2	OCL_OPAROLES_632	Terminated with Error : MSG-00010: 328900: SRW.RUN_REPORT failed. Updating faiulre text. REP-1825: Before Report trigger returned FALSE.	opareports	Cache		Rep60DBMSOPA	09/07/03, 07:25:23	09/07/03, 07:26:26	09/07/03, 07:26:55
1	OCL_OPAROLES_631	Cancelled	opareports	Cache		Rep60DBMSOPA	09/07/03, 07:25:14	09/07/03, 07:25:24	09/07/03, 07:26:26

3. **Scheduled Jobs** :

Job ID	Job Name	Job Status	Job Owner	Output Type	Output Name	Last Run At	Next Run At	Repeat Interval
5	OCLSCHED_RXCRCLRC_636	Enqueued	opareports	Cache		09/07/03, 08:02:29	09/07/03, 09:02:24	60 Minute(s)


Reports Queue Manager - rep60dbmsopa: admin
Queue Job View Options Help
rep60dbmsopa
Name Owner Destination Destination Name Queued At Last Run At Next Run At
OCLSCHED_RXCRCLRC_638 opareports Cache Only 9/7/2003 8:11:51 AM 9/7/2003 8:11:56 AM 9/7/2003 9:1
Job Details
Description
Name: OCLSCHED_RXCRCLRC_638
Owner: opareports
Destination: Cache Only
Destination Name:
Details
Last Run At: 9/7/2003 8:11:56 AM
Next Run At: 9/7/2003 9:11:51 AM
Repeat Interval: 1 hour
Close
Help
Ready
RUNNING
ADMIN

OC 4.5.0.18 Resubmit Scheduled Jobs Screen and Release Notes (next 4 Slides)



About the Resubmit Scheduled Jobs/Reports window's fields

This section describes the fields in the new Resubmit Scheduled Jobs/Reports window

Reschedule Jobs Submitted through Reports Server

(Default: ALL) Choose the Reports Server to which the jobs are currently assigned, or choose ALL to reschedule jobs on all Reports Servers.

Reschedule through Reports Server

(Default: SAME) You can re-assign jobs to a specific Reports Server, or you can choose SAME to assign jobs to its original server.

Stop Original Job

(Default: YES) Choose Yes to stop the scheduled job. If you select No, the original job remains scheduled.

Reschedule if Unable to stop

(Default: NO) Choose Yes if you want to reschedule the job even if stopping the original job fails. If the Stop Original Job setting is NO, then setting switches to YES and cannot be changed.

Reschedule Jobs Submitted on or after Date

This is a mandatory field. Enter the date at which you want to reschedule all jobs going forward.

Reschedule Jobs Submitted on or before Date

Use this field to set an upper date after which you cease rescheduling jobs. If you do not want to reschedule your Oracle Clinical 4.0 jobs, select a date that is after the last date that you scheduled a job in Oracle Clinical 4.0 (such as the date you started using Oracle Clinical 4.5).

Types of Jobs to Reschedule

(Default: SCHEDULED) This patch adds the RESCHEDFAILED classification to rescheduled jobs. It enables you to try running jobs that failed to run in an earlier rescheduling attempt, without rescheduling all jobs. These are your choices for this field:

- SCHEDULED jobs are jobs that are currently scheduled.
- RESCHEDFAILED jobs are jobs where an earlier rescheduling attempt failed. If you do not want 4.0 jobs to be rescheduled, enter an "on or after date" that is on or after the date you started using 4.5.

When you have completed the form, click the Submit button to initiate the rescheduling process.

Using the Resubmit Scheduled Jobs window

These are the tasks you can perform in the Resubmit Scheduled Jobs/Reports window:

- Rescheduling all jobs that you scheduled in Oracle Clinical 4.0
- Rescheduling jobs after changing your database password
- Moving all scheduled jobs to a different Reports Server

Note that if you do not want to reschedule Oracle Clinical 4.0 jobs, select a date that is after the last date that you scheduled a job in Oracle Clinical 4.0 (such as the date you started using Oracle Clinical 4.5).

Rescheduling all jobs that you scheduled in Oracle Clinical 4.0

To reschedule these jobs, choose the following settings from the Resubmit Scheduled Jobs window:

- **Reschedule through Reports Server**: the name of the 4.5 Reports Server
- **Stop Original Job**: NO (You should deactivate the 4.0 Reports Server, which stops those jobs.)
- **Type of Jobs to Reschedule**: RESCHEDFAILED

Rescheduling jobs after changing your database password

If you schedule a job, then change your database password in the Change Database Password window in Oracle Clinical (Admin > Users > Database Password), the system prompts you to reschedule any scheduled jobs.

You should accept all defaults, which reschedules all the jobs you scheduled using your old password.

Moving all scheduled jobs to a different Reports Server

The steps required to move all scheduled jobs to a different Reports Server depend upon whether the original Reports Server is still running or unavailable.

When the original Reports Server is still running

Set the following parameters:

- Reschedule Jobs Submitted through Reports Server: the name of the original Reports Server
- Reschedule through Reports Server: the name of the new Reports Server

Accept all other defaults in the Resubmit Scheduled Jobs/Reports window.

When the original Reports Server is unavailable

- Reschedule Jobs Submitted through Reports Server: the name of the original Reports Server
- Reschedule through Reports Server: the name of the new Reports Server
- Stop Original Jobs: NO

Accept all other defaults in the Resubmit Scheduled Jobs/Reports window.

If a job fails to reschedule and its status is set to RESCHEDFAILED

You can fix those issues and try to reschedule the job again. In this case, you would select RESCHEDFAILED for types of job to reschedule.

How settings "Stop" and "Resched" affect system behavior

This section describes how the manner in which the system handles stopped jobs changes based on your choices for the settings **Stop Original Job** and **Resched if Unable to stop**.

Stop Original Job=YES, Resched if Unable to stop=NO

If the job cannot be stopped, the status of current record is set to RESCHEDFAILED. After you resolve the problem you can reschedule them.

If the job can be stopped, the system sets the status of the current record to RESCHEDSTOPPED, and creates a new record.

Stop Original Job=YES, Resched if Unable to stop=YES

(Note: You probably wouldn't want to choose this combination; it is included here to illustrate the functionality.)

If the job cannot be stopped, the status of the current record is set to RESCHEDSTOPFAIL and the status of the new record is set to RESCHEDFAILED.

If the job can be stopped, the system sets the status of the current record to RESCHEDSTOPPED, and creates a new record.

Stop Original Job=NO, Resched if Unable to stop=YES

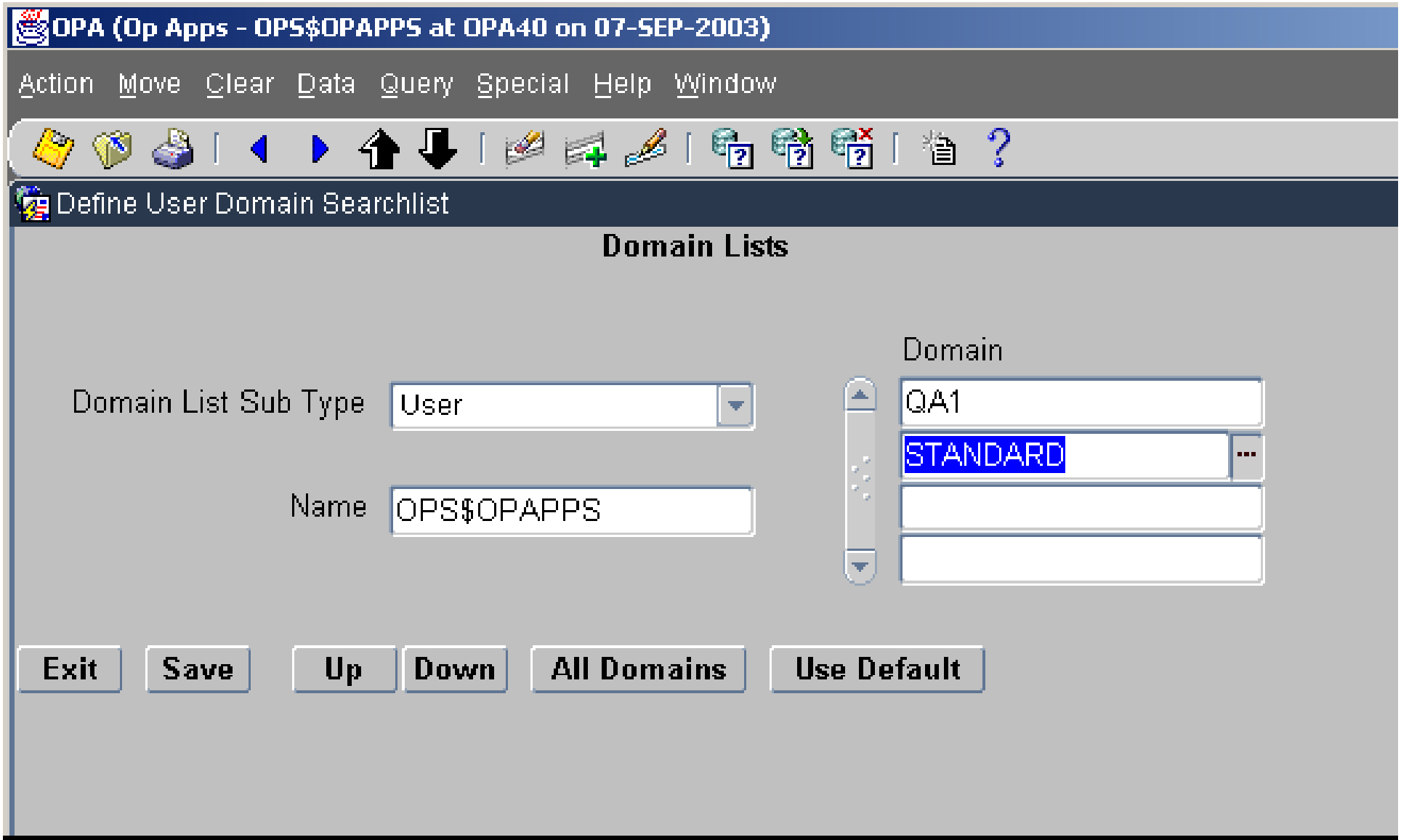
The system sets the status of the existing record to RESCHEDNOSTOP, and creates a new record

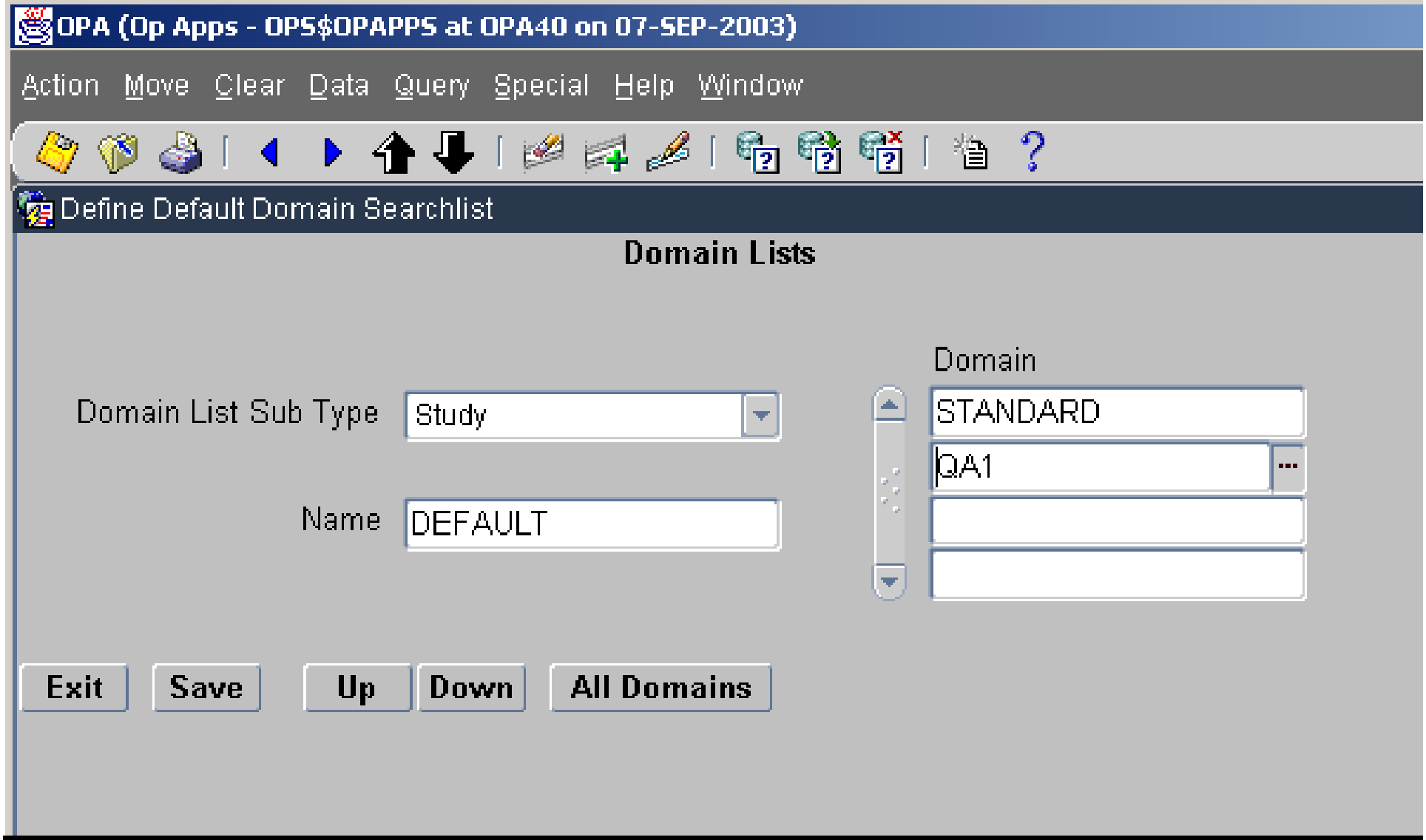
About the new record

If the rescheduling is successful, the status is SCHEDULED. If rescheduling fails, the new record's status is RESCHEDFAILED. This last case is most likely to happen if you are rescheduling to a different Reports Server where that has connection problems.

OC GLIB Access

- The GLIB in OC is divided into domains. These domains can be made available to a user or a study.
- A User is said to have access to a specific set of Domains in the Global Library. This can be controlled for all users (Admin => GLIB Admin => Default Domains, User)
- Domain access can also be controlled for a specific User (Admin => GLIB Admin => User Domain or Admin => Users => Special => Define Domain Searchlist).
- A Study is said to have access to a specific set of Domains in the GLIB when the study needs to inherit an object from the GLIB, such as the use of a question or question group when creating a DCM. (Admin => GLIB Admin => Default Domains, Study)
- Domain Access can also be controlled at the Study Level, (Design => Studies => Clinical Studies => Special => Define Domain Searchlist)


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Define User Domain Searchlist
Domain Lists
Domain List Sub Type
User
Name
OPS$OPAPPS
Domain
QA1
STANDARD
Exit
Save
Up
Down
All Domains
Use Default

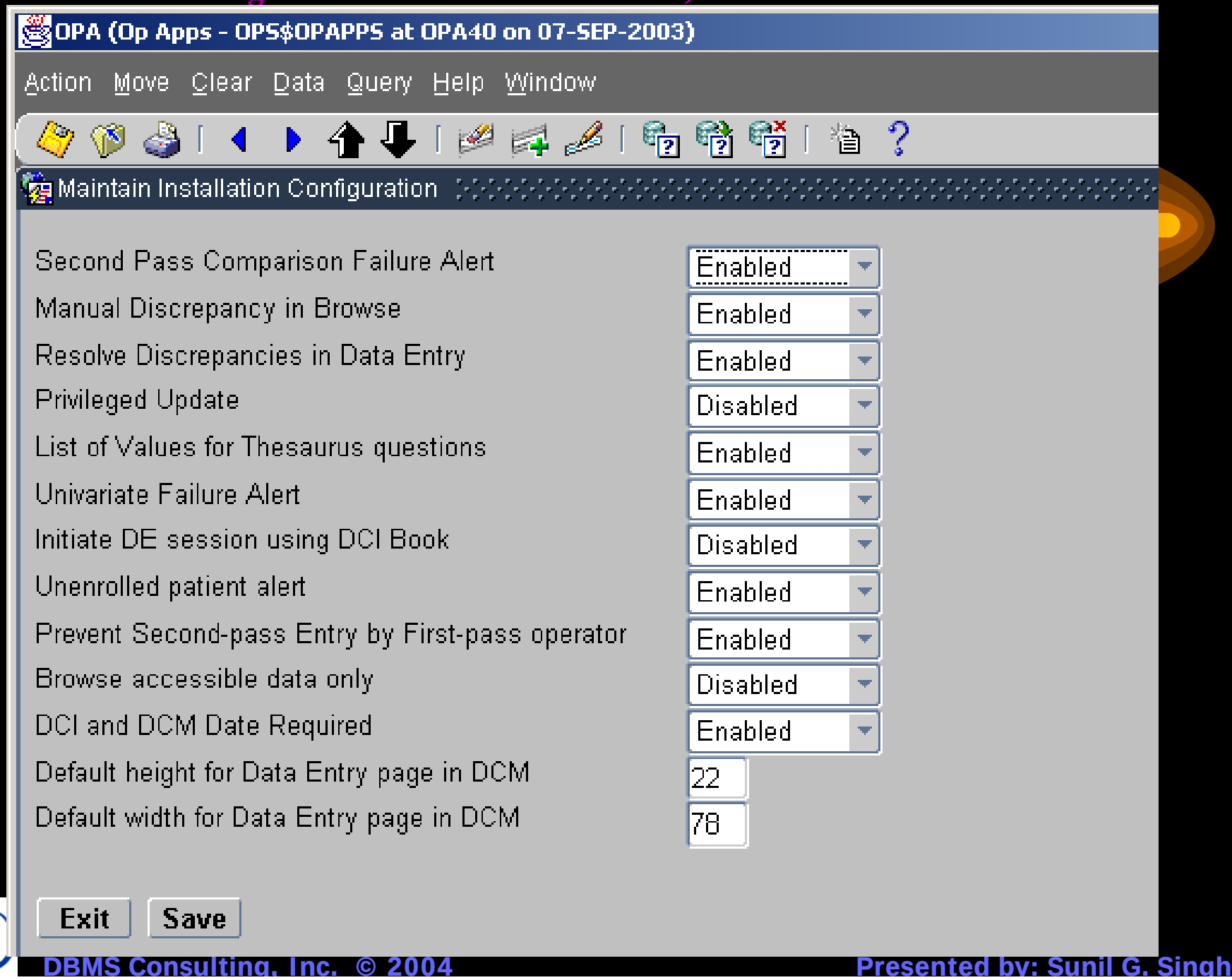

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Define Default Domain Searchlist
Domain Lists
Domain List Sub Type
Study
Name
DEFAULT
Domain
STANDARD
QA1
Exit
Save
Up
Down
All Domains

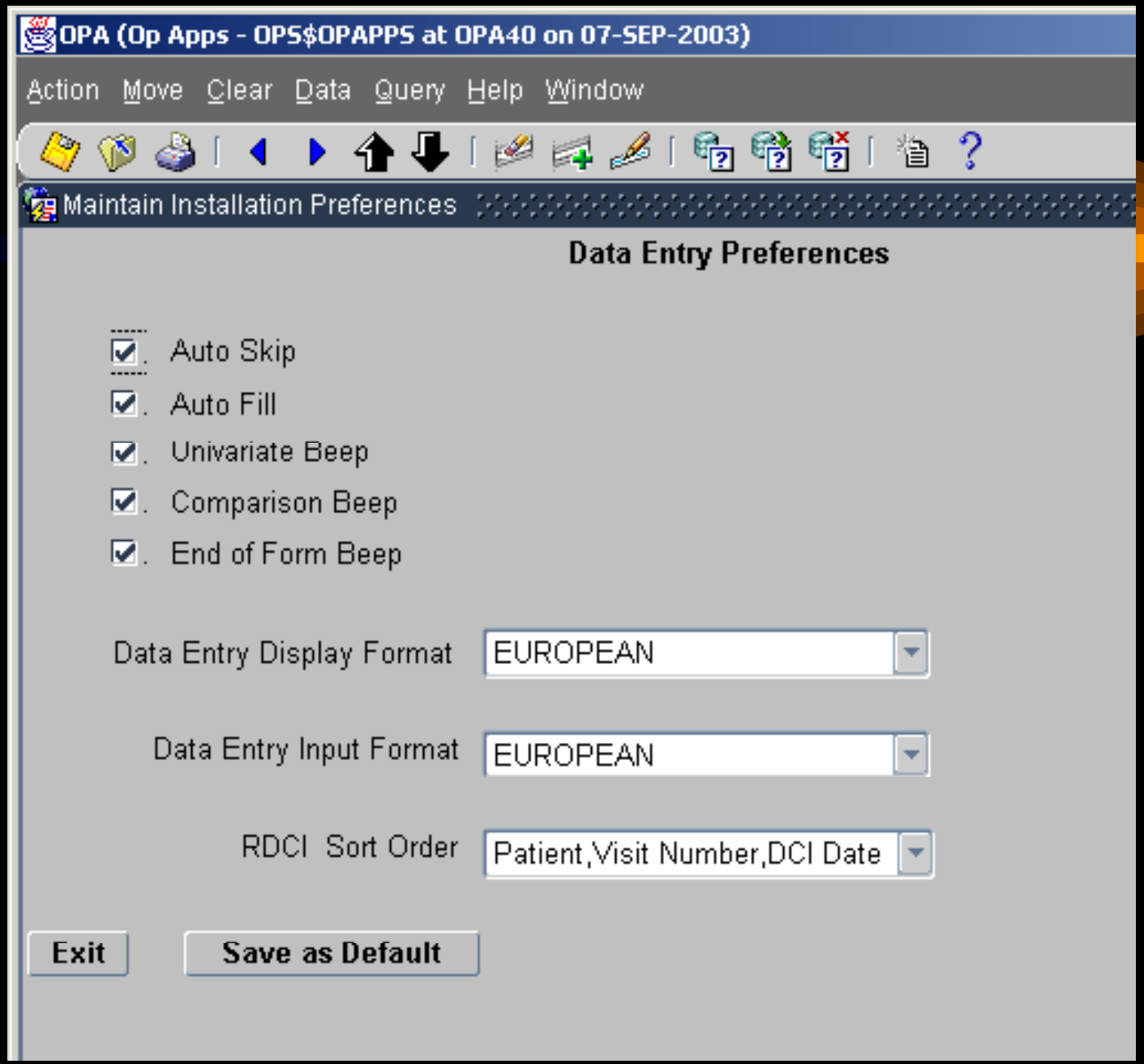
OC DE Configuration

- Data Entry Configuration can be controlled at the System Level, User Level and Study Level
  - Admin -> DE Admin -> DE Config Settings (System Level)
  - Admin -> Users -> Oracle Accounts, Special -> DE Configs (User Level)
  - Conduct -> Security -> Clinical Study States, Special -> DE Config (Study Level)
- Data Entry operator preferences can be controlled at the System and User Level
  - Admin -> DE Admin ->DE User Preferences (System Level)
  - Admin -> Users -> Oracle Accounts, Special -> DE Prefs (User Level)

OC DE Configuration (2)

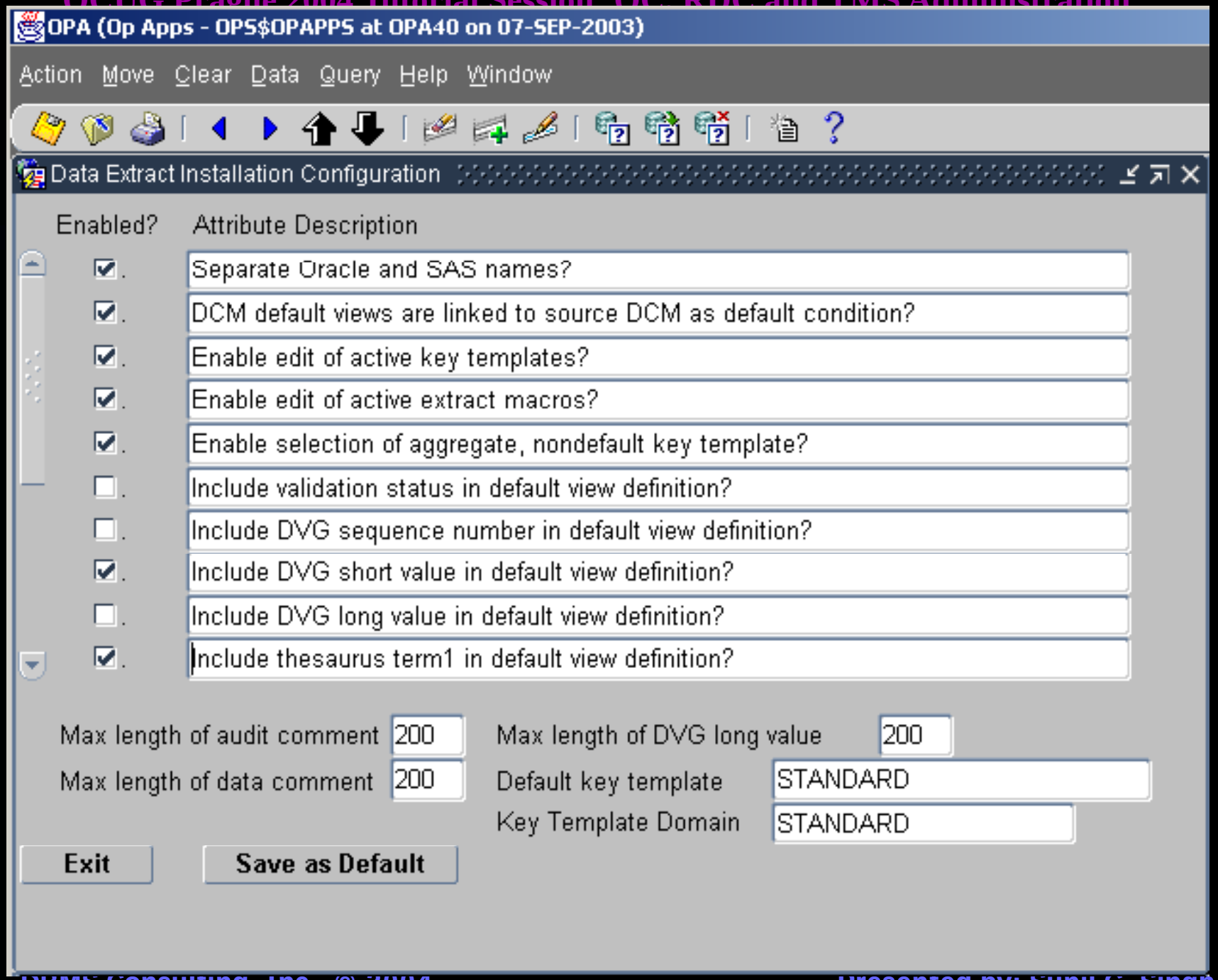
- Precedence of these options is User, then Study, then System
  - If an option is set at the User Level, it prevails all other settings.
  - If an option is not set at the User Level, but set at the Study Level, then the Study Level Prevails
  - If an option is set at neither the User nor the Study Level, then the System setting prevails

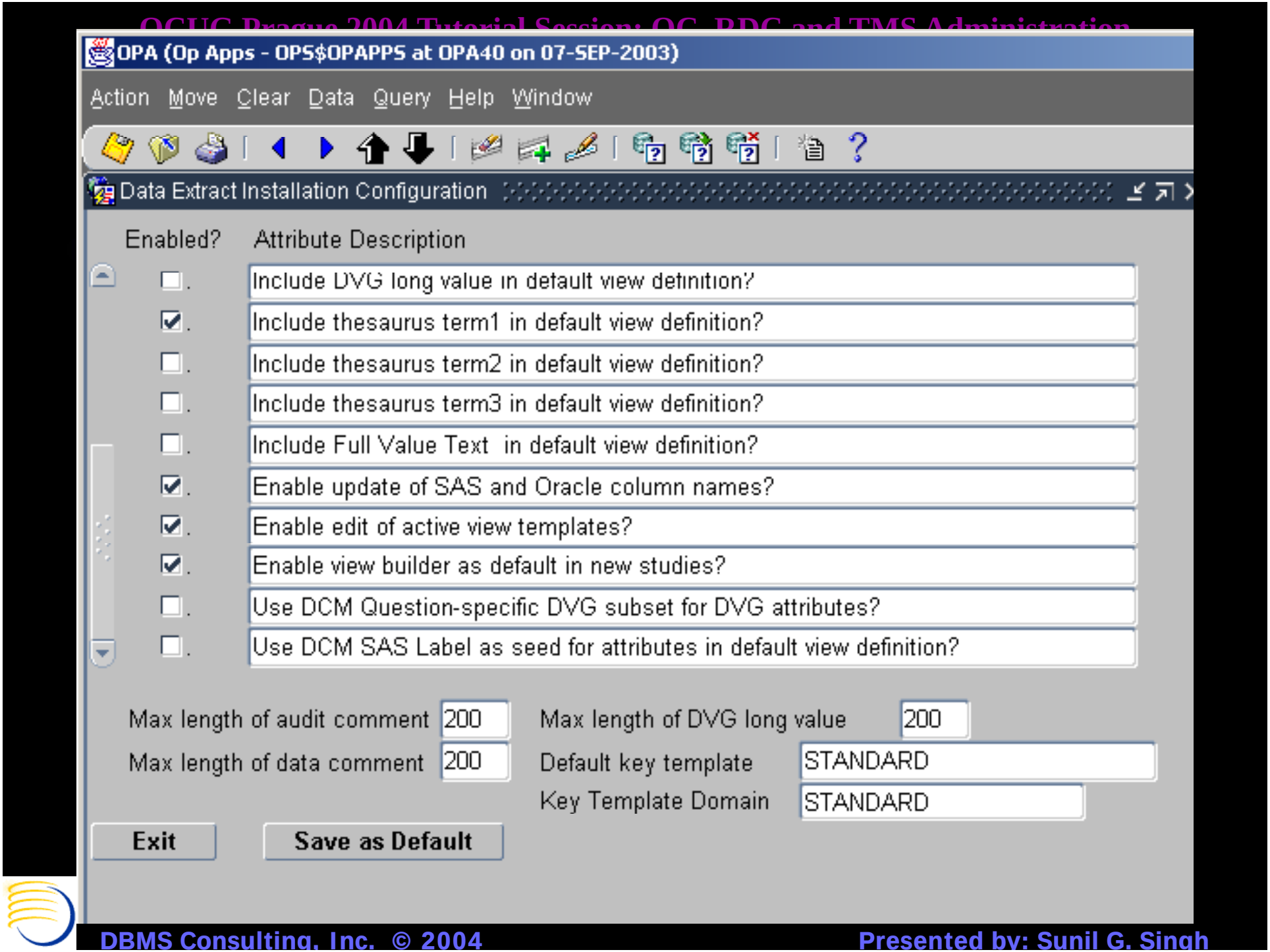

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Configuration
Second Pass Comparison Failure Alert
Enabled
Manual Discrepancy in Browse
Enabled
Resolve Discrepancies in Data Entry
Enabled
Privileged Update
Disabled
List of Values for Thesaurus questions
Enabled
Univariate Failure Alert
Enabled
Initiate DE session using DCI Book
Disabled
Unenrolled patient alert
Enabled
Prevent Second-pass Entry by First-pass operator
Enabled
Browse accessible data only
Disabled
DCI and DCM Date Required
Enabled
Default height for Data Entry page in DCM
22
Default width for Data Entry page in DCM
78
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Preferences
Data Entry Preferences
Auto Skip
Auto Fill
Univariate Beep
Comparison Beep
End of Form Beep
Data Entry Display Format
EUROPEAN
Data Entry Input Format
EUROPEAN
RDCI Sort Order
Patient,Visit Number,DCI Date
Exit
Save as Default

DX View Configuration

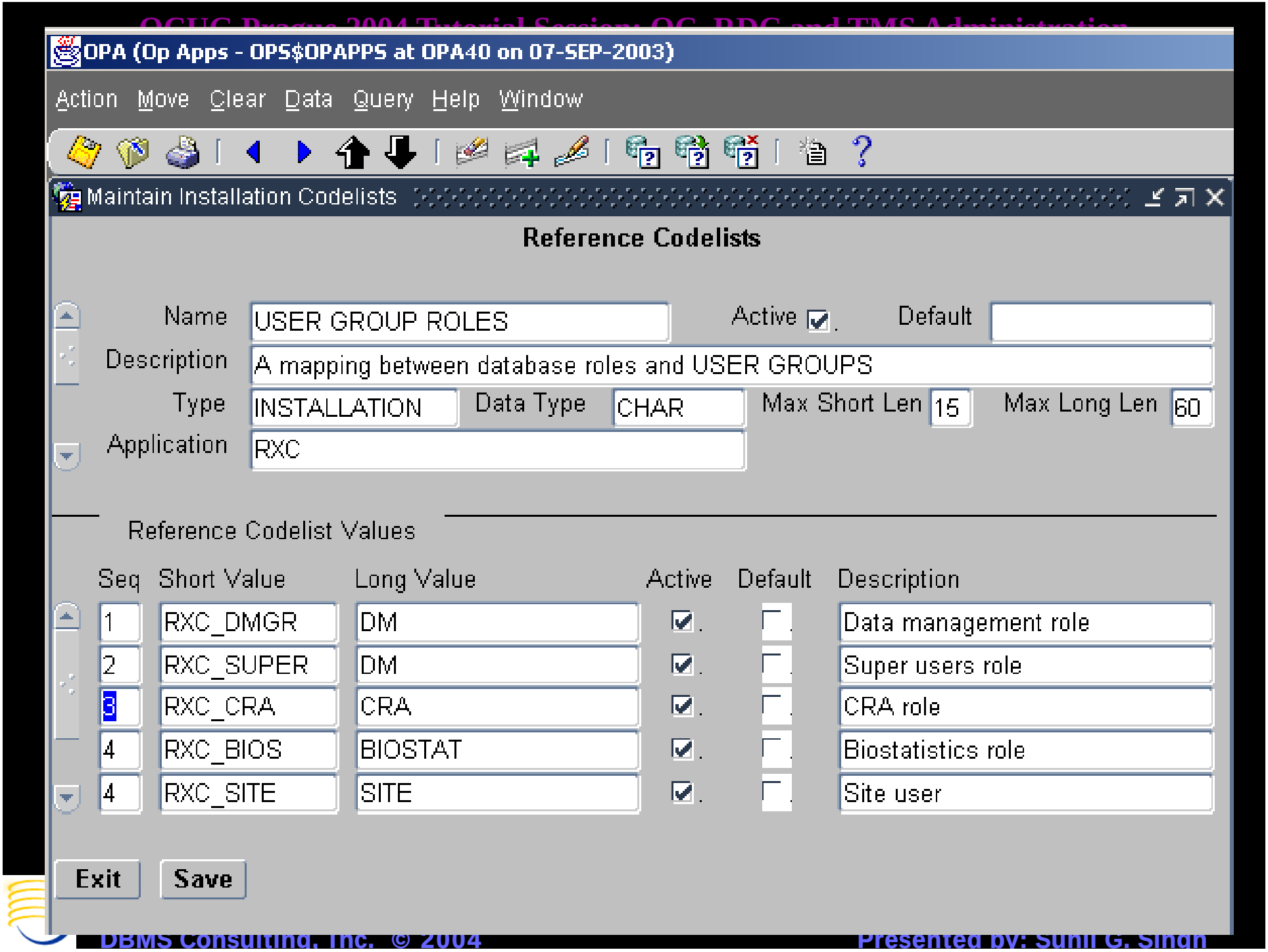
- System level configuration for Data Extract Views can be controlled either by Admin -> DX Installation Configuration or by the Installation Reference Codelist DX_CONFIG
- Default configurations controlled here are:
  - Key Template and Key Template domains
  - Editable characteristics of Key Templates, Extract Macros, View Templates, SAS and Oracle column names
  - Use of SAS Names and level of inheritance of the SAS Name
  - Extended Attribute creation for DVG, Thesaurus DVG and non-DVG questions
  - Default length of Audit Comment, Data Comment, DVG Long Value

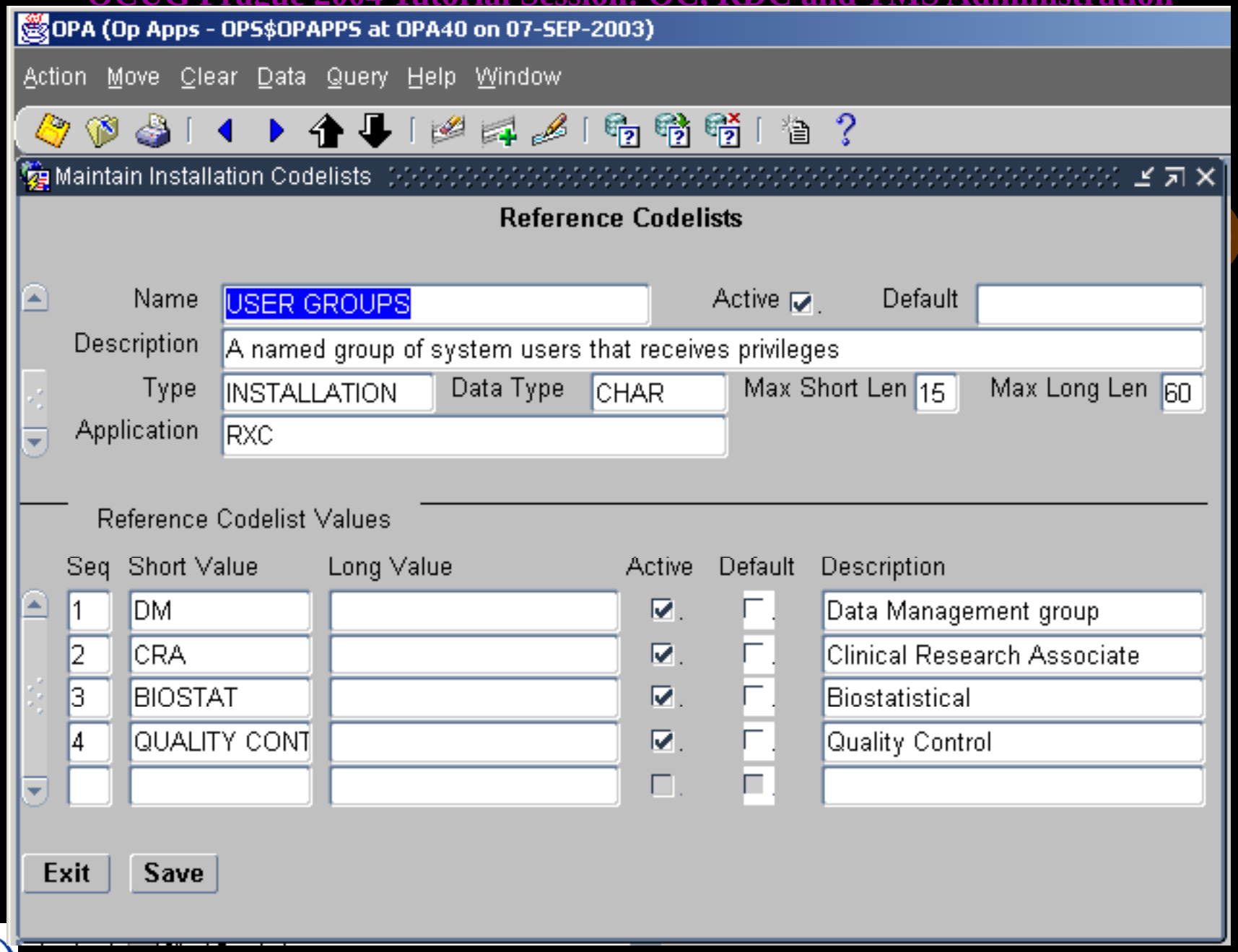

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Data Extract Installation Configuration
Enabled?
Attribute Description
Separate Oracle and SAS names?
DCM default views are linked to source DCM as default condition?
Enable edit of active key templates?
Enable edit of active extract macros?
Enable selection of aggregate, nondefault key template?
Include validation status in default view definition?
Include DVG sequence number in default view definition?
Include DVG short value in default view definition?
Include DVG long value in default view definition?
Include thesaurus term1 in default view definition?
Max length of audit comment
200
Max length of data comment
200
Max length of DVG long value
200
Default key template
STANDARD
Key Template Domain
STANDARD
Exit
Save as Default

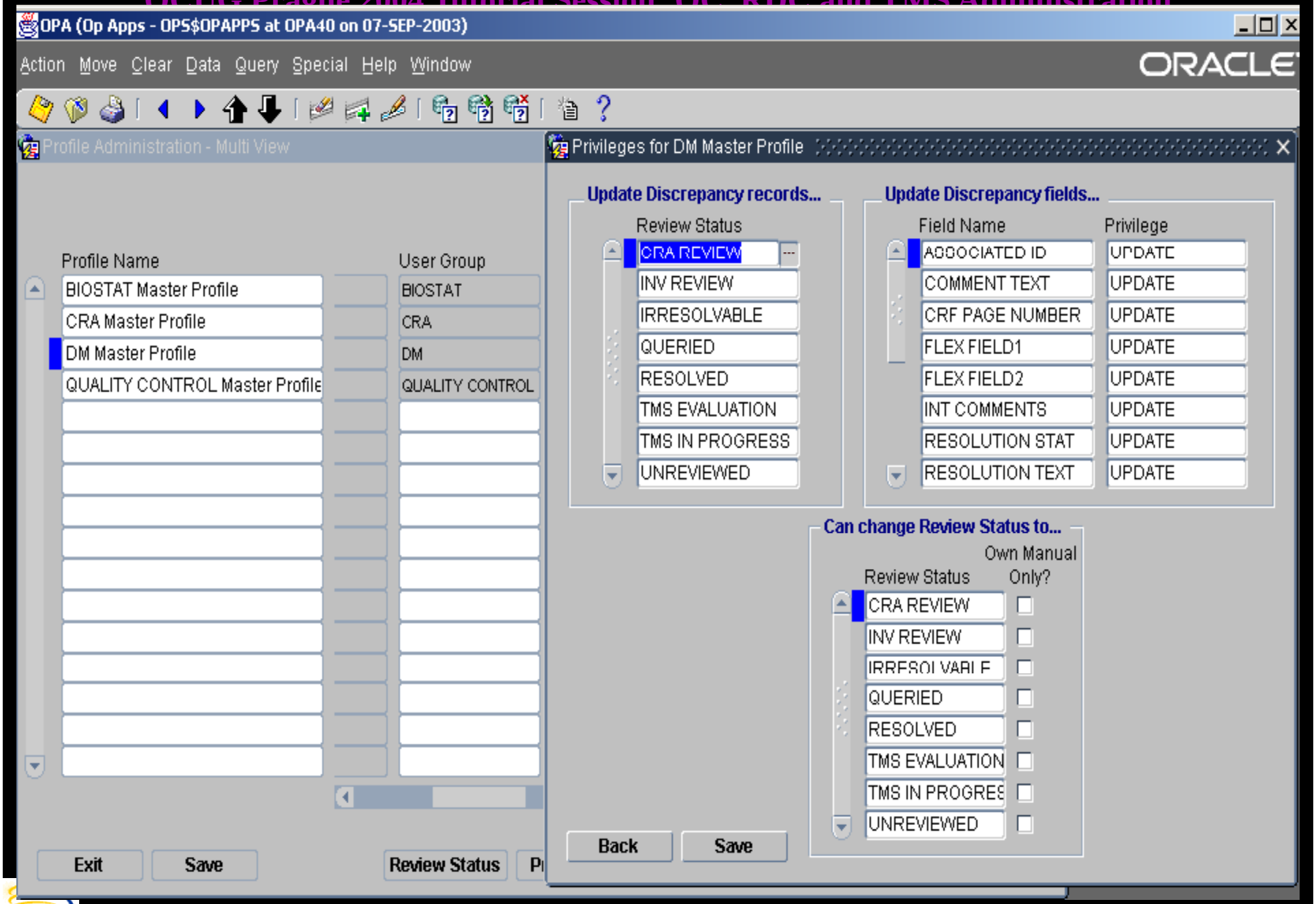

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Data Extract Installation Configuration
Enabled?
Attribute Description
Include DVG long value in default view definition?
Include thesaurus term1 in default view definition?
Include thesaurus term2 in default view definition?
Include thesaurus term3 in default view definition?
Include Full Value Text in default view definition?
Enable update of SAS and Oracle column names?
Enable edit of active view templates?
Enable view builder as default in new studies?
Use DCM Question-specific DVG subset for DVG attributes?
Use DCM SAS Label as seed for attributes in default view definition?
Max length of audit comment
200
Max length of data comment
200
Max length of DVG long value
200
Default key template
STANDARD
Key Template Domain
STANDARD
Exit
Save as Default

Enhanced Discrepancy Management Access

- EDMS controls specific actions on Discrepancies (sometimes known as queries) with a much finer level of granularity than just access to the menu path Conduct => Data Validation => Discrepancy Database. This is accomplished by assigning an EDMS profile to a user.
- EDMS identifies a Master Profile based on Database Roles defined in USER GROUPS and USER GROUP ROLES Installation Reference Codelists. A Database Role will have an entry in USER GROUP ROLES, which will associate that role to a USER GROUP. This USER GROUP will be associated to a default Master Profile.


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Codelists
Reference Codelists
Name USER GROUP ROLES
Active
Default
Description A mapping between database roles and USER GROUPS
Type INSTALLATION
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Reference Codelist Values
Seq Short Value Long Value Active Default Description
1 RXC_DMGR DM Data management role
2 RXC_SUPER DM Super users role
3 RXC_CRA CRA CRA role
4 RXC_BIOS BIOSTAT Biostatistics role
4 RXC_SITE SITE Site user
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Codelists
Reference Codelists
Name USER GROUPS
Active
Default
Description A named group of system users that receives privileges
Type INSTALLATION
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Reference Codelist Values
Seq Short Value Long Value Active Default Description
1 DM Data Management group
2 CRA Clinical Research Associate
3 BIOSTAT Biostatistical
4 QUALITY CONT Quality Control
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
ORACLE
Profile Administration - Multi View
Profile Name
User Group
BIOSTAT Master Profile
BIOSTAT
CRA Master Profile
CRA
DM Master Profile
DM
QUALITY CONTROL Master Profile
QUALITY CONTROL
Exit
Save
Review Status
Privileges for DM Master Profile
Update Discrepancy records...
Review Status
CRA REVIEW
INV REVIEW
IRRESOLVABLE
QUERIED
RESOLVED
TMS EVALUATION
TMS IN PROGRESS
UNREVIEWED
Update Discrepancy fields...
Field Name
Privilege
ASSOCIATED ID
UPDATE
COMMENT TEXT
UPDATE
CRF PAGE NUMBER
UPDATE
FLEX FIELD1
UPDATE
FLEX FIELD2
UPDATE
INT COMMENTS
UPDATE
RESOLUTION STAT
UPDATE
RESOLUTION TEXT
UPDATE
Can change Review Status to...
Review Status
Own Manual Only?
CRA REVIEW
INV REVIEW
IRRESOLVABLE
QUERIED
RESOLVED
TMS EVALUATION
TMS IN PROGRES
UNREVIEWED
Back
Save

OC EDMS Administrative options

- Admin => Discrepancy Management Admin => Profile Administration. Controls profile permissions within the EDMS module
- Admin => Discrepancy Management Admin => Standard Text Maintenance. Controls text for UNIVARIATE Discrepancies and some parts of DCFs.
- Admin => Discrepancy Management Admin => User Group Administration. Controls what functions a USER GROUP may access within EDMS
- Admin => Discrepancy Management Admin => Layout Definitions. Controls Multi-View of EDMS

RDC Database Roles

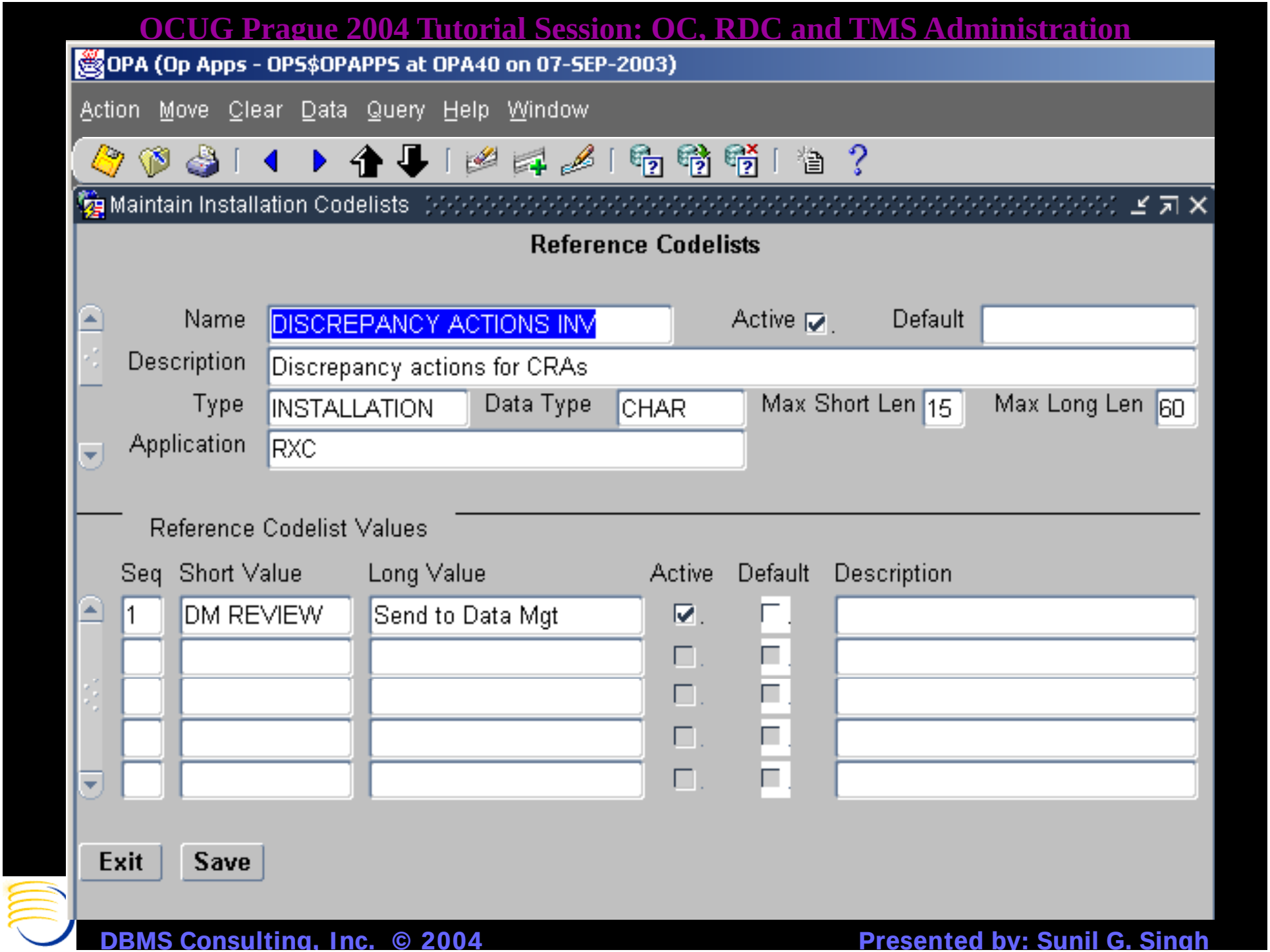
- The Database Roles RDC_ACCESS, RXC_RDC, RXC_INV, RXC_SITE, RXC_CRA, and RXC_DMGR control access to RDC by default
- The Database Role RDC_ACCESS must be granted to any user to access RDC, in addition to one or more of the other roles
- The Database Role RXC_RDC is required for any update access within the Production RDC interface, the Database Role RXC_RDCT is required for any Test mode Access
- The roles RXC_INV (intended for Investigators) and RXC_SITE (intended for Site Users) and RXC_DMGR (intended for Data Managers) and RXC_CRA (intended for CRAs) are defined in the Installation Reference Codelist USER_GROUP_ROLES. However, they are not associated with USER_GROUPS as EDMS Profiles.

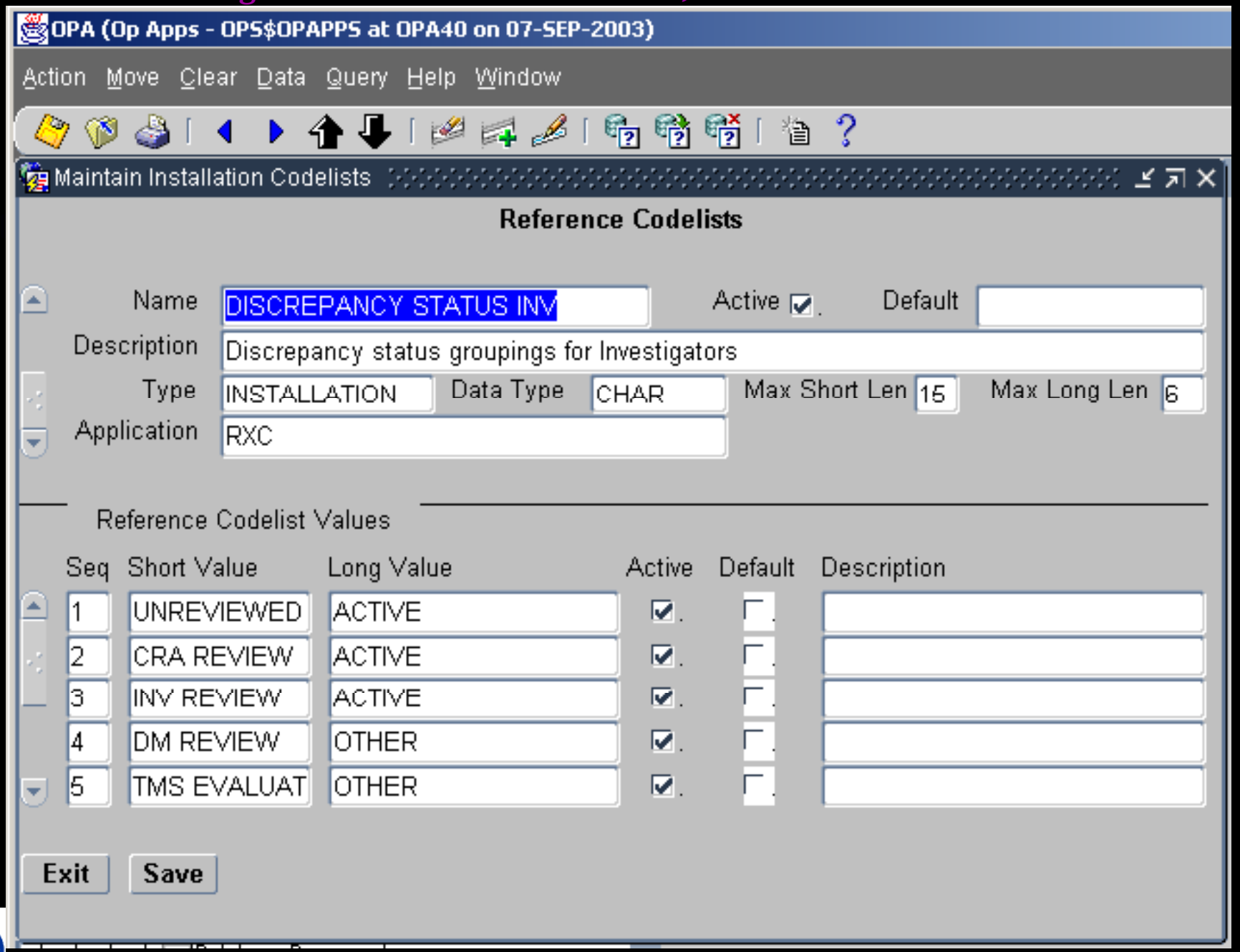
RDC Database Roles (2)

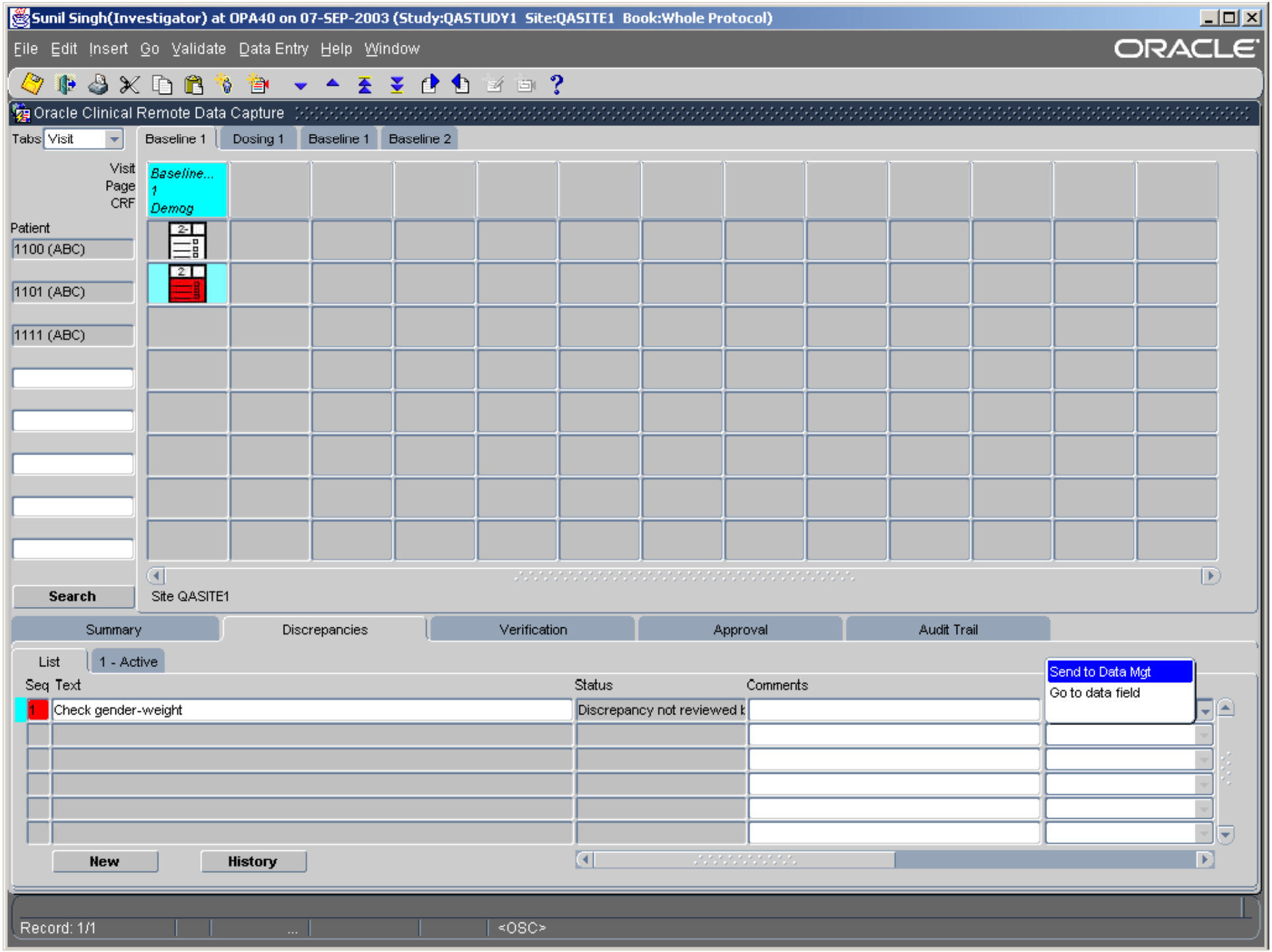
- Instead, two custom Installation reference codelists exist for each of these roles, which support some similar functionality to profiles:
  - Discrepancy Actions <ROLE>, e.g., SITE, INV, DM, CRA
  - Discrepancy Status <ROLE>, e.g., SITE, INV, DM, CRA
- The Discrepancy Actions <ROLE> lists the possible Review Statuses the user, within RDC, can set a discrepancy to.
- The Discrepancy Status <ROLE> lists the possible review status which can be seen by the user, within RDC.

RDC Database Roles (3)

- Generally, OC Accounts and RDC accounts are not the same. RDC Accounts do not require the OPS$ predication and therefore, to not run Database Server batch jobs (except for Validate → Study which runs Batch Validation)
- Custom roles for RDC can be created, and custom Discrepancy Actions <ROLE> and Discrepancy Status <ROLE> Installation Reference Codelists can be made to support these roles. These should be added via Developer's Toolkit => Maintain all Codelists. This requires the DTK_ADMIN role. Back-end updates to REFERENCE_CODELIST_VALUES should be avoided.


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Codelists
Reference Codelists
Name DISCREPANCY ACTIONS INV
Active
Default
Description Discrepancy actions for CRAs
Type INSTALLATION
Data Type CHAR
Max Short Len 15
Max Long Len 60
Application RXC
Reference Codelist Values
Seq
Short Value
Long Value
Active
Default
Description
1
DM REVIEW
Send to Data Mgt
Exit
Save


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Codelists
Reference Codelists
Name DISCREPANCY STATUS INV
Active
Default
Description Discrepancy status groupings for Investigators
Type INSTALLATION
Data Type CHAR
Max Short Len 15
Max Long Len 6
Application RXC
Reference Codelist Values
Seq Short Value Long Value Active Default Description
1 UNREVIEWED ACTIVE
2 CRA REVIEW ACTIVE
3 INV REVIEW ACTIVE
4 DM REVIEW OTHER
5 TMS EVALUAT OTHER
Exit
Save


Sunil Singh(Investigator) at OPA40 on 07-SEP-2003 (Study:QASTUDY1 Site:QASITE1 Book:Whole Protocol)
File Edit Insert Go Validate Data Entry Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Baseline 1
Dosing 1
Baseline 1
Baseline 2
Visit
Page
CRF
Baseline...
1
Demog
Patient
1100 (ABC)
1101 (ABC)
1111 (ABC)
Search
Site QASITE1
Summary
Discrepancies
Verification
Approval
Audit Trail
List
1 - Active
Seq Text
Status
Comments
1
Check gender-weight
Discrepancy not reviewed k
Send to Data Mgt
Go to data field
New
History
Record: 1/1
<OSC>

RDC Admin Form

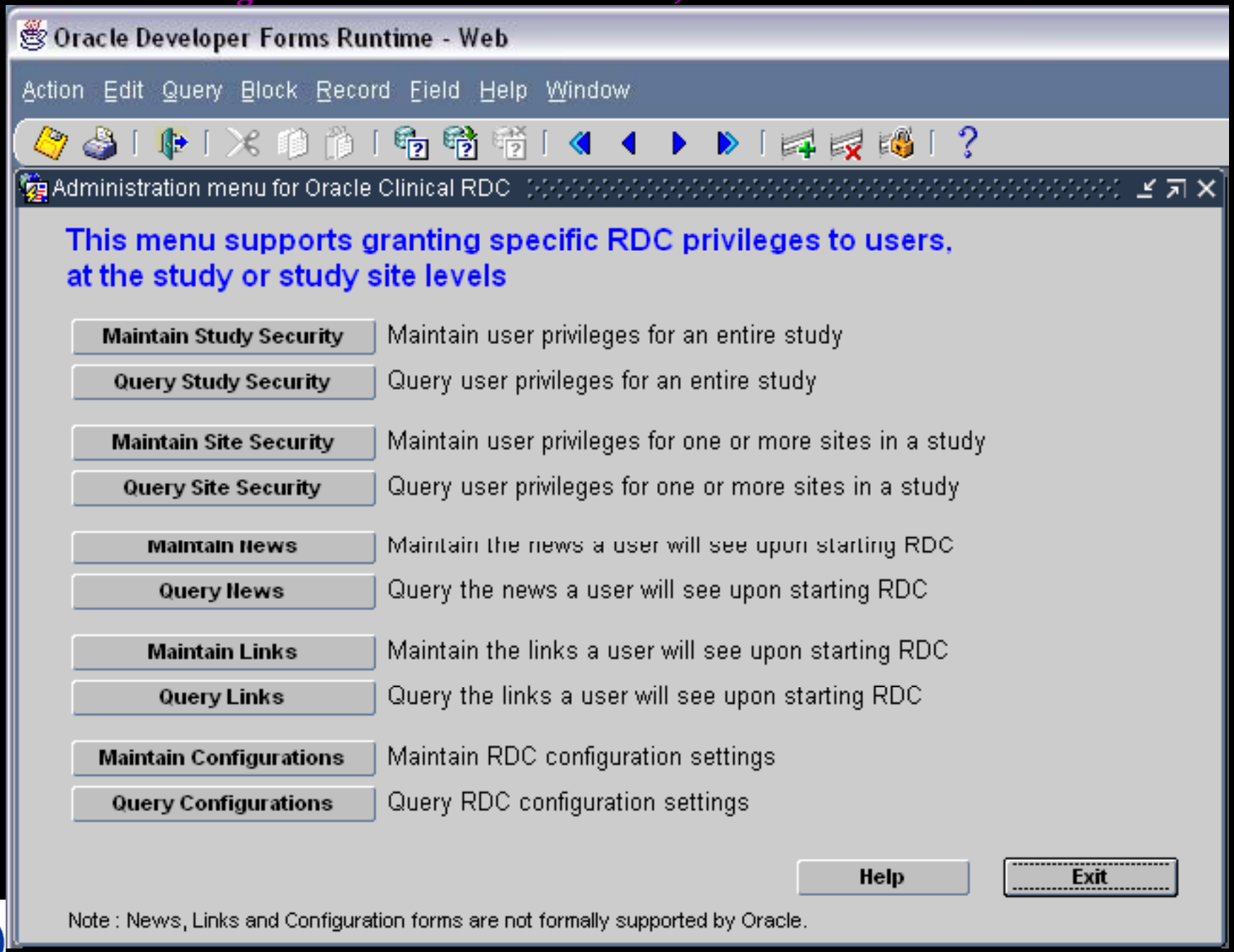
- Remote Data Capture has a special Administration Form which configures Study access and Site access from within RDC. The access to studies is NOT controlled only through Oracle Clinical => Admin => Users => Oracle Accounts. It is a different process from OC.
- The type of access control is similar to the control of EDMS profile privileges.
- The set of privileges which can be controlled in RDC at the Study Level are:
  - BROWSE (Browse Data-Entry Data)
  - BRW_BATCH (Browse Batch Loaded Data)
  - UPDATE (Update Data-Entry Data)
  - UPD BATCH (Update Batch Loaded Data)
  - UPD_DISCREP (Update Discrepancies)
  - VERIFY (Verify CRFs)

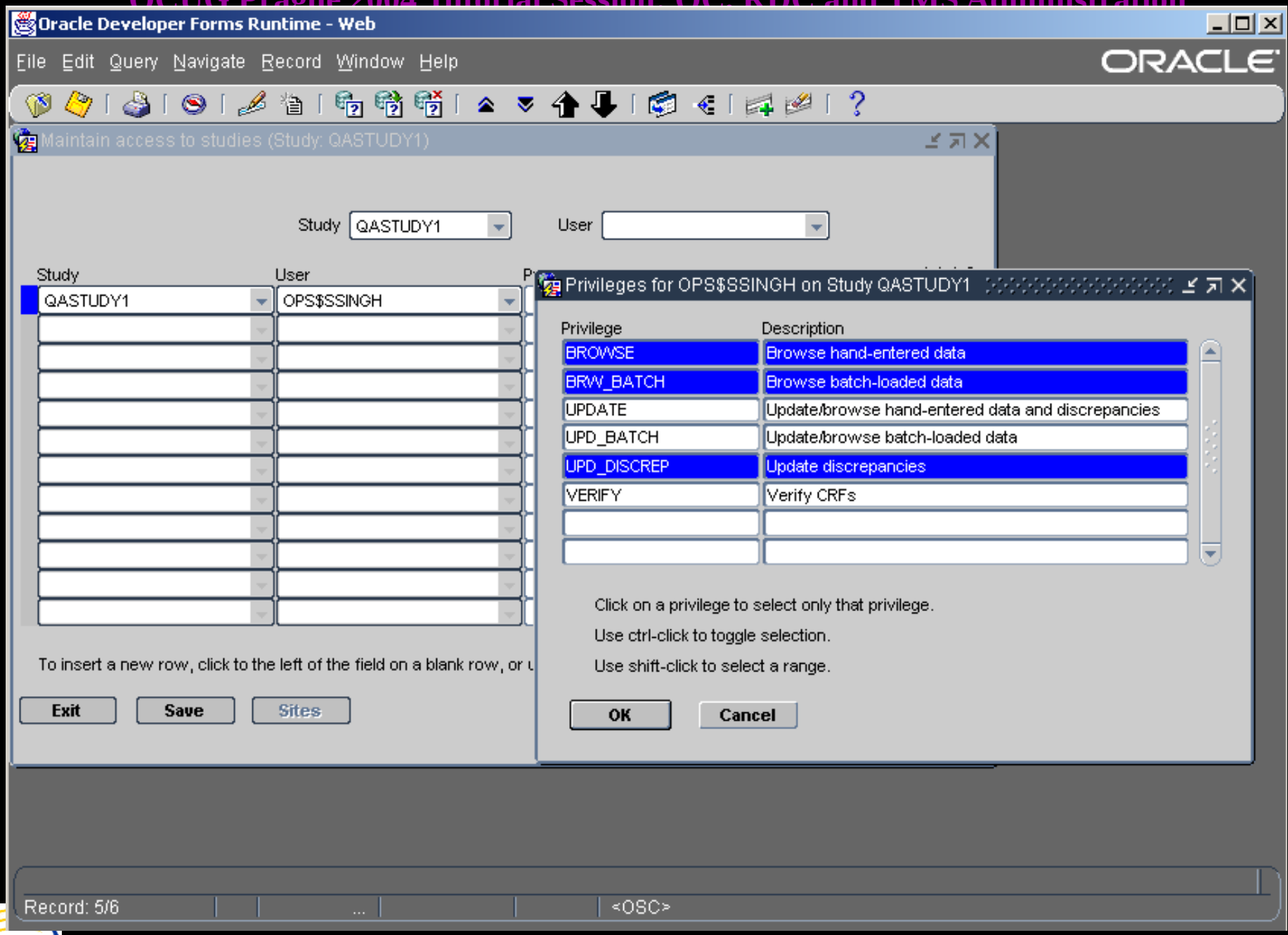
RDC Admin Form (2)

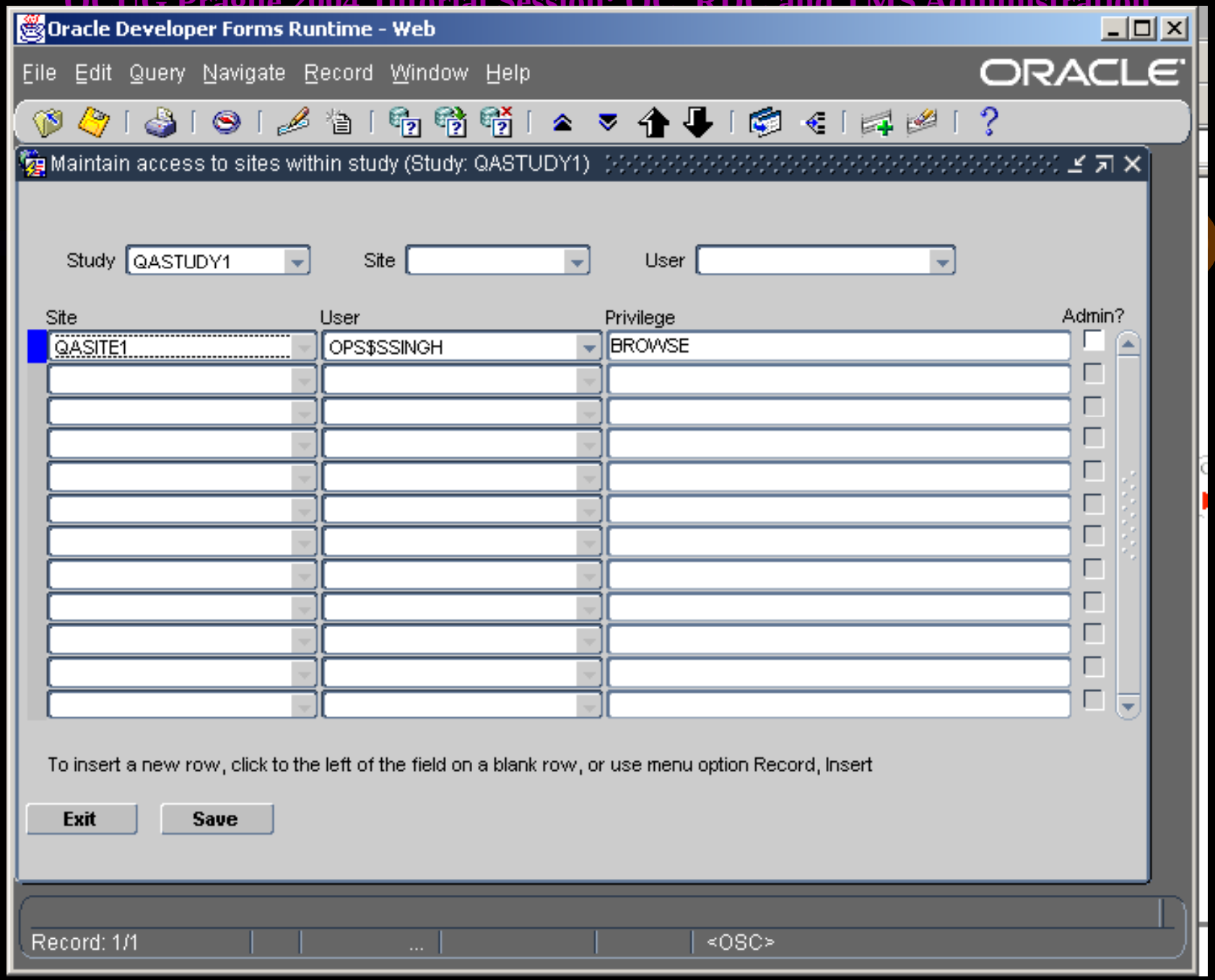
- The set of privileges which can be controlled in RDC at the Study Level are:
  - BROWSE (Browse Data-Entry Data)
  - BRW_BATCH (Browse Batch Loaded Data)
  - UPDATE (Update Data-Entry Data)
  - UPD_BATCH (Update Batch Loaded Data)
  - UPD_DISCREP (Update Discrepancies)
  - VERIFY (Verify CRFs)
  - LOCK (Lock CRFs, also allows Group Activities access)
  - UNLOCK (Unlock CRFs, Lock CRFs, also allows Group Activities access)

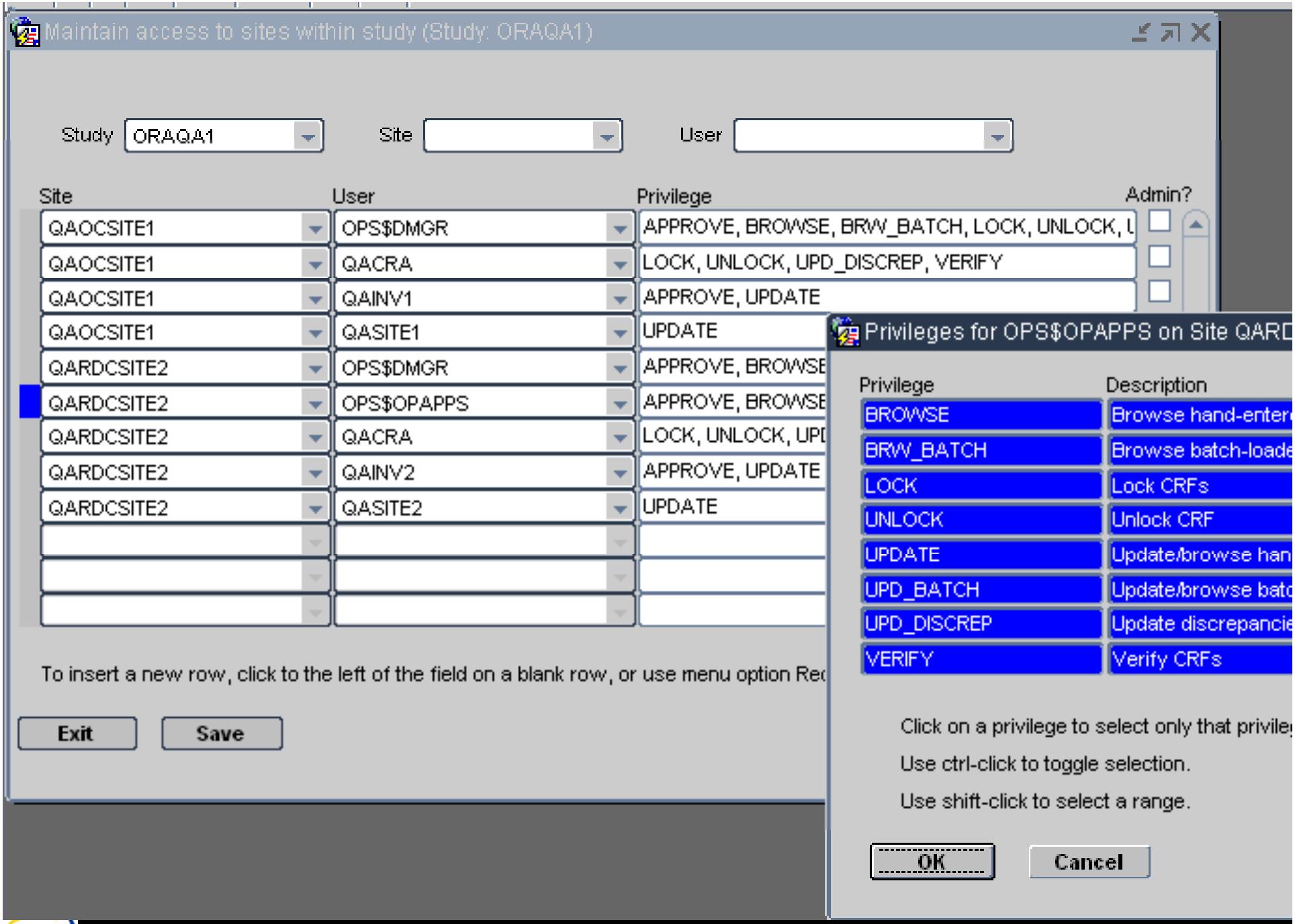
RDC Admin Form (3)

- Any subset of these privileges related to RDC can be assign to
  - study and user combination via Maintain Study Security
  - or a study, site and user combination via Maintain Site Security, or Maintain Study Security and pressing Sites button
- A privilege configuration at the Site level overrides a privilege configuration at the Study level
- From within OC, the Admin => Users => Study Security is the same form as the Maintain Study Security button
- From within OC, the Admin => Users => Site Security is the same form as the Maintain Site Security button


Oracle Developer Forms Runtime - Web
Action Edit Query Block Record Field Help Window
Administration menu for Oracle Clinical RDC
This menu supports granting specific RDC privileges to users, at the study or study site levels
Maintain Study Security
Maintain user privileges for an entire study
Query Study Security
Query user privileges for an entire study
Maintain Site Security
Maintain user privileges for one or more sites in a study
Query Site Security
Query user privileges for one or more sites in a study
Maintain News
Maintain the news a user will see upon starting RDC
Query News
Query the news a user will see upon starting RDC
Maintain Links
Maintain the links a user will see upon starting RDC
Query Links
Query the links a user will see upon starting RDC
Maintain Configurations
Maintain RDC configuration settings
Query Configurations
Query RDC configuration settings
Help
Exit
Note : News, Links and Configuration forms are not formally supported by Oracle.


Oracle Developer Forms Runtime - Web
File Edit Query Navigate Record Window Help
ORACLE
Maintain access to studies (Study: QASTUDY1)
Study QASTUDY1
User
Study
User
QASTUDY1
OPS$SSINGH
To insert a new row, click to the left of the field on a blank row, or u
Exit
Save
Sites
Privileges for OPS$SSINGH on Study QASTUDY1
Privilege
Description
BROWSE
Browse hand-entered data
BRW_BATCH
Browse batch-loaded data
UPDATE
Update/browse hand-entered data and discrepancies
UPD_BATCH
Update/browse batch-loaded data
UPD_DISCREP
Update discrepancies
VERIFY
Verify CRFs
Click on a privilege to select only that privilege.
Use ctrl-click to toggle selection.
Use shift-click to select a range.
OK
Cancel
Record: 5/6
<OSC>


Oracle Developer Forms Runtime - Web
File Edit Query Navigate Record Window Help
ORACLE
Maintain access to sites within study (Study: QASTUDY1)
Study QASTUDY1
Site
User
Site
User
Privilege
Admin?
QASITE1
OPS$SSINGH
BROWSE
To insert a new row, click to the left of the field on a blank row, or use menu option Record, Insert
Exit
Save
Record: 1/1
<OSC>

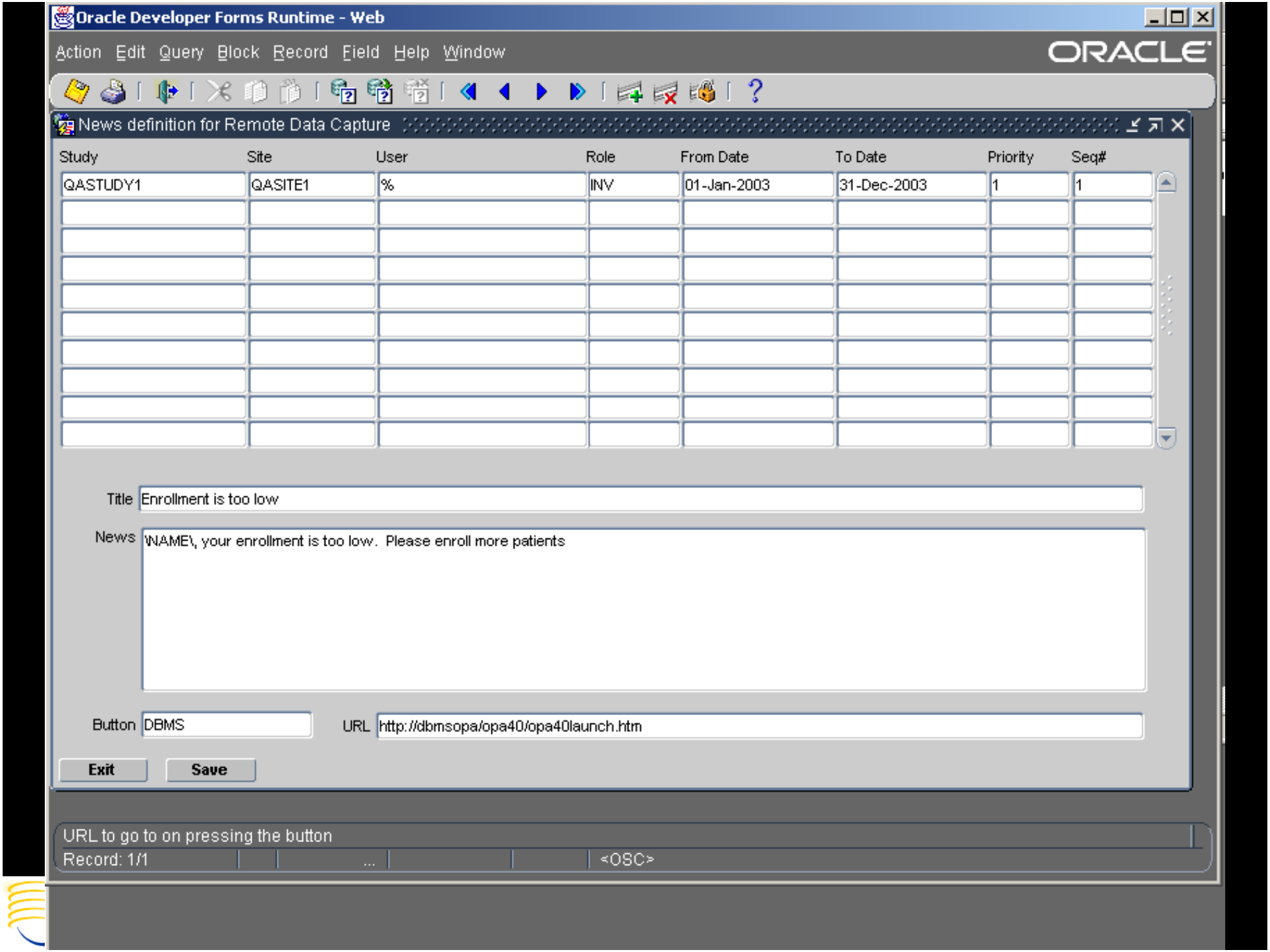

Maintain access to sites within study (Study: ORAQA1)
Study ORAQA1
Site
User
Site
User
Privilege
Admin?
QAOCSITE1 OPS$DMGR APPROVE, BROWSE, BRW_BATCH, LOCK, UNLOCK,
QAOCSITE1 QACRA LOCK, UNLOCK, UPD_DISCREP, VERIFY
QAOCSITE1 QAINV1 APPROVE, UPDATE
QAOCSITE1 QASITE1 UPDATE
QARDCSITE2 OPS$DMGR APPROVE, BROWSE
QARDCSITE2 OPS$OPAPPS APPROVE, BROWSE
QARDCSITE2 QACRA LOCK, UNLOCK, UPD
QARDCSITE2 QAINV2 APPROVE, UPDATE
QARDCSITE2 QASITE2 UPDATE
To insert a new row, click to the left of the field on a blank row, or use menu option Rec
Exit
Save
Privileges for OPS$OPAPPS on Site QARD
Privilege
Description
BROWSE Browse hand-entere
BRW_BATCH Browse batch-loade
LOCK Lock CRFs
UNLOCK Unlock CRF
UPDATE Update/browse han
UPD_BATCH Update/browse batc
UPD_DISCREP Update discrepancie
VERIFY Verify CRFs
Click on a privilege to select only that privile
Use ctrl-click to toggle selection.
Use shift-click to select a range.
OK
Cancel

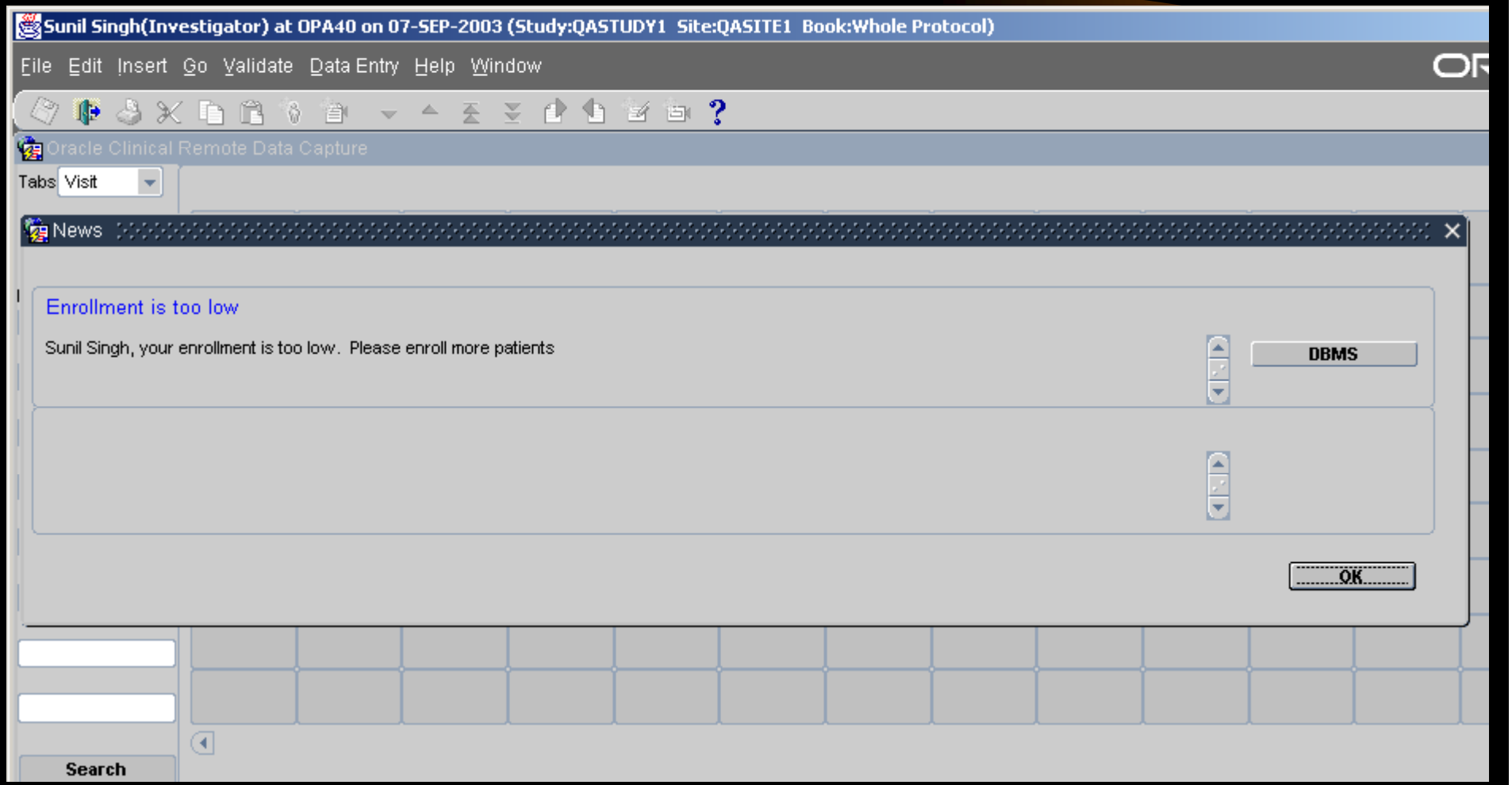
RDC Admin Form (4)

- Test mode RDC Administration is a separate form accessible from a separate link.
- RDC settings currently override EDMS profile settings. If a user has the same account for RDC and OC, and if some function is restricted in RDC, it will propagate into OC regardless of the current EDMS profile.

RDC News

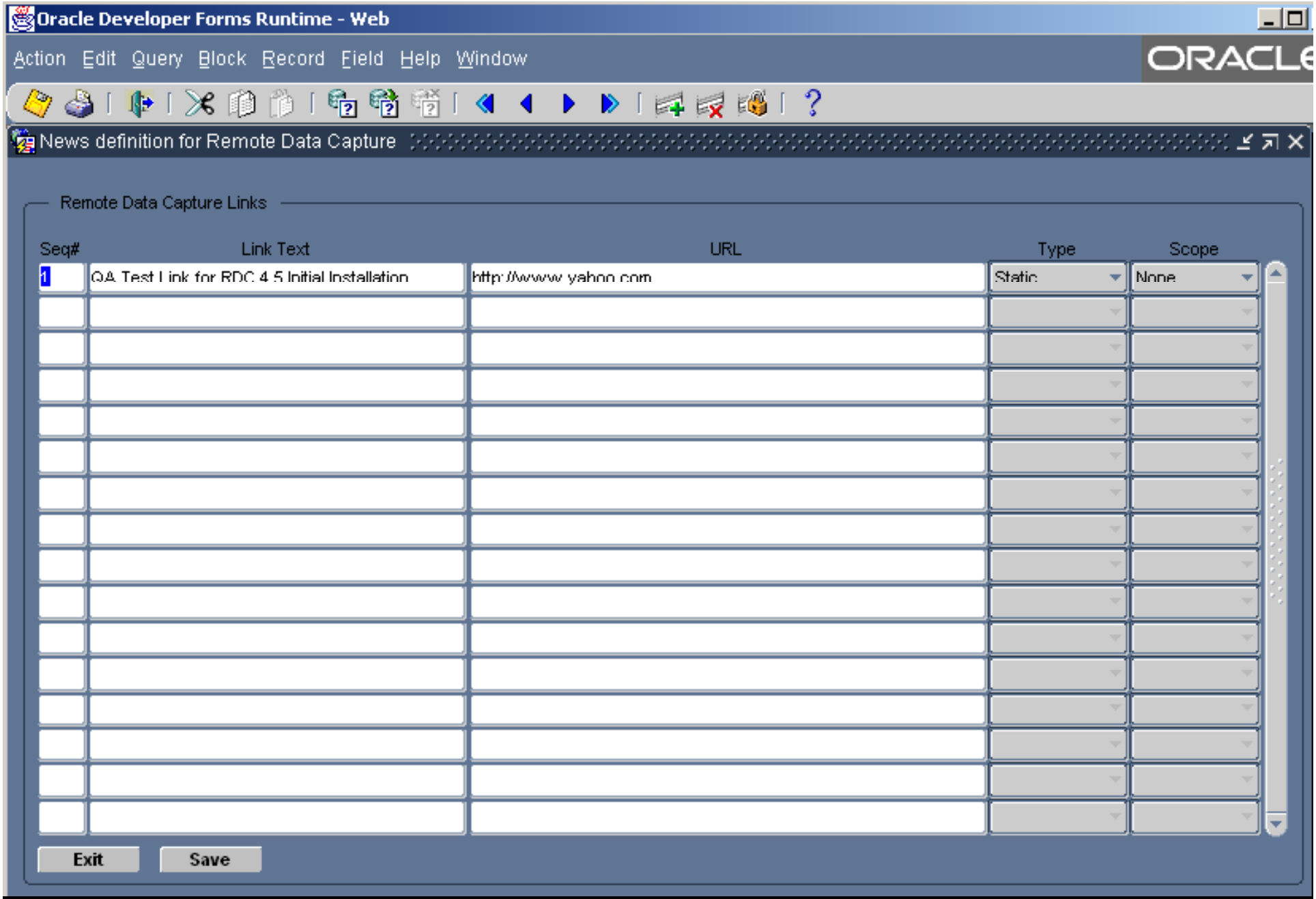
- Only visible from RDC Admin Form, Maintain News button
- Provides a way to communicate messages to any study, site or user combination
- RDC user matching criteria for the news message sees the message as soon as they select a study in RDC.
- Messages usually concern conduct of the ongoing study, related to topics such as enrollment or early termination rates
- Supports a link to a URL and a custom button
- Supports multiple messages
- All fields in the top of the News form are mandatory


Oracle Developer Forms Runtime - Web
Action Edit Query Block Record Field Help Window
ORACLE
News definition for Remote Data Capture
Study
Site
User
Role
From Date
To Date
Priority
Seq#
QASTUDY1
QASITE1
%
INV
01-Jan-2003
31-Dec-2003
1
1
Title
Enrollment is too low
News
\NAME\, your enrollment is too low. Please enroll more patients
Button
DBMS
URL
http://dbmsopa/opa40/opa40launch.htm
Exit
Save
URL to go to on pressing the button
Record: 1/1
<OSC>


Sunil Singh(Investigator) at OPA40 on 07-SEP-2003 (Study:QASTUDY1 Site:QASITE1 Book:Whole Protocol)
File Edit Insert Go Validate Data Entry Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
News
Enrollment is too low
Sunil Singh, your enrollment is too low. Please enroll more patients
DBMS
OK
Search

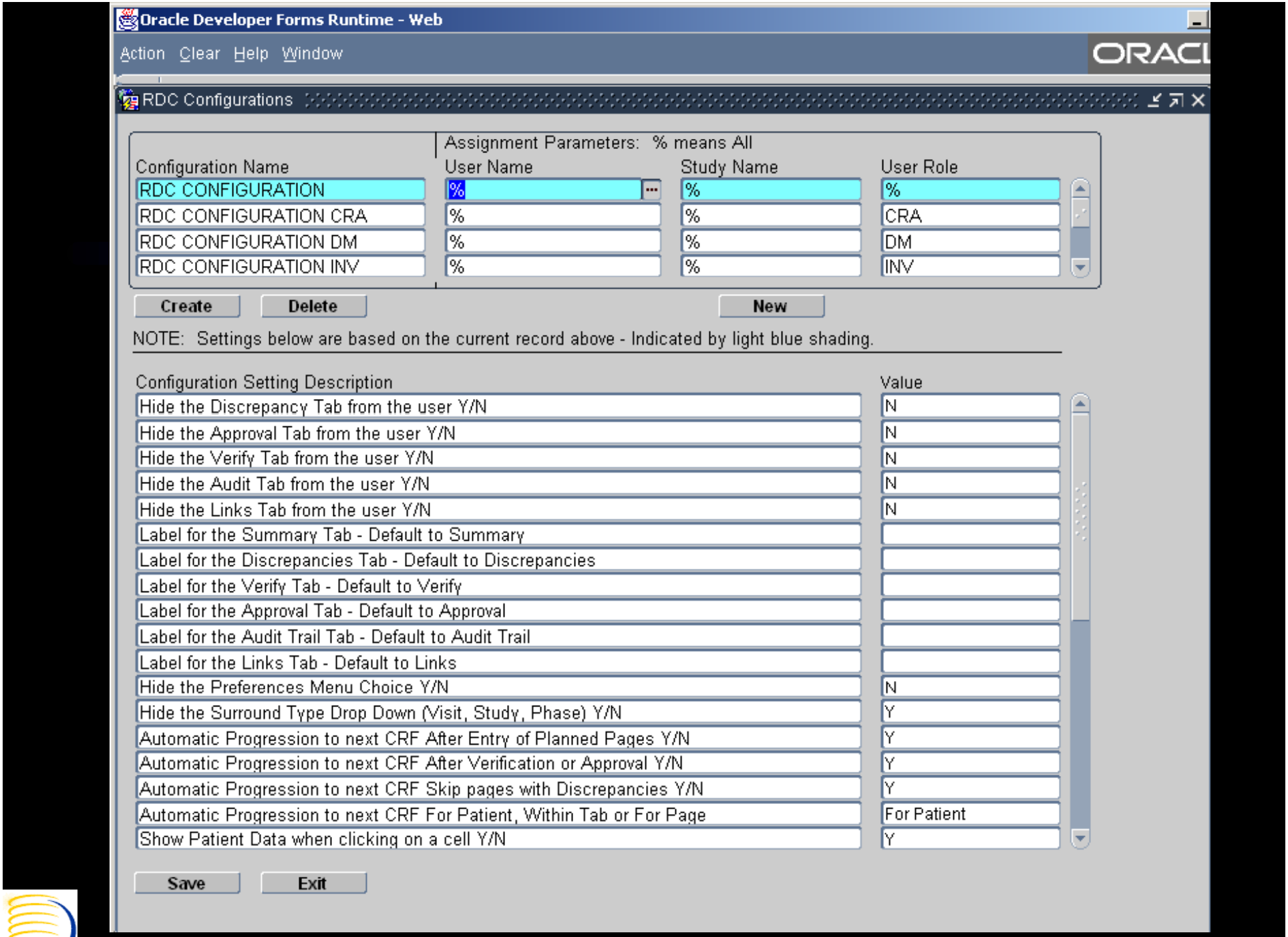
RDC Links

- Links are shown to users and are divided into three categories:
  - General
  - Site/Study
  - Patient/Page
- These correspond to three groups of Scope in the Links administration screen:
  - General = Scope of None or User
  - Study/Site = Scope of Study or Site
  - Patient/Page = Scope of Patient or CRF
- The Dynamic option allows customized calls to the PL/SQL package RDC_USER_ACTIVITIES_TAG

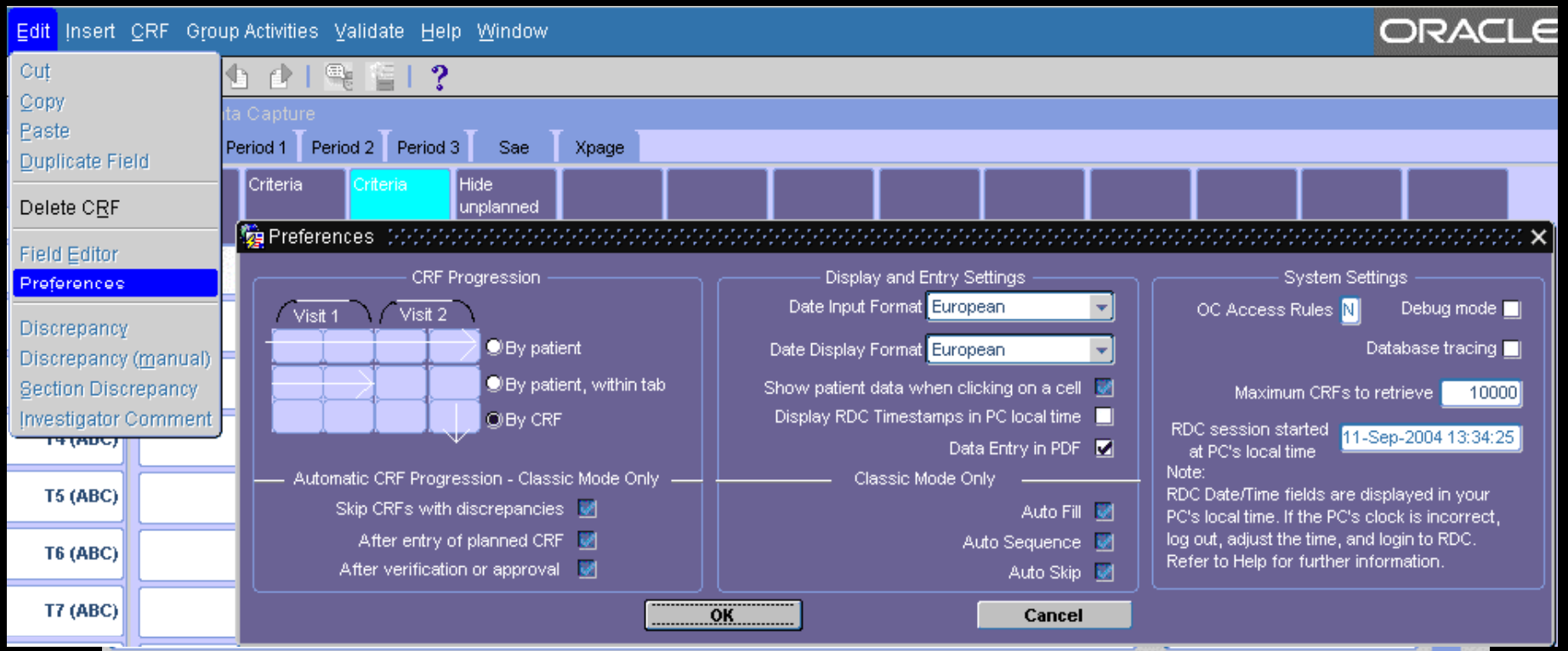

Oracle Developer Forms Runtime - Web
Action Edit Query Block Record Field Help Window
ORACLE
News definition for Remote Data Capture
Remote Data Capture Links
Seq#
Link Text
URL
Type
Scope
1
QA Test Link for RDC 4.5 Initial Installation
http://www.yahoo.com
Static
None
Exit
Save

RDC Configurator

- The RDC Configurator is an extremely flexible method of setting configuration options at the User Role, User or Study Level, with a precedence of User over Study over User Role Settings
- Most of the options are self explanatory. However, the more complex ones are at the bottom and deal with Accessibility Rules (when is validated data visible) and PDF vs. Classic mode DE by default.
- Almost all of these options are available to the user under the Edit -> Preferences menu, if this menu is made available to the user.


Oracle Developer Forms Runtime - Web
Action Clear Help Window
RDC Configurations
Assignment Parameters: % means All
Configuration Name
User Name
Study Name
User Role
RDC CONFIGURATION
RDC CONFIGURATION CRA
RDC CONFIGURATION DM
RDC CONFIGURATION INV
Create
Delete
New
NOTE: Settings below are based on the current record above - Indicated by light blue shading.
Configuration Setting Description
Value
Hide the Discrepancy Tab from the user Y/N
Hide the Approval Tab from the user Y/N
Hide the Verify Tab from the user Y/N
Hide the Audit Tab from the user Y/N
Hide the Links Tab from the user Y/N
Label for the Summary Tab - Default to Summary
Label for the Discrepancies Tab - Default to Discrepancies
Label for the Verify Tab - Default to Verify
Label for the Approval Tab - Default to Approval
Label for the Audit Trail Tab - Default to Audit Trail
Label for the Links Tab - Default to Links
Hide the Preferences Menu Choice Y/N
Hide the Surround Type Drop Down (Visit, Study, Phase) Y/N
Automatic Progression to next CRF After Entry of Planned Pages Y/N
Automatic Progression to next CRF After Verification or Approval Y/N
Automatic Progression to next CRF Skip pages with Discrepancies Y/N
Automatic Progression to next CRF For Patient, Within Tab or For Page
Show Patient Data when clicking on a cell Y/N
Save
Exit

OCUG Prague 2004 Tutorial Session: OC, RDC and TMS Administration



Hide the Surround Type Drop Down (Visit, Study, Phase) Y/N	Y
Automatic Progression to next CRF After Entry of Planned Pages Y/N	Y
Automatic Progression to next CRF After Verification or Approval Y/N	Y
Automatic Progression to next CRF Skip pages with Discrepancies Y/N	Y
Automatic Progression to next CRF For Patient, Within Tab or For Page	For Patient
Show Patient Data when clicking on a cell Y/N	Y
Display in Local Time Y/N	Y
Display and Entry Settings, Auto Skip Y/N	Y
Display and Entry Settings, Auto Fill Y/N	Y
Will user conduct data entry using PDF RDC Y/N	N
Default search option - ACTIVITY or SEARCH	SEARCH
Hide the Group Activities Menu Choice Y/N	Y
Use the OC Accessibility Rules Y/N	N

TMS vs. OC Administration

- Some differences in TMS administration vs. OC Administration
- No equivalent role of TMS_SUPER like RXC_SUPER which grants access to all TMS Menu Paths
- No Directory Mappings for TMS Jobs
- No use of ORACLE_ACCOUNTS table for storing TMS users' default log directories or printers
- Separate Local and Installation Reference Codelist paths, although codelists are repeated in Oracle Clinical for integrated installations.

TMS => Define Users

- There is an additional OPA_ACCOUNTS table, which is populated with the TMS=>Define Users option, which is only accessible with the database role OPA_ADMIN.
- Populating this table is required for TMS Lite Browser Access
- There were some bugs initially with the population of this table from the ORACLE_ACCOUNTS table which should be fixed with TMS 4.5.0.3, but identical ORACLE_ACCOUNTS$JN timestamps may still cause failures
- $RXC_TOOLS/ocl_add_user.sql **DOES NOT** populate this table.
- Not populating this OPA_ACCOUNTS table results in a "Missing Seed Data" when an account logs into the TMS Lite Browser and autologin is not configured in bc4j.xcfg

TMS vs. OC Administration (2)

- 11 roles exist which govern menu path access to the different parts of the TMS system
  - TMS_ACCESS
  - TMS_APPROVE_PRIV
  - TMS_CLASSIFY_PRIV
  - TMS_DEFINE_PRIV
  - TMS_DOC_CONFIG
  - TMS_DOC_MAINTAIN
  - TMS_INTEGRATE_PRIV
  - TMS_MAINTAIN_PRIV
  - TMS_OBJECT_CLASSIFY_PRIV
  - TMS_RECLASSIFY_PRIV
  - TMS_RESEARCH_PRIV
- These roles map at a general level to the various menu paths within TMS.

TMS Scheduled Jobs - Synchronization

- Definition => Synchronize Dictionary Data
- Synchronization – Updates TMS_VT_OMISSIONS and TMS_SOURCE_TERMS based on changes to the TMS Repositories from changes in Omission Management and VTA Maintenance.
- In other words, when a VTA is created, that is, something is classified, there is not immediately an entry in TMS_SOURCE_TERMS. Similarly, when a VTA is declassified, there is not immediately an entry in TMS_VT_OMISSIONS. Running Synchronization accurately reflects these changes in these tables.
- Synchronization is called in the beginning of Batch Validation, but can be scheduled periodically, in some companies, once an hour.

TMS Scheduled Jobs – Purge Classified Omissions

- Definition => Purge Classified Omission
- New job introduced in TMS 4.0.6
- Oracle's recommendation is to run weekly
- Bug 2359310, omissions were physically deleted from the tms_vt_omissions table causing symmetric replication to fail, if an omission existed at a master and slave, and was simultaneously classified at the master and deleted from the slave.
- The omissions are now logically deleted from the tms_vt_omissions table.
- Oracle strongly recommends to run this job weekly in order to avoid performance problems.

TMS Scheduled Jobs – Refresh Context Index

- Definition => Refresh Context Index
- Intermedia Indexes are not like normal indexes, so changes to the underlying table do not automatically update the index
- Index is referred to as a Domain Index in Intermedia terminology
- Index is on TMS_DICT_CONTENTS.TERM
- Table is updated when
  - New dictionary data is loaded
  - Base dictionaries are updated
  - Maintain Repository is used to update Dictionary
  - VTAs are created

TMS Scheduled Jobs – Refresh Materialized Views

- Required if Materialized Views are used for the External System Attributes (such as Oracle Clinical: Patient, Study, Investigator…).
- This is controlled by TMS -> Definition -> Installation Reference Codelists -> TMS_SOURCE_MAT_VIEWS has any option set to Y. After changing this Reference Codelist, it is **necessary to run this job for the changes to be effective**.
- This job replaces a manual call to a package to rebuilds Materialized Views call from Synchronization. There were horrific locking and concurrency issues when Materialized Views were built during simultaneous TMS Synchronization and Batch Validation activities, which were resolved in successive iPatches from TMS 4.0.5.9 and TMS 4.0.6.7.

Additional Questions ?

- E-mail: singh@clinicalserver.com
- Call: US 001-860-983-5848
- Call: International: 91-98-181-34-017
- Electronic copies will be posted on the OCUG Intranets Site and www.clinicalserver.com
- Additional copies will be available at DBMS Consulting's Vendor Booth along with OPA 4.5 Architecture Posters and other giveaways

Extra Info: PSUB Submission Process on UNIX Backend

- User submits a job with Submit Job button
- Job type identified from Modules as 3GL or other type of PSUB job
- PSUB database package RXCPS_PKG called for submit_batch_job (calles insert_batch_jobs, client_send and client_receive)
- Database Pipe is opened to PSUB daemon
- PSUB daemon takes message and submits as UNIX “at” job in “a” queue (by default) as user rxcprod
- At job then performs a remsh to the calling user’s UNIX account and executes the actual module command (such as rxcbvbvs)
- Status Message is returned to the Database Pipe and Batch Jobs table updated

Extra Info: Debugging ftp problems from UNIX

- In %OPA_HOME%\html\opabasejini.htm
- locate PSUBMAP= @
- add DEBUG_TOGGLE=SAVEFTP before PSUBMAP
- repeat step 1 and 2 for next occurrence of PSUBMAP.
- relaunch Oracle Clinical from a new Web browser.
- From cmd window on the Middle Tier:
  - cd <Middle_Tier_user_log_directory>
  - dir /od - you should see a file called s<id>.txt @
  - ftp -n -v -i -s:s<id>.txt
- This process can also be performed by saving a static html file locally, redirecting the forward slashes (/) to include the full middle tier URL, and saving locally.