Oracle® Clinical

Installation Guide

Release 4.6

A83779-08

September 2010

This guide describes how to install, configure, and upgrade Oracle Clinical 4.6. This release includes information about installing on Linux and corrects documentation errors.

ORACLE®

Oracle Clinical Installation Guide, Release 4.6

A83779-08

Contents

Preface

This guide describes installing — or upgrading to — Oracle Clinical 4.6. You perform some of these tasks once. Others you repeat as your system changes or grows.

Use of Remote Data Capture with Oracle Clinical: Oracle Clinical cannot be used for entering data at remote sites. Separate Remote Data Capture licenses are required for remote site use. Your Oracle Clinical license includes a Restricted Use license for Remote Data Capture that permits the licensed Oracle Clinical user population to use Remote Data Capture solely at the sponsor's location, but not at the clinical site.

Note: Our organization, formerly known as Oracle Life Sciences Applications (OLSA), is now part of the Oracle Health Sciences Global Business Unit (HSGBU).

Audience

The audience for this installation guide is database administrators (DBAs) and system administrators. Installing Oracle Clinical requires the skills listed below. If you want assistance with your installation, engage Oracle Consulting.

Database Administrators

Installing Oracle Clinical requires a level of knowledge equivalent to having mastered the material in the Oracle Architecture and Administration course for DBAs. You must be able to read and edit SQL*Plus scripts, run SQL scripts, and review logs for Oracle errors. For ongoing administration, additional training as a DBA is essential.

System Administrators

Installing and maintaining an Oracle Clinical network requires expertise in the following skill areas:

- UNIX operating systems
  - Creating and managing user accounts and groups
  - Installing Oracle database software and patches
  - Identifying space on a file system for Oracle database tablespaces
  - Setting and using environment variables

- Microsoft Windows operating systems
  - Creating and managing user accounts and groups
  - Installing Oracle software
  - Managing settings through the Control Panel and Administrative Tools
  - Managing network printers
  - Creating services

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Accessibility standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For more information, visit the Oracle Accessibility Program Web site at http://www.oracle.com/accessibility/.

Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/support/contact.html or visit http://www.oracle.com/accessibility/support.html if you are hearing impaired.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Clinical is Oracle Support's self-service Web site My Oracle Support (formerly MetaLink).

Before you install and use any Oracle product, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, white papers, bulletins, and patches.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the Web site.

To register for My Oracle Support:

1. Open a Web browser to http://support.oracle.com.

2. Click the **Register here** link to create a My Oracle Support account. The registration page opens.
3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click **Sign In.**
3. Enter your user name and password.
4. Click **Go** to open the My Oracle Support home page.

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for information, release notes, white papers, and bulletins is by the article ID number.

To search by the article ID number:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Locate the Search box in the upper right corner of the My Oracle Support page.
3. Click the sources icon to the left of the search box, and then select **Article ID** from the list.
4. Enter the article ID number in the text box.
5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

   The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the **Browse any Product, By Name** field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search — Once you have results from a search, use the Refine Search options on the right side of the Knowledge page to narrow your search and make the results more relevant.
- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

1. Sign in to My Oracle Support at http://support.oracle.com.

2. Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region. You have the following options:
   - In the **Patch ID or Number is** field, enter the primary bug number of the patch you want. This option is useful if you already know the patch number.
   - To find a patch by product name, release, and platform, click the **Product or Family** link to enter one or more search criteria.
3. Click **Search** to execute your query. The Patch Search Results page opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
5. Click **Download.** Follow the instructions on the screen to download, save, and install the patch files.

Finding Documentation on Oracle Technology Network

Use the Oracle Technology Network Web site to open PDF versions of user and reference documentation.

Visit the Oracle Technology Network Web site at the following address:

`http://www.oracle.com/technology/index.html`

Use the Documentation menu and the Documentation Index to find the manual you want, and then click its title to download and open the PDF version of the manual.

Related Documents

Disk V22168-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack includes the documentation for Oracle Clinical and for related Oracle Health Sciences applications. The manuals are located in the \doc directory.

In addition, you can download PDF copies of the manuals from the Oracle Technology Network. You can use the part number to search for a specific manual.

Oracle Clinical Documentation

The Oracle Clinical documentation set includes:

- *Oracle Clinical Installation Guide* (Part A83779)
- *Oracle Clinical Administrator's Guide* (Part A83791)
- *Oracle Clinical Getting Started* (Part B12308)
- *Oracle Clinical Creating a Study* (Part A85200)
- *Oracle Clinical Conducting a Study* (Part A85201)
- *Interfacing from Oracle Clinical* (Part A83793)

In addition, Oracle Health Sciences publishes PDF-format technical reference manuals that provide proprietary information on internal tables and APIs. If you are a licensed customer, contact Oracle Support to obtain a free electronic copy of the *Oracle Clinical Stable Interface Technical Reference Manual* (Part A83796).

Oracle Clinical Remote Data Capture (RDC) Documentation

The Oracle RDC documentation includes:

- *Oracle Clinical Remote Data Capture Onsite User's Guide* (Part B31158)
- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* (Part E11064)
- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide* (Part B13921)

Release Notes, Bulletins, and White Papers

As mentioned earlier in this preface, be sure to visit the My Oracle Support Web site for the most up-to-date installation information, including alerts, release notes, bulletins, white papers, and patches.

The My Oracle Support Web site includes these important installation topics:

- *Oracle Life Sciences Applications Supported Technology Stacks* (Article ID 180430.1)
- *Oracle Clinical Release 4.6 Release Notes* (Article ID 859753.1)
- *OLSA 4.6.x and 4.7.x Known Install and Configuration Issues* (Article ID 386941.1)
- *Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability* white paper (Article ID 873743.1)

Oracle CPU Security Update Patches

Oracle publishes a CPU Security Update patch quarterly. Install these patches on every computer with an Oracle Home. Check My Oracle Support for information on the latest patch tested with Oracle Health Sciences applications.

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1

Preparing to Install Oracle Clinical

This chapter describes Oracle Clinical's network architecture, hardware, and software requirements and the dependencies among the components. Before you begin installing or upgrading Oracle Clinical, check that your environment meets the requirements.

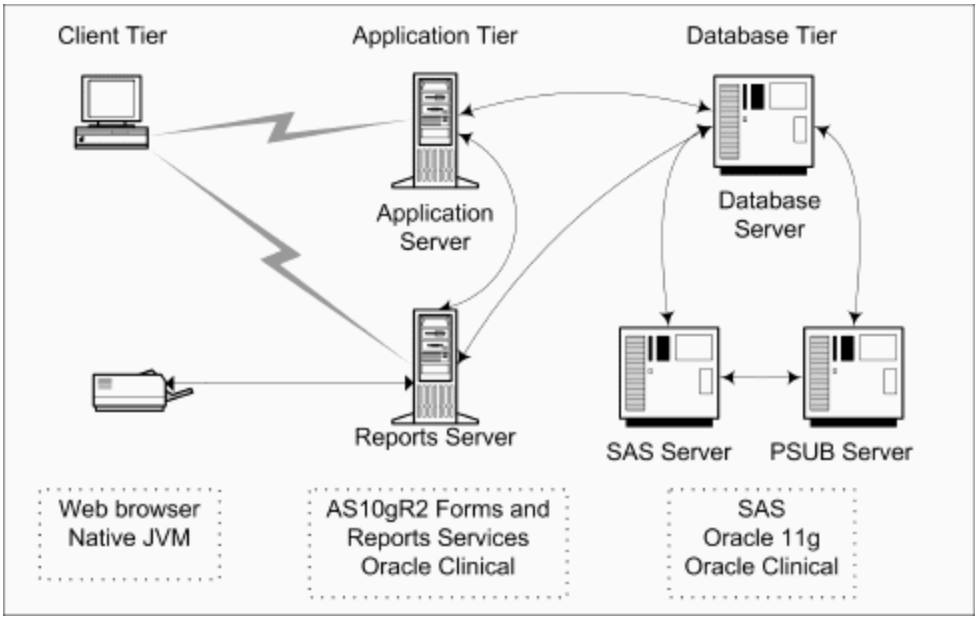
This chapter includes the following topics:

1.1 About the Oracle Clinical Network Architecture

The network architecture for Oracle Clinical consists of three tiers: the database tier, the application tier, and the client tier.

Figure 1–1 illustrates the basic network architecture for Oracle Clinical.

Figure 1–1 Oracle Clinical Network Architecture



The **database tier** in an Oracle Clinical environment includes the Oracle Database 11*g*, the Oracle Clinical Database Server, one or more Oracle Clinical databases, and the Parameterized Submission (PSUB) process. PSUB is the batch processor for Oracle Clinical. Optionally, the database tier can include SAS statistic software. In past releases, the database tier was called the back end.

The **application tier** includes the Oracle Application Server 10*g*R2 (Oracle AS10*g*R2), the Oracle Clinical application, and the Remote Data Capture (RDC) application. In addition, Oracle Clinical includes these components:

- **Oracle Clinical Forms Server** — The Forms Server performs all forms processing, communicates the display changes to the client, and calls forms to query, update, select, and delete data from the Database Server.
- **Oracle Clinical Reports Server** — The Reports Server runs most batch reports, schedules all jobs, including PSUB jobs, and runs job sets. In addition, it creates PDF output for RDC Patient Data Reports, RDC Blank Casebook Reports, and Oracle Clinical Audit Reports.

The **client tier** includes one or more clients, which communicate users' keystrokes and mouse movements to the application tier. In addition, you set up a client on each Forms Server.

1.2 Choosing a Character Set

Oracle Health Sciences supports certain character sets for each product or each combination of integrated products.

Oracle Clinical supports the following character sets:

- UTF8
- US7ASCII
- WEISO8859P1
- Any single byte character set

If you are only installing Oracle Clinical and RDC, Oracle recommends that you use the UTF8 character set.

Use the same character set on the database tier and the application tier. If you select US7ASCII for the database tier and UTF8 for the application tier, Oracle Clinical stores some special characters incorrectly in the database.

The supported character sets for different product combinations are as follows:

- Oracle Clinical and Thesaurus Management System (TMS): UTF8, US7ASCII, WEISO8859P1, or any single byte character set.
- All products, or any combination that includes Adverse Events Reporting System (AERS): AL16UTF16.

1.3 Planning an Oracle Clinical Database Tier Installation

This section describes the hardware and software requirements for the Oracle Clinical database tier.

1.3.1 Database Tier Operating System Requirements

The database tier for Oracle Clinical 4.6 supports these operating systems:

- **Oracle Enterprise Linux 5 x86-64** (64-bit versions only, US English)
- **Oracle Solaris (SPARC) 9** and **10** (64-bit versions only, US English)
- **HP-UX Itanium 11.31** (64-bit versions only, US English)
- **Microsoft Windows Server 2003** (32-bit version only, US English) with Service Pack 1 or 2.

1.3.2 Database Tier Character Set Requirements

See Section 1.2, "Choosing a Character Set."

1.3.3 Database Tier System Resource Requirements

Ensure that the Oracle Clinical database tier has these system resources:

- At least 500 MB in the tmp directory.
- At least 2 GB of physical memory.
- Swap space equal to three times the amount of physical memory. (If the system's physical memory exceeds 1 GB, two times is usually sufficient.)

1.3.4 Prerequisite Tasks for Oracle Database 11*g*

To ensure that your Database Server platform meets the minimum requirements for installing Oracle Database 11*g*, perform the following preparatory tasks:

1. Create the software owner and groups:
   - Create a UNIX user to own the Oracle software. Typically, the user name is **oracle**.
   - Create two groups: one is the Oracle Inventory group; the other is the operating system DBA group. Typically, the group names are **oinstall** and **dba,** respectively.
2. Create mount points owned by the oracle user:
   - Create a software mount point of at least 10 GB.
   - Create mount points to hold the database files, control files, and log files, respectively.
3. UNIX only. Create the following directory for the oratab file:

   ```
   /var/opt/oracle
   ```

   Ensure that the oracle user has write permissions on this directory.
4. Test permissions. Ensure that the oracle user can write to the new mount points and all subdirectories.
5. UNIX only. Configure kernel resources. See Oracle 11g's operating-specific instructions for setting kernel parameters.
6. Download and install the latest operating system patches required for Oracle, if necessary. Review Oracle 11g's latest platform-specific install bulletins.

1.3.5 UNIX Database Server Requirements

In addition to the required system resources and character sets, the supported UNIX operating systems have the following additional requirements. (See Section 1.3.6 for Windows-specific requirements.)

1.3.5.1 X Window System Capability

The Oracle Universal Installer utility installs the Oracle Clinical Database Server software. Because the Installer uses the X Window System to display its interface, you must perform the installation from either a system monitor that supports rasterized graphical displays, or a computer with X Window System emulation software.

For emulation software, Oracle recommends Hummingbird Exceed 10.0 or later. (If you experience screen display problems while running the Installer in Hummingbird Exceed, go to XConfig/Screen Definition/Screen 0. Change the Window Manager setting from **Default** to **Native.**)

1.3.5.2 Compatibility with Oracle9*i* Database on UNIX Database Servers

On UNIX platforms, you can have an Oracle Clinical 4.6 installation on the same computer as an Oracle Clinical 4.5.1 installation because it installs against the Oracle Database 11*g* Oracle Home instead of the Oracle9*i* Database Oracle Home. However, you can only use one copy of Oracle Clinical against one Oracle Database 11*g* Oracle Home.

1.3.5.3 C Run-time Libraries on UNIX Database Servers

The Oracle Clinical 4.6 Database Server requires C run-time libraries installed on the server. Table 1–1 lists the C compiler used to link the Oracle Clinical code during development and testing. Install the run-time libraries of the corresponding version on your Database Server.

Table 1–1 Supported UNIX Database Server Operating Systems and C Compilers

Operating System	Supported C Compiler
Oracle Enterprise Linux	GCC-4.1.2
Oracle Solaris 9 and 10	Oracle Solaris Studio 12
HP-UX Itanium 11.31	HP C/C++ B3010B A.06.20

1.3.6 Windows Database Server Requirements

In addition to the required system resources and character sets, the Windows operating system has the following additional requirements. (See Section 1.3.5 for UNIX-specific requirements.)

1.3.6.1 Compatibility with Oracle9*i* Database on Windows Database Servers

A Windows Database Server does not support multiple Oracle Clinical code environments. Therefore, you cannot have Oracle9*i* Database and Oracle Database 11*g* on the same Windows computer.

1.3.6.2 Access on Windows Platforms

You must have the Windows Administrator user ID and password for the operating system.

1.3.6.3 Windows Database Server Requires Separate Oracle Home

A Windows Database Server cannot share a computer with the Forms Server or Reports Server components. The Database Server DLLs are incompatible with the Forms Server DLLs.

1.3.7 Oracle Database 11*g* Requirements

Oracle Clinical 4.6 requires Oracle Database 11*g* Release 11.1.0.6.0 plus Patch Set 1 (11.1.0.7.0), Enterprise Edition.

1.3.7.1 Required Reading

Installing Oracle Database 11*g* to be compatible with your operating system and Oracle Clinical requires information from different sources. Before you start the Oracle Clinical installation, review the following documents:

- Oracle Database 11*g* Release 11.1.0.6.0 plus Patch Set 1 (11.1.0.7.0) installation documentation
- Latest platform-specific Oracle Database 11*g* installation bulletin that is available on My Oracle Support
- Latest supported component versions and alerts related to Oracle Database 11*g* and Oracle Health Sciences applications that are available on My Oracle Support

1.3.7.2 Oracle Text Option

Choose to install the Oracle Database 11*g* Text Option. Oracle Database 11*g* includes the Oracle Text Option, but note that installing and using it requires purchasing a separate license.

1.3.7.3 Oracle Database 11*g* Partitioning Option

Oracle Clinical 4.6 supports partitioning, but this feature is disabled by default. You must buy and install the Oracle Database 11*g* Partitioning Option. See the *Oracle Clinical Administrator's Guide* for information about partitioning.

1.3.8 Global Library Location

You must choose a database and a location for Oracle Clinical's Global Library — a definition object repository — for your installation or distributed environment. When you create a new Oracle Clinical database, you must enter the Source Location Code for the Global Library. In a distributed environment, you must arrange to share the Global Library with the other databases at other locations.

1.3.9 Database Seed Numbers in a Replicated Environment

When you create an Oracle Clinical 4.6 database, the Universal Installer prompts you to allocate a seed number. The system uses the seed number to generate unique primary keys and allows the data replication among databases without triggering unique key violations. You must consider and allocate the seed numbers for all databases in a replicated environment. Seed numbers for the databases within a particular replicated environment must be unique.

1.4 Planning an Oracle Clinical Application Tier Installation

The application tier includes the Forms Server and Reports Server components. Oracle AS10*g*R2 includes the Forms Server and Reports Server components in the same installation. You can add extra Reports Servers by installing Oracle AS10*g*R2 on additional computers.

1.4.1 Application Tier Operating System Requirements

For Oracle Clinical 4.6, the Forms Server and Reports Server support the following operating system only:

Microsoft Windows 2003 Server
US English
with Service Pack 1 or 2

1.4.2 Application Tier Character Set Requirements

The default installation configures Oracle Clinical and Oracle Thesaurus Management System applications to use the following character set:

AMERICAN_AMERICA.UTF8

However, verify the character set that you choose for the application tier is compatible with your database character set.

For more information about the guidelines and requirements for character sets, see Section 1.2, "Choosing a Character Set."

1.4.3 Forms Server Requirements

The Forms Server, which is the Oracle Clinical forms application, brokers transactions between clients and the Database Server.

This section describes its requirements. For installation instructions, see Chapter 5, "Installing the Oracle Clinical Forms Server."

1.4.3.1 CPU Security Update Patch

You must obtain the latest CPU Security Update patch approved by Oracle Health Sciences from My Oracle Support.

1.4.3.2 Permanent IP Address

Each Forms Server computer must have a permanent IP address. During installation, the Oracle Installer prompts you for site information. Be prepared to enter the computer's permanent IP address or the computer's network name when you install the Forms Server.

1.4.3.3 Oracle Application Server 10*g* Release 2 Forms and Reports Services

Oracle Application Server 10*g* Release 2 (Oracle AS10*g*R2) includes the Application Server, Oracle Forms, and the Reports Server. This guide includes only the instructions necessary to set up Oracle AS10*g*R2 to run Release 4.6 of Oracle Clinical and RDC. For other uses with the product, see the Oracle AS10*g*R2 documentation.

1.4.3.4 Java Runtime Environment

The Java Runtime Environment, or JRE (also known as Java Virtual Machine or JVM), is the Java applet browser plug-in required to run an Oracle Clinical session. You download the JRE and position it so Oracle Clinical and RDC automatically test that users logging in have the correct applet. Oracle Clinical and RDC support JRE Version 1.6, Update 15 or later.

1.4.3.5 Share a Directory with Separate Reports Servers

If you have separate Reports Servers, you must share a directory on a Forms Server. The Installer prompts you to perform this task when you install an Oracle Clinical Forms Server.

1.4.4 Reports Server Requirements

The Reports Server runs reports, schedules PSUB jobs and reports, and prints to screen or printers. This section describes the requirements for the Reports Server. For installation instructions, see Chapter 6, "Installing Reports Servers."

1.4.4.1 CPU Security Update Patch

You must obtain the latest CPU Security Update patch approved by Oracle Health Sciences from My Oracle Support.

1.4.4.2 Load Tuning Reports Servers

The Oracle Universal Installer sets the maximum number of simultaneously running Reports Server engines (*maxEngine*) to four. The lower this value, the greater the likelihood that long-running jobs appropriate all the engines and cause other jobs to time out. For Oracle Clinical 4.6, do not set this number lower than two.

The Installer sets the *maximum idle time* to one minute. For Oracle Clinical, keep the idle time low. Each idle engine remains connected to the database in the account of the last user whose job used the engine. That user cannot shift from test mode to production mode while the engine idles.

If you have more than one CPU in your Reports Server computer, set maxEngine to `4`*x*, where *x* is the number of CPUs. For more information, see the Oracle Reports Server documents and white papers about load tuning.

1.4.4.3 Planning File Viewing and Associated Directories

Set up user log directories for PSUB jobs on this Database Server and for Reports Server jobs on a server accessible to the Reports Server. Decide the protocol used by the file viewing servlet to view files on the database server. For more information, see the *Oracle Clinical Administrator's Guide*.

1.5 Planning an Oracle Clinical Client Installation

A client is the browser interface to the Forms Server. It displays data and transmits user actions to and from the Forms Server.

This section describes the requirements for a client. For installation instructions, see Chapter 7, "Setting Up Clients."

1.5.1 Client Tier Operating System Requirements

Oracle Clinical supports the following Microsoft operating systems for the client:

- Windows 2000 with Service Pack 4
- Windows 2003 Server with Service Pack 1 or 2
- Windows XP with Service Pack 1, 2, or 3
- Windows Vista with Service Pack 1

1.5.2 Client Tier Application Requirements

To access Oracle Clinical 4.6 and RDC, clients must have these applications installed:

- Microsoft Windows Internet Explorer, Release 6 or Release 7.

  Note: You can access RDC Onsite 4.6 using Internet Explorer 8. See the *Oracle Clinical Remote Data Capture Onsite User's Guide* for Internet Explorer settings.

  See Known Issue 8588321 in the *Oracle Clinical 4.6 Release Notes* for a setting specific to Internet Explorer 8.

- Java Runtime Environment (JRE) plug-in.

  The installation of the application tier includes installing the JRE so it may be downloaded automatically by the clients as necessary. (The Oracle Health Sciences Web launch page includes a test for the plug-in, as well as a link to download the JRE.) Oracle Clinical 4.6 supports JRE Version 1.6, Update 15 or later.

- An intranet or internet connection.
- Adobe Reader and Adobe Acrobat.
  - To view reports, including Patient Data Reports (PDRs), Adobe Reader 7.0, 8.0, or 9.0, English versions.
  - For annotated layouts, Adobe Acrobat 7.0 or later.

Note: If the client computer has a personal firewall, you must either disable it or configure it for RDC to function correctly. See the firewall documentation or your system administrator for assistance.

1.6 Integrating Oracle Clinical with Other Products and Options

You can integrate Oracle Clinical with some other products and options, combine Oracle Health Sciences products, and develop applications to read data from Oracle Clinical. The following sections describe the products that integrate with Oracle Clinical and any issues that can arise if you are combining them.

1.6.1 Oracle Remote Data Capture

Installing Oracle Clinical 4.6 also installs these Remote Data Capture (RDC) products:

- RDC Onsite 4.6
- RDC Classic 4.6 (based on the legacy character layout system)

1.6.2 Oracle Clinical Partitioning

In addition to the standard Oracle Database 11*g* installation, the Partitioning Option for Oracle Clinical 4.6 requires the Oracle Database 11*g* Partitioning option on the Oracle Clinical Database Server.

1.6.3 SAS 9.2 Software

Oracle Clinical 4.6 supports SAS 9.2 software.

The SAS/ACCESS Interface to Oracle requires Oracle SQL*NET on the computer with the SAS software installation.

For this statistics application to function with Oracle Clinical Data Extract, you must install these SAS components:

- Base SAS
- SAS/ACCESS

For more information on interfacing Oracle Clinical with the SAS statistical software application, see Chapter 8, "Setting Up SAS."

1.6.4 Oracle Clinical Stable Interface

For developers building applications that read data from Oracle Clinical, the Oracle Clinical Stable Interface provides easier access to data and smoother transition between Oracle Clinical versions.

The *Oracle Clinical Stable Interface Technical Reference Manual* (Part A83796) provides proprietary information on data access, internal tables, and APIs. If you are a licensed customer, contact Oracle Support to obtain a free electronic copy of this manual.

1.6.5 Oracle Clinical Data Capture API

See the *Interfacing from Oracle Clinical* manual for information about using Oracle Clinical's Data Capture API.

1.7 Following the Installation Constraints and Order

Oracle Clinical has one constraint to the order in which you install its components: you must have a working Oracle Database 11*g* on your database tier before you can install the Forms Server and the Reports Server to the application tier.

Use the following sequence to install Oracle Clinical:

1. Install the Oracle Clinical Database Server.
   - For any supported UNIX operating system, see Chapter 2.
   - For the Windows operating system, see Chapter 3.
2. Create an Oracle Clinical database. See Chapter 4.
3. Install a Forms Server. See Chapter 5.
4. Install a Reports Server. See Chapter 6.
5. Set up clients. See Chapter 7.
6. Set up SAS (optional). See Chapter 8.

1.8 Reviewing the Installation Log Files

During the installation of an Oracle Health Sciences component, the Oracle Universal Installer generates the following log file:

```
installActions.log
```

This log file records the actions of the Installer — such as loading information from the CD to the Forms Server or Database Server — and is useful for diagnosing problems with the Installer. You should include the log file if you report any problems that occur when installing an Oracle Health Sciences component.

On a Windows installation, the log files are located at:

```
\oracle\Inventory\logs
```

For example:

```
c:\Program Files\oracle\Inventory\logs
```

On a UNIX installation, the log files are located at:

```
$ORACLE_BASE/oraInventory/logs
```

For example:

```
/u01/app/oracle/oraInventory/logs
```

The current log file is installActions.log. All previous log generations have a timestamp appended to the name.

2

Installing the Oracle Clinical Database Server on UNIX

This chapter describes how to set up a new Oracle Clinical Database Server on a UNIX computer.

Installing an Oracle Clinical Database Server on a UNIX computer requires you to complete the following tasks:

- Section 2.1, "Installing and Patching Oracle Database 11g"
- Section 2.2, "Granting Write Access to Oracle-Owned Directories"
- Section 2.3, "Setting Up User Accounts and User Groups"
- Section 2.4, "Adjusting the Operating System Environment"
- Section 2.5, "Testing the C Compiler Installation"
- Section 2.6, "Installing the Oracle Clinical 4.6 Database Server"
- Section 2.7, "Performing Post-installation Tasks"

If you are installing the Oracle Clinical Database Server on a Windows computer, see Chapter 3 for installation instructions.

If you are upgrading to Oracle Clinical 4.6, see Chapter 9.

2.1 Installing and Patching Oracle Database 11*g*

To support Oracle Clinical Database Server, a UNIX computer requires the following version of Oracle Database software:

Oracle Database 11*g*
Release 11.1.0.6.0 plus Patch Set 1 (11.1.0.7.0), plus individual patches
Enterprise Edition

However, this requirement might change during the life of this document. Before you begin, check My Oracle Support for the latest requirement.

This section describes the following tasks:

- Section 2.1.1, "Install Oracle Database 11g Release 11.1.0.6.0"
- Section 2.1.2, "Install Oracle Database Examples 11g Release 1"
- Section 2.1.3, "Apply Oracle Database 11g Patch Set 1"
- Section 2.1.4, "Apply Oracle Database 11g Standalone Patches"

2.1.1 Install Oracle Database 11*g* Release 11.1.0.6.0

To install Oracle Database 11*g* Release 11.1.0.6.0:

1. Locate the Oracle Database 11*g* software for your operating system on the media pack:

Operating System	Disk	Software
Oracle Enterprise Linux	V14216-01	Oracle Database 11*g* Release 1 (11.1.0.6.0)
Oracle Solaris	V14414-01	Oracle Database 11*g* Release 1 (11.1.0.6.0)
HP-UX Itanium	V14232-01	Oracle Database 11*g* Release 1 (11.1.0.6.0)

2. Follow the included instructions for installing Oracle Database 11*g*.
3. Choose to install the Enterprise Edition option.

2.1.2 Install Oracle Database Examples 11*g* Release 1

Oracle Database Examples, which is required for Oracle Clinical 4.6, includes the following items:

- Oracle JDBC Development Drivers
- Oracle Database Examples
- Oracle Product Demonstrations (optional)

> **Note:** You do not need to install any of the sample schemas. They are not required for either Oracle Clinical or Thesaurus Management System. You can add them later if you change your mind.

To install Oracle Database Examples:

1. Locate the appropriate Database Examples zip file for your operating system on the media pack:

Operating System	Disk	Path	Zip File
Oracle Enterprise Linux	V22167-01	/patches	linux.x64_11gR1_examples.zip
Oracle Solaris	V18332-01	/patches	solaris.sparc64_11gR1_examples.zip
HP-UX Itanium	V18332-01	/patches	hpia64_11gR1_examples.zip

2. Install the software according to the *Oracle Database Examples Installation Guide*, which is included on the media pack.
3. Accept all the default values during the installation.

2.1.3 Apply Oracle Database 11*g* Patch Set 1

To apply Patch Set 1 (Patch Set 11.1.0.7.0) to the Oracle Database 11*g* installation:

1. Locate the appropriate Oracle Database 11*g* Patch Set 1 software for your operating system on the media pack:

Operating System	Disk	Path	Zip Files
Oracle Enterprise Linux	V22167-01	/patches	p6890831_111070_Linux-x86-64.zip
Oracle Solaris	V18476-01	/patches	p6890831_111070_SOLARIS64.zip
HP-UX Itanium	V18476-01	/patches	p6890831_111070_HPUX-IA64_1of2.zip p6890831_111070_HPUX-IA64_2of2.zip

2. Extract the patch zip file(s) to a location that is accessible to the Database Server.
3. Follow the operating system-specific instructions in the ReadMe file to apply Patch Set 1 to the Oracle Database 11*g* installation. The ReadMe file is located at the top level of the patch set extraction location.

2.1.4 Apply Oracle Database 11*g* Standalone Patches

After you apply Patch Set 1 to upgrade your Oracle Database 11*g* installation to Release 11.1.0.7.0, you must apply several Oracle Database 11*g* standalone patches.

To apply the standalone patches:

1. Locate the appropriate Oracle Database 11*g* standalone patches for your operating system on the media pack:

Operating System	Disk	Path	Zip Files
Oracle Enterprise Linux	V22167-01	/patches	p7327166_111070_Linux-x86-64.zip p8307947_111070_Linux-x86-64.zip p8348464_111070_Linux-x86-64.zip
Oracle Solaris	V18332-01	/patches	p7327166_11107_Solaris-64.zip p8307947_11107_Solaris-64.zip p8348464_11107_Solaris-64.zip
HP-UX Itanium	V18332-01	/patches	p7327166_111070_HPUX-IA64.zip p8307947_111070_HPUX-IA64.zip p8348464_111070_HPUX-IA64.zip

2. Extract the appropriate patch zip files to a location that is accessible to the Database Server.
3. Follow the operating system-specific instructions in the ReadMe file to apply the standalone patches to the Oracle Database 11*g* installation. The ReadMe file is located at the top level of the patch set extraction location.

2.2 Granting Write Access to Oracle-Owned Directories

Because the Oracle Universal Installer checks if the *ORACLE_HOME* directory exists and if it has write access, you must change the access settings for this directory before you install the Oracle Clinical component. You must grant write access to the Oracle Database 11*g* *ORACLE_HOME* directory.

Note: You might have to perform these instructions whenever you apply an HSGBU-approved CPU Security Update, or any Oracle software that uses the Oracle Database 11*g* *ORACLE_HOME* directory.

To grant write access to the *ORACLE_HOME* directory and its contents:

1. Log in to the server as `oracle` user.
2. Source the Oracle environment-setting script to define *ORACLE_HOME*.
   - For C shell, use `coraenv`.
   - For Bourne shell, use `oraenv`.

   These shells are located under your Oracle Database 11*g* installation.
3. Grant group users modification access to all files in the *ORACLE_HOME* directory:

   ```
   chmod -R g+rw $ORACLE_HOME
   ```

   If you receive any warning messages, you can ignore them.
4. Give recursive read and write permission to the oraInventory directory:
   a. Locate the path for the oraInventory directory. The location is the value of the `inventory_loc` setting in the /var/opt/oracle/oraInst.loc file.

      For example, suppose you enter:

      ```
      more /var/opt/oracle/oraInst.loc
      ```

      The system might return the oraInventory location as:

      ```
      inventory_loc=/u01/app/oracle/oraInventory
      ```

   b. Give recursive read and write permission for the oraInventory directory to the group:

      ```
      chmod -R g+rw /path_location_oraInventory
      ```

      For example:

      ```
      chmod -R g+rw /u01/app/oracle/oraInventory
      ```

      If you receive any warning messages, you can ignore them.

   c. Modify protections on the oraInventory directory to ensure that the group you set up as the oinstall group has write access:

      ```
      chmod -R g+w oraInventory
      ```

      Use oinstall instead of dba because the dba group membership gives you access to databases, which is a security issue. The oinstall group gives you access to the Oracle Inventory.

2.2.1 Change Permissions on the oraclehomeproperties.xml File

The oraenv script gives an error if run by a non-Oracle user. To avoid this error, set the following directory and file permissions:

```
drwxrwxr-x  18 oracle    oinstall  1024 Jul 29 19:11 inventory
drwxrwxr-x   3 oracle    oinstall  1024 Jul 29 18:29 ContentsXML
-rwxrwxrwx   1 oracle    oinstall   492 Sep 11 13:15 oraclehomeproperties.xml
```

2.2.2 Modify the oraenv Script for Oracle Solaris

In an Oracle Solaris environment, when you use the Bourne shell (sh) to run the oraenv script, the script may fail with the following error:

```
Test: Argument Expected
```

To work around this known issue:

1. Navigate to the following directory:

   $ORACLE_HOME/bin/oraenv

2. Open the oraenv script file and locate the following text string:

   `-e $ORABASE_EXEC`

3. Change the `-e` to `-f`:

   `-f $ORABASE_EXEC`

2.3 Setting Up User Accounts and User Groups

Perform the tasks in this section logged on to the server as *root*.

2.3.1 Create the oclsascr User Group for SAS

If you integrate the SAS statistics application with Oracle Clinical, define a method to control access to the files Oracle Clinical generates for SAS. Create a user group named `oclsascr` by adding it to the `/etc/group` file.

The preferred method for group authentication is that all groups assigned to a user should become the user's default group at login. If this method is acceptable, link the `/etc/logingroup` file to the `/etc/group` file.

If the `/etc/logingroup` file does not exist, create it as a symbolic link to the `/etc/group` file; changes in the `/etc/group` file automatically reflect in the `/etc/logingroup` file.

To create the symbolic link, enter these commands:

```
% su root
# cd /etc
# ln -s /etc/group /etc/logingroup
```

If the `/etc/logingroup` file already exists with entries, or if it is unacceptable to link it to the `/etc/group` file, you must change both the contents of `/etc/logingroup` and `/etc/group` each time you add a user to the `oclsascr` group.

2.3.2 Create the opapps Account

Create the operating system account to own Oracle Clinical. The user name for the account is `opapps`, with a home directory named `opapps`. For example:

`/home/opapps`

You can choose a different home directory name. The Oracle Clinical documentation uses the variable *OPA_HOME* to refer to this location on an Oracle Clinical Database Server.

Assign the following attributes to the opapps account:

- Make a shell for this user. For example, make the default shell:

  `/bin/csh`

- Make the opapps account a member of these two user groups:
  - oclsascr

- The user group that owns the Oracle Inventory. You specified the name of this group during the Oracle Database 11*g* installation. Typically, this user group is **oinstall.**

  If you do not know the name of this user group, log in as user `oracle` and enter the following command:

  ```
  more /var/opt/oracle/oraInst.loc
  ```

  The *`inst_group`* parameter defines the name of the user group that owns the Oracle Inventory (oraInventory). The *`inventory_loc`* parameter defines the path to the oraInventory directory.

  Neither the oclsascr group nor the *`inst_group`* has to be the primary group for the opapps account.

2.3.3 Create the rxcprod Account

Oracle Clinical processes most batch requests from clients on the server with the Parameterized Submission (PSUB) process. PSUB runs under a special privileged account named `rxcprod`, with a default Bourne shell of `/bin/sh`.

The rxcprod account requires some special privileges so that it can run job requests on behalf of other users who submit jobs with the `rsh` (`remsh` for HP-UX Itanium) command and the `at` command.

2.3.3.1 Configuring for the Remote Shell Commands

To use the `rsh` (`remsh` for HP-UX Itanium) command to submit jobs on behalf of another user, the rxcprod user must be present in the `/etc/hosts.equiv` file. Modify the existing file or create a new file, and then add this line:

`official_host_name` `rxcprod`

where *`official_host_name`* is the official name of the computer on which you are installing Oracle Clinical.

You must use the official name — not an alias — for the computer. The official name is the first listing after the IP address in the `/etc/hosts` file.

On some platforms and configurations, the `/etc/hosts.equiv` entry does not work because of security differences. For example, the `/etc/hosts.equiv` entry does not work on HP-UX Itanium 11.11 when YP or DNS are not used. The workaround involves creating a file named **.rhosts**. This user-specific file must reside in the login directory of each user who runs PSUB jobs. The .rhosts file should be owned by that user. (You can use the **chown** command to set the owner.) Create or modify the .rhosts file so that it contains the same entry as you would place in the `/etc/hosts.equiv` file.

2.3.3.2 Configuring for the at Command

To use the `at` command to submit jobs on behalf of another user, the rxcprod user must be present in the **at.allow** file.

To edit the at.allow file:

1. Change to the appropriate directory location depending on your operating system and open the file:

   Oracle Enterprise Linux: `/etc/at.allow`

Oracle Solaris: /usr/lib/cron/at.allow

HP-UX Itanium: /usr/lib/cron/at.allow

2. Add the following line to the at.allow file:

   ```
   rxcprod
   ```

You might have to edit the `/etc/group`.

2.4 Adjusting the Operating System Environment

The performance of Oracle Database 11*g* relies on proper tuning of operating system parameters. In addition, if you are creating several Oracle instances, you might have to increase the amount of shared memory and semaphores on the system by setting kernel parameters.

For details on this topic, see the "Configure Kernel Parameters" section of the *Oracle Database 11g Installation Guide* for your operating system.

2.5 Testing the C Compiler Installation

To test that the correct C compiler is installed and that it is accessible:

1. Log in as the `opapps` user.
2. Test for the C compiler type:

   ```
   ls -l `which cc`
   ```

   where the ` symbols that wrap the command are single back quotes.
3. Compare your results to the correct responses listed in Table 2–1.

Table 2–1 Responses to the 'which cc' Command

Operating System	Response	Symbolically Links To
Oracle Enterprise Linux	/usr/bin/gcc	(Not applicable)
Oracle Solaris	/opt/SUNWspro/bin/cc	../prod/bin/cc
HP-UX Itanium	/bin/cc	/opt/aCC/bin/cc

4. Test that the `make` command is accessible:

   ```
   ls -l `which make`
   ```

   where the ` symbols that wrap the command are single back quotes.
5. Compare your results to the correct responses listed in Table 2–2.

Table 2–2 Responses to the 'which make' Command

Operating System	Response	Symbolically Links To
Oracle Enterprise Linux	/usr/bin/make	(Not applicable)
Oracle Solaris	/usr/ccs/bin/make	(Not applicable)
HP-UX Itanium	/bin/make	/usr/bin/ccs/make

If you do not get the correct response, you can either add the path to the cc executable or add the make command to the path in the .cshrc file for the opapps user.

2.6 Installing the Oracle Clinical 4.6 Database Server

This section describes how to install and set up the Oracle Clinical 4.6 Database Server on one computer. Perform this task once for each Oracle Clinical Database Server computer.

> **Note:** Read this section completely before you begin. The Installer prompts you for information you should know before you start.

The Oracle Universal Installer performs the following operations:

- Creates the Oracle Clinical directory structure (see Section 2.6.1 for details)
- Installs the Oracle Clinical Database Server application
- Builds the executables
- Sets permissions on the directories
- Creates the environment setup files
- Modifies the environment setup files
- Creates the directory for storing the SAS files

2.6.1 Oracle Clinical 4.6 Database Server Directory Structure for UNIX

The Installer creates the following directory structure:

```
OPA_HOME
      /bin
      /xmltemp
      /oc
         /46
            /bin      (Symbolic links to the executables)
            /common   (Common files)
            /dcd      (Data Collection Definition)
            /des      (Design)
            /dm       (Data Management)
            /dx       (Data Extract)
            /glib     (Global Library)
            /install  (Install and upgrade scripts)
            /log      (PSUB log files)
            /lr       (Lab Ranges)
            /patch    (Patches to Oracle Clinical)
            /pd       (Procedure Definition)
            /psub     (Parameterized Submission process)
            /release  (Server code release marker)
            /sec      (Security tools)
            /tools    (Miscellaneous tools)
```

Note that *OPA_HOME* refers to the root installation directory of the Oracle Health Sciences products, which were formerly known as Oracle Pharmaceutical Applications (OPA). You specify the root installation directory when you install the Oracle Clinical Database Server. Typically, you specify the path to the opapps login directory; for example, /home/opapps.

2.6.2 Transfer the Oracle Clinical 4.6 Database Server Software

To transfer the Database Server software from the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack:

1. Locate the appropriate Database Server software for your operating system on the media pack:

Operating System	Disk	Path	Zip File
Oracle Enterprise Linux	V22167-01	/oc/server_code	server_code_linux-x86-64.zip
Oracle Solaris	V17174-01	/oc/server_code	server_code_sun.zip
HP-UX Itanium	V17174-01	/oc/server_code	server_code_hpia.zip

2. Extract the appropriate patch zip file to a location that is accessible to the Database Server computer.

2.6.3 Start Installing the Database Server Software

To start installing the Database Server software:

1. Log in to the server computer as the `opapps` user.
2. Change the primary group of the opapps account to the group that owns the Oracle Inventory:

   `newgrp` *`inst_group`*

   where *`inst_group`* is the name of the group that owns the Oracle Inventory. You specified the name during the Oracle Database 11*g* installation. Typically, this user group is `oinstall`. (See Section 2.3.2.)

   This temporary change is necessary so that the Installer can update the Oracle inventory.
3. Set the X Window display output to the IP address of your local computer. Use the standard format for IP addresses, and add `":0"` to the end of the address. For example:

   ```
   setenv DISPLAY 123.45.67.89:0
   ```
4. Navigate to this location in the folder where you extracted the server code:

   `server_code_platform``\Disk1\install`
5. Change protections on files to `755`:

   ```
   chmod 755 *
   ```
6. Start the Universal Installer:

   ```
   ./runInstaller
   ```

2.6.4 Attend to the Oracle Clinical 4.6 Database Server Installation Screens

The Installer acts in two phases. In the first phase, the Installer collects information about your system. During this phase, you can move backward and forward through the screens, revising your entries. During the second phase, the Installer runs the scripts to set up the Oracle Clinical 4.6 software according to the information you provided in the first phase. Attend to the Installer's screens as described below.

Welcome

Click **Next** to continue the installation. Alternatively, you can click **Installed Products** to review a list of installed Oracle products.

Select a Product to Install

Select **OC Server for UNIX 4.6.0.0.*XX*** (where *XX* is the build number). Click **Next.**

Specify Home Details

Select or enter the *ORACLE_HOME* location, which is where you installed Oracle Database 11*g*.

If you select a name, the Installer populates the Path field with the *ORACLE_HOME* location. You can also browse to the *ORACLE_HOME* location.

Note that the value you enter here does not indicate the destination of the Oracle Clinical Database Server software that you are currently installing. You define the location of the installation directory in the "Choose Directory OPA Home" screen that follows.

Click **Next.**

Choose Directory
OPA Home

Specify the directory that is the root installation directory of the Oracle Health Sciences products. Typically, you respond with the path to the opapps login directory. For example:

```
/home/opapps
```

The Oracle Clinical documentation uses the variable *OPA_HOME* to refer to this location. The Oracle Health Sciences products were formerly known as Oracle Pharmaceutical Applications (OPA).

Click **Next.**

Choose Owner
Owner of Oracle Clinical Server Code

Enter the name of the owner of the Oracle Clinical server code. The default value is `opapps`. Click **Next.**

Locate File
oratab

Enter the path to the directory where the oratab file is located. For example, `/etc`. Click **Next.**

Locate File
tnsnames

Enter the path to the directory where the tnsnames.ora file is located.

- **Oracle Enterprise Linux —** First looks in the `/etc` directory, and then looks in the `$ORACLE_HOME/network/admin` directory.
- **Oracle Solaris —** First looks in the `/var/opt/oracle` directory, and then looks in the `$ORACLE_HOME/network/admin` directory.
- **HP-UX Itanium —** First looks in the `/etc` directory, and then looks in the `$ORACLE_HOME/network/admin` directory.

Click **Next.**

Choose Directory
RXC_USER

Specify the location to store SAS files. The default value is the *OPA_HOME* directory. Click **Next.**

Confirmation

Review the destination settings before proceeding. To make changes to the settings, click **Back.** Otherwise, click **Next** to continue.

Summary

This screen lists the target directories. Note that the Installer only displays *ORACLE_HOME* in the Destination field. It might differ from your actual directory path.

Click **Install.**

Install

The Installer copies the files onto the server, and then links the files.

To watch the progress of the link, open another terminal session as `opapps` and then enter the following command:

```
tail -f OPA_HOME/oc/46/relink_rxc.log
```

In addition, the Install screen displays the location of the InstallAction*timestamp*.log file, which records the results of the installation activities. Note the location of this log file so that you can review it when the installation finishes.

End of Installation

This screen displays the location of the *OPA_HOME* and *OPA_HOME*/bin directories, and the name of the code environment. Make note of this information because you need it for several post-installation tasks.

To finish the installation:

1. Click **Exit**.
2. Click **Yes** to exit the Installer.

> **Tip:** You cannot perform the post-installation tasks (see Section 2.7) from this Installer session. You must close the Installer. However, you can use the same environment. You do not have to restart the Installer until you install the Oracle Clinical database (see Chapter 4).

2.6.5 Review the Installation Log Files

Review the generated installation log files for errors:

- InstallAction*timestamp*.log
- *OPA_HOME*/oc/46/relink_rxc.log

Work with Oracle Support, if necessary, to resolve any errors.

2.6.6 Remove Group Privileges from this Session

Recall that before you started this installation, you changed the primary group of the opapps account to the group that owns the Oracle Inventory (see Section 2.6.3). This

temporary change was necessary so that the Installer could update the Oracle inventory.

To reset the privileges for the opapps account, enter the following command:

```
newgrp group
```

where *group* is the name of your original primary group for the opapps account.

2.7 Performing Post-installation Tasks

This section describes the tasks you perform to complete the installation of Oracle Clinical Database Server on a UNIX computer.

2.7.1 Complete the Setup of the opapps Account

To complete the setup of the opapps account:

1. Create the log directory for opapps in the following location:

   OPA_HOME/log

2. Define the environment variables for the `opapps` user:

   a. Open the **.cshrc** file.

   b. Add the following lines to the file:

   ```
   set path=( $path ORACLE_HOME/bin ORACLE_HOME/lib )
   setenv RXC_LOG OPA_HOME/log
   source OPA_HOME/bin/copa_setup_alias
   ```

   where:

   ORACLE_HOME is the directory where you installed Oracle Database 11*g*

   OPA_HOME is the directory where you installed Oracle Clinical

   c. Source the .cshrc file when you finish editing it:

   ```
   source .cshrc
   ```

2.7.2 Complete the Setup of the rxcprod Account

To complete the setup of the rxcprod account:

1. Open the **.profile** file for the rxcprod account.
2. Add the following path to the file:

   PATH=$PATH:*OPA_HOME*/bin:*ORACLE_HOME*/bin

   where:

   OPA_HOME is the path of the Oracle Clinical home directory

   ORACLE_HOME is the path of the Oracle home directory

2.7.3 Review the opa_settings File

On UNIX systems, configurations are defined in the **opa_settings** file. The Installer creates the **opa_settings** file in the following directory:

opapps/bin

In addition, the Installer enters all necessary entries and default values for the Oracle Clinical 4.6 environment into this file.

The `db_env_setting` records in the opa_settings file define a default value for particular environment variables that are set when the application calls opa_setup. You can override the default values for all databases or for a particular database.

See the *Oracle Clinical Administrator's Guide* for a list of the environment variables and for information on changing, adding, and verifying values.

> **Note:** The default settings for all databases or the specific settings for a particular database, such as NLS_LANG, must be correct in the opa_ settings file.

Examine the `db_env_setting` records in the opa_settings file and adjust the default values, if necessary. Note the following details:

- NLS_LANG determines which language setting Oracle uses when it reads and writes values into the database. The NLS_LANG entry for your Oracle AS10*g*R2 home must be consistent with the NLS_LANG entry for the Oracle Database 11*g* home and your databases.
- For PSUB to work correctly for a UTF8 character set database, the opa_settings file must have the following setting:

  `db_env_setting:`*`database`*`:NLS_LANG:american_america.utf8`

  If you do not have a UTF8 character set database, you can use these character sets:

  `american_america.us7ascii`

  `american_america.we8iso8859p1`

> **Note:** Do not create new databases with the default character set (AL32UTF8) by the Assistant.

2.7.4 Apply the Latest CPU Security Update and Any New Patches

Oracle publishes a CPU Security Update patch quarterly. Apply the latest CPU Security Update patch approved for the Oracle Health Sciences applications to this computer. Check My Oracle Support to determine the latest version.

In addition, check My Oracle Support to determine if Oracle has released any new patch sets or any individual patches since the publication of this guide.

> **Note:** Applying the CPU Security Update might change permissions on *ORACLE_HOME* and oraInst.loc. You may have to repeat the instructions in Section 2.2, "Granting Write Access to Oracle-Owned Directories."

3

Installing the Oracle Clinical Database Server on Windows

This chapter describes how to set up a new Oracle Clinical Database Server on a Windows computer.

Installing the Oracle Clinical Database Server on a Windows computer requires you to complete the following tasks:

- Section 3.1, "Installing and Patching Oracle Database 11g"
- Section 3.2, "Setting Up User Accounts and User Groups"
- Section 3.3, "Installing the Oracle Clinical 4.6 Database Server"
- Section 3.4, "Performing Post-installation Tasks"

If you are installing the Oracle Clinical Database Server on a UNIX computer, see Chapter 2 for the installation instructions.

If you are upgrading to Oracle Clinical 4.6, see Chapter 9.

3.1 Installing and Patching Oracle Database 11*g*

To support Oracle Clinical Database Server, a Windows computer requires the following version of Oracle Database software:

Oracle Database 11*g*
Release 11.1.0.6.0 plus Patch Set 1 (11.1.0.7.0), plus individual patches
Enterprise Edition

However, this requirement might change during the life of this document. Before you begin, check My Oracle Support for the latest requirement.

This section describes the following tasks:

- Section 3.1.1, "Install Oracle Database 11g Release 11.1.0.6.0"
- Section 3.1.2, "Install Oracle Database Examples 11g Release 1"
- Section 3.1.3, "Apply Oracle Database 11g Patch Set 1"
- Section 3.1.4, "Apply Oracle Database 11g Patch Bundle 8451592"

3.1.1 Install Oracle Database 11*g* Release 11.1.0.6.0

To install Oracle Database 11*g* Release 11.1.0.6.0:

1. Insert Disk V14231-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
2. Locate the Oracle Database 11*g* software for Microsoft Windows (32-bit).
3. Follow the included instructions for installing Oracle Database 11*g*.
4. Choose to install the Enterprise Edition option.

3.1.2 Install Oracle Database Examples 11*g* Release 1

Oracle Database Examples, which is required for Oracle Clinical 4.6, includes the following items:

- Oracle JDBC Development Drivers
- Oracle Database Examples
- Oracle Product Demonstrations (optional)

Note: You do not need to install any of the sample schemas. They are not required for either Oracle Clinical or Thesaurus Management System. You can add them later if you change your mind.

To install Oracle Database Examples:

1. Locate the Oracle Database 11*g* Examples software for Windows on the media pack:

   Disk: V18332-01
   Path: \patches
   File: win32_11gR1_examples.zip
2. Install the software according to the *Oracle Database Examples Installation Guide*, which is also included on the media pack.
3. Accept all the default values during the installation.

3.1.3 Apply Oracle Database 11*g* Patch Set 1

To apply Patch Set 1 (Patch Set 11.1.0.7.0) to the Oracle Database 11*g* installation:

1. Locate the Oracle Database 11*g* Patch Set 1 software for Windows on the media pack:

   Disk: V18332-01
   Path: \patches
   File: p6890831_111070_Win32.zip
2. Extract the patch zip file to a location that is accessible to the Database Server.
3. Follow the instructions in the ReadMe file to apply Patch Set 1 to the Oracle Database 11*g* installation. The ReadMe file is located at the top level of the patch set extraction location.

3.1.4 Apply Oracle Database 11*g* Patch Bundle 8451592

To apply Patch Bundle 8451592 to the Oracle Database 11*g* installation:

1. Locate the Oracle Database 11*g* Patch Bundle 8451592 software for Windows on the media pack:

   Disk: V18332-01
   Path: \patches
   File: p8451592_111070_Win32.zip

2. Extract the patch zip file to a location that is accessible to the Database Server.
3. Follow the instructions in the ReadMe file to apply the patch bundle to the Oracle Database 11*g* installation. The ReadMe file is located at the top level of the patch set extraction location.

3.2 Setting Up User Accounts and User Groups

Before you install the Oracle Clinical Database Server on a Windows computer, you must create the following user accounts and user groups:

- The RXCPROD user account, which is the dedicated PSUB account
- The oclsascr user group, which controls access to the files Oracle Clinical generates on the database server

3.2.1 Create the RXCPROD Account

Oracle Clinical processes most batch requests from clients on the server with the Parameterized Submission (PSUB) process. The RXCPROD user account starts the PSUB service for Oracle Clinical databases on this server.

To create and configure the RXCPROD account:

1. Use Windows Administrative Tools to create a local user account named `RXCPROD`.
2. Add `RXCPROD` to the Power Users local group.
3. Navigate to the Windows Control Panel.
4. Double-click **Administrative Tools,** and then double-click **Local Security Policy.**
5. Expand the **Local Policies** folder, and then select **User Rights Assignment.**
6. Give RXCPROD these user rights:
   - Act as part of the operating system
   - Adjust memory quotas for a process
   - Log in as a service
   - Replace a process level token

3.2.2 Create the oclsascr User Group

The oclsascr user group controls access to the files Oracle Clinical generates on the database server, including data extract files, which contain patient data.

To create and configure the oclsascr user group:

1. Use Windows Administrative Tools to create a new Global Group in your Domain with the name `oclsascr`.

2. Add to the `oclsascr` user group each account to which you grant access to the server files generated by Oracle Clinical, including the SAS programs and SAS Pass Through Views.
3. Define a method to control access to the server files generated by Oracle Clinical, including the SAS programs and SAS Pass Through Views.

3.3 Installing the Oracle Clinical 4.6 Database Server

This section describes how to install and set up the Oracle Clinical 4.6 Database Server on one computer. Perform this task once for each Oracle Clinical Database Server computer.

> **Note:** Read this section completely before you begin. The Installer prompts you for information you should know before you start.

The Oracle Universal Installer performs the following operations:

- Creates the Oracle Clinical directory structure (see Section 3.3.1 for details)
- Installs the Oracle Clinical Database Server application
- Sets permissions on the directories
- Creates the environment setup files
- Modifies the environment setup files
- Creates the directory for storing the SAS files

3.3.1 Oracle Clinical 4.6 Database Server Directory Structure for Windows

The Installer creates the following directory structure:

```
OPA_HOME
      \bin
      \xmltemp
      \oc
         \46
            \bin      (Symbolic links to the executables)
            \dcd      (Data Collection Definition)
            \des      (Design)
            \dm       (Data Management)
            \dx       (Data Extract)
            \glib     (Global Library)
            \install  (Install and upgrade scripts)
            \log      (PSUB log files)
            \lr       (Lab Ranges)
            \patch    (Patches to Oracle Clinical)
            \pd       (Procedure Definition)
            \psub     (Parameterized Submission process)
            \release  (Server code release marker)
            \tools    (Miscellaneous tools)
```

Note that *OPA_HOME* refers to the root installation directory of the Oracle Health Sciences products, which were formerly known as Oracle Pharmaceutical Applications (OPA). You specify the root installation directory when you install the Oracle Clinical Database Server. Typically, you specify the path to the opapps login directory, for example, *drive*`:\opapps`.

3.3.2 Start the Oracle Clinical 4.6 Database Server Installation for Windows

You can install the Oracle Clinical 4.6 Database Server component for Windows directly from the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.

To begin the installation:

1. Log in to the server computer using an account with system administrator privileges.
2. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
3. Locate and execute the setup.exe file:

   `oc\server_code\win\install\setup.exe`

   The Installer opens to the Welcome screen.
4. Proceed with the installation steps in Section 3.3.3, "Attend to the Oracle Clinical 4.6 Database Server Installation Screens."

3.3.3 Attend to the Oracle Clinical 4.6 Database Server Installation Screens

The Installer acts in two phases. In the first phase, the Installer collects information about your system. During this phase, you can move backward and forward through the screens, revising your entries. During the second phase, the Installer runs the scripts to set up the Oracle Clinical 4.6 software according to the information you provided in the first phase. Attend to the installer's screens as described below.

Welcome

Click **Next** to continue the installation. Alternatively, you can click **Installed Products** to review a list of installed Oracle products.

File Locations

Enter the *ORACLE_HOME* location, which is where you installed Oracle Database 11*g*, in the Destination field.

Note that the value you enter here does not indicate the destination of the Oracle Clinical Database Server software that you are currently installing. You define the location of the installation directory in the "Choose Directory" screen that follows.

Click **Next.**

Available Products

Select **OC Server for Windows 4.6** and then click **Next.**

Choose Directory

Specify the directory that is the root installation directory of the Oracle Health Sciences products. Typically, you respond with the path to the opapps login directory. For example:

`drive``:\opapps`

where *`drive`* is the disk's letter designation and `opapps` is the directory name.

The Oracle Clinical documentation uses the variable *OPA_HOME* to refer to this location. The Oracle Health Sciences products were formerly known as Oracle Pharmaceutical Applications (OPA).

Click **Next.**

Choose Directory
SAS view

Select a location for storing SAS files. The default value is *OPA_HOME*\sas_view. (For more information, see Chapter 8, "Setting Up SAS.")

Confirmation

Review the destination settings before proceeding. To make changes to the settings, click **Back.** Otherwise, click **Next** to continue.

Summary

This screen lists the target directories. Note that the Installer only displays *ORACLE_HOME* in the Destination field. It might differ from your actual directory path.

Click **Install.**

Install

The Installer copies the files onto the server computer.

End of Installation

This screen displays the location of the *OPA_HOME*\bin directory. Make note of this location because you need it to complete the installation.

In addition, this screen displays the location of the log file, which records the results of the installation activities. Note the location of this log file so that you can review it when the installation finishes. If there are any errors in the log file, contact Oracle Support.

3.4 Performing Post-installation Tasks

This section describes the tasks you perform to complete the installation of Oracle Clinical Database Server on a Windows computer.

3.4.1 Limit Permissions on the XMLTEMP Folder

By default, a Windows installation grants read and write privileges to the XMLTEMP database folder to everyone. To reduce security risks, you should limit permissions on the XMLTEMP folder for all Windows Database Server installations.

To limit permissions on the XMLTEMP folder:

1. Use Windows Explorer to locate the XMLTEMP folder in the *OPA_HOME* directory.
2. Right-click on the XMLTEMP folder, and then select **Properties** from the menu.
3. Click the **Sharing** tab.
4. Click **Share this folder** to enable sharing with other users on your network.
5. Click **Permissions.**
6. Give Read and Write (Change) permissions to user `oracle`.
7. Click **OK** to save your changes and close the Permissions dialog box.
8. Click **OK** to save your changes and close the Properties dialog box.

3.4.2 Create the PSUB Root Directory for File Viewing

The PSUB root directory is the common directory for all Oracle Clinical users' PSUB log directories. For example, if user vsmith's log directory is:

`d:\users\vsmith\log` then `d:\users` is the PSUB root directory.

Create a PSUB root directory on the database server or create a new directory to hold user log directories, and make it shareable. (For more information, see the chapter titled "File Viewing" in the *Oracle Clinical Administrator's Guide*.)

3.4.3 Edit the opa_settings.bat File

On Windows systems, configurations are defined in the **opa_settings.bat** file. This file contains the commands to set environment variables at startup and execution of the PSUB process.

During installation of the server code, the Installer creates the **opa_settings.bat** file in the following directory:

`opapps\bin`

Edit this file, and change the following assignments, if necessary.

`set NLS_DATE_FORMAT=DD-MON-RRRR`

NLS_DATE_FORMAT determines the format in which client applications running on the Windows server transfer date information to and from the database. The format must specify the year as RRRR to be Year 2000 compliant.

`set NLS_LANG=american_america.utf8`

NLS_LANG determines which language setting Oracle uses when it reads and writes values into the database. The NLS_LANG entry for your Oracle AS10*g*R2 home must be consistent with the NLS_LANG entry for the Oracle Database 11*g* home and your databases.

In addition, for PSUB to work correctly for a UTF8 character set database, the opa_settings.bat file must have the following setting:

```
set NLS_LANG=american_america.utf8
```

If you do not have a UTF8 character set database, you can use these character sets:

```
american_america.us7ascii
```

```
american_america.we8iso8859p1
```

If you install more than one Oracle Health Sciences product, review Section 1.2, "Choosing a Character Set" for valid character sets with combined products.

> **Note:** Do not create new databases with the default character set (AL32UTF8) by the Assistant.

3.4.4 Apply the Latest CPU Security Update and Any New Patches

Oracle publishes a CPU Security Update patch quarterly. Apply the latest CPU Security Update patch approved for the Oracle Health Sciences applications to this computer. Check My Oracle Support to determine the latest version.

In addition, check My Oracle Support to determine if Oracle has released any new patch sets or any individual patches since the publication of this guide.

4

Creating an Oracle Clinical Database

This chapter describes how to create a new Oracle database for use with Oracle Clinical.

Oracle Database 11*g* and the Oracle Clinical Database Server installations must be complete before you can install the Oracle Clinical database. (See the Oracle Database 11*g* documentation and Chapter 2 for UNIX instructions or Chapter 3 for Windows instructions.)

This chapter includes the following topics:

4.1 Reviewing Prerequisites

Before you begin a database installation:

- Review Chapter 1, "Preparing to Install Oracle Clinical" to ensure that your system is up to date.
- Check My Oracle Support for the latest changes to the installation instructions.
- Review the *Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability* white paper (Article ID 873743.1), which is available on My Oracle Support.

4.2 Reviewing Database Requirements and Recommendations

Before you install the Oracle Clinical database component, review the requirements and recommendations — such as SID names, tablespace sizes, memory management, and initialization parameters — listed in this section.

Note: Repeat these instructions for each new database you create.

4.2.1 Start with a New Database Instance

Oracle recommends that you set up a new database instance so that neither Oracle Clinical 4.6 nor its installation process interferes with other applications. However, you can install Oracle Clinical on an existing database instance.

4.2.2 Decide on Lowercase or Uppercase SID Name for UNIX

On UNIX systems, when you define the Oracle Clinical SID name, consider these options:

- If you define the Oracle Clinical SID name using lowercase letters only, there are no conflicts in the Oracle Clinical Data Extract module.
- If you define the Oracle Clinical SID name using uppercase letters, you must create symbolic links. These links are required so that the path to the SAS_VIEW directory is recognized. For information on creating these links, see the *Oracle Clinical Administrator's Guide*.

4.2.3 Check Required Tablespaces

Table 4–1 lists the tablespaces, along with their minimum size, required for Oracle Clinical. Make sure the database contains these tablespaces. The best practice is to create them with the *Autoextend On* option, to avoid running out of space.

In addition, you may need to increase the minimum sizes for your installation.

Table 4–1 Required Tablespaces and Sizes

Tablespace	Minimum Size
SYSTEM	900 MB
TEMP	100 MB
UNDOTBS1	700 MB
USERS	500 MB
SYSAUX	500 MB

4.2.4 Use the Database Configuration Assistant

To create a new database, use the Database Configuration Assistant. For instructions about the Database Configuration Assistant, see the Oracle Database 11*g* documentation, including online help and the *Oracle Database Installation Guide 11g Release 1 (11.1)* for the appropriate operating system.

Note: The Database Configuration Assistant prompts you to "Keep the enhanced 11g default security settings (recommended)." Information on security settings is included in the *Oracle Database 2 Day + Security Guide 11g Release 1 (11.1)*.

4.2.5 Select Required Components

When you create an Oracle Clinical database, select the following mandatory components:

- Oracle Text
- Oracle JVM

- Oracle XML DB

4.2.6 Use Automatic Memory Management

Oracle recommends that you use Oracle Database 11*g*'s Automatic Memory Management feature for a new or an upgraded Oracle Clinical database.

In addition, download the following white paper from My Oracle Support for more information on memory management:

Title: *Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability*

Article ID: 873743.1

4.2.7 Review opa_settings

Review the entries in the opa_settings file. Ensure that the default settings are applicable to the installation or create specific settings applicable to the specific database. See Section 2.7, "Performing Post-installation Tasks" for more information.

Note: The default settings for all databases or the specific settings for a particular database, such as NLS_LANG, must be correct in the opa_ settings file.

4.2.8 Set Initialization Parameters

Table 4–2 lists the required and recommended init.ora parameter settings for Oracle Clinical. For those parameters that accept a value from within a range, the values in the table are minimum values.

Tip: Table 4–2 arranges the parameters in alphabetical order. In the Database Configuration Assistant, you can select the Parameter column to sequence the parameters in the same order.

Note: If you make any changes to the initialization parameters, be sure to stop and restart the database in order to acquire the new parameter settings.

Table 4–2 Required and Recommended init.ora Parameter Settings

Parameter	Value	Comments
COMPATIBLE	11.1.0.7.0	Specifies the release with which the Oracle server must maintain compatibility.
DB_BLOCK_SIZE	16384 bytes	You cannot change this value after you create the database.
DB_CACHE_SIZE	150 MB	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
DB_DOMAIN	*company*.com	Make this value the same as your company domain name.
DB_FILES	200	Oracle adds needed space to the control files up to the number specified in the DB_FILES parameter.
EVENT	31151 trace name context forever, level 0x100	Required for HTML generation.

Table 4–2 (Cont.) Required and Recommended init.ora Parameter Settings

Parameter	Value	Comments
JAVA_POOL_SIZE	50 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation. (Set greater than 150 MB with Oracle AERS, minimum.)
JOB_QUEUE_PROCESSES	10	Developer-specific parameter. You can change the value of this parameter after installation.
LARGE_POOL_SIZE	50 MB	Recommended value for 50 to 60 concurrent users.
MEMORY_MAX_TARGET	1000 MB (minimum)	Adjust this value according to your organization's needs.
MEMORY_TARGET	1000 MB (minimum)	Adjust this value according to your organization's needs.
NLS_DATE_FORMAT	*DD-MON-RRRR* (default value)	Determines the format in which client applications running on the Windows server transfer date information to and from the database. The format must specify the year as RRRR.
NLS_LENGTH_ SEMANTICS	BYTE	The CHAR value for this parameter is not supported.
OPEN_CURSORS	800 or greater	You can change the value of this parameter after installation.
OPTIMIZER_FEATURES_ ENABLE	9.2.0	Acts as an umbrella for enabling a series of optimizer features based on an Oracle release number. Oracle Clinical uses the optimizing features of Oracle9*i*.
OPTIMIZER_MODE	CHOOSE	If you run Oracle Clinical's statistics-gathering scripts, the CHOOSE value sets Oracle9*i*'s Optimizer to apply the execution plan that best minimizes response time. See the *Oracle9i Concepts Guide* and the *Oracle9i Tuning Guide* for more information. (CHOOSE is the default value when you specify 9.2.0 as the value of OPTIMIZER_FEATURES_ENABLE.)
OS_AUTHENT_PREFIX	"OPS$"	Enter the double quotes symbol (").
PGA_AGGREGATE_ TARGET	200 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
REMOTE_LOGIN_ PASSWORDFILE	EXCLUSIVE	The database must be set up to use password file authentication.
REMOTE_OS_AUTHENT	TRUE	If you intend to use Oracle Clinical and have SAS on a different computer, DX SAS jobs fail unless you set this parameter to TRUE. However, REMOTE_OS_AUTHENT is an obsolete parameter. When you start up a database that has this setting, Oracle Clinical displays the following warning: `ORA-32004: obsolete and/or deprecated parameter(s) specified. ORACLE instance started.` You can safely ignore this warning.
SEC_CASE_SENSITIVE_ LOGON	FALSE	Lets you enter passwords without case sensitivity.
SESSIONS	500 or greater	You can change the value of this parameter after installation.
SGA_MAX_SIZE	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
SGA_TARGET	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.

Table 4–2 (Cont.) Required and Recommended init.ora Parameter Settings

Parameter	Value	Comments
SHARED_POOL_SIZE	150 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
UNDO_MANAGEMENT	AUTO	Specifies which undo space management mode the system uses. When set to AUTO, the instance starts in Automatic Undo Management (AUM) mode.

UTL_FILE_DIR	*opa_home*\ xmltemp	Specifies each directory you access.
		If you share this environment with Oracle Clinical or Oracle AERS, you must specify entries to support Oracle Clinical PDF layout generation and Oracle AERS.
		If this environment is exclusively a Thesaurus Management System environment, you do not have to set this parameter.
		For **Windows** environments, samples of the valid syntax are as follows:
		`UTL_FILE_DIR=c:\e2b\import`
		`UTL_FILE_DIR=c:\opapps\xmltemp`
		For **UNIX** environments, UTL_FILE_DIR requires an entry with two specified paths: one with and one without a trailing slash. Add these lines before any other UTL_FILE_DIR entries:
		`UTL_FILE_DIR=/usr/opapps/oc/xmltemp/`
		`UTL_FILE_DIR=/usr/opapps/oc/xmltemp`

4.2.9 Modify tnsnames.ora

Add an entry to the tnsnames.ora file for the database. Add the tnsnames entry to file tnsnames.ora on any existing Oracle Clinical 4.6 Forms Servers or Reports Servers. The tnsnames.ora entry must match the Oracle SID.

4.3 Installing Oracle Clinical 4.6 Database Objects

Follow these instructions to add Oracle Clinical database objects to this database.

4.3.1 Transfer the Oracle Clinical 4.6 UNIX Media

If you are installing on a UNIX computer and you have not yet transferred the Database Server software from the media pack to this computer, see Section 2.6.2, "Transfer the Oracle Clinical 4.6 Database Server Software" for installation instructions.

4.3.2 Customize the Installer

Before you install database objects, you may want to modify some of the default SQL scripts used by the Installer.

4.3.2.1 Edit Tablespace Sizes

The Installer creates several new tablespaces with default sizes. To create larger databases, edit the following files:

UNIX: *OPA_HOME*`/oc/46/install/opadba2.sql`
OPA_HOME`/oc/46/install/rxcdba2.sql`

Windows: *OPA_HOME*`\oc\46\install\opadba2.sql`
OPA_HOME`\oc\46\install\rxcdba2.sql`

You can either increase the size of the data files or remove the autoextend clause from the data files. The default value is an autoextend of 1M and an unlimited maximum size.

4.3.2.2 Edit the User Account Creation Script

The Installer prompts to create accounts in this database. If you select Yes, the Installer runs a script that creates default guest accounts. Prior to running the Installer, edit the rxcdba4.sql script to customize the accounts that get created and their default settings:

UNIX: *OPA_HOME*/oc/46/install/rxcdba4.sql

Windows: *OPA_HOME*\oc\46\install\rxcdba4.sql

See the *Oracle Clinical Administrator's Guide* for more information about enrolling users.

4.3.3 Start the Installer

Follow these instructions to set the correct installation environment and start the Installer. Where the platforms have different instructions, there are separate sections.

The Installer acts in two phases. In the first phase, the Installer collects information about your system. During this phase, you can move back and forward through the screens, revising your entries. During the second phase, the Installer runs the scripts to set up the Oracle Clinical software according to the information you provided in the first phase.

4.3.3.1 Starting the Installer on a UNIX Server

To start the Installer on a UNIX server:

1. Log in to the server computer as the opapps user.
2. Change the primary group of the opapps account to the group that owns the Oracle Inventory:

   ```
   newgrp inst_group
   ```

   where *inst_group* is the name of the group that owns the Oracle Inventory. You specified the name during the Oracle Database 11*g* installation. Typically, this user group is oinstall.

   This temporary change is necessary so that the Installer can update the Oracle inventory.
3. Set the X Window display output to the IP address of your local computer. Use the standard format for IP addresses, and add ":0" to the end of the address. For example:

   ```
   setenv DISPLAY 123.45.67.89:0
   ```
4. Navigate to this location in the folder where you extracted the server code:

   server_code_platform\Disk1\install
5. Change protections on files to 755.

   ```
   chmod 755 *
   ```
6. Start the Universal Installer:

   ```
   ./runInstaller
   ```

7. Follow the instructions on the installation screens. For additional information on each screen, see Section 4.3.4, "Attend to the Oracle Clinical Database Installation Screens."

4.3.3.2 Starting the Installer on a Windows Server

To start the Installer on a Windows server:

1. Log in to the server computer using an account with system administrator privileges.
2. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
3. Locate and execute the setup.exe file:

   ```
   oc\server_code\win\install\setup.exe
   ```

   The Installer opens to the Welcome screen.
4. Follow the instructions on the installation screens. For additional information on each screen, see Section 4.3.4, "Attend to the Oracle Clinical Database Installation Screens."

4.3.4 Attend to the Oracle Clinical Database Installation Screens

This section describes the Installer's prompts for installing an initial Oracle Clinical database. The instructions are the same for all platforms.

Welcome

The Installer opens to the Welcome screen. Click **Next.**

Select a Product to Install

Select **OC Database Install 4.6.0.0.*XX*** (where *XX* is the build number). Click **Next.**

Specify Home Details

Select or enter the *ORACLE_HOME* location, which is where you installed Oracle Database 11*g*.

Choose Directory
OPA Home

Check that the displayed value is the correct location of the Oracle Clinical Database Server installation. If not, click **Browse** and locate the Oracle Clinical server installation. Click **Next.**

Choose Directory
SAS view

Specify the directory to create for locating Data Extract files. (See Chapter 8, "Setting Up SAS" for more information.) Click **Next.**

Choose Database
Enter connect string for database to be installed

Enter the Oracle SID. Click **Next.**

Choose Directory
for data tablespace datafiles

Enter the path for the directory where the Installer creates the data tablespace datafiles. The installer validates that the specified directory exists on the server.

In addition, the Installer creates the tablespaces with the default sizes defined in the opadba2.sql and rxcdba2.sql scripts. To increase the size of the initial database, edit these scripts before running the installer. For more information, see Section 4.3.2, "Customize the Installer."

Click **Next.**

Choose Directory
for index tablespace datafiles

Enter the path for the directory where the Installer creates files to hold tablespaces for Oracle Clinical indexes. The installer validates that the specified directory exists on the server.

In addition, the Installer creates the tablespaces with the default sizes defined in the opadba2.sql and rxcdba2.sql scripts. To increase the size of the initial database, edit these scripts before running the installer. For more information, see Section 4.3.2, "Customize the Installer."

Click **Next.**

Enter Password
for SYS

Enter and confirm the password for the SYS user to perform database administration activities during the installation. The Installer validates the password against the database before performing the install. Click **Next.**

Enter Password
for SYSTEM

Enter and confirm the password for the SYSTEM user to perform database administration activities during the installation. The Installer validates the password against the database before performing the install. Click **Next.**

Note: In the installation screens that follow, the Installer prompts for the passwords for many user accounts. Note that:

- The Installer encrypts and stores the passwords in the database.
- Passwords cannot contain the following characters: { } | ; @
- Passwords cannot contain spaces.

Choose Password
RXC_MAA

Enter and confirm the password for the account that creates and maintains data access accounts during data extract.

Click **Next.**

Choose Password
for RXC_PD

Enter and confirm the password for the account that creates stored procedures during validation procedure definition. Click **Next**.

Choose Password
for RXC_REP

Enter and confirm the password for the account that manages distributed study conduct. Click **Next**.

Choose Password
for RXC_DISC_REP

Enter and confirm the password for the account that manages disconnected replication. Click **Next.**

Choose Password
for RXCLIN_MOD

Enter and confirm the password for the database role that controls write access to the Oracle Clinical database. Click **Next.**

Choose Password
for BC4J_INTERNAL

Enter and confirm the password for the account that stores product objects. Click **Next.**

Choose Password
for OPA

Enter and confirm the password for the account that stores product objects. Click **Next.**

Choose Password
for RXC

Enter and confirm the password for the account that stores product objects. Click **Next.**

Choose Password
for TMS

Enter and confirm the password for the account that stores product objects. Click **Next.**

Choose Password
for RXA_DES

Enter and confirm the password for the account that stores product objects. Click **Next.**

Choose Password
for RXA_LR

Enter and confirm the password for the account that stores product objects. Click **Next.**

Enter Value
Database Seed Number

Each database in an Oracle Clinical installation (or group of databases that are replicating with each other) must have a unique seed starting number. The seed number must be an integer between 1 and 99. Click **Next.**

Enter Database Configuration Parameters

Enter the full name of the host where the database is located, and enter the SQL*Net port used to connect to this database. The port number is specified in the tnsnames.ora file for this database. Click **Next.**

Enter Location
a unique code for this location

Enter a unique code for the location of this database. The location code cannot exceed 15 characters, and is converted to all uppercase characters.

The default value is the value of ORACLE_SID. Click **Next.**

Enter Global Library Location
a unique code for the Global Library location

Enter a unique code for the location that owns the Global Library. The location code cannot exceed 15 characters, and is converted to all uppercase characters.

The default value is the location code entered in the previous screen. Click **Next.**

Yes/No
Do you want to create accounts in this database?

This setting controls whether the Installer runs the rxcdba4.sql script and creates the user accounts defined in the script. Prior to running the Installer, you can edit the script to customize the accounts that get created and their default settings. See Section 4.3.2, "Customize the Installer" for more information.

You can also create user accounts after the installation. Click **Next.**

Yes/No
Ignore Tablespace Creation Errors

This setting controls whether the Installer ignores errors that occur when creating the tablespaces. Tablespace creation can fail for several reasons.

The default value is No. In general, you do not want the Installer to ignore tablespace creation errors. For example, you want the Installer to report an error if there is not enough space to create the tablespace.

On the other hand, if you are reinstalling into an existing Oracle Clinical database, the tablespace creation fails because the tablespace already exists. In this case, you do not need to know about the error.

Click **Next.**

Information

This screen reports that the Installer will start an SQL*Plus session to complete the database installation. The screen confirms the name of the database installation, the location of the scripts used for the installation, and the location of the log file that you can view for the progress of the installation. Click **Next.**

Summary
OC Database Install 4.6.0.0.*XX* (Note: *XX* is the build number.)

This screen provides information about the global settings, languages, space requirements, and products for this installation.

Click **Install.** The Installer starts an SQL*Plus session to complete the installation.

The Installer configures the installed database to work with the Oracle Clinical 4.6 Database Server code by adding an entry to the following file:

UNIX: *opapps*/bin/opa_settings

Windows: *opapps*\bin\opa_settings.bat

End of Installation

The Installer displays this screen when it finishes. This screen provides information about the installation, including whether the processes completed without errors, the name of the PSUB service created, and the location of the log file for your review.

Note: You may need to modify or create some additional default entries in the opa_settings file for this database. See the *Oracle Clinical Administrator's Guide* for more information.

4.3.5 Remove Group Privileges from this Session (UNIX Only)

Recall that before you started this installation on UNIX, you changed the primary group of the opapps account to the group that owns the Oracle Inventory (see Section 4.3.3.1). This temporary change was necessary so that the Installer could update the Oracle inventory.

To reset the privileges for the opapps account, enter the following command:

```
newgrp group
```

where *group* is the name of your original primary group for the opapps account.

4.4 Performing Post-Installation Database Tasks

Follow the instructions in this section to complete your database installation.

4.4.1 Review the Log Files for Installation Errors

The Installer generates numerous log files and saves the files to the following location:

UNIX: *OPA_HOME*/oc/46/install

Windows: *OPA_HOME*\oc\46\install

Check the following log files for error messages and invalid objects. In each file name, *database* is the database SID.

- oclinst_*database*.log
- reall_*database*.log
- oclconfig_*database*.log
- flt_seeddata_*database_timestamp*.log
- html_dialg_templ_*database_timestamp*.log
- html_blob_seeddata_*database_timestamp*.log
- xmlp_clob_seeddata_*database_timestamp*.log
- xml_clob_seeddata_*database_timestamp*.log
- compile_all_invalid_*database*.log

- load_olsardcstatemachine_jar_*database*.log
- install_*database_timestamp*.log
- opaconnectcheck_system_*database*.log

4.4.2 Change Default Passwords

To improve security and to protect system access:

- Change the default passwords of all schemas and roles
- Use the set_pwd utility to encrypt the passwords in the database

See the *Oracle Clinical Administrator's Guide* for details about setting up user accounts and roles, changing passwords, and encrypting passwords.

4.4.3 Pin Database Packages

To improve performance, some of Oracle Clinical's packages are *pin-able* packages. Pinning allocates a stable memory location so that a package cannot be subjected to being swapped out of memory. Oracle Clinical provides the **rxcdbinit.sql** script to pin the database packages.

> **Note:** Oracle Clinical 4.6 pins additional packages. The new packages are included in the updated rxcdbinit.sql script.

4.4.3.1 Pin UNIX Database Packages

To pin the database packages located on a UNIX server:

1. Log in to the UNIX server computer as `opapps`.
2. Set the UNIX environment:

   `opa_setup` *`database`* `46`

   where *`database`* is the name of this database instance, and `46` is the alias for the version of Oracle Clinical.
3. Change to the RXC_INSTALL directory:

   `cd $RXC_INSTALL`
4. Start an SQL*Plus session, and connect to the database in the RXC account:

   `sqlplus rxc/`*`password`*
5. Run the rxcdbinit.sql script:

   `start rxcdbinit.sql`

   The script pins the database packages and exits upon completion.

> **Note:** You must reexecute this script *each* time you restart the database. Consider creating an entry in the database startup script that runs `rxcdbinit.sql`.

4.4.3.2 Pin Windows Database Packages

To pin the database packages located on a Windows server:

1. Set the Windows environment:

```
set p1=database
set p2=46
opa_setup
```

where *database* is the name of this database instance, and 46 is the alias for the version of Oracle Clinical.

2. Change to the drive where Oracle Clinical 4.6 is installed. For example:

   X:

3. Start an SQL*Plus session, and connect to the database in the RXC account:

   ```
   sqlplus rxc/password
   ```

4. Run the rxcdbinit.sql script to pin the database packages:

   ```
   start %RXC_INSTALL%\rxcdbinit.sql
   ```

If you are continuing the installation, note that you perform the next task in this environment.

4.4.4 Configure and Start the PSUB Process

The Parameterized SUBmission (PSUB) process schedules reports and batch processing. Note that:

- You start one PSUB process for each Oracle database instance supporting an Oracle Clinical installation.
- Each database instance can have only one PSUB process.
- You must locate PSUB on the same computer as the database installation.

4.4.4.1 Starting PSUB on UNIX

To start PSUB as a UNIX process:

1. Log in to the server as rxcprod.
2. Enter the following command:

   ```
   start_psub database code_environment
   ```

   For example:

   ```
   start_psub prod 46
   ```

4.4.4.2 Changing the Startup of the PSUB Service on Windows

To change the startup of the PSUB service on Windows:

1. Log in as Administrator.
2. Set the PSUB service parameters:
   a. Open the **Administrative Tools** control panel.
   b. Double-click **Services.**
   c. From the list of services in the Services dialog box, double-click the name of the database for this service. It is in this form:

      PSUB Service *database*

   d. For Startup type, select **Manual.**

e. Click the **Log On** tab.

f. For Log on as, select **This account** and then enter RXCPROD in the field.

(The task of creating the RXCPROD account occurs during the installation of the Database Server. See Section 3.2.1, "Create the RXCPROD Account" for more information).

g. In the Password and Confirm Password fields, enter the RXCPROD password.

h. Click **OK** to close the dialog box.

3. Exit from the Services dialog box.

4. Log off this Administrator session. You start PSUB from the RXCPROD account.

4.4.4.3 Configuring Windows Registry Setting for PSUB

To be able to start PSUB on Windows, the OSAUTH_PREFIX_DOMAIN setting in the Windows System Registry must be set to FALSE. Otherwise, the operating system authentication prefix is OPS$*hostname*\ instead of OPS$.

The OSAUTH_PREFIX_DOMAIN registry setting is located at:

HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE*HomeX*\

where *HomeX* is the Home number of your Oracle Database 11*g* installation.

4.4.4.4 Starting the PSUB Service on Windows

To start PSUB as a Windows process:

1. Log in to the computer as user `RXCPROD`. (You set up the PSUB service to start as the RXCPROD user, but in Windows you can start the service when logged on as another user.)

2. Set the PSUB service parameters:

a. Open the **Administrative Tools** control panel.

b. Double-click **Services.**

c. From the list of services in the Services dialog box, double-click the name of the database for this service. It is in this form:

PSUB Service *database*

d. Enter values for the Log On parameters:

```
database code_environment [verbose | noverbose]
value-of-RXC_ROOT
```

For example: `prod 46 verbose c:\\opapps\\oc\\46`

Note: If your entry requires a backslash (\), you must enter two (\\). Alternatively, you can enter the path using single forward slashes, for example, `c:/OPA_HOME/oc/46`.

---

3. Click **Start.**

4. Exit from the Services dialog box.

4.4.4.5 Configuring PSUB for Automatic Startup

By default, the PSUB service does not start automatically when you restart a server computer. However, you can configure the PSUB service to start automatically. For information about managing the PSUB process and defining automatic startup parameters, see the *Oracle Clinical Administrator's Guide*.

4.4.4.6 Changing PSUB Job Numbering

You can change Oracle Clinical's default job numbering algorithm. See the *Oracle Clinical Administrator's Guide* for details.

4.4.5 Enroll Users

See the *Oracle Clinical Administrator's Guide* for more information about enrolling users.

4.4.6 Check Disconnected Replication Tablespace

If you implement disconnected replication, you might need to increase the size of the DISC_REP_DATA tablespace to fit the amount of replicated data. Installing Oracle Clinical 4.6 creates the RXC_DISC_REP user account to manage disconnected replication. DISC_REP_DATA is the default tablespace for RXC_DISC_REP. For more information about distributed study conduct and disconnected replication, see the *Oracle Clinical Administrator's Guide*.

4.4.7 Review Optimization Statistics

Oracle Clinical provides scripts that analyze the storage characteristics of tables and indexes, and compute statistics. As you accumulate statistics for this database, run these scripts periodically. See the *Oracle Clinical Administrator's Guide*, Appendix E, "Collecting Statistics for Optimization" for more information.

4.4.8 Consider Implementing Partitioning

Oracle Clinical supports partitioning of the responses data entry table. Before implementing partitioning to responses data for your Oracle Clinical 4.6 installation, consider your requirements and options in migrating from a non-partitioned, pre-Oracle Clinical 4.0 responses table to Oracle Clinical 4.6.

To migrate your data from a non-partitioned responses table into a partitioned one, first backup your existing responses table, indexes, and data.

4.5 Completing File Viewing Tasks in the Database

You must install an Oracle Clinical Forms Server and Reports Server before you can continue. See "File Viewing" in the *Oracle Clinical Administrator's Guide* for more information.

4.6 Adding the Reports Server to the Database Reference Codelist

Before performing this step, you should have installed, or at least determined where you intend to install one, many, or all of the Reports Servers that you access from this database. For each Reports Server that you add and that you want to access from this database, you must repeat the steps in this section.

To set the Reports Server values:

1. Start Oracle Clinical.
2. Navigate to **Admin**, **Reference Codelist**, and then **Local Codelist** to open the Maintain Reference Codelists form.
3. Query for REPORT_SERVER in the Name field.
4. Complete the Short Value and Long Value fields as follows:
   - For each Short Value listed in Table 4–3, enter in the Long Value field the connection string of the Reports Server that you want to use as the default for the specified function.
   - To add additional, non-default Reports Servers, add rows to the reference codelist and specify a unique name in the Short Value field and the connection string in the Long Value field.

Table 4–3 REPORT_SERVER Reference Codelist Values

Short Value	Enter in Long Value Field
REPORT_SERVER	*The connection string for the Reports Server you want to use as the default for Oracle Reports.*
JOB_SET_SERVER	*The connection string for the Reports Server you want to use as the default for job sets.*
PSUB_SCHEDULER	*The connection string for the Reports Server you want to use as the default for PSUB jobs.*

5. Click **Save.**

5

Installing the Oracle Clinical Forms Server

The **Oracle Clinical Forms Server** performs the form processing, communicates the display changes to the client, and calls forms to query, update, select, and delete data from the Database Server.

An Oracle database does not have to be installed for you to install an Oracle Clinical Forms Server. However, you need a supported Oracle database to verify the Forms Server installation.

To install the Oracle Clinical Forms Server, you complete the following tasks:

Note: Installing the Oracle Clinical Forms Server also installs Oracle Clinical RDC Onsite on the same server.

5.1 Setting Up the OPAREPS Account

Oracle Clinical uses the OPAREPS user account when starting the Oracle Reports Server, the Oracle HTTP Server, and the Oracle Clinical application.

You use the OPAREPS account on the Reports Server to perform the following tasks:

- Generate Reports Server output and log files for individual users
- Review PSUB and report output for the HTTP Server
- Delete temporary PSUB and report output for the HTTP Server
- Run report jobs and print reports for the Report Server

OPAREPS is also used by the HTTP Server to view or delete report or PSUB output, and to print report output.

This section describes how to create the OPAREPS account for the first server in a network domain. You should make OPAREPS part of a network domain for the following reasons:

- You do not have to create a new account for each Web or Reports Server installation.
- You can direct the report output to other computers.

5.1.1 Create the OPAREPS Account

Use the Windows Administrative Tools to create the OPAREPS account.

If an OPAREPS account is already created in the domain, be sure that the tasks in Section 5.1.2 and Section 5.1.3 are also complete.

5.1.2 Add the OPAREPS Account to the Administrator's Group

Use the Windows Administrative Tools to add the OPAREPS account to the Administrators group for this computer.

5.1.3 Add Printers to the OPAREPS Account

Once you have created the OPAREPS account, you need to modify the account and specify every printer that you plan to use for printing Oracle Clinical reports.

To add a printer for the OPAREPS account:

1. Log in to Windows as the `OPAREPS` user.
2. Click **Start**, **Settings**, and then **Printers**. The Windows Printer dialog box opens.
3. Double-click the **Add Printer** icon. The Add Printer Wizard opens.
4. Click **Next.** The wizard prompts for the type of printer — local or network — that you want to add.
5. Select the **Network Printer** option, and then click **Next.**
6. Specify the name or address of the printer. If you do not know the name or address, you can browse for a printer. Click **Next** to continue.
7. Specify whether you want to use this printer as the default printer for Windows-based programs. Click **Next** to continue.
8. Click **Finish.** The system adds this printer to this computer.
9. Enter a printer specification in the Printer field or select a printer from the list of shared printers, and then click **OK** next to your selection.

5.2 Installing and Patching Oracle AS10*g*R2 Forms and Reports Services

To install Oracle AS10*g*R2 Forms and Reports Services:

1. Close all running applications on the computer.
2. Log in to the application server using an account with system administrator privileges.
3. Insert Disk B24458-01 from the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.

4. Use Windows Explorer or the command line to execute the setup.exe file:

   ```
   install\setup.exe
   ```

   The system briefly displays a DOS window while it checks your computer's compatibility, and then opens the Welcome screen.

5. Follow the instructions on the installation screens. For additional information on each screen, see Section 5.2.1, "Attend to the Oracle AS10gR2 Installation Screens."

For more information on AS10*g*R2, see the Oracle AS10*g*R2 Forms and Reports Services documentation.

5.2.1 Attend to the Oracle AS10*g*R2 Installation Screens

Welcome

Click **Next** to continue the installation. Alternatively, you can click **Installed Products** to review a list of installed Oracle products.

Specify File Locations

On this screen, you set up the Oracle AS10*g*R2 home:

- **Source Path:** Accept the default Source location path.
- **Destination Name:** Enter the home name of the application tier (middle tier). For example, `AS10gR2mt`.
- **Path:** Append your specified home name to the path. You can change the path to another location, or you can keep the default path. For example: `D:\oracle\AS10gR2mt`.

Click **Next.**

Language Selection
Oracle Application Server Forms and Reports Services 10*g* 10.1.2.0.2

Select a language for the Oracle Application Server Forms and Reports Services.

Specify Port Configuration Options

Select **Automatic**, and then click **Next.**

Provide Outgoing Mail Server Information

To enable and use the outgoing mail feature, enter the necessary mail server information. The mail server is optional. It is not needed to run Oracle Clinical 4.6.

Click **Next.**

Specify Instance Name and ias_admin Password

Each instance of Oracle AS10*g*R2 requires its own name and password combination, regardless of who installs the instance on the host computer. The name of the Oracle AS10*g*R2 instance cannot be the same as the infrastructure instance. The suggested name for this instance is `AS10gR2mt`.

Enter and confirm a valid password, and then click **Next.**

Summary

Review the installation details to verify that they are correct. To revisit earlier installation screens and make changes, click **Back.**

When you are ready to continue, click **Install.** The Installer configures this instance of Oracle AS10*g*R2. The configuration process can take several minutes. Do not interrupt the automated configuration.

End of Installation

Scroll through and review the information in the End of Installation section of the window. The Universal Installer saves all of this information in the following file:

```
setupinfo.txt
```

The Installer displays the location of this file near the top of the End of Installation section. Make note of this location in case you want to reference the file in the future.

When you have finished reviewing the installation information, click **Exit.** At the confirmation prompt, click **Yes** to exit from the Universal Installer.

5.2.2 Restart the Computer

To ensure that all configuration changes for Oracle AS10*g*R2 are initialized, you must restart the computer.

When the computer restarts, log in as a user with system administrator privileges. You are now ready to apply several patches for Oracle AS10gR2 Forms and Reports Services and the Application Server.

5.2.3 Apply Oracle AS10*g*R2 Patch Set 3 (10.1.2.3)

To apply Patch Set 3 (10.1.2.3) to Oracle AS10gR2 Forms and Reports Services:

1. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
2. Locate p5983622_10123_WINNT.zip, which is Oracle AS10gR2 Forms and Reports Services Patch Set 3 (10.1.2.3).
3. Extract the patch zip file to a location that is accessible to the Forms Server.
4. Follow the instructions in the ReadMe file to apply the patch set. The ReadMe file is located at the top level of the patch set extraction location.

5.2.4 Apply Application Server Patch 7384879

To apply Patch 7384879 to the Application Server:

1. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
2. Locate p7384879_10123_GENERIC.zip.
3. Extract the patch zip file to a location that is accessible to the Forms Server.
4. Follow the instructions in the ReadMe file to apply the patch. The ReadMe file is located at the top level of the patch extraction location.

5.2.5 Tune the Performance of the Application Server

To tune the application server for better performance, download the following white paper from My Oracle Support:

Title: *Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability*

Article ID: 873743.1

5.2.6 Set Resource Limits to Zero in Enterprise Manager

If you set up multiple Forms Servers:

1. Log in to Oracle AS10*g*R2 Enterprise Manager.
2. Select this Application Server. The utility displays a System Component list.
3. Click **Web Cache.**
4. Click the **Administration** tab.
5. Set the **Keep Alive Timeout (Seconds)** value in the Timeouts section to **0** (zero).
6. Click **OK.**
7. Click **Restart Web Cache.**

5.3 Applying a CPU Security Update Patch

Oracle publishes a CPU Security Update patch quarterly. Apply the latest CPU Security Update patch approved for the Oracle Health Sciences applications to this computer. Check My Oracle Support to determine the latest version.

You must stop the HTTP Server before you apply the patch.

5.4 Setting Up the SQL*Net Connections for Existing Databases

Establish that SQL*Net connections can be created to connect the Forms Server and the Reports Server to all databases.

To do this, modify *10g_oracle_home*\network\admin\tnsnames.ora. Ensure that it contains an entry for each database.

5.4.1 Maintain a Central Copy of the tnsnames.ora File

Consider maintaining a central copy of tnsnames.ora with all the system's tnsnames entries for the databases. Copy the file to all clients, Forms Servers, and Reports Servers.

Beginning with Release 4.6, Oracle Clinical no longer uses a tns entry for the Reports Server. The only entry needed on the Forms Server and the Reports Server is the entry for databases.

5.4.2 Troubleshoot Network Connection Issues

If the system returns a connection error, you must resolve this problem before continuing. Possible causes of errors include:

- The computer is not physically connected to the network.
- One of the databases does not exist.

- The network protocol software is not loaded on the computer (try a remote log-in to check).
- The SQL*Net software is not loaded on the computer.
- The database or SQL*Net listener process is not started on the server.
- An incorrect connect string, user ID, or password was entered.
- The `tnsnames.ora` file is not present in the correct directory or does not contain the correct entries.

5.5 Installing the Oracle Clinical 4.6 Forms Server

To install the Oracle Clinical 4.6 Forms Server:

1. Log in as a user with system administrator privileges.
2. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
3. Locate and execute the following file:

   `oc\middle_tier\install\setup.exe`

   The Installer opens to the Welcome screen.
4. Follow the instructions on the installation screens. For additional information on each screen, see Section 5.5.1, "Attend to the Oracle Clinical Forms Server Installation Screens."

5.5.1 Attend to the Oracle Clinical Forms Server Installation Screens

The following sections describe each Installer screen and the required action.

Welcome

Click **Next.**

Specify File Locations

In the **Source** section, specify the location where you extracted the Oracle Clinical 4.6 patch.

In the **Destination** section, accept the default values.

Click **Next.**

Select a Product to Install

Select **OC Front End 4.6,** and then click **Next.** The Installer installs both the Oracle Clinical Forms Server and the Remote Data Capture option. Click **Next.**

OC Front End
Choose OPA Home Directory

Specify the application tier installation directory. This is the directory that is the root of installations of Health Sciences products. Typically, you should respond with the path to the opapps46 directory.

The recommended installation directory for Release 4.6 is:

drive`:\opapps46`

where *drive* is the disk's letter designation, and `opapps46` is the directory name.

References to the *OPA_HOME* variable in all the application tier (middle tier) instructions in this guide take the value you enter here.

Click **Next.**

OC Front End
Select the PSUB File Access Mode

Select either **FTP** or **UNC** as the protocol for viewing files generated by PSUB. For more information, see "File Viewing" in the *Oracle Clinical Administrator's Guide*.

Click **Next.**

OPA Front End
Enter NLS Language

Select an NLS language setting that is appropriate for your database character set.

If you are only installing Oracle Clinical and RDC, Oracle recommends that you use the UTF8 character set. In addition, Oracle recommends UTF8 for new customers.

However, be sure to use the same character set on the database tier and the application tier. If your database is US7ASCII and you select UTF8 for the application tier, Oracle Clinical stores some special characters incorrectly in the database.

Click **Next.**

OPA Front End
Enter NLS Date Format

If the NLS_DATE_FORMAT entry in the system registry is not configured with an appropriate value, the Installer prompts for a value. The correct format is DD-MON-RRRR. Adjust the date format, if necessary, and click **Next.**

OPA Front End
Enter Report Queue Manager Machine

By default, the Installer displays the IP address or the name of the computer. Accept the default value. Click **Next.**

OPA Front End
Enter URL for the Report Queue Manager

Accept the default value. Click **Next.**

OPA Xhelp
Choose the URL location of your custom documentation.

If you have a directory for custom help, enter the location in this form. Otherwise, accept the default value. Click **Next.**

Summary

The Installer displays a diagram of the target directories. (The Installer only displays *oracle_home* in the Destination field. It may differ from your actual directory path.)

This concludes the information gathering phase of the installation process. To change any of the information, click **Previous** to revisit earlier screens. When you are satisfied with the information on this screen, click **Install.**

Install

The Installer copies the files onto the server and generates a log file of this installation.

End of Installation

The Installer informs you whether the installation was successful and prompts you to quit or continue with the next product installation. Click **Exit** to pause here, or click **Next Install** to install another Health Sciences product.

The Installer creates log files at *OPA_HOME*\log.

Note: Before you install a Reports Server, you should restart this computer.

5.6 Performing Post-Installation Tasks

5.6.1 Modify the Oracle AS10*g*R2 Process Manager Service

To change the login properties of the Oracle AS10*g*R2 Process Manager Service to use the OPAREPS account:

1. Log in as the OPAREPS user or as a user with system administrator privileges.
2. Open the Windows Control Panel.
3. Double-click **Administrative Tools.**
4. Double-click **Services.**
5. Select **Oracle AS10*g*R2 Process Manager Service.**
6. Open the **Action** menu, and then click **Properties.**
7. Click the **Log On** tab.
   a. Set the account to **OPAREPS.**
   b. Click **OK** to save your changes.
8. Close the Services dialog box.

5.6.2 Test the Connection from the Database Server

For PDF generation to succeed in Oracle Clinical, the Database Server must be able to communicate with the Forms Server computer. Ensure that the Database Server can *ping* the Forms Server computer using its network name.

5.6.3 Share the RDC Directory and Set Image Browsing

As part of the Forms Server setup, you need to:

- Share the RDC directory so that it is available to both the Reports Server and the Oracle Clinical Graphic Layout Editor
- Enable (or disable) image browsing by setting values in the Windows system registry

To share the RDC directory and to configure image browsing:

1. Log in to the Forms Server computer as a user with system administrator privileges.
2. Share the `\opapps46\html\rdc\` directory. Give the directory the name `RDC`. Make it readable by any user account that uses the Graphic Layout Editor.

3. Open the Windows System Registry Editor.
4. Navigate to the following key:

   \HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE*10g_oracle_home*
5. Set values for the following keys:
   - RDC_DCIF_IMAGES_BROWSE = **Y**
   - RDC_DCIF_IMAGES = *forms_server_name***rdc\dcif_images**

     The *forms_server_name* is the network name of the computer. You must use the reference syntax for the value. Entering the exact path does not work.
   - RDC_DCIF_IMAGES_URL = **http://***web_server_name.domain_name***/opa46/rdc/dcif_images**

     The *domain_name* is the fully qualified domain name. For example, `my.company.com`.
   - RDC_DCIF_IMAGES_VALIDATE = **Y** (enables image browsing) or **N** (disables image browsing)

     Note: The value for RDC_DCIF_IMAGES and RDC_DCIF_IMAGES_URL must be the same location.

5.6.4 Enable the JSpell Spelling Checker Application

The JSpell Spelling Checker application is a third-party product from The Solution Cafe (`http://www.thesolutioncafe.com/`). You can use it to check the spelling of text objects in graphic layouts.

The Graphic Layout Editor in Oracle Clinical supports the SDK 2004 Spell Checker version of JSpell. However, Oracle does not maintain the product itself. You must purchase the product separately.

To install the JSpell application on the Forms Server:

1. Extract the Jspell files on the Application Server.
2. Copy the jspell2k4s.jar and jspell2k4n.jar files into the following location:

   ORACLE_HOME`/forms/java`
3. Create the `jspell` directory in the root of the Application Server. For example, if the Application Server is installed in `c:/oracle` then create the `c:/jspell` directory.
4. Copy the `lex_enUS.jdx` file into the `jspell` directory.
5. Log in to the Enterprise Manager Application Server Control (http://*app_server*:18100).
6. Select the Application Server instance:
   a. Click the `opa` OC4J system component.
   b. Click the **Applications** tab.
   c. Click **Deploy WAR File.**

d. Enter the following values:

Web Application: Specify the location of the JSpellWAR file, `jspell2k4.war`, using the Browse feature.

Application Name: `jspell2k4`.

Map to URL: `/jspell2k4`.

e. Click **Deploy.**

f. Click **OK.**

5.6.4.1 Testing the JSpell Servlet

To test the JSpell Servlet, open the following URL:

```
http://server_name/jspell2k4/servlet/JSpellServlet?
operation=status
```

If the status page opens without error, JSpell is properly installed.

5.6.4.2 Changing the Lexicons Directory

When you installed the JSpell application, the instructions recommended that you create the `jspell` directory in the same root (parent) directory as the Application Server. For example, if the Application Server is installed in `c:/oracle`, then you create the `c:/jspell` directory.

If the JSpell and Application Server directories *are not* at the same root directory, you must map JSpell's lexicons directory:

1. Navigate to the following directory:

   ```
   oracle_as10gr2mt_home\j2ee\opa\applications\jspell2k4
   \jspell2k4\WEB-INF
   ```

2. Open the **web.xml** file.

3. Find the following lines in the web.xml file:

   ```
   <init-param>
   <param-name>indexDirectory</param-name>
   <param-value>/jspell/</param-value>
   </init-param>
   ```

4. Change the `/jspell/` text string to the location of the lex_enUS.jdx file on the Application Server.

5.6.4.3 Updating the formsweb.cfg File

Open formsweb.cfg. Under the `[opa46]` text section, append the following text string to the end of the archive_jini parameter value:

```
,jspell2k4n.jar,jspell2k4s.jar
```

5.6.4.4 Updating Registry Entries

Update the following registry entries:

```
OPA_SPELL_ENABLED=Y
OPA_SPELL_URL=http://app-server/jspell2k4/servlet/JSpellServlet
OPA_SPELL_LANGUAGE=English (US)
```

5.6.5 Download the Java Runtime Environment

The Oracle Clinical and RDC launch pages test that the Java Runtime Environment, or JRE (also known as the Java Virtual Machine, or JVM) exists on the user's computer. If the JRE does not exist, the Oracle Clinical and RDC plug-in pages provide a link to install the software.

Oracle Clinical supports JRE Version 1.6, Update 15 or later.

To download the latest version of the JRE and position the software so your users can install it directly from the plug-in page:

1. Go to the Java Web site:

   `http://www.java.com/en/download/index.jsp`

2. Download the latest Java Runtime Environment installer (for example, JavaSetup6u21-rv.exe) to the following location:

   OPA_HOME`\html`

3. Rename the download file to `sunjpi.exe`.

5.6.6 Download the Oracle Clinical PDF Plug-in

If your organization implements the DCI Forms graphic layout system for annotated CRFs, you must download the Oracle Clinical PDF plug-in from My Oracle Support, and then set it up on each Forms Server computer.

To download the Oracle Clinical PDF plug-in:

1. Sign in to My Oracle Support at `http://support.oracle.com`.
2. Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region.
3. In the **Patch ID or Number is** field, enter **8262425.** The current plug-in patch number is 8262425. If this patch becomes obsolete, download its successor.
4. Click **Search** to execute your query. The Patch Search Results page opens.
5. Click the patch ID number. The system displays details about the patch. In addition, you can view the ReadMe file before downloading the patch.
6. Click **Download.** Follow the instructions on the screen to download and save the patch zip file to this computer.
7. Extract the file to a temporary directory.
8. Follow the instructions in the ReadMe file to install the PDF plug-in on this Forms Server.

5.6.7 Upgrade Forms Server Customizations

If you modified any files or scripts in a previous Oracle Clinical installation, see Section 9.2.1, "Upgrade Forms Server Customizations."

6

Installing Reports Servers

This chapter describes how to install and connect Reports Servers. The Oracle Clinical 4.6 Reports Server runs on Oracle AS10*g*R2.

The Reports Server runs most batch reports, schedules all jobs, including PSUB jobs, and runs job sets. In addition, it creates PDF output for RDC Patient Data Reports, RDC Blank Casebook Reports, and Oracle Clinical Audit Reports.

There are two Reports Server installation types:

- **Combined**: a Reports Server on the same computer as a computer with a Forms Server installation.
- **Standalone**: a Reports Server on a computer without an installed Forms Server. You can add standalone Reports Servers to balance the workload between running Oracle Clinical and running reports jobs.

Tasks for Installing a Standalone Reports Server

The application-tier software components that support a Reports Server are the same as the Forms Server. To set up a standalone Reports Server, first perform these Forms Server installation tasks:

1. Section 5.1, "Setting Up the OPAREPS Account"
2. Section 5.2, "Installing and Patching Oracle AS10gR2 Forms and Reports Services"
3. Section 5.2.3, "Apply Oracle AS10gR2 Patch Set 3 (10.1.2.3)"
4. Section 5.2.4, "Apply Application Server Patch 7384879"
5. Section 5.2.6, "Set Resource Limits to Zero in Enterprise Manager"
6. Section 5.3, "Applying a CPU Security Update Patch"
7. Section 5.4, "Setting Up the SQL*Net Connections for Existing Databases"

   Next, continue with the tasks in this chapter:

8. Section 6.1, "Installing the Oracle Clinical 4.6 Reports Server"
9. Section 6.2, "Setting Up the Reports Server for Access and File Viewing"
10. Section 6.3, "Testing the Reports Server Installation"
11. Section 6.4, "Troubleshooting Reports Server Problems"

Tasks for Installing a Combined Forms and Reports Server

If you are installing a Reports Server on the same computer as the Forms Server, set up the Forms Server first, as described in Chapter 5. Next, continue with the tasks in this chapter:

1. Section 6.1, "Installing the Oracle Clinical 4.6 Reports Server"
2. Section 6.2, "Setting Up the Reports Server for Access and File Viewing"
3. Section 6.3, "Testing the Reports Server Installation"
4. Section 6.4, "Troubleshooting Reports Server Problems"

6.1 Installing the Oracle Clinical 4.6 Reports Server

Perform these instructions to deploy the Oracle Clinical Reports application onto the Oracle AS10*g*R2 installation.

Note: If you run Patient Data Reports from a Reports Server, install Acrobat Reader *before* installing the Oracle Clinical 4.6 Reports Server. The Installer detects the Reader's location and automatically configures the registry.

To install the Oracle Clinical 4.6 Reports Server:

1. Log in as a user with system administrator privileges.
2. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
3. Locate and execute the following file:

   ```
   oc\middle_tier\install\setup.exe
   ```

   The Installer opens to the Welcome screen.
4. Follow the instructions on the installation screens. For additional information on each screen, see Section 6.1.1, "Attend to the Oracle Clinical Reports Server Installation Screens."

6.1.1 Attend to the Oracle Clinical Reports Server Installation Screens

The Installer acts in two phases. In the first phase, the Installer collects information about your system. During this phase, you can move backward and forward through the screens, revising your entries. During the second phase, the Installer runs the scripts to set up the Oracle Clinical 4.6 software according to the information you provided in the first phase.

The following sections describe each Installer screen and the required action.

Welcome

Click **Next.**

Specify File Locations

Source Check that the displayed default path is the location of the jar file that contains Oracle Clinical Report Server component.

Destination Enter values for the Oracle Home you created when you installed Oracle AS10*g*R2 Forms and Reports Services on:

- a combined Forms and Reports server
- a separate Reports Server

Click **Next.**

Select a Product to Install

Select **OC Report Server 4.6.0.0.*XX*** (where *XX* is the build number). Click **Next.**

OC Report Server
Choose OPA home directory

Specify the directory that is the root of installations of Oracle Health Sciences products. This value must end with **opapps46.** Click **Next.**

OC Report Server
Enter Report Server Name

The default value is the `rep`*`computer_name`*. You can update this value. This document refers to the value you enter here as the *report_server_name*. If the name includes an underscore, remove it. Do not put underscores in the new value if you change it. Click **Next.**

OC Report Server
Acrobat Reader

If installed, the Installer detects the location of the computer's Acrobat Reader installation. The Acrobat Reader is necessary for generating Patient Data Reports.

Click **Next**.

OC Report Server
Do you want to store DCIF images locally

The Installer displays this screen only if you are installing a standalone Reports Server. The default value is Yes. Select No if you want to store DCIF images remotely. One of the following screens appears depending on your selection.

Click **Next**.

OC Report Server
Choose the local DCIF Images Directory

If you selected Yes for the option of storing DCIF images locally, enter or browse to the path of the local directory where you want to save the DCIF images.

Click **Next.**

OC Report Server
Enter the shared location of DCIF images

If you selected No for the option of storing DCIF images locally, enter the path of the remote directory where you want to store the DCIF images. This location is typically:

`\\`*`forms_server_name`*`\rdc\dcif_images`

Click **Next.**

Summary

This screen displays a navigation diagram of the target directories. (The Installer only displays *`oracle_home`* in the Destination field. It may differ from your actual directory path.) This concludes the information gathering phase of the installation process.

Click **Install.**

Install

The Installer copies the files onto the server and generates a log file of this installation.

End of Installation

This screen informs you whether the installation was successful.

Click **Exit**.

Restart the Computer

Restart the computer before continuing.

6.2 Setting Up the Reports Server for Access and File Viewing

Perform these Reports Server file viewing tasks once for each Oracle Clinical location.

6.2.1 Create the Reports Server Root Directory

Create a directory on a computer for report and log files. The Reports Server root directory can reside on the Forms Server, on any of the Reports Servers, or any other computer. The directory must be accessible by all Reports Servers.

6.2.2 Grant OPAREPS Read and Write Access to the Reports Server Root Directory

Make the Reports Server UNC sharable and grant the OPAREPS account read and write access to this directory.

To share the Reports Server root directory on Windows with the OPAREPS account:

1. Use Windows Explorer to select the Reports Server root directory.
2. Right-click on the folder and select **Properties.**
3. Click the **Sharing** tab.
4. Select **Shared This Folder,** and then enter a value in the Share Name field.
5. Click **OK** to save your changes.

Tip: The Universal Naming Convention (UNC) for any Report Server log directory cannot exceed 35 characters. The UNC syntax is:

`\\`*`computer`*`\`*`sharename`*`\`*`subdirectory`*

For example, if the computer name is `oclfsrv1`, and the share name is `opareportout`, and the report log is being stored in a subdirectory *`user`* under this shared directory, then the UNC is:

`\\oclfsrv1\opareportout\`*`user`*

This works as long as *`user`* does not exceed eight characters. If you want to have longer names for *`user`*, then shorten the share name.

6.2.3 Create Reports Server Log Directories for Each User

For each Oracle Clinical database account, create the Reports Server log directory for the user. See "Reports Server Tasks" in the *Oracle Clinical Administrator's Guide*.

6.2.4 Specify Directory Mappings for PSUB in Each Database

To set up file viewing by mapping directories in each database, see "Grant Access to Data" in the *Oracle Clinical Administrator's Guide* for information.

6.2.5 Configure the Reports Server for DCI Forms and PDRs

If you are using DCI Forms or Patient Data Reports (PDRs) on this computer, there are more configuration tasks you must perform. See the *Oracle Clinical Administrator's Guide* for more information. (In particular, if you run the PDR, and you send the output directly to a printer, be sure to set RDC_PDF_PRINT_TOOL according to the instructions in Appendix A of the *Oracle Clinical Administrator's Guide*.)

6.3 Testing the Reports Server Installation

To test that the Reports Server can create printouts and files:

1. Start Oracle Clinical.
2. Navigate to **Admin**, **Admin Reports**, and then **Reference Codelist**. The Report Reference Codelist submission screen opens.
3. Click the Reference Codelist Name field, and enter **OCL_STATE.**
4. Print the report:
   a. Click the **Job Details** button.
   b. Change the Output Type to **PRINTER.**
   c. Examine the printer's path to see if it is correct. If not, review the instructions in Section 5.1.3, "Add Printers to the OPAREPS Account."
   d. Click **Submit Job.** You receive a status prompt. Close the prompt to return to the Submission screen.
   e. Click **Job Status** to check the progress of your print job. Look for the printout from your printer.
5. Print the report to file:
   a. Return to the Report Reference Codelist submission screen.
   b. Click the Reference Codelist Name field, and enter **OCL_STATE.**
   c. Click **Job Details.**
   d. Change the Output Type to **FILE.**
   e. Click **Submit Job.** The system displays a status prompt. Close the prompt to return to the Submission screen.
   f. Click **Job Status.**
   g. Check its status in the Execution Status field.
   h. Click **View Output.** The system displays a path location prompt.
   i. Click **OK.** The Report Server processes the file and converts it to the selected format. If successful, the file then opens in a separate window.

6.4 Troubleshooting Reports Server Problems

This section lists solutions to a few Reports Server problems that can arise under certain conditions. In addition, see the *Reports Server Troubleshooting Guide* on My Oracle Support.

Preview for Form layout editor or DCI Form Generation Fails on Standalone Reports Servers

This problem can arise if you add separate Reports Servers to an installation with no Forms Servers configured to support them. For separate Reports Servers to work, you must set up registry settings on each separate Reports Server and a Forms Server, and share directories on the Forms Server. See Section 5.6.3, "Share the RDC Directory and Set Image Browsing" for more information.

Unable to stop a Reports job

Check if this is a scheduled job. If it is, use the Oracle AS10*g*R2 Enterprise Manager to stop it. Navigate to **Action**, **Report Queue Manager** from any screen, or **Admin**, **PSUB/Report Jobs**, **Enterprise Manager**. The Report Queue Manager window opens. The instructions vary by manager version, so follow the instructions in the window to stop the job.

7

Setting Up Clients

This chapter describes how to set up each client in your Oracle Clinical installation, including the client on each Forms Server.

This chapter includes the following topics:

Oracle Clinical has two layout systems supporting data entry:

- **Character-based layouts** support Oracle Clinical data entry and RDC Classic data entry.
- **Graphic-based layouts** support RDC Onsite (HTML) data entry. In addition, graphic-based layouts support annotated CRFs and Patient Data Reports.

  If you are annotating CRFs or generating Patient Data Reports, see the *Oracle Clinical Administrator's Guide* for more information.

7.1 Reviewing Requirements

Before you set up a client:

- Review Section 1.5, "Planning an Oracle Clinical Client Installation" for information about required Microsoft operating systems, Internet Explorer versions, and plug-ins.
- Check My Oracle Support for the latest information about setting up clients.

7.2 Configuring Personal Firewall

If the client computer has a personal firewall, you must either disable it or configure it in order for RDC to function correctly. See your firewall documentation or ask your system administrator for assistance.

7.3 Setting Internet Options for Microsoft Internet Explorer

This section describes how to configure Internet Explorer to work correctly with Oracle Clinical. (You can skip section if you set up clients for Oracle Clinical 4.6.)

Note: In Internet Explorer 8, ensure that it is set to Compatibility mode or IE7 mode.

7.3.1 Set Up for Proxy Usage on Fully Qualified Application Tier Names

You must configure your client proxy settings if one of the following conditions is true for your installation:

- You connect to the application tier with its fully qualified name (*server_name.domain_name*).
- You installed the application tier (Oracle AS10*g*R2 and Oracle Clinical 4.6) using the fully qualified name.
- You use proxies.

To configure your client proxy settings:

1. Start Internet Explorer.
2. Open the **Tools** menu, and then select **Internet Options.**
3. Click the **Connections** tab.
4. Click **LAN settings** to open the Local Area Network (LAN) Settings dialog box.
5. Select **Use a proxy server for your LAN,** and then click **Advanced.**
6. Define the **Exceptions** at the bottom of the panel.

   In the **Do not use proxy server for addresses beginning with** field, use the following format to enter the fully qualified name of each application server:

   server_name.domain_name

   For example, if the server name is OC1 and the domain name is mycompany.com, then you enter:

   `OC1.mycompany.com`

   If you are connecting to more than one application server, enter the fully qualified name of each server. Use the semicolon (;) to separate your entries.

7.4 Downloading Plug-ins

This section describes how to download and install the following plug-ins to the client:

- Java Runtime Environment (JRE) plug-in
- Oracle Clinical PDF plug-in
- Adobe Reader

7.4.1 Download the Java Runtime Environment Plug-in

The Oracle Health Sciences applications — Oracle Clinical, Oracle Clinical Remote Data Capture, Oracle Thesaurus Management System, and Oracle Adverse Event Reporting System — all require the Java Runtime Environment (JRE).

Before you download the JRE plug-in, uninstall any old versions of the JRE, if present. By uninstalling old versions, you avoid receiving the following message when starting an Oracle Health Sciences application:

```
The Application requires an earlier version of JRE. Do you want
to continue?
```

To download and install the JRE plug-in onto the client:

1. Open the Oracle Clinical launch page:
   a. Open Internet Explorer.
   b. Enter the following URL:

      `http://computer_name.domain:port/opa46/launch.htm`

      where:

      computer_name is the network name for the connecting Forms Server

      domain is the network domain name for your organization
2. Click the **Downloads** link on the right of the launch page. The Oracle Health Sciences Downloads page opens.
3. Follow the on-screen instructions to download and install the JRE.

   During the installation, you must accept all prompts to accept signed jar files.

7.4.2 Download the Oracle Clinical PDF Plug-in

If you want to be able to generate annotated layouts in Oracle Clinical, you must install the PDF plug-in onto the client.

> **Note:** The PDF plug-in is not required for RDC data entry.

To download and install the Oracle Clinical PDF plug-in onto the client:

1. Open the Oracle Clinical launch page:
   a. Open Internet Explorer.
   b. Enter the following URL:

      `http://computer_name.domain:port/opa46/launch.htm`

      where:

      computer_name is the network name for the connecting Forms Server

      domain is the network domain name for your organization
2. Click the **Downloads** link on the right of the launch page. The Oracle Health Sciences Downloads page opens.
3. Follow the on-screen instructions to download and install the PDF plug-in.

   The system downloads the plug-in from your Forms Server. When you set up the Forms Server, you installed the latest version of the PDF plug-in. See Section 5.6.6, "Download the Oracle Clinical PDF Plug-in" for more information.
4. Enable the JRE:
   a. Start Internet Explorer.

b. Open the **Tools** menu, and then select **Internet Options.**

c. Click the **Advanced** tab.

d. Scroll down to the Java settings.

e. Enable the **Use JRE *version_number* for <applet>** setting.

Note that you must restart the PC for your changes to take effect.

7.4.3 Download Adobe Reader

Oracle Clinical 4.6 supports Adobe Reader 7.0, 8.0, and 9.0. However, this requirement may change during the life of this document. Check My Oracle Support for the latest requirements.

To download the free Adobe Reader:

1. Go to the Adobe Corporation Web site:

   `http://get.adobe.com/reader/`

2. Follow the on-screen instructions to download the latest version of the Adobe Reader.

7.5 Starting and Logging In to Oracle Clinical and RDC Applications

To start and log in to the Oracle Clinical application:

1. Start Internet Explorer.
2. Enter the following URL:

   `http://`*`computer_name.domain:port`*`/opa46/launch.htm`

   where:

   - *`computer_name`* is the network name for the connecting Forms Server
   - *`domain`* is the network domain name for your organization
3. Click **Login.**
4. Enter your user name, your password, and the database name.
5. Click **Connect** to start the Oracle Clinical session.

> **Note:** If the JRE is not present on this client, Oracle Clinical automatically starts to download the JRE plug-in when you click **Login.** Follow the on-screen instructions to download and install the JRE plug-in to the default location.

Table 7–1 lists the URLs you enter in Internet Explorer to start the Oracle Clinical, RDC Onsite, or RDC Classic application.

When entering a URL, replace the variables as follows:

- *`computer_name`* is the network name for the connecting Forms Server.
- *`domain`* is the network domain name for your organization.

Table 7–1 URLs to Start Oracle Clinical and RDC Applications

Application	URL
Oracle Clinical	`http://computer_name.domain:port/opa46/launch.htm`
RDC Onsite	`http://computer_name.domain:port/olsa/oc/rdcLogin.do`
RDC Classic	`http://computer_name.domain:port/opa46/rdclaunch.htm`
RDC Classic (in Test Mode)	`http://computer_name.domain:port/opa46/rdclauncht.htm`
RDC Classic (in Admin Mode)	`http://computer_name.domain:port/opa46/rdcadmin.htm`
RDC Classic (in Admin Test Mode)	`http://computer_name.domain:port/opa46/rdcadmint.htm`

7.6 Mapping Network Drive for Image Browsing

If you intend to use this client to design graphic CRFs, you can enable an image browsing feature to simplify inserting graphic images in your layouts. Instead of entering the exact path and file name into the Insert Image field, you can use a conventional Windows Browse button.

You must first set up the Forms Server where you store your images. See Section 5.6.3, "Share the RDC Directory and Set Image Browsing" for details.

To enable image browsing, you must permanently map the Forms Server's drive to this client:

1. Open **My Computer.**
2. Open the **Tools** menu, and then select **Map Network Drive.**
3. Enter the drive letter that you want to assign to this connection.
4. Enter the path of the folder you want to be able to access. Alternatively, you can click **Browse** to select the folder location.
5. Click **Finish.**

7.7 Enabling Report Generation from the Command Line

In the RDC Onsite application, you can generate Patient Data Reports (PDRs) and Blank Casebook Reports from the Reports page if you have the necessary privileges.

In addition, you can configure your desktop to generate these reports from the MS-DOS command line. Generating reports from the command line can be useful when producing electronic submissions for new drug applications (NDAs). Adding the commands to a batch file lets you generate many Patient Data Reports at once.

For information on how to configure the Desktop PDR to generate reports from the command line, see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

8

Setting Up SAS

Oracle Clinical 4.6 supports SAS 9.2. You can validate your Oracle Clinical 4.6 installation, and then upgrade SAS 9.2 later. The SAS/ACCESS Interface to Oracle requires Oracle SQL*NET on the computer with the SAS software installation.

This chapter provides the Oracle Health Sciences-specific instructions for installing and configuring SAS 9.2 for Oracle Clinical 4.6.

This chapter includes the following topics:

- Section 8.1, "Modifying SAS 9.2 for UNIX"
- Section 8.2, "Modifying SAS 9.2 for Windows"
- Section 8.3, "Setting Up SAS on a Different Computer"

You can install SAS 9.2 and the Oracle Database on the same Windows computer. However, you must still execute SAS jobs manually after their generation from Oracle Clinical. See the "Data Extract" chapter in the *Oracle Clinical Conducting a Study* manual for more information.

8.1 Modifying SAS 9.2 for UNIX

Perform the tasks in this section for any supported UNIX platform.

8.1.1 Prepare the SAS Template File

Make the following modifications to the SAS template file:

1. Copy the SAS template file from *OPA_HOME*/oc/46/tools to *OPA_HOME*/bin.
2. Open the SAS file in a text editor and find this text string:

   `<path_to_SAS_executable>`
3. Replace the string with the SAS executable path.
4. Save your work.

8.1.2 Modify the opa_settings File

To use SAS 9.2 with Oracle Clinical on a UNIX platform:

1. Navigate to the following directory:

   OPA_HOME/bin
2. Open the opa_settings file.

3. Change the value of the SASORA environment variable from V8 to V9. For example:

   ```
   db_env_setting:_DEFAULT_:SASORA:V9
   ```

   You can use the scope to apply your change only to certain databases. In the following example, all databases use the V9 SAS/ACCESS engine with the exception of database OC45, which uses the V8 engine.

   ```
   db_env_setting:OC45:SASORA:V8
   ```

8.1.3 Additional Modifications for Oracle Solaris

This section describes Oracle Solaris-specific installation issues.

LD_LIBRARY_PATH

On Oracle Solaris, in previous releases of Oracle Clinical and versions of SAS before 8.2, you had to configure a script in *OPA_HOME*/bin that intercepted the SAS command to set some additional environment variables. The script then called the actual SAS executable. In Oracle Clinical 4.6, the SAS script file includes a step that points to the 32-bit libraries.

SAS/ACCESS Error with Oracle Database 11*g*

Using Oracle Database 11*g* may cause an error with SAS/ACCESS to Oracle. When using SAS/ACCESS to Oracle's SQL Pass Through Facility or Libname engine, you may receive an error similar to this one:

```
error: ld.so.1 sas: fatal: libclntsh.so.9.0:
       open failed: no such file or directory
```

To work around this problem, create a link from libclntsh.so.11.0 to libclntsh.so.9.0:

```
ln -s libclntsh.so.11.0 libclntsh.so.9.0
```

8.1.4 Additional Modifications for HP-UX Itanium

This section describes HP-UX Itanium-specific installation issues.

SHLIB_PATH

In Oracle Clinical 4.5.1, the SAS script file included a step that points to the 32-bit libraries.

Relink the Client Shared Libraries

In some cases, the Data Extract SAS jobs fail on HP-UX Itanium with the following error:

```
ERROR: Unsatisfied code symbol 'sem_destroy' in load module
```

To resolve this issue, implement the following workaround:

1. Log in to the database server where SAS is installed.
2. Change to the following directory:

   ```
   $ORACLE_HOME/lib
   ```

3. Open the sysliblist file.
4. Add the following option to the existing list of options:

   ```
   -lrt
   ```

5. Relink the client shared libraries:

   ```
   $ relink client_sharedlib
   ```

8.2 Modifying SAS 9.2 for Windows

To use SAS 9.2 with Oracle Clinical on a Windows platform:

1. Navigate to the following directory:

   OPA_HOME\bin

2. Open the opa_settings.bat file.
3. Verify that the value of the SASORA environment variable is set to V9.

8.3 Setting Up SAS on a Different Computer

This section describes setting up a connection to SAS if the SAS installation resides on a server computer *different from* that of the Oracle Clinical database tier (back end) installation. To set up the connection, you create SAS view descriptors on the Oracle Clinical back end in the $RXC_USER directory tree that the SAS server can access.

8.3.1 Setting Up SAS on a Different UNIX Server Computer

To set up SAS on a different UNIX server computer:

1. Use Network File System (NFS) protocol to make the directory on the Oracle Clinical server pointed to by the $RXC_USER environment variable visible to the SAS server. You must export this directory with write privileges because the SAS scripts generated by Oracle Clinical produce SAS view descriptors that are created in this directory tree.
2. Create the UNIX user accounts on the SAS server for all users of SAS within Oracle Clinical. Create identical groups for these users and put the users in the same groups. You may have to link `/etc/group` with `/etc/logingroup` on the SAS server if it is not the primary group for these users.
3. Open the init.ora file.
   - Verify that the REMOTE_OS_AUTHENT initialization parameter is set to TRUE for the Oracle Clinical 4.6 database instance. If you need to add this parameter or modify its value, you must shut down and restart the database for your changes to take effect
   - If SAS (and SQL*Plus and PSUB) reside on the same computer as the Oracle Clinical database, and RXC_SAS_CONNECT is set accordingly, then you can set REMOTE_OS_AUTHENT to FALSE.
4. Create a shell script that forces a "SAS" invocation on the Oracle Clinical 4.6 back end to run as a remote shell on the SAS server that invokes the SAS engine, passing it the name of the SAS file:
   a. Create the shell script on the Oracle Clinical 4.6 back end in a publicly visible directory, such as opapps/bin.
   b. Name the script `SAS`.
   c. Set the protection mode to `755`.

d. Insert the following code lines into the SAS file:

```
:
#!/bin/sh
SASDIR='pwd'
remsh sas_server /bin/sh -c ". .profile; cd $SASDIR;
/usr/bin/sas $*"
```

where:

- *sas_server* is the name of the computer with the SAS installation
- /usr/bin/sas is the absolute pathname for the SAS engine

5. Ensure that every Oracle Clinical user who needs to access SAS can create a remote shell on the SAS server:
   a. Create a .rhosts file on the SAS server in each Oracle Clinical user's $HOME directory.
   b. Ensure this file has an entry for the Oracle Clinical 4.6 back end, or any other method of granting remote shell privileges as documented for the UNIX remsh command.

8.3.2 Setting Up SAS Use on a Different Windows Server Computer

To be able to run SAS on the SAS server of a Windows computer, the user must have full control directory permissions to the following folders located in the SAS software folder:

- SASWORK
- SASUSER

8.3.3 Executing Data Extract PSUB Jobs

To enable executing data extract PSUB jobs:

1. On the computer with the PSUB service, create a local account. Note the password you create for this account. You must specify the same password when you create the SAS account in the next step.

   (Because you must have a local account on the computer that runs PSUB, you may have already created this account. See the user account requirements in the *Oracle Clinical Administrator's Guide*.)
2. On the computer with the SAS application, create a local account for the user. The password you specify must be the same as the password you specified in Step 1.
3. Create the oclsascr local group on the computer with the SAS application.
4. Enroll the user in the oclsascr group.
5. Set up RXC_SAS_VIEW:
   a. Using Universal Naming Conventions, define the RXC_SAS_VIEW environment variable in the opa_settings.bat file. For example:

   server_name\sas_view*database_name*

   b. Create a folder on the computer with the SAS application you defined in the RXC_SAS_VIEW environment variable.

c. Give full control share permissions to oclsascr on the folder you defined in the RXC_SAS_VIEW environment variable.

d. Give full control directory permissions to oclsascr on the folder you defined in the RXC_SAS_VIEW environment variable.

To be able to run SAS on the SAS server of a Windows computer, the user must have full access to the SASWORK and SASUSER folders located in the SAS software folder.

9

Upgrading to Oracle Clinical 4.6

This chapter describes the recommended approach to upgrading an Oracle Clinical Release 4.5.1, 4.5.2, or 4.5.3 installation to Release 4.6. If you are upgrading an Oracle Clinical Release 4.5 or earlier installation, see the *Oracle Clinical Release 4.5 Installation Guide* to upgrade to Release 4.5.1 before continuing.

Notes:

- Back up your existing Oracle Clinical installation before you begin.
- Oracle Clinical 4.6 does not support replication. Future releases will support replication. Oracle recommends that if you use replication, wait for the future release.

Most of the effort in upgrading from Release 4.5.1, 4.5.2, or 4.5.3 involves the database tier. However, you also have to install new Forms Servers, Reports Servers, and clients. Where the upgrades are the same as new installations, this guide refers you to the instructions for the new installations instead of repeating them here.

This chapter includes the following topics:

9.1 Upgrading the Database Tier

This section describes upgrading from Oracle Clinical Release 4.5.1, 4.5.2, or 4.5.3 database tier, which runs against Oracle Database 9*i*, to Release 4.6 database tier, which run against Oracle Database 11*g*. The upgrade process requires that you upgrade the technology stack in the order presented in this section.

Tasks for Database Tier Installation

The following list outlines the general sequence of the tasks you perform to upgrade the databases in your environment to Oracle Clinical 4.6. This section combines the instructions for the Database Server upgrade and the database upgrade because you have to implement them and their environments in this order:

1. Prepare the Database Tier for Oracle Database 11g.

2. Create a New Oracle Database 11g Oracle Home.
3. Upgrade the Database to the New Oracle Home.
4. Install Oracle Clinical 4.6 on the Database Server.
5. Repair Data.
6. Review Tablespace Sizes.
7. Halt the PSUB process.
8. Set Initialization Parameters.
9. Upgrade the Database Objects from Oracle Clinical 4.5.1, 4.5.2, or 4.5.3 to Oracle Clinical 4.6.
10. Implement Partitions.
11. Upgrade Indexes for Non-partitioned Databases.
12. Recompile Invalid Objects.
13. Pin Database Packages.
14. Check the Event Parameter in the init.ora File.
15. Start the PSUB Process.
16. Change Default Passwords.

9.1.1 Prepare the Database Tier for Oracle Database 11*g*

This section covers tasks to prepare your environment for a new Oracle Database 11*g* home. There is a list of general tasks followed by more detailed tasks.

9.1.1.1 Database Tier Upgrade Notes

Review the topics in this section, which might impact your upgrade strategy.

About Partitioning

If you chose not to partition your databases in earlier implementations, take this opportunity to reconsider.

Oracle Clinical partitioning requires the Partitioning Option to Oracle Database 11*g*. If you plan to implement Oracle Clinical partitioning, install this option just after you upgrade Oracle Database 11*g*.

Legacy Installation Dependencies

Oracle Clinical 4.6 is not dependent on previous installations. Once you have completed updating all users and migrated all databases to Oracle Clinical 4.6, you can archive earlier Oracle Clinical releases and delete them.

9.1.1.2 Oracle Database 11*g* Preliminary Tasks

Before you install Oracle Database 11*g* perform these preliminary tasks:

1. Check My Oracle Support for up-to-the-minute changes to the upgrade process.
2. Review the bug fix descriptions of bugs fixed in Oracle Clinical 4.6. Check for this information on My Oracle Support.
3. Ensure that you have a recent backup of your system, including operating system files and databases.

4. Ensure that your operating system and environment meet the requirements described in Section 1.3, "Planning an Oracle Clinical Database Tier Installation."
5. Stop all Oracle Clinical activity on the database tier, including databases, listeners, PSUB jobs, or Reports Server jobs.

When you have completed these preliminary tasks, continue with the instructions in the following sections.

9.1.1.3 Stopping Replication

Your Oracle Clinical installation may not use any form of replication, just conventional replication, or both conventional and symmetric replication. Before upgrading Oracle Clinical databases, assess which types of replication you use and take the steps described in this section to stop all replication before continuing the upgrade.

> **Note:** Oracle Clinical 4.6 does not support replication. If you use replication, wait for an upcoming release that will support replication.

The term replication includes these three areas:

- Conventional Oracle Clinical replication activities. Oracle Clinical provides PSUB activities for replicating the Global Library, lab ranges, study design, study definition, and study data. These are collectively referred to as "conventional Oracle Clinical replication."
- Automatic replication of study design via symmetric replication (as described in the *Oracle Clinical Administrator's Guide*). This area uses Oracle's *symmetric*, or *advanced*, replication to automatically propagate study design information among databases.
- In addition, Thesaurus Management System or a particular application in your company might be performing conventional or symmetric replication with Oracle Clinical databases.

> **Tip:** You must upgrade all databases in your Oracle Clinical installation to Oracle Clinical 4.6 before setting up, or resuming, replication in any of them.

9.1.1.4 Preparing Incremental Replication Environments

When upgrading a database you must either ensure that all incremental replications are up-to-date or perform full definition replications for each study and Global Library after you complete the upgrade. New Mandatory columns do not have values in the journal tables the system uses for both incremental replication and auditing. It would violate the audit trail to back-populate the journal tables with values for the new Mandatory fields, which are left null. An incremental replication that draws upon journal records created prior to the upgrade fails with the *Mandatory column is null* error.

Use caution when applying the percent symbol (%) wild card to specify which studies to bring across when doing FULL study replication. This wild card pulls all studies over that have the *Available for Replication* flag checked, from all owning locations. If your company has many studies at multiple locations, consider specifying studies uniquely.

9.1.1.5 Stopping Conventional Replication

To stop conventional replication activities in your installation:

- Cease the initiation of any new conventional replication activities.
- Ensure that no replication commands are issued, and no replication batch jobs are executed, until all database upgrades are complete.

Replicated Environments: If you have a replicated environment, follow these extra instructions:

1. Perform either an incremental or a full replication so that all sites are consistent.
2. Suspend replication.
3. Upgrade all databases in a replicated set according to the instructions in this section. Do not restart replication until you finish upgrading all databases in a replicated set.

If you follow the instructions above, you need only perform incremental replication after the upgrade. If you do not make all sites consistent before the upgrade, you must perform full replication after the upgrade.

9.1.1.6 Stopping Symmetric Replication

Because symmetric replication operates independently of Oracle Clinical, you must take action to stop the database activities that are controlling the symmetric replication activities. Take the following steps in *each* database in the installation.

1. Log in as user `REPSYS`.
2. Check the replication queue and push all pending jobs.

   ```
   select * from DEFTRAN;
   ```

   To push these pending transactions:

   ```
   dbms_defer_sys.execute(destination=>'other sites.WORLD',
   execute-as-user=>TRUE);
   ```

3. Disable the replication queues until the upgrade is complete.
   a. List the jobs in the queue:

      ```
      select * from USER_JOBS;
      ```

   b. Locate all the job ID numbers for all push transactions (`dbms_defer_sys.execute` transactions)
   c. Stop each of these jobs by running:

      ```
      dbms_jobs.broken(job_id,TRUE);
      ```

Note: This command halts *all* symmetric replication operations in and out of the affected database, including non-Oracle Clinical replication.

---

4. Stop all modifications to the database.

   As much as possible, avoid making changes to programs, projects, organization units, regions, planned studies, factors, strata, active substances, drugs, or treatment regimens.

5. Quiesce the databases by executing the following against the master database:

```
execute dbms_repcat.suspend_master_activity ('RXA_DES');
```

6. Drop the replication group from both databases:

```
execute dbms_repcat.drop_master_repgroup ('RXA_DES');
```

9.1.1.7 Altering the Default Tablespace of the Study Access Accounts

This step applies only if you are upgrading a database that has previously been at Oracle Clinical 4.0.

Starting with Oracle9*i* Database Release 2, a temporary tablespace is not allowed to be the default tablespace. The study access accounts in Oracle Clinical 4.0 were created with temporary tablespace as their default tablespace. If your database has been upgraded from Oracle Clinical 4.0 to Oracle Clinical 4.5.1, you should have run the alter_dx_tablespace.sql script as part of the upgrade process. This script changes the Data Extract Study Access Accounts default tablespace to the USERS tablespace.

If you are upgrading a database that has previously been at Oracle Clinical 4.0, check that you ran this script. If not, run the alter_dx_tablespace.sql script, located in the install directory at \oc\Misc.

9.1.2 Create a New Oracle Database 11*g* Oracle Home

Create a new Oracle home by following these operating system-specific tasks.

9.1.2.1 Creating a New UNIX Oracle Database 11*g* Oracle Home

To install Oracle Database 11*g* in a new UNIX Oracle home, follow the instructions in these sections:

1. Section 2.1.1, "Install Oracle Database 11g Release 11.1.0.6.0"
2. Section 2.1.2, "Install Oracle Database Examples 11g Release 1"
3. Section 2.1.3, "Apply Oracle Database 11g Patch Set 1"
4. Section 2.1.4, "Apply Oracle Database 11g Standalone Patches"
5. If necessary, perform the tasks in Section 2.3, "Setting Up User Accounts and User Groups."

9.1.2.2 Creating a New Windows Oracle Database 11*g* Oracle Home

To create a new Oracle Database 11*g* Oracle home on Windows, follow the instructions in these sections:

1. Section 3.1.1, "Install Oracle Database 11g Release 11.1.0.6.0"
2. Section 3.1.2, "Install Oracle Database Examples 11g Release 1"
3. Section 3.1.3, "Apply Oracle Database 11g Patch Set 1"
4. Section 3.1.4, "Apply Oracle Database 11g Patch Bundle 8451592"

9.1.2.3 Granting Write Access to Oracle-Owned Directories (UNIX)

Because the Installer checks for ORACLE_HOME directory, and if it has write access, you must change the access settings for this directory before installing the Oracle Clinical component. You must grant write access to the Oracle Database 11*g* ORACLE_HOME directory. See Section 2.2, "Granting Write Access to Oracle-Owned Directories" for instructions.

9.1.3 Upgrade the Database to the New Oracle Home

To upgrade the database from the old Oracle Home to the new Oracle Home, you can use either the export/import options or the Oracle Database Upgrade Assistant (DBUA).

For performing an in-place upgrade using the Oracle DBUA, see the following documents on My Oracle Support:

- *Complete Checklist for Upgrades to 11gR1 using DBUA*
  Article ID: 556477.1
- *Oracle Database Upgrade Guide 11g Release 1 (11.1)*
  Chapter 3, "Upgrading to the New Release"
  Part Number: B28300-03

9.1.4 Install Oracle Clinical 4.6 on the Database Server

Install the Oracle Clinical Database Server component against the new Oracle Home, choosing a new OPA Home directory for this installation so that you do not overwrite your existing environment.

To install the Database Server component, you log in to the server, run the Installer from the appropriate download location, and select the *OC Server* product. Here are platform-specific instructions:

9.1.4.1 Installing Oracle Clinical 4.6 Database Servers on UNIX

For UNIX Database Servers, run the Oracle Installer to install Oracle Clinical 4.6 and modify the default environment variable settings.

9.1.4.1.1 Installing the UNIX Oracle Clinical 4.6 Database Server Component Perform the UNIX-specific installation instructions in Chapter 2, Section 2.6, "Installing the Oracle Clinical 4.6 Database Server."

Then perform the installation instructions in Chapter 2, Section 2.6, "Installing the Oracle Clinical 4.6 Database Server" on page 2-8. When you finish, continue with the following task.

9.1.4.1.2 Modifying Default Environment Variable Settings Installing Oracle Clinical 4.6 creates the *OPA_HOME*`/bin/opa_settings` file. This file contains global environment setting defaults that you can now, if necessary, modify for this computer. See Section 2.7.3, "Review the opa_settings File" for instructions.

> **Note:** The default settings for all databases or the specific settings for a particular database, such as NLS_LANG, must be correct in the opa_settings file.

9.1.4.1.3 Preserving File Changes If you modified any Oracle Clinical files, you must reapply the changes to the Oracle Clinical 4.6 files. This section lists possible modified files.

Reapply Form, Menu, Report, or PLL Customizations

If you modified any of the following components, recompile them using Forms Builder 10g and redeploy the customized versions:

- rxcuser.fmb

- rxcuser.mmb
- rxclbcli.pll
- rxcdrptl.rdf
- rxcdrptp.rdf

Reapply SQL Customizations

If you have customized any of the scripts in the following list in Oracle Clinical 4.5.1, 4.5.2, or 4.5.3, you may need to reapply your customizations.

- **rxcptdxvb.sql**: No changes in Oracle Clinical 4.6. If you customized this file in Release 4.5.1, 4.5.2, or 4.5.3, you can copy the file from that release.
- **rdcpb_client.sql**: Changed in Oracle Clinical 4.5.3. If you customized before Release 4.5.3, you must reapply your customizations.
- **rdcps_client.sql**: Changed in Oracle Clinical 4.5.3. If you customized before Release 4.5.3, you must reapply your customizations.
- **ocl_client_pb.sql**: No changes in Oracle Clinical 4.6. If you customized this file in Release 4.5.1, 4.5.2, or 4.5.3, you can copy the file from that release.

Preserve the Replication Setup Script

To preserve edits to the replication setup script **rxasravw.sql**, copy it to the Oracle Clinical 4.6 RXC_INSTALL directory.

Note that the rxasravw.sql script is not automatically executed when upgrading. You must manually run the script after the upgrade.

Note: Oracle Clinical 4.6 does not support replication.

9.1.4.2 Install Oracle Clinical on Windows Database Servers

To install Oracle Clinical 4.6 on Windows Database Servers:

1. Perform the installation instructions in Section 3.3, "Installing the Oracle Clinical 4.6 Database Server."
2. Grant write access to the ORACLE_HOME directory and its contents.
3. Continue with the tasks in Section 9.1.5, "Repair Data."

9.1.5 Repair Data

Ensure that you applied the following data diagnostic and repair patches (or their successors) on your Oracle Clinical data.

9.1.5.1 Repairing Release 4.5.1 Data

Follow the patch instructions to apply the patches to *each* Oracle Clinical 4.5.1 database in your entire Oracle Clinical installation.

- **Patch OC_4.5.1.58**: Finds the data affected by bugs 5186346 and 5766849.
- **Patch OC_4.5.1.67**: Includes repairs in discrepancy management, soft-deleting documents in a study with enabled CRF page-tracking, replication problems, and modifications to the DCF report.
- **Patch OC_4.5.1.68**: Finds and fixes the data affected by bug 7515931.

9.1.5.2 Repairing Oracle Clinical 4.5.3 Data

Follow the patch instructions to apply the patches to *each* Oracle Clinical 4.5.3 database in your entire Oracle Clinical installation.

- **Patch OC_4.5.3.16** (or its successor). Run the find_inadv_approve.sql and the list_inadv_approve.sql scripts.
- **Patch OC_4.5.3.11** and **Patch OC_4.5.3.12** (or their successors). **Caution**: skip this task if you already applied these patches.

  Oracle Clinical 4.6 includes enhancements for tracking changes to audit data and verifications that were introduced in Oracle Clinical Patch OC_4.5.3.11 and Patch OC_4.5.3.12. Patch OC_4.5.3.11 repaired data and Patch OC_4.5.3.12 migrated existing data to work with the enhancements. Oracle Clinical 4.6 runs the repairs from Patch 4.5.3, however, you must manually migrate your data from that repair. For more information, see Appendix A, "Migrating Data for Approvals and Verifications Enhancements."

9.1.6 Review Tablespace Sizes

Oracle recommends that you create all tablespaces with the *Autoextend On* option on to avoid running out of storage space.

However, depending on your upgrade path, the upgrade process can be shortened, and the application's performance may be improved by modifying and manually running the ocl452indexchg.sql script. This operation can improve running queries from RDC.

Review the default values in the ocl452indexchg.sqlis script, which is located in the RXC_INSTALL folder. Adjust the values to fit your installation's data.

Note: During the database upgrade operation, the Installer creates default tablespace sizes contained in these upgrade scripts. Modify the scripts before you run the Installer.

In addition, review the following document on My Oracle Support for the latest information about tablespace sizes:

Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability
Article ID: 873743.1

Tablespace Sizes When Upgrading from Oracle Clinical 4.5.1

If upgrading from Oracle Clinical 4.5.1, the indexes are recreated automatically. This process could take a long time, depending on the amount of data in the application. Consider modifying ocl452indexchg.sql in resizing (redefining) the storage clause for the indexes being created there.

Tablespace Sizes When Upgrading from Oracle Clinical 4.5.2 or 4.5.3

If upgrading from Oracle Clinical 4.5.2 or 4.5.3 — and the indexes were not created during the upgrade to 4.5.3 — again, consider modifying ocl452indexchg.sql in resizing (redefining) the storage clause for the indexes and executing this script standalone.

Running the ocl452indexchg.sql Script

You can manually run the ocl452indexchg.sql script by following these instructions. The ocl452indexchg.sql script is located in the RXC_INSTALL folder.

Running ocl452indexchg.sql on UNIX From the command line, enter:

```
opa_setup database 46
cd $RXC_INSTALL
sqlplus /nolog @ocl452indexchg.sql
```

Running ocl452indexchg.sql on Windows From the command line, enter:

```
set p1=database
set p2=46
opa_setup
cd %RXC_INSTALL%
sqlplus /nolog @ocl452indexchg.sql
```

9.1.7 Halt the PSUB process

You must stop the PSUB process pointing at each database you upgrade.

To stop PSUB on Windows:

1. Navigate to the Services control panel.
2. Highlight the PSUB service.
3. Click **Stop.**

To stop PSUB on UNIX:

1. Log in to the operating system of the local computer in the RXCPROD account.
2. Set the environment variables for the database and code environment.
3. Enter the following command:

   `rxcpstop.sh rxc/`*`password`*

9.1.8 Set Initialization Parameters

After the upgrade completes, set the init.ora parameters according to the instructions in Section 4.2.8, "Set Initialization Parameters."

Review the Performance Tuning White Paper

In addition, review the following document on My Oracle Support for the latest information about setting the init.ora parameters:

Configuring Oracle Clinical Remote Data Capture Onsite 4.6 for Performance and Scalability
Article ID: 873743.1

Bounce the Database

Stop, and then start the database to activate the changed init.ora parameters.

9.1.9 Upgrade the Database Objects from Oracle Clinical 4.5.1, 4.5.2, or 4.5.3 to Oracle Clinical 4.6

This section describes running the Installer from the appropriate Oracle Clinical 4.6 Server for your Database Server platform to apply the product *OC Database Upgrade* to the database you are currently upgrading.

Note: If you upgrade a database from Releases 4.5.x to 4.6, the study data in the batch jobs table populates correctly except under these conditions:

- The study was hard deleted.
- Jobs were submitted from the Special menu of data management screens.
- PL/SQL jobs were submitted with or without using the PSUB screen.

Read this entire section before you start the Installer. It describes the information you should have available before you begin. This section contains the following sections, in the order listed:

- Detailed preliminary steps for UNIX systems
- Detailed preliminary steps for Windows systems
- Platform-independent steps for using the Installer screens.

Follow these instructions to set the correct installation environment and start the Installer. Where the platforms have different instructions, there are separate sections.

The Installer acts in two phases. In the first phase, the Installer collects information about your system. During this phase, you can move back and forward through the screens, revising your entries. During the second phase, the Installer runs the scripts to set up the Oracle Clinical software according to the information you provided in the first phase.

9.1.9.1 UNIX Installer Starting Instructions

The media is Disk V17174-01 from the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack. The media is already extracted on the computer from the server code installation. To install an Oracle Clinical database on a UNIX Database Server:

1. Set the installation environment:
   a. Log in to the server computer as the `opapps` user.
   b. Change the primary group of the opapps account to the oinstall group by entering this command, where oinstall is the name for your Inventory Owner group. Enter:

      ```
      newgrp oinstall
      ```

2. Set the X Window display output to your local computer's IP address, represented in the example by *123.45.67.89*. Note the addition of `":0"` to the end of the IP address:

   ```
   setenv DISPLAY 123.45.67.89:0
   ```

3. Navigate to this location in the folder where you extracted the database server code:

   server_code_platform\Disk1\install

4. Enter:

   ./runInstaller

The Universal Installer opens. Continue at Section 9.1.9.3, "Attend to the Upgrade Installer Screens."

9.1.9.2 Windows Installer Starting Instructions

To begin the installation.

1. Log in using an account with Windows system administrator privileges.
2. Insert Disk V17174-01 of the Oracle Clinical 4.6 and Oracle Thesaurus Management System 4.6.1 Media Pack.
3. Locate and execute file:

   oc\middle_tier\install\setup.exe

   The Installer opens to the Welcome screen.
4. Follow the instructions for each screen in the following section.

9.1.9.3 Attend to the Upgrade Installer Screens

This section describes each of the successive Installer screens.

Welcome

Click **Next** to continue the installation. Click **Installed Product**s to see a list of installed Oracle products.

Select a Product to Install

Select **OC Database Upgrade 4.6.0.0.*XX*** (where *XX* is the build number). Click**Next.**

Select Installation Type
OC Database Upgrade 4.6.0.0.*XX* (Note: *XX* is the build number.)

Select **Upgrade and Configure** (0 KB), and then click **Next.**

Specify Home Details
Destination

Enter or select a name for the installation and the full path where you want to install the product.

Choose Directory
OPA Home

Enter the path to the directory that you established during the installation of the Oracle Clinical 4.6 Database Server code.

Choose Database
Connect string for database to be upgraded

Enter the Oracle SID of the database — for example, `prod`.

Choose Directory
For new tablespaces

Specify the directory for these tablespaces:

BC4J_INTERNAL_TSPA: (Internal use only)

DX_TABLE_DATA: (Locally-managed tablespace for DX table data)

DX_INDEX_DATA: (Locally-managed tablespace for DX indexes)

Enter Database Configuration Parameters

Accept the default values for DB Hostname and DB Port Number.

Enter Password…

In successive screens, the Installer prompts you to enter passwords for the following DBA or subsystem schemas:

SYS	SYSTEM	RXC	RXA_DES
RXA_LR	OPA	RXC_REP	RXC_PD
RXC_DISC_REP	RXC_MAA	TMS	RXC_SERVLETST

For a description of each password, see Section 4.3.4, "Attend to the Oracle Clinical Database Installation Screens."

Yes/No
Ignore tablespace creation errors?

Tablespace creation can fail for various reasons. Here are two situations that can arise for Oracle Clinical:

- There is not enough space. If so, you should accept the default and leave the response to this dialog to **No.**
- The tablespace is already in existence, for instance, if you are reinstalling into an existing Oracle Clinical database. In this case, you should change the response to this dialog to **Yes.**

Select either the **Yes** or **No.**

Information

This screen confirms your parameters.

Summary

This concludes the information-gathering portion of the installation process. When you are satisfied that the entries to the previous screens are satisfactory, click **Install**.

The Installer starts an SQL*Plus session in the background that updates the database. To monitor the progress review the log file from the upgrade `install/oclupg_`*`database`*`.log`

End of Installation

This screen displays whether the installation succeeded. Click **Exit.**

9.1.9.4 Enroll Users

See the *Oracle Clinical Administrator's Guide* for information about enrolling users.

9.1.9.5 Check the Upgrade Results

After running the installer, check the log files to confirm that the upgrade succeeded. Upgrading the Oracle Clinical database produces the following log files:

- compile_all_invalid_*database*.log
- html_blob_seeddata_*database_timestamp*.log
- html_dialg_templ_*database_timestamp*.log
- load_olsardcstatemachine_jar_*database*.log
- oclconfig_*database*.log
- oclupg_*database*.log
- opaconnectcheck_system_*database*.log
- upgrade_*database_timestamp*.log
- xmlp_clob_seeddata_*database_timestamp*.log
- xml_clob_seeddata_*database_timestamp*.log

The rest of this section describes finding errors in the log files (as *logfile*), and descriptions of known errors.

9.1.9.5.1 Known Error Messages See the *Oracle Clinical 4.6 Release Notes* (Article ID 859753.1) for Known Installation Issues for a description of any error messages.

9.1.9.5.2 Reencrypting Account Passwords If the installation fails to reencrypt any password, it does not list them as errors. Instead, it lists them in the log files in a section titled, "Passwords for the following schema accounts were not converted." Check if this section exists and if it lists any accounts. If there are any accounts, you must reencrypt them by using set_pwd command.

9.1.9.5.3 Finding Errors To simplify reviewing upgrade results, run these commands for each of the four database upgrade log files:

Oracle Enterprise Linux. From the command line, enter:

```
opa_setup database 45
cd $RXC_INSTALL
 /bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

Oracle Solaris. From the command line, enter:

```
opa_setup database 45
cd $RXC_INSTALL
 /usr/xpg4/bin/grep -E '^ORA-|^PLS-|^SP2-' logfile | more
```

HP-UX Itanium. From the command line, enter:

```
opa_setup database 45
cd $RXC_INSTALL
/usr/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

Windows. From the command line, enter:

```
set p1=database
set p2=45
opa_setup
```

```
cd %RXC_INSTALL%
find /i "error" logfile | find /v "No error"
```

This section describes known error messages and possible actions you can take to resolve them.

9.1.10 Implement Partitions

See Chapter 6 of the *Oracle Clinical Administrator's Guide* for instructions on implementing partitioning for the responses table in Oracle Clinical 4.6.

9.1.11 Upgrade Indexes for Non-partitioned Databases

See "Upgrading Indexes" in the *Oracle Clinical Administrator's Guide* for instructions on upgrading your indexes.

9.1.12 Recompile Invalid Objects

The Oracle Clinical 4.6 database upgrade process runs the `compile_all_invalid.sql` script. To reduce the time required to run, this script does not recompile objects in RXC_PD beginning with RXCPD, or schemas that have a dollar symbol ($) in the name. Instead, you use the `compile_schema_invalid` script to selectively recompile invalid objects that match a pattern.

If there are any remaining invalid objects, run `compile_schema_invalid.sql` as `sys`. The compile_schema_invalid.sql is located in the $RXC_INSTALL directory. This section describes how to use this script.

Note: If you have any PL/SQL code referenced from your generated procedures, ensure that these objects are valid before running this script. For example, if you created a schema named `X`, which contains all of the PL/SQL code referenced from your generated procedures, you would first run:

```
compile_schema_invalid.sql X
```

Before running:

```
compile_schema_invalid.sql rxc_pd
```

Recompiling OPS$ Accounts

To compile any invalid objects in OPS$ accounts, enter this command:

```
start compile_schema_invalid OPS$%
```

Recompiling Study-level Data Extract View Accounts

To compile any invalid objects for the Data Extract views owned by a study, enter this command:

```
start compile_schema_invalid studyname$%
```

Recompiling any $ Accounts

To compile any invalid objects in accounts that have the $ symbol in the account name, enter this command:

```
start compile_schema_invalid %$%
```

Recompiling all Invalid Objects

To compile all invalid objects in all schemas, enter this command:

```
start compile_schema_invalid %
```

9.1.13 Pin Database Packages

To improve performance, some of Oracle Clinical's packages are pin-able packages; Pinning allocates a stable memory location so that a package cannot be subjected to being swapped out of memory. Oracle Clinical provides the rxcdbinit.sql script to pin the database packages.

Note: You must reexecute this script *each* time you restart the database. Consider creating an entry in the database startup script that runs `rxcdbinit.sql`.

9.1.14 Analyze Tables

Oracle Clinical provides scripts that analyze the storage characteristics of tables and indexes of computed statistics. Run these scripts now, and as you accumulate data in this database. See the *Oracle Clinical Administrator's Guide*, Appendix E, "Collecting Statistics for Optimization."

- Run **anarxctab.sql**.
- Run **anadestab.sql** as rxa_des.
- Run **analrtab.sql** as rxa_lr.
- Run **anaopatab.sql** as opa.

9.1.15 Check the Event Parameter in the init.ora File

If you set up the event parameter in the init.ora file to trace unique key constraints before upgrading, you should set the event parameter back to its required value. See Section 4.2.8, "Set Initialization Parameters" for details.

9.1.16 Start the PSUB Process

The instructions for starting the PSUB process are platform-specific.

Tip: By default, the PSUB service does not start automatically when you restart a Server computer. However, you can configure the PSUB service to start automatically. See "Managing the PSUB Process" in the *Oracle Clinical Administrator's Guide* for details.

Starting PSUB on UNIX

1. Log in as `rxcprod`, or as any other account that has *`OPA_HOME`*`/bin` in its path.
2. Enter:

   `start_psub` *`database`* `45`

   where *`database`* is the connect string for the database instance to which the PSUB process connects.

If you are not logged on as rxcprod, you are prompted to provide the password for the rxcprod account. If the PSUB process is already running, the system displays an error message.

Changing the Startup of the PSUB Service on Windows

1. Navigate to the Control Panel, Services window, and select the PSUB service.
2. In the Services dialog box, select the PSUB Service and enter values for the Startup parameters (one string):

   ```
   database-connect-string code-environment [verbose | noverbose] value-of-RXC_
   ROOT
   ```

   For example:

   ```
   prod 46 verbose c:\\opapps\\oc\\46
   ```

3. Click **Start.**

Troubleshooting PSUB on a Windows Database

If you have difficulty starting PSUB on a Windows database after upgrading to or installing Oracle Clinical 4.6:

1. Open the sqlnet.ora file.
2. Locate the following line:

   ```
   sqlnet.authentication_service=(NTS)
   ```

3. Insert the pound symbol (#) at the beginning of the line to comment the line.
4. Attempt to start PSUB.

If PSUB fails to start:

1. Open the sqlnet.ora file.
2. Remove the pound symbol (#) from the following line:

   ```
   #sqlnet.authentication_service=(NTS)
   ```

3. Open the init.ora file. Ensure that the following lines are not commented out:

   ```
   remote_os_authen=true
   os_authent_prefix="OPS$"
   ```

4. Shut down any databases on the 2000 machine.
5. Bring the databases back up.
6. Open the sqlnet.ora file. Insert the pound symbol to comment out the following line:

   ```
   sqlnet.authentication_service=(NTS)
   ```

9.1.17 Change Default Passwords

You should change the default passwords of all schemas and roles and, if appropriate, use the set_pwd utility located at $RXC_BIN/set_pwd to encrypt the passwords in the database. See Appendix C of the *Oracle Clinical Administrator's Guide* for a list of users. (For instructions about how to change encrypted passwords and schema passwords, see the *Oracle Clinical Administrator's Guide*.)

9.2 Upgrading Forms Servers

The technology stack is different for Oracle Clinical 4.6 Forms Servers, so you must create new Forms Servers.

> **Note:** If you changed the default values of the DE_GRIDWIDTH and DE_GRIDHEIGHT parameters, record their values before you upgrade your Forms Servers. You must reset them to the same values after you upgrade in order for your Data Entry windows to appear correctly.

The general tasks for each installation are as follows:

1. Install a new Oracle Clinical 4.6 Forms Server. See Chapter 5.
2. Recompile customized forms. (See Section 9.2.1, "Upgrade Forms Server Customizations.")

9.2.1 Upgrade Forms Server Customizations

If they are relevant to your installation, perform the procedures in this section after you complete installing at least one of each of the essential Oracle Clinical 4.6 components. See *Interfacing from Oracle Clinical* for more information about these customizations.

9.2.1.1 Upgrade the User Menu

Oracle Clinical no longer includes the rxclbgen.pll file.

The rxcuser.pll file is located on the Forms Server in the OPA_HOME\oc\admin directory. If you customized rxcuser, upgrade the following files located in the Forms Server's Admin directory:

- Recompile rxcuser.fmb with Forms Builder 10*g*.
- Recompile rxcuser.mmb with Forms Builder 10*g*.
- Detach rxclbgen.pll from rxcuser.fmb, and attach rxcuser.pll.

Replace your recompiled rxcuser.fmb and rxcuser.mmb files on each Forms Server in your network.

9.2.1.2 Upgrade rxclbcli.pll

If you have customized rxclbcli.pll, recompile it with Forms Builder 10*g*. See Chapter 3 of *Interfacing from Oracle Clinical* for more information.

Replace your recompiled rxclbcli.pll file on each Forms Server in your network.

9.2.1.3 Change DE_GRIDWIDTH and DE_GRIDHEIGHT Parameters

If you modified the DE_GRIDWIDTH and DE_GRIDHEIGHT parameters, change them to their original values so your Data Entry screens have the correct appearance.

9.3 Upgrading Reports Servers

The technology stack is different for Oracle Clinical 4.6 Reports Servers, so you must create new Reports Servers. For instructions on how to install a new Oracle Clinical 4.6

Reports Server, see Chapter 6. The following two sections are other Reports Server upgrade tasks.

9.3.1 Replace the Placeholder DCF Logo Graphic

Oracle Clinical's Data Clarification Form (DCF) report system is a utility for generating paper forms from an Oracle report. The report includes a placeholder graphic named `rxcdcf.bmp`.

You can replace rxcdcf.bmp with your own graphic, or redraw it with a graphics drawing application.

rxcdcf.bmp is located on Oracle Clinical Reports Server installations in the *OPA_HOME*\oc directory (for example, c:\ `opapps\oc\)`. You can edit it locally and then copy it to your server.

9.3.2 Upgrade Customized DCF Reports

If you customized DCF Reports files rxcdrptl.rdf and rxcdrptp.rdf, recompile them with Oracle 10g DS Reports Developer Release 2. The source files are located on the Forms Server in the *OPA_HOME*\oc\admin directory.

9.4 Upgrading Clients

Configure your application tier browsers and your users' browsers according to the instructions in Chapter 7, "Setting Up Clients."

A

Migrating Data for Approvals and Verifications Enhancements

Oracle Clinical 4.6 includes enhancements for tracking changes to audit data and verifications that were introduced in the following companion patches: Oracle Clinical patch OC_4.5.3.11 and Oracle Clinical patch OC_4.5.3.12.

Oracle Clinical 4.6 runs the repairs from these patches, however, you must manually migrate your data from that repair.

This section describes modifying existing data to enable the Approvals and Verifications enhancements introduced in Oracle Clinical patch OC_4.5.3.11 and Oracle Clinical patch OC_4.5.3.12.

WARNING: If you applied patch OC_4.5.3.11 or any of its successors, skip the tasks in this section. Rerunning the Data Migration script can corrupt your data. If you installed patch OC_4.5.3.11 or any of its successors, you already prepared and migrated your data. Do not migrate data again. Skip this section.

This appendix includes the following topics:

A.1 Determining Requirements Before Migrating Data

The way in which Oracle Clinical internally stores approvals and verifications changed beginning with patch OC_4.5.3.11. You must apply patch OC_4.5.3.11 (or one of its successors) and then migrate your existing received DCIs to the new format for representing approvals and verifications.

Note: If you installed patch OC_4.5.3.11 (or one of its successors), you already prepared and migrated your data. You do not need to migrate data again when you install any patch that obsoletes patch OC_4.5.3.11.

The data migration may be a lengthy process. To minimize downtime and give users the maximum possible access during the data migration process, divide the process into two stages:

- Data preparation, which can be done while users are active on the system
- Data migration, which along with the application of the patch itself, must be done while the system is inaccessible to users

A.1.1 Benchmarks for Estimating the Downtime Required

The Preparation and Data Migration scripts were tested on two different database servers with different hardware configurations. Table A–1 shows the results of the tests. Neither the total load on the system nor the database configuration in either environment was captured. All other factors being equal, the execution time of both scripts is directly related to the number of received DCIs (RDCIs) being processed.

Table A–1 Time Estimates for Running the Preparation and Data Migration Scripts

Hardware Configuration	Number of RDCIs	Preparation Script[1]	Data Migration Script[2]
HP-UX Itanium RP 4440: 4x 1000 MHz CPUs (2 dual core processors) with 16 GB RAM	90,000	40 min (2250 RDCIs/minute)	6 minutes (15,000 RDCIs/minute)
Oracle Sun e6800: 4x 900 MHz CPUs (4 single core processors) with 8 GB RAM	12,000,000	18 hours (11,111 RDCIs/minute)	2 hours (100,000 RDCIs/minute)

[1] The system can be accessible to users while you run the Preparation script.

[2] The system MUST NOT be accessible to users while you run the Data Migration script.

A.1.2 Tablespace Size Requirements

The Preparation and Data Migration scripts create temporary tables and indexes, and recreate both existing indexes on the RDCI_HISTORY table.

All the temporary tables are created in the tablespace represented by the script variable tbl_tbs. The default value is `RXC_DEF_TSPA`. To determine your space requirements for this tablespace, use the following formula as a guideline and add additional space because the script performs direct inserts, and direct inserts insert the data after the HWM.

```
<number of received DCIs> * 3 records * 3 tables * 350 bytes =
number of bytes required without allowance for direct inserts
```

The indexes are all created in the tablespace represented by the script variable idx_tbs. The default value is `RXC_DEF_IDX_TSPA`. To determine your space requirements for this tablespace, use the following formula:

```
(<number of received DCIs> * 10) + (<number of received DCIs> *
70) + (<number of received DCIs> * 70)
```

The formulas above are based on the shipped default tablespace usage. If you changed the default tablespace names or usage, you need to recompute accordingly.

A.1.3 Required Tablespaces

Oracle Clinical 4.5 included two new tablespaces:

- TEST_DATA
- TEST_INDEX

Note that:

- If you installed Oracle Clinical 4.5 as a fresh install, Oracle Clinical automatically created these tablespaces for you.
- If you applied patch OC_4.5.1.30, you already addressed the tablespace issue during the installation of that patch.
- If you created your database before Oracle Clinical 4.5, performed upgrades only, and did not install patch OC_4.5.1.30, you must create tablespaces for test indexes. You can either create the TEST_DATA and TEST_INDEX tablespaces, or edit the oclupg4.5.3.11drvr.sql script and change the tablespace definition in the received_dcm_site_nfk_idxt index creation to an existing tablespace such as RXC_LI_IDX_TSPA.

A.2 Preparing for Data Migration

If you installed patch OC_4.5.3.11, you already prepared and migrated your data. Do not migrate data again.

A.2.1 About the Preparation Script

You can run the Preparation script while users have access to the system.

The Preparation script:

- Analyzes which studies to process. For the purpose of this analysis, *RDC studies* means studies in which approvals and verifications have been entered through RDC. *Oracle Clinical studies* means studies that do not include any RDC-entered approvals and verifications. The Preparation script labels each study as being in one of four categories for processing as follows:
  - RDC non-frozen studies. All non-frozen RDC studies are marked for migration.
  - RDC frozen studies. All frozen RDC studies are marked for migration.
  - Oracle Clinical non-frozen studies. All non-frozen Oracle Clinical studies are marked for migration.
  - Oracle Clinical frozen studies. Frozen Oracle Clinical studies will not be migrated. If you anticipate that you will unfreeze an Oracle Clinical study in the future and use RDC to perform approvals and verifications, contact Oracle.
- Identifies received DCIs, and their current approval and verification statuses, in a temporary table.
- Counts the number of received DCIs to be migrated.
- Produces an output file that tells you how many studies need to be migrated and how many received DCIs they contain.

You can use these counts to estimate the amount of time required to run the Data Migration script. See Section A.1.1, "Benchmarks for Estimating the Downtime Required" for more information.

A.2.2 Set Up for the Preparation Script

A.2.2.1 Setting Up UNIX for the Preparation Script

To set up UNIX systems for the Preparation script:

1. Set the environment variables for the database you are patching:

   ```
   opa_setup database_name 45
   ```

   where *database_name* is the name of your database.

2. Change to the RXC_INSTALL directory:

   ```
   cd $RXC_INSTALL
   ```

A.2.2.2 Setting Up Windows for the Preparation Script

To set up Windows systems for the Preparation script:

1. Log in to the server as an administrator.
2. Open an MS-DOS command window.
3. Set the environment variables for the database you are patching:

   ```
   set p1=database_name
   set p2=45
   opa_setup
   ```

   where *database_name* is the name of your database.

4. Change to the RXC_INSTALL directory:

   ```
   cd /d %RXC_INSTALL%
   ```

A.2.3 Run the Preparation Script for Data Migration

To run the Preparation script for data migration:

1. Open an SQL*Plus session, connecting as `opa`.
2. Edit the tablespace variable definitions at the top of the script as appropriate for your environment. For example:

   ```
   define tbl_tbs='TABLESPACE RXC_DEF_TSPA'
   ```

   ```
   define idx_tbs='TABLESPACE RXC_DEF_IDX_TSPA'
   ```

3. Ensure that there is enough space in each of the tablespaces you define for the amount of data you have. See Section A.1.2, "Tablespace Size Requirements" for more information.
4. Run the oclupg45311prepare.sql script. The script prompts you for the following passwords:

   ```
   OPA password
   RXC password
   ```

Once you enter your passwords, the script displays the new database session ID on screen.

A.2.4 Check the Progress of the Preparation Script

To view the progress of the script, connect as `opa` in a different session and enter the following command:

```
select * from opa_debug where sessionid = your_session_id
```

The script displays the database session ID on screen.

A.2.5 View the Output File Created by the Preparation Script

The preparation script creates the following output file:

`oclupg45311prepare-`*`dbname-yyyymmddhh24miss`*`.lis`

The output file, which is created in the same location as the script, includes the following information:

- A list of all studies in the database, with their categories, where *RDC study* means a study with RDC-entered approvals and verifications, and *Oracle Clinical study* indicates a study without such approvals or verifications:
  - RDC non-frozen studies. These studies are marked for migration.
  - RDC frozen studies. These studies are marked for migration.
  - Oracle Clinical non-frozen studies. These studies are marked for migration.
  - Oracle Clinical frozen studies. These studies are not marked for migration.
- A count of the received DCIs for each study to be migrated.

You can use these counts to estimate how long the Data Migration script will run. See Section A.1.1, "Benchmarks for Estimating the Downtime Required" for more information.

Note: CRFs created while the Preparation script is running may not be included in the count. However, they will be processed by the Data Migration script.

A.3 Before You Migrate Data

A.3.1 Prevent Access to Oracle Clinical Databases During Data Migration

You can run the Preparation script while users have access to the system. However, you must ensure that no data entry is performed, and no jobs that update data (such as batch validation) run during the rest of the installation and migration process, including:

- Run these diagnostic scripts and migrate data on each database.
  - On each database, back up the database. This step is very strongly recommended.
  - Install patch OC_4.5.3.11 on each database.

    - On each database, run the Data Migration script.
- Upgrade the application and report servers.
    - Install patch OC_4.5.3.11 on each Oracle AS10*g*R2 server. See the *Oracle Clinical Patch OC_4.5.3.11 Release Notes* for instructions.
    - Install patch OC_4.5.3.12 on the Oracle9*i* Application Server. See the *Oracle Clinical Patch OC_4.5.3.12 Release Notes* for instructions.
    - Install patch OC_4.5.3.12 on the AS10*g*R1 Reports Server and restart the Report Server services. See the *Oracle Clinical Patch OC_4.5.3.12 Release Notes* for instructions.

To prevent users from accessing the data during migration and upgrade (applying the patch), place the database in restricted mode. Provide restricted session access to the following accounts used by the Data Migration script:

- OPA
- RXC
- RXA_DES
- RXC_SERVLETST
- SYSTEM

After the database has been upgraded and data migration has finished, remove the restricted access from the databases and user accounts.

If users have access to RDC at any point in this process, approval and verification statuses will be misrepresented in all RDC user interfaces and RDC-entered approvals and verifications will not be correctly captured. These changes are not recoverable and must be reentered.

A.3.2 Back Up the Databases Before Data Migration

Oracle strongly recommends that you have a complete database backup available for each database before applying the patch. If any users make changes to data while you are applying the patch or running the Data Migration script, data will be corrupted. The only way to correct the data is to restore the database from the backup and reenter the data updated or added during the installation and data migration process.

A.4 Patching Each Oracle Clinical Database

Follow these instructions to patch each Oracle Clinical database.

A.4.1 Patch Each Oracle Clinical Database on a UNIX Server

To patch each Oracle Clinical 4.5.3 database on a UNIX server:

1. Set the environment variables for the database you are patching:

   `opa_setup` *database_name* `45`

   where *database_name* is the name of your database

2. Change to the RXC_INSTALL directory:

   `cd $RXC_INSTALL`

3. Open an SQL*Plus session, connecting as `opa`.

4. Confirm that you are connected to the correct database. The following SQL statement returns the name of the current database:

   ```
   select * from global_name;
   ```

5. Run the patch driver script:

   ```
   start oclupg4.5.3.11drvr.sql
   ```

6. Exit from SQL*Plus.

7. Review the generated log files for errors:

   - oc4.5.3.11_*database_datetime*.log
   - xmlp_clob_seeddata_*database_datetime*.log
   - compile_all_invalid.log

   Work with Oracle Support, if necessary, to resolve any errors.

8. Repeat these instructions for each Oracle Clinical database on this Windows server.

When you have applied the patch to all appropriate databases, you have completed the application of the patch on this UNIX server.

A.4.2 Patch Each Oracle Clinical Database on a Windows Server

To patch each Oracle Clinical 4.5.3 database on a Windows server:

1. Log in to the server as an administrator.
2. Open an MS-DOS command window.
3. Set the environment variables for the database you are patching:

   ```
   set p1=database_name
   set p2=45
   opa_setup
   ```

   where *database_name* is the name of your database.

4. Determine the location of the ORACLE_HOME directory on this server:

   a. Open the Windows Registry Editor. (Click Start, click Run, enter `regedit`, and then click OK.)

   b. Navigate to the following key:

      HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE\KEY_*oraclehomename*

   c. Double-click ORACLE_HOME, and note its location. This value is commonly *drive*:\oracle\ora92080. The remaining instructions refer to this location as the *ORACLE_HOME_VALUE*.

   d. Exit from the Windows Registry Editor.

5. Define the ORACLE_HOME environment variable to ensure that the driver script can locate the import utility:

   ```
   set oracle_home=ORACLE_HOME_VALUE
   ```

6. Change the working directory to the INSTALL directory:

   ```
   cd /d OPA_HOME_VALUE\oc\45\install
   ```

7. Open an SQL*Plus session, connecting as `opa`.

8. Confirm that you are connected to the correct database. The following SQL statement returns the name of the current database:

   ```
   select * from global_name;
   ```

9. Run the patch driver script:

   ```
   start oclupg4.5.3.11drvr.sql
   ```

10. Exit from SQL*Plus.

11. Review the generated log files for errors:

    - ocl4.5.3.11_*database_datetime*.log
    - xmlp_clob_seeddata_*database_datetime*.log
    - compile_all_invalid.log

    Work with Oracle Support, if necessary, to resolve any errors.

12. Repeat these instructions for each Oracle Clinical database on this Windows server.

When you have applied the patch to all appropriate databases, you have completed the application of the patch on this Windows server.

A.5 Migrating Your Data

A.5.1 About the Data Migration Script

The Data Migration script:

- Upgrades all live (unfrozen) studies, whether they use RDC or not.
- Upgrades all frozen studies that used RDC (specifically, that have approvals and verifications).
- Does not migrate data for frozen studies that do not have approvals and verifications. CRFs in Oracle Clinical frozen studies are displayed as not approved and not verified both before and after the application of the patch, when viewed through RDC. If you anticipate that you will unfreeze an Oracle Clinical study in the future and use RDC to perform approvals and verifications, contact Oracle.

The Data Migration script processes all studies that the Preparation script determined should be migrated (3 out of 4 categories). In addition, the Data Migration script identifies and compensates for updates that were made during and after the Preparation script was executed, so normal data entry activities can continue while the Preparation script is running. However, you should ensure that users do not make the following study-level change during this time:

Do not unfreeze a frozen Oracle Clinical study that never used RDC (specifically, has no approvals or verifications).

If you do, only newly created CRFs are migrated. The existing data continues to be represented as not approved and not verified. If you anticipate that you will start using RDC to perform approvals and verifications for existing CRFs in a frozen non-RDC study, contact Oracle.

To minimize the downtime required, run the Data Migration script as soon as possible after running the Preparation script.

A.5.2 Set Up the Environment Before Migrating Data

A.5.2.1 Setting Up UNIX Before Running the Data Migration Script

1. Set the environment variables for the database you are patching:

   ```
   opa_setup database_name 45
   ```

   where *database_name* is the name of your database.

2. Change to the RXC_INSTALL directory:

   ```
   cd $RXC_INSTALL
   ```

A.5.2.2 Setting Up Windows Before Running the Data Migration Script

1. Log in to the server as an administrator.
2. Open an MS-DOS command window.
3. Set the environment variables for the database you are patching:

   ```
   set p1=database_name
   set p2=45
   opa_setup
   ```

   where *database_name* is the name of your database.

4. Change to the RXC_INSTALL directory:

   ```
   cd /d %RXC_INSTALL%
   ```

A.5.3 Run the Data Migration Script

Note: If you installed patch OC_4.5.3.11, you already ran the Data Migration script to migrate your data. You do not need to run the script again.

To run the Data Migration script:

1. Open an SQL*Plus session, connecting as `opa`.
2. Edit the tablespace variable definitions at the top of the script as appropriate for your environment. For example:

   ```
   define tbl_tbs='TABLESPACE RXC_DEF_TSPA'

   define idx_tbs='TABLESPACE RXC_DEF_IDX_TSPA'
   ```

   Ensure that there is enough space in each of the tablespaces you define for the amount of data you have. See Section 9.1.6, "Review Tablespace Sizes" for details.

3. Run the oclupg45311migrate.sql script. The script prompts you for the following passwords:

   ```
   OPA password
   RXC password
   ```

   Once you enter your passwords, the script displays the new database session ID on screen.

A.5.4 Check the Progress of the Data Migration Script

To view the progress of the script, connect as `opa` in a different session and enter the following command:

```
select * from opa_debug where sessionid = your_session_id
```

The script displays the database session ID on screen.

A.5.5 View the Output File Created by the Data Migration Script

The Data Migration script creates the following output file:

`oclupg45311migrate-`*`dbname-yyyymmddhh24miss`*`.lis`

This output file, which is created in the same location as the script, tracks the progress of the job and provides the following information:

- If any entries have been inserted into the OPA_DEBUG table in the current database session, an indication that they are being deleted
- The database session ID for the current script execution
- The number of CRFs that were created and modified between the time the Preparation script started running and the time the Data Migration script started, for which the approval and verification statuses are recomputed
- An indication that entries are being written to the OPA_DEBUG table
- Information about enabling and disabling logging, triggers, and indexes
- An indication that rows are being deleted from the OPA_DEBUG table, which means that those rows have successfully finished processing

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