Oracle® Clinical
Installation Guide
Release 4.6.2
E18817-04

December 2013
This guide describes how to install, configure, and upgrade Oracle Clinical. It has been updated to include information on installing the database tier on Windows, which is supported with Patch Set 4.6.4 or its successor.
# Preface

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Preface

This Oracle Clinical Installation Guide describes installing — or upgrading to — Oracle Clinical Release 4.6.2. You perform some of these tasks once. Others you repeat as your system changes or grows.

This preface contains the following topics:

- **Audience** on page xi
- **Documentation Accessibility** on page xii
- **Finding Information and Patches on My Oracle Support** on page xii
- **Finding Oracle Documentation** on page xiv
- **Related Documents** on page xiv
- **Conventions** on page xiv

### 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
For information about Oracle’s commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Access to Oracle Support
Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs 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 Oracle Clinical, always visit the My Oracle Support Web site for the latest information, including alerts, White Papers, installation verification (smoke) tests, 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 https://support.oracle.com.
2. Click the Register 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 https://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.

Finding Information on My Oracle Support
There are many ways to find information on My Oracle Support.
Searching by Article ID
The fastest way to search for information, including alerts, White Papers, installation verification (smoke) tests, and bulletins is by the article ID number, if you know it.

To search by article ID:
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.

Searching by Product and Topic
You can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page under Select Product, type part of the product name and the system immediately filters the product list by the letters you have typed. (You do not need to type "Oracle.") Select the product you want from the filtered list and then use other search or browse tools to find the information you need.

- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find information. This option is available from the Advanced link on almost all pages.

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:
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 field, enter the number of the patch you want. (This number is the same as the primary bug number fixed by the patch.) 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 Oracle Documentation

The Oracle Web site contains links to all Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences Documentation

To get user documentation for Oracle Health Sciences applications, go to the Oracle Health Sciences documentation page at:


Note: Always check the Oracle Health Sciences Documentation page to ensure you have the latest updates to the documentation.

Finding Other Oracle Documentation

To get user documentation for other Oracle products:

1. Go to the following Web page:
   http://www.oracle.com/technology/documentation/index.html
   Alternatively, you can go to http://www.oracle.com, point to the Support tab, and then click Documentation.

2. Scroll to the product you need and click the link.

3. Click the link for the documentation you need.

Related Documents

This section lists the documents in the Oracle Clinical documentation set, followed by their part number. The most recent version of each guide is posted on the Oracle Web site; see "Finding Oracle Health Sciences Documentation" on page xiv.

- Oracle Clinical Installation Guide (Part E18817)
- Oracle Clinical Administrator’s Guide (Part E18818)
- Oracle Clinical Getting Started (Part E18819)
- Oracle Clinical Creating a Study (Part E18820)
- Oracle Clinical Conducting a Study (Part E18821)
- Oracle Clinical Application Programming Interface Guide (Part E18866)
- Oracle Clinical Remote Data Capture Onsite Administrator’s Guide (Part E18823)
- Oracle Clinical Remote Data Capture Onsite User’s Guide (Part E18822)
- Oracle Clinical Remote Data Capture Classic Data Entry User’s Guide (Part E18824)

The release notes and the release content document are also posted in the Oracle Health Sciences documentation library.

In addition, Oracle Clinical customers can request a copy of the Oracle Clinical Stable Interface Technical Reference Manual from Oracle Support.

Conventions

The following text conventions are used in this document:
<table>
<thead>
<tr>
<th>Convention</th>
<th>Meaning</th>
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<tr>
<td><strong>boldface</strong></td>
<td>Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.</td>
</tr>
<tr>
<td><em>italic</em></td>
<td>Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.</td>
</tr>
<tr>
<td><strong>monospace</strong></td>
<td>Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.</td>
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Preparing to Install Oracle Clinical

This chapter describes Oracle Clinical’s architecture, the 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:

- Section 1.1, "Oracle Clinical Architecture"
- Section 1.2, "Oracle Clinical and RDC 4.6.2 Technology Stack"
- Section 1.3, "Product Organization, Licenses, and Related Install Documentation"
- Section 1.4, "Choosing a Character Set"
- Section 1.5, "Downloading the Media Pack"
- Section 1.6, "Planning an Oracle Clinical Database Tier Installation"
- Section 1.7, "Planning an Oracle Clinical Application Tier Installation"
- Section 1.8, "Planning an Oracle Clinical Client Installation"
- Section 1.9, "Integrating Oracle Clinical with Other Products and Options"
- Section 1.10, "Applying Oracle Critical Patch Updates"
- Section 1.11, "Applying the Latest Oracle Clinical Patch Set"
- Section 1.12, "Following the Installation Constraints and Order"
- Section 1.13, "Reviewing the Installation Log Files"

1.1 Oracle Clinical Architecture

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

Figure 1–1 illustrates the architecture and technology stack for Oracle Clinical.
The **database tier** in an Oracle Clinical environment includes Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1, 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 10g Release 3 (Oracle AS10gR3), Oracle Application Server 10g Release 2 (Oracle AS10gR2), 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.
1.2 Oracle Clinical and RDC 4.6.2 Technology Stack

Table 1–1 lists the technology stack requirements for the database tier, the application tier, and the client tier for Release 4.6.2 of Oracle Clinical and RDC.

For information about updates to the technology stack, see Oracle Life Sciences Applications Supported Technology Stacks (Article ID 180430.1) on My Oracle Support.

Table 1–1 Oracle Clinical and RDC 4.6.2 Technology Stack

<table>
<thead>
<tr>
<th align="center"><strong>Database Tier</strong></th>
<th align="center"></th>
</tr>
</thead>
<tbody>
<tr>
<td align="center"><strong>Operating System</strong></td>
<td align="center">Oracle Enterprise Linux 5 Update 5 x86-64; 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Oracle Solaris SPARC 10; 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">HP-UX Itanium 11i v3 (11.31); 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Windows Server 2008 Release 2, Service Pack 1; 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"><strong>Oracle Database</strong></td>
<td align="center">11g Release 2 (11.2.0.2.0)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Enterprise Edition</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">64-bit</td>
</tr>
<tr>
<td align="center"><strong>Compiler</strong></td>
<td align="center">For Oracle Enterprise Linux x86-64: GNU GCC-4.1.2</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">For Oracle Solaris SPARC 10: Oracle Sun ONE Studio 12 Update 2</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">For HP-UX Itanium: HP C/C++ B3910B A.06.20</td>
</tr>
<tr>
<td align="center"><strong>Additional Software</strong></td>
<td align="center">SAS 9.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th align="center"><strong>Application Tier</strong></th>
<th align="center"></th>
</tr>
</thead>
<tbody>
<tr>
<td align="center"><strong>Operating System</strong></td>
<td align="center">Microsoft Windows Server 2008; Release 2; Service Pack 1; 64-bit architecture</td>
</tr>
<tr>
<td align="center"><strong>Oracle Application Server</strong></td>
<td align="center">Oracle Application Server 10g Release 2 (10.1.2.0.2)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Oracle Application Server 10g Release 2 Patch Set 3 (10.1.2.3.0)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Oracle Application Server 10g Release 3 (10.1.3.1.0)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Oracle Application Server 10g Release 3 Patch Set 5 (10.1.3.5.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th align="center"><strong>Client Tier</strong></th>
<th align="center"></th>
</tr>
</thead>
<tbody>
<tr>
<td align="center"><strong>Operating System</strong></td>
<td align="center">Microsoft Windows XP; Service Pack 1, 2, or 3; 32-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows Vista; Service Pack 1; 32-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows 7; Service Pack 1; 32-bit or 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows Server 2008; Release 2; Service Pack 1; 64-bit architecture (US English)</td>
</tr>
<tr>
<td align="center"><strong>Microsoft Internet Explorer</strong></td>
<td align="center">Supported version depends on operating system:</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows XP: Internet Explorer 7 or 8</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows Vista: Internet Explorer 7 or 8</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows 7: Internet Explorer 8 or 9</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Microsoft Windows Server 2008: Internet Explorer 8</td>
</tr>
<tr>
<td align="center"><strong>Adobe Reader</strong></td>
<td align="center">Release 7.x or later (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Required for viewing reports, including Patient Data Reports (PDRs)</td>
</tr>
<tr>
<td align="center"><strong>Adobe Acrobat</strong></td>
<td align="center">Release 7.x or 8.x (US English)</td>
</tr>
<tr>
<td align="center"></td>
<td align="center">Required for creating annotated layouts</td>
</tr>
<tr>
<td align="center"><strong>Oracle Java Runtime Environment (JRE)</strong></td>
<td align="center">Java SE 6 Update 24 (Standard Edition, Version 1.6.0.24) or later</td>
</tr>
</tbody>
</table>

1.3 Product Organization, Licenses, and Related Install Documentation

This section describes the name changes to the organizational unit that includes the Oracle Clinical products, the licenses required for the RDC application, and the additional documentation to review for important installation topics.
**Oracle Health Sciences Global Business Unit**

The Oracle Clinical and Oracle Clinical Remote Data Capture products are now part of the Oracle Health Sciences Global Business Unit (HSGBU). These products were formerly part of the Oracle Life Sciences Applications (OLSA) and the Oracle Pharmaceutical Applications (OPA) organizations. During the installation, you will see references to OLSA and OPA in the software (such as in directory names, file names, and screen text) that have not been changed.

**License for Using 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.

**Release Notes, Bulletins, and White Papers**

Visit the My Oracle Support Web site for the most up-to-date installation information, including alerts, release notes, bulletins, White Papers, and patches; see "Finding Information and Patches on My Oracle Support" on page xii.

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 Notes* (Part E18815-01)
- *OLSA 4.6.x and 4.7.x Known Install and Configuration Issues* (Article ID 386941.1)
- *Configuring Oracle Clinical Remote Data Capture Onsite 4.6.2 for Performance and Scalability* (Article ID 1300850.1)
- *Oracle Clinical RDC Onsite 4.6 and 4.6.2 Installation Verification Test* (Article ID 966171.1)
- *Oracle Clinical Versions 4.6.2, 4.6, 4.5 and 4.0 Summary of Patches Available* (Article ID 121863.1)
- *Oracle Clinical, Oracle Clinical Remote Data Capture Onsite, and Oracle Thesaurus Management System Security Configuration Guide* (Article ID 1300836.1)

### 1.4 Choosing a Character Set

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

For Oracle Clinical and RDC, Oracle strongly recommends that you use the UTF8 character set (default). These applications support UTF8, US7ASCII, WE8ISO8859P1, or any single byte character set.

Oracle Clinical and RDC use the NLS_LANG environment variable to control the *language, territory, and character set* used for database connections. The NLS_LANG variable concatenates the three components as follows:

```
LANGUAGE_TERRITORY.CHARSET
```

The default installation configures the Oracle Clinical and RDC applications to use the following character set:

```
AMERICAN_AMERICA.UTF8
```
You must set the CHARSET component of the NLS_LANG variable to match the character set of the database.

Make sure you 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.

1.5 Downloading the Media Pack

Oracle Clinical 4.6.2 and its technology stack are contained on the Oracle Clinical 4.6.2 and Oracle Thesaurus Management System 4.6.2 media pack for various platforms.

To receive a physical media pack with all the required DVDs, contact Oracle Support. To expedite your request you can either call Oracle Support directly or open a Service Request (SR) selecting problem category: Version Update Request.

To download the media pack from the Oracle Software Delivery Cloud:

2. From the Select a Product Pack drop-down list, select Health Sciences.
3. From the Platform drop-down list, select the appropriate operating system.
4. Click Go.

**Note:** If this media pack is the only one available in Health Sciences for the platform you selected, the system takes you immediately to the media pack page from which you can download the software disk by disk.

5. Select Oracle Clinical 4.6.2 and Oracle Thesaurus Management System 4.6.2 Media Pack for Your Operating System and click Continue.
6. Download the software.

1.6 Planning an Oracle Clinical Database Tier Installation

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

1.6.1 Database Tier Operating System Requirements

The database tier for Oracle Clinical supports these operating systems:

- Oracle Enterprise Linux 5 Update 5 x86-64 (64-bit architecture, US English)
- Oracle Solaris SPARC 10 (64-bit architecture, US English)
- HP-UX Itanium 11.31 (64-bit architecture, US English)
- Windows Server 2008 Release 2, Service Pack 1 (64-bit architecture, US English)

**UNIX** To verify UNIX operating system details, enter the following command:

```
uname -a
```

In addition, to verify the update version for Linux, enter the following command:

```
cat /etc/issue
```
Windows
To verify Windows operating system details, navigate to the Control Panel, then System and Security, then System.

1.6.2 Database Tier Character Set Requirements
For information about the guidelines and requirements for character sets, see Section 1.4, "Choosing a Character Set."

1.6.3 Database Tier System Requirements
For database tier system requirements, see the Oracle Database 11g Release 2 (11.2) Installation Guide for your operating system.

1.6.3.1 C Run-time Libraries on UNIX Database Servers
The Oracle Clinical Database Server requires C run-time libraries installed on the server. Table 1–2 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>
<thead>
<tr>
<th>Operating System</th>
<th>Supported C Compiler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>GNU GCC-4.1.2</td>
</tr>
<tr>
<td>Oracle Solaris SPARC 10</td>
<td>Oracle Sun ONE Studio 12 Update 2</td>
</tr>
<tr>
<td>HP-UX Itanium 11.31</td>
<td>HP C/C++ B3910B A.06.20</td>
</tr>
</tbody>
</table>

1.6.4 Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Requirements and Options
Oracle Clinical requires Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1, Enterprise Edition.

1.6.4.1 Required Reading
Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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 11g Release 2 (11.2.0.2) Patch Set 1 installation documentation
-Latest platform-specific Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation bulletin that is available on My Oracle Support
- Latest supported component versions and alerts related to Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 and Oracle Health Sciences applications that are available on My Oracle Support

1.6.4.2 Oracle Text Option
Choose to install the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Text Option. Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 includes the Oracle Text Option, but note that installing and using it requires purchasing a separate license.

1.6.4.3 Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Partitioning Option
Oracle Clinical supports partitioning, but this feature is disabled by default. You must buy and install the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Partitioning Option. See the Oracle Clinical Administrator’s Guide for information about partitioning.
1.6.4.4 Oracle Distributed Study Conduct Option

In addition to the standard Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation, the Distributed Study Conduct Option for Oracle Clinical requires the following Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 options:

- Distributed Database Option
- Advanced Replication Option

See the Oracle Clinical Administrator’s Guide to configure the proper codelists and database links to support replication, and for setup instructions.

1.6.5 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.

1.6.6 Database Seed Numbers in a Replicated Environment

When you create an Oracle Clinical database, Oracle 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.

1.7 Planning an Oracle Clinical Application Tier Installation

The application tier includes the Forms Server and Reports Server components. Oracle Application Server 10g Release 2 includes the Forms Server and Reports Server components in the same installation. You can add extra Reports Servers by installing Oracle Application Server 10g Release 2 on additional computers.

1.7.1 Application Tier Operating System Requirements

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

- Microsoft Windows Server 2008
- Release 2
- Service Pack 1
- US English

1.7.2 Application Tier Character Set Requirements

For information about the guidelines and requirements for character sets, see Section 1.4, "Choosing a Character Set.”

1.7.3 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.
1.7.3.1 Critical Patch Update
You must obtain the latest Critical Patch Update (CPU) approved by Oracle Health Sciences from My Oracle Support.

1.7.3.2 Permanent IP Address
Each Forms Server computer must have a permanent IP address.

1.7.3.3 Oracle Application Servers
Oracle Clinical requires Oracle Application Server 10g Release 3 and Oracle Application Server 10g Release 2 Forms and Reports Services.

1.7.3.4 Java Runtime Environment
The Java Runtime Environment, or JRE (also known as Java Virtual Machine or JVM), is the Java applet required to run an Oracle Clinical or a RDC Classic session.


1.7.3.5 Shared Directory on Application Server
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.

1.7.3.6 Planning File Viewing and Associated Directories
PSUB jobs require user log directories on the Database Server; Reports Server jobs require user log directories on a server accessible to the Reports Server. When you install the Forms Server, you can select SFTP or UNC as the default protocol for viewing the files generated by the PSUB and Reports Server jobs. Oracle Clinical also supports FTP, HTTP, and HTTPS for file viewing.

For information about implementing SFTP for file viewing, see Chapter 9. For information about changing the file viewing protocol after the installation, see the Oracle Clinical Administrator’s Guide.

1.7.4 Reports Server Requirements
The Reports Server runs reports, schedules PSUB jobs and reports, and outputs to screen or printers.

1.7.4.1 Critical Patch Update
You must obtain the latest Critical Patch Update (CPU) approved by Oracle Health Sciences from My Oracle Support.

1.7.4.2 Permanent IP Address
Each Reports Server computer must have a permanent IP address.

1.7.4.3 Oracle Application Servers
Oracle Clinical requires Oracle Application Server 10g Release 3 (Oracle AS10gR3) and Oracle Application Server 10g Release 2 Forms and Reports Services (Oracle AS10gR2).
1.7.4.4 Load Tuning Reports Servers
The Oracle Universal Installer sets the maximum number of simultaneously running Reports Server engines (\textit{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, do not set this number lower than two.

The Installer sets the \textit{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 \textit{maxEngine} to $4 \times x$, where $x$ is the number of CPUs. For more information, see the Oracle Reports Server documents and White Papers about load tuning.

1.8 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.

1.8.1 Client Tier Operating System Requirements
Oracle Clinical supports the following Microsoft operating systems for the client:
- Windows XP; Service Pack 1, 2, or 3; 32-bit architecture (US English)
- Windows Vista; Service Pack 1; 32-bit architecture (US English)
- Windows 7; Service Pack 1; 32-bit or 64-bit architecture (US English)
- Windows Server 2008; Release 2; Service Pack 1; 64-bit architecture (US English)

1.8.2 Client Tier Application Requirements
To access Oracle Clinical, RDC Onsite, or RDC Classic, clients must have these applications installed:
- Microsoft Windows Internet Explorer.
  - For Windows XP: Internet Explorer 7 or 8
  - For Windows Vista: Internet Explorer 7 or 8
  - For Windows 7: Internet Explorer 8 or 9
  - For Windows Server 2008: Internet Explorer 8
- Adobe Reader and Adobe Acrobat.
  - To view reports, including Patient Data Reports (PDRs), Adobe Reader, Release 7.x or later, US English versions.
  - For annotated layouts, Adobe Acrobat 7.x or 8.x, US English versions.

In addition, a client requires an intranet or internet connection.
1.9 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.

1.9.1 Oracle Remote Data Capture

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

- RDC Onsite 4.6.2
- RDC Classic 4.6.2 (based on the legacy character layout system)

For information about using these products, see the Oracle Clinical Remote Data Capture Onsite User’s Guide and the Oracle Clinical Remote Data Capture Classic Data Entry User’s Guide.

1.9.2 Oracle Thesaurus Management System

To integrate Oracle Thesaurus Management System (TMS) with Oracle Clinical, you can install TMS and Oracle Clinical on the same application tier or on different application tiers. You must install both products on the same database.

For more information, see the Oracle Thesaurus Management System Installation Guide.

1.9.3 Siebel Clinical

You can integrate Siebel Clinical with Oracle Clinical. Release 4.6.2 automatically includes the Oracle Clinical portion of the integration. In addition, you must configure new Web services. For details, see the Oracle Clinical Application Programming Interface Guide.

1.9.4 SAS 9.2 Software

Oracle Clinical 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 about interfacing Oracle Clinical with the SAS statistical software application, see Chapter 11, "Setting Up SAS."

1.9.5 Custom Applications for Oracle Clinical

For developers building applications for Oracle Clinical:

---

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

- See the Oracle Clinical Stable Interface Technical Reference Manual for proprietary information about data access, internal tables, and APIs. Oracle Clinical Stable Interface provides an easy access to data and a smooth transition between Oracle Clinical versions. If you are a licensed customer, contact Oracle Support to obtain a free electronic copy of the manual.
- See the Oracle Clinical Application Programming Interface Guide for information about using Oracle Clinical’s Data Capture API.

1.10 Applying Oracle Critical Patch Updates

Every quarter, Oracle provides Critical Patch Updates (CPUs) to address security vulnerabilities. Install these patches on every computer with an Oracle Home. Check My Oracle Support for information about the latest patch tested with Oracle Health Sciences applications. Article ID 180430.1, Oracle Health Sciences Supported Technology Stacks, lists the latest CPUs supported and contains a link to the separate article about each one.

1.11 Applying the Latest Oracle Clinical Patch Set

Check My Oracle Support article Oracle Clinical Versions 4.6.2, 4.6, 4.5 and 4.0 Summary of Patches Available (Article ID 121863.1) for the latest patch set (4.6.4 or its successor) and apply it. This will provide you with the latest bug fixes and validate the data migration status of all your studies. See the patch set release notes for more information.

If you are installing your database on Windows, you must apply the latest patch set. Oracle Clinical is not supported on Windows without Patch Set 4.6.4 or later.

1.12 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 11g Release 2 (11.2.0.2) Patch Set 1 installation 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. See Chapter 2.
2. Create an Oracle Clinical database. See Chapter 4.
3. Install Oracle Application Server. See Chapter 5.
4. Install Oracle Clinical Front End (Forms Server and more). See Chapter 6.

1.13 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/oraInventory/logs

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

installActions2011-04-30_11-22-52AM.log
2

Installing Oracle Clinical Database Server on UNIX

This chapter describes how to install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 and Oracle Clinical Database Server products on a UNIX computer.

This chapter includes the following topics:

- Section 2.1, "Performing Prerequisite Tasks for Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1"
- Section 2.2, "Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1"
- Section 2.3, "Setting Permissions and Write Access to Oracle-Owned Directories"
- Section 2.4, "Setting Up User Groups and Accounts"
- Section 2.5, "Installing the Oracle Clinical Database Server"
- Section 2.6, "Performing Post-installation Tasks"

If you are upgrading to Oracle Clinical 4.6.2, see Chapter 12.

2.1 Performing Prerequisite Tasks for Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

To ensure that your platform meets the minimum requirements for installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 and Oracle Clinical Database Server products, you must perform the following preparatory tasks:

- Create Owners, Groups, and Mount Points
- Configure Kernel Resources and Adjust Operating System Environment
- Test the C Compiler Installation
- Install Latest Operating System Patches

2.1.1 Create Owners, Groups, and Mount Points

To create the software owner, required groups, and mount points:

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. Test permissions. Ensure that the oracle user can write to the new mount points and all subdirectories.

### 2.1.2 Configure Kernel Resources and Adjust Operating System Environment

The performance of Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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, see the "Configure Kernel Parameters" section of the Oracle Database 11g Release 2 Installation Guide for your operating system.

### 2.1.3 Test 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>
<thead>
<tr>
<th>Operating System</th>
<th>Response</th>
<th>Symbolically Links To</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>/usr/bin/gcc</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>Oracle Solaris SPARC</td>
<td>/opt/SUNWspro/bin/cc</td>
<td>../prod/bin/cc</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>/bin/cc</td>
<td>/opt/aCC/bin/cc</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Operating System</th>
<th>Response</th>
<th>Symbolically Links To</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>/usr/bin/make</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>Oracle Solaris SPARC</td>
<td>/usr/ccs/bin/make</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>/bin/make</td>
<td>/usr/bin/ccs/make</td>
</tr>
</tbody>
</table>

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.
2.1.4 Install Latest Operating System Patches

Download and install the latest operating system patches required for Oracle, if necessary. Review the latest platform-specific install bulletins for Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1.

2.2 Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

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

Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1
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 required to install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1:

- Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1
- Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Examples
- Install Patch 10213073 to Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1
- Install CPU/PSU 10248523

2.2.1 Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

To install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1:

1. Locate the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 software for your operating system on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 operating_system Tech Stack Patches disk in the media pack:

<table>
<thead>
<tr>
<th>Operating System</th>
<th>Zip File</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>p10098816_112020_Linux-x86-64_xof7.zip</td>
</tr>
<tr>
<td>Oracle Solaris SPARC</td>
<td>p10098816_112020_SOLARIS64_xof7.zip</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>p10098816_112020_HPUX-IA64_xof7.zip</td>
</tr>
</tbody>
</table>

2. Follow the instructions in the Oracle Database 11g Release 2 (11.2) Installation Guide for your respective operating system to install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1.

3. Choose to install the Enterprise Edition option.

2.2.2 Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Examples

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

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

To install Oracle Database Examples:
1. Navigate to the folder where you extracted the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 software.
2. Change to the examples directory.
3. Start Oracle Universal Installer from the examples directory and install Oracle Database Examples.
4. Accept all the default values during the installation.

For more information about installing software and various Oracle product demonstrations from the Oracle Database Examples media, see the Oracle Database Examples Installation Guide.

### 2.2.3 Install Patch 10213073 to Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

To install patch 10213073 to the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation:

1. Locate the appropriate Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 patch for your operating system on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 operating_system Tech Stack Patches disk in the media pack:

<table>
<thead>
<tr>
<th>Operating System</th>
<th>Path</th>
<th>Zip File</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>/patches</td>
<td>p10213073_112020_Linux-x86-64.zip</td>
</tr>
<tr>
<td>Oracle Solaris SPARC</td>
<td>/patches</td>
<td>p10213073_112020_SOLARIS64.zip</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>/patches</td>
<td>p10213073_112020_HPUX-IA64.zip</td>
</tr>
</tbody>
</table>

2. Extract the patch zip file to a location that is accessible to the Database Server.
3. Follow the operating system-specific instructions in the ReadMe file to apply patch 10213073 to the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation. The ReadMe file is located at the top level of the patch set extraction location.

### 2.2.4 Install CPU/PSU 10248523

Every quarter, Oracle provides Critical Patch Updates (CPUs) to address security vulnerabilities, and Patch Set Updates (PSUs) to address proactive, critical fixes and security vulnerabilities.

CPU/PSU 10248523 is current as of this document release and current with the information in the Oracle Health Sciences Applications Critical Patch Update for January 2011 note on My Oracle Support. Be sure to check My Oracle Support for the latest version of CPUs and PSUs, and then apply the latest patch approved for the Oracle Health Sciences applications.

To install CPU/PSU 10248523:

1. Locate the appropriate Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 patch for your operating system on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 operating_system Tech Stack Patches disk in the media pack:

<table>
<thead>
<tr>
<th>Operating System</th>
<th>Path</th>
<th>Zip File</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>/patches</td>
<td>p10248523_112020_Linux-x86-64.zip</td>
</tr>
</tbody>
</table>
2. Extract the patch file to a location that is accessible to the Database Server.

3. Follow the operating system-specific instructions in the ReadMe file to apply patch 10248523 to the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation. The ReadMe file is located at the top level of the patch set extraction location.

### 2.3 Setting Permissions and Write Access to Oracle-Owned Directories

After you install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 and before you install the Oracle Clinical component, you must:

- **Change Permissions for Running oraenv Script**
- **Grant Access to the ORACLE_HOME Directory**
- **Set Permissions for the Oracle Inventory Directory**

Note: You might have to perform these instructions whenever you apply an HSGBU-approved Critical Patch Update, or any Oracle software that uses the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 ORACLE_HOME directory.

#### 2.3.1 Change Permissions for Running oraenv Script

With the Bourne shell, you use the Oracle environment-setting script (`oraenv`) when granting write access to the ORACLE_HOME directory.

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

#### 2.3.2 Grant Access to the ORACLE_HOME Directory

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.

To grant write access to the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 ORACLE_HOME directory and its contents:

1. Log in to the server as the `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 11g Release 2 (11.2.0.2) Patch Set 1 installation.

---

<table>
<thead>
<tr>
<th>Operating System</th>
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<td>Oracle Solaris SPARC</td>
<td>/patches</td>
<td>p10248523_112020_SOLARIS64.zip</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>/patches</td>
<td>p10248523_112020_HPUX-IA64.zip</td>
</tr>
</tbody>
</table>

---
Note that the oraenv script gives an error if run by a non-Oracle user. To avoid this error, see Section 2.3.1, "Change Permissions for Running oraenv Script" for setup instructions.

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.

### 2.3.3 Set Permissions for the Oracle Inventory Directory

To set the permissions for the Oracle Inventory (oraInventory) directory:

1. Log in to the server as the oracle user.

2. Locate the path for the oraInventory directory. The location is defined in the inventory_loc parameter 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/oraInventory
   
3. Give recursive read and write permission for the oraInventory directory to the group:
   
   chmod -R g+rw /oraInventory_location
   
   For example:
   
   chmod -R g+rw /u01/app/oraInventory
   
   If you receive any warning messages, you can ignore them.

4. 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.

### 2.4 Setting Up User Groups and Accounts

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

- **oclsascr** — the group that controls access to the files Oracle Clinical generates for SAS
- **opapps** — the operating system account that owns Oracle Clinical
- **rxcprod** — a special privileged account that runs the Parameterized Submission (PSUB) process

#### 2.4.1 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.

2.4.2 Create the opapps Account

You must create the operating system account that owns 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 11g Release 2 (11.2.0.2) Patch Set 1 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.

2.4.3 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 Secure Shell (ssh) command or schedule jobs with the at command.

2.5 Installing the Oracle Clinical Database Server

This section describes how to install and set up the Oracle Clinical 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 2.5.1 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

2.5.1 Oracle Clinical Database Server Directory Structure for UNIX

The Oracle Universal Installer creates the following directory structure for an Oracle Clinical Database Server on UNIX:

```
OPA_HOME
/bin
/xmltemp
/oc
/462
/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.
2.5.2 Transfer the Oracle Clinical Database Server Software

To transfer the Database Server software from the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Media Pack:

1. Locate the appropriate Database Server software for your operating system on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 operating_system Tech Stack Patches disk in the media pack:

<table>
<thead>
<tr>
<th>Operating System</th>
<th>Path</th>
<th>Zip File</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Enterprise Linux x86-64</td>
<td>/oc/server_code</td>
<td>server_code_linux-x86-64.zip</td>
</tr>
<tr>
<td>Oracle Solaris SPARC</td>
<td>/oc/server_code</td>
<td>server_code_sun.zip</td>
</tr>
<tr>
<td>HP-UX Itanium</td>
<td>/oc/server_code</td>
<td>server_code_hpia.zip</td>
</tr>
</tbody>
</table>

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

2.5.3 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 11g Release 2 (11.2.0.2) Patch Set 1 installation. Typically, this user group is oinstall. (See Section 2.4.2, "Create the opapps Account.")

   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 Oracle Universal Installer:

   ./runInstaller

7. Follow the instructions on the installation screens. For additional information about each screen, see Section 2.5.4, "Attend to the Oracle Clinical Database Server Installation Screens."
2.5.4 Attend to the Oracle Clinical Database Server Installation Screens

The Oracle Universal Installer guides you through the installation and configuration of Oracle Clinical Database Server.

Welcome
Click Next to continue the installation.

Select a Product to Install
Select Oracle Clinical Server for UNIX 4.6.2.0.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 11g Release 2 (11.2.0.2) Patch Set 1.

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. This directory defines the destination of the Oracle Clinical Database Server software that you are currently installing. 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 or /var/opt/oracle.

Click Next.
Locate File

**tnsnames**

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

- **Oracle Enterprise Linux x86-64** — First looks in the `/etc` directory, and then looks in the `$ORACLE_HOME/network/admin` directory.
- **Oracle Solaris SPARC** — First looks in the `/var/opt/oracle` directory, and then looks in the `$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**

Enter the directory where Oracle Clinical generates and saves SAS view files. The Installer creates a `sas_view` sub-directory within the directory you specify.

The default value is the `OPA_HOME` directory. For example, `/home/opapps`.

Click Next.

**Confirmation**

Review the information on the Confirmation screen before proceeding.

To make changes to your installation settings, click Back. Otherwise, click Next to continue.

**Summary**

**Oracle Clinical Server for UNIX 4.6.2.0.XX**

Review the information on the Summary screen, which displays the global settings, the space requirements, and the product to install.

To make changes to your installation settings, click Back. Otherwise, click Install to continue.

**Install**

Oracle Universal Installer copies the files onto the server, links the files, and sets permissions.

To review the progress of the linking phase of the installation:

1. Open another terminal session as the `opapps` user.
2. Enter the following command:

   ```
   tail -f OPA_HOME/oc/462/relink_rxc.log
   ```

In addition, the Install screen displays the location of the log file that records the results of the installation activities for this session. Make note of this information so you can view the log file after the installation.

**End of Installation**

The End of Installation screen displays the:

- Location of the `OPA_HOME` directory
- Location of the `OPA_HOME/bin` directory
■ Name of the code environment
Make note of this information because you need it for several post-installation tasks.
When you have finished reviewing the installation information, click Exit. At the confirmation prompt, click Yes to exit from Oracle Universal Installer.

   Tip: You cannot perform the post-installation tasks (see Section 2.6) 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).

2.5.5 Review the Installation Log Files
Review the generated installation log files for errors:
■ installActions_timestamp.log (See Section 1.13, "Reviewing the Installation Log Files" for details.)
■ OPA_HOME/oc/462/relink_rxc.log
Work with Oracle Support, if necessary, to resolve any errors.

2.5.6 Remove Group Privileges from this Session
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 2.5.3, "Start Installing the Database Server Software"). 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.

2.6 Performing Post-installation Tasks
This section describes the following tasks that you perform to complete the installation of Oracle Clinical Database Server on a UNIX computer:
■ Complete the Setup of the opapps Account
■ Complete the Setup of the rxcprod Account
■ Review the opa_settings File
■ Apply the Latest Critical Patch Updates and Any New Patches

2.6.1 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. This file is located in the home directory after you log in as the opapps user. You can use the following command to view the hidden .cshrc file:
      ls -arl
b. Add the following lines to the .cshrc file:

```csh
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 11g Release 2 (11.2.0.2) Patch Set 1.
- **OPA_HOME** is the directory where you installed Oracle Clinical Database Server.

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

```csh
source .cshrc
```

### 2.6.2 Complete the Setup of the rxcprod Account

To complete the setup of the rxcprod account:

1. Open the `.profile` file for the rxcprod account. This file is located in the home directory after you log in as the rxcprod user. You can use the following command to view the hidden .profile file:

   ```bash
   ls -arl
   ```

2. Add the following path to the `.profile` file:

   ```bash
   PATH=$PATH:OPA_HOME/bin:ORACLE_HOME/bin
   ```

   where:
   - **OPA_HOME** is the directory where you installed Oracle Clinical Database Server.
   - **ORACLE_HOME** is the directory where you installed Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1.

### 2.6.3 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:

- **OPA_HOME/bin**

In addition, the Installer enters all necessary entries and default values for the Oracle Clinical environment into the `opa_settings` 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 about changing, adding, and verifying values.

---

**Note:** The default settings for all databases or the specific settings, such as NLS_LANG, for a particular database 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 AS10gR2
home and Oracle AS10gR3 home must be consistent with the NLS_LANG entry
for the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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_americ_utf8
```

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

- american_americ_us7ascii
- american_americ_we8iso8859p1

### 2.6.4 Apply the Latest Critical Patch Updates and Any New Patches

Every quarter, Oracle provides Critical Patch Updates (CPUs) to address security
vulnerabilities. Install these patches on every computer with an Oracle Home. Check
My Oracle Support for information about the latest patch tested with Oracle Health
Sciences applications. Article ID 180430.1, *Oracle Health Sciences Supported Technology
Stacks*, lists the latest CPUs supported and contains a link to the separate article about
each one.

**Note:** Applying the CPU might change permissions on `ORACLE_HOME` and `oraInst.loc`. You may have to repeat the instructions in
Section 2.3, "Setting Permissions and Write Access to Oracle-Owned
Directories."

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

**Note:** The Oracle Clinical 4.6.2 database tier is supported on Windows only with Patch Set 4.6.4 or its successor.

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 Release 2 (11.2.0.2) Patch Set 1"
- Section 3.2, "Setting Up User Accounts and User Groups"
- Section 3.3, "Installing the Oracle Clinical 4.6.2 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 4.6.2, see Chapter 12.

### 3.1 Installing and Patching Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

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

**Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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 2 (11.2.0.2) Patch Set 1"
- Section 3.1.2, "Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Examples"
- Section 3.1.3, "Apply Patch Bundle 12767726"
3.1.1 Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1

To install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1:

1. Locate the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 software for your operating system on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Windows Tech Stack Patches disk in the media pack.

2. Follow the included instructions for installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1.

3. Choose to install the Enterprise Edition option.

3.1.2 Install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Examples

Oracle Database Examples, which is required for Oracle Clinical 4.6.2, 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 Oracle Thesaurus Management System. You can add them later if you change your mind.

To install Oracle Database Examples:

1. Locate the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Examples software for Windows on the same disk of the media pack:

   Path: \patches
   File: Win64_11gR2_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 Patch Bundle 12767726

To apply Patch Bundle 12767726 to the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation:

1. Locate the Patch Bundle 12767726 software for Windows on the media pack:

   Path: \patches
   File: p12767726_112020_Win64.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 11g Release 2 (11.2.0.2) Patch Set 1 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 and Remote Desktop Users local groups.
3. In the Start menu, navigate to Administrative Tools.
4. Open Administrative Tools, and then 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

Note: The next task is also required in the Local Security Policy user interface.

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.

3.2.3 Setting Up Local Policy Security Options

1. In the Start menu, navigate to Administrative Tools.
2. Open Administrative Tools, and then Local Security Policy.
3. Expand the Local Policies folder and then select Security Options.

4. Set the following values:
   
   Set **Network security: Restrict NTLM: Outgoing NTLM traffic to remote servers to Allow All.**
   
   Set **Network security: Restrict NTLM: Incoming NTLM traffic to Allow All.**
   
   Set **Network Security:Allow Local System to use Computer identity for NTLM to Enabled.**
   
   Set **Network Security:Allow Local System NULL session feedback to Enabled.**

5. Enforce the policy by opening a command prompt and entering:
   
   `gpupdate/force`

### 3.3 Installing the Oracle Clinical 4.6.2 Database Server

This section describes how to install and set up the Oracle Clinical 4.6.2 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 4.6.2 Database Server Directory Structure for Windows

The Installer creates the following directory structure:

```
OPA_HOME
  \bin
  \xmltemp
  \oc
  \462
  \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 4.6.2 Database Server Installation for Windows

You can install the Oracle Clinical 4.6.2 Database Server component for Windows directly from the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Media Pack.

To begin the installation:

1. Log in to the server computer using an account with system administrator privileges.
2. Insert the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk from the 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 4.6.2 Database Server Installation Screens."

3.3.3 Attend to the Oracle Clinical 4.6.2 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 4.6.2 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 11g Release 2 (11.2.0.2) Patch Set 1, 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 4.6.2 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 11, "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, then click Advanced Sharing.
4. Select the Share this folder check box 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 Advanced Sharing dialog box.

9. Click Close to 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\vsmit\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 AS10gR2 home must be consistent with the NLS_LANG entry for the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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 1.4, "Choosing a Character Set" for valid character sets with combined products.
Performing Post-installation Tasks

3.4.4 Apply the Latest CPU Security Update and Any New Patch Sets and Patches

Every quarter, Oracle provides Critical Patch Updates (CPUs) to address security vulnerabilities. Install these patches on every computer with an Oracle Home. Check My Oracle Support for information about the latest patch tested with Oracle Health Sciences applications. Article ID 180430.1, *Oracle Health Sciences Supported Technology Stacks*, lists the latest CPUs supported and contains a link to the separate article about each one.

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

---

**Note:** When you have finished installing Oracle Clinical 4.6.2, you must apply the latest Oracle Clinical patch set. Oracle Clinical is not supported on Windows without Patch Set 4.6.4 or later.
This chapter describes how to create a new Oracle database for use with Oracle Clinical.

Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 and the Oracle Clinical Database Server installations must be complete before you can install the Oracle Clinical database. (See Chapter 2 and the Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 documentation for instructions.)

This chapter includes the following topics:

- Section 4.1, "Reviewing Database Requirements and Recommendations"
- Section 4.2, "Installing Oracle Clinical Database Objects"
- Section 4.3, "Reviewing the Log Files for Installation Errors"
- Section 4.4, "Performing Post-Installation Database Tasks"

### 4.1 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:** Review these requirements for each new database you create.

#### 4.1.1 Start with a New Database Instance

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

#### 4.1.2 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. Oracle recommends that you use all lowercase letters for the SID name.

- 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 about creating these links, see the Oracle Clinical Administrator’s Guide.
4.1.3 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>
<thead>
<tr>
<th>Tablespace</th>
<th>Minimum Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYSTEM</td>
<td>900 MB</td>
</tr>
<tr>
<td>TEMP</td>
<td>100 MB</td>
</tr>
<tr>
<td>UNDOTBS1</td>
<td>700 MB</td>
</tr>
<tr>
<td>USERS</td>
<td>500 MB</td>
</tr>
<tr>
<td>SYSAUX</td>
<td>600 MB</td>
</tr>
</tbody>
</table>

4.1.4 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 11g Release 2 documentation, including online help and the Oracle Database 11g Release 2 Installation Guide for the appropriate operating system.

4.1.5 Select Required Components

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

- Oracle Text
- Oracle JVM
- Oracle XML DB

4.1.6 Use Automatic Memory Management

Oracle recommends that you use Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1’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 about memory management:

Title: Configuring Oracle Clinical Remote Data Capture Onsite 4.6.2 for Performance and Scalability

Article ID: 1300850.1

4.1.7 Review Entries in the opa_settings File

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 2.6.3, "Review the opa_settings File" for more information.
4.1.8 Set Initialization Parameters

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPATIBLE</td>
<td>11.2.0.0.0</td>
<td>Specifies the release with which the Oracle server must maintain compatibility.</td>
</tr>
<tr>
<td>DB_BLOCK_SIZE</td>
<td>16384 bytes</td>
<td>You cannot change this value after you create the database.</td>
</tr>
<tr>
<td>DB_CACHE_SIZE</td>
<td>150 MB</td>
<td>Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.</td>
</tr>
<tr>
<td>DB_DOMAIN</td>
<td>company.com</td>
<td>Make this value the same as your company domain name.</td>
</tr>
<tr>
<td>DB_FILES</td>
<td>200</td>
<td>Oracle adds needed space to the control files up to the number specified in the DB_FILES parameter.</td>
</tr>
<tr>
<td>EVENT</td>
<td>31151 trace name context forever, level 0x100</td>
<td>Required for HTML generation. NOTE: Do not include the EVENT parameter when you create the database. Once the database is created, you can add the EVENT parameter to the init.ora file.</td>
</tr>
<tr>
<td>JAVA_POOL_SIZE</td>
<td>50 MB</td>
<td>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.)</td>
</tr>
<tr>
<td>JOB_QUEUE_PROCESSES</td>
<td>10</td>
<td>Developer-specific parameter. You can change the value of this parameter after installation.</td>
</tr>
<tr>
<td>LARGE_POOL_SIZE</td>
<td>50 MB</td>
<td>Recommended value for 50 to 60 concurrent users.</td>
</tr>
<tr>
<td>MEMORY_MAX_TARGET</td>
<td>1000 MB (minimum)</td>
<td>Adjust this value according to your organization's needs.</td>
</tr>
<tr>
<td>MEMORY_TARGET</td>
<td>1000 MB (minimum)</td>
<td>Adjust this value according to your organization's needs.</td>
</tr>
<tr>
<td>NLS_DATE_FORMAT</td>
<td>DD-MON-RRRR (default value)</td>
<td>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.</td>
</tr>
<tr>
<td>NLS_LENGTH_SEMANTICS</td>
<td>BYTE</td>
<td>The CHAR value for this parameter is not supported.</td>
</tr>
<tr>
<td>OPEN_CURSORS</td>
<td>800 or greater</td>
<td>You can change the value of this parameter after installation.</td>
</tr>
<tr>
<td>OPTIMIZER_FEATURES_ENABLE</td>
<td>9.2.0</td>
<td>Acts as an umbrella for enabling a series of optimizer features based on an Oracle release number. Oracle Clinical uses the optimizing features of Oracle9i.</td>
</tr>
</tbody>
</table>
4.1.9 Modify the tnsnames.ora File

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

Follow the instructions in this section to add Oracle Clinical database objects to this database.

4.2.1 Transfer the Oracle Clinical 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 2.5.2, "Transfer the Oracle Clinical Database Server Software" for installation instructions.

4.2.2 Customize the Installation

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

4.2.2.1 Edit the Tablespace Size Scripts

The Installer creates several new tablespaces with default sizes. To create larger databases, you can edit two scripts. 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 1MB and an unlimited maximum size.

**UNIX** To create larger databases in UNIX, edit the following scripts:

- `OPA_HOME/oc/462/install/opadba2.sql`
- `OPA_HOME/oc/462/install/rxcdba2.sql`

**Windows** To create larger databases in Windows, edit the following scripts:

- `OPA_HOME\oc\462\install\opadba2.sql`
- `OPA_HOME\oc\462\install\rxcdba2.sql`

4.2.2.2 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. Before running the Installer, edit the `rxcdba4.sql` script to customize the accounts that get created and their default settings:

**UNIX**

- `OPA_HOME/oc/462/install/rxcdba4.sql`

**Windows**

- `OPA_HOME\oc\462\install\rxcdba4.sql`

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

4.2.3 Start Installing the Oracle Clinical Database

Follow the instructions appropriate for your operating system.

4.2.3.1 Start the Installer on a UNIX Server

To start installing the Oracle Clinical database:

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 11g Release 2 (11.2.0.2) Patch Set 1 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 Oracle Universal Installer:

   ./runInstaller

7. Follow the instructions on the installation screens. For additional information about each screen, see Section 4.2.4, "Attend to the Oracle Clinical Database Installation Screens."

4.2.3.2 Start the Installer on a Windows Server

To start installing the Oracle Clinical database:

1. Log in to the server computer using an account with system administrator privileges.

   Note: To avoid an error when you run the Installer, give this account read and write permissions on the opapps folder and its subfolders.

2. Insert the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk from the 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 4.2.4, "Attend to the Oracle Clinical Database Installation Screens".

4.2.4 Attend to the Oracle Clinical Database Installation Screens

The Oracle Universal Installer guides you through the installation and configuration of an Oracle Clinical database.

Welcome

Click Next to continue the installation.
Select a Product to Install
Select **Oracle Clinical Database Install 4.6.2.0.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 11g Release 2 (11.2.0.2) Patch Set 1.

Note that the value you enter here does not indicate the destination of the Oracle Clinical database 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**
Select or enter the directory that is the root installation directory of the Oracle Health Sciences products. This directory defines the destination of the Oracle Clinical database that you are currently installing. Typically, you respond with the path to the opapps login directory. For example:

**UNIX** /home/opapps

**Windows** C:\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).

The default **OPA_HOME** directory is /home/opapps.
Click **Next**.

Choose Directory
**SAS view**
Specify the directory to create for locating and storing SAS Data Extract files. (See Chapter 11, "Setting Up SAS" for more information.)
Click **Next**.

Choose Database
**Enter connect string for database to be installed**
Enter the Oracle SID for the database; for example, **prod**.
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 based on the default sizes defined in the following scripts:

- opadba2.sql
- rxcdba2.sql
To increase the size of the initial database, edit these scripts before running the Installer. For more information, see Section 4.2.2, "Customize the Installation."

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 based on the default sizes defined in the following scripts:

- opadba2.sql
- rxcdba2.sql

To increase the size of the initial database, edit these scripts before running the Installer. For more information, see Section 4.2.2, "Customize the Installation."

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 for 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 standard replication in a distributed study installation. Click Next.

Choose Password for RXC_DISC_REP
Enter and confirm the password for the account that manages disconnected replication in a distributed study installation. 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.

Choose Password for RXA_SERVLETSP
Enter and confirm the password for the account that controls ancillary data for RDC Onsite data entry in Production mode. Click Next.

Choose Password for RXA_SERVLETST
Enter and confirm the password for the account that controls ancillary data for RDC Onsite data entry in Test mode. Click Next.
Choose Password for RXA_WS
Enter and confirm the password for the account that controls AIA Web services. Click Next.

Choose Password for RXA_READ
Enter and confirm the password for the account that provides read-only access to design tables. In addition, Oracle Clinical uses this account during design replication. Click Next.

Choose Password for RXA_RAND
Enter and confirm the password for the account used for randomization. Click Next.

Choose Password for RXA_ACCESS
Enter and confirm the password for the account used for randomization. Click Next.

Choose Password for OPS$OPAPPS
Enter and confirm the password for the account used to access the Oracle Clinical application. 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. Before running the Installer, you can edit the script.
to customize the accounts that get created and their default settings. See Section 4.2.2, "Customize the Installation" 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**
The Information screen reports that the Installer will start a 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**
**Oracle Clinical Database Install 4.6.2.0.XX (Note: XX is the build number.)**
The Summary 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.

**Install**
The Install screen displays the progress of the installation. The Installer configures the installed database to work with the Oracle Clinical Database Server code by adding an entry to the following file:

**UNIX**  
`OPA_HOME/bin/opa_settings`

**Windows**  
`OPA_HOME\bin\opa_settings.bat`

**End of Installation**
The End of Installation screen provides information about the installation, including whether the processes completed without errors and the location of the log file for your review.

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

---

**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.
4.2.5 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 4.2.3, "Start Installing the Oracle Clinical Database"). 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.

4.3 Reviewing the Log Files for Installation Errors

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

**UNIX**  
`OPA_HOME/oc/462/install`

**Windows**  
`OPA_HOME\oc\462\install`

Check the following log files (where `database` is the database SID) for error messages and invalid objects:

- `oclinst_database.log`
- `real1_database.log`
- `oclconfig_database.log`
- `flt_seeddata_database_timestamp.log`
- `html_diaglempl_database_timestamp.log`
- `html_blob_seeddata_database_timestamp.log`
- `xmlclob_seeddata_database_timestamp.log`
- `xmlclob_seeddata_database_timestamp.log`
- `compile_all_invalid_database.log`
- `load_olsardcstatemachine.jar_database.log`
- `install_database_timestamp.log`
- `opaconnectcheck_system_database.log`

4.4 Performing Post-Installation Database Tasks

This section describes the following tasks for completing the installation of your Oracle Clinical database:

- Change Default Passwords for Schemas and Roles
- Enroll Users
- Set the Database Time Zone
- Pin Database Packages
- Check Disconnected Replication Tablespace
- Review Optimization Statistics
- Consider Implementing Partitioning
4.4.1 Change Default Passwords for Schemas and Roles
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.

4.4.2 Enroll Users
See the Oracle Clinical Administrator’s Guide for information about enrolling users.

4.4.3 Set the Database Time Zone
The Oracle Clinical Remote Data Capture Onsite (RDC Onsite) application uses the dbtimezone value for internal calculations when the Display timestamps in local timezone preference is set.

To set the time zone in the database:
1. Connect to the database as any user that has ALTER DATABASE privileges.
2. Enter the following command:

   ```sql
   alter database set time_zone='GMT_offset'
   ```

   where:

   `GMT_offset` is the offset hours from Greenwich Mean Time (GMT) to the time zone of the database location.

   - Set the offset to 0 for the GMT time zone.
   - Set the offset to a positive number if the database is in a time zone east of Greenwich, England.
   - Set the offset to a negative number if the database is in a time zone west of Greenwich, England.

   For example, to set the database time zone to Eastern Standard Time (EST), enter the following command:

   ```sql
   alter database set time_zone='-05:00'
   ```

4.4.4 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 pins additional packages. The new packages are included in the updated rxcdbinit.sql script.

---

4.4.4.1 Pin UNIX Database Packages
To pin the database packages located on a UNIX server:

1. Log in to the UNIX server computer as the opapps user.
Performing Post-Installation Database Tasks

2. Set the UNIX environment:
   
   `opa_setup database_name code_environment`

3. Change to the RXC_INSTALL directory:
   
   `cd $RXC_INSTALL`

4. Connect to SQL*Plus as the rxc user:
   
   `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 rerun this script *each* time you restart the database.
Consider creating an entry in the database startup script that runs `rxcdbinit.sql` automatically.

4.4.4.2 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 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.

4.4.5 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 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 disconnected replication, see the *Oracle Clinical Administrator’s Guide*.

4.4.6 Review Optimization Statistics

Oracle Clinical provides scripts that analyze the storage characteristics of tables and indexes of computed 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.

### 4.4.7 Consider Implementing Partitioning

Oracle Clinical supports partitioning of the responses data entry table. Before implementing partitioning to responses data for your Oracle Clinical installation, consider your requirements and options in migrating from a non-partitioned, pre-Oracle Clinical 4.0 responses table to Oracle Clinical 4.6.2.

Before you migrate your data from a non-partitioned responses table into a partitioned one, back up your existing responses table, indexes, and data.
For Oracle Clinical 4.6.2, the required Oracle Application Server technology stack includes Oracle Application Server 10g Release 3 and its Patch Set 5, and Oracle Application Server 10g Release 2 and its Patch Set 3.

For the latest information about updates to the technology stack, see Oracle Life Sciences Applications Supported Technology Stacks (Article ID 180430.1) on My Oracle Support; see "Finding Information on My Oracle Support" on page xii.

This chapter describes how to install and configure these components. It includes the following topics:

- Section 5.1, "Installing the Oracle Application Server Technology Stack"
- Section 5.2, "Setting Up Oracle Application Server 10g Release 3 for SSL"
- Section 5.3, "Modifying the Oracle Process Manager Service"
- Section 5.4, "Applying Critical Patch Updates"
- Section 5.5, "Setting Up the SQL*Net Connections for Existing Databases"
- Section 5.6, "Installing Printers on the Application Tier"

5.1 Installing the Oracle Application Server Technology Stack

To install the Oracle Application Server technology stack, you complete the following tasks:

- Set the Windows Compatibility Mode for the setup.exe File
- Install Oracle Application Server 10g Release 2 (10.1.2.0.2)
- Apply Oracle Application Server 10g Release 2 Patch Set 3 (10.1.2.3.0)
- Install Oracle Application Server 10g Release 3 (10.1.3.1.0)
- Apply Oracle Application Server 10g Release 3 Patch Set 5 (10.1.3.5.0)

5.1.1 Set the Windows Compatibility Mode for the setup.exe File

Before installing the Oracle Application Server technology stack on Windows 2008 server, you must set the compatibility mode for the setup.exe file for each component in the technology stack.

To set the Windows compatibility mode:

1. Right-click on a setup.exe file, and then select Properties.
2. Select the Compatibility tab.

3. Select Run this program in compatibility mode for check box, and then select Windows Server 2008 (Service Pack 1) from the list.

4. Click OK to save your changes.

5. Continue with the software installation.

5.1.2 Install Oracle Application Server 10g Release 2 (10.1.2.0.2)

Oracle Application Server 10g Release 2 provides forms and reports services.

To install Oracle Application Server 10g Release 2:

1. Close all running applications on the computer.

2. Log in to the application server using an account with system administrator privileges.

---

**Caution:** You cannot run the setup.exe file for Oracle Application Server 10g Release 2 on Microsoft Windows 2008. Oracle Universal Installer fails on start up because of compatibility issues with the operating system. Note that setting the Compatibility mode for the AS10gR2 setup.exe file does not resolve this known issue.

To work around this issue, you must start Oracle Universal Installer by running the setup.exe file for **Patch Set 3 (10.1.2.3.0) for Oracle Application Server 10g Release 2**. Once the Installer starts, you must change the source directory to the location of the Oracle Application Server 10g Release 2 installation files. The steps that follow provide detailed instructions.

---

3. Insert the Oracle Clinical 4.6.2 and Oracle Thesaurus Management System 4.6.2 disk from the media pack.

4. Copy and extract the p5983622_10123_WINNT.zip file, which is Patch Set 3 (10.1.2.3.0) for Oracle Application Server 10g Release 2 Forms and Reports Services onto your application server.

5. Insert the Oracle Application Server Forms and Reports Services (10.1.2.0.2) Microsoft Windows (32-bit) disk. (This disk is included in the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Media Pack.)

6. Navigate to the setup.exe file for the Patch Set 3 software that you previously copied and extracted.

7. Set the Windows Compatibility mode for this setup.exe file. (See Section 5.1.1, "Set the Windows Compatibility Mode for the setup.exe File" for details.)

8. Use Windows Explorer or the command line to run the setup.exe file for the Patch Set 3 software.

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

9. Follow the instructions on the installation screens. For additional information about each screen, see Section 5.1.2.1, "Attend to the Oracle Application Server 10g Release 2 Installation Screens."
5.1.2.1 Attend to the Oracle Application Server 10g Release 2 Installation Screens

The Oracle Universal Installer guides you through the installation and configuration of Oracle Application Server.

**Welcome**
Click **Next** to continue the installation.

**Specify File Locations**
Define where to install Oracle Application Server 10g Release 2 (10.1.2.0.2). The directory into which you install this instance of Oracle Application Server is called the `ORACLE_AS10gR2_HOME`.

- **Source Path**

  Caution: Do not accept the default value. Because you had to start Oracle Universal Installer by running the setup.exe file for **Patch Set 3 (10.1.2.3.0)** for Oracle Application Server 10g Release 2, the default value specifies the location of the source files for Patch Set 3.

  Instead, click **Browse** to specify the location of the source files for the Oracle Application Server 10g Release 2 installation. For example, `D:\Disk xxxxxxxxx-01\stage\products.xml`.

- **Destination Name**: Enter the home name of the application tier. For example, `AS10gR2`.

- **Destination Path**: Enter the complete directory path where this instance of Oracle Application Server will be installed. You can change the path to another location, or you can keep the default path. For example, `D:\oracle\AS10gR2`.

  Click **Next**.

**Available Product Components**
**Oracle Application Server Forms and Reports Services 10g**
Select the **Oracle Application Server Forms and Reports Services 10g 10.1.2.0.2** check box to install all components. Click **Next**.

**Specify Port Configuration Options**
Select **Automatic**, and then click **Next**.

**Provide Outgoing Mail Server Information**
The mail server is optional. It is not needed to run Oracle Clinical.

Click **Next**.

**Specify Instance Name and ias_admin Password**
Complete this screen as follows:

- Enter a name for the Oracle Application Server 10g Release 2 instance you are installing. The suggested name for this instance is `AS10gR2`.

  Oracle Application Server appends the host name and the domain name to the instance name you specify to form a complete instance name. For example, if you install an instance on a host computer named `comp1`, and you name the instance `AS10gR2`, then the full name of the instance is as follows:
AS10gR2.compl.domain_name.com

- Enter and confirm a valid ias_admin password to use for the administration of this instance of Oracle Application Server.

Click Next.

Summary
Oracle Application Server Forms and Reports Services 10g 10.1.2.0.2

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.

Install
The Install screen displays the progress of the installation. Oracle Universal Installer configures this instance of Oracle Application Server 10g Release 2. The configuration process can take several minutes. Do not interrupt the automated configuration.

You can view a log of this installation session at:
\Program Files (x86)\Oracle\Inventory\logs\installActions\timestamp.log

End of Installation
Scroll through and review the information on the End of Installation screen. Oracle Application Server 10g Release 2 saves this information in the following file:
setupinfo.txt

Oracle Universal Installer displays the location of the setupinfo.txt 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 Oracle Universal Installer.

5.1.2.2 Apply Oracle Oracle Application Server 10g Release 2 Patch Set 3 (10.1.2.3.0)
To apply Patch Set 3 (10.1.2.3.0) to Oracle Application Server 10g Release 2 Forms and Reports Services:

1. Navigate to the location where you already copied and extracted the Patch Set 3 software.
   (Patch Set 3 is the p5983622_10123_WINNT.zip file on the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk.)

2. Locate the setup.exe file for the Patch Set 3 software.

3. Set the Windows Compatibility mode for this setup.exe file. (See Section 5.1.1, "Set the Windows Compatibility Mode for the setup.exe File" for details.)

4. Execute setup.exe to start the Installer and follow the instructions on screen.
5.1.2.3 Restart the Computer

To ensure that all configuration changes for Oracle Application Server 10g Release 2 and Patch Set 3 (10.1.2.3.0) are initialized, you must restart the computer before you continue with the next task in the installation process.

5.1.3 Install Oracle Application Server 10g Release 3 (10.1.3.1.0)

Oracle Application Server 10g Release 3 provides the latest Java environment for an Oracle Clinical installation.

To install Oracle Application Server 10g Release 3:

1. Close all running applications on the computer.
2. Log in to the application server using an account with system administrator privileges.
3. Insert the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk.
4. Copy and extract Patch Set 5 (10.1.3.5.0) constituted by V17522-01_1of2.zip and V17522-01_2of2.zip folders, from Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk.
5. Insert the Oracle SOA Suite 10g (10.1.3.1.0) for Microsoft Windows (32-bit) disk. (This disk is included in the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Media Pack.)
6. Navigate to the setup.exe file for the Patch Set 5 software that you previously copied and extracted.
7. Set the Windows Compatibility mode for this setup.exe file. (See Section 5.1.1, "Set the Windows Compatibility Mode for the setup.exe File" for details.)

**Note:** During the installation, the system may display the following error message:

The procedure entry point GetProcessImageFileNameW could not be located in the dynamic link library PSAPI.DLL.

You can safely ignore this error message, and click OK to continue.

**Note:** Do not do any of the configuration steps described in the patch release notes.

**Caution:** You cannot run the setup.exe file for Oracle Application Server 10g Release 3 on Microsoft Windows 2008. Oracle Universal Installer fails on start up because of compatibility issues with the operating system. Note that setting the Compatibility mode for the AS10gR3 setup.exe file does not resolve this known issue.

To work around this issue, you must start Oracle Universal Installer by running the setup.exe file for Patch Set 5 (10.1.3.5.0) for Oracle Application Server 10g Release 3. Once the Installer starts, you must change the source directory to the location of the Oracle Application Server 10g Release 3 installation files. The steps that follow provide detailed instructions.
8. Use Windows Explorer or the command line to run the setup.exe file for the Patch Set 5 software.
   The system briefly displays a DOS window while it checks your computer’s compatibility, and then opens the Welcome screen.

9. Follow the instructions on the installation screens. For additional information about each screen, see Section 5.1.3.1, “Attend to the Oracle Application Server 10g Release 3 Installation Screens.”

5.1.3.1 Attend to the Oracle Application Server 10g Release 3 Installation Screens
The Oracle Universal Installer guides you through the installation of Oracle Application Server.

Welcome
Click Next to continue the installation.

Specify File Locations
Define where to install Oracle Application Server 10g Release 3. The directory into which you install this instance of Oracle Application Server is called the ORACLE_AS10gR3_HOME. You specify the full path to this directory.

- **Source Path**

  **Caution:** Do not accept the default value. Because you had to start Oracle Universal Installer by running the setup.exe file for Patch Set 5 (10.1.3.5.0) for Oracle Application Server 10g Release 3, the default value specifies the location of the source files for Patch Set 5.

  Instead, click **Browse** to specify the location of the source files for the Oracle Application Server 10g Release 3 installation. For example, D:\Disk xxxxxx-01\stage\products.xml.

- **Destination Name:** Enter the home name of the application tier. For example, AS10gR3.

- **Destination Path:** Enter the complete directory path where this instance of Oracle Application Server will be installed. You can change the path to another location, or you can keep the default path. For example: D:\oracle\AS10gR3.

  Click Next.

Select a Product to Install
Select Oracle Application Server SOA Suite 10.1.3.1.0.

Click Next.

Select Installation Type
Oracle Application Server SOA Suite 10.1.3.1.0
Select J2EE Server and Web Server (586MB), and then click Next.

Selecting this option installs and configures Oracle Container for J2EE (OC4J), including HTTP Server with SSL support, Oracle Enterprise Manager Application Server Control, and Oracle Process Manager and Notification Server (OPMN).
Specify Port Configuration Options
Select Automatic, and then click Next.

Administration Settings
You need to specify the following administration settings for this instance of Oracle Application Server 10g Release 3:

- Enter a unique name for this instance of Oracle Application Server 10g Release 3 you are installing.
- Enter and confirm an administrator password for this instance of Oracle Application Server 10g Release 3. Note that the administrator user name is oc4jadmin.
- Select the Configure this as an Administration OC4J instance check box.

In addition, specify the name of the default OC4J instance that is created by the Oracle Universal Installer.
Click Next.

Cluster Topology Configuration
You can ignore all settings on this screen. Oracle Clinical does not use cluster topology. Click Next.

Summary
Oracle Application Server SOA Suite 10.1.3.1.0
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.

Install
The Install screen displays the progress of the installation. Oracle Universal Installer configures this instance of Oracle Application Server 10g Release 3. The configuration process can take several minutes. Do not interrupt the automated configuration.

You can view a log of this installation session at:
\Program Files (x86)\Oracle\Inventory\logs\installAction\timestamp.log

End of Installation
The End of Installation screen reports whether the software installed successfully.

Scroll through and review the information, which includes the command for viewing the status of the server and the URL for accessing the Welcome page of the server.

In addition, you can view all this information in the readme.txt file located at:
\ORACLE_AS10gR3_HOME\install\readme.txt

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

5.1.3.2 Apply Oracle Application Server 10g Release 3 Patch Set 5 (10.1.3.5.0)
To apply Patch Set 5 (10.1.3.5.0) to Oracle Application Server 10g Release 3:

1. Navigate to the location where you already copied and extracted the Patch Set 5 software.
5.1.3.3 Configure the Oracle AS10gR3 Process Manager
Go to the Oracle Application Server 10g Release 3 Process Manager.
Change the startup type to Automatic.

5.1.3.4 Restart the Computer
To ensure that all configuration changes for Oracle Application Server 10g Release 3 and Patch Set 5 (10.1.3.5.0) are initialized, you must restart the computer before you continue with the next task in the installation process.

5.2 Setting Up Oracle Application Server 10g Release 3 for SSL
By default, Oracle Clinical is set up to work with HTTPS, which combines the Hypertext Transfer Protocol with a Secure Sockets Layer (SSL) / Transport Layer Security (TLS) protocol. The SSL/TLS protocol provides encrypted communication, secure identification of a network Web server, and communications security over the Internet.

Therefore, you must ensure that the default URL for Oracle Application Server 10g Release 3 uses HTTPS. For example:


Oracle Clinical will not run if the security certificate is not configured properly.

5.3 Modifying the Oracle Process Manager Service
To change the login properties of the Oracle AS10gR2 Process Manager Service to use the administrator account:

1. Log in as a user with system administrator privileges.
2. Open the Windows Control Panel.
5. Select Oracle AS10gR2 Process Manager Service.
6. Open the Action menu, and then click Properties.
7. Click the Log On tab.
   a. Set the account to a user with system administrator privileges.
   b. Click OK to save your changes.
8. Close the Services dialog box.
Repeat the procedure to change the login properties of the Oracle AS10gR3 Process Manager Service to use the administrator account. Be sure to select the Oracle AS10gR3 Process Manager Service.

5.4 Applying Critical Patch Updates
Every quarter, Oracle provides Critical Patch Updates (CPUs) to address security vulnerabilities. These patches are cumulative: each one contains all the fixes contained in the previous patch.

Check My Oracle Support article ID 121863.1, Oracle Clinical Summary of Patches Available, for the latest CPU patch tested with Oracle Health Sciences applications, with a link to the separate article about each one. Install these patches on every computer with an Oracle Home.

Before you run the OPatch utility to apply the CPUs, set the OPatch compatibility as follows:

```
set OPATCH_PLATFORM_ID=215
```

Follow the instructions in the ReadMe file to apply these CPUs.

Please make sure to follow the recommended CPU note as mentioned in the OC 4.6.x patchset you plan to install.

5.5 Setting Up the SQL*Net Connections for Existing Databases
To establish that SQL*Net connections can be created to connect the application server to all databases:

- Modify `ORACLE_AS10gR3_HOME\network\admin\tnsnames.ora`. Ensure that it contains an entry for each database.
- Modify `ORACLE_AS10gR2_HOME\network\admin\tnsnames.ora`. Ensure that it contains an entry for each database.

5.5.1 Test the Connection from the Application Servers to the Database
For Oracle Clinical and RDC applications to work properly, the Oracle Clinical Database must be able to communicate with the application servers.

To ensure that you can connect to the database from each application server:

1. Open a Microsoft DOS command window.
2. Test the connection from Oracle Application Server 10g Release 2:
   a. Define the `ORACLE_HOME` environment variable:
      ```
      set ORACLE_HOME=ORACLE_AS10gR2_HOME
      For example:
      set ORACLE_HOME=D:\oracle\as10gr2
      ```
   b. Use SQL*Plus to verify that you can connect to the database:
      ```
      sqlplus system/password
      ```
3. Test the connection from Oracle Application Server 10g Release 3:
   a. Define the `ORACLE_HOME` environment variable:
set ORACLE_HOME=ORACLE_AS10gR3_HOME

For example:
set ORACLE_HOME=D:\oracle\as10gr3

b. Use SQL*Plus to verify that you can connect to the database:
sqlplus system/password

5.5.2 Troubleshoot Network Connection Issues
If the system returns a connection error, you must resolve this problem before continuing with the installation of Oracle Clinical.

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 login to check.
- 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.

5.6 Installing Printers on the Application Tier
Use an account that has administrative privileges on this computer, such as the operaps account, to add every printer that you plan to use for printing Oracle Clinical reports.
6

Installing Oracle Clinical Front End

The Oracle Clinical Front End installation includes the Oracle Clinical Forms Server, which 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.

In addition, the Oracle Clinical Front End includes the Oracle Clinical Remote Data Capture application, the online help, and the creation of the OPA OC4J instance and the RDC OC4J instance.

The Oracle Application Server technology stack must be installed before you install the Oracle Clinical Front End. See Chapter 5, "Installing and Configuring Oracle Application Server" for installation instructions.

This chapter includes the following topics:

- Section 6.1, "Installing the Oracle Clinical Front End Components"
- Section 6.2, "Making the Java Runtime Environment Available for Download"
- Section 6.3, "Downloading the Oracle Clinical PDF Plug-in"
- Section 6.4, "Changing the Password for the opaconfig User"
- Section 6.5, "Sharing the RDC Directory and Setting Image Browsing"
- Section 6.6, "Installing and Configuring the JSpell Spell Checker SDK"
- Section 6.7, "Applying Forms Server Customizations"

6.1 Installing the Oracle Clinical Front End Components

To install the Oracle Clinical Front End components:

1. Log in as a user with system administrator privileges.
2. Insert the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk.
3. Locate and run the following file:

   oc\application_tier\install\setup.exe

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

The Oracle Universal Installer guides you through the installation and configuration of the Oracle Clinical components.

Welcome
Click Next to continue the installation.

Select a Product to Install
Select Oracle Clinical Front End 4.6.2.0.XX (where XX is the build number).

The Oracle Clinical Front End components include the Oracle Clinical Forms Server, the Oracle Clinical Remote Data Capture application, and the online help.
Click Next.

Specify Home Details
Enter values for the Oracle Home location you created when you installed Oracle Application Server 10g Release 2. This installation guide refers to this location as ORACLE_AS10gR2_HOME.

- Name: Select the name of the correct Oracle Home; for example, AS10gR2.
- Path: Browse for the path to the correct Oracle Home; for example, D:\Oracle\AS10gR2.

Click Next.

Oracle Clinical Front End
Choose the Oracle AS10gR3 Home Directory
Click Next.

Oracle Clinical Front End
Choose OPA Home Directory
Specify the directory that is the root directory for installations of Oracle Health Sciences products. Typically, you respond with the path to the opapps46 directory.

The recommended installation directory for Release 4.6.x is:

`drive:\opapps46`

This installation guide refers to this location as OPA_HOME.

Click Next.

Oracle Clinical Front End
Enter OC4J Admin Password
When you installed Oracle Application Server 10g Release 3, you created a password for the OC4J administrator. You must enter and confirm that password.

Oracle Clinical Front End
Enter OPMN Port Number
Enter the port number that the Oracle Process Manager and Notification Server (OPMN Server) uses. The default port number is 6004.

If you modified the default installation, you can check the following configuration file for the OPMN port number:

`\ORACLE_AS10gR3_HOME\opmn\conf\opmn.xml`
Oracle Clinical Front End
Select the PSUB File Access Mode

Select the file access mode that the system uses to transfer or access the files generated by batch jobs submitted by the PSUB process. You can select SFTP or UNC as the protocol for viewing files generated by PSUB.

For more information, see Chapter 9, "Implementing Secure FTP for File Viewing (UNIX Only)."

- **SFTP (Secure File Transfer Protocol)** — Select SFTP for installations with UNIX on the database tier. The output files are transferred from the database tier to the application tier using SFTP, and then displayed to the user.

- **UNC (Microsoft Windows Universal Naming Convention)** — Select UNC for installations with Windows on the database tier. The output files are accessed on the database tier using UNC, and then displayed to the user.

Click Next.

Oracle Clinical Remote Data Capture Front End
Debug Information
Click Next to continue.

OPA Front End
Choose OPAConfig Password

Enter and confirm the password that you will use to secure access to the OPAConfig application. The default user name for logging in to the OPAConfig application is opaconfig.

Ensure that all your passwords are strong passwords. You can strengthen passwords by creating and using password policies for your organization.

For information about how to change this password after installation, see Section 6.4, "Changing the Password for the opaconfig User."

Click Next.

OPA Front End
Enter NLS Language

Enter the NLS language setting that is appropriate for your database character set.

The default value is AMERICAN_AMERICA.UTF8.

If you are only installing Oracle Clinical and Remote Data Capture, 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.

The NLS language setting (NLS_LANG) is stored in the following file:

```
ORACLE_HOME\forms\server\opa46.env
```

Click Next.
Installing the Oracle Clinical Front End Components

**OPA Front End**

**Enter NLS Date Format**

All Oracle Health Sciences applications require a date format with a four-digit year. For example, DD-MON-RRRR.

If the NLS_DATE_FORMAT entry in the system registry is configured, Oracle Universal Installer displays that value by default. Adjust or enter the date format.

The NLS date format setting (NLS_DATE_FORMAT) is stored in the following file:

$ORACLE_HOME/forms/server/opa46.env

Click Next.

**OPA Front End**

**Enter Report Queue Manager Machine**

By default, Oracle Universal Installer displays either the IP address or the name of the computer that has the Report Queue Manager installed. Accept the default value. Click Next.

**OPA Front End**

**Enter URL for the Report Queue Manager**

Accept the default value. Click Next.

**OPA Xhelp**

**Enter the URL location of your custom documentation**

If you have a directory for custom help, enter the URL location. Use the following syntax:

http://computer.domain:port/opa46/xhelp

**Summary**

**Oracle Clinical Front End 4.6.2.0.XX**

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

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.

**Install**

Oracle Universal Installer copies the files onto the server, completes the setup and configuration tasks, and generates a log file of this installation.

In addition, the Install screen displays the location of the log file that records the results of the installation activities for this session. Make a note of this information so you can view the log file after the installation.

**End of Installation**

The End of Installation screen reports whether the installation was successful. In addition, this screen lists the URLs that you use to access the Oracle Clinical, OPAAadmin, RDC, and RDC Administration applications.

The Installer saves the URL information in the following file:

$OPA_HOME/log/setup.txt

When you have finished reviewing the installation information, click Exit.
6.1.2 Review the Installation Log File

Review the generated installation log file for errors. See Section 1.13, "Reviewing the Installation Log Files" for details.

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

6.1.3 Restart the Computer

To ensure that all configuration changes are initialized, you must restart the computer before you continue with the next task in the installation process or before you install Oracle Clinical Reports Server.

6.1.4 Update the Mandatory System Registry Values for Oracle Clinical Front End

After you install Oracle Clinical Front End, you must update the Windows System Registry for Oracle Clinical to work properly.

To update the Windows System Registry:

1. Open the Windows System Registry Editor.
2. Navigate to the following key:
   \HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\ORACLE\ORACLE_AS10gR2_HOME
3. Update the OPA_XML_TEMP_HTTP value to include the port number for the Oracle Application Server 10g Release 3 HTTP Server. For example:
   http://myserver.us.oracle.com:7777/opa46/rdc/temp
4. Update the OPA_LOCAL_MT_URL value to include the port number for the Oracle Application Server 10g Release 3 HTTP Server. For example:
   OPA_LOCAL_MT_URL=http://127.0.0.1:7777

6.2 Making the Java Runtime Environment Available for Download

The Oracle Clinical, RDC Classic, and RDC Administration applications require that the Java Runtime Environment (JRE) exists on the user's computer. These applications support Java SE 6 Update 24 (Standard Edition, Version 1.6.0.24) or later.

The Launch pages for these applications include a Downloads link, which opens the Downloads page. You can configure the Downloads page so your users can install the required JRE software if it does not exist on their computer.

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

1. Go to the following Oracle Web site:
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.
6.3 Downloading 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
- Install the plug-in on each Forms Server computer

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

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.

6.4 Changing the Password for the opaconfig User

The Users page in Oracle Enterprise Manager 10g Application Server Control provides the options that let you change user passwords, add users, and delete users for the OPAAdmin application.

To change the password for the opaconfig user:

1. Open a Web browser and enter your URL to the Oracle Application Server Forms and Reports Services Welcome page:
   
   computer-name.company-name.com

2. Click the Log on to Oracle Enterprise Manager 10g Application Server Control link to open the Application Server Home page.
3. Log in as user ias_admin with the password you set when you installed the Application Server.
4. Select the appropriate instance.
5. Click the opa OC4J instance.
6. Click the Applications tab.
7. Click the opaadmin link.
8. Click the Administration tab.
9. Expand the Security administration task, and then select the Go to Task icon for Security Provider.
10. Click the Realms tab.
11. Locate the jazn.com realm, and then click the number in its Users column.
12. Click the opaconfig user name.
   a. Enter the old password, enter the new password, and then confirm your new password.
   b. Click Apply. Note that the user name remains opaconfig.

13. Restart the opa OC4J instance.

6.5 Sharing the RDC Directory and Setting 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\Wow6432Node\ORACLE\ORACLE_AS10gR2_HOME
5. Find and verify that the following values are set:
   - 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 = https://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 (to enable image browsing)
     or
   - RDC_DCIF_IMAGES_VALIDATE = N (to disable image browsing)

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

6.6 Installing and Configuring the JSpell Spell Checker SDK
The JSpell Spell Checker SDK is a third-party product from Page Scholar Inc (http://www.jspell.com/). You can use it to check the spelling of text objects in graphic layouts.
The Graphic Layout Editor in Oracle Clinical supports the JSpell Spell Checker SDK for Java J2EE. However, Oracle does not maintain the product itself. You must purchase the product separately.

### 6.6.1 Download and Install JSpell

To download the JSpell SDK files and install the JSpell libraries:

1. Download the JSpell SDK files from the following location:
   

2. Extract the JSpell files from the downloaded ZIP file.

3. Locate the following two JAR files:
   
   - jspellsdks.jar
   - jspellsdkn.jar

4. Copy the JAR files into the following Application Server 10gR2 location:
   
   \$ORACLE_HOME/as10gr2/forms/java

5. Create the jspell directory in the root of the Application Server 10gR2.
   
   For example, if you installed Application Server 10gR2 in the D:\oracle directory then you should create the D:\jspell directory.

6. Open the lexicons folder that you extracted from the JSpell ZIP file.

7. Copy the lex_enUS.jdx file into the jspell directory that you created in Step 5.

### 6.6.2 Install the JSpell WAR File on Application Server 10gR3

To install the JSpell WAR file on Application Server 10gR3:

1. Log in to the Enterprise Manager Application Server Control by entering the URL in the following format:
   
   [http://server_name/em/console](http://server_name/em/console)

   where:

   - server_name is the name of the server onto which you installed Application Server 10gR2 and Application Server 10gR3.

2. Select the Application Server 10gR3 instance.

3. Deploy the JSpell WAR file:
   
   a. Click the opa OC4J system component.
   
   b. Click the Applications tab.
   
   c. Click Deploy WAR File.
   
   d. Complete the following fields:
      
      - **Web Application**: Enter the path to the jspellsdk.war file. You can click Browse to navigate to the location of this file.
      - **Application Name**: jspellsdk
      - **Map to URL**: /jspellsdk
   
   e. Click Deploy to start the installation. The system displays a message when the installation is done.
4. Click OK. Note that you can now see the JSpell application listed along with the other applications already installed.

6.6.3 Test the JSpell Servlet

To test the JSpell Servlet:

1. Open an internet browser.
2. Enter the following URL:
   
   https://server_name/jspellsdk/servlet/JSpellServlet?operation=status

   where:

   server_name is the name of the server onto which you installed Application Server 10gR2 and Application Server 10gR3.

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

6.6.4 Change the Lexicons Directory

When you installed the JSpell SDK, 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 D:\oracle, then you create the D:\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_AS10gR3_HOME\j2ee\opa\applications\jspellsdk \jspellsdk\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 10gR3.

6.6.5 Update the formsweb.cfg File for JSpell

To update the formsweb.cfg file:

1. Navigate to the following directory:
   
   ORACLE_AS10gR2_HOME\forms\server

2. Open the formsweb.cfg file.
4. Append the following text string to the end of the archive_jpi parameter value:
   
   jspellsdks.jar,jspellsdkn.jar
6.6.6 Update the Windows System Registry for JSpell

After you install the JSpell SDK, you need to add several keys to the Microsoft System Registry to support the JSpell application.

To add the required keys to the Windows System Registry:

1. Open the Windows System Registry Editor.
2. Navigate to the following key:
   \HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\ORACLE\ORACLE_AS10gR2_HOME
3. Add the following keys to the registry:
   - OPA_SPELL_ENABLED=Y
   - OPA_SPELL_URL=https://server_name/jspell/sdk/servlet/JSpellServlet
   - OPA_SPELL_LANGUAGE=English (US)

6.7 Applying Forms Server Customizations

If you are upgrading from an earlier release of Oracle Clinical, you must create new Forms Servers because the technology stack is different for Oracle Clinical 4.6.2 Forms Servers. If you modified any files in a previous Oracle Clinical installation, preserve your customizations.

6.7.1 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 10g.
- Recompile rxcuser.mmb with Forms Builder 10g.
- 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.

See the Oracle Clinical Administrator’s Guide for more information about these customizations.

6.7.2 Upgrade rxclbcli.pll

If you have customized rxclbcli.pll, recompile it with Forms Builder 10g. See the Oracle Clinical Application Programming Interface Guide for more information.

Replace your recompiled rxclbcli.pll file on each Forms Server in your network.

6.7.3 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.
This chapter describes how to install Oracle Clinical Reports Server. The Oracle Clinical Reports Server runs on the application tier.

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 Oracle Application Server technology stack must be installed before you install the Reports Servers. See Chapter 5, "Installing and Configuring Oracle Application Server" for installation instructions.

This chapter includes the following topics:

- Section 7.1, "Types of Reports Server Installations"
- Section 7.2, "Installing the Oracle Clinical Reports Server"
- Section 7.3, "Setting Up the Reports Server for Access and File Viewing"
- Section 7.4, "Adding the Reports Server to the Database Reference Codelist"
- Section 7.5, "Replacing the Placeholder DCF Logo Graphic"
- Section 7.6, "Customizing and Upgrading DCF Reports"
- Section 7.7, "Testing the Reports Server Installation"
- Section 7.8, "Troubleshooting Reports Server Problems"

7.1 Types of Reports Server Installations

Oracle Clinical supports two types of Reports Server installations:

- **Combined**: a Reports Server on the same computer as a computer with a Forms Server installation.

  To install a Reports Server on the same computer as the Forms Server, set up the Forms Server first as described in Chapter 6, "Installing Oracle Clinical Front End." When you finish that installation, restart your computer and then continue with the tasks in this chapter to install the Reports Server.

- **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.

  To set up a standalone Reports Server, set up the application server as described in Chapter 5, "Installing and Configuring Oracle Application Server." When you finish that installation, restart your computer and then continue with the tasks in this chapter to install the Reports Server.
7.2 Installing the Oracle Clinical Reports Server

Perform these instructions to deploy the Oracle Clinical Reports Server onto the application tier installation.

---

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

---

To install the Oracle Clinical Reports Server:

1. Log in as a user with system administrator privileges.
2. Insert the *Oracle Clinical and Oracle Thesaurus Management System 4.6.2* disk.
3. Locate and run the following file:
   
   `oc\application_tier\install\setup.exe`

   The Installer opens to the Welcome screen.
4. Follow the instructions on the installation screens. For additional information about each screen, see Section 7.2.1, “Attend to the Oracle Clinical Reports Server Installation Screens.”

7.2.1 Attend to the Oracle Clinical Reports Server Installation Screens

The Oracle Universal Installer guides you through the installation and configuration of Oracle Clinical Reports Server.

**Welcome**
Click Next to continue the installation.

**Select a Product to Install**
Select *Oracle Clinical Report Server 4.6.2.0.XX* (where XX is the build number).
Click Next.

**Specify Home Details**
**Destination**
In the Name field and the Path field, enter values for the Oracle Home you created when you installed Oracle Application Server 10g Release 2 Forms and Reports Services on:

- A combined Forms and Reports server
- A separate Reports Server
Click Next.

**Oracle Clinical Report Server**
**Choose the Oracle AS10gR3 Home Directory**
Select the location where you installed Oracle Application Server 10g Release 3. This installation guide refers to this location as the `ORACLE_AS10gR3_HOME`.
Click Next.
Oracle Clinical Report Server
Choose OPA home directory
Specify the directory that is the root directory for installations of Oracle Health Sciences products. Typically, you respond with the path to the opapps46 directory.

The recommended installation directory for Release 4.6.x is:

\drive:\opapps46

where drive is the disk’s letter designation.

This installation guide refers to this location as OPA_HOME.

Click Next.

Oracle Clinical Report Server
Enter OC4J Admin Password
When you installed Oracle Application Server 10g Release 3, you created a password for the OC4J administrator. You must enter and confirm that password. Click Next.

Oracle Clinical Report Server
Enter OPMN Port Number
Enter the port number that the Oracle Process Manager and Notification Server (OPMN Server) uses. The default port number is 6004.

If you modified the default installation, you can check the following configuration file for the OPMN port number:

\ORACLE_AS10gR3_HOME\opmn\conf\opmn.xml

Oracle Clinical Report Server
Enter Report Server Name
The default value is the repcomputer_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.

Oracle Clinical Report Server
Acrobat Reader
If installed, Oracle Universal Installer detects the location of the computer’s Acrobat Reader installation. The Acrobat Reader is necessary for generating Patient Data Reports. Click Next.

Oracle Clinical Report Server
Do you want to store DCIF images locally
Note that Oracle Universal Installer displays this screen only if you are installing a standalone Reports Server.

- To store the DCIF images locally, select Yes and then click Next. The Installer displays the Choose the Local DCIF Images Directory screen. Enter or browse to the path of the local directory where you want to save the DCIF images.

- To store the DCIF images remotely, select No and then click Next. The Installer displays the Enter the Shared Location of DCIF Images screen. Enter the path of the remote directory where you want to store the DCIF images. Typically, this location is:

  \\forms_server_name\rdc\dcif_images
Click Next.

Summary
Oracle Clinical Report Server 4.6.2.0.XX
The Summary screen provides information about the global settings, languages, space requirements, and products for this installation.
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.

Install
Oracle Universal Installer copies the files onto the server, completes the setup and configuration tasks, and generates a log file of this installation.
In addition, the Install screen displays the location of the log file that records the results of the installation activities for this session. Make a note of this information so you can view the log file after the installation.

End of Installation
The End of Installation screen reports whether the installation was successful.
Click Exit.

7.2.2 Review the Installation Log File
Review the generated installation log file for errors. See Section 1.13, "Reviewing the Installation Log Files" for details.
Work with Oracle Support, if necessary, to resolve any errors.

7.2.3 Restart the Computer
To ensure that all configuration changes are initialized, you must restart the computer before you continue with the next task in the installation process.

7.3 Setting Up the Reports Server for Access and File Viewing
Perform these Reports Server file viewing tasks once for each Oracle Clinical location.

7.3.1 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.

7.3.2 Share and Grant Access to the Reports Server Root Directory
Make the Reports Server UNC sharable, and grant the administrator account read and write access to this directory.
To share the Reports Server root directory on Windows with the administrator 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 Microsoft Windows Universal Naming Convention (UNC) for any Reports 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 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.

---

### 7.3.3 Create Reports Server Log Directories for Each User

For each Oracle Clinical database account, create the Reports Server log directory for the user. See the *Oracle Clinical Administrator’s Guide* for information.

### 7.3.4 Specify Directory Mappings for PSUB in Each Database

To set up file viewing by mapping directories in each database, see the *Oracle Clinical Administrator’s Guide* for information.

### 7.3.5 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*.)

### 7.4 Adding the Reports Server to the Database Reference Codelist

For each Reports Server that you install and want to access from this database, you must edit the Maintain Reference Codelists in Oracle Clinical to specify the values for the Reports Server.

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 7–1, 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.
For each additional, non-default Reports Servers, add a row to the reference codelist. Specify a unique name in the Short Value field and the connection string in the Long Value field.

<table>
<thead>
<tr>
<th>Short Value</th>
<th>Enter in Long Value Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>REPORT_SERVER</td>
<td>The connection string for the Reports Server you want to use as the default for Oracle Reports.</td>
</tr>
<tr>
<td>JOB_SET_SERVER</td>
<td>The connection string for the Reports Server you want to use as the default for job sets.</td>
</tr>
<tr>
<td>PSUB_SCHEDULER</td>
<td>The connection string for the Reports Server you want to use as the default for PSUB jobs.</td>
</tr>
</tbody>
</table>

5. Click Save.

### 7.5 Replacing the Placeholder DCF Logo Graphic

The Oracle Clinical Data Clarification Form (DCF) report system is a utility for generating paper forms from an Oracle report. The report includes a bitmap image on the cover page.

You can replace the default image with your own graphic or logo, or you can use a graphics application to redraw the image.

The source file for the bitmap image is at the following location on Oracle Clinical Reports Server installations:

`OPA_HOME/oc/rxcdcf.bmp`

You can edit the image locally and then copy it to your server.

### 7.6 Customizing and Upgrading DCF Reports

For DCF Reports, you can customize the following files:

- `rxcdrptl.rdf`
- `rxcdrptp.rdf`

These source files are located on the Forms Server in the following directory:

`OPA_HOME/oc/admin`

If you customized these files for a previous release and you are upgrading Oracle Clinical, recompile the files with Oracle 10g DS Reports Developer Release 2.

### 7.7 Testing the Reports Server Installation

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

1. Start Oracle Clinical.
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.

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:


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.

### 7.8 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 6.5, "Sharing the RDC Directory and Setting Image Browsing" for more information.

**Unable to stop a Reports job**

Check if this is a scheduled job. If it is, use the Oracle AS10gR2 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.
The Parameterized SUBmission process (PSUB) schedules jobs, reports, and batch processing for Oracle Clinical.

This chapter describes how to set up a UNIX or Windows server to enable the Oracle Clinical PSUB process. On UNIX servers, you must set up the Secure Shell (ssh) before starting PSUB.

This chapter includes the following topics. The first five topics apply to UNIX only.

- Section 8.1, "PSUB Uses Secure Shell (UNIX Only)"
- Section 8.2, "Setting Up Secure Shell for the rxcprod User (UNIX Only)"
- Section 8.3, "Setting Up Oracle Clinical PSUB Users (UNIX Only)"
- Section 8.4, "Testing the Secure Shell Setup (UNIX Only)"
- Section 8.5, "Configuring for the at Command (UNIX Only)"
- Section 8.6, "Starting and Testing the PSUB Process"
- Section 8.7, "Customizing the PSUB Process"

### 8.1 PSUB Uses Secure Shell (UNIX Only)

The PSUB daemon submits 3GL and PL/SQL jobs (C programs like Batch Validation and PL/SQL programs like Study Unfreeze) on a UNIX server. PSUB is run as rxcprod user. When a user submits a job from Oracle Clinical, PSUB creates a process on behalf of the user on the same machine and runs the program.

Beginning with Oracle Clinical 4.6.2, PSUB uses a Secure Shell (ssh) execution service for the rxcprod account to run job requests on behalf of other users who submit jobs with the ssh command or schedule jobs with the at command.

The Secure Shell protocol is designed to create encrypted communications between hosts. In addition to remote shell logins, the Secure Shell protocol allows ssh connections between the accounts of the same name on either system without requiring a password.

Secure Shell replaces Remote Shell (rsh, remsh, and rlogin) used in earlier Oracle Clinical releases.
### 8.2 Setting Up Secure Shell for the rxcprod User (UNIX Only)

By default, Secure Shell is installed when the UNIX operating system, such as Oracle Enterprise Linux, Oracle Solaris, and HP-UX Itanium, is installed.

This section describes how to set up Secure Shell on UNIX for RSA-based authentication, which uses a public/private key pair for authentication purposes.

The set up for the public/private key authentication is as follows:

- Save the public key in each PSUB user’s home directory on the PSUB server machine that they want to access through Secure Shell.
- Keep the private key under the rxcprod account on the PSUB server machine.

When the Secure Shell daemon on the PSUB server receives an authentication request from a client, it checks whether the public key is present in the user’s home directory. If present, Secure Shell challenges the client with a random string. The client then uses the user’s private key to sign the random string, and sends the signature back to the server. The server can then check the validity of the signature using the user’s public key, and therefore, authenticating the connection.

To set up Secure Shell and public/private key authentication:

1. Log in to the Oracle Clinical UNIX server as the rxcprod user.
2. Use `ssh-keygen` to create a password-less set of identity keys:
   ```bash
   ssh-keygen -t rsa -N ''
   ```
   The system prompts for the file into which the set of identity keys is saved.

3. Press `Return` to accept the default location. This process creates two files in the `RXCPROD_HOME` directory:
   ```
   ~/.ssh/id_rsa — Contains the private key that represents your identity on that particular machine. Note that the private key is neither world nor group readable. You should never transfer the private key from the machine or change its modes.
   ~/.ssh/id_rsa.pub — Contains the public key, which is world readable. Secure Shell and other programs can use the public key to encrypt messages that only you can decrypt using the private key. The `-N ''` argument to the ssh-keygen command specifies that no passwords are associated with the public keys.
   ```

### 8.3 Setting Up Oracle Clinical PSUB Users (UNIX Only)

Before setting up the PSUB user, make sure that any user account that will run PSUB jobs uses the C Shell (`csh`). The default shell gets set up when you create the user account.

To set up a PSUB user:

1. Log in to the Oracle Clinical UNIX server as a PSUB user.
   
   For example, log in as the `guest1` OS user for the `ops$guest1` Oracle Clinical account.

2. Navigate to the `GUEST1_HOME` directory.

3. Create the `.ssh` directory if it does not exist, and set the permission to 700:
   ```bash
   mkdir .ssh
   chmod 700 .ssh
   cd ~/.ssh
   ```
4. Append the contents of the `id_rsa.pub` file located in the `RXCPROD_HOME/.ssh` directory to the `authorized_keys` file located in the `GUEST1_HOME/.ssh` directory. For example:

```
cat /tmp/id_rsa.pub >> authorized_keys
```

You may need to create the `authorized_keys` file if it does not exist. To do this, user `rxcprod` must copy the `id_rsa.pub` file to the `/tmp` directory and make the file world readable. Then, user `guest1` can read the file from there. Make sure you remove the copy from `/tmp` when you are done.

5. Change the permission of the `authorized_keys` file to 600:

```
chmod 600 authorized_keys
```

---

**Note:** You must repeat this procedure for each user who needs to run PSUB.

---

### 8.4 Testing the Secure Shell Setup (UNIX Only)

Before you start up the PSUB process, test that you configured Secure Shell properly for your PSUB users.

To verify your configuration, run the following tests from the `rxcprod` account:

- Validate Use of Public/Private Key Authentication
- Verify the Fingerprint of the Public Key

#### 8.4.1 Validate Use of Public/Private Key Authentication

You can validate whether a PSUB user can authenticate using the public keys (no password). You must run this test from the `rxcprod` account.

For example, to validate whether PSUB user `ops$jjsmith` can authenticate using the public keys, enter the following command:

```
ssh -n -l jjsmith $HOST 'ls -arlt'
```

In addition, Secure Shell provides mutual machine-level (IP address) authentication. This authentication is done by using public/private keys that are created when Secure Shell is installed on a given machine.

When connecting to the same local machine using Secure Shell for the first time, Secure Shell displays a set of messages and prompts, including a unique key. For example:

```
The authenticity of host 'server_name.us.oracle.com (IP_address)' can't be established.

Are you sure you want to continue connecting (yes/no)?
```

**Note:** Save a copy of the RSA key fingerprint. You will need this information to test the fingerprint of the public key.

---

Your Secure Shell client wants to make sure that you are connecting to the server you intended, and not to some other server playing man-in-the-middle. When you answer
yes to the question, Secure Shell saves the public key presented by the server into your known_hosts file, proceeds with the connection, and displays the following message:

Warning: Permanently added 'server_name.us.oracle.com, IP_address' (RSA) to the list of known hosts.

### 8.4.2 Verify the Fingerprint of the Public Key

Once you establish a connection, check the fingerprint of the public key of the server, which resides somewhere on its disk.

To check the RSA key fingerprint:

1. Enter the following command:
   
   ```sh-3.2$ ssh-keygen -l -f /etc/ssh/ssh_host_rsa_key.pub```
   
   The server returns the unique RSA key fingerprint found in the /etc/ssh/ssh_host_rsa_key.pub file. For example:
   

2. Verify that this key matches the key returned when you validated the IP address. (See Section 8.4.1.)
   
   - If the keys match, then the server's public key that is saved in the known_hosts file is good. From now on, the system will not prompt for confirmation before connecting to the server.
   - If the keys do not match, contact your system administrator.

### 8.5 Configuring for the at Command (UNIX Only)

To use the `at` command to schedule jobs on behalf of another user, the rxcprod user must be listed 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 `at.allow` file:

   - **Oracle Enterprise Linux x86-64**: `/etc/at.allow`
   - **Oracle Solaris SPARC**: `/usr/lib/cron/at.allow`
   - **HP-UX Itanium**: `/usr/lib/cron/at.allow`

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

### 8.6 Starting and Testing the PSUB Process

The 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.

**Note:** For information on starting PSUB automatically on UNIX and Windows, see the *Oracle Clinical Administrator’s Guide*.

### 8.6.1 Starting the PSUB Process on UNIX

To start the PSUB process on UNIX:

1. Log in to the Oracle Clinical UNIX server as the *rxcprod* user. Note that you must log in as *rxcprod* to start the PSUB process.

2. Set up the environment:
   
   ```
   p1=database_name
   p2=code_environment
   . opa_setup
   
   For example:
   
   p1=prod
   p2=462
   . opa_setup
   ```

3. Start the PSUB process:
   
   ```
   start_psub database_name code_environment
   
   For example:
   
   start_psub prod 462
   ```

### 8.6.2 Changing the Startup Type 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. In the Start menu, navigate to *Administrative Tools*, then *Services*.
   
   b. 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`
   
   c. For Startup type, select *Manual*.
   
   d. Click the *Log On* tab.
   
   e. 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.)
   
   f. In the Password and Confirm Password fields, enter the RXCPROD password.
   
   g. Click *OK* to close the dialog box.

3. Exit from the Services dialog box.

4. Log off this Administrator session.

Note: For information on starting PSUB automatically on UNIX and Windows, see the *Oracle Clinical Administrator’s Guide*.
8.6.3 Configuring Windows Registry Setting for PSUB (Windows Only)

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\KEY_OraDb11g_home1

where OraDb11g_home1 is the Home name of your Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 installation.

8.6.4 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. In the Start menu, navigate to Administrative Tools, then Services.
   b. 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
   c. Enter values for the Log On parameters:
      database code_environment [verbose | noverbose] value-of-RXC_ROOT
      For example: prod 462 verbose c:\opapps\oc\462

      **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.

8.6.5 Test the PSUB Installation

To test your PSUB installation:

1. Open Oracle Clinical.
2. Submit a 3GL job such as Batch Validation or a PL/SQL job such as Study Unfreeze.
3. Verify that Oracle Clinical creates the log and output files in the user's log directory.

If you encounter problems or errors, review the messages in the PSUB log files created in the following directory:

**UNIX** $RXC_ROOT/log

**Windows** %RXC_ROOT%\log
8.6.5.1 Home Permissions and Secure Shell (UNIX Only)
If the PSUB user’s home directory or the rxcprod home directory has 777 permissions, then Secure Shell will not work.

8.6.5.2 Settings for the UTF8 Character Set and the PSUB Process
For PSUB to work correctly for a UTF8 character set database, the opa_settings file must have the following setting:

**UNIX**
```
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`

**Windows**
```
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`

8.7 Customizing the PSUB Process
You can customize the PSUB process as follows:

- **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.

- **Job Numbering** — You can change Oracle Clinical’s default job numbering algorithm.

For more information about managing and customizing the PSUB process, see the *Oracle Clinical Administrator’s Guide*. 
Implementing Secure FTP for File Viewing (UNIX Only)

You must have a full Oracle Clinical Release 4.6.2 installation in place, including functioning PSUB. See Chapter 8, “Setting Up the Parameterized Submission Process” for details.

This chapter includes the following topics:

- Section 9.1, “About Secure FTP and Oracle Clinical”
- Section 9.2, “Obtaining and Installing SFTP Software”
- Section 9.3, “Setting Up SFTP”
- Section 9.4, “Testing that Password Prompt Is Bypassed”
- Section 9.5, “Setting the Oracle Entries in the System Registry for SFTP”
- Section 9.6, “Testing SFTP for File Viewing”
- Section 9.7, “Viewing New Lines in PSUB Files”

9.1 About Secure FTP and Oracle Clinical

When you submit a 3GL and PL/SQL job (C programs like Batch Validation or PL/SQL programs like Study Unfreeze) from Oracle Clinical, the system creates the log (.LOG) and out (.OUT) files on the UNIX server computer.

When you select a log or out file from the client computer to view a file that is physically located on a UNIX server computer, Oracle Clinical uses secure FTP to transfer the file to a temporary local directory on the application tier.

You then view the file using SFTP. With SFTP, you do not need to enter a password. Instead, Oracle Clinical uses Secure Shell (ssh) for RSA-based authentication. Oracle Clinical 4.6.2 uses an SFTP command stored in the registry on the application tier.

Oracle Clinical deletes the file from the temporary local directory when you close the log or out file after viewing.

In addition, Oracle Clinical configures the rxcpsbjb.fmx file so that the administrator account (for example, the opareps account) on the application tier is the only account that has permission to exercise the SFTP protocol.
9.2 Obtaining and Installing SFTP Software

You must install software for transferring files securely between computers. Several applications for the Secure Shell, Telnet, and Rlogin network protocols are available for Windows platforms. This installation guide refers to this transfer software as SFTP software.

You must obtain SFTP software for the Windows 2008 platform that uses RSA-based authentication and provides a way for you to create a public/private key pair for authentication purposes.

You can choose the SFTP software that you want to use. PSFTP, which is PuTTY's SFTP, is one common SFTP software.

Once you acquire your preferred SFTP software, install the SFTP software onto the Oracle Clinical application tier computer. This installation guide uses the variable 
\texttt{SFTP\_HOME} to designate the installation location.

9.3 Setting Up SFTP

This section provides a general description of how to generate the private/public key pair. Refer to the documentation for your SFTP software for detailed instructions.

9.3.1 Generate and Configure the Private/Public Key Pair

To generate and configure the private/public key pair:

1. Log in as a user with system administrator privileges.
2. Start the SFTP software. For example, if you use PuTTY's SFTP software, start puttygen to generate the private/public key.
3. Set the software to generate key type \texttt{SSH2 RSA}.
4. Set the number of bits to \texttt{1024}.
5. Generate the private/public key pair.

\textbf{Note:} Some SFTP software includes a passphrase option. If you want to be able to run SFTP in batch mode, do not define a passphrase for the key.

6. Save your work. Specify the directory path and name for the private/public key (.ppk) file. For example:
\texttt{SFTP\_HOME/\key/private_key.ppk}

For security purposes, specify an obscure file name.

7. Change the permission of the private key file so that only the administrator account has read and write permission. This ensures that only the administrator user has permission to perform SFTP without specifying the password.

8. Copy the public key from your SFTP software and save it in a temporary text file. Note that the text in this file should be a single line.

9.3.2 Create the \texttt{restricted\_sftp.sh} File

To create the \texttt{restricted\_sftp.sh} file:
1. Log in to the UNIX server computer. You can log in as the opapps user or as the user who owns the RXC_ROOT/psub directory.

2. Navigate to the RXC_ROOT/psub directory. (To check the path to the RXC_ROOT directory, run opa_setup and then execute the echo $RXC_ROOT command from the shell prompt.)

3. Create a file named restricted_sftp.sh in the RXC_ROOT/psub directory.

4. Add the following lines to the restricted_sftp.sh file:

```bash
#!/bin/sh

# SSH1 only; for SSH2, you may need to use $SSH2_ORIGINAL_COMMAND

# or check your operating system documentation.

# You can add logic to allow only certain client computers by changing the value of $SSH_CLIENT
exit 0
```

5. Change the permission of the restricted_sftp.sh file to 777:

   chmod 777 restricted_sftp.sh

9.3.3 Modify Accounts to Use SFTP

This section describes how to modify the operating system account for each user to use SFTP.

To modify the authorized_keys file for a single user:

1. Log in to the UNIX server computer.

2. Navigate to the authorized_keys file for the user. For each user, the authorized_keys file is located in the following directory:

   USER_HOME/.ssh

3. Add the public key into the authorized_keys file.

   The public key entry has the following syntax:

   ```
   command="sh RXC_ROOT/psub/restricted_sftp.sh",from="host_name" ssh-rsa
   public_key_string
   ```

   where:

   - RXC_ROOT is the complete path to the RXC_ROOT directory.
   - host_name is either the host name or the IP address (to restrict SFTP to a particular host).
9.4 Testing that Password Prompt Is Bypassed

To test that you have successfully bypassed a SFTP password prompt:

1. Log in to the application tier computer.
2. Open the Microsoft Windows Command Prompt.
3. Change to the $SFTP_HOME directory.
4. Make sure the system does not prompt for a password when executing the SFTP command:
   
   psftp -i private_key_file_path user_name@UNIX_computer_name

   For example:
   
   psftp -i C:\Program Files\sftp_software\s491.ppk bruce@solaris491
5. Close the Command Prompt window.

9.5 Setting the Oracle Entries in the System Registry for SFTP

Oracle Clinical installation adds the following two variables into the Microsoft Windows System Registry for SFTP and FTP:

- PSUB_FTP_SECURE
- PSUB_FTP_COMMAND
9.5.1 Modifying PSUB_FTP_SECURE and PSUB_FTP_COMMAND

To modify PSUB_FTP_SECURE and PSUB_FTP_COMMAND so Oracle Clinical uses SFTP:

1. Open the Windows Registry Editor.
2. Navigate to the following key:

   HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\ORACLE

3. Locate the PSUB_FTP_SECURE entry in the Windows Registry.
   For SFTP, set the value to Y to enable the protocol. You must also define a value for PSUB_FTP_COMMAND.
4. Locate the PSUB_FTP_COMMAND entry in the Windows Registry.
   For SFTP, enter the command for the SFTP application you are using for file transfer. Table 9–1 provides the command syntax and examples for WinSCP (Windows Secure CoPy) and PuTTY.

Table 9–1  WinSCP and PuTTY Commands for the PSUB_FTP_COMMAND Entry

<table>
<thead>
<tr>
<th>SFTP Application</th>
<th>Command Syntax and Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>WinSCP</td>
<td>&quot;SFTP_HOME\WinSCP.com&quot; /privatekey=&quot;SFTP_HOME\WinSCP\sftp_keys\PRIVATE_KEY&quot; /script=SCRIPT_FILE</td>
</tr>
<tr>
<td></td>
<td>where: SFTP_HOME is the complete directory path to the location where you installed the WinSCP application. PRIVATE_KEY is the name for your private key (.ppk). Note: SCRIPT_FILE is a placeholder for the script file that the File Viewing form generates dynamically prior to file transfer. The system deletes the file immediately after transfer. For example: &quot;C:\ProgramFiles\WinSCP\WinSCP.com&quot; /privatekey=&quot;C:\ProgramFiles\WinSCP\sftp_keys\b1z92cy.ppk&quot; /script=SCRIPT_FILE</td>
</tr>
<tr>
<td>PuTTY</td>
<td>&quot;SFTP_HOME\psftp&quot; -i &quot;SFTP_HOME\PRIVATE_KEY&quot; -b SCRIPT_FILE -be -batch</td>
</tr>
<tr>
<td></td>
<td>where: SFTP_HOME is the complete directory path to the location where you installed the PuTTY application. PRIVATE_KEY is the name for your private key (.ppk). Note: SCRIPT_FILE is a placeholder for the script file that the File Viewing form generates dynamically prior to file transfer. The system deletes the file immediately after transfer. For example: &quot;C:\Programs\putty\psftp&quot; -i &quot;C:\Programs\putty\b1z92cy.ppk&quot; -b SCRIPT_FILE -be -batch</td>
</tr>
</tbody>
</table>

9.5.2 Ensuring Files Transfer in ASCII Mode with WinSCP

To ensure that files are transferred in ASCII mode when using WinSCP:
1. Start the WinSCP application.
2. Open the Preferences dialog box.
3. Select the Transfer tab.
4. Select Text in the Transfer mode section.
5. Click OK to save your changes.

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9.5.3 Switching Between SFTP and FTP File Viewing Post-Installation

To switch between SFTP and FTP for file viewing:

1. Navigate to the following directory:
   \ORACLE\AS10GR2\HOME\forms\server
2. Open the \formsweb.cfg configuration file with a text editor.
3. Locate the following line in the file and update the PSUBMAP parameter:
   \opa_file_viewing=PSUBMAP=SFTP RSMAP=UNC
   Set the parameter to SFTP or to FTP.

   **Note:** The RSMAP setting does not affect file viewing.

4. Open the Windows Registry Editor.
5. Update the PSUB_FTP_SECURE entry in the Windows Registry as follows:
   - For FTP, set the value to N or null (blank).
   - For SFTP, set the value to Y to enable the protocol. You must also define a value for PSUB_FTP_COMMAND.
6. Update the PSUB_FTP_COMMAND entry as follows:
   - For FTP, enter the command for FTP. If you want file viewing to use the default FTP command on your application tier computer, set the PSUB_FTP_COMMAND value to null (blank).
   - For SFTP, enter the command for the SFTP application you are using for file transfer. Table 9–1 provides the command syntax and examples for WinSCP (Windows Secure Copy) and PuTTY.
7. Restart Oracle Clinical Forms Server.

9.6 Testing SFTP for File Viewing

To test SFTP for file viewing:

1. Open an Oracle Clinical URL that uses SFTP for file transfer.
2. Log in to Oracle Clinical with a user account set up for SFTP.
3. Submit a PSUB job for 3GL or a PSUB module that creates a log file and an out file.
4. Go to the Batch Job Statuses screen.
5. Click either View Logfile or View Outfile.
   If you set up SFTP correctly, Oracle Clinical opens the files for you to view.

9.7 Viewing New Lines in PSUB Files

For each client computer, you must associate the .LOG and .OUT files types with an editor that can interpret UNIX new line characters. For example, WordPad interprets UNIX new line characters.

If the .LOG or .OUT file types are associated with an editor that cannot interpret UNIX new line characters, such as NotePad, the PSUB file content will be displayed as one line.
A client is the Web browser interface to the application server. It displays data and transmits user actions to and from the application server. This chapter describes how to set up each client in your Oracle Clinical installation.

This chapter includes the following topics:

- Section 10.1, "About an Oracle Clinical Client Installation"
- Section 10.2, "Configuring Personal Firewall"
- Section 10.3, "Setting Internet Options for Microsoft Internet Explorer"
- Section 10.4, "Starting and Logging In to Oracle Clinical"
- Section 10.5, "Downloading Required Applications for Clients"
- Section 10.6, "Mapping Network Drive for Image Browsing"
- Section 10.7, "Enabling Report Generation from the Command Line"

10.1 About an Oracle Clinical Client Installation

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.

10.1.1 Operating System Requirements for Oracle Clinical and RDC Clients

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

- Windows XP; Service Pack 1, 2, or 3; 32-bit architecture (US English)
- Windows Vista; Service Pack 1; 32-bit architecture (US English)
- Windows 7; Service Pack 1; 32-bit or 64-bit architecture (US English)
- Windows Server 2008; Release 2; Service Pack 1; 64-bit architecture (US English)

10.1.2 Application Requirements for Oracle Clinical and RDC Clients

To access Oracle Clinical, RDC Onsite, RDC Classic, and RDC Administration, clients must have the following applications installed:
**10.2 Configuring Personal Firewall**

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

**10.3 Setting Internet Options for Microsoft Internet Explorer**

This section describes how to configure Internet Explorer on a client computer so you can run the Oracle Clinical, RDC Onsite, RDC Classic, and RDC Administration applications.

**10.3.1 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 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 sys63 and the domain name is mycompany.com, then you enter:

sys63.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.

### 10.3.2 Set Internet Explorer Modes

Clients use Microsoft Windows Internet Explorer (Release 7, 8, or 9) to access the Oracle Clinical and RDC applications. The supported version of Internet Explorer depends on the version of Microsoft Windows you are using. For details, see Section 10.1.2, "Application Requirements for Oracle Clinical and RDC Clients."

If you are using Internet Explorer 8 or 9, check the Browser Mode and Document Mode settings. Table 10–1 lists the possible settings for each mode.

Oracle Clinical and RDC work properly with the default settings configured when Internet Explorer is installed. However, a user can change the Document Mode setting such that RDC Onsite does not work properly. For information about this known issue, see Section 10.3.3, "Using Internet Explorer 8 or 9 with RDC Onsite."

#### Table 10–1 Browser Mode and Document Mode Settings

<table>
<thead>
<tr>
<th>Internet Explorer</th>
<th>Browser Mode</th>
<th>Document Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release 8</td>
<td>■ Internet Explorer 8 (default for internet sites)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 8 Compatibility View (default for intranet sites)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 7</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Document Mode</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Quirks Mode (default)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 8 Standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 7 Standards</td>
<td></td>
</tr>
<tr>
<td>Release 9</td>
<td>■ Internet Explorer 9 (default for internet sites)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 9 Compatibility View (default for intranet sites)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 8</td>
<td></td>
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<td></td>
<td>■ Internet Explorer 7</td>
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<tr>
<td></td>
<td><strong>Document Mode</strong></td>
<td></td>
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<tr>
<td></td>
<td>■ Quirks Mode (default)</td>
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<tr>
<td></td>
<td>■ Internet Explorer 9 Standards</td>
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<tr>
<td></td>
<td>■ Internet Explorer 8 Standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>■ Internet Explorer 7 Standards</td>
<td></td>
</tr>
</tbody>
</table>

### 10.3.3 Using Internet Explorer 8 or 9 with RDC Onsite

Internet Explorer 8 and Internet Explorer 9 include a set of tools that enable Web site developers to prototype and test Web sites they develop. The Document Mode setting is one of those tools.

Although RDC Onsite supports Internet Explorer 8 and 9, a user can change the Document Mode setting such that RDC Onsite does not work properly. It is not
anticipated that RDC Onsite users will change the Document Mode setting, as it is targeted at Web developers.

If you plan to use Internet Explorer 8 or 9 for RDC Onsite, ensure the Document Mode for the browser is set to Quirks Mode (Page Default).

To verify or configure the Document Mode setting:
1. Launch Internet Explorer 8 or 9.
2. Open the Tools menu, and then select Developer Tools.
3. Set the Document Mode to Quirks Mode (Page Default).

### 10.4 Starting and Logging In to Oracle Clinical

To start and log in to the Oracle Clinical:

1. Start Internet Explorer.
2. Enter the following URL:
   
   \[https://computer_name.domain:port/opa46/launch.htm\]
   
   where:
   
   - `computer_name` is the network name for the application 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 when you click **Login**. Follow the on-screen instructions to download and install the JRE to the default location.

Table 10–2 lists the URLs you enter in Internet Explorer to start the Oracle Clinical, RDC Onsite, RDC Classic, and RDC Administration applications.

When entering a URL, replace the variables as follows:

- `computer_name` is the network name for the application server
- `domain` is the network domain name for your organization

<table>
<thead>
<tr>
<th>Application</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle Clinical</td>
<td><code>https://computer_name.domain:port/opa46/launch.htm</code></td>
</tr>
<tr>
<td>RDC Onsite</td>
<td><code>https://computer_name.domain:port/olsa/cc/rdcLogin.do</code></td>
</tr>
<tr>
<td>RDC Classic</td>
<td><code>https://computer_name.domain:port/opa46/rdclaunch.htm</code></td>
</tr>
<tr>
<td>RDC Administration</td>
<td><code>https://computer_name.domain:port/opa46/rdcadmin.htm</code></td>
</tr>
</tbody>
</table>
10.5 Downloading Required Applications for Clients

This section describes how to download and install the following applications:

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

10.5.1 Download the Java Runtime Environment

Oracle Clinical, RDC Classic, and RDC Administration require the Java Runtime Environment (JRE).

Before you download the JRE, 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 onto a client:

1. Open Internet Explorer and enter the URL to open the Launch page for the Oracle Clinical application. For example:
   https://computer_name.domain:port/opa46/launch.htm

2. Click the Downloads link on 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.

   The system downloads the JRE from your Forms Server. When you set up the Forms Server, you installed the latest version of the JRE. See Section 6.2, "Making the Java Runtime Environment Available for Download" for more information.

10.5.2 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 Internet Explorer and enter the URL to open the Launch page for the Oracle Clinical application. For example:
   https://computer_name.domain:port/opa46/launch.htm

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 6.3, "Downloading the Oracle Clinical PDF Plug-in" for more information.

10.5.3 Download Adobe Reader

Oracle Clinical and RDC support Adobe Reader 7.x or later, English versions. 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:
   https://get.adobe.com/reader/
2. Follow the on-screen instructions to download the latest version of the Adobe Reader.

10.6 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 the standard Windows Browse button.

You must first set up the Forms Server where you store your images. See Section 6.5, "Sharing the RDC Directory and Setting 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.

10.7 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 about how to configure the Desktop PDR to generate reports from the command line, see the Oracle Clinical Remote Data Capture Onsite Administrator’s Guide.
This chapter includes the following topics:

- Section 11.1, "Modifying SAS 9.2 and opa_settings on UNIX"
- Section 11.2, "Installing SAS on the Same UNIX Computer as Oracle Clinical"
- Section 11.3, "Installing SAS on a Different UNIX Computer from Oracle Clinical"
- Section 11.4, "Modifying SAS 9.2 for Windows"
- Section 11.5, "Installing SAS on the Same Windows Server Computer"
- Section 11.6, "Installing SAS on a Different Windows Server Computer"

**UNIX**  Performing the steps in Section 11.1 and in either Section 11.2 or Section 11.3 is required before you use SAS for Oracle Clinical Data Extract. The steps are the same for any supported UNIX platform.

**Windows**  Performing the steps in Section 11.4 and either Section 11.5 or Section 11.6 is required before you use SAS for Oracle Clinical Data Extract.

### 11.1 Modifying SAS 9.2 and opa_settings on UNIX

Oracle Clinical supports SAS 9.2. You can validate your Oracle Clinical 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.

#### 11.1.1 Prepare the SAS Template File

Make the following modifications to the SAS template file:

1. Copy the SAS template file from $OPA_HOME/oc/462/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.

#### 11.1.2 Edit 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`

### 11.1.3 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, the SAS script file includes a step that points to the 32-bit libraries.

**SAS/ACCESS Error with Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1**

Using Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 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`

### 11.2 Installing SAS on the Same UNIX Computer as Oracle Clinical

Oracle recommends installing SAS on the same server computer as the Oracle Clinical Database Server installation, following instructions in this section.

#### 11.2.1 Set REMOTE_OS_AUTHENT to FALSE

Verify that the REMOTE_OS_AUTHENT initialization parameter is set to FALSE for the Oracle Clinical database instance in the init.ora file:

```
REMOTE_OS_AUTHENT=FALSE
```

See Section 4.1.8, "Set Initialization Parameters" for further information.

#### 11.2.2 Edit the opa_setup Script

Change the following lines:

```bash
if [ $local_db = TRUE ] ; then
    RXC_SAS_CONNECT='oracle(path="${ORACLE_SID}"')
    # 20010308 (dkacher) bug 749959: force reference to ORACLE_SID to lowercase
    RXC_SAS_VIEW=$RXC_USER/sas_view/`echo $ORACLE_SID | tr "[:upper:]" "[:lower:]"
```

to:

```bash
if [ $local_db = TRUE ] ; then
    RXC_SAS_CONNECT='oracle(path="${ORACLE_SID}"')
    # 20010308 (dkacher) bug 749959: force reference to ORACLE_SID to lowercase
    RXC_SAS_VIEW=$RXC_USER/sas_view/`echo $ORACLE_SID | tr "[:upper:]" "[:lower:]"`
```
if [ $local_db = TRUE ]; then
    # RXC_SAS_CONNECT='oracle(path="**${ORACLE_SID}"')'
    RXC_SAS_CONNECT='oracle()'  
    # 20010308 (dkacher) bug 749959: force reference to ORACLE_SID to lowercase
    RXC_SAS_VIEW=$RXC_USER/sas_view/`echo $ORACLE_SID | tr ":upper:" ":lower:"`

The changed portions are in bold text.

11.3 Installing SAS on a Different UNIX Computer from Oracle Clinical

Oracle recommends installing SAS on the same UNIX server computer as the Oracle Clinical database server installation.

If you choose to install SAS on a UNIX server computer different from that of the Oracle Clinical Database Server installation, you need to set up a connection to SAS. To set up a connection, you create SAS view descriptors on the Oracle Clinical Database Server in the $RXC_USER directory that the SAS server can access.

11.3.1 Establish the Connection to SAS

Note: The following procedure uses secure shell (ssh) to establish the connection to SAS.

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.

4. Verify that the REMOTE_OS_AUTHENT initialization parameter is set to TRUE for the Oracle Clinical database instance in the init.ora file:

   REMOTE_OS_AUTHENT=TRUE

   See Section 4.1.8, "Set Initialization Parameters" for more information.

5. Create a shell script that forces a "SAS" invocation on the Oracle Clinical Database Server 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 Database Server 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'

ssh 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

### 11.3.2 Configuring Private and Public Keys for Using SSH with SAS

Perform the following tasks on the Oracle Clinical UNIX Database Server computer:

1. Log into the Oracle Clinical UNIX Database Server computer as the database user running SAS Data Extract jobs. The user must have PSUB privileges.

2. Use ssh-keygen to create a password-less set of identity keys:

   ```bash
   ssh-keygen -t rsa -N ''
   ```

   The system prompts for the file into which you want to save the set of identity keys.

3. Press **Return** to accept the default location. This process creates two files in the user's home directory:

   - `~/.ssh/id_rsa` This file contains the private key that represents your identity on that particular machine. Note that the private key is neither world nor group readable. You should never transfer the private key from the machine or change its modes.
   - `~/.ssh/id_rsa.pub` This file contains the public key, which is world readable. The ssh program and other programs can use the public key to encrypt messages that only you can decrypt using the private key. The `-N ' '` argument to the ssh-keygen command specifies that no passwords are associated with the private keys.

4. Transport the file `id_rsa.pub` to a location on the SAS Server (for example, `/tmp`) using a secure method as defined by the policies of your organization.

Perform the following tasks on the SAS Server computer:

1. Log in to the SAS Server computer as the same database PSUB user that you logged in as on the Oracle Clinical Database Server.

2. In the home directory Create the `.ssh` directory if it does not exist, and set the permission to 700:

   ```bash
   mkdir .ssh
   chmod 700 .ssh
   cd ~/.ssh
   ```

3. Append the contents of the `id_rsa.pub` file in the `/tmp` directory to the `authorized_keys` file in the `GUEST1_HOME/.ssh` directory. For example:

   ```bash
   cat /tmp/id_rsa.pub >> authorized_keys
   ```

4. Change the permission of the `authorized_keys` file to 600:

   ```bash
   chmod 600 authorized_keys
   ```

5. Repeat this procedure for each user who runs SAS Data Extract jobs.
11.4 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 commented in opa_settings.bat (is preceded by REM).
   REM set SASORA=V9

11.5 Installing SAS on the Same Windows Server Computer

Oracle recommends installing SAS on the same Windows server computer as the Oracle Clinical database server installation.

If you choose to install SAS on a Windows server computer different from that of the Oracle Clinical database server installation, you must execute SAS jobs manually. However, that configuration is also possible; see Section 11.6, "Installing SAS on a Different Windows Server Computer".

11.5.1 Set REMOTE_OS_AUTHENT to FALSE

Verify that the REMOTE_OS_AUTHENT initialization parameter is set to FALSE for the Oracle Clinical database instance in the init.ora file; see Section 4.1.8, "Set Initialization Parameters" for further information.

11.5.2 Set System Path

Ensure that the system path is updated with respect to SAS:

1. Log in to the Oracle Clinical Database Server as an administrator.
2. If the PSUB process is running, stop it.
3. In the command prompt, enter: path
   The system lists the set of directories in which the system will search for an executable file (in this case, the SAS executable). Among others, the following path must be present (in this example, SAS 9.2 is installed in C:\Program Files):
   C:\Program Files\SAS92\SharedFiles\Formats(32);C:\Program Files\SAS92\SASFoundation\9.2;
   If not present:
   a. Navigate to the Control Panel, then System and Security, then System.
   b. Select the Advanced tab, then Environment Variables.
   c. In the System Variable sections select PATH and click the Edit button.
   d. In the Variable Value box, append the correct value for your location, for example:
      ;C:\Program Files\SAS92\SharedFiles\Formats(32);C:\Program Files\SAS92\SASFoundation\9.2;
      to the existing value and click OK.
   e. Click OK in the Environment Variables dialog box.
f. Click **OK** in the System Properties dialog box.

4. If PSUB should be running, start it.

5. Log out of the computer.

### 11.5.3 Edit the SAS Config File and Grant Permissions

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**

To accomplish this:

1. Log in to the Oracle Clinical Database Server as an administrator.

2. Using Windows Explorer, navigate to the following location (in this example SAS 9.2 is installed in C:\Program Files): C:\Program Files\SAS92\SASFoundation\9.2\nls\en


4. Comment the existing lines about -SASUSER and -WORK and add new ones, substituting any directory you choose for D:\sasuser and D:\sastemp, so that the section looks like this:

   /* Setup the default SAS System user profile folder */
   /*-SASUSER "?CSIDL_PERSONAL\My SAS Files\9.2"*/
   -SASUSER "D:\sasuser"

   /* Setup the default SAS System user work folder */
   /*-WORK "!TEMP\SAS Temporary Files"*/
   -WORK "D:\sastemp"

5. Save the file.

6. Create directories D:\sasuser and D:\sastemp or your preferred equivalents. (In Windows Explorer, right-click and then select **New**, then **Folder**.)

7. Give full control directory permissions on these directories to the oclsascr group.

### 11.6 Installing SAS on a Different Windows Server Computer

You can also install SAS on a computer other than the Oracle Clinical database. However, if you do you must 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.

#### 11.6.1 Set REMOTE_OS_AUTHENT to TRUE

Verify that the REMOTE_OS_AUTHENT initialization parameter is set to TRUE for the Oracle Clinical database instance in the init.ora file; see Section 4.1.8, "Set Initialization Parameters" for further information.

#### 11.6.2 Enable Executing Data Extract PSUB Jobs

To enable executing data extract PSUB jobs:
1. Create a local account on the computer with the PSUB service. 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. Create a local user account on the computer with the SAS application. 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.

11.6.3 Edit the SAS Config File and Grant Permissions

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

To accomplish this:

1. Log in to the Oracle Clinical Database Server as Administrator.

2. Using Windows Explorer, navigate to the following location (in this example SAS 9.2 is installed in C:\Program Files):
   C:\Program Files\SAS92\SASFoundation\9.2\nl\en


4. Comment the existing lines about -SASUSER and -WORK and add new ones, substituting any directory you choose for D:\sasuser and D:\sastemp, so that the section looks like this:

/* Setup the default SAS System user profile folder   */
/*-SASUSER "?CSIDL_PERSONAL\My SAS Files\9.2"*/
-SASUSER "D:\sasuser"

/* Setup the default SAS System user work folder      */
/*-WORK "!TEMP\SAS Temporary Files"*/
-WORK "D:\sastemp"

5. Save the file.
6. Create directories D:\sasuser and D:\sastemp or your preferred equivalents. (In Windows Explorer, right-click and then select New, then Folder.)

7. Give full control directory permissions on these directories to the oclsascr group.
This chapter describes the recommended approach to upgrading an existing Oracle Clinical installation to Release 4.6.2. You can use the instructions in this chapter to upgrade from any of the following releases:

- Release 4.5.1
- Release 4.5.2
- Release 4.5.3
- Release 4.6.0

**Note:** If you are upgrading from Oracle Clinical Release 4.5 or earlier, you must upgrade to Release 4.5.1 first. Download the software and the *Oracle Clinical Release 4.5.1 Installation Guide* from the Oracle Life Sciences 4.5 media pack for your operating system on http://edelivery.oracle.com. (Although the media pack is labeled "4.5" it contains Release 4.5.1.)

This chapter includes the following topics:

- Section 12.1, "Determining Whether You Need to Prepare and Migrate Data"
- Section 12.2, "Completing Other Pre-Upgrade Tasks"
- Section 12.3, "Create a New Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Oracle Home"
- Section 12.4, "Installing Oracle Clinical 4.6.2 on the Database Server"
- Section 12.5, "Upgrading Oracle Clinical to the New Oracle 11gR2 Home"
- Section 12.6, "Upgrading Database Objects to Oracle Clinical 4.6.2"
- Section 12.7, "Installing and Configuring Other Components"
- Section 12.8, "Preserving Customizations"
- Section 12.9, "Repairing Oracle Clinical Data"
- Section 12.10, "Preparing and Migrating Data If Necessary"
- Section 12.11, "Starting the PSUB Process"
- Section 12.12, "Re-enable Replication"
- Section 12.12.1, "Upgrading Installations that Use Replication"
Section 12.13, "Applying the Latest Patch Set"

Review Chapter 1, "Preparing to Install Oracle Clinical" for system requirements and planning information. Ensure that your operating system and environment meet the requirements.

Check the Health Sciences Clinical documentation page at http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html to be sure you have the latest version of this guide.

12.1 Determining Whether You Need to Prepare and Migrate Data

Companion patches OC_4.5.3.11 and OC_4.5.3.12 introduced enhancements that expect approval and verification data to be represented in a new format in the database. Oracle Clinical 4.6.2 includes all these enhancements.

In addition, patches OC_4.5.3.11 and OC_4.5.3.12 included a Preparation script and a Data Migration script to migrate existing data from the old format to the new format. Oracle Clinical 4.6.2 includes these scripts.

Before you start to upgrade to Oracle Clinical 4.6.2, you must determine if the Preparation and Data Migration scripts have been run on your databases. Then take the appropriate action as outlined below to prevent data corruption:

- **If you are upgrading from 4.5.1 or 4.5.2** (or 4.5.3 without having applied 4.5.3.11 or its successor), you must run the Preparation and Data Migration scripts after you complete the 4.6.2 upgrade and before you open the Oracle Clinical 4.6.2 database for user access. Opening the Oracle Clinical 4.6.2 database for user access without migrating your data to the new data model will cause problems maintaining and reporting the correct approval and verification status for patient CRFs.

- **If you are upgrading from 4.5.3.11 (or a successor patch) or 4.6**, you have probably already migrated your data. However it is important that you follow the checks in Section 12.1.1, "Methods to Identify If Scripts Were Already Run". Otherwise, proceed with the instructions in Section 12.2, "Completing Other Pre-Upgrade Tasks". You will migrate your data later; see Section 12.10, "Preparing and Migrating Data If Necessary".

---

**Note:** Preparing and migrating data is a lengthy process, so you should calculate the required downtime BEFORE you start the upgrade process; see Appendix A for guidelines.

---

- **If you are upgrading from 4.5.3.11 (or a successor patch) or 4.6**, you have probably already migrated your data. It is important that you follow the instructions in Section 12.1.1, "Methods to Identify If Scripts Were Already Run" to be sure you run the migration once and only once.
  - **If you are upgrading from 4.5.3.11 or a successor patch, or 4.6, and you determine that you have NOT run the Preparation and Data Migration scripts, or you are not sure, contact Oracle Support for assistance. DO NOT CONTINUE with the upgrade.**
  - **If you determine that you have already migrated your data, DO NOT prepare and migrate the data again.** Re-running the scripts will cause problems maintaining and reporting the correct approval and verification status for patient CRFs. Proceed with the instructions in Section 12.2, "Completing Other Pre-Upgrade Tasks".
Completing Other Pre-Upgrade Tasks

12.1.1 Methods to Identify If Scripts Were Already Run

To determine if the Preparation script and the Data Migration script have been run against a database already:

1. Execute the following query against the database:
   ```sql
   select table_name from all_tables
   where table_name like 'APPVER_RDCIH%'
   ```
   If this query returns a record, it indicates that the Preparation script has been run. However, it does not indicate that the Data Migration script was run.

2. Navigate to the INSTALL directory on the database server. Look for a file with the following name:
   `oclupg45311migrate-database_name-timestamp.lis`
   If the file exists, it indicates that the Data Migration script has been run against the specified database (`database_name`).

3. Open and review the file to verify that the Data Migration script completed without any errors.

---

Caution: If you are on 4.5.3.11 or later and have not run the Preparation and Data Migration scripts, or you are not sure, contact Oracle Support for assistance. DO NOT CONTINUE with the upgrade.

---

12.2 Completing Other Pre-Upgrade Tasks

Before you start to upgrade your system to Oracle Clinical 4.6.2, complete the preliminary tasks described in this section:

- Section 12.2.1, "Back Up Your Database(s)"
- Section 12.2.2, "Stop Replication"
- Section 12.2.3, "Prevent Access to Oracle Clinical Databases"
- Section 12.2.4, "Stop PSUB"

12.2.1 Back Up Your Database(s)

Oracle recommends backing up your database(s) at this point.

12.2.2 Stop Replication

If you have a distributed environment in which you replicate data and metadata among multiple databases, stop all replication before continuing the upgrade.

Note: Oracle Clinical 4.6 does not support replication. If you are upgrading from Oracle Clinical 4.6, you can skip this section.

This section includes the following topics:

- Section 12.2.2.1, "Preparing All Replication Environments"
- Section 12.2.2.2, "Stopping Standard Replication"
Completing Other Pre-Upgrade Tasks

- **Section 12.2.2.3, “Stopping Symmetric Replication”**

  **Tip:** You must upgrade all databases in your Oracle Clinical installation to Oracle Clinical 4.6.2 before setting up, or resuming, replication in any of them.

### 12.2.2.1 Preparing All 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 following error:

```
Mandatory column is null.
```

Use caution when applying the percent symbol (%) wildcard to specify which studies to bring across when doing a full study replication. The % wildcard pulls over all studies that are available for replication from all owning locations. (A study is available for replication if its Ready to Repl check box is selected.) If your company has many studies at multiple locations, consider specifying studies uniquely.

### 12.2.2.2 Stopping Standard Replication

To stop standard replication activities in your installation:

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

In a distributed environment:

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. Do not restart replication until you finish upgrading all databases in a replicated set.

If you follow these instructions, 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.

### 12.2.2.3 Stopping Symmetric Replication

Because symmetric replication operates independently of Oracle Clinical, you must stop the database activities that control the symmetric replication activities. In addition, you must stop the symmetric replication activities for each database in your installation.

To stop symmetric replication for one database in your installation:

1. Log in as the REPSYS user.
2. Check the replication queue for all pending jobs.
   a. List the pending jobs in the queue:
      ```
      select * from DEPTRAN;
      ```
   b. Push these pending transactions:
Completing Other Pre-Upgrade Tasks

3. Disable the replication queues until the upgrade is complete.
   a. List the jobs in the queue:
      ```sql
      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:
      ```sql
      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 this command against the master database:
   ```sql
   execute dbms_repcat.suspend_master_activity ('RXA_DES');
   ```

6. Drop the replication group from both databases:
   ```sql
   execute dbms_repcat.drop_master_repgroup ('RXA_DES');
   ```

12.2.3 Prevent Access to Oracle Clinical Databases

You must ensure that no data entry is performed, and no jobs that update data (such as batch validation) run during the upgrade process.

To prevent users from accessing the data, place the database in restricted mode. Provide restricted session access to the following accounts:
- OPA
- RXC
- RXA_DES
- RXC_SERVLETST
- SYSTEM

After you complete the upgrade, remove the restricted access from the databases and user accounts.

12.2.4 Stop PSUB

Stop PSUB on the database.

**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

To stop PSUB on Windows:
1. Navigate to the Services control panel.
2. Highlight the PSUB service.
3. Click Stop.

12.3 Create a New Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Oracle Home

Create a new Oracle home by following these operating system-specific tasks.

12.3.1 Creating a New UNIX Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Oracle Home

To install Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 in a new UNIX Oracle home, follow the instructions in these sections in Chapter 2:

- Section 2.2, "Installing Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1"
- Section 2.3, "Setting Permissions and Write Access to Oracle-Owned Directories"

If necessary, perform the tasks in Section 2.4, "Setting Up User Groups and Accounts."

12.3.2 Creating a New Windows Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Oracle Home

On a Windows 2008 R2 Server, follow the instructions in Section 3.1, "Installing and Patching Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1" in Chapter 3.

If necessary, perform the tasks in Section 3.2, "Setting Up User Accounts and User Groups".

12.4 Installing Oracle Clinical 4.6.2 on the Database Server

To install the Database Server component, you log in to the server, run Oracle Universal Installer from the appropriate download location, and select the OC Server product. Follow instructions for your operating system:

- Section 12.4.1, "Install Oracle Clinical 4.6.2 on a UNIX Database Server"
- Section 12.4.2, "Install Oracle Clinical 4.6.2 on a Windows Database Server"

12.4.1 Install Oracle Clinical 4.6.2 on a UNIX Database Server

This section describes the tasks that you complete to install Oracle Clinical 4.6.2 on UNIX Database Servers.

12.4.1.1 Installing the UNIX Oracle Clinical Database Server Component

Perform the UNIX-specific installation instructions in Chapter 2, Section 2.5, "Installing the Oracle Clinical Database Server."
12.4.1.2 Modifying the Default Environment Variable Settings
Installing Oracle Clinical 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 2.6.3, "Review the opa_settings File" 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.

---

12.4.2 Install Oracle Clinical 4.6.2 on a Windows Database Server
To install Oracle Clinical 4.6.2 on Windows Database Servers:

1. Perform the installation instructions in Section 3.3, "Installing the Oracle Clinical 4.6.2 Database Server."
2. Grant write access to the ORACLE_HOME directory and its contents.

12.5 Upgrading Oracle Clinical to the New Oracle 11gR2 Home
Table 12–1 shows which versions of the Oracle database and which operating systems are required by different releases of Oracle Clinical. If you are upgrading from an Oracle Clinical release that runs on an earlier operating system version than is supported for Oracle Clinical 4.6.2, you must install Oracle Database 11.2.0.2 and Oracle Clinical 4.6.2 on a computer with the newer operating system and then export/import your Oracle Clinical database(s).

If you are using Oracle Clinical 4.5.x you must first upgrade your Oracle Database to 9.2.0.8 by installing the April 2010 or later CPU, if you have not already done so, before exporting your database(s).

<table>
<thead>
<tr>
<th>Oracle Clinical</th>
<th>Oracle Database</th>
<th>UNIX</th>
<th>Windows</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5.1, 4.5.2, 4.5.3</td>
<td>9.2.0.8 (after the April 2010 CPU)</td>
<td>HP-UX PA-RISC 11iV1 or 11iV2 (64-bit) Solaris SPARC 8, 9, or 10 (64-bit)</td>
<td>Windows NT, 2000 or 2003</td>
</tr>
<tr>
<td>4.6</td>
<td>11.1.0.7</td>
<td>HP-UX Itanium 11.31 (64-bit) Solaris SPARC 9 or 10 (64-bit) Oracle Enterprise Linux 5 x86-64</td>
<td>Windows 2003 (32-bit)</td>
</tr>
<tr>
<td>4.6.2</td>
<td>11.2.0.2</td>
<td>HP-UX Itanium 11.31 (64-bit) Solaris SPARC 10 (64-bit) Oracle Enterprise Linux 5 Update 5 x86-64 (64-bit)</td>
<td>Windows 2008 R2, SP 1 (64-bit)</td>
</tr>
</tbody>
</table>

12.5.1 Review Options Before Upgrading the Database
Review the topics in this section, which might impact your upgrade strategy.

12.5.1.1 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 11g Release 2 (11.2.0.2) Patch Set 1. If you plan to implement Oracle Clinical partitioning,
install this option just after you upgrade Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1.


12.5.1.2 Legacy Installations
Oracle Clinical 4.6.2 is not dependent on previous installations. Once you complete the update of all users and migrate all databases to Oracle Clinical 4.6.2, you can archive earlier Oracle Clinical releases and then delete those releases from your system.

12.5.2 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.sql 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 4.6.2 for Performance and Scalability*
Article ID: 1300850.1

12.5.2.1 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.

12.5.2.2 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 — consider modifying ocl452indexchg.sql in resizing (redefining) the storage clause for the indexes and executing this script standalone.

**To run the ocl452indexchg.sql script on UNIX:**
1. Log in to the UNIX Database Server.
2. Set the environment variables for the database and code environment.
3. Change to the installation directory:
   ```
   cd $RXC_INSTALL
   ```
4. Run the ocl452indexchg.sql script:

   sqlplus /nolog @ocl452indexchg.sql

**To run the ocl452indexchg.sql script on Windows:**

1. Log in to the Windows Database Server.

2. Enter the following commands:

   set p1=database
   set p2=462
   opa_setup
   cd %RXC_INSTALL%
   sqlplus /nolog @ocl452indexchg.sql

### 12.5.3 Upgrade the 9.2.0.8 or 11.1.0.7 Oracle Clinical Database to the 11.2.0.2.0 Oracle Home

Depending on your current Oracle Clinical installation, you may be able to upgrade in place or do an export/import of your database(s).

---

**Note:** If you are using Oracle Clinical 4.5.x, you must first upgrade your database to 9.2.0.8, if you have not already done so, by applying the April 2010 or later CPU.

---

Oracle recommends that you create all tablespaces with the *Autoextend On* option on to avoid running out of storage space; see Section 12.5.2, "Review Tablespace Sizes".

**Upgrading in Place**  If your current Oracle Clinical installation is on an operating system that is also supported for Oracle Clinical 4.6.2 (see Table 12–1, "Oracle Clinical Releases and Supported Database Operating Systems") and you choose to use the same hardware for OC 4.6.2, you can upgrade in place using the Oracle Database Upgrade Assistant (DBUA).

For performing an in-place upgrade using the Oracle DBUA, see the following documents:

- **Complete Checklist to Upgrade the Database to 11gR2 using DBUA**
  My Oracle Support article ID 870814.1; see "Finding Information on My Oracle Support" on page xii

- **Oracle Database Upgrade Guide 11g Release 2 (11.2), Chapter 3, "Upgrading to the New Release"**; see "Finding Other Oracle Documentation" on page xiv

**Using New Hardware**  If your current Oracle Clinical installation is on an operating system version that is not supported for 4.6.2, or if you prefer to use new hardware, you must perform an export/import.

For export/import instructions see *Cloning Oracle Clinical 4.6 and TMS 4.6.1 Databases*; My Oracle Support Article ID: 883213.1.

---

**Note:** Be sure to follow all the instructions in the document, including running the chown.sql script, the opachown.sql script, and if you are using TMS with Oracle Clinical, the tmschown.sql script. Use the Oracle Clinical 4.6.2 server code for cloning.
12.6 Upgrading Database Objects to Oracle Clinical 4.6.2

This section describes how to run Oracle Universal Installer to upgrade your database to Oracle Clinical 4.6.2.

12.6.1 Windows Installer Starting Instructions

To begin the installation:

1. Log in using an account with Windows system administrator privileges.
2. Insert the Oracle Clinical and Oracle Thesaurus Management System 4.6.2 disk from the media pack.
3. Locate and execute file:
   
   `oc\server_code\win\install\setup.exe`
   
   The Installer opens to the Welcome screen.
4. Follow the instructions for each screen in the following section.

12.6.2 UNIX Installer Starting Instructions

To start the upgrade of an Oracle Clinical database on a UNIX Database 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 11g Release 2 (11.2.0.2) Patch Set 1 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 Oracle Universal Installer:

   `./runInstaller`

7. Follow the instructions on the installation screens. For additional information about each screen, see Section 12.6.3, "Attend to the Oracle Clinical Database Upgrade Installation Screens."

12.6.3 Attend to the Oracle Clinical Database Upgrade Installation Screens

The Oracle Universal Installer guides you through installing and upgrading an Oracle Clinical database.
Welcome
Click Next to continue the installation.

Select a Product to Install
Select Oracle Clinical Database Upgrade 4.6.2.0.XX (where XX is the build number).
Click Next.

Select Installation Type
Oracle Clinical Database Upgrade 4.6.2.0.XX (Note: XX is the build number.)
Select Upgrade and Configure (0 KB), and then click Next.

Specify Home Details
Destination
Accept the default values, and then click Next.

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 Database Server installation. Click Next.

Choose Database
Connect string for database to be upgraded
Enter the Oracle SID for the database; for example, prod.
Click Next.

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 the full name of the host where the database is located, and 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 Password for...
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_SERVLETP
RXC_SERVLEST RXA_WS

For a description of each password, see Section 4.2.4, "Attend to the Oracle Clinical Database Installation Screens."
Yes/No
Ignore tablespace creation errors?
This setting controls whether the Installer ignores errors that occur when creating the
namespaces. 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
The Information screen reports that the Installer will start a SQL*Plus session to
complete the database upgrade. 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
Oracle Clinical Database Upgrade 4.6.2.0.XX  (Note:  XX is the build number.)
The Summary screen provides information about this installation.

Click Install.

The Installer starts a 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.

12.6.4 Remove Group Privileges from this Session
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 12.6.2, "UNIX Installer Starting Instructions"). 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.

12.6.5 Review the Log Files for Upgrade Results and Errors
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
The rest of this section describes finding errors in the log files (as logfile), and descriptions of known errors.

12.6.5.1 Known Error Messages
See the Oracle Clinical 4.6.2 Release Notes for Known Installation Issues for a description of any error messages.

12.6.5.2 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.

12.6.5.3 Finding Errors
To simplify reviewing upgrade results, run these commands for each of the database upgrade log files:

Oracle Enterprise Linux x86-64. From the command line, enter:

```bash
opa_setup database 462
cd $RXC_INSTALL
/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

Oracle Solaris SPARC. From the command line, enter:

```bash
opa_setup database 462
cd $RXC_INSTALL
/usr/xpg4/bin/grep -E '\^ORA-\|^PLS-\|^SP2-' logfile | more
```

HP-UX Itanium. From the command line, enter:

```bash
opa_setup database 462
cd $RXC_INSTALL
/usr/bin/grep -n -E '\^ORA-\|^PLS-\|^SP2-' logfile | more
```

Windows. From the command line, enter:

```bash
set p1=database
set p2=462
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.
12.6.6 Compile Invalid Objects

When upgrading the Oracle Clinical database, the Oracle Universal Installer automatically calls and runs the following script to compile invalid objects:

```
compile_all_invalid.sql
```

However, to reduce the time required to run the script and to ensure that the installation completes in a timely manner, the `compile_all_invalid.sql` script does not compile these invalid objects:

- Packages owned by RXC_PD (that is, the validation and derivation procedures that you have created). The package name starts with RXC_PD.
- Data Extract views that belong to a study. In the database, these views are owned by an internal user whose name starts with `study_name$`.
- Objects owned by any `ops$` account. The `compile_all_invalid.sql` script ignores objects if the owner has a dollar symbol ($) in the name.

The log file generated by the `compile_all_invalid.sql` script lists the objects that could not be compiled.

To view the list of invalid objects, open the following log file:

```
$RXC_INSTALL\compile_all_invalid_database.log
```

To compile the remaining invalid objects (see Table 12–2), run the script `compile_schema_invalid.sql`.

You can run the `compile_schema_invalid.sql` script at a suitable time after the Installer finishes upgrading the Oracle Clinical database. You can recompile the invalid objects for a given schema by connecting to the schema and then running the `compile_schema_invalid.sql` script.

### 12.6.6.1 Compiling PL/SQL Code Before Running the Script

If you have any PL/SQL code referenced from your generated procedures, ensure that these objects are valid before running the `compile_schema_invalid.sql` script.

For example, if you created a schema named `X` that contains all the PL/SQL code referenced from your generated procedures, you would first run:

```
compile_schema_invalid.sql X
```

Then, you would run:

```
compile_schema_invalid.sql RXC_PD
```

### 12.6.6.2 Running the `compile_schema_invalid.sql` Script

Follow the instructions appropriate for your operating system.

#### 12.6.6.2.1 UNIX

To run the `compile_schema_invalid.sql` script on UNIX:

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

   ```
   opa_setup database_name code_environment
   ```

   where:

   - `database` is the name of this database instance.
   - `code_environment` is the value in the `opa_settings` file for this code environment. For Oracle Clinical 4.6.2, the default value is **462**.
3. Change to the RXC_INSTALL directory:
   cd $RXC_INSTALL

4. Start an SQL*Plus session, and connect to the database as sys:
   sqlplus sys/sys_password as sysdba

5. Run the script. Table 12–2 lists the options you can use to run the script depending on which invalid objects you want to compile.

<table>
<thead>
<tr>
<th>To…</th>
<th>Enter this SQL Command…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compile any invalid objects in RXC_PD</td>
<td><code>start compile_schema_invalid RXC_PD</code></td>
</tr>
<tr>
<td>Compile any invalid objects for the Data Extract views that belong to a study</td>
<td><code>start compile_schema_invalid study_name$%</code></td>
</tr>
<tr>
<td>Compile any invalid objects in OPS$ accounts</td>
<td><code>start compile_schema_invalid OPS$%</code></td>
</tr>
<tr>
<td>Compile any invalid objects in any account that has the dollar symbol ($) in the account name</td>
<td><code>start compile_schema_invalid %$%</code></td>
</tr>
<tr>
<td>Compile all invalid objects in all schemas</td>
<td><code>start compile_schema_invalid %</code> Note that this command compiles all invalid objects, including those in other schemas such as RXC and RXA_DES. However, the compile_all_invalid.sql script that the Oracle Universal Installer automatically runs after upgrading the Oracle Clinical database already compiles the invalid objects for those schemas.</td>
</tr>
</tbody>
</table>

6. Check the log file to verify that the script compiled the invalid objects successfully:
   `$RXC_INSTALL\compile_schema_invalid_database.log`

12.6.6.2.2 Windows To run the `compile_schema_invalid.sql` script on Windows:

1. From the command line, enter:
   ```
   set p1=database
   set p2=462
   opa_setup
   cd %RXC_INSTALL%
   ```

2. Start an SQL*Plus session, and connect to the database as sys:
   ```
   sqlplus sys/sys_password as sysdba
   ```

3. Run the script. Table 12–3 lists the options you can use to run the script depending on which invalid objects you want to compile.

<table>
<thead>
<tr>
<th>To…</th>
<th>Enter this SQL Command…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compile any invalid objects in RXC_PD</td>
<td><code>start compile_schema_invalid RXC_PD</code></td>
</tr>
<tr>
<td>Compile any invalid objects for the Data Extract views that belong to a study</td>
<td><code>start compile_schema_invalid study_name$%</code></td>
</tr>
</tbody>
</table>
4. Check the log file to verify that the script compiled the invalid objects successfully:

   %RXC_INSTALL%/compile_schema_invalid_database.log

12.6.7 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 4.1.8, "Set Initialization Parameters" for details.

12.6.8 Perform Post-Upgrade Database Tasks

Do each of the following tasks.

12.6.8.1 Set Initialization Parameters

After the upgrade completes, set the init.ora parameters according to the instructions in Section 4.1.8, "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 4.6.2 for Performance and Scalability
  * Article ID: 1300850.1

Restart the Database

Stop, and then start the database to activate the changed init.ora parameters.

12.6.8.2 Change Default Passwords for Schemas and Roles

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.

12.6.8.3 Enroll Users

See the Oracle Clinical Administrator’s Guide for information about enrolling users.
12.6.8.4 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 in the rxc_install directory to pin the database packages.

Run the script rxcdbinit.sql as RXC.

12.6.8.5 Analyze Tables and Review Optimization Statistics
Oracle Clinical provides scripts that analyze the storage characteristics of tables and indexes of computed statistics. Run these scripts after the installation in the RXC_INSTALL directory:

- Run anarxctab.sql as RXC.
- Run anadestab.sql as RXA_DES.
- Run analrtab.sql as RXA_LR.
- Run anaopatab.sql as OPA.

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.

12.7 Installing and Configuring Other Components
Because Oracle Clinical 4.6.2 uses a different technology stack than earlier releases of Oracle Clinical, you must install new Application Servers, Forms Servers, and Reports Servers.

In addition, beginning with Oracle Clinical 4.6.2, PSUB uses a Secure Shell (ssh) execution service and Oracle Clinical uses SFTP for file viewing. You need to set up PSUB and configure SFTP before using Oracle Clinical.

Optionally, you may want to set up additional clients or configure the SAS statistical software application to function with Oracle Clinical Data Extract.

For information about installing and configuring:

- Application Servers — See Chapter 5, "Installing and Configuring Oracle Application Server."
- Forms Servers — See Chapter 6, "Installing Oracle Clinical Front End."
- Reports Server — See Chapter 7, "Installing Reports Servers."
- PSUB — See Chapter 8, "Setting Up the Parameterized Submission Process."
- SFTP — See Chapter 9, "Implementing Secure FTP for File Viewing (UNIX Only)."
- Clients — See Chapter 10, "Setting Up Clients."
- SAS — See Chapter 11, "Setting Up SAS."

12.8 Preserving Customizations
If you customized any of the following scripts in Oracle Clinical 4.5.1, 4.5.2, or 4.5.3, you may need to reapply your customizations after upgrading to 4.6.2. They are located in the RXC_INSTALL directory.
12.9 Repairing Oracle Clinical Data

Ensure that you applied the following data diagnostic and repair patches (or their successors) on your Oracle Clinical data.

12.9.1 Repairing Oracle Clinical 4.5.3 Data

The code fixes from the following patches are included in the Oracle Clinical 4.6.2. You do not need to apply the patches. However, if you have not already done so, you must run the Find and Fix scripts for each patch; see the patch release notes for instructions. The Find and Fix scripts are also shipped with Oracle Clinical 4.6.2.

- **Patch OC_4.5.3.21** (or its successor). Includes scripts to find and fix the data affected by Bug 8908711. The Find script in this patch identifies received DCM's (CRF sections) with an invalid status of PASS 1 COMPLETE and Blank flag = Y. (When Blank flag = Y, the status should be RECEIVED.) Once you run the script, you can open and update the affected CRFs without encountering the following error message:

  300500 ERROR WHILE TRYING TO ADD A DISCREPANCY

- **Patch OC_4.5.3.14** (or its successor). Provides a Find script to address data issues that may have been introduced with the use of group activities (for example, Approve or Verify) from the Activity list in RDC Classic only. (Note that the problem does not occur in RDC Onsite). For more information, see Bug 8271954.

12.9.2 Repairing Release 4.5.1 Data

The code fixes from the following patches are included in the Oracle Clinical 4.6.2. You do not need to apply the patches. However, if you have not already done so, you must run the Find and Fix scripts for each patch; see the patch release notes for instructions. The Find and Fix scripts are also shipped with Oracle Clinical 4.6.2.

- **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.

- **Patch OC_4.5.1.76**: Finds and fixes the data affected by bug 8925493.

12.10 Preparing and Migrating Data If Necessary

If you determined in Section 12.1, "Determining Whether You Need to Prepare and Migrate Data" that you have not yet migrated data for the approval and verification
enhancement introduced in 4.5.3.11, prepare and migrate your data now; see Appendix A, “Migrating Data for Approvals and Verifications Enhancements”.

---

**Note:** It is very important to migrate your data once and only once. If you are in doubt, contact Oracle Support.

### 12.11 Starting the PSUB Process

Follow instructions below for your operating system. For additional information see the *Oracle Clinical Administrator’s Guide*.

#### 12.11.1 Starting the PSUB Process on UNIX

To start the PSUB process 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_name code_environment
   ```

   where `database_name` 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.

   **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 the *Oracle Clinical Administrator’s Guide* for details.

#### 12.11.2 Changing the Startup Type 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. In the Start menu, navigate to Administrative Tools, then Services.
   b. 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
      ```

   c. For Startup type, select Manual.
   d. Click the Log On tab.
   e. 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.)
   f. In the Password and Confirm Password fields, enter the RXCPROD password.
   g. Click OK to close the dialog box.
3. Exit from the Services dialog box.
Upgrading Installations that Use Replication

12.11.3 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. In the Start menu, navigate to Administrative Tools, then Services.
   b. 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
   c. Enter values for the Log On parameters:
      
      database code_environment [verbose | noverbose] value-of-RXC_ROOT
      
      For example: prod 462 verbose c:\\opapp\\oc\\462

   | 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/462.

3. Click Start.

4. Exit from the Services dialog box.

12.11.4 Troubleshooting PSUB on a Windows Database

If you have difficulty starting PSUB on a Windows database after upgrading to or installing Oracle Clinical:

1. Open the sqlnet.ora file and confirm that following line is not commented (that is, there is no '#' at the beginning of the line). If there is, uncomment the line (remove the #):
   
   sqlnet.authentication_service=(NTS)

2. Attempt to start PSUB.

If PSUB fails to start:

1. Open the init.ora file. Ensure that the following lines are not commented out and have the values specified. If not, uncomment and/or change the values.
   
   remote_os_authen=FALSE
   os_authent_prefix="OPS$"

2. Shut down any databases on the Windows server, then start the databases.

12.12 Upgrading Installations that Use Replication

If you are using replication to conduct Oracle Clinical studies in a distributed environment, you may need to:

- Re-enable Replication
12.12.1 Re-enable Replication

If you use replication and have upgraded all databases in this distributed environment, follow instructions in the Oracle Clinical Administrator’s Guide to enable the type(s) of replication you use—standard or symmetric replication.

12.12.2 Replicate Approval and Verification Tracking Records

The oclupg45311replicate.sql script replicates the approval and verification system tracking records in the RDCI_HISTORY table from the source location to the target location for the data replicated studies. See Section A.4.6, “Replicate Approval and Verification Tracking Records” for instructions.

12.12.3 Replicate Page Tracking, Discrepancies, and DCFs

If all the following conditions apply to you, follow instructions in this section:

- You have a replicated environment.
- You are upgrading from a release prior to Oracle Clinical 4.5.1.60 and you have not executed full replication since then.
- You have Page Tracking-enabled studies or you want to replicate discrepancy and DCF information.

Patch OC_4.5.1.60 introduced replication of page tracking information, DCFs, and discrepancies. If you never applied patch OC_4.5.1.60 or its successor 4.5.1.75, you should perform an initial replication of this data.

You have two choices:

- Use full replication
- Use incremental replication and run a script

12.12.3.1 Option 1: Do a Full Replication Following the Upgrade

To do a full replication following the upgrade:

1. Complete the upgrade to Oracle Clinical 4.6.2.
2. Set the value of ALLOW_DISC_REPL in the OCL_INSTALLATION reference codelist to Y.
3. Run Full Study Data replication for all current studies.

If you do not want to run full replication, follow the instructions in “Option 2: Do an Incremental Replication and Run a Script” on page 12-21.

12.12.3.2 Option 2: Do an Incremental Replication and Run a Script

If you choose to use incremental replication to upgrade your replicated environment, you must also run the replicate_rpages_disc_dcf_tables.sql script. This script replicates existing received pages, discrepancy entries, and DCF related tables for all studies or for a given study. Running these two processes is likely to take less time than running full replication.

You run this script:
To do an incremental replication following the upgrade and run the replicate script:

1. Complete the upgrade to Oracle Clinical 4.6.2.
2. Run **Incremental Study Data** replication for studies that you want received pages, discrepancies, and DCFs data migrated. (The script will not pick up the study unless you execute this step.)

   **Note:** You need to run **Incremental Study Data** from all locations against all remote locations.

3. Set the value of ALLOW_DISC_REPL in the OCL_INSTALLATION reference codelist to Y at the Global Library-owning location.
4. Run **Full Global Library** replication at all non-Global-Library-owning locations.

**UNIX** To run **replicate_rpages_disc_dcf_tables.sql** on UNIX:

1. Log in to the database server as the opapps user.
2. Set up the environment variables:

   `opa_setup database_name code_environment`

3. Change to the installation directory:

   `cd $RXC_INSTALL`

4. Connect to SQL"Plus as the RXC_REP user.
5. Run the **replicate_rpages_disc_dcf_tables.sql** script:

   ```
   start replicate_rpages_disc_dcf_tables.sql
   ```

   The script prompts for the following information:

   - Name of the source data location.
   - Name of the database link for the source data location.
   - Name of the study. You can enter % for all studies, or you can enter the name of one study.

   The script commits the data for each study after it has successfully replicated the data. If an error occurs while processing a study, the script records the error message in the log file and then starts processing the next study.

6. Review the following generated log file after the script completes processing:

   `replicate_rpages_disc_dcf_tables-timestamp.lis`

   where `timestamp` is the date and time (yyyymmddhhmiss).

**Windows** To run **replicate_rpages_disc_dcf_tables.sql** on Windows:

1. From the command line, enter:

   `set p1=database`
   `set p2=462`
Applying the Latest Patch Set

12.13 Applying the Latest Patch Set

Check My Oracle Support article Oracle Clinical Versions 4.6.2, 4.6, 4.5 and 4.0 Summary of Patches Available (article ID 121863.1) for the latest patch set (4.6.4 or its successor) and apply it. This will provide you with the latest bug fixes and validate the data migration status of all your studies.

If you are installing your database on Windows, you must apply the latest patch set. Oracle Clinical 4.6.2 is not supported on Windows without Patch Set 4.6.4 or later.

Applying the Latest Patch Set

1. opa_setup
   cd %RXC_INSTALL%

2. Start an SQL*Plus session and connect to the database as the RXC_REP user:
   sqlplus RXC_REP/RXC_REP_password

3. Run the script:
   start replicate_rpages_disc_dcf_tables.sql

4. Verify that the script ran successfully.

5. Review the following generated log file after the script completes processing:
   replicate_rpages_disc_dcf_tables-timestamp.lst
   where timestamp is the date and time (yyyyymmddhhmiss).
Patch OC_4.5.3.11 and patch OC_4.5.3.12 introduced enhancements that expect approval and verification data to be stored internally in a new data model. Oracle Clinical 4.6.2 includes all these enhancements.

In addition, Patch OC_4.5.3.11 and patch OC_4.5.3.12 included a Preparation script and a Data Migration script that migrate existing data from the old format to the new format. Oracle Clinical 4.6.2 includes these scripts.

It is very important that you migrate your data ONCE and ONLY ONCE. Both failing to migrate your data and running the scripts to prepare and migrate data more than once will cause problems maintaining and reporting the correct approval and verification status for patient CRFs.

Oracle strongly recommends applying the latest patch set—4.6.4 or later—immediately after upgrading to Oracle Clinical 4.6.2 to ensure proper data migration because:

- The Installer for the patch set automatically checks the data migration status of each study on each database being upgraded and prevents the database upgrade from completing until you have successfully upgraded all nonfrozen studies to the enhanced data model. Failing to migrate causes problems maintaining and reporting the correct approval and verification status for patient CRFs.

- The versions of the preparation and data migration scripts shipped with the patch set include a mechanism that prevents running these scripts more than once, which can also cause problems with CRF approval and verification status.

You can also perform several manual checks to determine if the preparation and data migration scripts have already been run on your database(s); see Section 12.1.1, "Methods to Identify If Scripts Were Already Run".

---

**Caution:** If you are not sure if the Preparation and Data Migration scripts have been run against the database, contact Oracle Support for assistance. **DO NOT CONTINUE** with the upgrade.

---

This appendix includes the following topics:

- Section A.1, "Determining Requirements Before Preparing and Migrating Data"
- Section A.2, "Before You Prepare and Migrate Data"
- Section A.3, "Preparing Your Data for Migration"
- Section A.4, "Migrating Your Data"
A.1 Determining Requirements Before Preparing and Migrating Data

This section describes the following requirements:

- Benchmarks for Estimating Downtime Required to Prepare and Migrate Data
- Tablespace Size Requirements

A.1.1 Benchmarks for Estimating Downtime Required to Prepare and Migrate Data

If you determined that you need to run the Preparation and Data Migration scripts during the upgrade, note that:

- Preparing and migrating data is a lengthy process.
- Users cannot access the system. You must perform all data preparation and data migration while the system is inaccessible to users.
- You should calculate the required downtime **BEFORE** you start the upgrade process. Once you start the upgrade, you cannot start up the database until after you run the Preparation and Data Migration scripts.

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>
<thead>
<tr>
<th>Hardware Configuration</th>
<th>Number of RDCIs</th>
<th>Preparation Script</th>
<th>Data Migration Script</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP-UX Itanium RP 4440: 4x 1000 MHz CPUs (2 dual core processors) with 16 GB RAM</td>
<td>90,000</td>
<td>40 min (2250 RDCIs/minute)</td>
<td>6 minutes (15,000 RDCIs/minute)</td>
</tr>
<tr>
<td>Oracle Sun e6800: 4x 900 MHz CPUs (4 single core processors) with 8 GB RAM</td>
<td>12,000,000</td>
<td>18 hours (11,111 RDCIs/minute)</td>
<td>2 hours (100,000 RDCIs/minute)</td>
</tr>
</tbody>
</table>

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.

\[
\text{number of DCIs} * 3 \text{ records} * 3 \text{ tables} * 350 \text{ bytes} = \text{number of bytes required without allowance for direct inserts}
\]

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:
Before You Prepare and Migrate Data

Migrating Data for Approvals and Verifications Enhancements

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.2 Before You Prepare and Migrate Data

Before you prepare and migrate any data, confirm that you completed the following steps:

- Have you determined that you need to run the Preparation and Data Migration scripts? See Section 12.1, "Determining Whether You Need to Prepare and Migrate Data" for details.
- Have you upgraded the database to Oracle Clinical 4.6.2? See Section 12.6.2 through Section 12.6.6 for details.
- Have you backed up your newly upgraded database? See Section A.2.1 for details.
- Have you prevented access to Oracle Clinical databases? Section A.2.2 for details.

A.2.1 Back Up the Databases Before Preparing and Migrating Data

Back up your newly upgraded database. You should have a complete database backup available for each database before you run the Preparation and Data Migration scripts.

A.2.2 Prevent Access to Oracle Clinical Databases

You must ensure that no data entry is performed, and no jobs that update data (such as batch validation) run during the data preparation and migration process.

To prevent users from accessing the data, place the database in restricted mode. Provide restricted session access to the following accounts:

- OPA
- RXC
- RXA_DES
- RXC_SERVLETST
- SYSTEM

After the data preparation and migration process has finished, remove the restricted access from the databases and user accounts.

---

Caution: 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 Preparing Your Data for Migration

Caution: If you already ran the Preparation script on your data, do not run the script again; see Section 12.1, "Determining Whether You Need to Prepare and Migrate Data.” The Preparation script takes a long time to run. See Section A.1.1, "Benchmarks for Estimating Downtime Required to Prepare and Migrate Data”.

A.3.1 About the Preparation Script

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.

A.3.2 Set Up for the Preparation Script

The setup steps vary depending on the operating system your database uses.

A.3.2.1 Setting Up for the Preparation Script in UNIX

To set up UNIX systems for the Preparation script:

1. Set the environment variables for your database:

   opa_setup database_name code_environment

   For example: opasetup db0001 462

   where your database is named db0001 and you have Patch Set 4.6.3 installed.

2. Change to the RXC_INSTALL directory:

   cd $RXC_INSTALL
A.3.2.2 Setting Up for the Preparation Script in Windows
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 your database:

```
set p1=database_name
set p2=code_environment
opa_setup
```

For example:

```
set p1=db0001
set p2=462
opa_setup
```

where your database is named db0001 and you have Patch Set 4.6.3 installed.

4. Change to the RXC_INSTALL directory:

```
cd /d %RXC_INSTALL%
```

A.3.3 Run the Preparation Script
To run the Preparation script to prepare your data for 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:

```
start oclupg45311prepare.sql
```

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.3.4 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
```

A.3.5 View the Output File Created by the Preparation Script
The preparation script creates the following output file:

```
oclupg45311prepare-database_name-timestamp.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.

### A.4 Migrating Your Data

**Caution:** If you already ran the Data Migration script, do not run the script again; see Section 12.1, “Determining Whether You Need to Prepare and Migrate Data”.

#### A.4.1 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).
- Migrates the data for all non-frozen Oracle Clinical studies.
- Does not migrate any data for frozen Oracle Clinical studies.

While the Data Migration script is running, users must not be allowed to perform any data entry or updates. Additionally, you must not unfreeze a frozen Oracle Clinical study that never used RDC (specifically, has no approvals or verifications). If you anticipate that you will unfreeze an Oracle Clinical study in the future and use RDC to perform approvals and verifications, contact Oracle.

#### A.4.2 Set Up the Environment Before Migrating Data

The setup steps vary depending on the operating system your database uses.

##### A.4.2.1 Setting Up for the Data Migration Script in UNIX

1. Set the environment variables for your database:

   `opa_setup database_name code_environment`

   For example: `opasetup db0001 462`

   where your database is named `db0001` and you have Patch Set 4.6.3 installed.

2. Change to the RXC_INSTALL directory:

   `cd $RXC_INSTALL`
A.4.2.2 Setting Up for the Data Migration Script in Windows

1. Log in to the server as an administrator.
2. Open an MS-DOS command window.
3. Set the environment variables for your database:
   ```
   set p1=database_name
   set p2=code_environment
   opa_setup
   
   For example:
   ```
   ```
   set p1=db0001
   set p2=462
   opa_setup
   
   where your database is named db0001 and you have Patch Set 4.6.3 installed.
```
4. Change to the RXC_INSTALL directory:
   ```
   cd /d %RXC_INSTALL%
   ```

A.4.3 Run the Data Migration Script

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 12.5.2, "Review Tablespace Sizes" for details.
```
3. Run the oclupg45311migrate.sql script.
   ```
   start oclupg45311migrate.sql
   ```
   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.

A.4.4 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
   ```

A.4.5 View the Output File Created by the Data Migration Script

The Data Migration script creates the following output file:
   ```
   oclupg45311migrate-database_name-timestamp.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:
Migrating Your Data

- 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. This number should be zero (0). However, if the number is not zero, note that all approval and verification statuses were recomputed as long as data access was prevented when running the Data Migration script.
- 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.

A.4.6 Replicate Approval and Verification Tracking Records

**Note:** You can skip this section if you plan to apply Patch Set 4.6.4 or its successor immediately after upgrading to Oracle Clinical 4.6.2.

The `oclupg45311replicate.sql` script replicates the approval and verification system tracking records in the RDCI_HISTORY table from the source location to the target location for the data replicated studies.

### A.4.6.1 Determining If You Need to Run the `oclupg45311replicate.sql` Script

You must run the `oclupg45311replicate.sql` script on the slave database only if the following conditions are true:

- You are upgrading a replicated environment.
- Replicated data has approval and verification records at the source location.
- This data existed and was replicated before you ran the following scripts:
  - Preparation script (`oclupg45311prepare.sql`)
  - Data Migration script (`oclupg45311migrate.sql`)

**Note:** The Preparation and Data Migration scripts must have been run (once and only once) in all of the databases within the replication installation before running the `oclupg45311replicate.sql` script.

For information about whether you ran these scripts, see Section 12.1, "Determining Whether You Need to Prepare and Migrate Data."

You run the `oclupg45311replicate.sql` script at the target location so the system can populate the RDCI_HISTORY table for all data replicated studies. The script uses the list of studies in the STUDY_REPLICATION_JOBS table in the database at the target location. Running the script synchronizes the data in the RDCI_HISTORY table between the source location and the target location.

### A.4.6.2 Running the `oclupg45311replicate.sql` Script

**UNIX** To run the `oclupg45311replicate.sql` script on UNIX:
1. Log in to the database server as the opapps user.

2. Set up the environment variables:

   
   ```
   opa_setup database_name code_environment
   ```

   where:

   - `database_name` is the name of the target database
   - `code_environment` = 462

3. Change to the installation directory:

   ```
   cd $RXC_INSTALL
   ```

4. Connect to SQL*Plus. You can connect as any user; the script prompts for the correct user.

   ```
   sqlplus user_name/password
   ```

5. Run the script:

   ```
   start oclupg45311replicate.sql
   ```

   The script prompts for the opa and rxc_rep passwords.

6. Enter the passwords.

7. Verify that the script ran successfully.

8. Review the following generated log file after the script completes processing:

   ```
   oclupg45311replicate-timestamp.lis
   ```

   where `timestamp` is the date and time (yyyymmddhhmiss).

**Windows** To run the oclupg45311replicate.sql script on Windows:

1. From the command line, enter:

   ```
   set p1=database
   set p2=462
   opa_setup
   cd %RXC_INSTALL%
   ```

2. Start an SQL*Plus session, and connect to the database as `sys`:

   ```
   sqlplus sys/sys_password as sysdba
   ```

3. Run the script:

   ```
   start oclupg45311replicate.sql
   ```

   The script prompts for the opa and rxc_rep passwords.

4. Verify that the script ran successfully.

5. Review the following generated log file after the script completes processing:

   ```
   oclupg45311replicate-timestamp.lis
   ```

   where `timestamp` is the date and time (yyyymmddhhmiss).

---

**A.5 Migrating a Single Study Before Unfreezing It**

After you install Oracle Clinical Patch Set 4.6.3 or later, the only studies that remain unmigrated are frozen studies that have never had any approvals or verifications performed. All other studies are migrated.
If you later try to unfreeze an unmigrated study, the system automatically checks if the study has been migrated to the enhanced approve/verify data model and prevents you from unfreezing the study until you have migrated its data. This prevents any problems from occurring if you later use RDC to perform approvals and verifications.

If necessary, you can migrate the study’s data using the script ocl_appver_single_migrate.sql that is shipped with the latest patch set.

A.5.1 Setting Up for the Data Migration Script in UNIX

1. Set the environment variables for your database:
   
   ```bash
   opa_setup database_name code_environment
   
   For example: opasetup db0001 462
   where your database is named db0001 and you have Patch Set 4.6.3 installed.
   ```

2. Change to the RXC_INSTALL directory:
   
   ```bash
   cd $RXC_INSTALL
   ```

A.5.2 Setting Up for the Data Migration Script in Windows

1. Log in to the server as an administrator.

2. Open an MS-DOS command window.

3. Set the environment variables for your database:
   
   ```bash
   set p1=database_name
   set p2=code_environment
   opa_setup
   
   For example:
   set p1=db0001
   set p2=462
   opa_setup
   
   where your database is named db0001 and you have Patch Set 4.6.3 installed.
   ```

4. Change to the RXC_INSTALL directory:
   
   ```bash
   cd /d %RXC_INSTALL%
   ```

A.5.3 Migrating a Nonmigrated Frozen Study

To set up and run the ocl_appver_single_migrate.sql script:

1. Log in to SQL*Plus as the user RXC.

2. Run the single-study migration script.
   
   ```bash
   start ocl_appver_single_migrate.sql
   
   The script prompts you for the following passwords:
   
   OPA password
   RXC password
   ```

3. The script prompts you for the name of the study you want to migrate.
The system migrates the study to the enhanced data model and generates log file 
ocl_appver_single_migrate-database-timestamp.lis, with the timestamp in format 
YYYYMMDDHH24MISS.

The log file contains 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
- 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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