OC, TMS and RDC Administration: An Application and Back-end 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.

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
- Not every administrative option can be covered due to time constraints, will not cover replication administration

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

OC Administrative Functions (2)

- Data Entry Configuration
  - System
  - Study
  - User

TMS Administrative Functions

- Menu Roles for TMS
- Scheduled Jobs

RDC Administrative Functions

- User account roles
- Study Security
- Site Security
- News Configuration

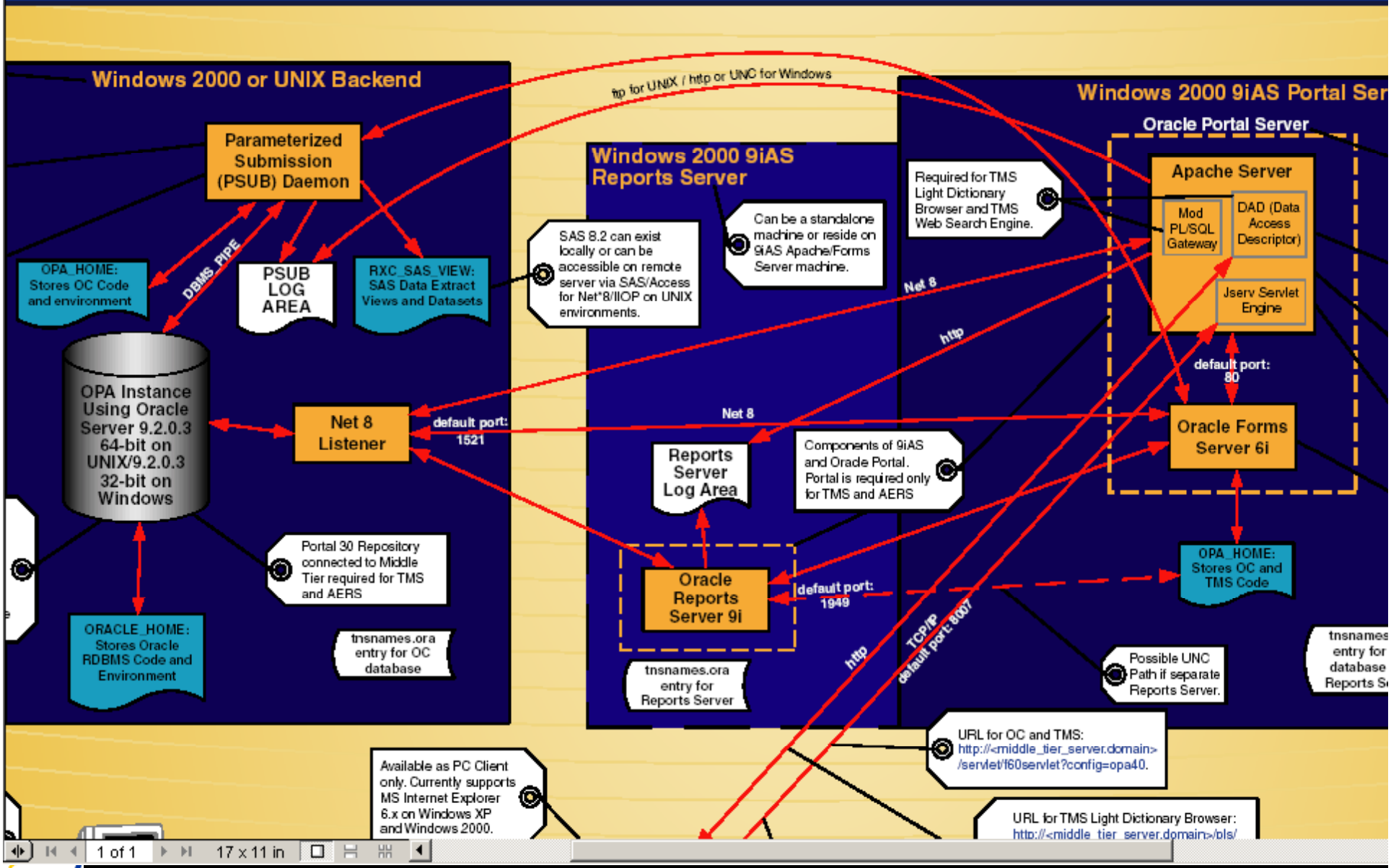
OC User Account Concepts

- 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.

Oracle Pharmaceutical Applications 4.5 3-Tier C

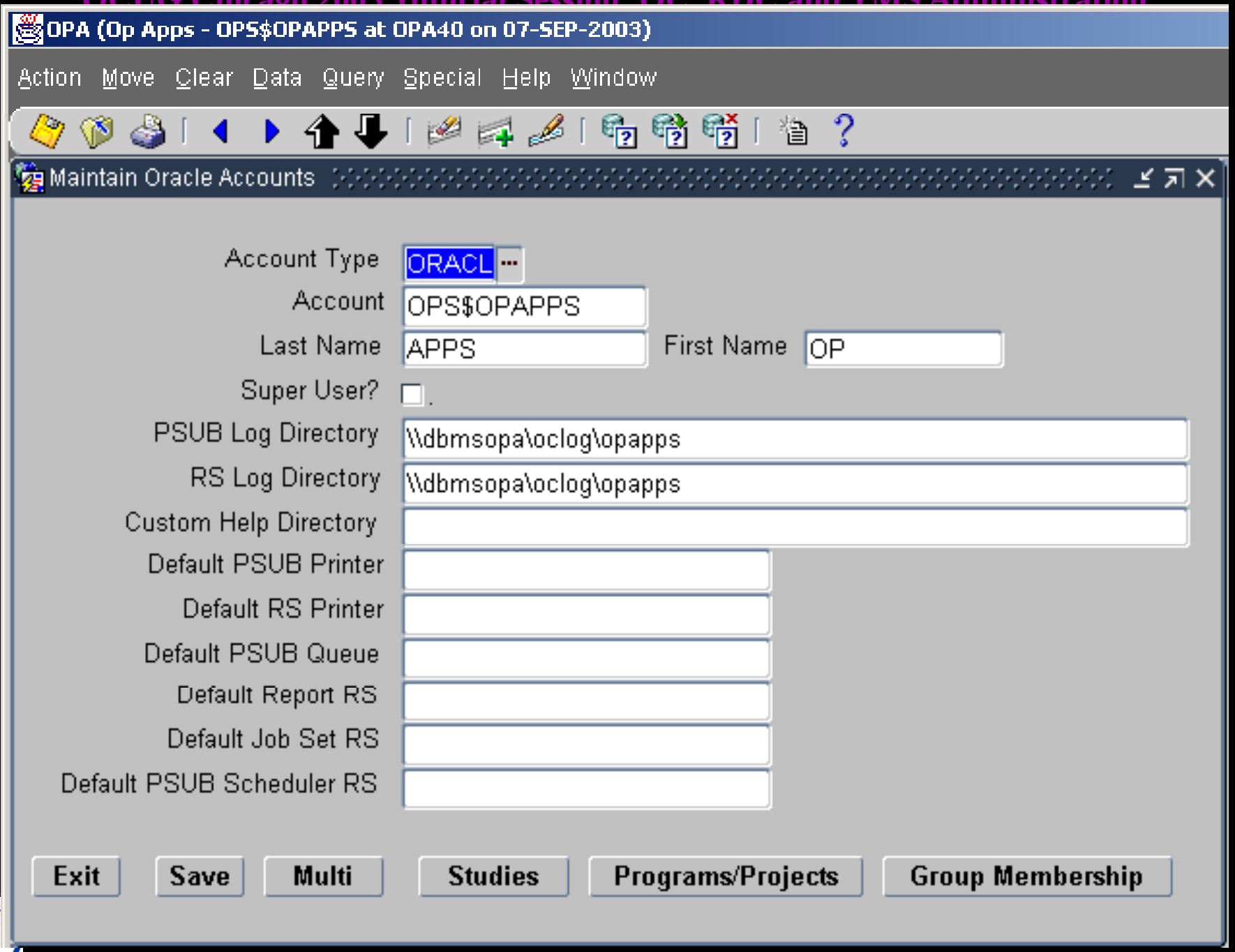


OC Users Accounts Concepts (3)

- 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

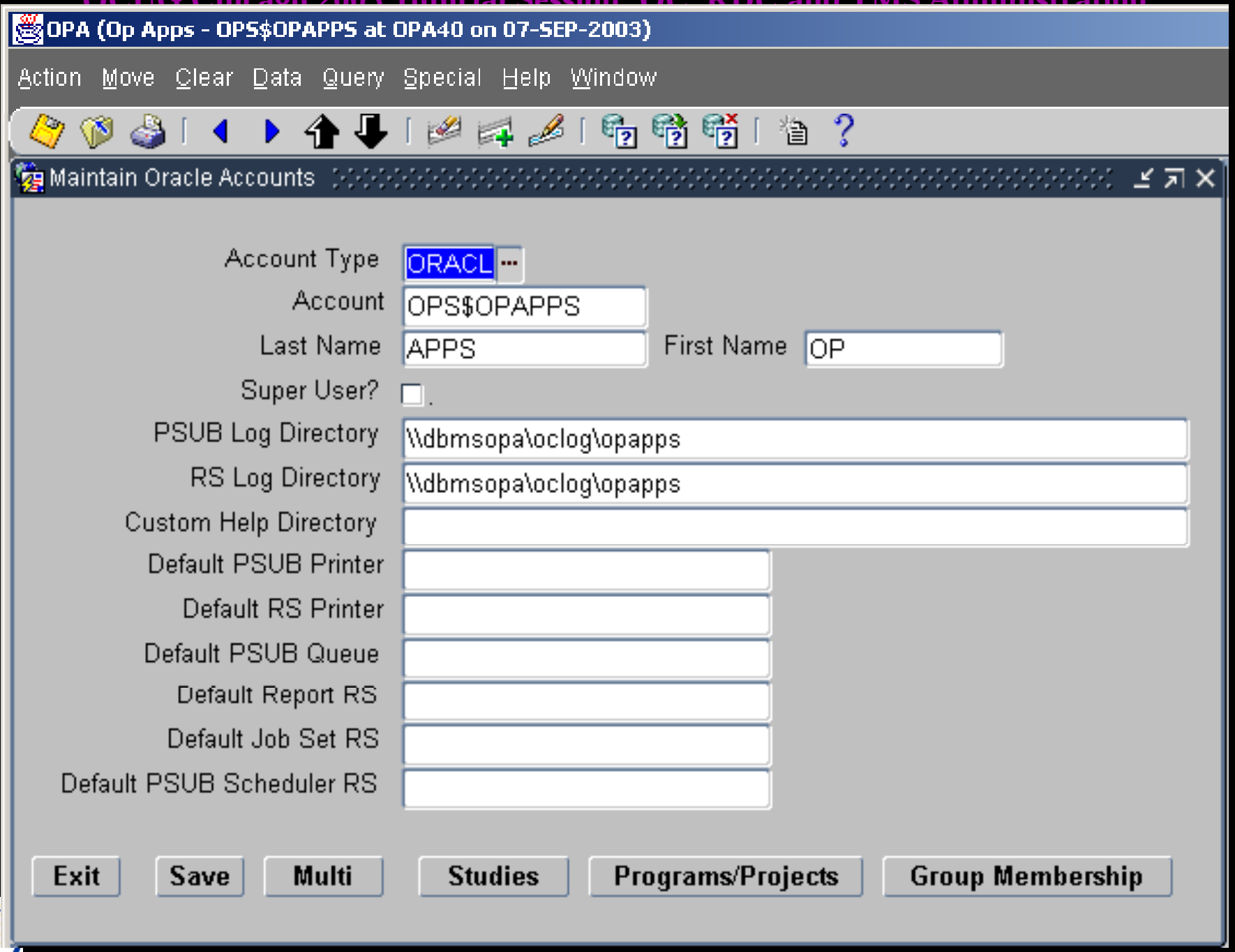
Using ocl_add_user.sql

- 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 and whether or not the role RXC_SUPER should be granted to the user (more explanation to follow)
- The other parameters are optional.

```
C:\ocserver\oc\40\tools>sqlplus system @ocl_add_user

SQL*Plus: Release 8.1.7.0.0 - Production on Sun Sep 7 09:55:43 2003

(c) Copyright 2000 Oracle Corporation.  All rights reserved.

Enter password:

Connected to:
Oracle8i Enterprise Edition Release 8.1.7.2.1 - Production
With the Partitioning option
JServer Release 8.1.7.2.1 - Production

User ID, starting with OPS$    : ops$ssingh
Password                       : ssingh
Last Name                      : Singh
First Name                     : Sunil
PSUB Log Directory                    : /export/home/log/ssingh
Report Server Log Directory           : \\dbmsopa\oclog\ssingh
Grant RXC_Super Role (Y/N)            : N
Grant Super-User Status (Y/N)         : N
.
Custom Doc Dir (optional)             :
.
PSUB Defaults (optional):
.
Printer :
Queue   :
.
Report Server (RS) Defaults (optional) :
.
Printer              :
Report RS            :
Job Set RS           :
PSUB Scheduler RS    :



User created.

Grant succeeded.

User altered.

1 row created.

Commit complete.

SQL> _
```

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


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
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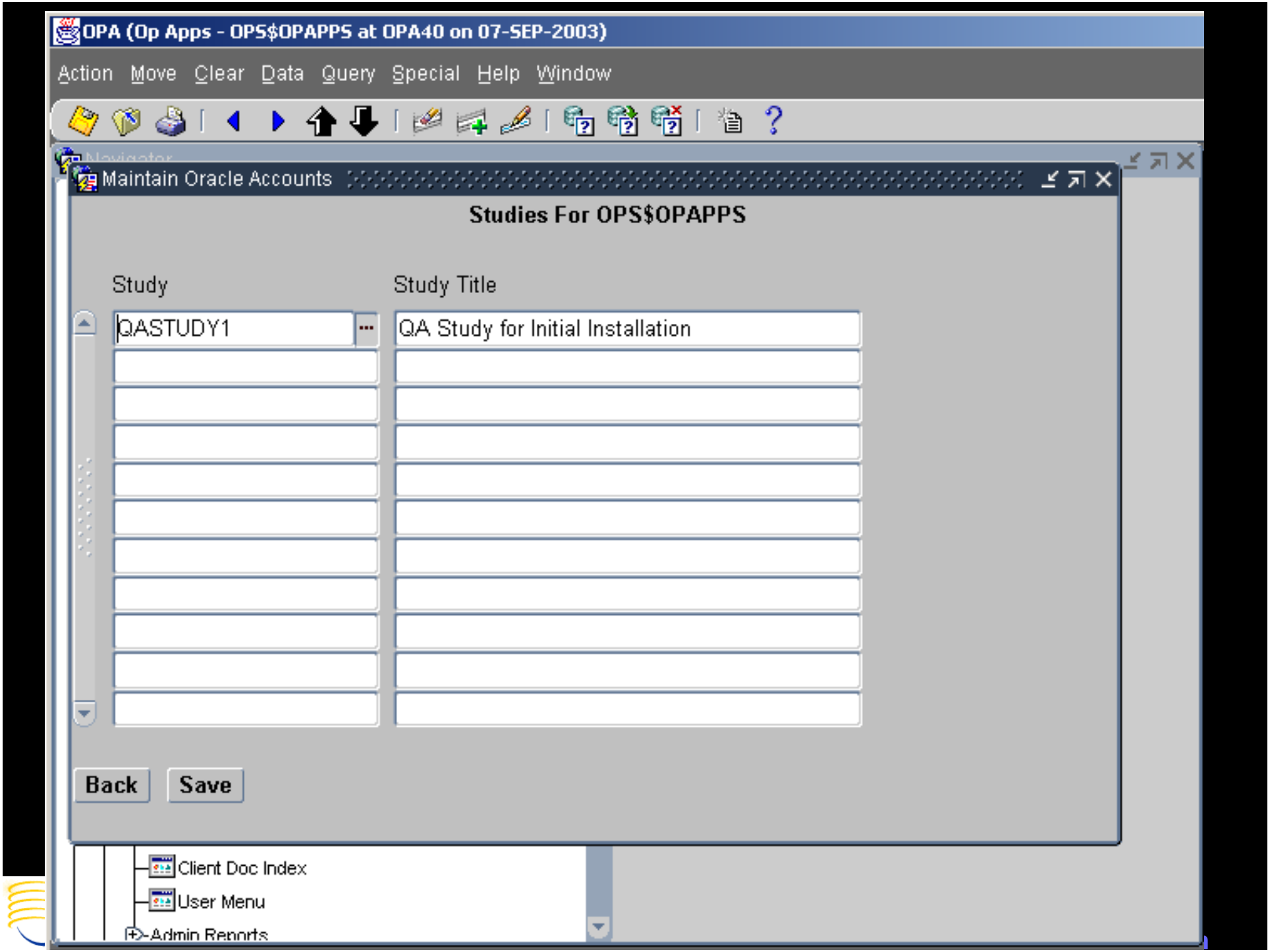
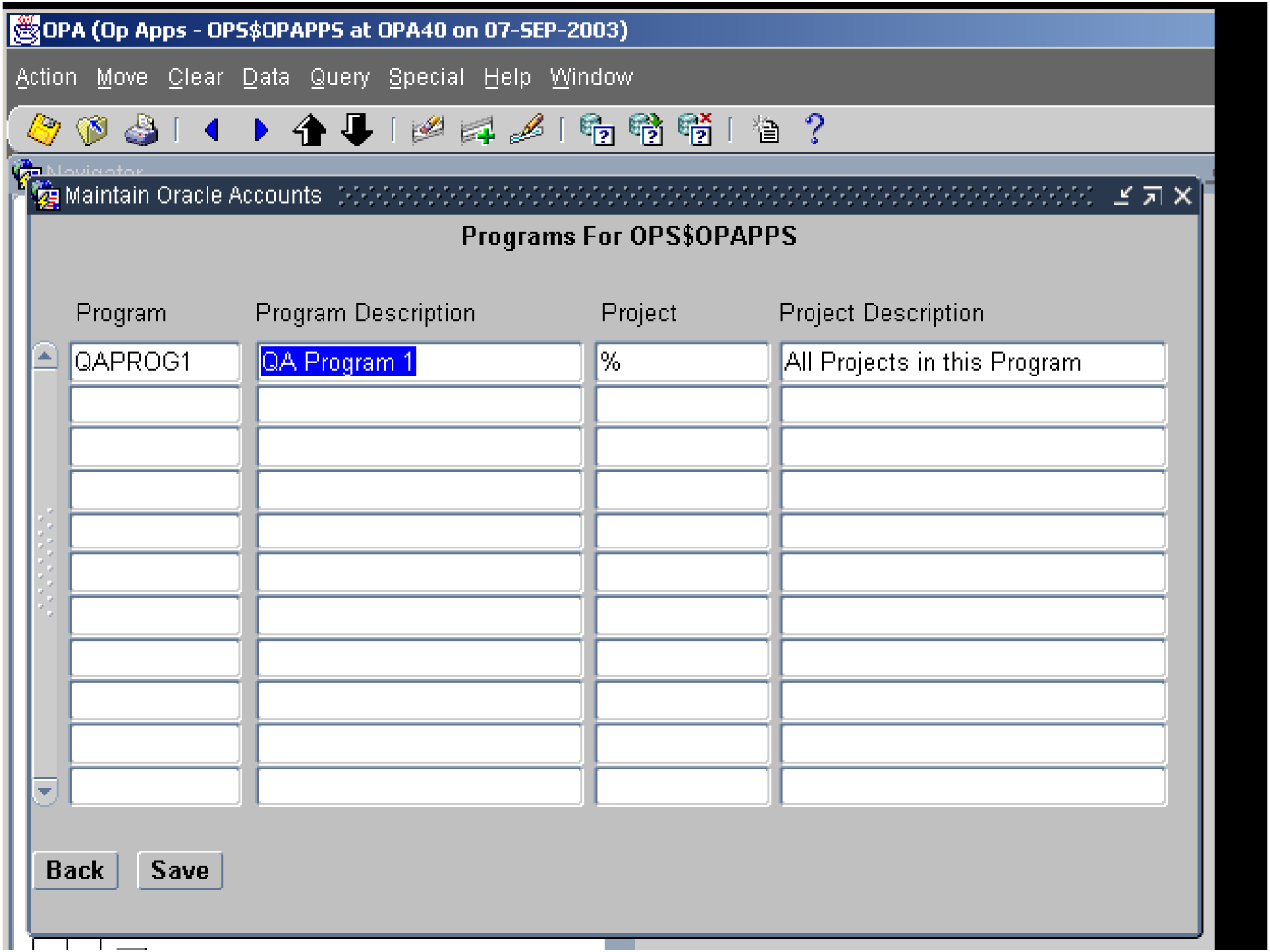
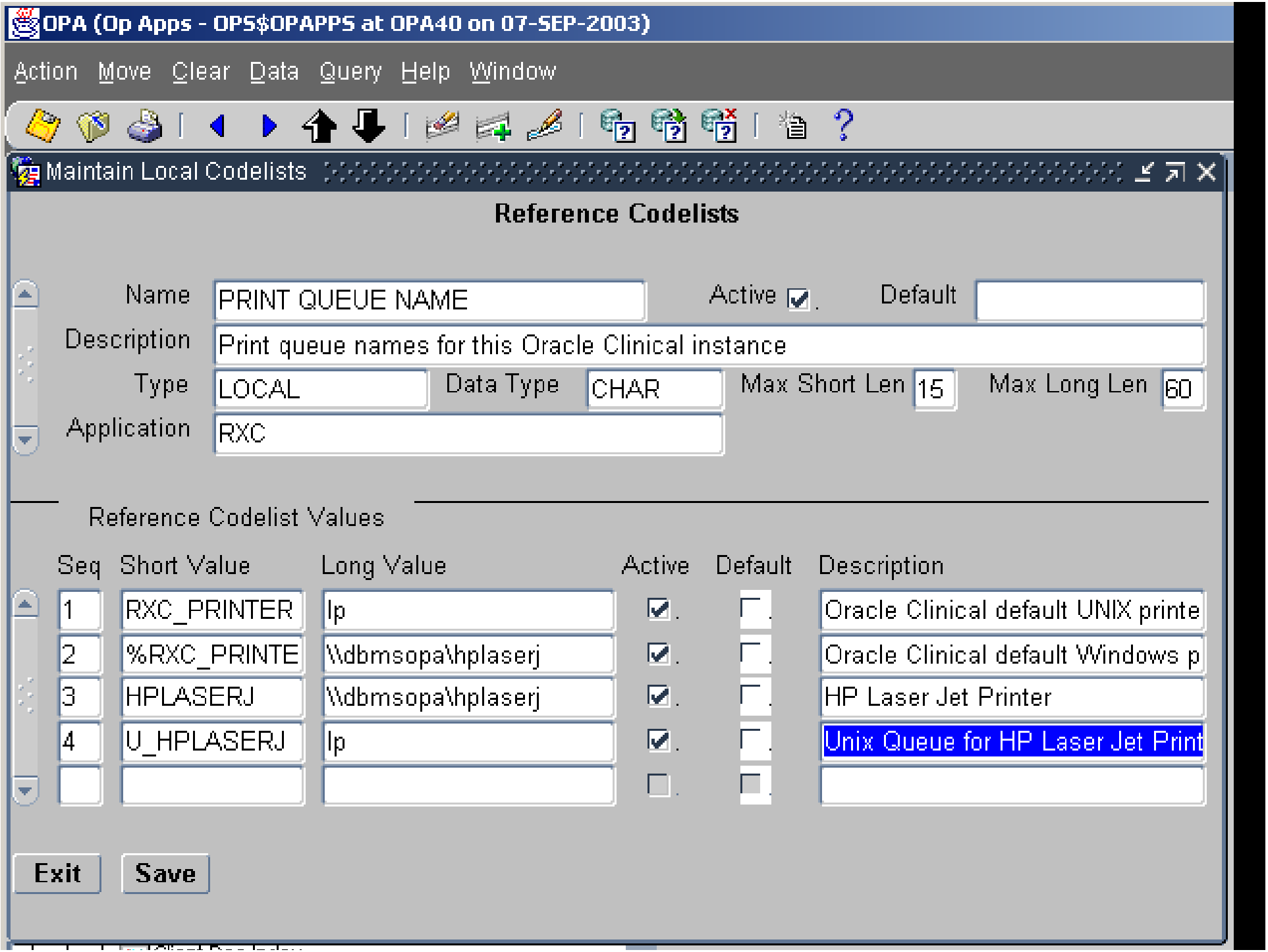
Super User?
PSUB Log Directory
\\dbmsopa\oclog\opapps
RS Log Directory
\\dbmsopa\oclog\opapps
Custom Help Directory
Default PSUB Printer
Default RS Printer
Default PSUB Queue
Default Report RS
Default Job Set RS
Default PSUB Scheduler RS
Exit
Save
Multi
Studies
Programs/Projects
Group Membership

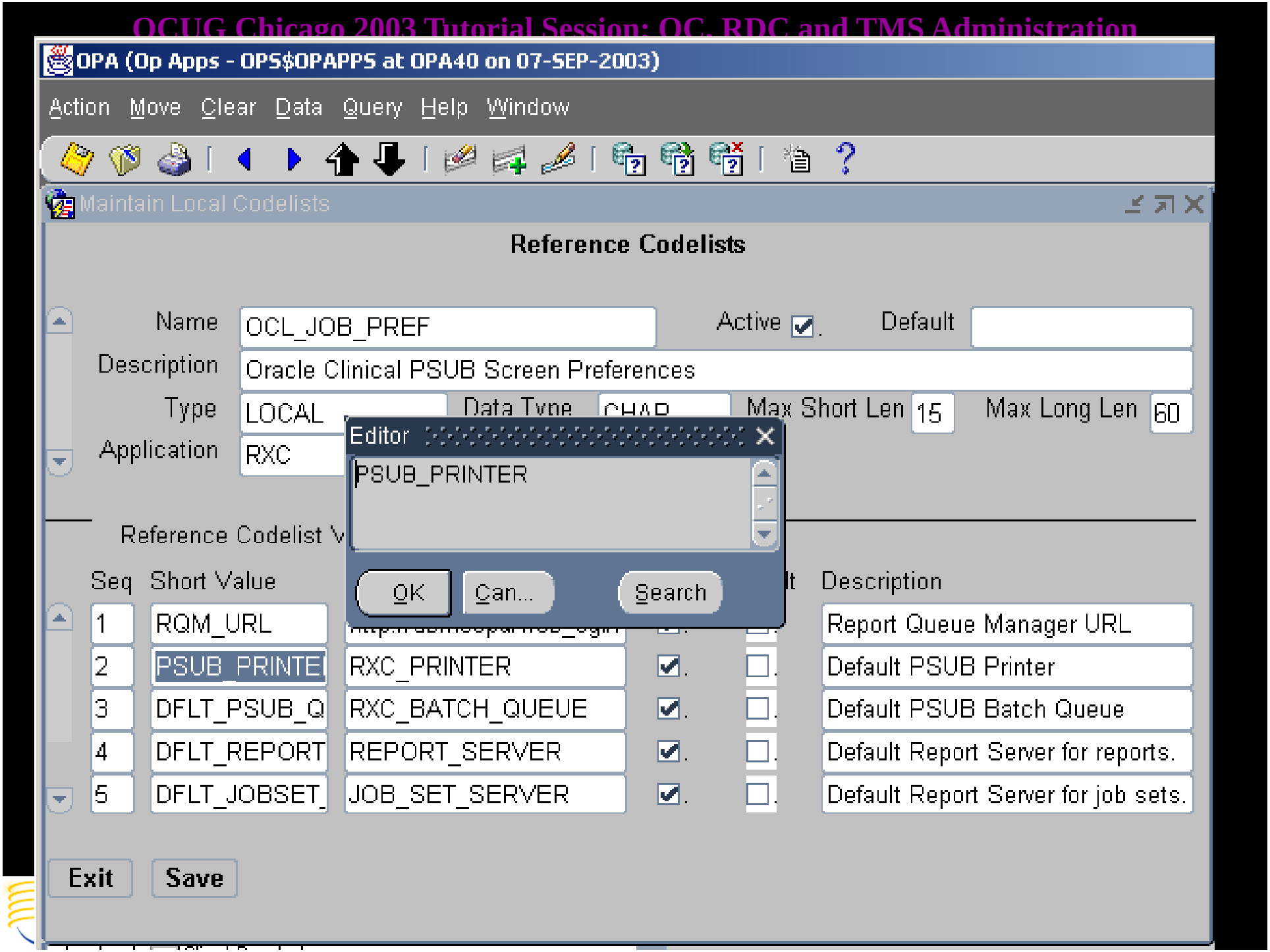

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Maintain Oracle Accounts
Studies For OPS$OPAPPS
Study
Study Title
QASTUDY1
QA Study for Initial Installation
Back
Save
Client Doc Index
User Menu
Admin Reports

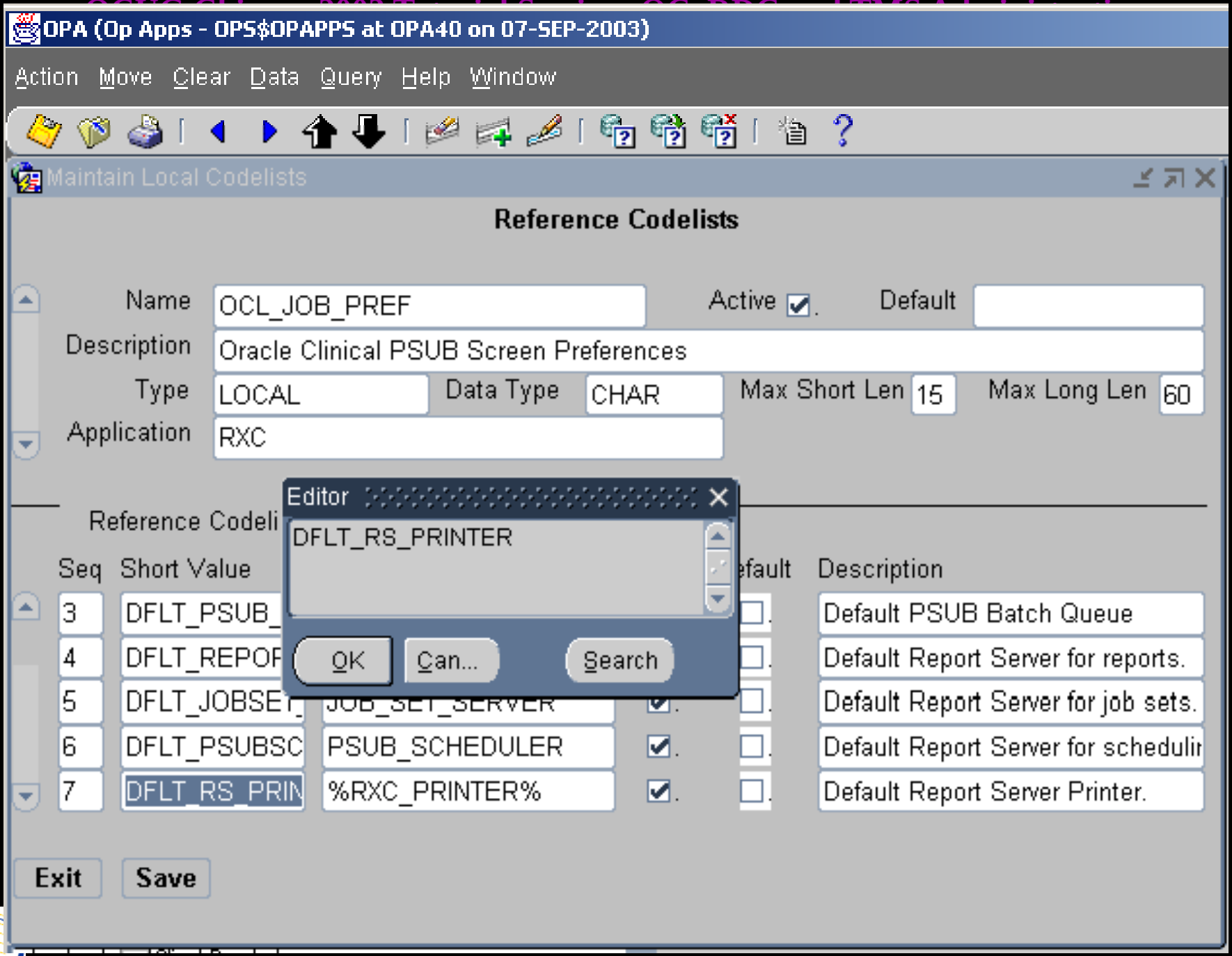

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Maintain Oracle Accounts
Programs For OPS$OPAPPS
Program
Program Description
Project
Project Description
QAPROG1
QA Program 1
%
All Projects in this Program
Back
Save

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

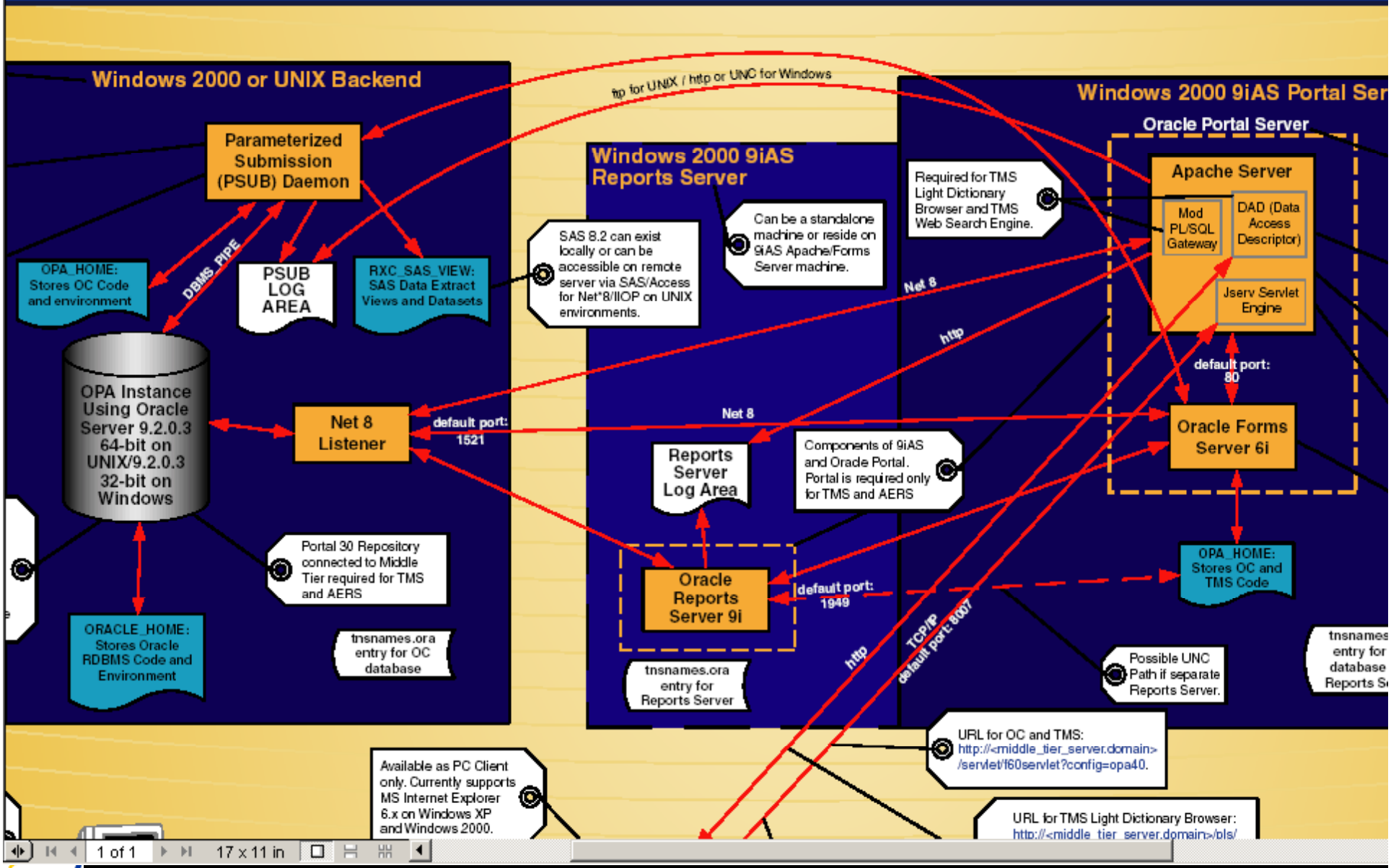
OC Report Servers

- 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.

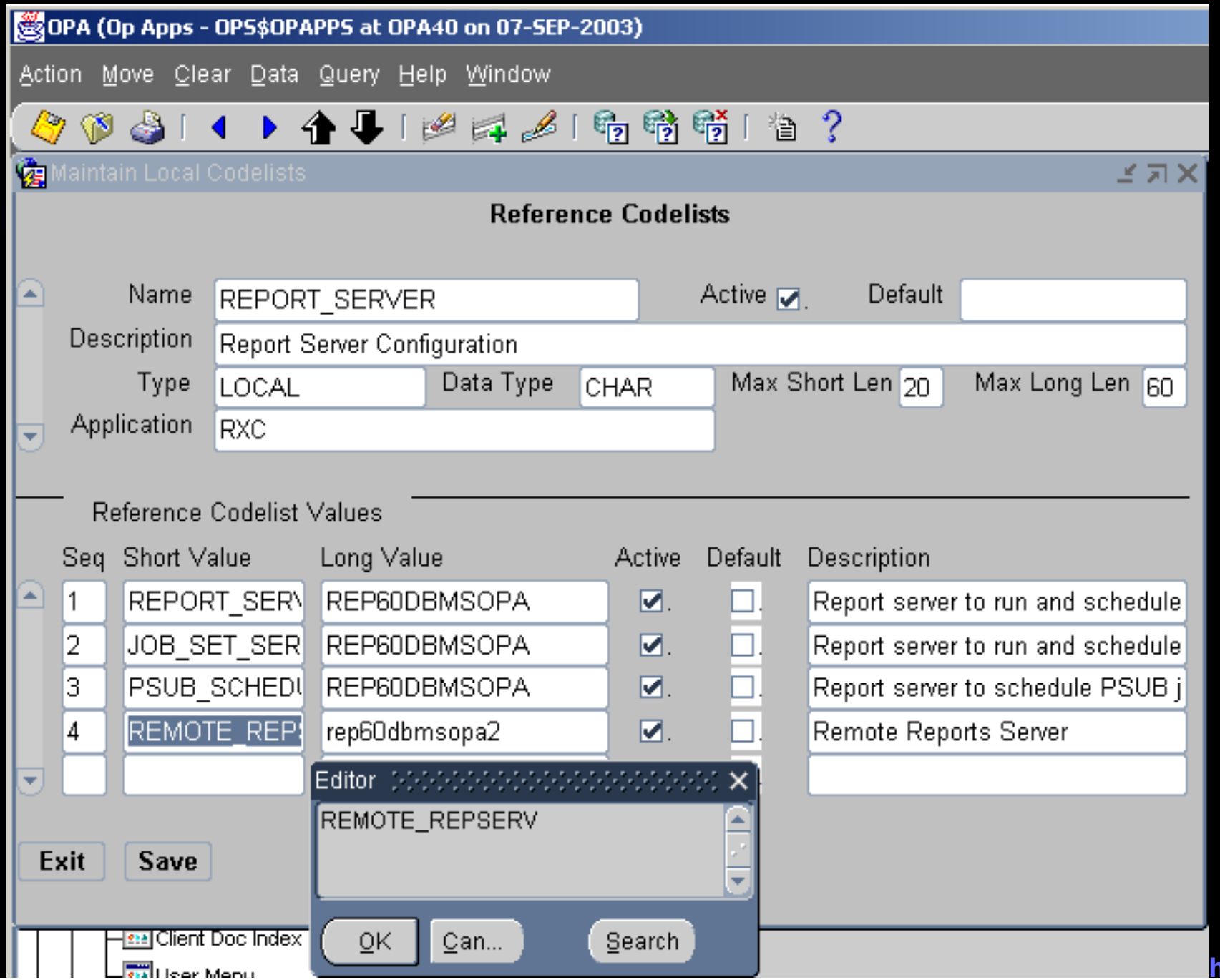
OC Report Servers (2)

- The 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.
- Additional entries must be defined for Report Servers which are Stand-Alone or Remote Report Servers

Oracle Pharmaceutical Applications 4.5 3-Tier C



OCUG Chicago 2003 Tutorial Session: OC, RDC and TMS Administration



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)

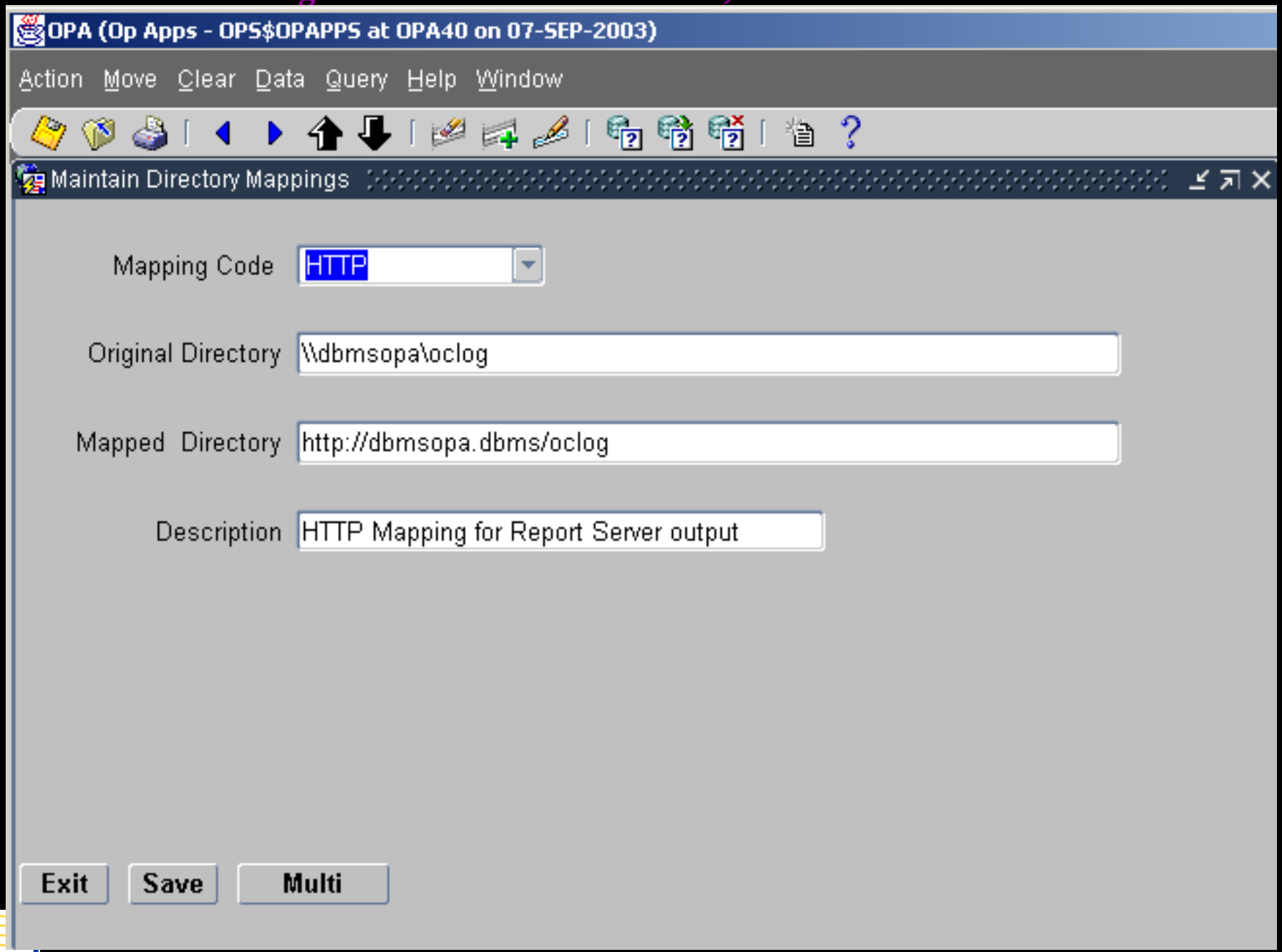
- A complete list of the Database Roles and the Menu Paths which they provide access to is available from the report Developer's Toolkit => Menu Roles. However, to access this report, the OC account must have the special role DTK_ADMIN.
- Run this job with OPA Application Codes set to OCL. Setting to any other OPA Application Code does not currently work in OPA 4.0.3 and produces the output for OCL.
- 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.

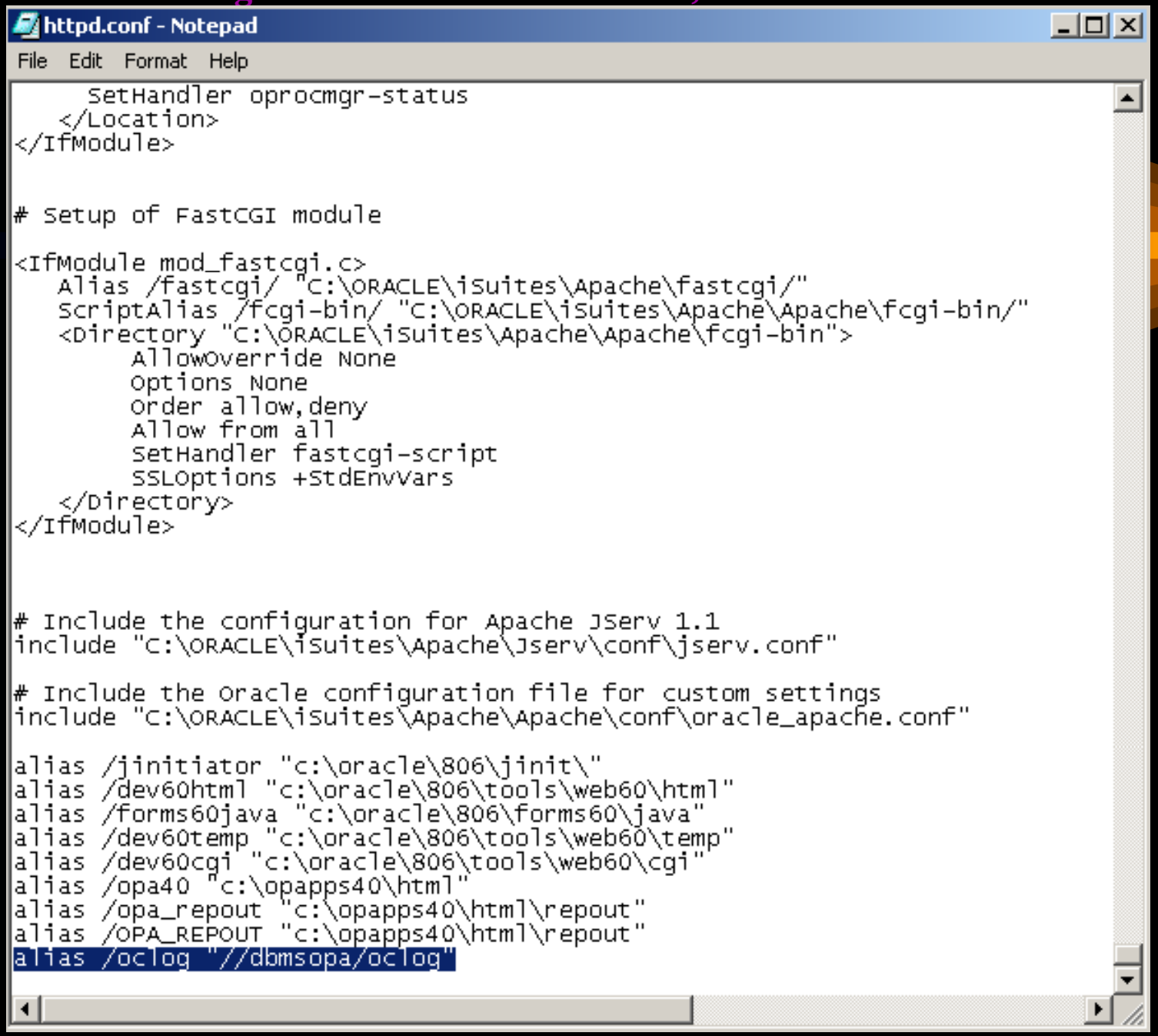
Menu Roles for OCL version 4.0.3.33 in OPA40

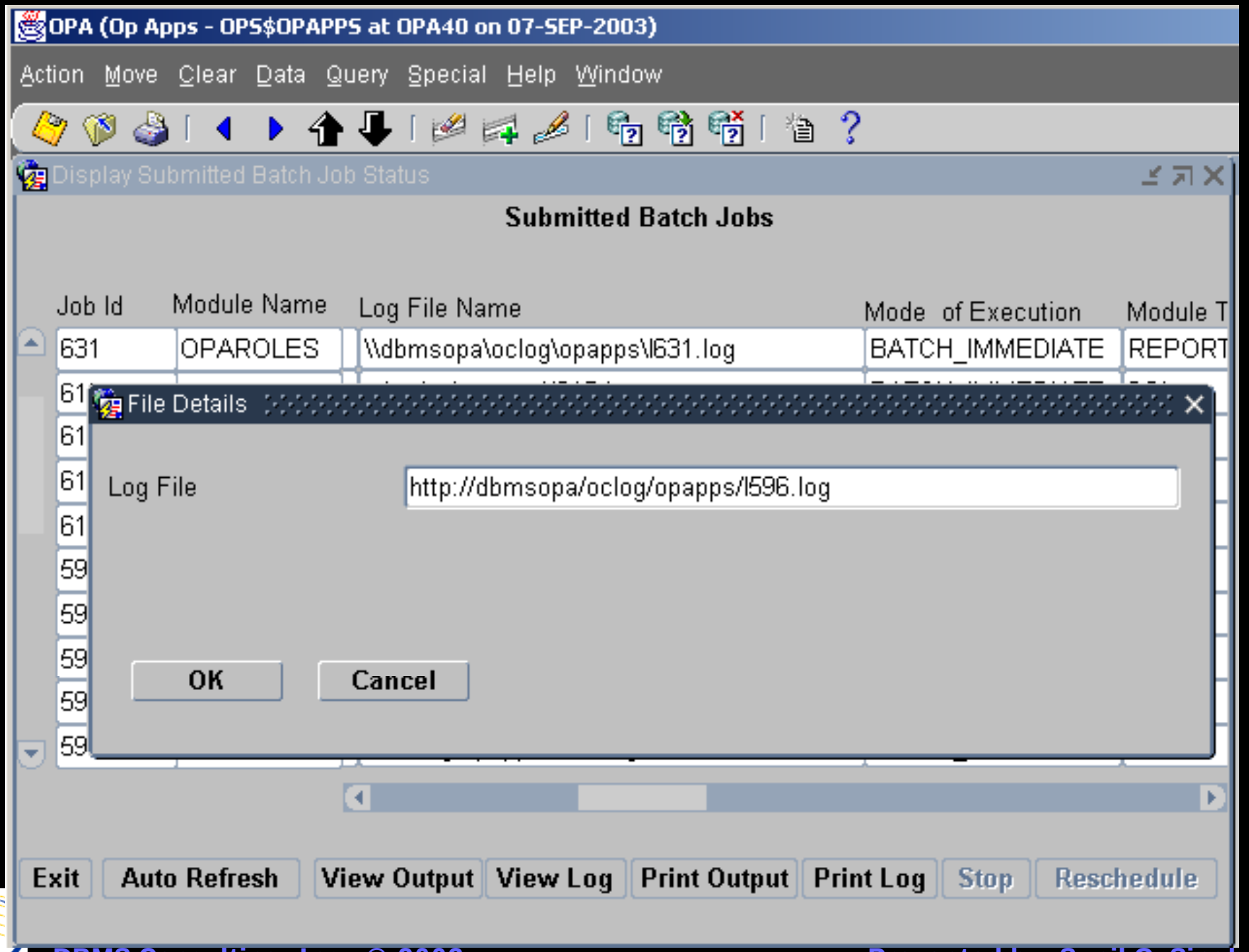
	ADM	ANY	BDT	BIO	BVT	CRA	DBA	DE	DE2	DFP	DLT	DER	DES	DST	DET	DMG	DQA	DX	EDA	GLA	GLF	GLP
Admin		*																				
PSUB/Report Jobs		*																				
Batch Jobs		*																				
Report Queue Manager		*																				
Job Sets		*																				
Qry Job Sets		*																				
Submit Job Set		*																				
Reference Codelists		*																				
Local Codelists	*																					
Qry Local Codelists		*																				
Installation Codelists	*																				*	
Qry Installation Codelists		*																				
Design Installation Codelists													*									
Qry Design Installation Codelists		*																				
Qry System Codelists		*																				
DE Admin	*																					
DE User Prefs	*																					
DE Config Settings	*																					
Log-in Layout Editor	*																					
Glib Admin	*																			*	*	
Default Domains	*																			*	*	
User Domain	*																			*	*	
Discrepancy Mgmt Admin																						
Profile Administration	*																					
Standard Text Maintenance	*																					
User Group Administration	*																					
Layout Definitions	*																					
DX Installation Configuration	*																					
Users		*																				
Oracle Accounts	*																					
Query Accounts		*																				
OS Password	*																					
Database Password	*																					
Study Security	*																					
Query Study Security		*																				
Site Security	*																					
Query Site Security		*																				
Directory Mappings		*																				
Directory Mappings	*																					
Query Directory Mappings		*																				
Replication	*																				*	
Full Library	*																				*	
Full Study	*																					
Incremental Library	*																				*	
Incremental Study	*																					
Data	*																					
Labs and Ranges	*																					
Global Lab Info	*																					

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 and map this to the alias for the same path defined in httpd.conf for Apache. The UNC output path is then dynamically translated to the http path when a user attempts to view the output from the Reports Server.
- In a UNIX Database Server environment, no entry should be required for Directory Mappings to view PSUB Batch Job output and log files


OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
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


httpd.conf - Notepad
File Edit Format Help
SetHandler oprocmgr-status
</Location>
</IfModule>
Setup of FastCGI module
<IfModule mod_fastcgi.c>
Alias /fastcgi/ "C:\ORACLE\iSuites\Apache\fastcgi/"
ScriptAlias /fcgi-bin/ "C:\ORACLE\iSuites\Apache\Apache\fcgi-bin/"
<Directory "C:\ORACLE\iSuites\Apache\Apache\fcgi-bin">
AllowOverride None
Options None
Order allow,deny
Allow from all
SetHandler fastcgi-script
SSLOptions +StdEnvVars
</Directory>
</IfModule>
Include the configuration for Apache JServ 1.1
include "C:\ORACLE\iSuites\Apache\Jserv\conf\jserv.conf"
Include the Oracle configuration file for custom settings
include "C:\ORACLE\iSuites\Apache\Apache\conf\oracle_apache.conf"
alias /jinitiator "c:\oracle\806\jinit\"
alias /dev60html "c:\oracle\806\tools\web60\html"
alias /forms60java "c:\oracle\806\forms60\java"
alias /dev60temp "c:\oracle\806\tools\web60\temp"
alias /dev60cgi "c:\oracle\806\tools\web60\cgi"
alias /opa40 "c:\opapps40\html"
alias /opa_repout "c:\opapps40\html\repout"
alias /OPA_REPOUT "c:\opapps40\html\repout"
alias /oclog "//dbmsopa/oclog"

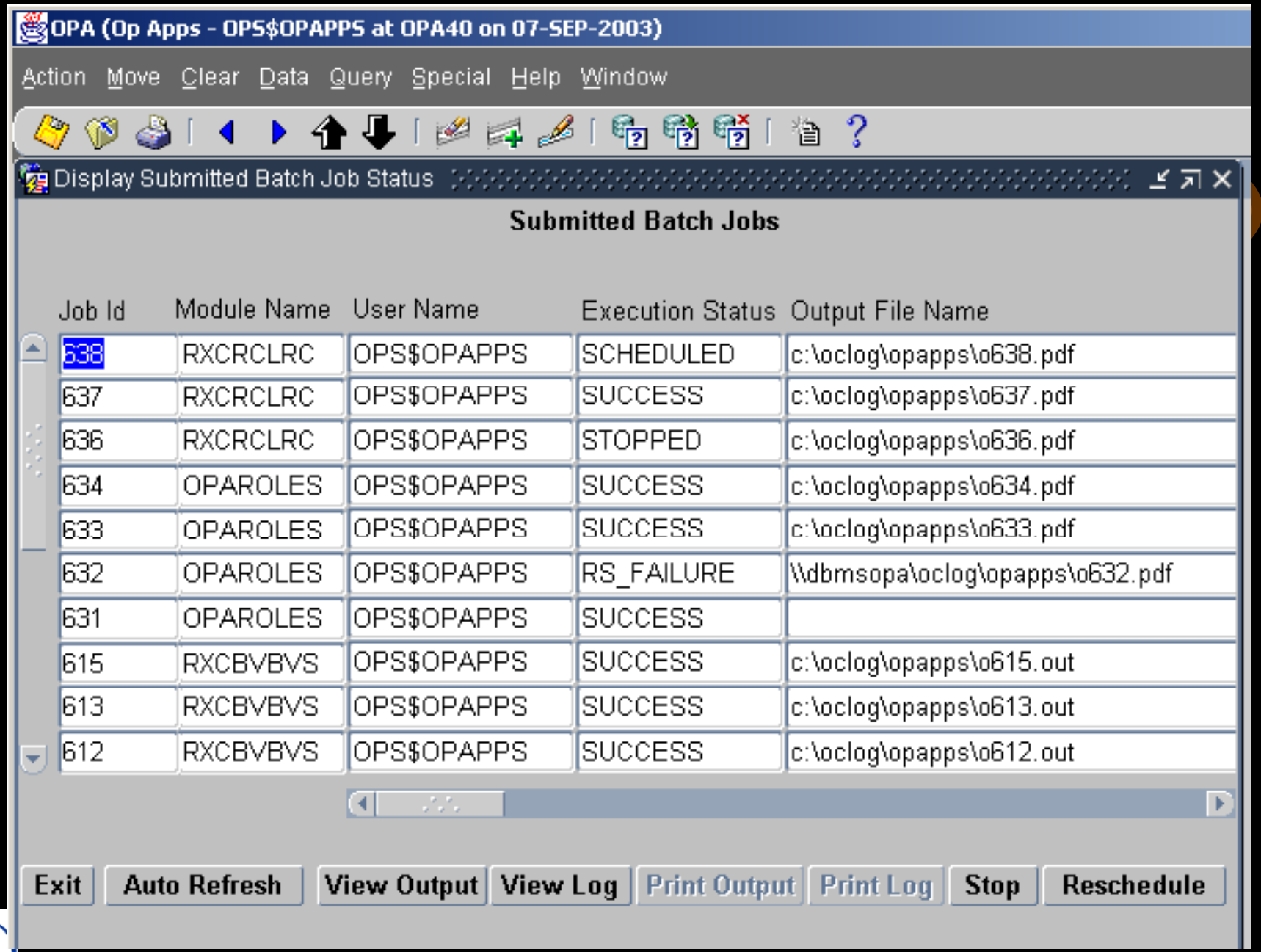

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Display Submitted Batch Job Status
Submitted Batch Jobs
Job Id
Module Name
Log File Name
Mode of Execution
Module T
631
OPAROLES
\\dbmsopa\oclog\opapps\l631.log
BATCH_IMMEDIATE
REPORT
File Details
Log File
http://dbmsopa/oclog/opapps/l596.log
OK
Cancel
Exit
Auto Refresh
View Output
View Log
Print Output
Print Log
Stop
Reschedule

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.
- 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 Reports 6i => 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).

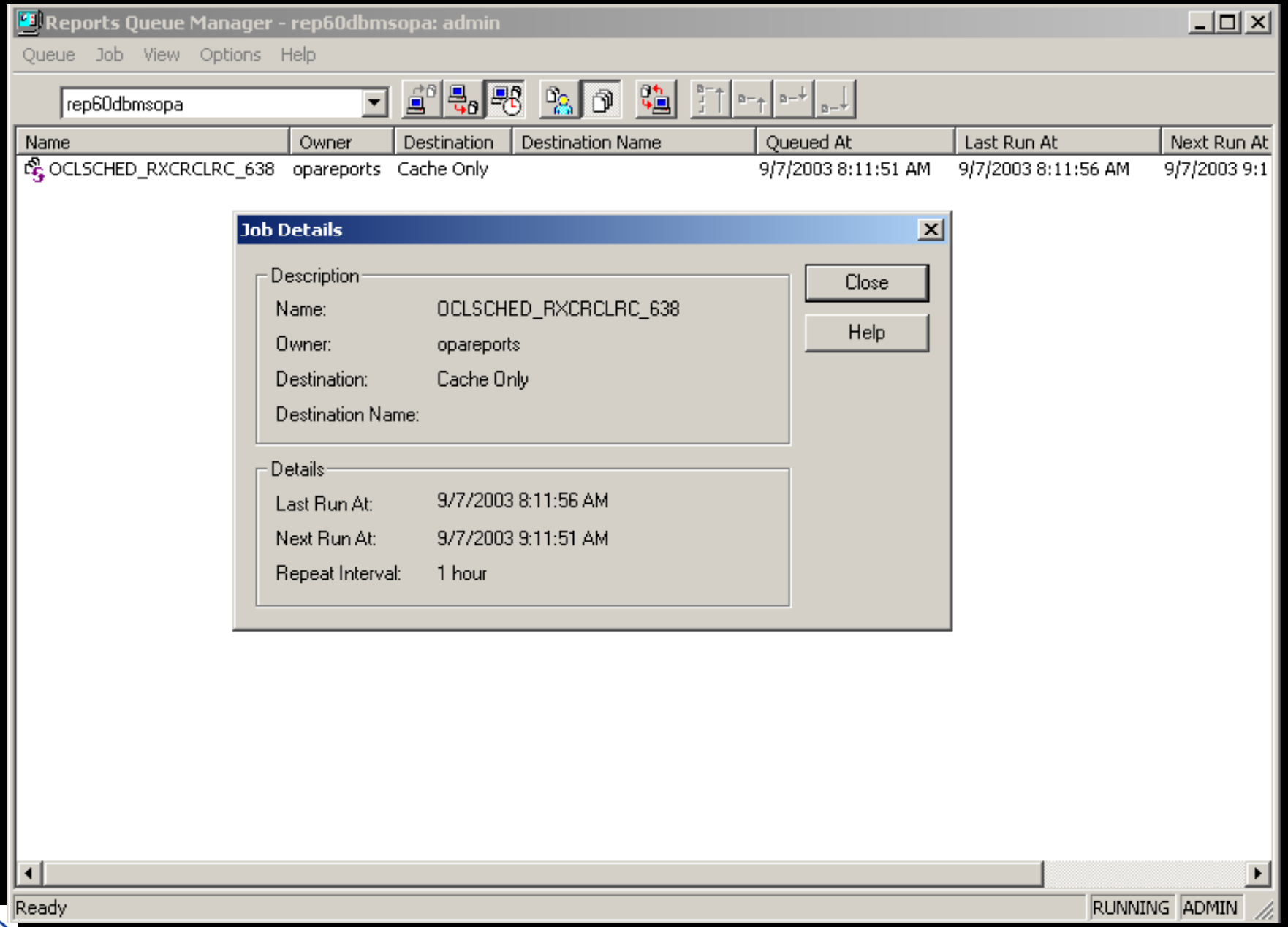
1. **Current Jobs** : **None**

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

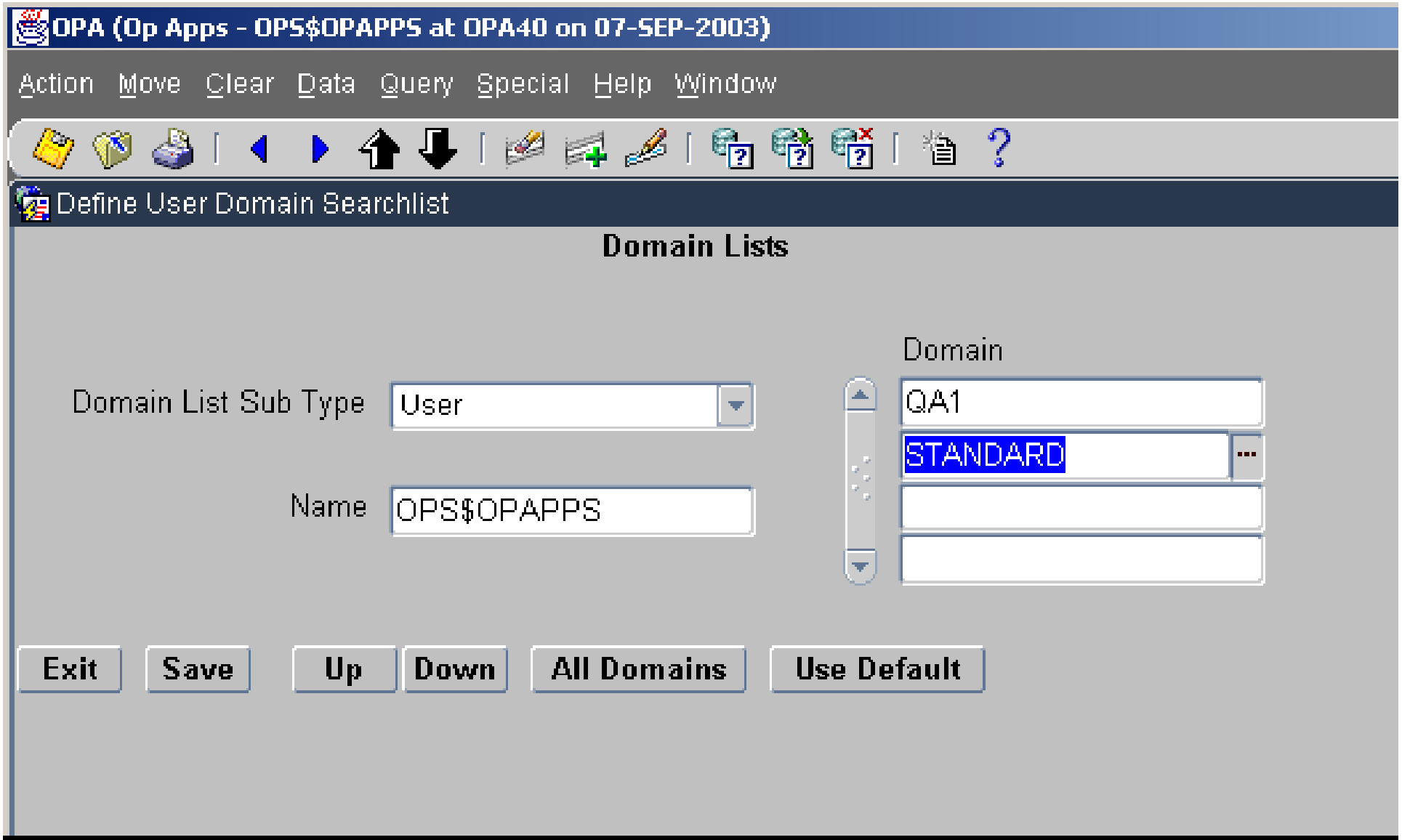
3. **Scheduled Jobs** :

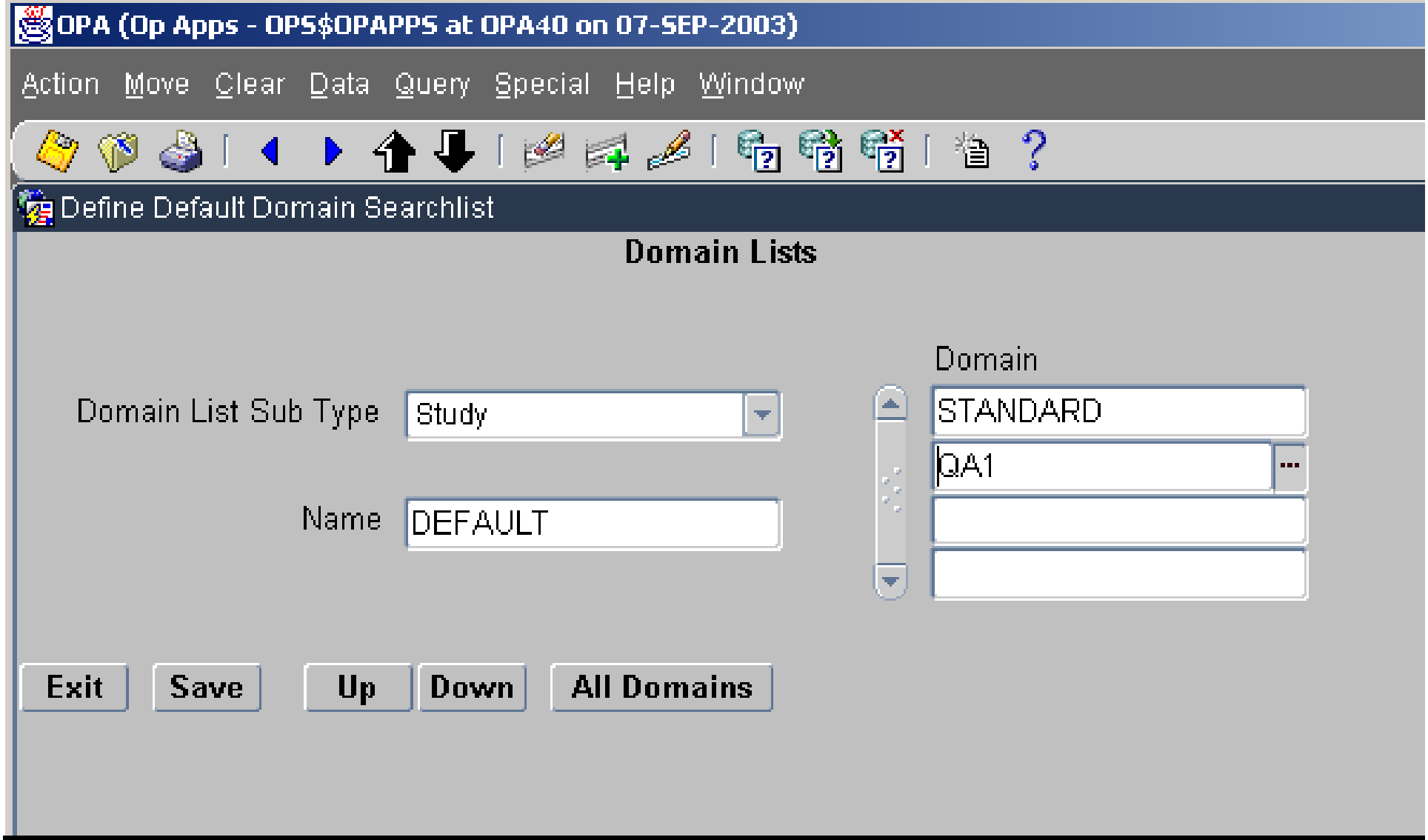
Job ID	Job Name	Job Status	Job Owner	Output Type	Output Name	Last Run At	Next Run At	Repeat Interval
5	OCLSCHED_RXCRCLRC_636	Enqueued	opareports	Cache		09/07/03, 08:02:29	09/07/03, 09:02:24	60 Minute(s)


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 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

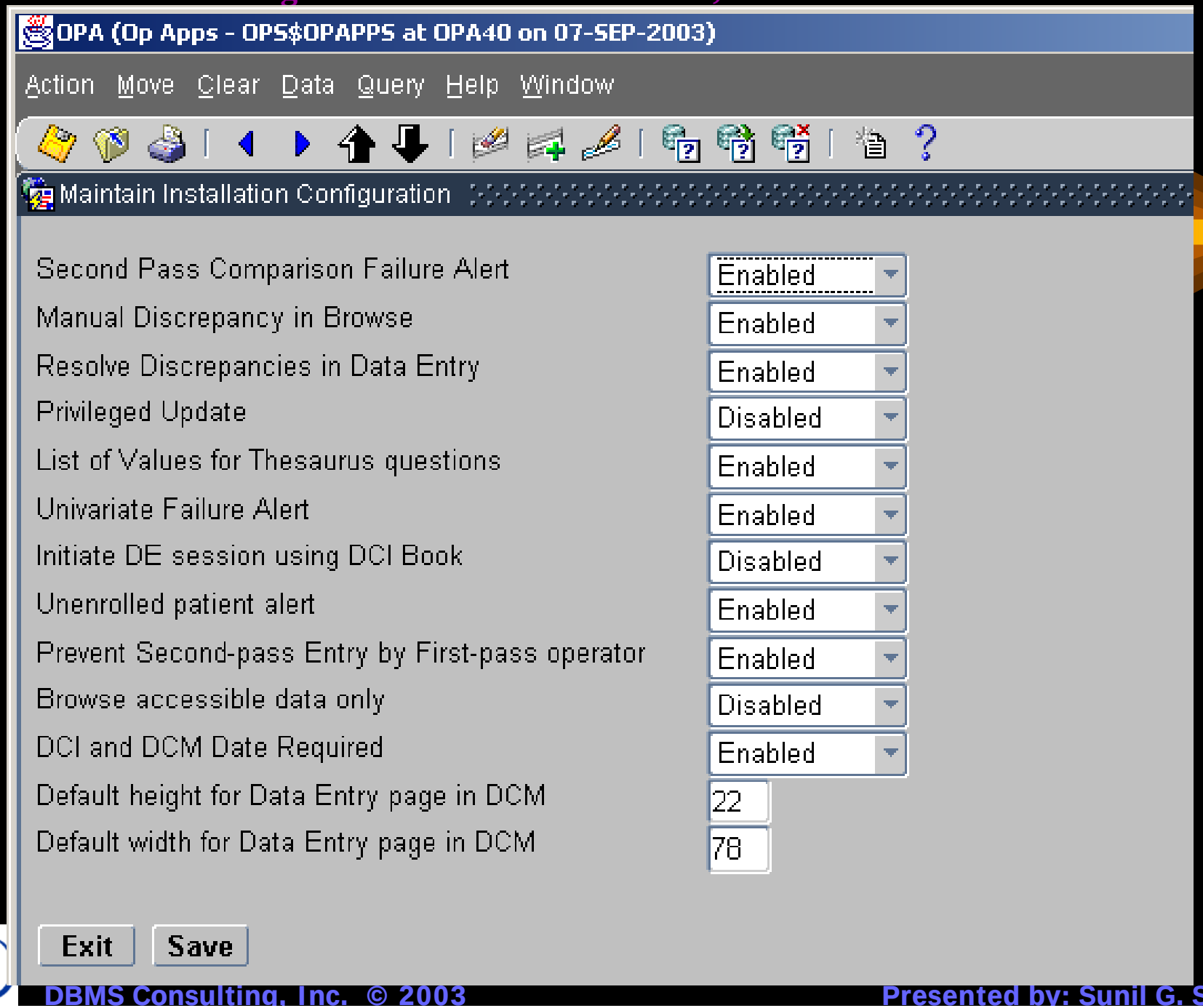

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Special Help Window
Define Default Domain Searchlist
Domain Lists
Domain List Sub Type
Study
Name
DEFAULT
Domain
STANDARD
QA1
Exit
Save
Up
Down
All Domains

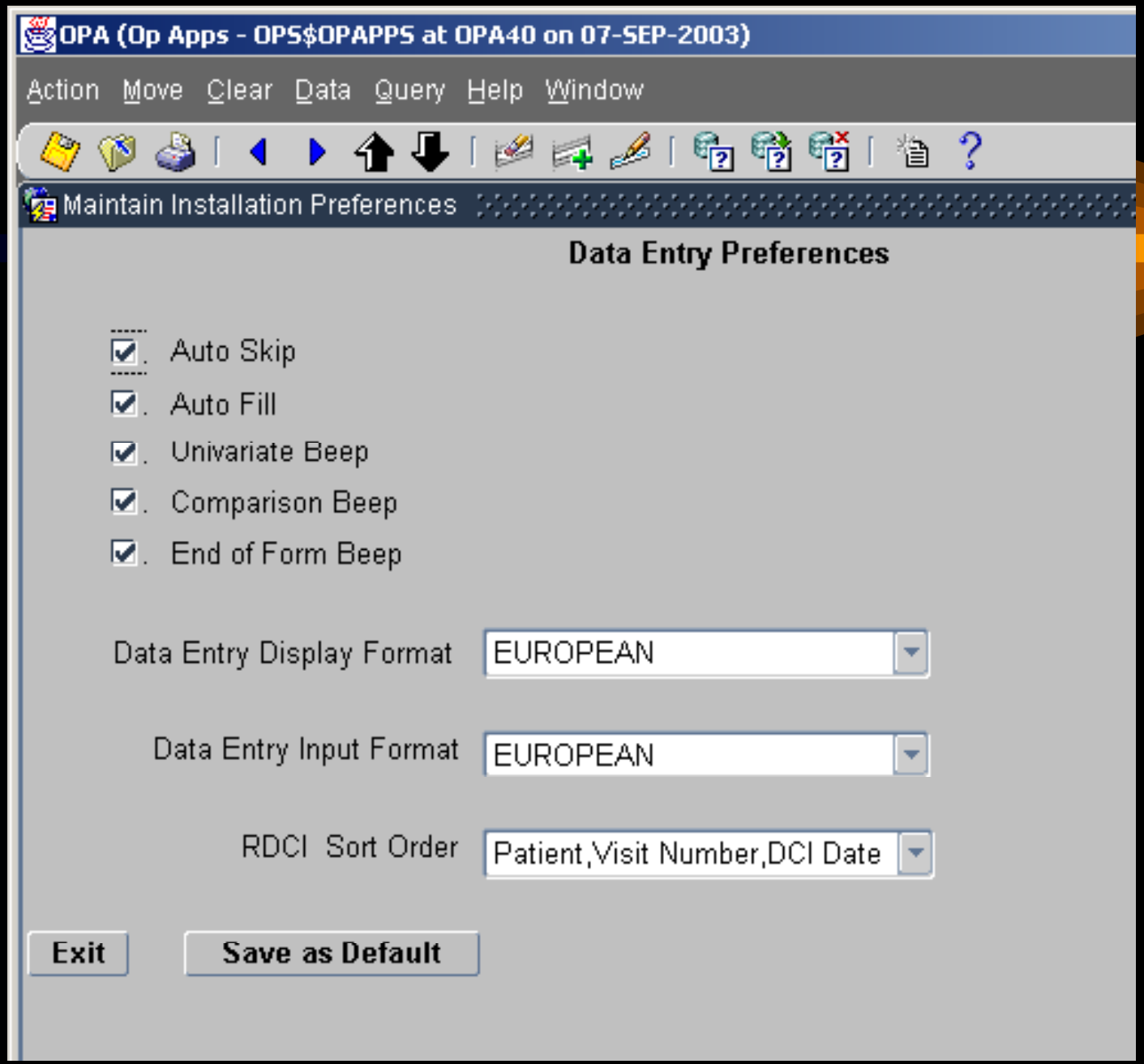
OC DE Configuration

- Data Entry Configuration can be controlled at the System Level, User Level and Study Level
  - Admin -> DE Config (System Level)
  - Admin -> Users -> Oracle Accounts, Special -> DE Config (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 User Preferences (System Level)
  - Admin -> Users -> Oracle Accounts, Special -> DE User Preferences (User Level)

OC DE Configuration (2)

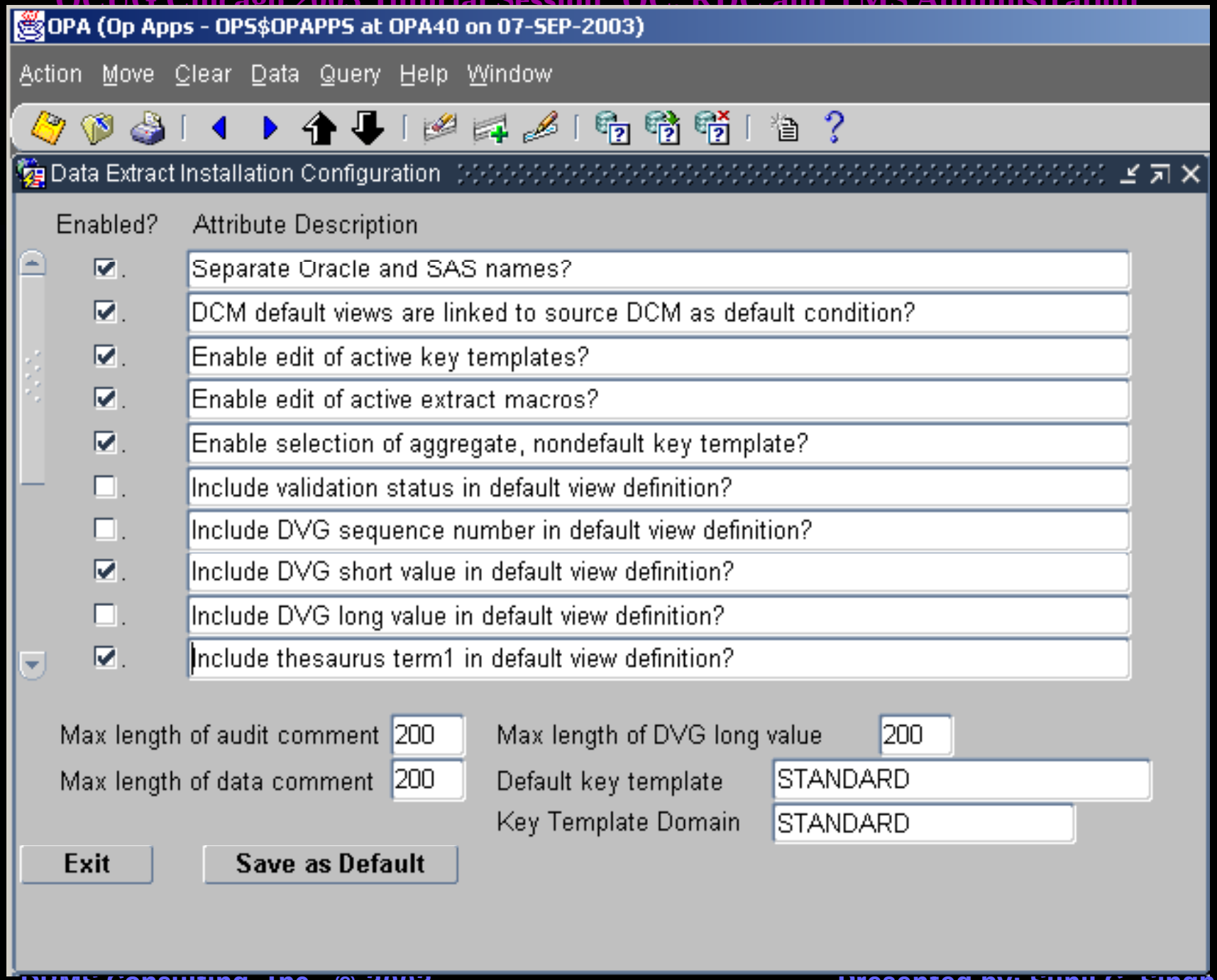
- Precedence of these options is User, then Study, then System
  - If an option is set at the User Level, it prevails all other settings.
  - If an option is not set at the User Level, but set at the Study Level, then the Study Level Prevails
  - If an option is set at neither the User nor the Study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

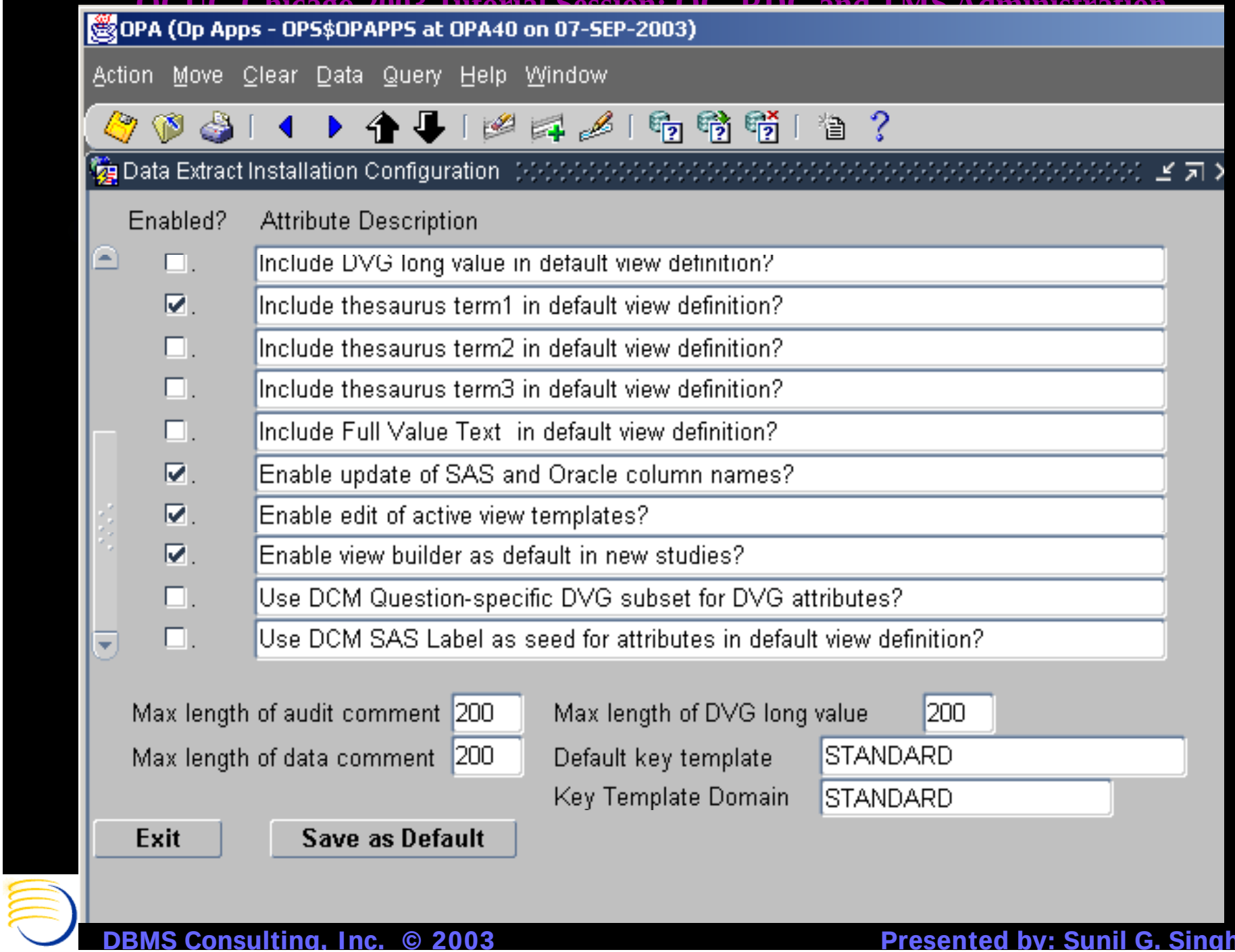

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Maintain Installation Configuration
Second Pass Comparison Failure Alert
Enabled
Manual Discrepancy in Browse
Enabled
Resolve Discrepancies in Data Entry
Enabled
Privileged Update
Disabled
List of Values for Thesaurus 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

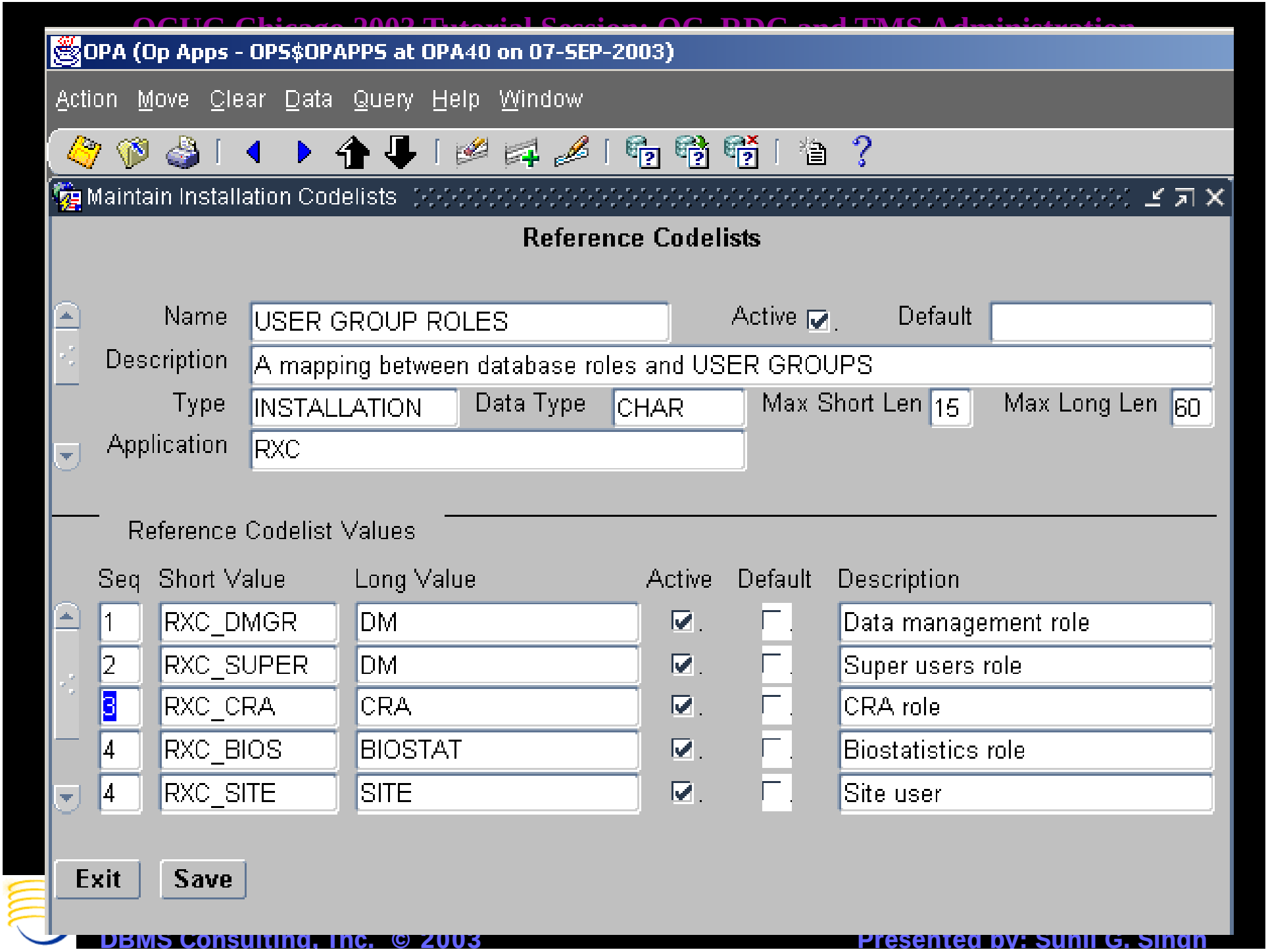
- System level configuration for Data Extract Views can be controlled either by Admin -> DX Installation Configuration or by the Installation Reference Codelist DX_CONFIG
- Default configurations controlled here are:
  - Key Template and Key Template domains
  - Editable characteristics of Key Templates, 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

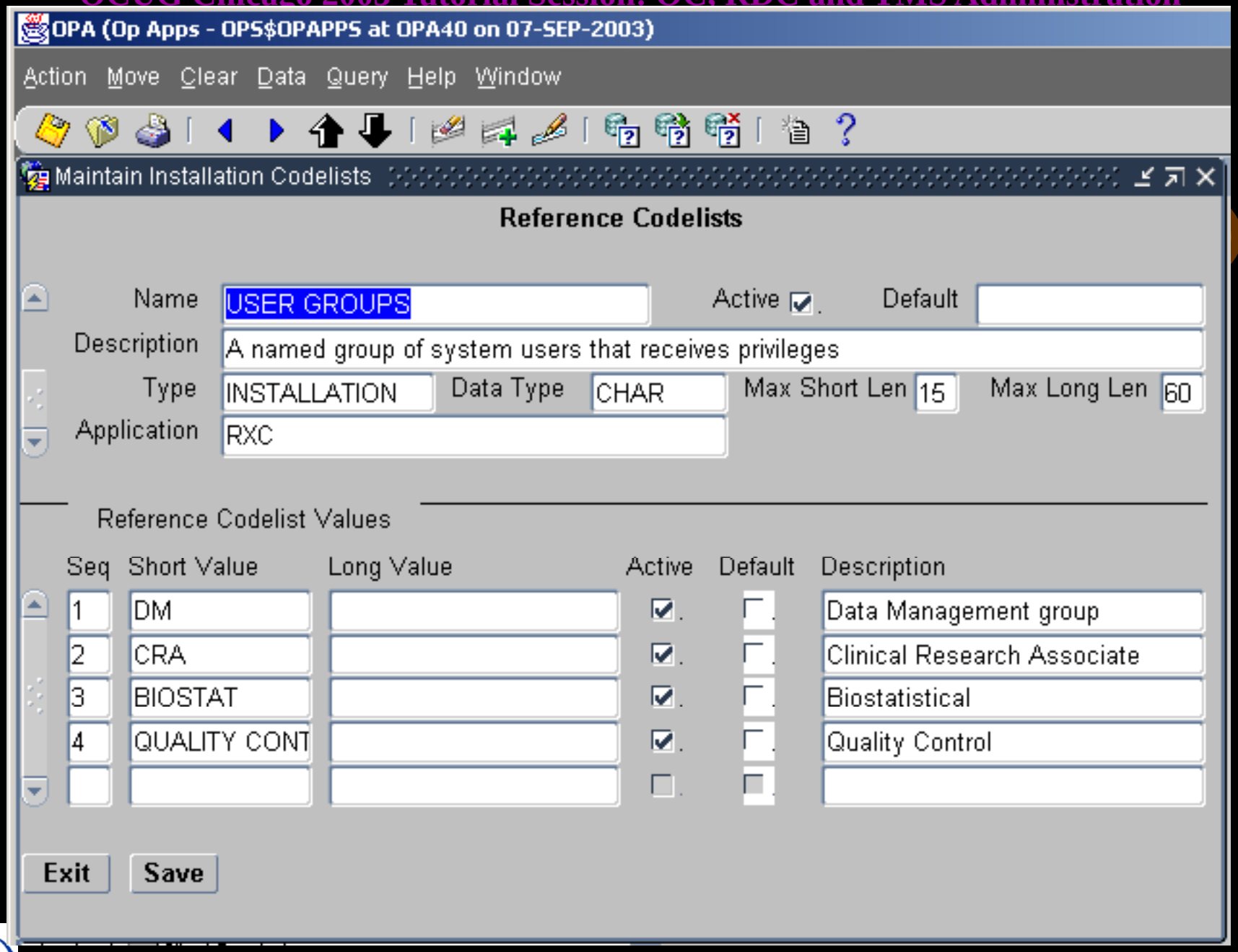

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Data Extract Installation Configuration
Enabled?
Attribute Description
Separate Oracle and SAS names?
DCM default views are linked to source DCM as default condition?
Enable edit of active key templates?
Enable 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

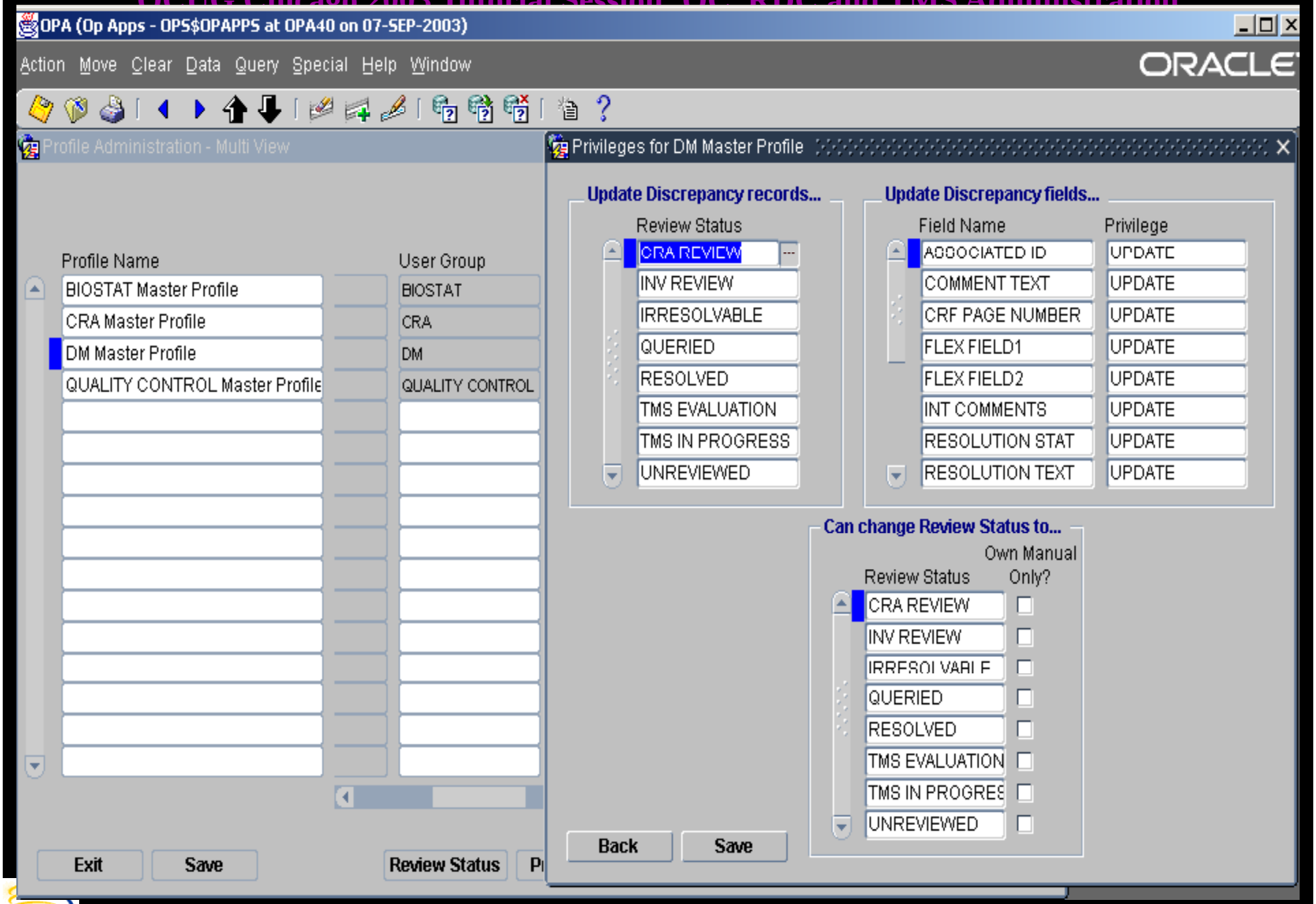

OPA (Op Apps - OPS$OPAPPS at OPA40 on 07-SEP-2003)
Action Move Clear Data Query Help Window
Data Extract Installation Configuration
Enabled?
Attribute Description
Include DVG long value in default view definition?
Include thesaurus term1 in default view definition?
Include thesaurus term2 in default 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 DVG long value
200
Max length of data comment
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

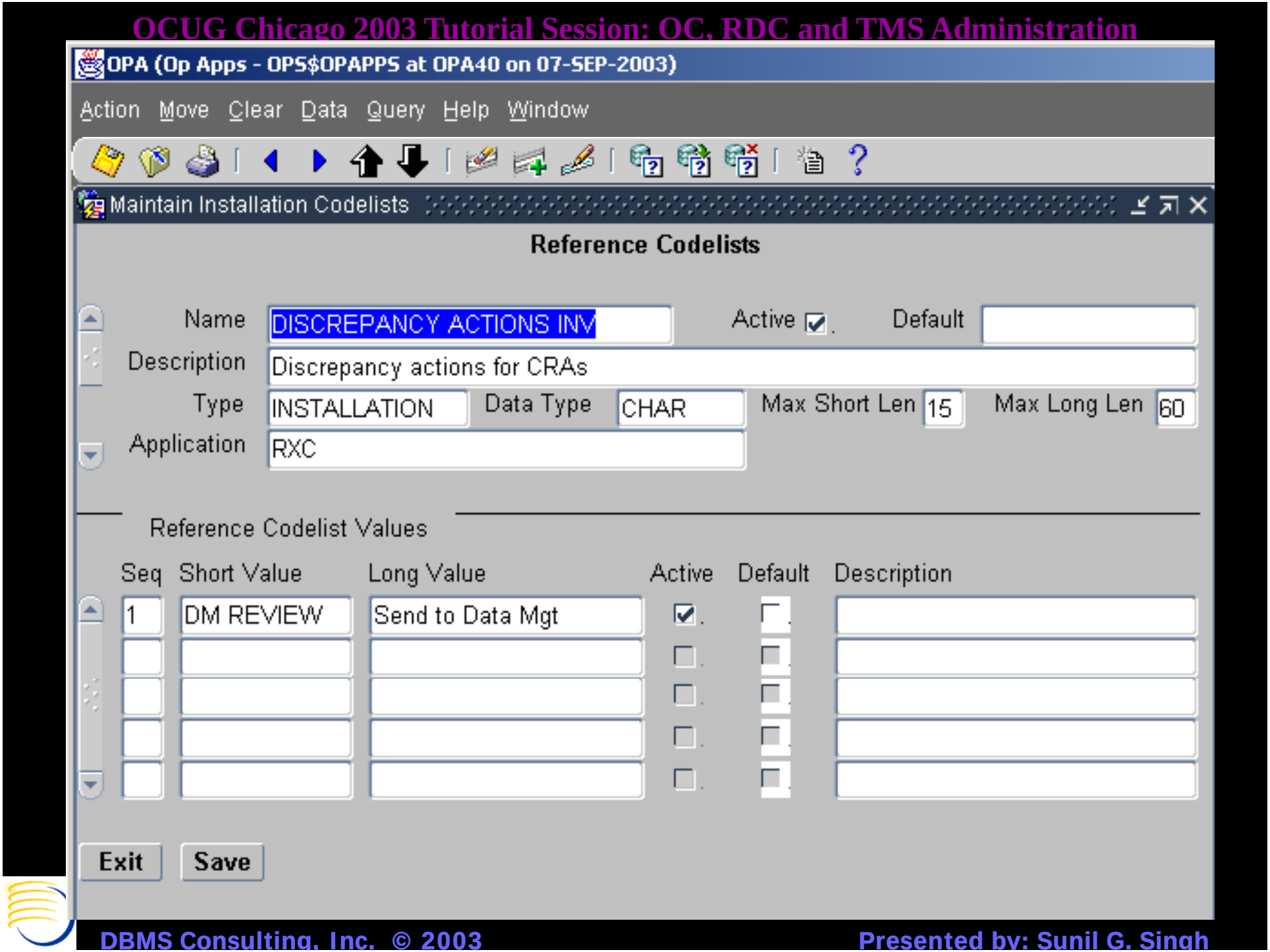
- The Database Roles RXC_RDC, RXC_INV and RXC_SITE control access to RDC by default
- The Database Role RXC_RDC is required for any update access within the RDC interface
- The roles RXC_INV (intended for Investigators) and RXC_SITE (intended for CRAs) are defined in the Installation Reference Codelist USER_GROUP_ROLES. However, they are not associated with USER_GROUPS as EDMS Profiles.

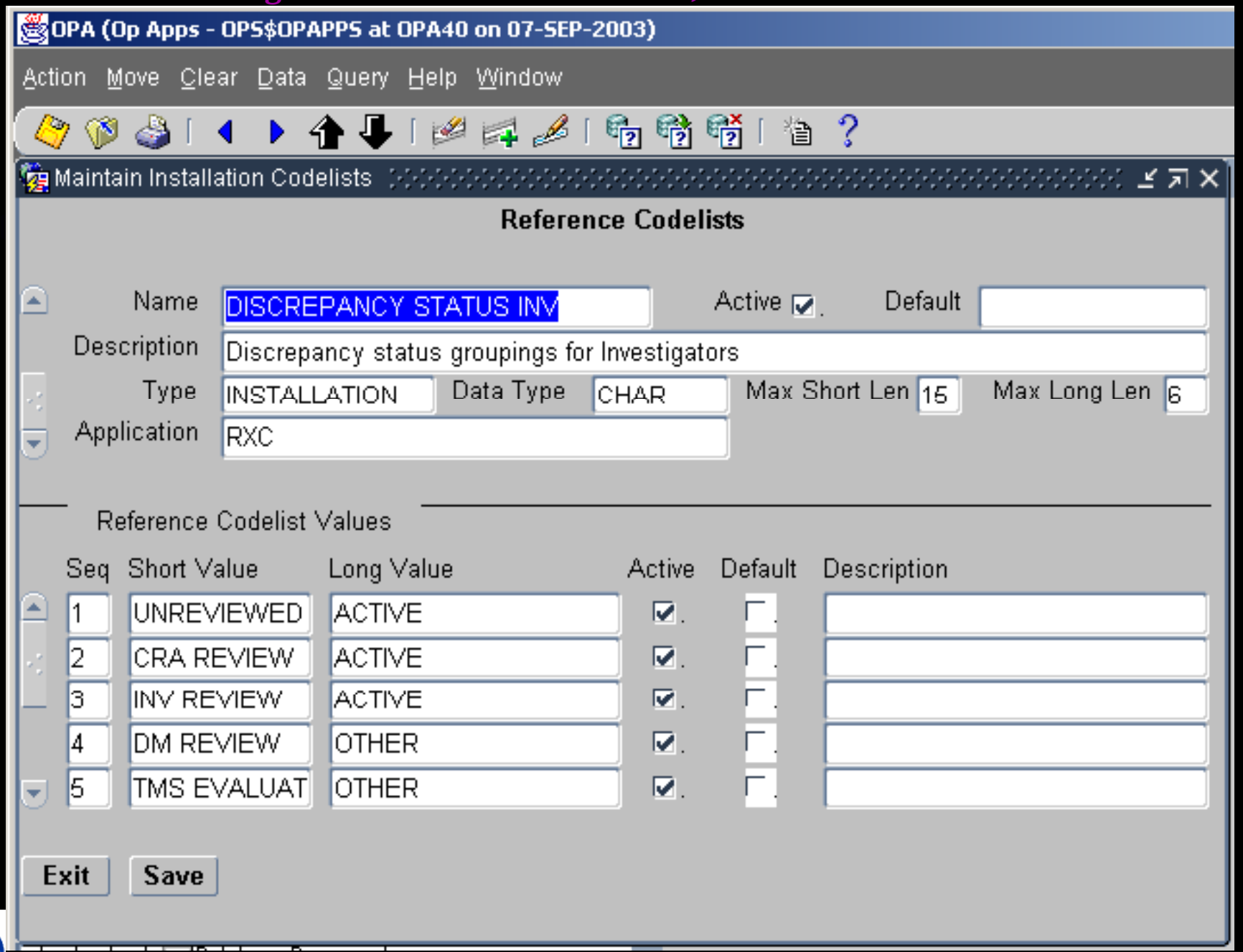
RDC Database Roles (2)

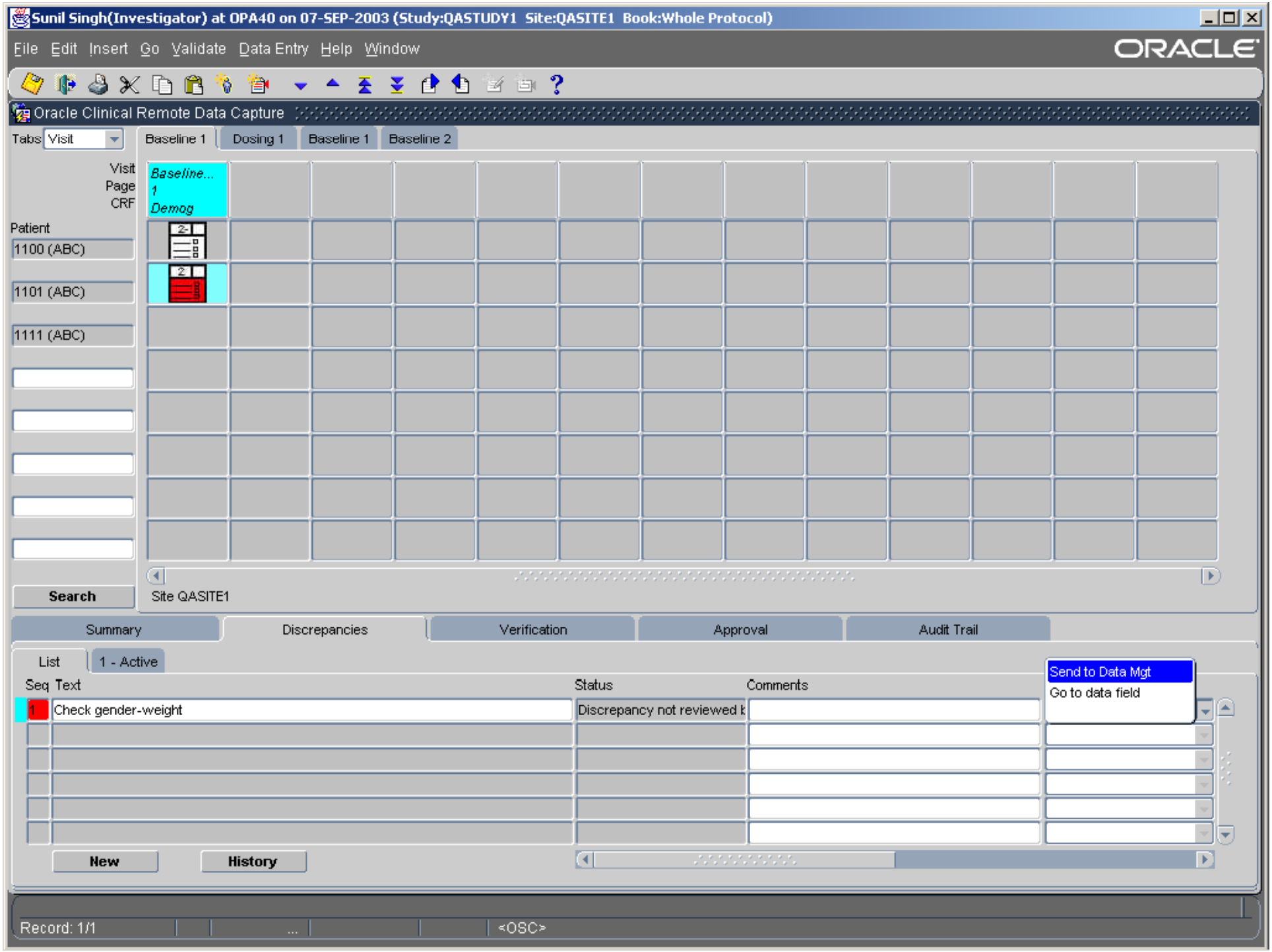
- Instead, two custom Installation reference codelists exist for each of these roles, which support some similar functionality to profiles:
  - Discrepancy Actions Site
  - Discrepancy Status Site
  - Discrepancy Actions Inv
  - Discrepancy Status Inv
- The Discrepancy Actions <ROLE> lists the possible 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.
- 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

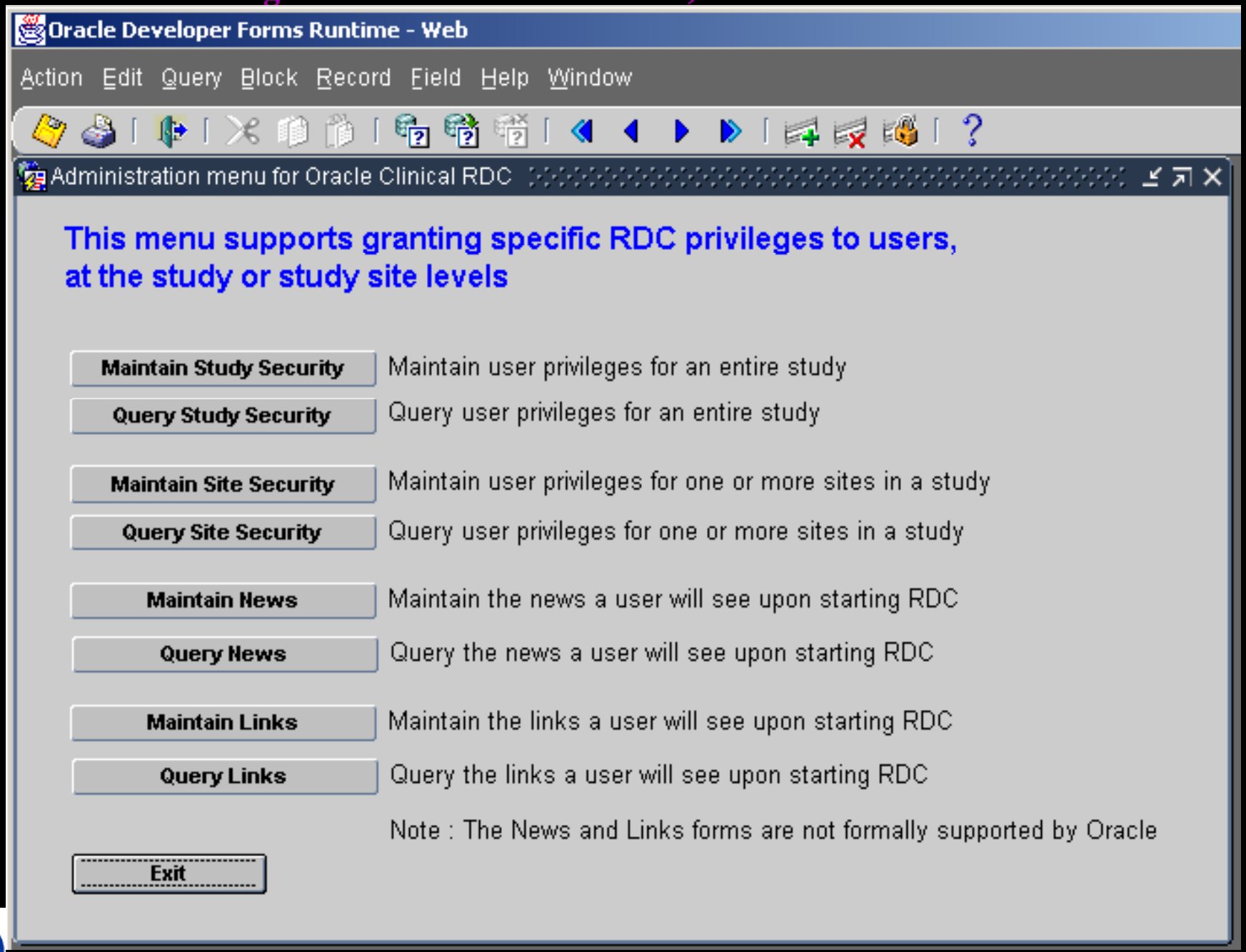

Sunil Singh(Investigator) at OPA40 on 07-SEP-2003 (Study:QASTUDY1 Site:QASITE1 Book:Whole Protocol)
File Edit Insert Go Validate Data Entry Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Baseline 1
Dosing 1
Baseline 1
Baseline 2
Visit
Page
CRF
Baseline...
1
Demog
Patient
1100 (ABC)
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
Send to Data Mgt
Go to data field
New
History
Record: 1/1
<OSC>

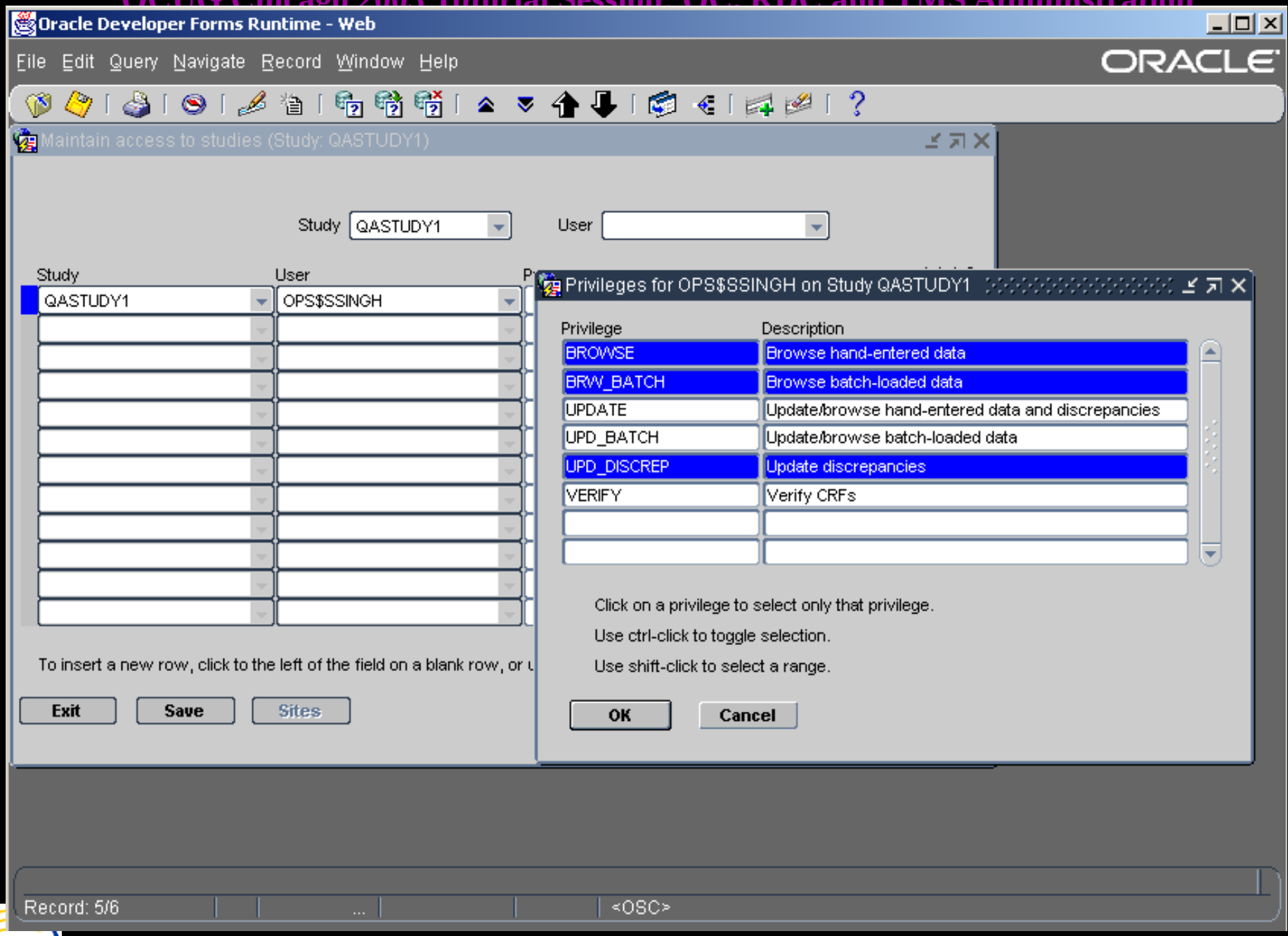
RDC Admin Form

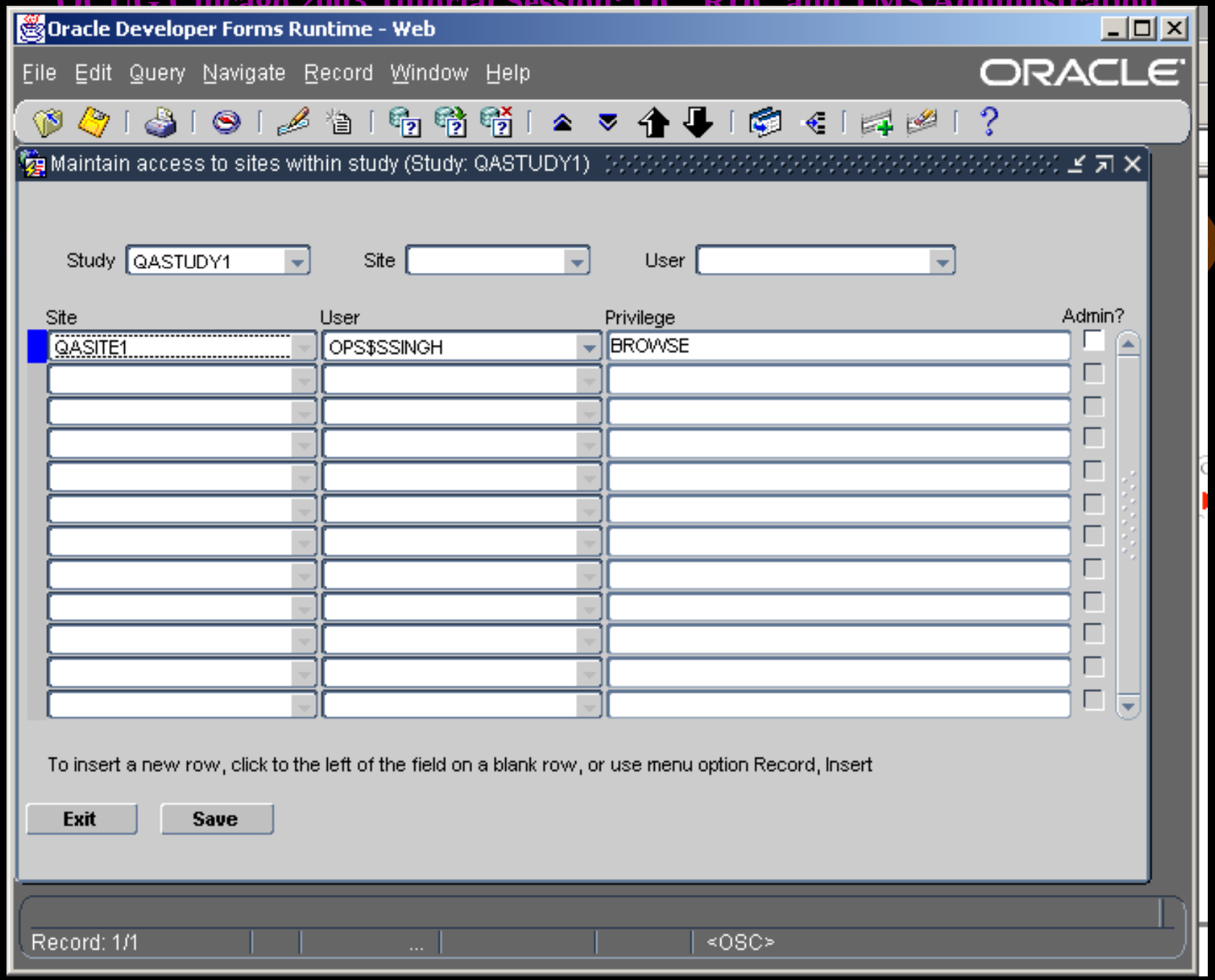
- Remote Data Capture has a special Administration Form which configures Study access and Site access from within RDC. The access to studies is NOT controlled through Oracle Clinical => Admin => Users => Oracle Accounts. It is a different process from OC.
- The type of access control is similar to the control of EDMS profile privileges.
- The set of privileges which can be controlled in RDC 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)

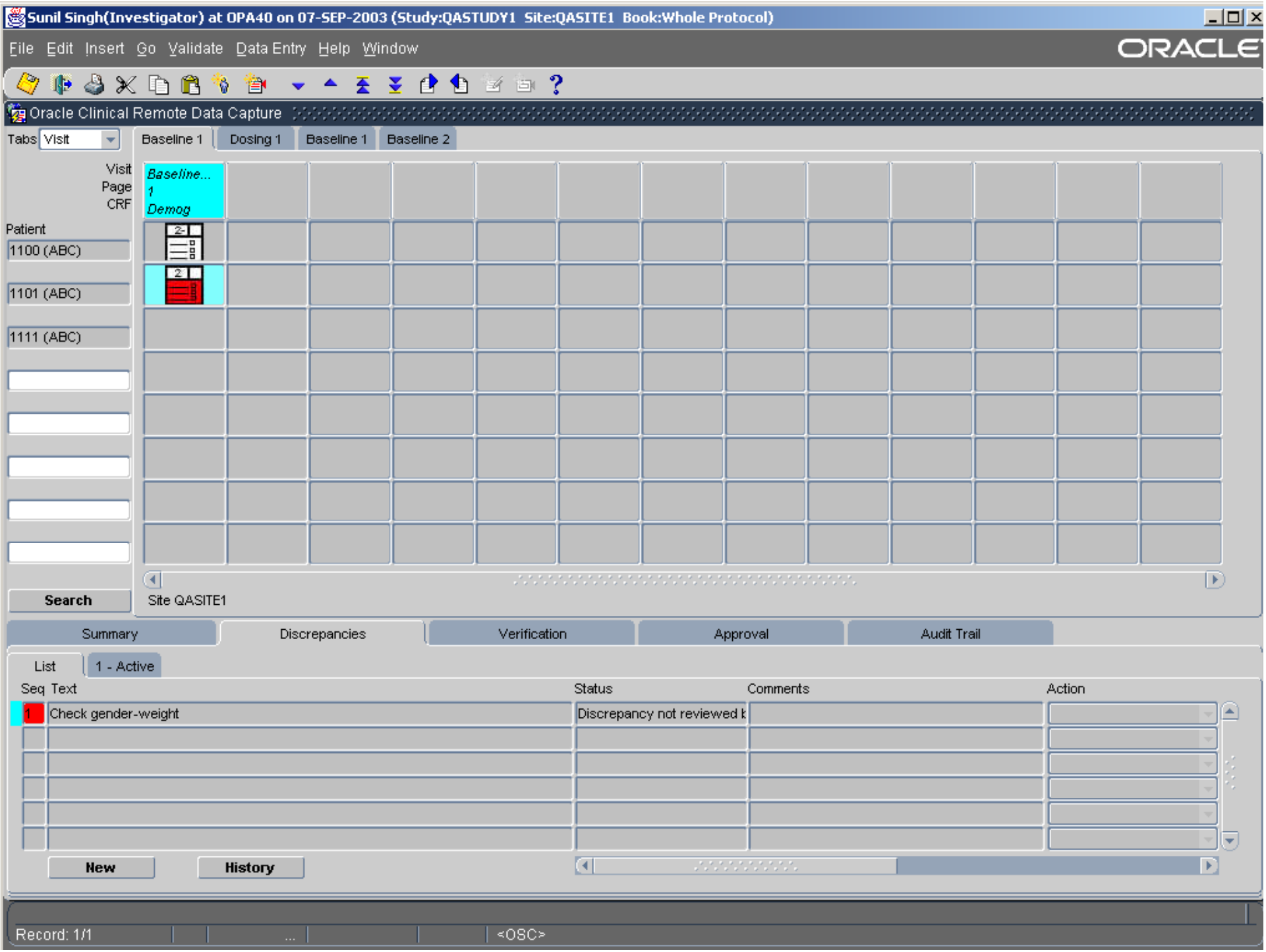
RDC Admin Form (2)

- 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
Note : The News and Links forms are not formally supported by Oracle
Exit


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>

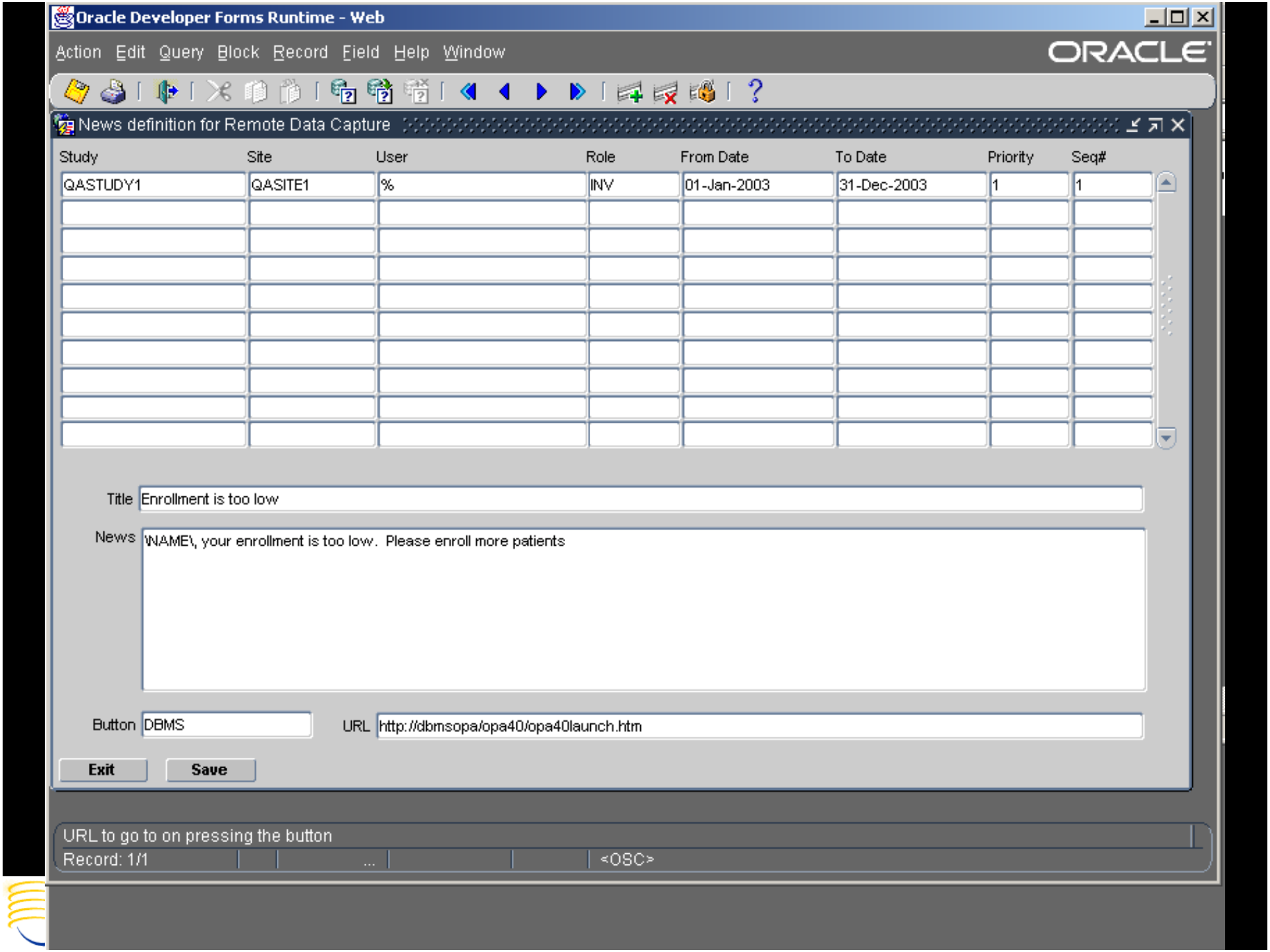

Sunil Singh(Investigator) at OPA40 on 07-SEP-2003 (Study:QASTUDY1 Site:QASITE1 Book:Whole Protocol)
File Edit Insert Go Validate Data Entry Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Baseline 1
Dosing 1
Baseline 1
Baseline 2
Visit
Page
CRF
Baseline...
1
Demog
Patient
1100 (ABC)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

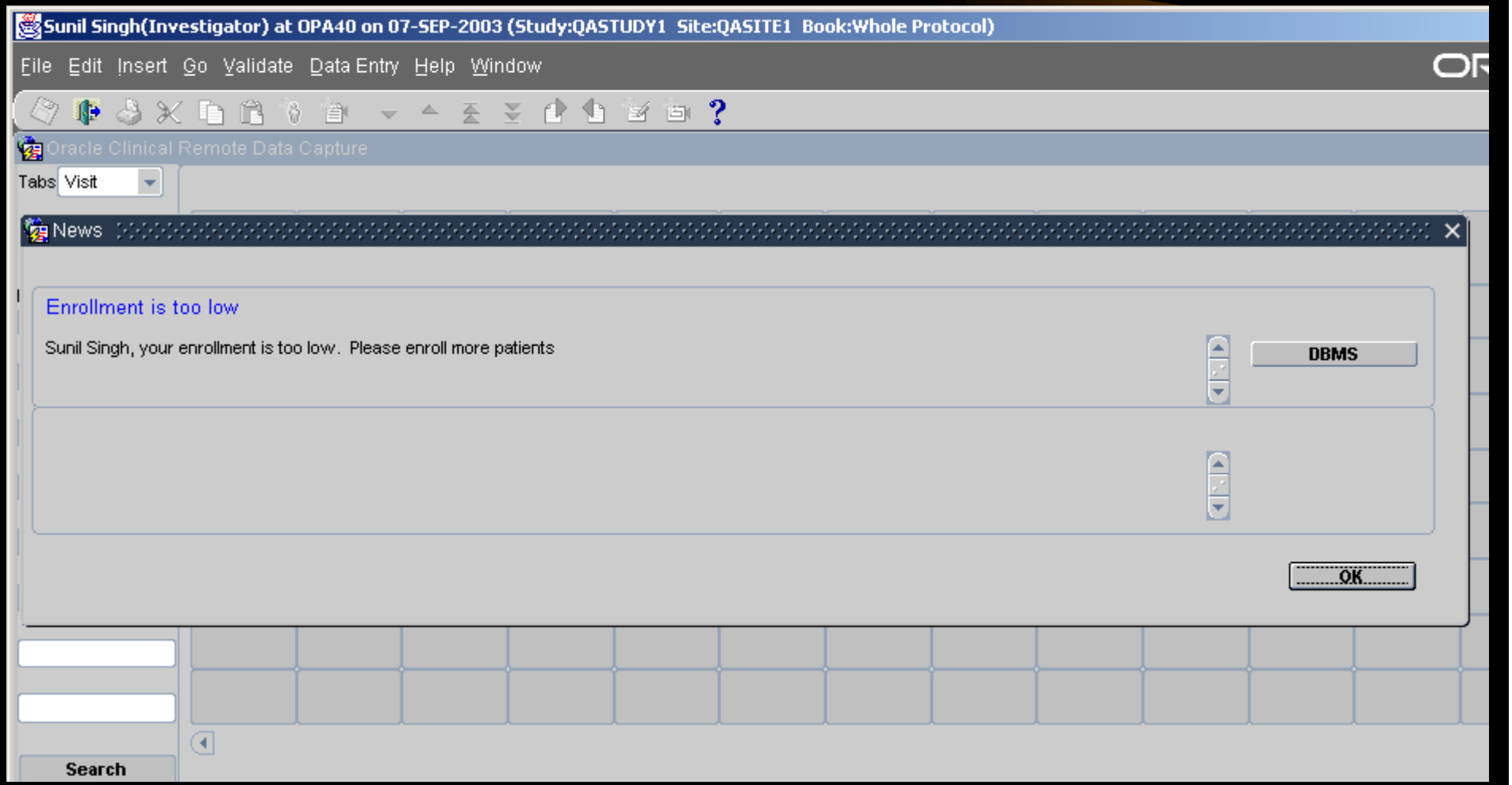
RDC Admin Form (3)

- Test mode RDC administration is possible, but not with the config=rdcadmint link from formsweb.cfg. This form stopped working from version OC 4.0.2 and higher. Instead, to administer test mode RDC, open a session in OC and go to a test menu path, then open the RDC Admin Form. The RDC Admin form will now Administer RDC Test mode, based on the local test synonyms for the Administrative user.
- 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

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 vs. OC Administration (2)

- 9 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_INTEGRATE_PRIV
  - TMS_MAINTAIN_PRIV
  - TMS_RECLASSIFY_PRIV
  - TMS_DOC_CONFIG
  - TMS_DOC_MAINTAIN
- 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

Additional Questions ?

- Electronic copies will be posted on the OCUG Intranets Site and www.clinicalserver.com
- Additional copies will be available at DBMS Consulting's Booth #3 in the Exhibit Hall, along with
  - OPA 4.5 Architecture Posters
  - Flashlight giveaways