

Oracle® Clinical

Installation Guide

Release 5.1

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This guide describes how to install, configure, and upgrade Oracle Clinical.

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Preface

This *Oracle Clinical Installation Guide* describes installing or upgrading to Oracle Clinical Release 5.1. You perform some of these tasks once. Others you repeat as your system changes or grows.

This preface contains:

- [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 that have purchased support 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:

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

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

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:

1. Sign in to My Oracle Support at <https://support.oracle.com>.
2. Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region. You have the following options:
 - In the **Patch ID or Number** 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 the latest user documentation for Oracle Health Sciences applications, including an HTML version of this guide, go to the Oracle Health Sciences documentation page at:

<http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>

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. 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*
- *Oracle Clinical Administrator's Guide*
- *Oracle Clinical Getting Started*
- *Oracle Clinical Creating a Study*
- *Oracle Clinical Conducting a Study*
- *Oracle Clinical Application Programming Interface Guide*
- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*
- *Oracle Clinical Remote Data Capture Onsite User's Guide*
- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide*
- *Oracle Clinical, Oracle Clinical Remote Data Capture, and Oracle Thesaurus Management System Security Configuration Guide*

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:

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

Preparing to Install Oracle Clinical

This chapter includes:

- [Section 1.1, "Installation and User Documentation"](#)
- [Section 1.2, "Architecture"](#)
- [Section 1.3, "Technology Stack"](#)
- [Section 1.4, "Supported Configurations with Oracle Data Guard and RAC"](#)
- [Section 1.5, "Downloading and Extracting the Software"](#)
- [Section 1.6, "Using the Silent Installer"](#)
- [Section 1.7, "Reviewing the Installation Log Files"](#)
- [Section 1.8, "Choosing a Character Set"](#)
- [Section 1.9, "Applying Oracle Critical Patch Updates"](#)
- [Section 1.10, "Applying the Latest Oracle Clinical Patch Set"](#)
- [Section 1.11, "Integrating Oracle Clinical with Other Products and Options"](#)

Licenses for Remote Data Capture with Oracle Clinical

The installation of Oracle Clinical automatically includes the installation of Oracle Clinical Remote Data Capture Onsite (RDC). However, Oracle Clinical licenses do not cover entering data at remote sites. Separate Remote Data Capture Onsite 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 at the sponsor's or CRO's location, but not at the clinical site.

OPA and OLSA Internal Names

The Oracle Clinical and Oracle Clinical Remote Data Capture (RDC) 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.

1.1 Installation and User Documentation

Be aware of these additional resources.

1.1.1 My Oracle Support Articles

Visit the My Oracle Support website 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 website includes these important installation topics:

- *Oracle Clinical 5.1 Release Notes* (Article ID 1931214.1) The latest version of these release notes are on My Oracle Support.
- *Installation Verification Test* (Article ID 329494.1)
- *OLSA Known Installation and Configuration Issues* (Article ID 1572864.1)
- *Oracle Clinical, Oracle Clinical Remote Data Capture, and Oracle Thesaurus Management System Security Configuration Guide* available with the user documentation; see [Section 1.1.2, "User Documentation."](#)
- *Oracle Health Sciences (Life Sciences/ Pharmaceutical/ Healthcare) Supported Technology Stacks* (Article ID 180430.1)
- *Oracle Clinical Summary of Patches Available* (Article ID 121863.1)
- *Oracle Clinical/RDC Product Information Center* (Article ID 1331795.1): Check here for new notes and White Papers, including the performance White Paper and the Installation Verification Test, which are not available at the time of publication of this document.

1.1.2 User Documentation

The most current Oracle Clinical and Oracle Clinical Remote Data Capture (RDC) Onsite user documentation is located on oracle.com at:

<http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>

Oracle Clinical and RDC Onsite user documentation includes the following guides.

- *Oracle Clinical Installation Guide*
- *Oracle Clinical Administrator's Guide*
- *Oracle Clinical Getting Started*
- *Oracle Clinical Creating a Study*
- *Oracle Clinical Conducting a Study*
- *Oracle Clinical Application Programming Interface Guide*
- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*
- *Oracle Clinical Remote Data Capture Onsite User's Guide*
- *Oracle Clinical, Oracle Clinical Remote Data Capture, and Oracle Thesaurus Management System Security Configuration Guide*

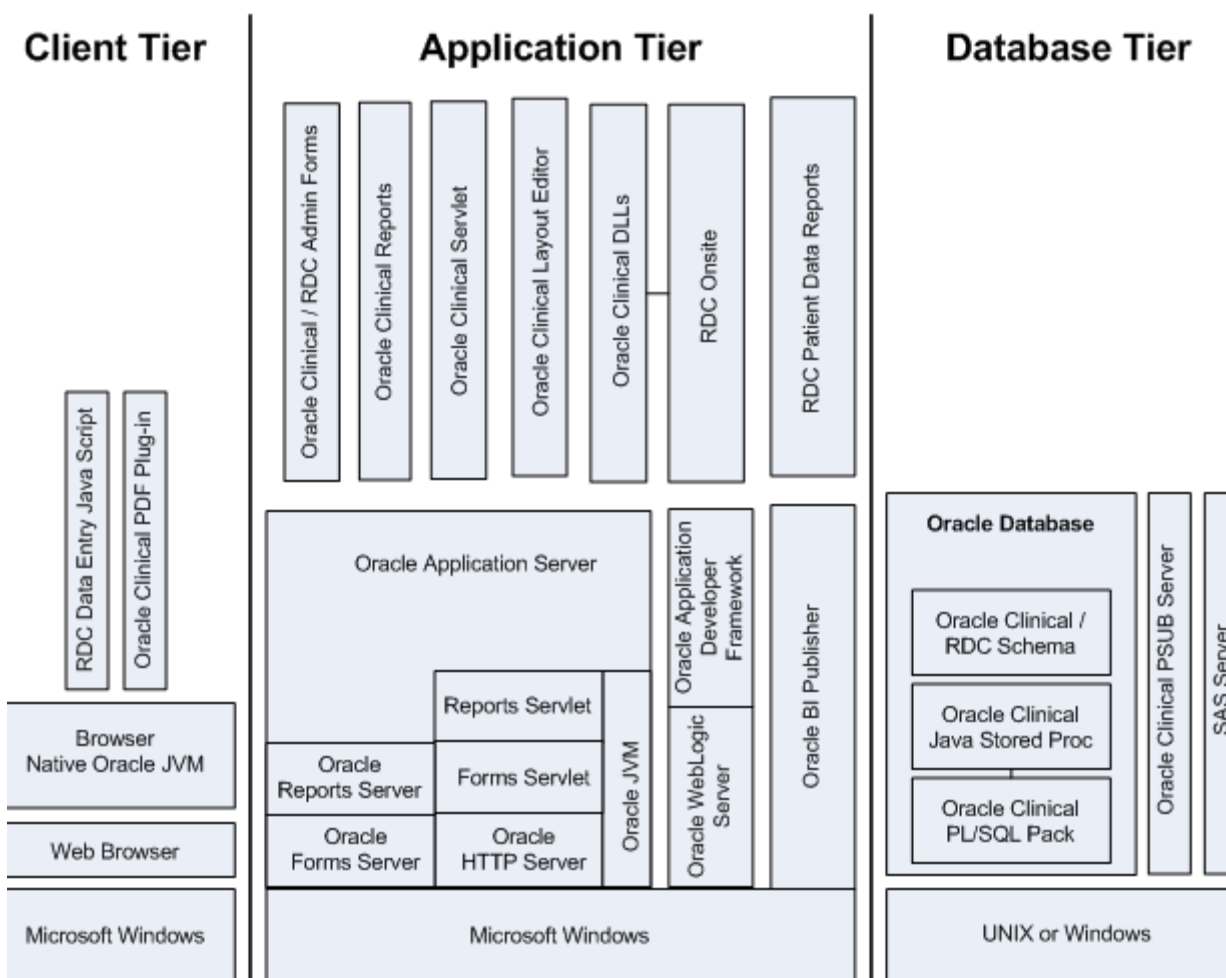
In addition, Oracle Clinical customers can request a copy of the *Oracle Clinical Stable Interface Technical Reference Manual* from Oracle Support.

1.2 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.

Figure 1–1 Oracle Clinical and RDC Onsite Logical Architecture



The **database tier** in an Oracle Clinical environment includes Oracle Database, the Oracle Clinical database server, one or more Oracle Clinical databases, and the Oracle Clinical parameterized submission (PSUB) process, which is the batch processor for Oracle Clinical. Optionally, the database tier can include SAS. The database tier can run on UNIX or Windows. (However, a Real Application Clusters (RAC) installation is supported only on UNIX.)

The **application tier** must be installed on Windows. It has three parts:

- **Oracle Application Server**, which includes Oracle Forms Server and servlet, Oracle Reports Server and servlet, Oracle HTTP Server, and Oracle JVM (Java Virtual Machine) and supports the following Oracle Clinical components:
 - **Oracle Clinical 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 for the Oracle Forms-based applications: Oracle Clinical and the RDC Administration module.
 - **Oracle Clinical Reports Server** — runs most batch reports, schedules all jobs, including PSUB jobs, and runs job sets. In addition, it creates PDF output for Patient Data Reports, Blank Casebook Reports, and Audit Reports.

- **Oracle Clinical Graphic Layout Editor** — supports creating CRF layouts from Oracle Clinical DCIs.
- **Oracle Clinical Servlet** — supports file viewing
- **DLLs** — used for data entry in both Oracle Clinical and RDC Onsite
- **Oracle WebLogic Server and Oracle Application Developer's Runtime, also known as Oracle Application Developer's Framework (ADF)** — support Oracle Clinical Remote Data Capture Onsite.
- **Oracle Business Intelligence (BI) Publisher** — runs the Patient Data Report and the Blank Casebook Report.

The **client tier** communicates users' input to the application tier. It must run on Windows through a browser, using native Oracle JVM. Both the RDC Onsite data entry Java script and the Oracle Clinical PDF Plug-In, which is required for graphic layout design, run on the client tier. See [Section 6.5, "Make the Oracle Clinical PDF Plug-in Available to Users"](#).

The Oracle HTTP Server (OHS) handles the communication between clients and the application tier.

Figure 1–2 Oracle Clinical Network Topology

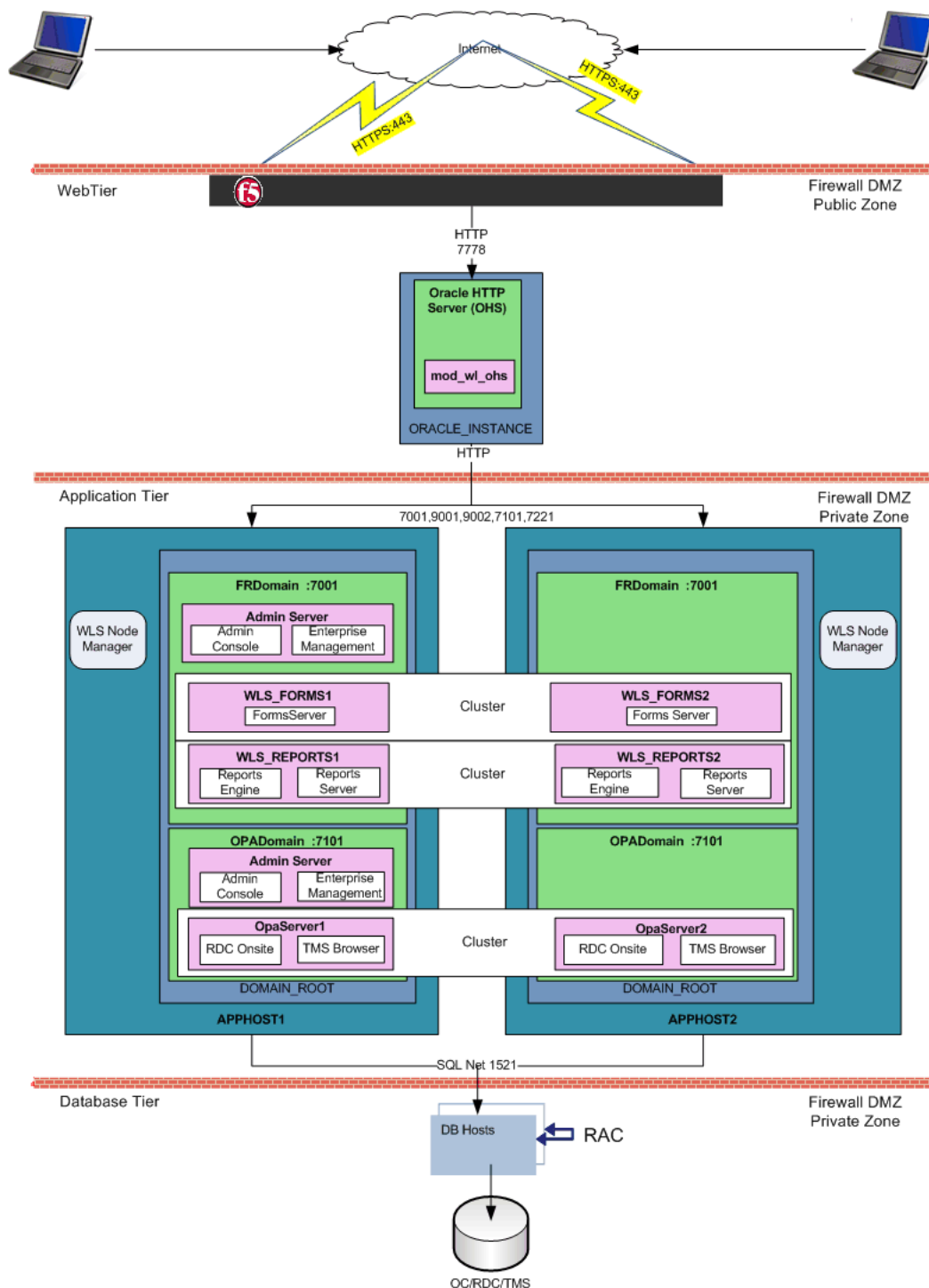


Figure 1–2 shows how the Oracle Clinical and RDC Onsite components and technology stack are related and provides an example of how the product can be installed. The left side of the Application Tier—APPHOST1—is a standard installation, while the whole—with APPHOST2—shows a multi-node middle tier installation using Oracle Clusterware.

In the **client tier**, end users' browsers communicate via HTTPS with the Oracle HTTP Server (OHS), which is located inside a firewall. When users log in, OHS detects the product they logged in to and consults formsweb.cfg to connect them to the appropriate application tier service.

The **application tier** comprises Oracle Application Server and Oracle WebLogic Server. The integrated tier has two domains:

- **FRDomain** includes the Oracle Forms runtime service and Forms Server, and the Oracle Reports Server and engine. It also includes the WebLogic Server Admin Server and Oracle Enterprise Manager.

The Oracle Application Server domain must be named FRDomain and must use port number 7001.

- **OPADomain** includes the WebLogic Server Administration Console, WebLogic Server Java, and OpaServer1, which are required to run RDC Onsite and, if you have Oracle Thesaurus Management System (TMS) installed, the TMS Browser and TMS reports. It also contains the database connections. Note that when you install the Oracle Enterprise Manager in the FRDomain, it serves for monitoring the OPADomain as well.

The Oracle Clinical Installer automatically creates the OPADomain. OPADomain must use port number 7101.

You can distribute the application tier over multiple nodes in a network using Oracle Clusterware. The Admin Server is required only on the primary node.

The WebLogic Server Node Manager exists outside the domains on the host. The Oracle Clinical Installer automatically stops the Node Manager before each Java deployment and starts the Node Manager afterward so you do not need to do that.

The **database tier** includes Oracle Database with Oracle Clinical and (optionally) Oracle Thesaurus Management System. Remote Data Capture Onsite uses the Oracle Clinical database. The diagram shows a distributed installation using Oracle Real Application Clusters (RAC); this is one example of how it can be installed.

1.3 Technology Stack

The following tables list technology stack requirements for the database tier, the application tier, and the client tier:

- [Table 1–1, "Oracle Clinical Database Tier Technology Stack"](#)
- [Table 1–2, "Oracle Clinical and RDC Onsite Application Tier Technology Stack"](#)
- [Table 1–3, "Oracle Clinical and RDC Onsite Client Tier Technology Stack"](#)

The following sections following the tables provide additional information about requirements:

- [Section 1.3.1, "Planning an Oracle Clinical Database Tier Installation"](#)
- [Section 1.3.2, "Planning an Oracle Clinical Application Tier Installation"](#)
- [Section 1.3.3, "Planning an Oracle Clinical Client Installation"](#)

For updates to the technology stack, see *Oracle Health Sciences (Life Sciences/ Pharmaceutical/ Healthcare) Supported Technology Stacks* (Article ID 180430.1) on My Oracle Support; see ["Finding Information on My Oracle Support"](#) on page xii.

Table 1–1 Oracle Clinical Database Tier Technology Stack

Component	Supported Version
Operating System	Oracle Linux 6.4 with Unbreakable Enterprise Kernel (UEK), 64 bit (US English) Oracle Solaris SPARC 10 and 11, 64-bit architecture (US English) HP Itanium 11.31; 64-bit architecture (US English) Windows Server 2008 Release 2, Service Pack 1; 64-bit architecture (US English)
Oracle Database	12c Release 1 (12.1.0.1) Enterprise Edition, 64-bit
Compiler	For Oracle Linux x86-64: GNU GCC-4.4.6 For Oracle Solaris SPARC 10 and 11: Sun Studio 12 For HP Itanium: HP C/aC++ for Integrity Servers B3910B A.06.27
Optional Software	SAS 9.3—Note that if you install the Oracle Clinical database tier on Windows, you must install SAS on Windows. Oracle Real Application Clusters (RAC) on Sun, HP, and Linux, including Exadata Oracle Virtual Machine (OVM) 3.2 Pro*C/C++ Release 12.1.0.1 Visual C++ in Microsoft Visual Studio 2010—Optional. Can be used to invoke Data Capture API methods from custom clients.

Table 1–2 Oracle Clinical and RDC Onsite Application Tier Technology Stack

Component	Supported Version
Operating System	Microsoft Windows Server 2008 Release 2; Service Pack 1 or 2; 64-bit architecture
Oracle Application Server	Oracle Application Server 11g Release 2 (11.1.2.1.0); 64-bit architecture
Oracle WebLogic Server	Oracle WebLogic Server 11g R1 (10.3.6)
Oracle ADF	Oracle Application Developer's Framework 11g R2 (11.1.2.4)
Oracle Java Development Kit (JDK)	Oracle Java Development Kit 1.6.0_65, also known as JDK 6 Update 65.

Table 1–3 Oracle Clinical and RDC Onsite Client Tier Technology Stack

Component	Supported Version
Operating Systems	Microsoft Windows 7; Service Pack 1; 32-bit or 64-bit architecture (US English) Microsoft Windows Server 2008; Release 2; Service Pack 1; 64-bit architecture (US English) Microsoft Windows 8/8.1; 64-bit architecture
Mobile Operating Systems	iOS 7.1.2—iPad and OS X 10.7.5—for RDC Onsite only
Supported Browsers	Microsoft Internet Explorer versions depend on the operating system: <ul style="list-style-type: none"> ■ Microsoft Windows 7 (32-bit): Internet Explorer 9 ■ Microsoft Windows 7 (64-bit): Internet Explorer 9, 10, or 11 ■ Microsoft Windows Server 2008; Release 2; Service Pack 1 (64-bit): Internet Explorer 9, 10, or 11 ■ Microsoft Windows 8/8.1 (64-bit): Internet Explorer 10 or 11 Safari 7.0.3 on iOS 7.1.2, for Oracle RDC Onsite only

Table 1–3 (Cont.) Oracle Clinical and RDC Onsite Client Tier Technology Stack

Component	Supported Version
Adobe Reader	Releases 8x, 9.x, 10.x, 11.x (US English) Required for viewing reports, including Patient Data Reports (PDRs)
Adobe Acrobat	Releases 8x, 9.x, 10.x, 11x (US English) Required for creating annotated layouts
Oracle Java Runtime Environment (JRE)	Java SE 7 Update 65 (Standard Edition, Version 1.7.0.65)

1.3.1 Planning an Oracle Clinical Database Tier Installation

This section provides additional information about installation requirements.

1.3.1.1 Character Set Requirements

For information about the guidelines and requirements for character sets, see [Section 1.8, "Choosing a Character Set."](#)

1.3.1.2 Critical Patch Update

You must obtain the latest Critical Patch Update (CPU) certified by Oracle Health Sciences from My Oracle Support and install it on each database and application tier server computer; see [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

1.3.1.3 Database Tier Operating System Requirements

See [Table 1–1, "Oracle Clinical Database Tier Technology Stack"](#) for basic information.

To verify that your system fits the requirements listed in [Table 1–1, "Oracle Clinical Database Tier Technology Stack"](#) do the following in [UNIX](#) or [Windows](#):

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.

1.3.1.4 Oracle Database Requirements and Options

Oracle Clinical has the following database options:

1.3.1.4.1 Oracle Database Partitioning Option Oracle Clinical supports partitioning, but this feature is disabled by default. To use it, buy and install the Partitioning Option. See the *Oracle Clinical Administrator's Guide* for information about partitioning.

1.3.1.4.2 Distributed Database Option and Advanced Replication Option are required if and only if you are using Oracle Clinical Distributed Study Conduct (Replication).

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

1.3.1.5 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 (using the replication feature), you must arrange to share the Global Library with the other databases at other locations.

1.3.1.6 Database Seed Numbers in a Replicated Environment

When you create an Oracle Clinical database, the Installer prompts you to allocate a seed number. The system uses the seed number to generate unique primary keys and allows data replication among databases without triggering unique key violations. Seed numbers for the databases within a particular replicated environment must be unique. See the section on reseeding sequences in the *Oracle Clinical Administrator's Guide* for more information.

1.3.2 Planning an Oracle Clinical Application Tier Installation

See [Table 1–2, "Oracle Clinical and RDC Onsite Application Tier Technology Stack"](#) for basic information.

Note: The default application tier installation uses HTTPS.

1.3.2.1 Character Set Requirements

For information about the guidelines and requirements for character sets, see [Section 1.8, "Choosing a Character Set."](#)

1.3.2.2 Critical Patch Update

You must obtain the latest Critical Patch Update (CPU) certified by Oracle Health Sciences from My Oracle Support and install it on each database and application tier server computer; see [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

1.3.2.3 Oracle Clinical Forms and Reports Servers

The Oracle Clinical Forms Server is part of the Front End Installer. The Oracle Clinical Reports Server has its own Installer. You can install both on the same server computer or install them on different computers.

To ensure high availability of the Reports Server, you can set up and use more than one Reports Server on a subnet and they can access each other. For more information see the *Oracle Clinical Administrator's Guide*.

You must install the full application tier technology stack on each server computer.

1.3.2.3.1 Shared Directory If you have multiple Oracle Clinical Forms and/or Reports Server computers, you must select a shared directory to be accessible from all servers for storing report output and logs.

1.3.2.3.2 Permanent IP Address Every computer on which either the Oracle Clinical Forms or Reports Server is installed must have a permanent IP address.

1.3.3 Planning an Oracle Clinical Client Installation

In addition to the software noted in [Table 1–3, "Oracle Clinical and RDC Onsite Client Tier Technology Stack"](#), a client requires an intranet or internet connection to the

application tier. In addition, see [Chapter 10, "Setting Up Clients."](#)

1.4 Supported Configurations with Oracle Data Guard and RAC

Oracle Clinical 5.1 supports a distributed environment over a network or within an Exadata machine without using Oracle Clinical replication.

This section contains:

- [Section 1.4.1, "Supported Configurations with Oracle Real Application Clusters \(RAC\)"](#)
- [Section 1.4.2, "Supported Configurations with Oracle Data Guard"](#)

For more information, see:

- [Section 2.1, "Installing Oracle Clinical on a Real Applications Cluster \(RAC\) Database Configuration \(Optional\)"](#)
- [Section 8.5, "Running PSUB in a RAC Environment"](#)

1.4.1 Supported Configurations with Oracle Real Application Clusters (RAC)

Oracle Clinical was re-architected in Release 5.0 to support Oracle Real Application Clusters (RAC). The Parameterized Submission process (PSUB), which runs and schedules most jobs in Oracle Clinical, no longer uses DBMS pipes, which can only be used within a single database instance, for communication between the user session and the PSUB service. It now uses Oracle Advanced Queuing.

Because databases have traditionally been constrained to run only on a single server, customers have typically followed a hardware "scale-up" strategy for the database tier: Whenever the database server becomes a bottleneck to overall application performance, the server is replaced with a larger, faster machine. While this approach is well understood, it can be highly disruptive to ongoing business.

Oracle Real Application Clusters (RAC) provides an alternative approach for scaling database performance. It is designed to tolerate server failures with little impact to mission-critical applications and users. As workloads and user connections are increased, additional nodes (servers) can be easily added to the cluster. Each server runs against the same database simultaneously. This approach is less disruptive to ongoing business operations, more reliable, and less expensive to implement.

RAC nodes can be individual computers in a network or nodes on an Oracle Exadata machine. RAC shares the database internally among all nodes so that even if the node where the database was originally installed goes down, the other nodes can still access the database. You can configure RAC nodes as follows:

Node 1: Install and Set Up Everything Required for Oracle Clinical including:

- Oracle Real Application Clusters (RAC)—installed with Oracle Database
- Oracle Clinical database server code
- Oracle Clinical database(s)
- Run the Oracle Clinical PSUB service on this node (one per database)
- Create user-specific PSUB log file directories for randomization, batch data load, and labs batch jobs that require input files
- Enter PSUB-related values in local reference codelist OCL_STATE
- Install SAS 9.3 (Optional)

Node 2: Install the Minimum Required as a RAC Node Install Oracle Database with Oracle Real Application Clusters (RAC).

You can have multiple nodes set up this way, each accessing the same database(s). Additional nodes set up this way improve database performance.

Node 3: Install Everything Required for Oracle Clinical as Backup In case either the PSUB service or Node 1 itself fails, install all required software on another node so that you can start the PSUB service as quickly as possible to continue normal operation. PSUB can run on only one server at a time.

A node set up this way also improves performance but requires additional maintenance; any Oracle Clinical database server patches you install on the primary node (Node 1 in this example) must also be installed on this node.

- Install Oracle Real Application Clusters (RAC) and Oracle Database
- Install Oracle Clinical database server code (includes PSUB server code)
- Create the same PSUB directory structure as on Node 1 so that the OCL_STATE reference codelist values on the middle tier still work. If you use NFS to share the files, users will still be able to access files for jobs performed on the other node unless the node itself fails; see [Section 8.5, "Running PSUB in a RAC Environment"](#) for more information.

Note: You do not need to reinstall the Oracle Clinical database.

You can have multiple nodes set up this way, each accessing the same database(s).

1.4.2 Supported Configurations with Oracle Data Guard

The following Oracle Data Guard configurations are supported. All Oracle Clinical components (database server, database) must be installed on each node.

- Standalone server with Oracle Data Guard failover
- Oracle Clusterware for One Node with Oracle Data Guard failover
- Oracle RAC One Node with Oracle Data Guard failover
- Multi-node RAC with Oracle Data Guard failover

1.5 Downloading and Extracting the Software

- [Section 1.5.1, "Creating Staging Areas"](#)
- [Section 1.5.2, "Downloading and Extracting the Oracle Clinical 5.1.0.0.x and Oracle Thesaurus Management System 5.1.0.0.x Media Pack"](#)
- [Section 1.5.3, "Downloading and Extracting Patches from My Oracle Support"](#)
- [Section 1.5.4, "Downloading Oracle Java Development Kit"](#)
- [Section 1.5.5, "Downloading the Java Runtime Environment"](#)
- [Section 1.5.6, "Downloading Adobe Reader"](#)
- [Section 1.5.7, "Downloading JSpell \(Optional\)"](#)

1.5.1 Creating Staging Areas

Oracle recommends creating one staging area on the database server and another on the application server. In each staging area, create one directory for each media pack disk, patch, or other software unit that needs to be downloaded to that server, as shown in [Table 1–4, "Software to Download to the Database Server Staging Area"](#) and [Table 1–5, "Software to Download to the Application Server Staging Area"](#).

Give each directory a logical name such as the media pack disk or patch name (not part or patch number) to make instructions later in this guide easier to follow.

1.5.1.1 Database Server Staging Area

[Table 1–4, "Software to Download to the Database Server Staging Area"](#) shows which software to download to the database server staging area.

Table 1–4 Software to Download to the Database Server Staging Area

Disk or Patch Name	Source
Oracle Clinical 5.1.0.0 Documentation—The latest versions are posted at http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html .	Media pack or www.oracle.com
Oracle Clinical 5.1.0.0	Media pack
Oracle Database 12c Release 1 (12.1.0.1) — Linux x86-64	Media pack
Oracle Database 12c Release 1 (12.1.0.1) — Solaris Sparc 64	Media pack
Oracle Database 12c Release 1 (12.1.0.1) — HP IA	Media pack
Oracle Database 12c Release 1 (12.1.0.1) — Windows x64	Media pack

1.5.1.2 Application Server Staging Area

[Table 1–5, "Software to Download to the Application Server Staging Area"](#) shows which software to download to the application server staging area.

Table 1–5 Software to Download to the Application Server Staging Area

Disk or Patch Name	Source
Oracle Clinical 5.1.0.0 Documentation—The latest versions are posted at http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html .	Most recent version is on www.oracle.com
Oracle Clinical 5.1.0.0	Media pack
Oracle WebLogic Server 11gR1 (10.3.6) Generic and Coherence	Media pack
Oracle Application Development Runtime 11g Patch Set 5 (11.1.1.6.0) (also known as Application Developer's Framework or ADF)	Media pack
ADF 11.1.2.4 patches 16546129 and 16546157	My Oracle Support
Internet Explorer 11 compatibility patch for ADF 11.1.2.4 (patch 18277436) or its successor; consult My Oracle Support document <i>Supportability on Internet Explorer 11 (IE11) with Oracle ADF</i> (ID 1599898.1).	My Oracle Support
Oracle Forms and Reports 11gR2 (11.1.2.1.0) for Microsoft Windows x64 (64-bit)	Media pack
Oracle Clinical PDF Plug-In (patch 12733341)	My Oracle Support
Oracle Java Development Kit 1.6.0_65, also known as JDK 6 Update 65 (patch 17046855); see Section 1.5.4, "Downloading Oracle Java Development Kit"	My Oracle Support

Table 1–5 (Cont.) Software to Download to the Application Server Staging Area

Disk or Patch Name	Source
Java Runtime Environment (JRE) 1.7.0_65; see Section 1.5.5, "Downloading the Java Runtime Environment"	www.oracle.com
Adobe Reader; see Section 1.5.6, "Downloading Adobe Reader"	http://www.adobe.com
JSPELL Spell Checker SDK for J2EE; see Section 1.5.7, "Downloading JSPELL (Optional)"	http://www.jspell.com

1.5.2 Downloading and Extracting the Oracle Clinical 5.1.0.0.x and Oracle Thesaurus Management System 5.1.0.0.x Media Pack

Note: 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 software:

1. Go to <http://edelivery.oracle.com> and log on.
2. From the **Select a Product Pack** drop-down list, select **Health Sciences**.
3. From the **Platform** drop-down list, select your database tier operating system.
4. Click **Go**.
5. Select Oracle Clinical 5.1.0.0.x and Oracle Thesaurus Management System 5.1.0.0.x Media Pack **for Your_Operating_System** and click **Continue**.
6. Download each disk into a recognizably named directory in the appropriate staging area as shown in [Table 1–4, "Software to Download to the Database Server Staging Area"](#) or [Table 1–5, "Software to Download to the Application Server Staging Area"](#). Each download consists of a single file named *part_number.zip*.
7. Extract each *part_number.zip* file into a meaningfully named directory.
8. For the Oracle Clinical software, extract the appropriate .zip file for the server:
 - On the database server, extract *server_code_platform.zip*.
 - On the application server, extract *application_server.zip*.

1.5.3 Downloading and Extracting Patches from My Oracle Support

To download a patch from My Oracle Support:

1. Go to My Oracle Support at <https://support.oracle.com> and sign in.
2. Click the Patches & Updates tab, then enter the patch number in the **Patch Name or Number is** field and click **Search**.
3. Click the link for your operating system and download the patch file to a recognizably named directory in the appropriate staging area.
4. Extract the .zip file.

1.5.4 Downloading Oracle Java Development Kit

To download and install JDK:

1. Go to My Oracle Support at <https://support.oracle.com> and sign in.
2. In the Search Knowledge Base field in the upper right, enter: 1439822.1
A page appears with a list of documents.
3. Click the link *All Java SE Downloads on MOS* [Article ID 1439822.1].
4. Scroll down the list of JDK versions to **Oracle JDK 6 Update 65** (Patch 17046855).

Note: Check *Oracle Clinical Summary of Patches Available* (Article ID 121863.1) on My Oracle Support to see if a more recent version is supported; see "[Finding Information on My Oracle Support](#)" on page xii.

5. Click the patch number link.
6. Select Microsoft Windows x64 (64-bit) and click **ReadMe** to read the release notes and **Download** to download the patch to the staging area in a recognizably named directory.

Installation instructions are in [Section 5.3, "Install Oracle Java Development Kit"](#).

1.5.5 Downloading the Java Runtime Environment

Oracle Clinical and the RDC Administration application require that Java Standard Edition (SE) Runtime Environment (JRE) 1.7.0.65—also known as JRE 7 Update 65—exist on the user's computer.

The Launch page is configured to prompt users to install JRE if it does not exist on their computer. To make this work, you need to download JRE into the `OPA_HOME\html` directory and rename it; see [Section 6.4, "Make the Java Runtime Environment Available for Download."](#)

To download JRE:

1. On the application server, go to the following Oracle Web site:
<http://www.oracle.com/technetwork/java/javase/downloads/index.html>
2. Under Java SE 7u65, click the **Download** button for JRE.
3. Select the **Windows x86 Offline** version.

Note: This is the version for 32-bit browsers (not operating systems). The default browser for Windows machines is 32-bit, but Windows machines also come with a 64-bit version. To support the 64-bit version, you must either customize your Launch page to point to `sunjpi64.exe` or instruct users with 64-bit browsers to download the 64-bit version of JRE from the link in Step 1.

4. Download it to the staging area in a recognizably named directory.

1.5.6 Downloading Adobe Reader

Adobe Reader is required on the Reports Server and on client computers. Download it from <http://www.adobe.com>. At this time no particular version is required.

1.5.7 Downloading JSpell (Optional)

The Oracle Clinical Graphic Layout Editor supports the JSpell Spell Checker SDK for Java J2EE for use in checking the spelling of text objects in graphic layouts.

The JSpell Spell Checker SDK is a third-party product from Page Scholar Inc. You must purchase the product separately.

1. Download JSpell SDK for Java J2EE from <http://www.jspell.com/java-spell-checker.html> to the staging area in a recognizably named directory.
2. Extract jspellsdk.zip.

Additional instructions are in [Section 6.7, "Install and Configure JSpell Spell Checker SDK \(Optional\)."](#)

1.6 Using the Silent Installer

You can run any of the Oracle Universal Installers—including the Oracle Clinical Database Server, Database, Front End, or Reports Server Installers—in silent mode. This may be useful to promote uniform installations in multiple sites or computers.

Oracle Clinical ships with .rsp (response) files that include parameter prompts and sample parameter values for each component. They are located on the Oracle Clinical and Oracle Thesaurus Management System 5.1 media pack disk under Disk1\stage\ Response in the .zip file for the application server or for the appropriate database operating system.

[Table 1–6](#) lists each Oracle Clinical component, the response file name for each, and the section of this guide with information on the Installer parameters for each.

Table 1–6 Response Files and Parameter Information

Component Installed	Reponse File	Parameter Information
Oracle Clinical Database Server for Linux	oracle.pharma.oc.server.unix.Complete.rsp	Section 2.5.1
Oracle Clinical Database Server for Solaris	oracle.pharma.oc.server.unix.Complete.rsp	Section 2.5.1
Oracle Clinical Database Server for HP	oracle.pharma.oc.server.unix.Complete.rsp	Section 2.5.1
Oracle Clinical Database Server for Windows	oracle.pharma.oc.server.windows.Complete.rsp	Section 3.4.1
Oracle Clinical Database—fresh installation	oracle.pharma.oc.db.install.Complete.rsp	Section 4.2.2
Oracle Clinical Database—upgrade and configure	oracle.pharma.db.upgrade.install_type_1.rsp	Section 4.2.2
Oracle Clinical Database—reruns all the re-createable object scripts (views, packages, functions etc) against the database	oracle.pharma.db.upgrade.install_type_2.rsp	Section 4.2.2
Oracle Clinical Front End	oracle.pharma.oc.frontend.Custom.rsp	Section 6.1
Oracle Clinical Reports Server	oracle.pharma.oc.reportserver.Complete.rsp	Section 7.1

1. Open the file in a text editor and enter values directly
2. Run the file.

In UNIX:

```
./runInstaller
```


Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

In Windows (as an administrator):

```
setup.exe -responseFile response_file_name
```

3. When you run the file at each location, edit the local parameters as required.

Alternatively, you can run the Installer once, entering values on screen, and record the process to create a response file.

In UNIX:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

In Windows (as an administrator):

```
setup.exe -record -destinationFile complete_path_to_response_file_name
```

For more information about using response files see the 12.1.0.1 *Oracle Database Installation Guide* for your operating system:

- **Linux:** http://docs.oracle.com/database/121/LADBI/app_nonint.htm#LADBI7831
- **Solaris:** http://docs.oracle.com/database/121/SSDBI/app_nonint.htm#SSDBI7831
- **HP:** http://docs.oracle.com/database/121/HPDBI/app_nonint.htm#HPDBI7831
- **Windows:** <http://docs.oracle.com/database/121/NTDBI/advance.htm#NTDBI009>

1.7 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:

```
installActions2013-04-30_11-22-52AM.log
```

1.8 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 AL32UTF8 character set**. These applications also support UTF8, US7ASCII, WE8ISO8859P1, or any single byte character set.

Oracle Clinical and RDC use the NLS_LANG environment variable in the opasettings/opasetting.bat file to control the language, territory, and character set used for database connections. The NLS_LANG variable concatenates the three components as LANGUAGE_TERRITORY.CHARSET.

- You must set the LANGUAGE_TERRITORY components of the NLS_LANG variable to **american_america**.
- You must set the CHARSET component of the NLS_LANG variable to **match the character set of the database**.
- You must use the **same character set on the database tier and the application tier**. If you select US7ASCII for the database tier and AL32UTF8 or UTF8 for the application tier, for example, Oracle Clinical stores some special characters incorrectly in the database.

For more information, see [Section 2.6.2, "Review the opa_settings File"](#) for UNIX and [Section 3.5.2, "Review the opa_settings.bat File"](#) for Windows.

1.9 Applying Oracle 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.

At the time of publication the current CPU for Oracle Clinical is the October 2014 CPU. For more information, see My Oracle Support article ID 1930332.1.

Check My Oracle Support article ID 180430.1, *Oracle Health Sciences (Life Sciences/Pharmaceutical/Healthcare) Supported Technology Stacks*, 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.

1.10 Applying the Latest Oracle Clinical Patch Set

Check My Oracle Support article *Oracle Clinical Summary of Patches Available* (Article ID 121863.1) for the latest patch set and apply it. This will provide you with the latest bug fixes. See the patch set release notes for more information.

1.11 Integrating Oracle Clinical with Other Products and Options

You can integrate Oracle Clinical with some other products and options and develop applications that read data from Oracle Clinical. Each product listed below must be purchased separately from Oracle Clinical.

1.11.1 Oracle Clinical Remote Data Capture Onsite

Oracle Clinical Remote Data Capture Onsite (RDC Onsite) is an electronic data capture (EDC) Web application that works with studies that are defined and designed using Oracle Clinical. You can use RDC Onsite to collect, perform immediate validation on, review, verify, approve, and report clinical data collected during a patient visit in a clinical study. Patient data is stored in the Oracle Clinical database. You can use Oracle Clinical features including batch validation, discrepancy management, mass changes, and data extract with data collected using RDC Onsite.

Installing Oracle Clinical also installs Oracle Remote Data Capture (RDC) Onsite. For information about using RDC, see the *Oracle Clinical Remote Data Capture Onsite User's Guide*. For license information, see ["Licenses for Remote Data Capture with Oracle Clinical"](#) on page 1-1.

1.11.2 Oracle Thesaurus Management System

Oracle Thesaurus Management System (TMS) allows you to code specified patient data to standard terminologies such as MedDRA and WHO-Drug so that the data can be accurately analyzed. When fully integrated with Oracle Clinical, TMS processes new and updated patient data during each Oracle Clinical batch validation and either automatically codes incoming data—those that match standard terms exactly or match previously manually coded terms exactly—or creates an omission that must be manually coded in TMS. TMS can return to Oracle Clinical related terms from one or more levels of the standard terminology—for example the preferred term and system organ class in MedDRA, or the preferred name and Anatomical-Therapeutic-Chemical Level 1 term in WHO-Drug—for each coded term, associated with the correct RDCI (collected CRF).

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 if you want integrate the two systems. Oracle recommends installing Oracle Clinical before TMS.

For more information, see the *Oracle Thesaurus Management System Installation Guide* and the *Oracle Thesaurus Management System User's Guide*.

1.11.3 Siebel Clinical

Siebel Clinical is a clinical trial management system that uses a customer relationship management (CRM) software paradigm. The approach focuses on strengthening relationships with trial participants, especially investigators and patients, enhancing collaboration and information sharing across the many different teams involved in clinical trials. CRM solutions also gather and maintain a wealth of valuable data that can be leveraged for a variety of other purposes, such as marketing, sales, and pharmacovigilance.

- You can create Oracle Clinical Sites, Investigators and Study Sites based on protocol site information sent from Siebel Clinical.
- You can use the Oracle Clinical user interface to define Oracle Clinical/Remote Data Capture (RDC) data collection events that should be treated as visits/activities in Siebel Clinical.

- Oracle Clinical passes information to Siebel Clinical to signal the completion of these visits/activities for patients.

For more information, see the chapter on clinical trial management system integration in *Oracle Clinical Creating a Study*.

In addition, you must configure new Web services. For details, see the *Oracle Clinical Application Programming Interface Guide* chapter on web services.

1.11.4 Oracle Life Sciences Data Hub

Oracle Life Sciences Data Hub (Oracle LSH) is a powerful data warehouse and transformation tool with built-in version control, data auditing, lifecycle management, and validation tools. Oracle LSH includes adapters specifically designed to load most metadata and patient data from Oracle Clinical into Oracle LSH. In Oracle LSH you can then, for example, create your own reports on study patient data, merge data from multiple trials and create reports on cross-study data, and view data using state-of-the-art visualization tools.

You can load Oracle Clinical metadata and Oracle LSH converts it to appropriate LSH objects, for example:

- Oracle LSH loads all Oracle Clinical Questions and converts them to Oracle LSH Variables.
- If a Question is associated with a Discrete Value Group (DVG) in Oracle Clinical, Oracle LSH converts the Question to a Parameter and converts its DVG values to a list of allowable values for the Parameter.
- Oracle LSH loads all Oracle Clinical Question Groups and converts them to Oracle LSH Table definitions with Columns based on the Variables corresponding to each Question in the Question Group.

Other Oracle Clinical adapters include:

- Oracle Clinical SAS and Oracle Data Extract Views—load patient data from views you create in Oracle Clinical
- Oracle Clinical Stable Interface—loads the metadata of all Oracle Clinical tables that are part of Oracle Clinical's stable interface.
- Oracle Clinical Design and Definition—loads DCMs, DCIs, Procedures, Copy Groups, and Data Extract queries and templates.
- Oracle Clinical Labs—load lab reference ranges and associated information from Oracle Clinical Labs-related tables.
- Oracle Clinical Randomization—loads real or dummy treatment pattern information for Oracle Clinical studies.
- Oracle Clinical Study Data—loads study-specific non-patient data into LSH, including discrepancies, data clarification forms, patient status information, and page tracking information.

In addition, other non-Oracle Clinical-specific adapters allow you to load data from any Oracle table or view, text file, SAS data set, or SAS CPORT or XPORT file.

1.11.5 SAS

Oracle Clinical supports integration with the statistical software application SAS 9.3. For more information, see [Chapter 9, "Setting Up SAS."](#)

1.11.6 Custom Applications for Oracle Clinical

You can build custom applications for Oracle Clinical:

- See the *Oracle Clinical Stable Interface Technical Reference Manual* for proprietary information about data access, internal tables, and APIs. The Oracle Clinical Stable Interface provides access to data and a smooth transition between Oracle Clinical versions. Contact Oracle Support to obtain a free electronic copy of the manual. You must be a licensed customer.
- See the *Oracle Clinical Application Programming Interface Guide* for information about using Oracle Clinical's Data Capture API.

Installing Oracle Clinical Database Server on UNIX

This chapter describes how to install Oracle Database and the Oracle Clinical database server on a UNIX computer.

This chapter includes:

- Section 2.1, "Installing Oracle Clinical on a Real Applications Cluster (RAC) Database Configuration (Optional)"
- Section 2.2, "Perform Prerequisite Tasks for Installing Oracle Database"
- Section 2.3, "Install Oracle Database"
- Section 2.4, "Set Permissions"
- Section 2.5, "Install the Oracle Clinical Database Server"
- Section 2.6, "Perform Post-installation Tasks"

If you are upgrading Oracle Clinical, see [Chapter 11](#). If you are using Oracle Real Application Clusters (RAC), see [Section 1.4, "Supported Configurations with Oracle Data Guard and RAC"](#).

For database tier system requirements, see the 12.1.0.1 *Oracle Database Installation Guide* for your operating system at http://docs.oracle.com/cd/E16655_01/nav/portal_11.htm.

Critical Patch Updates See [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

Oracle Database 12.1.0.1 includes many new features including multitenancy, which allows you to create one or more **pluggable databases** (PDBs) contained in a single **root** or **container** database (CDB). You can install Oracle Clinical on either a pluggable database or a non-CDB database (as in 11g). For more information on multitenancy, see <http://docs.oracle.com/database/121/CNCPT/cdbovrvw.htm>.

Oracle recommends learning about these new features in Oracle White Paper *Plug into the Cloud with Oracle Database 12c* at

<http://www.oracle.com/technetwork/database/plug-into-cloud-wp-12c-1896100.pdf> and, for more details, the *Oracle® Database New Features Guide 12c Release 1 (12.1)* at <http://docs.oracle.com/database/121/NEWFT/toc.htm>.

2.1 Installing Oracle Clinical on a Real Applications Cluster (RAC) Database Configuration (Optional)

Oracle Clinical 5.1 is supported with an Oracle Real Applications Cluster (RAC) distributed database installation on UNIX. Oracle recommends:

- Configuring a Maximum Availability Architecture (MAA) in which you use Oracle RAC for both your primary and standby database, synchronized using Oracle Data Guard.
- Using the Single Client Access Name (SCAN) option. This RAC feature provides a single name for clients to access Oracle databases running in a cluster. The benefit is that the client's connect information does not need to change if you add or remove nodes in the cluster. Having a single name to access the cluster allows clients to use the EZConnect client and the simple JDBC thin URL to access any database running in the cluster, independent of which server(s) in the cluster the database is active. SCAN provides load balancing and failover for client connections to the database. The SCAN works as a cluster alias for databases in the cluster.
- SCAN is configured during the installation of Oracle Grid Infrastructure that is distributed with Oracle Database. Oracle Grid Infrastructure is a single Oracle Home that contains Oracle Clusterware and Oracle Automatic Storage Management (ASM). You must install Oracle Grid Infrastructure first in order to use Oracle RAC.

Oracle Data Guard is included in Oracle Database Enterprise Edition.

See [Section 1.4, "Supported Configurations with Oracle Data Guard and RAC"](#).

For more information see:

- *Oracle® Database 2 Day + Real Application Clusters Guide* both at http://docs.oracle.com/cd/E16655_01/nav/portal_16.htm
- *Grid Infrastructure Single Client Access Name (SCAN) Explained* (My Oracle Support Article ID 887522.1). See ["Finding Information on My Oracle Support"](#) on page xii.
- Oracle Data Guard and other high availability documentation at http://docs.oracle.com/cd/E16655_01/nav/portal_14.htm

2.2 Perform Prerequisite Tasks for Installing Oracle Database

To ensure that your platform meets the minimum requirements for installing Oracle Database 12c Release 1 (12.1.0.1) and Oracle Clinical database server, 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](#)

If you are using Real Application Clusters (RAC) you need to perform these tasks on every machine.

2.2.1 Create Owners, Groups, and Mount Points

For more information, see "Creating Required Operating System Group and User" in the Oracle Database 12.1.0.1 *Installation Guide* for your operating system. For example,

the link for Oracle Solaris is:

<http://docs.oracle.com/database/121/SXCQI/toc.htm#BGBEAGAJ>

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. These instructions refer to the user name as **oracle**.
 - Create two groups: one is the Oracle Inventory group; the other is the operating system DBA group. These instructions refer to the group names as **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.
4. Ensure that the oinstall group can write to the new mount points and all subdirectories.

2.2.2 Set Up the opapps User Account and oclsrcr User Group

Before you install Oracle Clinical database server, create the following user group and account:

- **oclsasr** — The group that controls access to the files Oracle Clinical generates for SAS
- **opapps** — The operating system account that owns Oracle Clinical and that runs the Parameterized Submission (PSUB) process.

2.2.2.1 Create the oclsrcr User Group for SAS

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

Create a user group named oclsrcr 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 oclsrcr group.

2.2.2.2 Create the opapps Account

You must create the operating system account that owns Oracle Clinical. This account also has the privileges to run parameterized submission (PSUB) jobs. The user name for the account is `opapps`, with a home directory named `opapps`. For example:

```
/home/opapps
```

Oracle Clinical documentation uses the variable `OPA_HOME` to refer to this location on an Oracle Clinical database server.

Do the following:

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

```
/bin/csh
```

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

- `oclsascr`
- `oinstall`
- `dba`

Neither `oclsascr` nor `oinstall` group needs to be the primary group for the `opapps` account.

The `opapps` account also runs the PSUB service `RXCPSDPS` and the PSUB Launcher `PSLAUNCH`.

2.2.3 Configure Kernel Resources and Adjust Operating System Environment

The performance of Oracle Database 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 section on configuring kernel parameters in the of the *Oracle Database 12c Installation Guide* for your operating system available here:

http://docs.oracle.com/database/121/nav/portal_11.htm

2.2.4 Test the C Compiler Installation

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

1. Log in to the database server 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](#).

Note: The symbolic link may vary depending on where the C Compiler is installed.

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

Operating System	Response	Symbolically Links To
Oracle Linux x86-64	/usr/bin/gcc	(Not applicable)

Table 2–1 (Cont.) Responses to the 'which cc' Command

Operating System	Response	Symbolically Links To
Oracle Solaris SPARC	/bin/cc	/Studio12.2/solstudio12.2/bin/cc
HP Itanium 11.31	/bin/cc	/opt/aCC/bin/cc

4. Test that the make command is accessible:

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

where the ` symbols that wrap the command are single back quotes.

5. Compare your results to the correct responses listed in [Table 2–2](#).

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

Operating System	Response	Symbolically Links To
Oracle Linux x86-64	/usr/bin/make	(Not applicable)
Oracle Solaris SPARC	/usr/ccs/bin/make	(Not applicable)
HP Itanium 11.31	/bin/make	/usr/ccs/bin/make

If you do not get the correct response, you can either add the path to the cc executable or add the make command to the path in the .cshrc file for the opapps user; see [Section 2.2.2.2, "Create the opapps Account"](#).

2.2.5 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 12c Release 1 (12.1.0.1).

2.3 Install Oracle Database

This section includes:

- [Install Oracle Database 12c Release 1 \(12.1.0.1\) Enterprise Edition](#)
- [Install Oracle Database 12c Release 1 \(12.1.0.1\) Examples](#)

2.3.1 Install Oracle Database 12c Release 1 (12.1.0.1) Enterprise Edition

To install Oracle Database 12c Release 1 (12.1.0.1):

1. Locate the Oracle Database software in the staging area on the database server where you downloaded it; see [Section 1.5, "Downloading and Extracting the Software."](#)
2. Start the Installer:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

3. Install Oracle Database 12c Release 1 (12.1.0.1). For instructions see the readme file and the section "Running Oracle Universal Installer" in the appropriate installation guide for your operating system at http://docs.oracle.com/database/121/nav/portal_11.htm.
4. Choose to install the Enterprise Edition.

2.3.2 Install Oracle Database 12c Release 1 (12.1.0.1) Examples

Oracle Database Examples includes the following items:

- Oracle JDBC Development Drivers (required)
- Oracle Database Examples (required)
- 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. Extract the zip file containing Oracle Database Examples in the `examples` directory.
2. Start Oracle Universal Installer from the `examples` directory.

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

3. 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* at http://docs.oracle.com/database/121/nav/portal_11.htm.

2.4 Set Permissions

After you install Oracle Database 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 steps whenever you apply an HSGBU-approved Critical Patch Update, or any Oracle software that uses the Oracle Database `ORACLE_HOME` directory.

2.4.1 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
```

2.4.2 Grant Access to the `ORACLE_HOME` Directory

Because the Oracle Clinical 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 Oracle Clinical.

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

1. Log in to the server as the `oracle` user.
2. Find 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 12c Release 1 (12.1.0.1) installation.

Note that the `oraenv` script gives an error if run by a non-Oracle user. To avoid this error, see [Section 2.4.1, "Change Permissions for Running oraenv Script"](#).

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.

2.4.3 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.

2.5 Install the Oracle Clinical Database Server

This section describes how to install and set up the Oracle Clinical database server.

The Installer performs the following operations:

- Creates the Oracle Clinical directory structure (see [Section 2.5.6, "Oracle Clinical Database Server Directory Structure for UNIX"](#) for details)
- Installs the Oracle Clinical database server
- Builds the executables
- Sets permissions on the directories
- Creates the environment setup files
- Modifies the environment setup files
- Creates the Oracle Wallet to store credentials for OCPSUB and RXC_DISC_REP
- Creates the directory for storing the SAS files

2.5.1 Gather Required Information

You must have the following information ready to enter in the Installer screens:

1. Home Details: The *ORACLE_HOME* location, which is where you installed Oracle Database 12c Release 1 (12.1.0.1); for example:

```
root:app/oracle/product/12101/dbhome
```

2. If you are installing in a RAC installation, the names of all RAC nodes where the same product(s) should be installed.
3. OPA Home: the directory where Oracle Clinical will be installed; Oracle recommends:

```
/home/opapps
```

4. Owner of Oracle Clinical Server Code must be opapps
5. Location for files oratab, tnsnames; for example:

- /etc
- \$ORACLE_HOME/network/admin

6. RXC_SAS_VIEW: the directory where Oracle Clinical will generate SAS views; Oracle recommends:

```
/home/opapps/sas_view
```

7. Oracle Wallet location and password. The Installer uses these to create the database Wallet in the location you specify. The database Wallet stores the password for two accounts:

- The OCPSUB proxy account, which is used for database access for parameterized submission (PSUB) jobs. If your installation includes multiple databases using either replication or RAC, each database needs an OCPSUB account and its credentials are created in this Wallet on the database server during Oracle Clinical database installation.
- The RXC_DISC_REP account. If you use disconnected replication you must insert credentials for this account manually. See [Section 4.4.3, "Set Up Disconnected Replication \(Optional\)."](#)

Note: If you have already created a Wallet through a previous installation of Oracle Clinical 5.0 or higher, you can continue using it instead of creating a new one by entering the location and password for the existing Wallet.

2.5.2 Prepare to Install the Oracle Clinical Database Server Software

To start installing the database server software:

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

Note: Make a note of the current group so that you can set it back after the installation.

```
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 installation. Typically, this user group is `oinstall`. (See [Section 2.2.2.2, "Create the opapps Account."](#))

This temporary change is necessary so that the Installer can update the Oracle Home.

3. Set the X Window display output to the IP address of your local computer. Use the standard format for IP addresses.

For example:

```
setenv DISPLAY 123.45.67.89
```

4. Locate the Oracle Clinical software in the directory in the staging area on the database server where you downloaded it; see [Section 1.5, "Downloading and Extracting the Software."](#)
5. Open the `ldflags` file at `root: app/oracle/product/12.1.0.1/lib` and add the following flag:

```
-lnnz12
```

2.5.3 Install the Oracle Clinical Database Server Software

To start the Installer:

1. Log in to the server computer using the `opapps` account.

2. In the staging area, locate the directory where you downloaded Oracle Clinical (see [Section 1.5, "Downloading and Extracting the Software"](#)) and extract the .zip file if you have not already done so.
3. Navigate to this location:
`server_code_platform\Disk1\install`
4. Change protections on all files to 755:
`chmod 755 *`
5. Run one of the following commands, depending on whether or not you are using Oracle Real Application Cluster (RAC):

- For a non-RAC installation:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

- For a RAC installation:

```
./runInstaller -local
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -local -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

This ensures that the installation is performed only on the local node.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical or Oracle Clinical Remote Data Capture (RDC) Onsite.

6. In the Select a Product to Install page, select **Oracle Clinical Server for UNIX 5.1.0.0.x**.
7. Follow the instructions on the installation screens, providing the information you assembled in [Section 2.5.1, "Gather Required Information"](#).
8. You can review the progress of the installation:
 - a. Open another terminal session as the opapps user.
 - b. To review the relinking progress, run the following:
`tail -f $OPA_HOME/oc/51/relink_rxc.log`

- c. Open the `InstallActiontimestamp.log` in the `oraInventory/logs` directory.

2.5.4 Save the Installation Information

At the end of the installation, the installer 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. You need it for several post-installation tasks.

2.5.5 Review the Installation Log Files

Review the generated installation log files for errors:

- `$ORACLE_BASE/oraInventory/logs/installActions.log`
The current log file is `installActions.log`. All previous log generations have a timestamp appended to the name.
- `OPA_HOME/oc/51/relink_rxc.log`—information on the relinking activities
- `OPA_HOME/oc/51/config_wallet_timestamp.log`—information on Oracle Wallet configuration
- `OPA_HOME/oc/51/config_wallet_err_timestamp.log`—this file is created only if there are errors in the Oracle Wallet configuration

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

2.5.6 Oracle Clinical Database Server Directory Structure for UNIX

The Installer creates the following directory structure for an Oracle Clinical database server on UNIX:

```
OPA_HOME
  /bin
  /xmltemp
  /oc
    /51
      /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 Oracle Health Sciences products that 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`.

2.5.7 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 2.5.2, "Prepare to Install the Oracle Clinical 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 Perform 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](#)
- [Review the opa_settings File](#)

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 -arlt
```

- b. Add the following lines to the `.cshrc` file:

```
set path=( $path ORACLE_HOME/bin ORACLE_HOME/lib )
```

```
setenv RXC_LOG OPA_HOME/log
```

```
source OPA_HOME/bin/copa_setup_alias
```

where:

ORACLE_HOME is the directory where you installed Oracle Database 12c Release 1 (12.1.0.1).

OPA_HOME is the directory where you installed Oracle Clinical database server.

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

```
source .cshrc
```


2.6.2 Review the opa_settings File

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

`OPA_HOME/bin`

The Installer enters all necessary entries and default values for the Oracle Clinical environment into the opa_settings file.

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

Review the opa_settings file and adjust the default values, if necessary. Note:

- The db_env_setting records in opa_settings 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 [Section 1.8, "Choosing a Character Set"](#) for important information.
- NLS_DATE_FORMAT must be set to DD-MON-RRRR. It is possible to override this setting for display in RDC Onsite, the Patient Data Report, and Oracle Clinical data entry, but the value in opa_settings must be DD-MON-RRRR.

Installing the Oracle Clinical Database Server on Windows

This chapter describes how to install Oracle Database and the Oracle Clinical database server on a Windows computer.

Note: Installing Oracle Clinical with Oracle Real Application Clusters (RAC) is not supported on Windows.

- [Section 3.1, "Set Up the opapps User Account and the oclsascr User Group"](#)
- [Section 3.2, "Set Up Local Policy Security Options"](#)
- [Section 3.3, "Install Oracle Database"](#)
- [Section 3.4, "Install the Oracle Clinical Database Server"](#)
- [Section 3.5, "Perform Post-installation Tasks"](#)

If you are upgrading Oracle Clinical, see [Chapter 11](#).

For database tier system requirements, see the Oracle Database 12c Release 1 (12.1.0.1) *Oracle Database Installation Guide* for Windows at http://docs.oracle.com/cd/E16655_01/nav/portal_11.htm.

Note: If you install the Oracle Clinical database on Windows and use SAS, you must also install SAS on Windows; see [Chapter 9, "Setting Up SAS"](#).

Critical Patch Updates See [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

Oracle Database 12.1.0.1 includes many new features including multitenancy, which allows you to create one or more **pluggable databases** (PDBs) contained in a single **root** or **container** database (CDB). You can install Oracle Clinical on either a pluggable database or a non-CDB database (as in 11g). For more information on multitenancy, see <http://docs.oracle.com/database/121/CNCPT/cdbovrvw.htm>.

Oracle recommends learning about these new features in Oracle White Paper *Plug into the Cloud with Oracle Database 12c* at <http://www.oracle.com/technetwork/database/plug-into-cloud-wp-12c-1896100.pdf> and, for more details, the *Oracle® Database New Features Guide 12c Release 1 (12.1)* at <http://docs.oracle.com/database/121/NEWFT/toc.htm>.

3.1 Set Up the opapps User Account and the oclsascr User Group

Before you install Oracle Clinical database server, create the following user group and account:

- **oclsascr** — The group that controls access to the files Oracle Clinical generates for SAS. This user group is required if you use SAS integrated with Oracle Clinical.
- **opapps** — The operating system account that owns Oracle Clinical and that runs the Parameterized Submission (PSUB) process. This account is required.

3.1.1 Create the oclsascr and oinstall User Groups

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

Use Windows Administrative Tools to create a new Global Group in your Domain named oclsascr.

See the Oracle Database 12.1.0.1 Installation Guide for Windows chapter "Configuring Users, Groups and Environments for Oracle Database" at

http://docs.oracle.com/database/121/NTDBI/user_grps.htm#CIHCAABC.

3.1.2 Create the opapps Account and Add It to Groups

You must create the operating system account that owns Oracle Clinical. This account also has the privileges to run the parameterized submission (PSUB) service RXCPDPS and the PSUB Launcher (PSLAUNCH).

The user name for the account is opapps, with a home directory named opapps. For example:

Drive:\opapps

The Oracle Clinical documentation uses the variable *OPA_HOME* to refer to this location on an Oracle Clinical database server.

Using Windows administrative tools, assign opapps to the following user groups:

- ORA_DBA
- ORA_ASMDBA
- OCLSASCR

Note: Beginning in Oracle Clinical 5.0, no other accounts need to be added to the oclsascr user group.

3.2 Set 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 fallback** to **Enabled**.

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

3.3 Install Oracle Database

This section describes the following tasks:

- [Section 3.3.1, "Install Oracle Database 12.1.0.1 Enterprise Edition"](#)
- [Section 3.3.2, "Install Oracle Database 12.1.0.1 Examples"](#)

3.3.1 Install Oracle Database 12.1.0.1 Enterprise Edition

To install Oracle Database 12.1.0.1:

1. Locate the Oracle Database software in the staging area on the database server where you downloaded it; see [Section 1.5, "Downloading and Extracting the Software."](#)
2. Install Oracle Database 12.1.0.1. For instructions see the readme file and the *12.1.0.1 Oracle Database Installation Guide* at <http://docs.oracle.com/database/121/NXDQI/toc.htm#NXDQI120>.
3. Choose to install the Enterprise Edition.

3.3.2 Install Oracle Database 12.1.0.1 Examples

Oracle Database Examples includes the following items:

- Oracle JDBC Development Drivers (required)
- Oracle Database Examples (required)
- 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. Extract the zip file containing Oracle Database Examples in the `examples` directory.
2. Run the following file as an administrator:
`examples\setup.exe`
3. 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* at <http://docs.oracle.com/database/121/EXMPL/toc.htm>.

3.4 Install the Oracle Clinical Database Server

This section describes how to install and set up the Oracle Clinical database server.

The Oracle Universal Installer performs the following operations:

- Creates the Oracle Clinical directory structure (see [Section 3.4.4](#) for details)
- Installs the Oracle Clinical database server
- Sets permissions on the directories
- Creates the environment setup files
- Modifies the environment setup files
- Creates the Oracle Wallet to store credentials for OCPSUB and RXC_DISC_REP
- Creates the directory for storing the SAS files

3.4.1 Gather Required Information

You must have the following information ready to enter in the Installer screens:

1. Home Details: The *ORACLE_HOME* location, which is where you installed Oracle Database 12.1.0.1; for example:

drive:\app\oracle\product\12.1.0.1\dbhome

2. OPA Home: The directory where Oracle Clinical will be installed; Oracle recommends:

drive:\opapps

3. SAS View: The directory where Oracle Clinical will generate SAS views; Oracle recommends:

drive:\opapps\sas_view

4. Oracle Wallet location and password. The Installer uses these to create the database Wallet in the location you specify. The database Wallet stores the password for two accounts:
 - The OCPSUB proxy account, which is used for database access for parameterized submission (PSUB) jobs. If your installation includes multiple databases using either replication or RAC, each database needs an OCPSUB account and its credentials are created in this Wallet on the database server during Oracle Clinical database installation.
 - The RXC_DISC_REP account. If you use disconnected replication you must insert credentials for this account manually. See [Section 4.4.3, "Set Up Disconnected Replication \(Optional\)."](#)

Note: If you have already created a Wallet through a previous installation of Oracle Clinical 5.0 or higher, you can continue using it instead of creating a new one by entering the location and password for the existing Wallet.

3.4.2 Install the Oracle Clinical 5.1 Database Server for Windows

1. Log in to the server computer using the opapps account.
2. In the staging area, locate the directory where you downloaded and extracted Oracle Clinical (see [Section 1.5, "Downloading and Extracting the Software"](#)).
3. Run the following file as an administrator:

Disk1\install\setup.exe

The Installer opens to the Welcome screen.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical or Oracle Clinical Remote Data Capture (RDC) Onsite.

4. In the Select a Product to Install page, select **OC Server for Windows 5.1.0.0.x**.
5. Follow the instructions on the installation screens, providing the information you assembled in [Section 3.4.1, "Gather Required Information"](#).

3.4.3 Review the Log Files

The log files are located at:

\Oracle\Inventory\logs

For example:

C:\Program Files\Oracle\Inventory\logs

3.4.4 Oracle Clinical Database Server Directory Structure for Windows

The Installer creates the following directory structure:

```
OPA_HOME
  \bin
  \xmltemp
  \oc
    \51
      \bin      (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*.

3.5 Perform Post-installation Tasks

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

3.5.1 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.

3.5.2 Review 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 service.

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

Drive:opapps\bin

See [Section 1.8, "Choosing a Character Set"](#) for important information, and see the *Oracle Clinical Administrator's Guide* for a list of the settings and for information about changing, adding, and verifying values.

Review the opa_settings.bat file and adjust the default values, if necessary. Note:

- The `db_env_setting` records in opa_settings.bat 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 [Section 1.8, "Choosing a Character Set"](#) for important information.
- `NLS_DATE_FORMAT` must be set to `DD-MON-RRRR`. It is possible to override this setting for display in RDC Onsite, the Patient Data Report, and Oracle Clinical data entry, but the value in opa_settings must be `DD-MON-RRRR`.

Creating an Oracle Clinical Database

This chapter describes how to create a new Oracle database for use with Oracle Clinical. You must install Oracle Database first; see [Chapter 2, "Installing Oracle Clinical Database Server on UNIX"](#) or [Chapter 3, "Installing the Oracle Clinical Database Server on Windows."](#)

This chapter includes:

- [Section 4.1, "Review Oracle Database Requirements and Recommendations"](#)
- [Section 4.2, "Install Oracle Clinical Database Objects"](#)
- [Section 4.3, "Review the Log Files for Installation Errors"](#)
- [Section 4.4, "Perform Post-Installation Database Tasks"](#)

4.1 Review Oracle Database Requirements and Recommendations

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

Note: Follow these requirements for each 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 Check Required Tablespaces

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

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

Table 4–1 *Required Tablespaces and Sizes*

Tablespace	Minimum Size
SYSTEM	900 MB
TEMP	100 MB
UNDOTBS1	700 MB

Table 4–1 (Cont.) Required Tablespaces and Sizes

Tablespace	Minimum Size
USERS	500 MB
SYSAUX	600 MB

4.1.3 Use the Database Configuration Assistant

To create a new database, use the Database Configuration Assistant (DBCA). For instructions about the Database Configuration Assistant, see the Oracle Database 12c Release 1 (12.1.0.1) *2 Day DBA* guide at

<http://docs.oracle.com/database/121/ADMQS/install.htm#ADMQS0232>.

Note:

- Use the Custom Database installation option. This option allows access to the Database Storage screen, where you can expand the Tablespaces folder in the tree on the left side of the screen and edit the following tablespaces as required; see [Section 4.1.2, "Check Required Tablespaces"](#)
- The following parameters are not listed under All Initialization Parameters. Click **Show Advanced Parameters** to set the following parameters as described in [Section 4.1.8, "Set Initialization Parameters"](#):
 - Db_cache_size
 - Db_files
 - Java_pool_size
 - Job_queue_process
 - Large_pool_size

4.1.4 Decide Which Type of 12c Database to Create

You can install an Oracle Clinical database on either a pluggable database (PDB) in a container database (CDB) or on a non-CDB (pre-12c-style) database.

- To create a PDB, enable CDB and immediately create the PDB as well by entering its name in the **Pluggable database name** field.
- To create a non-CDB database, do not enable the option to create a CDB.

For more information see the Oracle Database 12c Release 1 (12.1.0.1) *2 Day DBA* guide at <http://docs.oracle.com/database/121/ADMQS/install.htm#ADMQS0232>.

4.1.5 Select Required Components

Select the following database options that are required for Oracle Clinical:

- Oracle JVM
- Oracle XML DB

Note: If you are creating a CDB and PDB, these are already selected by default.

4.1.6 Use Automatic Memory Management

Oracle recommends that you use Oracle Database 12c Release 1 (12.1.0.1)'s Automatic Memory Management feature for a new or an upgraded Oracle Clinical database.

4.1.7 Accept Connections as a Service

Choose to configure the database to accept connections as a service instead of a SID. Service name **requirements** for Oracle Clinical include:

- The service name must be less than 15 characters long.
- It must not include the domain.
- It must be **all lowercase**.

Note: If you are installing the Oracle Clinical database on a pluggable Oracle 12.1.0.1 database (PDB), see My Oracle Support article ID 1910177.1, *How To Configure TNS / SQLNET using the local_listener parameter for Pluggable Database In Oracle 12c, Allowing a SQLNET Connection to the PDB*. See ["Finding Information on My Oracle Support"](#) on page xii.

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 for the new settings to take effect.

Table 4–2 Required and Recommended Initialization Values in the init.ora File

Parameter	Value	Comments
COMPATIBLE	11.2.0.4	Specifies the release with which the Oracle server must maintain compatibility.
DB_BLOCK_SIZE	16384 bytes	You cannot change this value after you create the database.
DB_CACHE_SIZE	150 MB	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
DB_DOMAIN	null	DO NOT set this value. In Release 5.1 onward setting this value causes problems.
DB_FILES	200	Oracle adds needed space to the control files up to the number specified in the DB_FILES parameter.
EVENT	31151 trace name context forever, level 0x100	Required for HTML generation. 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.
JAVA_POOL_SIZE	50 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation. (Set greater than 150 MB with Oracle AERS, minimum.)

Table 4–2 (Cont.) Required and Recommended Initialization Values in the init.ora File

Parameter	Value	Comments
JOB_QUEUE_PROCESSES	10	Developer-specific parameter. You can change the value of this parameter after installation.
LARGE_POOL_SIZE	50 MB	Recommended value for 50 to 60 concurrent users.
MEMORY_MAX_TARGET	1000 MB (minimum)	Adjust this value according to your organization's needs.
MEMORY_TARGET	1000 MB (minimum)	Adjust this value according to your organization's needs.
NLS_DATE_FORMAT	DD-MON-RRRR (default value)	Determines the format in which client applications running on the Windows server transfer date information to and from the database. The format must specify the year as RRRR.
NLS_LENGTH_SEMANTICS	BYTE	The CHAR value for this parameter is not supported.
OPEN_CURSORS	800 or greater	You can change the value of this parameter after installation.
OPTIMIZER_DYNAMIC_SAMPLING	2 or greater	The default setting is 2. Oracle recommends using dynamic sampling for Batch Data Load temporary tables; see the <i>Oracle Clinical Administrator's Guide</i> .
OPTIMIZER_FEATURES_ENABLE	11.2.0.4	Acts as an umbrella for enabling a series of optimizer features based on an Oracle release number. NOTE: Oracle Clinical 5.1 is certified on the Oracle Database 11g optimizer features; see Section 11.4.6.6.4, "Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer."
OPTIMIZER_MODE	CHOOSE	If you run Oracle Clinical's statistics gathering scripts, the CHOOSE value sets Oracle Optimizer to apply the execution plan that best minimizes response time. See the Oracle Database documentation for more information. (CHOOSE is the default value when you specify 11.2.0.4 as the value of OPTIMIZER_FEATURES_ENABLE.)
PGA_AGGREGATE_TARGET	200 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
REMOTE_LOGIN_PASSWORDFILE	EXCLUSIVE	The database must be set up to use password file authentication.
SEC_CASE_SENSITIVE_LOGON	FALSE	Lets you enter passwords without case sensitivity.
SESSIONS	500 or greater	You can change the value of this parameter after installation.
SGA_MAX_SIZE	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
SGA_TARGET	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
SHARED_POOL_SIZE	150 MB (minimum)	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
UNDO_MANAGEMENT	AUTO	Specifies which undo space management mode the system uses. When set to AUTO, the instance starts in Automatic Undo Management (AUM) mode.
UTL_FILE_DIR	opa_home\xmltemp	Specifies each directory you access. Required to support Oracle Clinical PDF layout generation and Oracle AERS. For Windows environments, samples of the valid syntax are as follows: UTL_FILE_DIR=c:\e2b\import UTL_FILE_DIR=c:\opapps\xmltemp In a UNIX environment, UTL_FILE_DIR requires an entry with two specified paths: one with and one without a trailing slash. Add these lines before any other UTL_FILE_DIR entries: UTL_FILE_DIR=/usr/opapps/oc/xmltemp/ UTL_FILE_DIR=/usr/opapps/oc/xmltemp

4.1.9 Modify the tnsnames.ora File on the Database Server

The tnsnames.ora file must have a connect string entry for each database that matches the database's service name. There is a tnsnames.ora file in at least two locations in the installation. Oracle recommends maintaining a master file and copying it to each location whenever you add a database. See [Section 5.8, "Modify the tnsnames.ora File on the Application Server"](#) for the application server locations.

The tnsnames.ora file is on each database server at: *oracle_home/network/admin*.

If the database server has multiple Oracle Homes, the tns entries for all databases should be maintained in a central location; for example: */etc/tnsnames.ora*.

For the requirements for disconnected replication, see [Section 4.4.3.2, "Create a Wallet Credential for the RXC_DISC_REP Database User."](#)

4.2 Install Oracle Clinical Database Objects

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

4.2.1 Customize the Installation

Before you install database objects, you may want to modify some of the default SQL scripts used by the Installer; see [Section 4.2.1, "Customize the Installation"](#).

4.2.1.1 Edit the Tablespace Size Scripts

The Installer creates several new tablespaces with default sizes. To create larger databases, you can edit two scripts. 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/51/install/opadba2.sql
```

```
OPA_HOME/oc/51/install/rxcdba2.sql
```

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

```
OPA_HOME\oc\51\install\opadba2.sql
```

```
OPA_HOME\oc\51\install\rxcdba2.sql
```

4.2.1.2 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/51/install/rxcdba4.sql*

Windows *OPA_HOME\oc\51\install\rxcdba4.sql*

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

4.2.1.3 Create a Secret Store Directory

Create a directory that is accessible to the `opapps` user and different from the Oracle Wallet location. The Installer fails if this directory is not created before running the Installer.

Example location: `/pharm/home/opapps/sec_store/db_name`

4.2.2 Gather Required Information

Make sure you have the information below, which is arranged in the order it is prompted for by the Installer during a fresh installation. The order for upgrades is somewhat different.

Note: You must install the Oracle Clinical database server before you install or upgrade the Oracle Clinical database.

1. The `ORACLE_HOME` location, which is where you installed Oracle Database 12.1.0.1; for example:
`root:app/oracle/product/12.1.0.1/dbhome`
2. OPA Home: the directory where Oracle Clinical will be installed; Oracle recommends:
`/pharm/home/opapps`
3. SAS View: the directory where Oracle Clinical will generate SAS views; Oracle recommends:
 - UNIX: `$OPA_HOME/sas_view`
 - Windows: `%OPA_HOME%\sas_view`

Note: The upgrade Installer does not prompt for this value.

4. Service name for the database to be installed
5. Know if you plan to use either Automatic Storage Management (ASM) or Real Application Clusters (RAC). This affects the Installer behavior for validating tablespaces.
6. Location for tablespace datafiles. You can change the default sizes by editing the script before running the Installer; see [Section 4.2.1, "Customize the Installation"](#).
7. Location and password for the Wallet created during Oracle Clinical database server installation to store credentials for OCPSUB and RXC_DISC_REP.
8. You will need to enter passwords for the following:
 - Oracle Wallet
 - SYS
 - SYSTEM
 - RXC_MAA
 - RXC_PD
 - RXC_REP

- RXC_DISC_REP
- OPA
- RXC
- TMS
- RXA_DES
- RXA_LR
- OCPSUB
- RXA_WS
- RDC_MIDTIER_PROXY

Note: When you upgrade a database, the Installer does **not** prompt for the following passwords. For new installations, it does prompt for the following passwords.

- BC4J_INTERNAL
- RXA_READ
- RXA_RAND
- RXA_ACCESS
- OPS\$OPAPPS

Note: For information on changing the passwords for these accounts on a regular basis to avoid expiration, see the *Oracle Clinical Administrator's Guide*.

9. A database seed number between 1 and 99. Each database in an Oracle Clinical installation (or group of databases that are replicating with each other) must have a unique seed starting number.
10. Database host name and port number
11. Global library code. There can be only one Global Library location. If you have only one database, this value should be the same as the database host name. If you are using Oracle Clinical replication and have multiple databases, enter the host name for the database designated as the Global Library location.
12. Location of the secret store folder you created in [Section 4.2.1.3, "Create a Secret Store Directory"](#).

4.2.3 Start Installing the Oracle Clinical Database

Follow the instructions appropriate for your operating system:

- [Section 4.2.3.1, "Start the Installer on a UNIX Server"](#)
- [Section 4.2.3.2, "Start the Installer on a Windows Server"](#)

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical or Oracle Clinical Remote Data Capture (RDC) Onsite.

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:

Note: Make a note of the current group so that you can set it back after the installation.

```
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 12c Release 1 (12.1.0.1) 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. For example:

```
setenv DISPLAY 123.45.67.89
```

4. In the staging area, locate the directory where you downloaded Oracle Clinical (see [Section 1.5, "Downloading and Extracting the Software"](#)) and extract the .zip file if you have not already done so.

5. Navigate to this location:

```
server_code_platform\Disk1\install
```

6. Change protections on files to 755.

```
chmod 755 *
```

7. Start the Installer:

- Non-RAC Installation:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

- RAC Installation:

```
./runInstaller -local
```

Or, if the database server has multiple Oracle Homes, then enter:


```
./runInstaller -local -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

8. In the Select a Product to Install page, select **OC Database Install 5.1.0.0.x**.
9. Follow the instructions on the installation screens, providing the information you assembled in [Section 4.2.2, "Gather Required Information"](#).

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 the opapps account.
2. In the staging area, locate the directory where you downloaded and extracted Oracle Clinical (see [Section 1.5, "Downloading and Extracting the Software"](#)).
3. Run the following file as an administrator:

```
Disk1\install\setup.exe
```

The Installer opens to the Welcome screen.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical or Oracle Clinical Remote Data Capture (RDC) Onsite.

4. In the Select a Product to Install page, select **OC Database Install 5.1.0.0.x**.
5. Follow the instructions on the installation screens, providing the information you assembled in [Section 4.2.2, "Gather Required Information"](#).

4.2.4 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 Review the Log Files for Installation Errors

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

```
UNIX OPA_HOME/oc/51/install
```

Windows `OPA_HOME\oc\51\install`

Check the following log files for error messages and invalid objects:

- `oclinst_database_service.log`
- `reall_database_service.log`
- `ociconfig_database_service.log`
- `flt_seeddata_database_service_timestamp.log`
- `html_dialg_tmpl_database_service_timestamp.log`
- `html_blob_seeddata_database_service_timestamp.log`
- `xmlp_clob_seeddata_database_service_timestamp.log`
- `xml_clob_seeddata_database_service_timestamp.log`
- `compile_all_invalid_database_service.log`
- `load_olsardcstatemachine_jar_database_service.log`
- `install_database_service_timestamp.log`
- `opaconnectcheck_system_database_service.log`

4.4 Perform Post-Installation Database Tasks

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

- [Section 4.4.1, "Set the Database Time Zone"](#)
- [Section 4.4.2, "Pin Database Packages"](#)
- [Section 4.4.3, "Set Up Disconnected Replication \(Optional\)"](#)
- [Section 4.4.4, "Consider Implementing Partitioning"](#)

See also [Section 8.1, "Set Up PSUB"](#) for additional required tasks.

4.4.1 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.

Oracle recommends setting time zone to a named location rather than a numeric offset so that standard and daylight time adjustments are made automatically.

You can find valid named location strings in the `V$TIMEZONE_NAMES` view. For example, to find a time zone in the United States, enter the following query:

```
SELECT distinct tzname
FROM V$TIMEZONE_NAMES
WHERE tzname like 'US/%'
```

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:

```
alter database set time_zone='tzname_value';
```

For example:

```
alter database set time_zone='US/Eastern';
```

4.4.2 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.

4.4.2.1 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.
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 `rx` user:

```
sqlplus rx/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.

4.4.2.2 Pin Windows Database Packages

To pin the database packages located on a Windows server:

1. Set the Windows environment:

```
set p1=database
```

```
set p2=51
```

```
opa_setup
```

where `database` is the name of this database instance, and 51 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 rx/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.

4.4.3 Set Up Disconnected Replication (Optional)

Do the following only if you plan to use disconnected replication.

4.4.3.1 Check Tablespace Size

If you use 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*.

4.4.3.2 Create a Wallet Credential for the RXC_DISC_REP Database User

The system stores these credentials in the same Wallet as the one created for OCPSUB.

1. Log in as opapps.

2. Set environment variables.

In UNIX:

```
opa_setup database_name 51
```

In Windows:

```
set p1=database_connect_string
set p2=51
opa_setup
```

3. Create an alias for the disconnected replication wallet alias in tnsnames.ora. The disconnected replication wallet alias is the name of the database appended with: _disc.

For example, if the database name is ny123x, the tnsnames entry would look something like:

```
ny123x, ny123x_disc, ny123x.world, ny123x.us.oracle.com = (DESCRIPTION=
  (ADDRESS= (PROTOCOL=tcp) (HOST=example.us.company.com) (PORT=1124))
  (CONNECT_DATA=(service=ny123x))
```

See [Section 4.1.9, "Modify the tnsnames.ora File on the Database Server."](#)

4. For the disconnected replication wallet alias enter tnsping wallet_alias to test that it returns success. For example:

```
tnsping ny123x_disc
```

5. Create the credentials for the disconnected replication wallet alias and account.

In UNIX:

```
mkstore -wrl /pharm/home/opapps/wallet51 -createCredential wallet_alias rxc_
disc_rep rxc_disc_rep_password
```

In Windows:

```
mkstore -wrl %walletpath% -createCredential wallet_alias rxc_disc_rep rxc_
disc_rep_password
```

4.4.3.3 Test Wallet Connection for RXC_DISC_REP

1. Set tns_admin:

In UNIX:

```
setenv TNS_ADMIN path_of_sqlnet.ora
```

In Windows:

```
set TNS_ADMIN=%walletpath%
```

2. For the disconnected replication wallet alias run `sqlplus /@wallet_alias.` for example:

```
sqlplus /@ny123x_disc
```

The connection should be a success.

3. Run `show user`

This should display the `rxcdisc_rep` user.

4.4.3.4 Add Reference Codelist Value

In the OCL_STATE reference codelist:

1. Add a value called `DISC_REP_WALLET`. See the *Oracle Clinical Administrator's Guide* for more information.
2. Enter the `wallet_alias` you just created as the long value.

4.4.4 Consider Implementing Partitioning

The Oracle Clinical RESPONSES table contains all patient data entered for all studies in an Oracle Clinical installation. You can partition this table. See the *Oracle Clinical Administrator's Guide* for more information.

Installing and Configuring the Application Tier

This chapter describes how to install Oracle Application Server, which includes the Oracle Forms Server and the Oracle Reports Server, Oracle WebLogic Server, and Oracle Application Developer Framework.

This chapter includes:

- [Section 5.1, "Before You Start"](#)
- [Section 5.2, "Install Adobe Reader"](#)
- [Section 5.3, "Install Oracle Java Development Kit"](#)
- [Section 5.4, "Install Oracle WebLogic Server 10.3.6"](#)
- [Section 5.5, "Install and Configure Oracle Application Server 11gR2"](#)
- [Section 5.6, "Enable SSL Between a Browser and Oracle HTTP Server"](#)
- [Section 5.7, "Install Oracle Application Developer Framework and Apply Patches"](#)
- [Section 5.8, "Modify the tnsnames.ora File on the Application Server"](#)
- [Section 5.9, "Test Connectivity to Databases for Forms and Reports Servers"](#)
- [Section 5.10, "Restart the Computer"](#)

Critical Patch Updates See [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

5.1 Before You Start

Do the following.

5.1.1 Identify a Single Account to Perform All Application Tier Installation Tasks

You must install all application tier components using the same user account. The account must have administrator privileges on the server computer.

5.1.2 Get a CA Certificate for HTTPS

To support HTTPS, you need to request a certificate from a Certificate Authority (CA) vendor such as Thawte, Entrust, or Verisign, and then import the certificate into the Oracle Wallet for the Oracle Application Server.

In the last step in [Section 5.6.1.1, "Creating an Oracle Wallet and Generating a Certificate Request"](#) you generate an encoded plain text certificate request file that you can email to the CA vendor. The vendor will sign the file and send you a Trusted Certificate and a User Certificate.

Allow some time for the certificates to be issued.

Note: If your intention is to install an environment that will never be taken into production, you can skip this step and create a self-signed demo certificate for testing purposes; see [Section 5.6.2, "Enabling SSL Between a Browser and Oracle HTTP Server With Self Signing."](#)

5.2 Install Adobe Reader

Adobe Reader is required on the Reports Server and on client computers. If you have not already downloaded it, following instructions in [Section 1.5.6, "Downloading Adobe Reader"](#), do so now.

5.3 Install Oracle Java Development Kit

To install Oracle Java Development Kit (JDK):

1. If you have not already done so, follow instructions in [Section 1.5.4, "Downloading Oracle Java Development Kit."](#)
2. Follow instructions in the release notes to apply the patch.

Note: Do not use the default download location. By default, the download directory is C:\Program Files\java\jdkversion. "Program Files" includes a space, which can cause problems. Oracle recommends specifying a **directory with no spaces in the name**.

In addition, the directory name **must** have **no more than 8 characters**; for example, C:\app\java\jdk16065.

3. Make a note of the directory in which you install JDK. You will need it when you install WebLogic Server.

5.4 Install Oracle WebLogic Server 10.3.6

Instructions in this section should be complete. However, additional information is in the WebLogic 10.3.6 following instructions in *Oracle® Fusion Middleware Installation Guide for Oracle WebLogic Server 11g Release 1 (10.3.6)*, which you can find on the media pack or at http://docs.oracle.com/cd/E23943_01/doc.1111/e14142/overview.htm, or download the PDF from here: http://docs.oracle.com/cd/E23943_01/web.1111/e13708/toc.htm.

The complete documentation set for Oracle WebLogic Server 10.3.6 is available at: http://docs.oracle.com/cd/E23943_01/wls.htm.

1. In the staging area where you downloaded the media pack (see [Section 1.5, "Downloading and Extracting the Software"](#)) locate the directory where you downloaded Oracle WebLogic Server 11gR1 (10.3.6) Generic and Coherence and extract the WebLogic Server .zip file if you have not already done so.
2. Log in as the user you selected in [Section 5.1.1, "Identify a Single Account to Perform All Application Tier Installation Tasks"](#).
3. Install Oracle WebLogic Server using a Generic Package installer—This type of installer is a .jar file; wls1036_generic.jar. Double-click on the .jar file to open the Installer.

You can accept most default values, with the exceptions noted below.

Note: You can change the default value of the *middleware_home* directory, which is C:\Oracle\Middleware, if you wish but some code examples in this guide use that value to make it easier to copy and paste, so remember to change these if you change the value.

You must NOT change the names for any of the middleware home's subdirectories, including wlsrserver_10.3.

Security Updates

Specify whether you want to register the product installation with My Oracle Support. If you register, Oracle Support emails you immediately of any security updates that are specific to your installation. Follow instructions on screen to register or to reject the option.

Note: Even if you accept this option you should check My Oracle Support for quarterly Oracle Critical Patch Update (CPU) security patches certified for use with Oracle Clinical; see [Section 1.9](#), "[Applying Oracle Critical Patch Updates](#)."

Choose the "Custom" Install Type

Select a "Custom" installation type rather than the default value, "Typical." This is required in order to create a Node Manager.

JDK Selection

Browse to the Oracle Java Development Kit (JDK) 1.6.0_65 (JDK 6) that you installed in the previous section.

Include the Node Manager

Be sure to install the Oracle WebLogic Node Manager in the **Install Windows Service** screen. The Node Manager is used to monitor, start, and stop server instances in a WebLogic domain.

Note: Continue to click **Next** until you are finished. After the Installation Summary the processing may take a few minutes. You can safely ignore the Quick Start screen.

5.5 Install and Configure Oracle Application Server 11gR2

Install Oracle Applications Server as indicated below.

5.5.1 Install Oracle Application Server 11gR2 (11.1.2.1)

Oracle Application Server 11.1.2.1 provides Oracle Forms, Oracle Reports, and Oracle HTTP Server (OHS).

To install Oracle Application Server 11.1.2.1:

1. Restart the computer.
2. Log in as the user you selected in [Section 5.1.1](#), "[Identify a Single Account to Perform All Application Tier Installation Tasks](#)".

3. Stop the WebLogic Node Manager:
 - a. Close the command shell in which the Node Manager is running, if any.
 - b. If any DOS windows are open that are running the node manager, close them.
 - c. Go to the Windows Control Panel, then Services, and stop the Oracle WebLogic Node Manager service.

For more information on the Node Manager, see the *Oracle® Fusion Middleware Node Manager Administrator's Guide for Oracle WebLogic Server 11g Release 1 (10.3.6)* at http://docs.oracle.com/cd/E23943_01/web.1111/e13740/toc.htm.

4. In the staging area where you downloaded the media pack—see [Section 1.5, "Downloading and Extracting the Software"](#)—locate the directory where you downloaded Oracle Forms and Reports 11g R2 (11.1.2.1.0) for Microsoft Windows x64 (64-bit) and extract the .zip file if you have not already done so.
5. Run the following file as an administrator:

Disk1\setup.exe

6. Follow the instructions on the installation screens as the Oracle Universal Installer guides you through the installation. You can accept most defaults except as noted below:

SKIP Software Updates

Select **Skip Software Updates** instead of the default value, Search My Oracle Support for Updates. Oracle Clinical may not be certified with these updates.

Domain Name Must Be FRDomain

In the **Select Domain** window, the default name for the domain created by the Installer is **ClassicDomain**. You **must** rename it to **FRDomain** or RDC Onsite installation will fail.

In the same screen, enter and confirm a password for WebLogic Server.

Oracle Instance Must Be asinst_1

When prompted for the Oracle Instance, accept the default value: *middleware_home\asinst_1*.

Specify Security Updates

Specify whether you want to register the product installation with My Oracle Support. By registering, Oracle Support emails you immediately of any security updates that are specific to your installation. Follow instructions on screen to register or to reject the option.

Note: Even if you accept this option you should check My Oracle Support for quarterly Oracle Critical Patch Update (CPU) security patches certified for use with Oracle Clinical; see [Section 1.9, "Applying Oracle Critical Patch Updates."](#)

Port

For greater security, you may want to customize the port. Auto Port Configuration is the default setting.

Proxy

For greater security, you may want to use a proxy. No proxy is the default setting.

Do NOT Use Application Identity Store

Uncheck the Use Application Identity Store check box at the top of the screen; Oracle Clinical does not use OID (Oracle Identity).

Note: After installing Oracle Application Server, you can check the log file which by default is in C:\Program Files\Oracle\Inventory\logs.

5.5.2 Stop Services

Shut down the following services:

- WLS_FORMS under ORACLE_HOME
- WLS_REPORTS under ORACLE_HOME
- Oracle Process Manager

5.5.3 Apply Patch

Download patch **16837591** from My Oracle Support and apply it following instructions in the patch readme file. It is required to support JRE7 Update 65.

Note: The readme says "Ensure that the directory containing the OPatch script appears in your \$PATH." The OPatch here is the one under ORACLE_FRHOME. For example:

```
set ORACLE_FRHOME= your_ORACLE_FRHome
set path=%oracle_frhome%\opatch;%path%
```

In addition, you can safely ignore the Prerequisites section in the readme.

5.5.4 Create ORACLE_INSTANCE Environment Variable

Create the ORACLE_INSTANCE environment variable and define it as the Oracle Application Server Home:

1. From the Control Panel, select **System**, then **Advanced System Settings**.
2. Create a system variable named ORACLE_INSTANCE and set its value to your Oracle Instance Home; for example C:\oracle\middleware\asinst_1.

5.6 Enable SSL Between a Browser and Oracle HTTP Server

Create the following SSL (HTTP Secure Socket Layer) configuration: from users' browsers, HTTPS to Oracle HTTP Server (Web proxy), then HTTP to Oracle WebLogic Server.

Follow instructions in **one** of the following sections:

- [Section 5.6.1, "Enabling SSL Between a Browser and Oracle HTTP Server Using a Certificate Authority"](#)

- [Section 5.6.2, "Enabling SSL Between a Browser and Oracle HTTP Server With Self Signing"](#)—This may be useful if you want to set up HTTPS with a demo certificate for internal testing purposes.

5.6.1 Enabling SSL Between a Browser and Oracle HTTP Server Using a Certificate Authority

The following basic steps are required:

- [Creating an Oracle Wallet and Generating a Certificate Request](#)
- [Import the User Certificate and Trusted Certificate to OWM](#)
- [Edit the Oracle HTTP Server Configuration File](#)

Oracle HTTP Server uses a utility called Oracle Wallet Manager (OWM) to manage certificates on the server. An Oracle Wallet is a container that stores your credentials, such as certificates, trusted certificates, certificate requests, and private keys.

The Oracle Clinical Installer automatically enables traffic from Oracle HTTP Server to Oracle WebLogic Server.

Note: Do all steps in this section with the same user account you have used in the previous steps in this chapter. You must have administrator privileges on the machine.

Note: If you have not set the Oracle Instance variable as instructed in [Section 5.5.4](#), do so now.

5.6.1.1 Creating an Oracle Wallet and Generating a Certificate Request

To create an Oracle Wallet:

1. Log in to Oracle HTTP Server as the user that installed Oracle Application Server.
2. Start Oracle Wallet Manager. From the Start menu, navigate to Oracle Classic 11g, then Integrated Management Tools, then Wallet Manager.
3. In Oracle Wallet Manager, from the Wallet menu, click New.

A dialog asks if you want to create a default directory.

4. Click **No**. Your account probably does not have privileges to do this. For Oracle Clinical the Wallet will be in the directory where the Installer created the default certificate and Wallet.
5. Enter and confirm a password that conforms to the rules listed in the dialog. This password will be required every time you open the Wallet.

Leave the Wallet Type set to Standard and click **OK**.

6. A new dialog opens, asking if you want to create a certificate request. Click **Yes**.
7. In the Create Certificate Request dialog, enter values in the following fields:

- **Common Name:** Enter *host.your_company_domain*.

Note: The Common Name must match the Server Name directory that is specified in the primary configuration file (httpd.conf), which is created during Oracle HTTP Server installation in C:\app\oracle\middleware\asinst_1\config\OHS\ohs1.

The rest of the fields do not affect SSL functionality.

- **Organizational Unit:** Your unit within your company.
 - **Organization:** Your company.
 - **Locality or City, State or Province, and Country**
 - **Key Size:** 2048 (bits)
-

Note: Most providers encourage 2048-bit keys on all certificates.

- **DN:** OHS generates this value from the values you entered.

Click **OK**. The system displays a confirmation that a certificate request has been created. Click **OK**.

8. Go to the directory where the Wallet has been created:

`oracle_instance_home\config\OHS\ohs1\keystores\default`

For example:

`C:\oracle\middleware\asinst_1\config\OHS\ohs1\keystores\default`

9. In the keystores directory, create a new directory with a meaningful name such as your organizational unit:

`oracle_instance_home\config\OHS\ohs1\keystores\your_unit`

For example:

`C:\oracle\middleware\asinst_1\config\OHS\ohs1\keystores\your_unit`

10. In the navigation tree on the left, select **Certificate: [Requested]** and then select **Export Certificate Request** from the Operations menu.
11. Navigate to the new directory you created and enter a name for a file to be created; for example, `server_name.csr`. Click **Save**.
12. Select **Save As** from the Wallet menu, navigate to the new directory, and click **OK**. The wallet file is always named **ewallet.p12**.

The system displays a confirmation message along the bottom of the screen that a certificate request has been exported successfully.

The new directory now contains the certificate request file as well as the wallet file.

5.6.1.2 Obtain Trusted Certificate and User Certificate from Certificate Authority

Obtain the certificates from the Certificate Authority as described in [Section 5.1.2, "Get a CA Certificate for HTTPS"](#). Depending on the Certificate Authority, you will need to send either the certificate request file generated in the previous section or you will need to copy and paste the text in that file.

5.6.1.3 Import the User Certificate and Trusted Certificate to OWM

After you have received the User Certificate and Trusted Certificate from a CA vendor:

1. Log in to Oracle HTTP Server as the admin user that owns OHS processes.
2. Start Oracle Wallet Manager. From the Start menu, navigate to Oracle Classic 11g, then Integrated Management Tools, then Wallet Manager.
3. In Oracle Wallet Manager, select **Open** from the Wallet menu.
A dialog asks if you want to create a default directory.
4. Click **Yes**.
5. Navigate to the directory where you saved the Wallet file and click **OK**.
6. Enter the Wallet password that you created.
7. From the Operations menu, select **Import Trusted Certificate**.
8. In the dialog, select the option **Select a file that contains the certificate** and click **OK**.
9. Navigate to the trusted certificate and click **OK**.

The system displays a confirmation message along the bottom of the screen that the trusted certificate has been imported successfully.

10. In the navigation tree on the left, select **Certificate: [Requested]** and then select **Import User Certificate** from the Operations menu.
11. Navigate to the signed certificate and click **OK**.
The system displays a confirmation message along the bottom of the screen that a certificate has been imported successfully.
12. In the Wallet menu, select **Auto Login**, then **Exit**.

5.6.1.4 Edit the Oracle HTTP Server Configuration File

Make the following two changes in the OHS configuration file, `ssl.conf`.

5.6.1.4.1 Add the New Wallet Location and Specify Port WebLogic Server installation creates a default, unsigned SSL wallet file for OHS. Its location is specified in the configuration file (`ssl.conf`) loaded at startup from the *oracle_instance\config\OHS\ohs1* directory.

1. Make a backup copy of `ssl.conf`, which is located at:
`oracle_instance\config\OHS\ohs1`
2. Open `ssl.conf` in a text editor.
3. Find the string `#Path to the wallet` and comment out the default location that follows it.

```
SSLWallet ${ORACLE_INSTANCE}/config/${COMPONENT_TYPE}/${COMPONENT_NAME}/keystores/default
```

4. Replace the above string (in bold) with the path to the directory you created:
`SSLWallet oracle_instance_home\config\OHS\ohs1\keystores\your_unit`
5. By default, the port for SSL is 8890, which means all URLs need to include `:8890`. You can change the value to 443 in which case the URLs do not need to include any port. To change the port to 443, change the following lines:

```
Listen 8890
<VirtualHost *:8890>
```

to:

```
Listen 443
<VirtualHost *:443>
```

6. Stop and start Oracle HTTP Server using Oracle Process Manager Notification Server (OPMN) to load the configuration change:

```
oracle_instance\bin\opmnctl restartproc process-type=OHS
```

The OPMN opmnctl executable for the instance is located in *oracle_instance_home*\bin directory.

7. Test that you can connect from a browser to your virtual host in HTTPS URL:

```
https://host.your_company_domain
```

5.6.1.4.2 Make OHS Compatible with Internet Explorer 9 and Above

While you have the ssl.conf file open, make the following additional change to make the application compatible with Internet Explorer 9 and 10.

OHS always returns HTTP 1.0 to Internet Explorer (IE) user-agents, which causes some problems in RDC Onsite in an IE 9 or 10 browser. It appears this configuration is outdated and should be commented out to work properly in IE 9 and 10.

Comment out or remove the following lines:

```
BrowserMatch ".*MSIE.*" \
nokeepalive ssl-unclean-shutdown \
downgrade-1.0 force-response-1.0
```

5.6.1.4.3 Add Security Settings

While you have the ssl.conf file open, make the following additional change to avoid weak ciphers and protocols for SSL (HTTPS):

1. Search for the following text:

```
SSL Protocol Support
```

2. Comment out the following line:

```
SSLProtocol nzos_Version_1_0 nzos_Version_3_0
```

3. Add the line:

```
SSLProtocol -ALL +SSLv3 +TLSv1
```

4. Search for the following text:

```
SSL Cipher Suite
```

5. Comment out the current entry for SSL Cipher Suite:

```
SSLCipherSuite SSL_RSA_WITH_RC4_128_MD5,SSL_RSA_WITH_RC4_128_SHA,SSL_
RSA_WITH_3DES_EDE_CBC_SHA,SSL_RSA_WITH_DES_CBC_SHA,TLS_RSA_WITH_AES_
128_CBC_SHA,TLS_RSA_WITH_AES_256_CBC_SH
```

6. Add the line:

```
SSLCipherSuite
ALL:!aNULL:!ADH:!eNULL:!LOW:!EXP:!NULL:RC4+RSA:+HIGH:+MEDIUM:!SSLv2:!EX
PORT
```

5.6.2 Enabling SSL Between a Browser and Oracle HTTP Server With Self Signing

To set up HTTPS with a demo certificate for internal testing purposes:

1. Log in to Oracle HTTP Server as the user that installed Oracle Application Server.
2. Start Oracle Wallet Manager. From the Start menu, navigate to Oracle Classic 11g, then Integrated Management Tools, then Wallet Manager.
3. In Oracle Wallet Manager, from the Wallet menu, click New.

A dialog asks if you want to create a default directory.

4. Click **No**. Your account probably does not have privileges to do this. For Oracle Clinical the Wallet will be in the directory where the Installer created the default certificate and Wallet.

5. Enter and confirm a password that conforms to the rules listed in the dialog. This password will be required every time you open the Wallet.

Leave the Wallet Type set to Standard and click **OK**.

6. A new dialog opens, asking if you want to create a certificate request. Click **No**.
7. Do Save As to save the empty password-protected Wallet to a meaningful location like *your_unit*. For example:

```
oracle_instance\config\OHS\ohs1\keystores\oc
```

8. Open a DOS window.
9. Navigate to: *Middleware_Home*\oracle_common\bin
10. Create and set the *java_home* environment variable; for example:

```
set java_home=c:\app\java\jdk16065
```

11. Run following orapki command for the Wallet created above:

```
c:\Oracle\Middleware\oracle_common\bin>orapki wallet add -wallet
full-path-to-the-location-of-the-Wallet-after-step-7 -dn
"CN=hostname.domain, OU=Department, O=Company, L=City, ST=State/Province,
C=Country"
-keysize 2048 -self-signed -validity 2190 -pwd password
```

Note: Double quotes where specified above are **required**.

Validity is hardcoded above to 2190 days, which is six years. You can change this value as required.

12. Start Oracle Wallet Manager. From the Start menu, navigate to Oracle Classic 11g, then Integrated Management Tools, then Wallet Manager.
13. Click **Yes** when prompted with "Your default wallet directory does not exist. Do you want to continue?"
14. In the Wallet Manager, open the Oracle Clinical Wallet. The self-signed certificate should be displayed with a status of READY.

15. In the Wallet menu, select **Auto Login**.
16. Save and exit.
17. To complete the setup, follow these instructions:
 - a. [Section 5.6.1.4, "Edit the Oracle HTTP Server Configuration File"](#)
 - b. [Section 5.6.1.4.2, "Make OHS Compatible with Internet Explorer 9 and Above"](#)
 - c. [Section 5.6.1.4.3, "Add Security Settings"](#)

Note: Since this is a demo certificate and is not from a recognized certificate authority, the browser will display a certificate warning. To prevent this, you can import the certificate into the browser and store it as a trusted publisher and trusted root CA, then restart the browser.

For more information, see *How To Generate A Wallet Containing A Self Signed Certificate Using ORAPKI in Oracle Application Server and Fusion Middleware* on My Oracle Support (Article ID 560982.1).

5.7 Install Oracle Application Developer Framework and Apply Patches

Install Oracle Application Developer Framework (ADF, also known as Oracle Application Developer) and apply required patches.

5.7.1 Install Oracle Application Developer Framework (ADF)

Install Oracle Application Developer 11g R1 (11.1.1.6.0), also known as ADF, which is included in the media pack.

Additional information is included in the *Oracle® Fusion Middleware Installation Guide for Application Developer 11g Release 1 (11.1.1.6.0)*, which you can find on the media pack or at http://docs.oracle.com/cd/E23943_01/doc.1111/e14827/toc.htm.

1. In the staging area where you downloaded the media pack (see [Section 1.5, "Downloading and Extracting the Software"](#)) locate the Oracle Application Development Runtime 11g Patch Set 5 (11.1.1.6.0) directory where you extracted the ADF .zip file.
2. If you have not done so already, log in as the user you selected in [Section 5.1.1, "Identify a Single Account to Perform All Application Tier Installation Tasks"](#).
3. In a DOS Command window, navigate to the above directory.
4. Execute the following command:

```
setup -jreLoc drive:\location_where_you_installed_jdk1.6.0_65
```

for example:

```
setup -jreLoc C:\app\Java\jdk16065
```

However, if you installed JDK in the default location, C:\Program Files\Java\jdk1.6.0_65, this command may not work because of the space between "Program" and "Files." The following command works for the same location:

```
setup -jreLoc C:\Progra~1\Java\jdk16065
```

Tip: ADF's setup.exe file does not run if you double-click it. You must use the above command.

5. Follow instructions on the Installer screens.

Note: If you see the message "WLS installation detected, WebLogic Server support available in this Middleware Home." Press **Next** to continue the installation.

5.7.2 Upgrade ADF

Upgrade ADF to the latest patch set that is certified with Oracle Clinical. See *Oracle Health Sciences (Life Sciences/ Pharmaceutical/ Healthcare) Supported Technology Stacks* (Article ID 180430.1) on My Oracle Support for the latest information.

To upgrade ADF, apply two patches, a JDeveloper patch and a WebCenter Composer patch, and enter an upgrade command as detailed below. For ADF 11.1.2.4 the patch numbers are:

- 16546129—JDeveloper patch
- 16546157—WebCenter Composer patch

Note: Oracle supports only English OS language settings for the application tier.

Additional information is in the patch readme files. However, because there are no WebCenter components explicitly installed, you cannot follow the patch readme instructions completely.

1. Restart the server.
2. Locate the patch files in the staging area where you downloaded them in [Section 1.5, "Downloading and Extracting the Software."](#)
3. Go to the Windows Control Panel, then Services, then stop all Oracle services (Oracle Process Manager, Oracle WebLogic Node Manager).
4. Open a DOS command window and set the *oracle_home* and path. For ADF (only) this should be:

```
set ORACLE_HOME=your_oracle_common_home
```

```
For example: set ORACLE_HOME=C:\Oracle\Middleware\Oracle_Common
```

```
set path=%oracle_home%\bin;%oracle_home%;%oracle_home%\opatch;%path%
```

Note: The readme for the WebCenter patch directs you to set *oracle_home* to Oracle_WC1—the WebCenter install directory. However, if there are no WebCenter components explicitly installed, set *oracle_home* to *oracle_common* as above.

5. Navigate to one patch directory. For example, for ADF 11.1.2.4:

```
cd c:\downloads\p16546129_111160_Generic\16546129
```

6. Enter

```
opatch apply
```

7. Navigate to the other patch directory. For example, for ADF 11.1.2.4:

```
cd c:\downloads\p16546157_111160_Generic\16546157
```

8. Enter

```
opatch apply
```

9. If you have started any WebLogic services, including the Administration and Managed Servers, close them now:

- If any DOS windows are open that are running the node manager, close them.
- Go to the Windows Control Panel, then Services, and turn off the Oracle WebLogic Node Manager service.

10. From the DOS command line, navigate to *middleware_home*\oracle_common\common\bin and execute the following commands:

```
setWlstEnv.cmd
wlst.cmd
```

Then, in the WebLogic Server Scripting Tool shell, enter the following commands:

```
upgradeADF('middleware_home/user_projects/domains/frdomain')
exit()
```

Note: Be sure to use forward slashes (/) in the path.

By default *middleware_home* is C:\oracle\middleware.

In the WLS Scripting Tool shell you can type `help()` to get information on available commands.

5.7.3 Patch ADF to Support Internet Explorer 11

Consult My Oracle Support article *Supportability on Internet Explorer 11 (IE11) with Oracle ADF* (ID 1599898.1) for information on what patches, if any, are required to make your version of ADF compatible with IE 11.

For ADF 11.1.2.4, the required patch is **18277436**.

Download the patch from My Oracle Support at <https://support.oracle.com> and apply it, following instructions in the readme file.

5.8 Modify the tnsnames.ora File on the Application Server

The tnsnames.ora file must have an entry for each database that matches the database's service name. There is a tnsnames.ora file in at least two locations in the installation. Oracle recommends maintaining a master file and copying it to each location whenever you add a database. See [Section 4.1.9, "Modify the tnsnames.ora File on the Database Server"](#) for the database server location.

The tnsnames.ora locations on the application server include:

- *middleware_home*\asinst_1\config
- *oracle_fr_home*\network\admin. Oracle Clinical requires a copy here. Check this location and if no tnsnames.ora file is present, create it there.

5.9 Test Connectivity to Databases for Forms and Reports Servers

The Oracle Clinical database must be able to communicate with the application servers. Establish that SQL*Net connections can be created to connect the application server to all databases.

5.9.1 Test the Connection from the Application Servers to the Database

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

1. Open a Microsoft DOS command window.
2. Use SQL*Plus to verify that you can connect to the database:

```
sqlplus system/password@dbname
```

5.9.2 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 (service name), user ID, or password was entered.
- The tnsnames.ora file is not present in the correct directory or does not contain the correct entries.

5.10 Restart the Computer

To ensure that all configuration changes for the Oracle Application Server are initialized, restart the computer before you continue with the next task in the installation process.

Installing the Oracle Clinical Front End

This chapter includes:

- [Section 6.1, "Gather the Required Information"](#)
- [Section 6.2, "Restart Computer and Stop All Servers and Services"](#)
- [Section 6.3, "Install the Oracle Clinical Front End Components"](#)
- [Section 6.4, "Make the Java Runtime Environment Available for Download"](#)
- [Section 6.5, "Make the Oracle Clinical PDF Plug-in Available to Users"](#)
- [Section 6.6, "Share the RDC Directory for Image Access"](#)
- [Section 6.7, "Install and Configure JSpell Spell Checker SDK \(Optional\)"](#)
- [Section 6.8, "Verify and Fix Environment Variables"](#)
- [Section 6.9, "Setting Up Automatic Startup"](#)
- [Section 6.10, "Starting Servers Manually"](#)
- [Section 6.11, "Verify the Application Tier Installation"](#)
- [Section 6.12, "Stopping Servers"](#)

The Oracle Clinical and RDC Onsite Front End includes:

- The Oracle Clinical Forms Server, which is required for Oracle Clinical and for the RDC Administration application
- The Oracle Clinical Remote Data Capture application, the online help, 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 the Application Tier"](#) for instructions.

6.1 Gather the Required Information

Have the following information ready to enter in the Installer screens:

- Home Details: Select the Oracle Home that corresponds to the Oracle Forms and Reports home, similar to C:\oracle\middleware\Oracle_FRHome1.

On the Installer screen there are two drop downs, Name and Path. Use the Path drop-down to do the selection. When you select the directory, the Name value changes automatically.

- Your OPA Home directory; by default:

C:\opapps51

- Oracle HTTPS Server (OHS) SSL Listener Port number. You may have set this to 443 per the instructions in the previous chapter; see [Section 5.6.1.4.1, "Add the New Wallet Location and Specify Port."](#)
- Oracle HTTP Server (OHS) Non-SSL Listener Port number.

Tip: To find these two port numbers:

1. Open an MS DOS window.
2. Go to *oracle_instance/bin*.
3. Enter `opmnctl status -l`
where the last character is a lowercase L.

To check, go to the URL `https://host:port` with each port.

- WebLogic username: The account created when you installed the WebLogic Server.
- Passwords for:
 - WebLogic Server (Enter a new password or use the password you created when installing WebLogic Server)
 - OPA Proxy (bc4j_internal)—the password you created when installing Oracle Clinical database objects
 - RDC Proxy (rdc_midtier_proxy)—the password you created when installing Oracle Clinical database objects
- Database details:
 - *Server.Domain*; for example:
servername.your_company.com
 - Database service name
 - Port number
- Wallet location: for the Wallet you created in [Section 5.6, "Enable SSL Between a Browser and Oracle HTTP Server."](#) (You can browse for it on screen.)
- Online help URL: If you have customized the online help, the URL where the customized online help is located.

6.2 Restart Computer and Stop All Servers and Services

Restart the computer and then stop all servers and services:

1. Restart the computer.
2. In the Windows Services control panel, find Oracle WebLogic Node Manager service and stop it.
3. From the Windows Start menu, go to All Programs, then Oracle Classic Instance_
asinst_1, then:
 - Forms Services, then Stop WebLogic Server - WLS_FORMS
 - Reports Services, then Stop WebLogic Server - WLS_REPORTS
 - Stop the WebLogic FRDomain Admin Server via Stop Weblogic Admin Server

6.3 Install the Oracle Clinical Front End Components

To install the Oracle Clinical Front End components:

1. Log in as the user you selected in [Section 5.1.1, "Identify a Single Account to Perform All Application Tier Installation Tasks"](#).
2. In the staging area, locate the directory where you downloaded and extracted Oracle Clinical (see [Section 1.5, "Downloading and Extracting the Software"](#)).
3. Run the following file as an administrator:

Disk1\install\setup.exe

The Installer opens to the Welcome screen.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical.

4. In the Select a Product to Install page, select **Oracle Clinical Front End 5.1.0.0.x**.
5. Follow the instructions on the installation screens, providing the information you assembled in [Section 6.1, "Gather the Required Information"](#).
6. If the Installer detects that you have already installed Release 5.0 or above and created the OPADomain, the Installer asks if you want to overwrite OPADomain or not.

Choose to overwrite it if your previous installation failed or only partially completed; for example, the RDC Onsite URL does not work. If you have created it successfully, and especially if you have done customizations such as setting up clusters or multiple databases, do not overwrite OPADomain.

7. **Summary:** 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**.

8. **Install:** The 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.

9. **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, RDC Onsite, and RDC Administration applications.

The Installer saves the URL information in the following file:

\opapps51\log\setup.txt

When you have finished reviewing the installation information, click **Exit**.

6.3.1 Review the Installation Log File

Review the generated installation log file for errors. See [Section 1.7, "Reviewing the Installation Log Files"](#) for details.

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

6.3.2 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.

6.3.3 Add WebLogic Data Sources If Using Multiple Databases

When you run the Oracle Clinical Installer, it sets up two data source connections, one for OPA and one for RDC Onsite, from the WebLogic Server (WLS) to the database you specify in the Installer screens.

If you plan to use more than one database, you must create a WLS data source for RDC for each additional database. If you also are using TMS on multiple databases, you need to create additional data sources for OPA and the TMS Browser. The OPA connection is used for running TMS reports.

Instructions are in the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* and the *Oracle Thesaurus Management System User's Guide*.

6.4 Make the Java Runtime Environment Available for Download

The Oracle Clinical and RDC Administration applications require that Java Standard Edition (SE) Runtime Environment (JRE) exist on the user's computer.

The Oracle Clinical Launch page is configured to prompt users to install JRE if it does not exist on their computer. To make this work, you need to download JRE into the `OPA_HOME\html` directory and rename it.

1. If you have not already done so, download the software following instructions in [Section 1.5.5, "Downloading the Java Runtime Environment."](#)
See that section if you are using the 64-bit version.
2. Copy the downloaded file from the staging area to `OPA_HOME\html`.
3. Rename the file to `sunjpi.exe`.

If your users need to have both JRE 6 and 7 installed to support different versions of Oracle Clinical, check My Oracle Support article 1570682.1 for guidance; see ["Finding Information on My Oracle Support"](#) on page xii.

6.5 Make the Oracle Clinical PDF Plug-in Available to Users

Users who use the DCI Forms graphic layout system for annotated CRFs need the Oracle Clinical PDF Plug-in. There is a link to download this plug-in on the Oracle Clinical launch page. The link on the launch page resolves to:
`https://machine/opa51/rdc/opapdf.exe`.

You should already have downloaded the plug-in, following instructions in [Section 1.5, "Downloading and Extracting the Software."](#)

To make the plug-in available from the launch page, follow the instructions in the readme file to install the PDF plug-in on the Forms server in the opa_home\html\rdc directory.

6.6 Share the RDC Directory for Image Access

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

- Share the directory that stores image files used by the Reports Server for the Patient Data Report and the Oracle Clinical Graphic Layout Editor for DCI Form generation and migration. Name the directory `rdc`. Its default location is `opapps51\html\rdc`. Make the directory readable by the account that is used to start up the OPADomain and FRDomain Servers.
- Enable image browsing by setting values in the Windows system registry

6.6.1 Sharing the Directory Across Multiple Computers

To share the image directory across multiple machines:

1. Log in to the Forms Server computer as a user with system administrator privileges.
2. Select a directory to store the images. The default location is `<OPA_HOME>\html\rdc\dcif_images` (for example `C:\opapps51\html\rdc\dcif_images`) but you can select a different location.
3. Select a directory in that path that you will share. The default directory is `<OPA_HOME>\html\rdc` (`opapps51\html\rdc`).
4. Share that directory. The default share name is `rdc`.
5. Make the directory readable by the account that is used to start up the OPADomain and FRDomain Admin Servers that use the Graphic Layout Editor.
6. Set the related Windows registry settings under `\HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE\KEY_OHnumber`:

Note: There are two Oracle keys with randomly generated numbers. Only one of them contains these settings.

- `RDC_DCIF_IMAGES`: Enter the UNC for the images directory. If you used the above defaults, the value would be:
`\\forms_server_machine_name\rdc\dcif_images`.
 - `RDC_DCIF_IMAGES_URL`: Enter the URL for the same location; for example:
`https://server_name.domain/opa51/rdc/dcif_images`
 - `RDC_DCIF_IMAGES_BROWSE`: Set to Y.
 - `RDC_DCIF_IMAGES_VALIDATE`: Set to Y to enable image browsing or N to disable image browsing.
7. Put the images that should be available for the Patient Data Report and graphic layouts in the image directory; by default, `dcif_images`.

6.6.2 Setting Up the Image Directory on a Single Computer

If you have a single Forms server, do the setup in [Section 6.6.1](#) except skip sharing the directory (Step 4 above) and set the RDC_DCIF_IMAGES registry entry to the full path; for example, C:\opapps51\html\rdc\dcif_images.

6.7 Install and Configure JSpell Spell Checker SDK (Optional)

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 Oracle Clinical DCM and DCI graphic layouts. You must purchase the product separately.

6.7.1 Install JSpell on Oracle Application Server

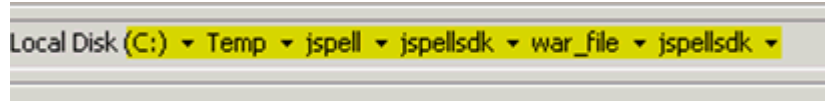
To install the JSpell on Oracle Application Server:

1. If you have not already done so, download and extract JSpell, following instructions in [Section 1.5.7, "Downloading JSpell \(Optional\)."](#)
2. Identify the following files in the download directory:
 - jspellsdks.jar
 - jspellsdkn.jar
 - jspellsdk.war
3. Copy the two .jar files to the following location on the Oracle Application Server: *middleware_home \ Oracle_FRHome1\forms\java*; for example: C:\app\oracle\middleware\Oracle_FRHome1\forms\java.

6.7.2 Install the JSpell WAR File on the WebLogic Server

To install the JSpell .war file on the WebLogic server:

1. Copy the jspellsdk.war file to any location on the WebLogic server:
2. Extract the contents of jspellsdk.war to a folder named jspellsdk:



Local Disk (C:) > Temp > jspell > jspellsdk > war_file > jspellsdk

3. Copy the jspellsdk folder to default Admin Server upload location: *middleware_home\user_projects\domains\OPADomain\servers\AdminServer\upload*.
4. Also copy the jspellsdk folder to the Target Server stage location. (*middleware_home\user_projects\domains\OPADomain\servers\OpaServer1\stage*)

Note: If the stage directory does not already exist, create it.

5. Log in to the OPADomain Admin Server console at: `http://server_namedomain:7101/console`
6. Click the **Deployments** tab.
7. Click the **Install** button.

8. Check the Current Location. If it does not show the upload directory under AdminServer shown in Step 3 above, navigate to that location.
9. Select **jspellsdk (open directory)** and click **Next**.
10. Select **Install this deployment as an application** and click **Next**.
11. Select the Target Server **OpaServer1** and click **Next**.
12. Under General, **What do you want to name this deployment?** enter `jspellsdk` in the **Name:** field.
13. Click **Finish**. In a moment the summary screen appears.
14. Restart the OpaServer1 process; see [Section 6.10.5, "Starting the OpaServer1 Server."](#)
15. In the Summary of Deployments page in the OPADomain Admin Server console, check that jspellsdk is listed as Active and its Health value is OK.

6.7.3 Update the mod_wl_ohs.conf File for JSpell

By default JSpell uses port 7221. To make this work with either HTTP port 8888 or HTTPS port 443, edit `mod_wl_ohs.conf` and restart OHS.

To update the `mod_wl_ohs.conf` file:

1. Navigate to the following directory:
`middleware_home\asinst_1\config\OHS\ohs1`
2. Open the **fmod_wl_ohs.conf** file.
3. Add the following entry:

```
<Location /jspellsdk>
setHandler weblogic-handler
webLogicHost localhost
weLogicPort 7221
</Location>
```

6.7.4 Restart Oracle HTTP Server (OHS)

To restart OHS:

1. Open a DOS prompt.
2. Enter:
`opmnctl restartproc process-type=OHS`

6.7.5 Test the JSpell Servlet

To test the JSpell Servlet:

1. Open an internet browser.
2. Enter the following URL:
`https://server_namedomain:7221/jspellsdk/servlet/JSpellServlet?operation=status`

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

6.7.6 Update the formsweb.cfg File for JSpell

To update the formsweb.cfg file:

1. Navigate to the following directory:
`middleware_home\user_projects\domains\FRDomain\config\fmwconfig\servers\WLS_FORMS\applications\formsapp_11.1.2\config`
2. Open the **formsweb.cfg** file.
3. Find the **[opa51]** text section.
4. Append the following text string to the end of the **archive** parameter value:
`jspellsdks.jar,jspellsdkn.jar`

6.7.7 Update the Windows System Registry for JSpell

Update the Windows System Registry:

1. Open the Windows System Registry Editor.
2. Navigate to the following key:
`\HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE\KEYnumber` where the Oracle Clinical and OPA registry settings are.
3. Add the following keys to the registry:
 - `OPA_SPELL_ENABLED=Y`
 - `OPA_SPELL_LANGUAGE=English (US)`
 - `OPA_SPELL_URL= http://server_name/jspellsdk/servlet/JSpellServlet`

Note: In the above registry value, use either HTTP or HTTPS, depending on how your system is configured.

6.7.8 Test JSpell in the Graphic Layout Editor

If you already have a study set up that uses the Graphic Layout Editor:

1. In Oracle Clinical, navigate to a study DCM.
2. From the **Special** menu, select **Graphic Layout**, then **Edit**. The Graphic Layout Editor opens.
3. From the **Edit** menu, select **Spell Check Current**.
4. If you receive a warning that the application is unsigned, click **Run**. The system displays the first misspelled word it finds and suggests alternative spellings.
5. To find another misspelled work, select **Find Next Misspelling** from the **Edit** menu.

If you do not already have such a study set up, see *Oracle Clinical Creating a Study*.

6.8 Verify and Fix Environment Variables

Check values and correct them if required.

6.8.1 Check Values

To check variable values:

1. Open a DOS prompt window.
2. Run:

```
middleware_home\user_projects\domains\OPADomain\bin\setDomainEnv.cmd
```

For example:

```
c:\oracle\middleware\user_projects\domains\OPADomain\bin\setDomainEnv.cmd
```

The script should run with no errors.

3. Inspect the value of JAVA_HOME:
 - a. At the DOS command prompt, type: `set JAVA_HOME`. You should see the location where you installed JDK following instructions in [Section 5.3, "Install Oracle Java Development Kit."](#)
 - b. Enter: `dir %java_home%`. You should see the directory specified as your JAVA_HOME containing a file called **src.zip** and four subdirectories: **jre**, **lib**, **bin**, and **include**.

If you do not see these things, you will need to add them as directed in [Section 6.8.2, "Correct Values"](#).

If JAVA_HOME contains any spaces or if any of the directories in its path are greater than 8 characters, you will need to correct them as directed in [Section 6.8.2, "Correct Values"](#).

4. Inspect the value of JAVA_VM. At the command prompt, enter: `set JAVA_VM`. You should see something like `JAVA_VM=-server`. If not, correct as directed in [Section 6.8.2, "Correct Values"](#).

6.8.2 Correct Values

To correct any of the above problems:

1. Navigate to `middleware_home\wlserver_10.3\common\bin`
2. Back up `commEnv.cmd`.
3. Open `commEnv.cmd` in a text editor.
4. The first `set` command in the file, before any other `set` command, must identify the JAVA_HOME value. For example:

```
set JAVA_HOME=c:\app\java\jdk16065
```

5. Find:

```
set JAVA_VM=-client
```

change it to:

```
set JAVA_VM=-server
```

6. Close the DOS window and open a new one, then repeat the steps in [Section 6.8.1, "Check Values"](#).

6.9 Setting Up Automatic Startup

It is possible to configure any Windows service to restart itself upon failure. These are standard options available when configuring a Windows service in the context of Windows Services Manager.

However, it is important to understand that Windows Services Manager only monitors the service's JVM process. If the JVM process fails (shuts down), then Windows Services Manager will attempt to restart it. But there are some scenarios where the WebLogic Admin Server or Managed Server may go into an unhealthy or failed state while the JVM is still running. The Windows Service Manager will not know to restart the process in these cases, whereas if the Admin Server and Managed Server had been started using the WebLogic Node Manager, Node Manager would recognize such a state and restart the process.

Oracle recommends starting the Admin and Managed Servers through the Node Manager using python scripts and then configuring the Windows server to execute the python scripts at startup.

To start servers manually, see [Section 6.10, "Starting Servers Manually."](#)

6.9.1 Set Up Script to Execute Automatically at Machine Startup

Create a task and set up the Task Scheduler to run the job on bootup:

1. From **Start**, then **Control Panel**, then **Administrative Tools**, open **Task Scheduler**.
2. Select **Create Basic Task** on the right side of the Task Scheduler.
3. Enter following values:
Name: Oracle FRDomain Autostart
Trigger: When the computer starts
Action: Start a program
Select: `opa_home\config\autostartFRDomain.cmd`
4. Click **Next** and then **Finish** to complete creation of the scheduled task.
5. Find the task **Oracle Domain Autostart** under the Active Tasks list (center pane) and double-click to select it. Right-click on the task you just created and select **Properties**.
6. Click **OK**.
7. When prompted, enter the user name and password.
8. On the **General** tab, select **Run whether user is logged on or not**.
9. Repeat these steps for OPADomain, with two differences. In Step 3, enter:

Name: Oracle OPADomain Autostart

Select: `opa_home\config\autostartOPADomain.cmd`

6.9.2 Verify Autostart Scripts

1. From a DOS window, enter command:

`opa_home\config\autostartfrdomain2.cmd`

to start the FRDomain server. This command will print a lot of messages and will take some time. While this is executing, proceed to next step.

2. From a different DOS window, enter command:

```
opa_home\config\autostartopadomain2.cmd
```

to start the OPADomain server.

3. When both windows are complete, you will see messages like below, followed by the DOS prompt which will indicate script is complete:

```
Starting server WLS_FORMS .....
Server with name WLS_FORMS started successfully
Starting server WLS_REPORTS .....
Server with name WLS_REPORTS started successfully

Successfully Connected to Node Manager.
Starting server AdminServer ...
Successfully started server AdminServer ...
Starting server OpaServer1 ...
Successfully started server OpaServer1 ...
```

4. Verify that these URLs work and you can log into application:
 - Oracle Clinical: <https://server.domain/opa51/launch.htm>
 - RDC Onsite: <https://server.domain/rdcadfsrnd/faces/Login>

6.9.3 Test Autostart

To test:

1. Restart the computer.
2. Allow some time for the services to start.
3. Try the URLs in [Section 6.9.2, "Verify Autostart Scripts."](#)

If the URLs do not work after several minutes, check files in *opa_home\log*:

- autostartfrdomain2.log
- autostartfrdomain2.err
- autostartopadomain2.log
- autostartopadomain2.cmd

6.10 Starting Servers Manually

If you have not set up automatic startup, you can start the required servers manually using the instructions in this section.

For information about these servers and the server architecture, see [Figure 1–2, "Oracle Clinical Network Topology"](#).

6.10.1 Starting the FRDomain Admin Server

The Oracle FRDomain Admin Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001. You must start the Admin Server before you can start either the Oracle Forms Server or the Oracle Reports Server.

Do one of the following.

- Go to the **Start** menu, then **All Programs**, then **Oracle Classic asinst_1**, then **Start Admin Server**.
- Go to the **Start** menu, then **All Programs**, then **Oracle WebLogic**, then **User Projects**, then **FRDomain**, then **Start Admin Server WebLogic Server Domain**.

Note: You cannot start it from the Admin Console because if the server is not running, the FRDomain Admin Console is not available.

6.10.2 Starting the Forms Server

The Oracle Forms Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001. You must start the FRDomain Admin Server before the Reports Server.

To start the Forms Server, go to **Start**, then **All Programs**, then **Oracle Classic asinst_1**, then **Forms**, then **Start WLS_FORMS**.

6.10.3 Starting the Reports Server

The Oracle Reports Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001. You must start the FRDomain Admin Server before the Reports Server.

To start the Reports Server, go to **Start**, then **All Programs**, then **Oracle Classic asinst_1**, then **Reports**, then **Start WLS_REPORTS**.

6.10.4 Starting the OPADomain Admin Server

The Oracle OPADomain Admin Server is located on the WebLogic Server domain that the Installer names OPADomain, and which must use port number 7101. You must start the Admin Server before you can start the OpaServer1.

To start the OPADomain Admin Server, go to the **Start** menu, then **All Programs**, then **Oracle WebLogic Server**, then **User Projects**, then **OPADomain**, then **Start Admin Server**.

Note: You cannot start from the Admin Console because if the server is not running, the OPADomain Admin Console is not available.

6.10.5 Starting the OpaServer1 Server

The OpaServer1 Server is located on the WebLogic Server domain named OPADomain, which must use port number 7101. The OpaServer1 Server runs on Oracle ADF and supports RDC Onsite, the TMS Browser, and TMS reports. It also contains the database connections.

You must start the OPADomain Admin Server before the OpaServer1 Server.

To start the OpaServer1 Server, use the Admin Console at either:

- <http://host:7101/console>
- <https://host/opaconsole> (if configured)

6.11 Verify the Application Tier Installation

Verify that these URLs work and you can log into application:

- <https://host/opa51/launch.htm>
- <https://host/rdcadfsrnd/faces/Login>

6.12 Stopping Servers

You can stop each server either in the appropriate WLS Admin Console or from the Windows **Start** menu. These instructions are provided for your information; you do not need to do them now.

6.12.1 Stopping the Forms Server

The Oracle Forms Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001.

To stop the Forms Server, do either:

- **Start**, then **All Programs**, then **Oracle Classic asinst_1**, then **Forms**, then **Stop WLS_FORMS**.
- Use the Admin Console at <https://host:7001/console>.

Note: The Admin Console is available only if the Admin Server is running.

6.12.2 Stopping the Reports Server

The Oracle Reports Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001.

To stop the Reports Server, do either:

- **Start**, then **All Programs**, then **Oracle Classic asinst_1**, then **Reports**, then **Stop WLS_REPORTS**.
- Use the Admin Console at <https://host:7001/console>.

Note: The Admin Console is available only if the Admin Server is running.

6.12.3 Stopping the FRDomain Admin Server

The Oracle FRDomain Admin Server is located on the WebLogic Server domain that must be named FRDomain and must use port number 7001.

To stop the Admin Server, do either:

- **Start**, then **All Programs**, then **Oracle Classic asinst_1**, then **Stop Admin Server**.
- Use the Admin Console at <https://host:7001/console>.

6.12.4 Stopping the OPADomain Admin Server

The Oracle OPADomain Admin Server is located on the WebLogic Server domain that the Installer names OPADomain, and which must use port number 7101.

To stop the Admin Server, do either:

- **Start**, then **All Programs**, then **Oracle WebLogic Server**, then **User Projects**, then **OPADomain**, then **Stop Admin Server**.
- Use the OPADomain Admin Console at <https://host/opaconsole> or <https://host:7101/opaconsole>

6.12.5 Stopping the OpaServer1 Server

The OpaServer1 Server is located on the WebLogic Server domain named OPADomain, which must use port number 7101.

To stop the OpaServer1 Server, use the Admin Console at either:

- <http://host:7101/console>
- <https://host/opaconsole> (if configured)

Note: The Admin Console is available only if the Admin Server is running.

Installing the Oracle Clinical Reports Server

This chapter includes:

- [Section 7.1, "Gather Required Information"](#)
- [Section 7.2, "Restart Computer and Stop Servers"](#)
- [Section 7.3, "Start the WebLogic FRDomain Admin Server"](#)
- [Section 7.4, "Install the Oracle Clinical Reports Server"](#)
- [Section 7.5, "Set Up the Reports Server for Access and File Viewing"](#)
- [Section 7.6, "Add the Reports Server to the Database Reference Codelist"](#)
- [Section 7.7, "Test the Reports Server Installation"](#)
- [Section 7.8, "Set Up Automatic Startup of Services"](#)

You can install Forms Servers and Reports Servers to suit your needs. If you choose to have Reports Servers on computers that do not have a Forms Server installation, you must configure both computers to share a directory on the Forms Server computer.

Note: To ensure high availability of the Reports Server, you can set up and use more than one Reports Server on a subnet and they can access each other. For more information see the *Oracle Clinical Administrator's Guide*.

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

7.1 Gather Required Information

You must have the following information ready to enter in the Installer screens:

- A name for the Oracle Home location on your application server and its full path; for example:
C:\oracle\Middleware\Oracle_FRHome1 (you can browse for this in the Installer screen)
- Your OPA Home directory; for example:
C:\opapps51
- WebLogic username and password
- Report Server name

- Adobe Reader location; for example:
C:\Program Files (x86)\Adobe\Reader 11.0\Reader\AcroRd32.exe

7.2 Restart Computer and Stop Servers

If you are installing the Oracle Clinical Report Server immediately after the Oracle Clinical Front End and have already stopped the services and servers, you can skip this step.

1. Restart the computer.
2. In the Windows Services control panel, find Oracle Node Manager service and stop it.
3. Stop the Forms Server. From the Windows **Start** menu, go to **All Programs**, then **Oracle Classic asinst_1**, then **Forms**, then **Stop WLS_FORMS**.
4. Stop the Reports Server. From the Windows **Start** menu, go to **All Programs**, then **Oracle Classic asinst_1**, then **Reports**, then **Stop WLS_REPORTS**.

Note: TheWebLogic FRDomain Admin Server must be running when you install the Reports Server. This is different from the Front End installation.

7.3 Start the WebLogic FRDomain Admin Server

Make sure that the WebLogic FRDomain Admin Server is running. Do one of the following.

- Go to the **Start** menu, then **All Programs**, then **Oracle Classic asinst_1**, then **Start Admin Server**.
- Go to the **Start** menu, then **All Programs**, then **Oracle Weblogic**, then **User Projects**, then **FRDomain**, then **Start Admin Server Weblogic Server Domain**.

7.4 Install the Oracle Clinical Reports Server

Follow 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 components:

1. Log in as a user with system administrator privileges.
2. Navigate to the location where you downloaded and extracted the software in [Section 1.5, "Downloading and Extracting the Software"](#).
3. Run the following file as an administrator:

Disk1\install\setup.exe

The Installer opens to the Welcome screen.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

Note: Although there is a button for deinstalling products on the Welcome screen, Oracle does not support using the Installer to deinstall Oracle Clinical or Oracle Clinical Remote Data Capture (RDC) Onsite.

4. Select a Product to Install: Select **Oracle Clinical Report Server 5.1.0.0.x**.
5. Follow the instructions on the installation screens.
6. Follow instructions on screen, entering the information you have gathered; see [Section 7.1, "Gather Required Information"](#).
7. **Summary:** 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**.
8. **Install:** The 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.
9. **End of Installation:** The End of Installation screen reports whether the installation was successful. Please check the install logs if any errors are displayed.
When you have finished reviewing the installation information, click **Exit**.

7.4.1 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.

7.5 Set Up the Reports Server for Access and File Viewing

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

7.5.1 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 the user that started up the auto process; see [Section 6.9, "Setting Up Automatic Startup"](#).

7.5.2 Share and Grant Access to the Reports Server Root Directory

This step is not required if you are installing the application tier on a single computer. 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 `oc1fsrv1`, and the share name is `opareportout`, and the report log is stored in a subdirectory `user` under this shared directory, then the UNC is:

```
\\oc1fsrv1\opareportout\user
```

This works as long as `user` does not exceed eight characters. To have longer names for `user`, shorten the share name.

7.5.3 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.

7.5.4 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*.)

7.6 Add the Reports Server to the Database Reference Codelist

For each Reports Server that you install, you must edit 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 7–1 REPORT_SERVER Local Reference Codelist Values

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

5. Click **Save**.

7.7 Test the Reports Server Installation

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

1. Start Oracle Clinical.
2. Navigate to **Admin, Admin Reports**, and then **Reference Codelist**. The Report Reference Codelist submission screen opens.
3. Click the Reference Codelist Name field, and enter **OCL_STATE**.
4. Print the report:
 - a. Click the **Job Details** button.
 - b. Change the Output Type to **PRINTER**.
 - c. Examine the printer's path to see if it is correct.
 - d. Click **Submit Job**. You receive a status prompt. Close the prompt to return to the Submission screen.
 - e. Click **Job Status** to check the progress of your print job. Look for the printout from your printer.
5. Print the report to file:
 - a. Return to the Report Reference Codelist submission screen.
 - b. Click the Reference Codelist Name field, and enter **OCL_STATE**.
 - c. Click **Job Details**.
 - d. Change the Output Type to **FILE**.
 - e. Click **Submit Job**. The system displays a status prompt. Close the prompt to return to the Submission screen.
 - f. Click **Job Status**.
 - g. Check its status in the Execution Status field.
 - h. Click **View Output**. The system displays a path location prompt.
 - i. Click **OK**. The Report Server processes the file and converts it to the selected format. If successful, the file then opens in a separate window.

7.8 Set Up Automatic Startup of Services

Oracle recommends setting up the server so that the Node Manager automatically restarts services when necessary. If you are installing this on a machine with the Oracle Clinical Front End, you will have done this as part of executing [Section 6.9, "Setting Up Automatic Startup"](#).

- **If this is a standalone reports server**, follow the same instructions except, in script `autostartfrdomainscript.py` located in `opa_home\config`, comment out the following line:

```
start ('WLS_FORMS')
```

- **If you are not installing TMS, also** comment out the following line in script `autostartopadomainscript.py` located in `opa_home\config`:

```
domainName='OPADomain' domainDir='your_middleware_home/USER_  
P~1/domains/OPADomain' nmConnect(userConfigFile=configfile,  
userKeyFile=keyfile, nmPort=port,  
domainName=domainName, domainDir=domainDir, nmType='ssl') nmStart('Admin Server')  
connect(userConfigFile=configfile, userKeyFile=keyfile) nmStart('OpaServer1')
```

Setting Up the Parameterized Submission Process

The Parameterized Submission process (PSUB) schedules and runs jobs, reports, and batch processing for Oracle Clinical. In order to support using Oracle Real Application Clusters (RAC), the implementation of PSUB changed in Oracle Clinical 5.0. See [Section 11.1.1, "Changes to Parameterized Submission \(PSUB\)"](#) for more information.

You must start one PSUB service for each Oracle Clinical database on the same server as the database.

This chapter includes:

- [Section 8.1, "Set Up PSUB"](#)
- [Section 8.2, "Starting and Stopping the PSUB Service"](#)
- [Section 8.3, "Testing the PSUB Installation"](#)
- [Section 8.4, "Customizing the PSUB Service"](#)
- [Section 8.5, "Running PSUB in a RAC Environment"](#)

8.1 Set Up PSUB

The following steps are required to set up the parameterized submission process:

- [Section 8.1.1, "Create Directories and Enter Values in OCL_STATE Local Reference Codelist"](#)
- [Section 8.1.2, "Enable Users to Submit PSUB Jobs"](#)
- [Section 8.1.3, "Enable opapps to Use the at Command \(UNIX Only\)"](#)

8.1.1 Create Directories and Enter Values in OCL_STATE Local Reference Codelist

You must create several directories on the PSUB server and enter their paths in the OCL_STATE local reference codelist, with a few related values; see the "Setting Up Batch Job File Viewing" section of the "Setting Up File and Image Viewing" chapter of the *Oracle Clinical Administrator's Guide* for more information.

Note: See [Chapter 9, "Setting Up SAS"](#) for information about new OCL_STATE settings related to SAS configuration.

8.1.2 Enable Users to Submit PSUB Jobs

Beginning in Release 5.0, PSUB users no longer need:

- their own OS account
- a user name beginning with OPS\$
- their own directory for PSUB outputs

New Users To add new users, use the `ocl_add_user.sql` script, indicating which new users need to run PSUB jobs; for more information see the *Oracle Clinical Administrator's Guide*.

Existing Users If you are upgrading from a pre-5.0 version of Oracle Clinical, use the migration script `oclupg50migrateusers.sql` to give users who need to run PSUB jobs access to the `opapps` account; see the *Oracle Clinical Administrator's Guide*.

PSUB Administrator User You can give a user the role `RXC_VWJOBS` (new in 5.0) to allow him or her to:

- View all users' jobs
- View the output from those jobs.
- Stop any job.

The following scripts can grant this role to a user:

- `ocl_add_user`—Use this script for new users.
- `ocl_grant_revoke_rxc_vwjobs.sql`—Use this script for existing users. (This script can also be used to revoke the role.)

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

8.1.3 Enable opapps to Use the at Command (UNIX Only)

To use the **at** command to schedule jobs on behalf of another user, the owner's user account must be listed in the **at.allow** file. The owner is `opapps`.

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 Linux x86-64: `/etc/at.allow`
 - Oracle Solaris SPARC: `/usr/lib/cron/at.allow`
 - HP Itanium: `/usr/lib/cron/at.allow`
2. Add the following line to the **at.allow** file:
`opapps`

8.1.4 Set Up Active Directory (Windows Only)

If you are running PSUB on a Windows server that is a primary domain controller running Active Directory, you must add the PSUB account (typically `opapps`) to the domain and reassign the following domain user privileges to the PSUB account, through the domain controller security policy and the domain security policy:

- Load and unload device drivers
- Act as part of operating system
- Increase Quotas

- Log on as a Service
- Replace a process-level token

8.2 Starting and Stopping the PSUB Service

The Installer automatically installs the PSUB service on the database server. You must start it using the instructions below.

- [Section 8.2.1, "Starting and Stopping PSUB Automatically in UNIX"](#)
- [Section 8.2.1.3, "Starting PSUB Automatically in Windows"](#)
- [Section 8.2.2, "Starting PSUB Manually in UNIX"](#)
- [Section 8.2.3, "Starting PSUB Manually in Windows"](#)

Instructions for stopping PSUB manually are included in the *Oracle Clinical Administrator's Guide*.

8.2.1 Starting and Stopping PSUB Automatically in UNIX

On UNIX systems, you can automate the process of starting and stopping PSUB.

8.2.1.1 Starting PSUB Automatically in UNIX

The following example shell scripts for Sun Solaris show how to make the process start automatically at system startup:

```
# File: /etc/init.d/dbora
ORA_HOME=/u01/app/oracle/product/11.1.0.7.0
ORA_OWNER=oracle
if [ ! -f $ORA_HOME/bin/dbstart -o ! -d $ORA_HOME ]
then
    echo 'Oracle startup: cannot start'
    exit
fi
case "$1" in
'start')
    echo 'Starting Oracle...'
    su - $ORA_OWNER -c $ORA_HOME/bin/dbstart
    su - $ORA_OWNER -c "lsnrctl start"
    su - opapps -c start_psub
    ;;
'stop')
    echo 'Stopping Oracle...'
    su - opapps -c stop_psub
    su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
    ;;
esac
# File: start_psub
# Start database 1
start_psub db_name1 code_environment wallet_alias
# Start database 2
start_psub db_name2 code_environment wallet_alias
```

For example:

```
# Start database 1
start_psub venus 51 venus
# Start database 2
start_psub pluto 51 pluto
```

where the database names are venus and pluto and your code environment is 51.

8.2.1.2 Stopping PSUB Automatically in UNIX

You can automate the shutdown of the PSUB service on UNIX so that it does not require the entry of a password.

The following example shell scripts for Sun Solaris show how.

```
# File: /etc/init.d/dbora
ORA_HOME=/u01/app/oracle/product/11.1.0.7.0
ORA_OWNER=oracle
if [ ! -f $ORA_HOME/bin/dbstart -o ! -d $ORA_HOME ]
then
    echo 'Oracle startup: cannot start'
    exit
fi
case "$1" in
'start')
    echo 'Starting Oracle...'
    su - $ORA_OWNER -c $ORA_HOME/bin/dbstart
    su - $ORA_OWNER -c "lsnrctl start"
    su - opapps -c start_psub
    ;;
'stop')
    echo 'Stopping Oracle...'
    su - opapps -c stop_psub
    su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
    ;;
esac
# File: stop_psub
# Stop database 1
set TNS_ADMIN= opapps_home_dir
export TNS_ADMIN
stop_psub venus 51 wallet_alias
# Stop database 2
stop_psub pluto 51 wallet_alias
```

where the database names are venus and pluto and your code environment is 51.

8.2.1.3 Starting PSUB Automatically in Windows

This section includes:

- [Section 8.2.1.3.1, "Creating a System Environment Variable"](#)
- [Section 8.2.1.3.2, "Creating a Batch File"](#)
- [Section 8.2.1.3.3, "Scheduling the Batch File and Testing the Setup"](#)
- [Section 8.2.1.3.4, "Adding a Shortcut"](#)

The batch file is required in large databases that take so much time to come up during a server reboot so that the system tries to start PSUB before the database is fully up. In this case the PSUB service does not start and an error like the following appears in the PSUB log file (found in the *drive:\opapps\oc\51\log* directory):

```
ERROR:Daemon error while connecting:/@devoc
ORA-1033: ORACLE initialization or shutdown in progress
```

8.2.1.3.1 Creating a System Environment Variable You can specify that the PSUB service starts automatically when the Windows PSUB server re-boots. The service parameters

are read from a system environment variable whose name concatenates PSUBSERVICE with the database name.

To create a system environment variable in Windows:

1. Navigate from Start to the Control Panel, then click on the **System and Security** link. The System and Security window opens.
2. Click the **System** link. The System window opens.
3. Click the **Advanced System Settings** link at the top left corner. The System Properties window opens.
4. Select the **Advanced** tab, then click **Environment Variables**.
5. Click **New** under System Variables in the lower portion of the window to define the variable.

For the **variable name**, enter the string PSUBSERVICE concatenated with the database name; for example, for the database sun6x2:

PSUBSERVICESUN6X2

For the **variable value**, use the format: *database_id code_environment verbose RXC_ROOT wallet_alias*; for example:

pluto 51 verbose t:\opapps\oc\51 wallet_alias

where pluto is the database ID and RXC_ROOT is t:\opapps\oc\51.

Note that if you need a backslash (\) in the text box, you must double it (\\).

8.2.1.3.2 Creating a Batch File Create a batch file called 'psub_start1.bat' in the %RXC_ROOT%/log directory (for example, D:\opapps\oc\51\log) with the following contents.

```
cmd /c echo Current Date/time= %DATE% %TIME% > psub_start1.log
cmd /c echo Starting Time Delay > psub_start1.log
ping localhost -n 180 > nul
cmd /c net start "PSUB Service database_id" > psub_start1.log
```

Notes:

- "PSUB Service *database_id*" is the PSUB service name that appears in the Services window (under Administrative Tools from the Control Panel).
- You can repeat the following command for different databases if needed:
cmd /c net start "PSUB Service *database_id*" > psub_start1.log
- The 'ping localhost' command introduces a time delay to ensure that the database is up before starting PSUB. You can increase this value—set to 180 seconds (3 minutes) in the example above—if required.

8.2.1.3.3 Scheduling the Batch File and Testing the Setup To schedule batch file execution:

1. Navigate to Start, then Administrative Tools, then Services. Scroll down and make sure that the **Task Scheduler** service is started.
2. Navigate to Start, then Administrative Tools, then Task Scheduler. The Task Scheduler window opens.
3. Click the **Create Basic Task** link on the right. The Create Basic Task wizard appears.
4. Enter a **Name** and **Description** and click **Next**.

5. In the Task Trigger window, select **When the computer starts** and click **Next**. The Action window appears.
6. In the Action window select **Start a program** and click **Next**. The Start a Program window appears.
7. In the Start a Program window, click **Browse**. The Browse window appears.
8. In the Browse window, browse to the directory where `psub_start1.bat` is saved and then select **psub_start1.bat**. Leave the other boxes empty and click **Next**.
9. Select **Open the Properties dialog for this task when I click Finish** and click **Finish**. The Properties dialog box opens.
10. In the Properties dialog box, General tab, Security options section, click **Change User or Group** and select **Administrator**.

To test, shut down the service if necessary (instructions are in the *Oracle Clinical Administrator's Guide*) and double-click on file **psub_start1.bat** to test that it starts the PSUB service. Verify that the log file `psub_start1.log` is created in the same directory unless a different path was specified.

11. In the Services window under Administrative Tools in the Control Panel, right-click the PSUB Service, click **Properties**, and change its Startup Type to **Manual**.

To test, restart the computer and check the Services window to see if the PSUB service has started. If it has, submit a PSUB job such as Batch Validation and check if it runs.

8.2.1.3.4 Adding a Shortcut For convenience add a shortcut for `psub_start1.bat` on the desktop to manually start PSUB by double-clicking the icon.

8.2.2 Starting PSUB Manually in UNIX

To start the PSUB service on UNIX:

1. Log in as the `opapps` user. By default, the `opapps` uses the C shell.
2. Set up the environment:

```
opa_setup <database_name> <code_environment>
```

For example, where `prod` is the database name:

```
opa_setup prod 51
```

3. Start the PSUB service:

```
start_psub database_name code_environment wallet_alias
```

For PSUB, `wallet_alias` is the same as the database name. For example:

```
start_psub prod 51 prod
```

where `prod` is the connect string for the database instance to which the PSUB service connects;

where `51` is the name of the code environment;

where `wallet_alias` is the name of the Wallet specified during installation. By default it is the same as the database name.

4. If there are any errors, check the following log files in the `$RXC_CENTRAL_LOG` directory:

- `rxcpd_instance_environment_1.log`
- `rxcpd_instance_environment_2.log`

8.2.3 Starting PSUB Manually in Windows

To start the PSUB service on Windows:

1. Log in as `opapps`. (You set up the PSUB service to start as the `opapps` 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
wallet_alias
```

For example: `prod 51 verbose c:\\opapps\\oc\\51 <wallet_alias>`

where *prod* is the connect string for the database instance to which the PSUB service connects;

where *51* is the name of the code environment;

where *wallet_alias* is the name of the Wallet specified during installation.

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/51`.

3. Click **Start**.
4. Exit from the Services dialog box.
5. Check the PSUB service log file in `<RXC_ROOT>\log` for any warning or error messages.

8.3 Testing 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 by clicking on the **View log** and **View output** buttons.

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`

8.4 Customizing the PSUB Service

You can customize the PSUB service 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 service, see the *Oracle Clinical Administrator's Guide*.

8.5 Running PSUB in a RAC Environment

PSUB considerations in a RAC installation:

- In a RAC installation, Oracle recommends installing the Oracle Clinical database server, which includes the PSUB Server, on at least two RAC nodes. If PSUB goes down on one node, or if the node itself goes down, you can start PSUB on the other node with little interruption of service.
- You must start one and only one PSUB service for each database. Oracle Clinical cannot detect if more than one PSUB service is running, so results are unpredictable in that case.
- Create the same directory structure for PSUB files on each computer where PSUB may run. That way you do not have to change the OCL_STATE reference codelist value for the five PSUB directories.

Note: However, you do have to change the OCL_STATE SERVER_NAME value when you start PSUB on a different server.

- If you use NFS to share the files, users will still be able to access files for jobs performed on the other node unless the node itself fails.

PSUB supports the following scenarios in a RAC environment:

- If the database instance on the PSUB server goes down, but its server is still active, PSUB will transparently continue to process jobs for the other database instances in the RAC environment.
- If one PSUB service or server fails, PSUB can be started for that database on another server.
- If another node is added or removed, PSUB continues to work.
- If the PSUB server goes down or is removed, an administrator can manually start the PSUB service on another server with minimum downtime.

In the event of a PSUB failure, current PSUB jobs are affected differently based on their state at the time of PSUB failure:

- SCHEDULED or ENTERED jobs are picked up by the newly started PSUB service.
- SUBMITTED jobs will likely need to be re-submitted.
- STARTED jobs continue to run, regardless of PSUB status.

Note: There is no notification if a PSUB service fails. In this case, a user's job does not complete and he or she must contact the administrator. The administrator checks the log file, starts PSUB on another node, and changes the SERVER_NAME value in the OCL_STATE reference codelist.

See [Section 1.4, "Supported Configurations with Oracle Data Guard and RAC"](#) for more information.

Setting Up SAS

This chapter includes:

- [Section 9.1, "Setting Up SAS Data Extract"](#)
- [Section 9.2, "Installing SAS on a UNIX Computer"](#)
- [Section 9.3, "Installing SAS on a Windows Computer"](#)

Oracle Clinical 5.1 supports the following configurations with SAS:

- SAS and Oracle Clinical on the same UNIX or Windows computer
- SAS on a separate UNIX or Windows computer from Oracle Clinical within an intranet

Note: If the Oracle Clinical database server is installed on a Windows computer, SAS must also be installed on a Windows computer, even if it is a separate machine.

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

9.1 Setting Up SAS Data Extract

Users need access to the opapps account to run Oracle Clinical SAS Data Extract jobs.

9.1.1 Give Users Access to the opapps Account

The same setup is required for SAS users in Oracle Clinical as for PSUB users; see [Section 8.1.2, "Enable Users to Submit PSUB Jobs"](#).

9.1.2 Add the opapps Account to the oclsascr User Group

In addition, you must add the opapps user to the oclsascr user group. It is the only user required to be in this group; see [Section 2.2.2.1, "Create the oclsascr User Group for SAS."](#)

9.1.3 Give opapps Access to the Directory Specified in the RXC_SAS_VIEW Environment Variable

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

9.1.4 Set Up SAS User Authentication and Set OCL_STATE Reference Codelist Values

Choose one of two methods—Oracle Wallet or SAS password encryption with a proxy user—and indicate your choice in the OCL_STATE local reference codelist along with other SAS-related settings. By default the value is set to Oracle Wallet. See the *Oracle Clinical Administrator's Guide* and the instructions below for more information.

9.2 Installing SAS on a UNIX Computer

This section contains:

- [Section 9.2.1, "Modify SAS 9.3 and opa_settings on UNIX"](#)
- [Section 9.2.2, "Installing SAS on the Same UNIX Computer as Oracle Clinical"](#)
- [Section 9.2.3, "Installing SAS on a Different UNIX Computer from Oracle Clinical"](#)

9.2.1 Modify SAS 9.3 and opa_settings on UNIX

Oracle Clinical supports SAS 9.3. You can validate your Oracle Clinical installation, and then upgrade to SAS 9.3 later. The SAS/ACCESS Interface to Oracle requires Oracle SQL*NET on the computer with the SAS software installation.

Follow these instructions on the SAS server—whether SAS is on the same computer or a different one from Oracle Clinical.

9.2.1.1 Prepare the SAS Template File

Make the following modifications to the SAS template file:

1. Copy the SAS template file from `OPA_HOME/oc/51/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 actual SAS executable path; for example:
`/root/SAS93/SASFoundation/9.3/sas $*`
4. Save your work.

9.2.1.2 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

Using Oracle Database 11g 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: libcintsh.so.9.0:
      open failed: no such file or directory
```

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

```
ln -s libcintsh.so.12.0 libcintsh.so.9.0
```

9.2.2 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.

9.2.2.1 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 more information.

9.2.2.2 Set Up a SAS Connection

You can set up a SAS connection to the Oracle database in two ways—using Oracle Wallet or SAS encryption. The Oracle Clinical Installer sets the SAS_CONNECTION value in the OCL_STATE reference codelist to ORACLE_WALLET.

9.2.2.2.1 Oracle Wallet This is the default option. The SAS connection is set up automatically.

9.2.2.2.2 SAS Encryption You must manually set SAS_ENCRYPTION as the SAS_CONNECTION long value in the OCL_STATE local reference codelist. In addition:

1. Log in to the database as system user and create the sas_proxy_user database account:

```
create user sas_proxy_user identified by <password>;
```

2. Grant proxy connection for each database user account who needs to submit SAS Data Extract jobs:

```
alter user <oc user> grant connection through sas_proxy_user
```

OR

Run the script **ocl_grant_revoke_sas_proxy_user.sql** in the install directory to grant or revoke user connections through proxy account sas_proxy_user

3. Log in to the PSUB server as RXC_SAS_VIEW owner and set the environment:

- C shell:

```
opa_setup database_name code_environment
```

- Bourne shell:

```
p1 = database_name
p2 = code_environment
. opa_setup
```

4. Run the command:

```
cd $RXC_SAS_VIEW
```

5. Create a temporary SAS file named `pwd.sas` to contain the password for the `sas_proxy_user` account:

```
filename pwfile 'sas_proxy_password_encoded_file';  
proc pwencode in='password' out=pwfile method=sas002;  
run;
```

6. Run the file created in Step 4 to encrypt the file. This creates the `sas_proxy_password_encoded_file` which stores the encrypted password of the `sas_proxy_user` db user (where `pwd.sas` is the name of the temporary file you created):

In UNIX:

```
sas pwd.sas
```

In Windows:

```
sas pwd.sas -sysin
```

7. Remove the file created in Step 4.
8. Run the SAS files.

9.2.3 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, it must be on the same intranet and you need to set up a connection to SAS.

9.2.3.1 Establish the Connection to SAS on a Different Computer

To set up SAS on a different UNIX server computer

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

9.2.3.1.1 NFS Use Network File System (NFS) protocol to make the directory on the Oracle Clinical server pointed to by the `$RXC_USER /sas_view` 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.

Note: By default the `$RXC_USER` environment variable is the `opapps` home directory.

9.2.3.1.2 Create opapps on the SAS Server Create the `opapps` UNIX user account on the SAS server. Create a group for `opapps` and put it in the group. You may have to link `/etc/group` with `/etc/login/group` on the SAS server if it is not the primary group for `opapps`.

9.2.3.1.3 Check init.ora Open the init.ora file.

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 more information.

9.2.3.1.4 Create a Shell Script 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:

1. Create the shell script on the Oracle Clinical database server in a publicly visible directory, such as opapps/bin.
2. Name the script sas.
3. Set the protection mode to 755.
4. Insert code lines into the SAS file.

```
#!/bin/sh
RXC_LOG1=log_path_on_the_SAS_server
SASDIR=`dirname $3`
FILENAME=`basename $2`
LOGNAME=$RXC_LOG1$FILENAME
ssh server_name /bin/sh -c ". .profile;setenv
TNS_ADMIN $HOME ;setenv ORACLE_HOME
oracle_home_on_sas_server;cd $SASDIR ;
path_to_sas_script_on_SAS_server -log $LOGNAME $3 $4 $5 $6 "
```

Where:

- RXC_LOG1 is the path of the log directory in the SAS server
- SASDIR is the directory RXC_SAS_VIEW where SAS view is created and folder is NFS mounted; comes as input
- FILENAME is the SAS log file name; comes as input
- *server_name* is the SAS server connected through ssh
- *path_to_sas_script_on_SAS_server* is the sas file created in the OPA_BIN directory on the SAS server

For example:

```
#!/bin/sh
RXC_LOG1=/pharm/home/opapps/log
SASDIR=`dirname $3`
FILENAME=`basename $2`
LOGNAME=$RXC_LOG1$FILENAME
ssh opapps@server_name /bin/sh -c ". .profile;setenv
TNS_ADMIN $HOME ;setenv ORACLE_HOME
/u01/app/oracle/product/12.0.0.1;cd $SASDIR ;
/home/opapps/bin/sas -log $LOGNAME $3 $4 $5 $6 "
```

9.2.3.2 Set Up SAS Security on a Different Computer

You can set up a SAS connection to the Oracle database in two ways—using Oracle Wallet or SAS encryption. The Oracle Clinical Installer sets the SAS_CONNECTION value in the OCL_STATE reference codelist to ORACLE_WALLET.

9.2.3.2.1 Oracle Wallet This is the default option. You do not need to change the OCL_STATE reference codelist SAS_CONNECTION value, but you must enter the SAS server as the REMOTE_SAS_SERV value in OCL_STATE. See the *Oracle Clinical Administrator's Guide* for information.

And, on the SAS server:

1. Create an opapps account in the same way you did on database server with default shell C Shell. See [Section 2.2.2.2, "Create the opapps Account."](#)
2. Log on as opapps.
3. Set the environment variables in .cshrc so you can connect to the database using SQL*Plus.
4. Set up the Oracle Wallet on the SAS server. See [Section 5.6.1.1, "Creating an Oracle Wallet and Generating a Certificate Request."](#) You may use the same Wallet password that you used during Oracle Clinical installation or a different one:

```
mkstore -wrl wallet_location -create -nologo
```

Example wallet location: /home/opapps/wallet

5. Enter your password, then enter it again.
6. Add OCPSUB credentials:

```
mkstore -wrl wallet_location -createCredential db_connect_string OCPSUB
```

7. Enter information as follows at the prompts:

- **Enter your secret password:** Enter the OCPSUB password.
- **Re-enter your secret password:** Re-enter the OCPSUB password.
- **Enter wallet password:** Enter the Wallet password created above.

8. Create sqlnet.ora in opapps home. Specify the Wallet path. For example:

```
WALLET_LOCATION=(SOURCE =(METHOD = FILE) (METHOD_DATA =(DIRECTORY =  
/pharm/home/opapps/510010/wallet)))  
SQLNET.WALLET_OVERRIDE = TRUE
```

where /pharm/home/opapps/510010/wallet is the wallet path

9. In the opapps home, add the following in .cshrc:

```
setenv TNS_ADMIN $HOME
```

10. Test the Wallet connection:

- a. Open another telnet/putty session of SAS server and log in as opapps.
- b. Try connecting. It should not require specifying a password.

```
sqlplus /@db_connect_string  
sql> show user
```

You should see the OCPSUB user.

9.2.3.2.2 SAS Encryption To set up a SAS connection using SAS encryption, follow instructions in [Section 9.2.2.2.2, "SAS Encryption."](#)

9.2.3.3 Configure Private and Public Keys for Using SSH with SAS

If you are installing SAS on different server on an intranet, do the following to establish an SSH connection from PSUB server to SAS server.

Oracle Clinical DB Server Perform the following tasks on the Oracle Clinical UNIX database server computer:

1. Log in to the Oracle Clinical UNIX database server computer as the opapps user.
2. Use ssh-keygen to create a password-less set of identity keys:

```
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 public 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.

SAS Server Perform the following tasks on the SAS Server computer:

1. Log in to the SAS Server computer as opapps.
2. In the home directory Create the .ssh directory if it does not exist, and set the permission to 700:

```
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:

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

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

```
chmod 600 authorized_keys
```

Verify SSH To test the ssh setup from the Oracle Clinical Database server:

1. Log in as opapps.
2. Enter:

```
ssh sas_servername
```

It should log you in to the Sas server without the password.

9.3 Installing SAS on a Windows Computer

This section contains:

- [Section 9.3.1, "Modify the opasettings.bat file"](#)
- [Section 9.3.2, "Installing SAS on the Same Windows Server Computer"](#)
- [Section 9.3.3, "Installing SAS on a Different Windows Server Computer"](#)

9.3.1 Modify the opasettings.bat file

To use SAS 9.3 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
```

9.3.2 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 9.3.3, "Installing SAS on a Different Windows Server Computer"](#).

9.3.2.1 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; see [Section 4.1.8, "Set Initialization Parameters"](#) for more information.

9.3.2.2 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 service 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 9.3 is installed in C:\Program Files):

```
C:\Program Files\SAS93\SharedFiles\Formats(32);C:\Program  
Files\SAS93\SASFoundation\9.3;
```

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\SAS93\SharedFiles\Formats(32);C:\Program Files\SAS93\SASFoundation\9.3;
```

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.

9.3.2.3 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 9.3 is installed in C:\Program Files):

```
C:\Program Files\SAS93\SASFoundation\9.3\nls\en
```

3. Open SASV9.cfg file in a text editor.
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.

9.3.3 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.

9.3.3.1 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 more information.

9.3.3.2 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.
2. Create the oclsascr local group on the computer with the SAS application.
3. Enroll the user in the oclsascr group.
4. 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.

9.3.3.3 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 server as Administrator.
2. Using Windows Explorer, navigate to the following location (in this example SAS 9.3 is installed in C:\Program Files):

```
C:\Program Files\SAS93\SASFoundation\9.3\nls\en
```

3. Open SASV9.cfg file in a text editor.
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\9.3"*/
-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.

9.3.3.4 Set Values in OCL_STATE Reference Codelist

Set the following values in the Oracle Clinical OCL_STATE reference codelist:

- REMOTE_SASOUT
- REMOTE_SAS_SERV
- REMOTE_SAS_VIEW

Setting Up Clients

This chapter describes how to set up client computers in your Oracle Clinical/RDC Onsite installation.

This chapter includes:

- [Section 10.1, "Configuring Personal Firewall"](#)
- [Section 10.2, "Using Safari on an iPad"](#)
- [Section 10.3, "Setting Internet Options for Microsoft Internet Explorer"](#)
- [Section 10.4, "Download Required Applications for Clients"](#)
- [Section 10.5, "Mapping Network Drive for Image Browsing"](#)
- [Section 10.6, "Enabling Report Generation from the Command Line"](#)
- [Section 10.7, "Logging In"](#)

For client technical requirements, see [Section 1.3, "Technology Stack"](#).

10.1 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.

10.2 Using Safari on an iPad

On an iPad, which is supported for RDC Onsite, some functionality available on a personal computer using a mouse is not available, including:

- Right-click and double-click options.
- Selecting multiple records using Ctrl+click

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, 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 Document Mode to Quirks (the Default Setting)

Internet Explorer 8 and above include a set of tools that enable Web site developers to prototype and test Web sites they develop, including the Document Mode setting.

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.

Ensure that the Document Mode is set to Quirks Mode (Page Default):

1. Launch Internet Explorer.
2. Open the Tools menu, and then select **Developer Tools**.
3. Set the Document Mode to **Quirks Mode (Page Default)**.

10.3.3 Allow More Connections

By default, Internet Explorer allows only two connections at a time to the same server. However, RDC Onsite users need more, both when they are working in RDC Onsite and in order to connect to the application initially, when up to 5 connections are created and then all but one released. To allow additional connections, follow instructions from Microsoft at <http://support.microsoft.com/kb/282402#fixit4me>. The problem description is about being unable to download only two files at a time, but the fixes described work for this issue as well.

10.3.4 Turn Off Compatibility View in Internet Explorer

RDC Onsite does not support the Compatibility View available on Internet Explorer 8 and above. If the setting is enabled in the browser, when a user tries to access the

RDC Onsite, he or she sees the following message: "The current compatibility setting is not supported." There are several places to turn off Compatibility View:

- In the IE Tools menu, toggle between turning Compatibility View on an off by clicking Compatibility View.
- The above setting is overridden by those found in the Tools menu under Compatibility View Settings. Uncheck both: **Display intranet sites in Compatibility View** and **Display all websites in Compatibility View**
- The Compatibility View icon:



appears in the address bar when it is turned on for the current website. Click the icon to turn it off.

10.4 Download 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

Instructions for setting up downloads from the Oracle Clinical Launch page are included in [Section 6.4, "Make the Java Runtime Environment Available for Download"](#) and [Section 6.5, "Make the Oracle Clinical PDF Plug-in Available to Users"](#).

10.4.1 Download the Java Runtime Environment

Oracle Clinical and RDC Administration require the Java Runtime Environment (JRE) version 7 (1.7.0.65).

If you have older versions of JRE and do not need them, uninstall these versions before installing the new version. 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?

If you need to have both JRE 6 and 7 installed, check My Oracle Support article 1570682.1 for guidance; see ["Finding Information on My Oracle Support"](#) on page xii.

To download and install the JRE onto a client:

1. Open a browser and enter the URL to open the Launch page for the Oracle Clinical application. For example:
`https://server.domain:port/opa51/launch.htm`
2. Click **Download JRE** on the Launch page.
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 6.4, "Make the Java Runtime Environment Available for Download"](#) for more information.

10.4.2 Download the Oracle Clinical PDF Plug-in

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

Oracle Clinical has two layout systems supporting data entry:

- **Character-based layouts** support Oracle Clinical data entry.
- **Graphic-based layouts** support RDC Onsite (HTML) data entry. In addition, graphic-based layouts support annotated CRFs and Patient Data Reports. The PDF Plug-in is required for graphic layouts.

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

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

1. Open your browser and enter the URL to open the Launch page for the Oracle Clinical application. For example:

`https://computer_name.domain:port/opa51/launch.htm`

2. Click **Download PDF Plug-in** on the Launch page.
3. Follow the on-screen instructions to download and install the 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 6.5](#), "Make the Oracle Clinical PDF Plug-in Available to Users" for more information.

10.4.3 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.

10.5 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 6.6](#), "Share the RDC Directory for Image Access" 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**.

10.6 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*. The same guide has information on embedding additional fonts in patient data reports.

10.7 Logging In

To log in to the Oracle Clinical, RDC Onsite, or the RDC Administration application:

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

Table 10–1 URLs to Start Oracle Clinical and RDC Applications

Application	URL
Oracle Clinical	<code>https://computer_name.domain:port/opa51/launch.htm</code>
RDC Onsite	<code>https://computer_name.domain:port/olsa/oc/rdcLogin.do</code>
RDC Administration	<code>https://computer_name.domain:port/opa51/rdcadmin.htm</code>
RDC Administration (in Test Mode)	<code>https://computer_name.domain:port/opa51/rdcadmin.t.htm</code>

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 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.

Upgrading an Oracle Clinical Installation to Release 5.1

This chapter describes the recommended approach to upgrading an existing Oracle Clinical installation to Release 5.1. Supported upgrade paths include:

- Release 4.5.x
- Release 4.6
- Release 4.6.2
- Patch Set 4.6.3, 4.6.4, 4.6.5, 4.6.6 or later
- Release 5.0
- Patch Set 5.0.1

Note: If you are upgrading from Release 4.5.x you must upgrade to Release 4.6.2 first. You must open a Service Request (SR) on My Oracle Support at <https://support.oracle.com> to download the Release 4.6.2 media. The most recent version of the Release 4.6.2 *Oracle Clinical Installation Guide* is at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>.

Be sure you are using the latest documentation:

- Check My Oracle Support Article ID 1572864.1 for any known installation issues; see ["Finding Information and Patches on My Oracle Support"](#) on page xii.
- Go to the Health Sciences Clinical documentation page at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html> and check the installation guide's release date and part number on the title page to be sure you have the latest version.
- Check My Oracle Support Article ID 1931214.1 for the latest release of the *Oracle Clinical 5.1 Release Notes*

Review [Chapter 1, "Preparing to Install Oracle Clinical"](#) for system requirements and planning information.

This chapter includes:

- [Section 11.1, "Changes Introduced in Oracle Clinical 5.0"](#)
- [Section 11.2, "Changes Introduced in Oracle Clinical and RDC 5.1"](#)
- [Section 11.3, "Database Server"](#)

- [Section 11.4, "Database"](#)
- [Section 11.5, "Application Tier"](#)
- [Section 11.6, "Postupgrade Steps"](#)

Oracle Database 12.1.0.1 includes many new features including multitenancy, which allows you to create one or more **pluggable databases** (PDBs) contained in a single **root** or **container** database (CDB). You can install Oracle Clinical on either a pluggable database or a non-CDB database (as in 11g). For more information on multitenancy, see <http://docs.oracle.com/database/121/CNCPT/cdbovrvw.htm>.

For information about upgrading and migrating your existing database, see "Upgrading to Oracle Database 12c (12.1.0.2)" at <http://www.oracle.com/technetwork/database/upgrade/upgrading-oracle-database-wp-12c-1896123.pdf>.

For more information about new features see Oracle White Paper *Plug into the Cloud with Oracle Database 12c* at <http://www.oracle.com/technetwork/database/plug-into-cloud-wp-12c-1896100.pdf> and, for more details, the *Oracle® Database New Features Guide 12c Release 1 (12.1)* at <http://docs.oracle.com/database/121/NEWFT/toc.htm>.

11.1 Changes Introduced in Oracle Clinical 5.0

Release 5.0 included the following important changes that affect the way you set up Oracle Clinical:

- [Section 11.1.1, "Changes to Parameterized Submission \(PSUB\)"](#)
- [Section 11.1.2, "Changes in SAS Data Extract Implementation"](#)
- [Section 11.1.3, "Changes to File and Image Viewing"](#)

11.1.1 Changes to Parameterized Submission (PSUB)

PSUB was re-architected in Release 5.0 to support an Oracle Real Application Cluster (RAC) installation across multiple nodes. Instead of using `dbms_pipes`, which can be used only within a single database instance, to communicate between the user session and the PSUB service, Release 5.0 and later use Oracle Advanced Queuing.

Changes include:

- the RXCPROD account formerly responsible for starting and stopping PSUB (RXCPSPDS) has been eliminated. The PSUB start and stop privilege is now held by the `opapps` account, which continues to be responsible for the installation. If your company has previously allocated these responsibilities to separate individuals, be aware that your PSUB administrator now requires access to the `opapps` account.
- The `opapps` account will not only execute the RXCPSPDS (PSUB) process, but all of the batch jobs launched by that process, such as batch validation and batch data load, using the `ocpsub` proxy database account. These jobs will no longer be executed by individual users' operating system accounts.
- The connection information for the proxy account is securely stored in Oracle Wallet, with information you provide when you run the Oracle Clinical Installer. Oracle Wallet replaces the Secure Shell which replaced Remote Shell (`rsh`, `remsh`, and `rlogin`) used in earlier Oracle Clinical releases.
- Users who need to submit PSUB jobs **no longer need**:

- a user account beginning with OPS\$
- an individual operating system account

Instead, a new property identifies users as PSUB users and grants them access to the new ocpsub proxy database account account. To grant this access to existing user accounts, **run the migration script oclupg50migrateusers.sql** provided with Oracle Clinical 5.1 and described in the *Oracle Clinical Administrator's Guide*.

- PSUB log files are no longer stored on the server but on the database. You need to create a directory to temporarily hold PSUB output files on the PSUB server, but you no longer need to set up a directory for each user. The system does this automatically the first time a user runs a PSUB job on the database.
- Some PSUB jobs require input files and/or produce special output files that are still stored on the file server, not in the database. You can choose to have user-specific directories to store these or to store them all together. If you choose to have user-specific directories, you must create them yourself.
- The local reference codelist OCL_STATE has new settings to configure the changed PSUB implementation.

See [Chapter 8, "Setting Up the Parameterized Submission Process"](#) for more information.

11.1.2 Changes in SAS Data Extract Implementation

SAS Data Extract jobs are run by PSUB, so the PSUB changes in 5.0 and later affect SAS as well. Users no longer have individual operating system accounts and are no longer members of the oclscr user's group.

- Like other PSUB users, SAS Data Extract users no longer need individual operating system accounts, and therefore these accounts do not need to belong to the oclscr user group. Only opapps needs to belong to oclscr.
- Since Oracle Clinical no longer uses individual operating system accounts to run SAS jobs, the authentication method must change. You can set up SAS authentication two different ways:
 - Using Oracle Wallet
 - Using SAS proxy encryption file

New OCL_STATE settings also support these options; see [Section 9.1.4, "Set Up SAS User Authentication and Set OCL_STATE Reference Codelist Values"](#) for more information.

- Four Data Extract processes require input and output files in addition to the usual output files (.log and .out) that in Oracle Clinical 5.0 are stored in the database. Three of the four processes are very similar in structure in that they each require the execution of two jobs. The first job creates files that are executed by SAS in the second job. New settings in the OCL_STATE local reference codelist allow you to execute these two jobs separately. This can be useful when SAS resides on a separate server from the PSUB server; see [Chapter 9, "Setting Up SAS."](#)

Note: SAS files generated in earlier releases of Oracle Clinical cannot be re-used in Release 5.0 because they contain a database connection string that is no longer usable. You can regenerate all your SAS view files to include the correct database connection string using the existing **gen_views** utility; see the *Oracle Clinical Administrator's Guide*.

11.1.3 Changes to File and Image Viewing

Release 5.0 included a few changes related to file viewing:

- You no longer need to specify or set up SFTP or FTP as the method of transferring PSUB log and output files because they are read directly from the database. You no longer need to edit formsweb.cfg for this purpose.
- HTTP(S) set up is done during installation of Oracle HTTP Server; see [Section 5.6, "Enable SSL Between a Browser and Oracle HTTP Server"](#).
- The location for the **crfimages** folder used to display images during RDC Onsite data entry has changed. Additional information is available in the *Oracle Clinical Administrator's Guide*.

Pre-5.0 Location: `ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\de`

Location in 5.0 and Later: `OPA_HOME\html\rdc\dcif_images`

For example: `opapps51\html\rdc\dcif_images`

- The setup required for viewing **PSUB log and output files** has changed; see [Section 11.1.1, "Changes to Parameterized Submission \(PSUB\)"](#). In addition, see the *Oracle Clinical Administrator's Guide*.

Note: The location and handling of **Reports Server log and output files** has not changed. They are still located on the on Report Server Windows machine and are accessed using UNC; see [Section 7.5, "Set Up the Reports Server for Access and File Viewing"](#). In addition, see the *Oracle Clinical Administrator's Guide*.

11.1.4 Reset Application Account Passwords Proactively

Beginning with Oracle Database 11gR2, the DEFAULT profile, which applies to all users by default, including internal users/schemas, enforces password requirements including an expiration period, which is 180 days by default. You must proactively change the passwords before they expire or parts of the system may stop working.

For a list of internal accounts, see [Section 4.2.2, "Gather Required Information."](#)

For more information see the *Oracle Clinical Administrator's Guide*, Chapter 1, and http://docs.oracle.com/cd/E16655_01/network.121/e17607/authentication.htm#CHDCGJED in the *Oracle® Database Security Guide*.

11.2 Changes Introduced in Oracle Clinical and RDC 5.1

For a description of all enhancements in Release 5.1, see the release notes or the "What's New" section of *Oracle Clinical Getting Started*. The enhancements do not require changes to the installation process, but new administrative tasks are required:

11.2.1 Grant Users Access to New and Changed Oracle Clinical Menu Items

Several new menu items support audited study data deletion and partial source data verification. Grant access to them to the appropriate users following instructions in the chapter on menu-based security in the *Oracle Clinical Administrator's Guide*. Menu items are listed below with recommended access.

11.2.1.1 Audited Study Data Deletion Menu Items

- **Delete Study Information with Audit** under Conduct, Security. Oracle recommends giving access to the same users who have access to the pre-5.1 menu item Delete Study Information. This job always audits data deletion.
- **Delete Study Information** under Conduct, Security. This menu item has the same name as before, but Oracle recommends that access to it should be changed to only a few users. It now has a parameter allowing users to audit study data deletion or not. With the introduction of the feature allowing audit, Oracle recommends that auditing should be the norm and only a few users allowed to delete data without an audit.

11.2.1.2 Partial Source Data Verification Menu Items

Users with access to any of these jobs must have an account configured to run batch jobs: granted the OCPSUB proxy database account (see [Section 11.1.1, "Changes to Parameterized Submission \(PSUB\)."](#)).

You may simply grant access to a user who already has privileges to execute a job like Batch Validation. However, to take a more task-specific approach:

- **Publish SDV Plans for All Sites** under Conduct, Security. Grant access to users who have responsibility for initiating a Source Data Verification plan for a study.
- **Load Patient SDV Attributes** under Design, Patient Positions, Patients. Grant access to users who define and initiate the source data verification plan for a study or to users who otherwise work in the Maintain Patient Positions window.
- **Execute Pending Patient Updates** under Conduct, Security. Same as [Load Patient SDV Attributes](#).
- **Schedule Pending Patient Updates Job** under Admin, DE Admin. Grant access to the system administrator.

Note: For documentation of the Partial Source Data Verification feature, start with the section "Setting Up Partial Source Data Verification" in *Oracle Clinical Creating a Study*.

11.2.2 Grant RDC Onsite Users New Verify Privileges

There are new privileges in RDC Onsite required to view and update Source Data Verification Plans. See the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for information.

In addition, a new privilege, BROWSE_VERIFY, is now required to view CRF verification status and history, even if you are not using partial source data verification. Before release 5.1, all users with BROWSE or UPDATE privileges could view this information. For studies using partial source data verification, users with the BROWSE_VERIFY privilege will also be able to see the verification requirement for individual CRFs.

Users with the VERIFY privilege can still see this information and update the verification status of a CRF.

11.2.3 Set Up Custom Review Types and Assign Custom Review Privileges

Create custom review types and their corresponding privileges in the CUSTOM REVIEW TYPE installation codelist in Oracle Clinical. See the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more information about this feature.

11.3 Database Server

- [Section 11.3.1, "Install Oracle Database Server 12.1.0.1"](#)
- [Section 11.3.2, "Install the Oracle Clinical Database Server"](#)
- [Section 11.3.3, "Preserving Your Database Customizations"](#)

11.3.1 Install Oracle Database Server 12.1.0.1

You must install Oracle Database Server Oracle Database 12c Release 1 (12.1.0.1). You cannot upgrade your existing Oracle Database installation.

11.3.1.1 Installing the Oracle Database Server on UNIX

For information on using a RAC installation across multiple databases, see [Section 2.1, "Installing Oracle Clinical on a Real Applications Cluster \(RAC\) Database Configuration \(Optional\)."](#)

To install on UNIX, follow these instructions:

1. [Section 2.2, "Perform Prerequisite Tasks for Installing Oracle Database"](#)
2. [Section 2.3, "Install Oracle Database"](#)
3. [Section 2.4, "Set Permissions"](#)

11.3.1.2 Installing the Oracle Database Server on Windows

To install on Windows, follow these instructions:

1. [Section 3.1, "Set Up the opapps User Account and the oclscri User Group"](#)
2. [Section 3.2, "Set Up Local Policy Security Options"](#)
3. [Section 3.3, "Install Oracle Database"](#)

Note: If you are upgrading a the Oracle Database Server on Windows, be sure there is only one Oracle Home, and that the path points to the 12.1.0.1 home. Otherwise, you will not be able to start PSUB.

11.3.2 Install the Oracle Clinical Database Server

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

- [Section 11.3.2.1, "Installing the Oracle Clinical 5.1 Database Server on UNIX"](#)
- [Section 11.3.2.2, "Installing the Oracle Clinical 5.1 Database Server on Windows"](#)

Then follow instructions in [Section 11.4.4, "Set Initialization Parameters"](#).

11.3.2.1 Installing the Oracle Clinical 5.1 Database Server on UNIX

This section describes the tasks that you complete to install Oracle Clinical 5.1 on UNIX database servers.

Note: See ["Using the Silent Installer"](#) on page 1-15 for instructions for running the Installer as a file with pre-entered parameter values.

1. Grant write access for the opapps account to the ORACLE_HOME directory and its contents.
2. Follow instructions in [Section 2.5, "Install the Oracle Clinical Database Server."](#)

Note: When you run the Installer, choose the Upgrade option.

3. Follow instructions in [Section 2.6, "Perform Post-installation Tasks."](#)

11.3.2.2 Installing the Oracle Clinical 5.1 Database Server on Windows

To install Oracle Clinical 5.1 on a Windows Database Server, follow instructions in:

1. [Section 3.4, "Install the Oracle Clinical Database Server."](#)
2. [Section 3.5, "Perform Post-installation Tasks."](#)

11.3.3 Preserving Your Database Customizations

Since the 12.1.0.1 database server code will be in a different directory from the 11g code, you do not have to copy customized files to save your changes. When you have finished your database installation, copy the customized portions of the files into the 5.1 version of the file.

All customizable scripts are located in the same directories in Release 5.1 as in Release 4.6.2. For information about customizing them, see the *Oracle Clinical Administrator's Guide*.

Table 11–1 Customizable Database Scripts and Packages

File Name	Location	Purpose of Customization	Changed?
ocl_add_user.sql	\$RXC_TOOLS	Create new user accounts.	Changed in 5.0 and 5.1
ocstats.sql	\$RXC_INSTALL	Gather statistics; see "Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer" on page 11-18.	New in 5.0, unchanged in 5.1
opastats.sql	\$RXC_INSTALL	Gather statistics; see "Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer" on page 11-18.	New in 5.0, unchanged in 5.1
rxcptdxvb.sql	\$RXC_INSTALL	Customize data extract views.	Not changed
pop_vb_static_views.sql	\$RXC_INSTALL	Customize data extract views.	Not changed
ocl_client_pb.sql	\$RXC_INSTALL	Customize to add PLSQL code to be invoked from various parts of the application.	Not changed
rxasravw.sql/rxasravw_custom.sql	\$RXC_INSTALL	Customize Study Design replication.	Not changed
rdcpb_client.sql	\$RXC_INSTALL	Customize flex fields for DCI Forms.	Not changed
OCL_UTILS	\$RXC_INSTALL	See <i>Oracle Clinical Creating a Study</i> for information on customizing this package for making patients eligible for a PSDV plan and the <i>Oracle Clinical Remote Data Capture Onsite Administrator's Guide</i> for other uses.	Changed in 5.1

11.4 Database

- [Section 11.4.1, "Stop Processes"](#)

- [Section 11.4.2, "Back Up Your Database\(s\)"](#)
- [Section 11.4.3, "Upgrade the Database to Oracle Database 12c Release 1 \(12.1.0.1\)"](#)
- [Section 11.4.4, "Set Initialization Parameters"](#)
- [Section 11.4.5, "Create a Secret Store Directory"](#)
- [Section 11.4.6, "Upgrade Databases to Oracle Clinical 5.1"](#)
- [Section 11.4.7, "Check Internal Sequence Numbers"](#)
- [Section 11.4.8, "Upgrade Installations that Use Replication"](#)

11.4.1 Stop Processes

Before you start to upgrade your system to Oracle Clinical 5.1, complete the preliminary tasks described in this section:

- [Section 11.4.1.1, "Stop PSUB"](#)
- [Section 11.4.1.2, "Prevent Access to Oracle Clinical Databases"](#)
- [Section 11.4.1.3, "Stop Replication \(If Applicable\)"](#)

11.4.1.1 Stop PSUB

Stop PSUB on the database.

To stop PSUB on UNIX:

The preferred way to stop the PSUB service is with a utility, from the opapps account, after setting the correct environment. The TNS_ADMIN environment variable must be set to the location of the sqlnet.ora file. The Installer puts sqlnet.ora in the opapps Home directory; see "Setting TNS_ADMIN on UNIX" in the *Oracle Clinical Administrator's Guide*.

If you are upgrading from a release lower than 5.0

1. Log in to the operating system of the local computer with the rxcpd account.
2. Set the environment variables for the database and code environment.
3. Enter the following command:

```
stop_psub database_name code_environment rxc_password
```

If you are upgrading from Release 5.0.x Use the echo command to check the setting, then stop PSUB.

1. Log in to the operating system of the local computer in the opapps account.
2. Set the environment variables for the database and code environment.
3. Enter the following command:

```
echo $TNS_ADMIN
setenv TNS_ADMIN $HOME
stop_psub database_name code_environment Wallet_alias
```

To stop PSUB on Windows:

1. Navigate to the Services control panel.
2. Highlight the PSUB service.
3. Click **Stop**.

11.4.1.2 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 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.

11.4.1.3 Stop Replication (If Applicable)

If you have a distributed environment in which you replicate data and metadata among multiple databases using one of Oracle Clinical's replication features, stop all replication before continuing the upgrade.

This section includes:

- [Section 11.4.1.3.1, "Prepare All Replication Environments"](#)
- [Section 11.4.1.3.2, "Stop Standard Replication"](#)
- [Section 11.4.1.3.3, "Stop Symmetric Replication"](#)

Tip: You must upgrade all databases in your Oracle Clinical installation to Oracle Clinical 5.1 before setting up, or resuming, replication in any of them.

11.4.1.3.1 Prepare 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.

11.4.1.3.2 Stop 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.

11.4.1.3.3 Stop 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 DEFTRAN;
```
 - b. Push these pending transactions:

```
dbms_defer_sys.execute(destination=>'other sites.WORLD',  
execute-as-user=>TRUE);
```
3. Disable the replication queues until the upgrade is complete.
 - a. List the jobs in the queue:

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

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

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

4. Stop all modifications to the database.

As much as possible, avoid making changes to programs, projects, organization units, regions, planned studies, factors, strata, active substances, drugs, or treatment regimens.
5. Quiesce the databases by executing this command against the master database:

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

```
execute dbms_repcat.drop_master_repgroup ('RXA_DES');
```

11.4.2 Back Up Your Database(s)

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

11.4.3 Upgrade the Database to Oracle Database 12c Release 1 (12.1.0.1)

Do **one** of the following:

- [Upgrade in Place](#)
- [Clone Your Database](#)

Note: Choose to configure the database to **accept connections as a service instead of a SID**. Service name **requirements** for Oracle Clinical include:

- The service name must be less than 15 characters long.
- It must not include the domain.
- It must be **all lowercase**.

The Oracle Clinical Installer no longer works if you set up connections using the SID.

Note: If you are installing the Oracle Clinical database on a pluggable Oracle 12.1.0.1 database (PDB), see My Oracle Support article ID 1910177.1, *How To Configure TNS / SQLNET using the local_listener parameter for Pluggable Database In Oracle 12c, Allowing a SQLNET Connection to the PDB*. See "[Finding Information on My Oracle Support](#)" on page xii.

11.4.3.1 Upgrade in Place

1. Create an Oracle Database Container Database (CDB) to use one or more pluggable databases. (If you are upgrading multiple databases, you still need only one CDB.) **OR** create one non-CDB (11g-style) database.

Update the listener and tnsnames.ora either before or after the next step.

2. Upgrade your database to Oracle Database 12.1.0.1 using the Database Upgrade Assistant (DBUA) following Method 1 described in "Upgrading to Oracle Database 12c (12.1.0.2)" at <http://www.oracle.com/technetwork/database/upgrade/upgrading-oracle-database-wp-12c-1896123.pdf>.

11.4.3.2 Clone Your Database

1. Create an Oracle Database Container Database (CDB) to use one or more pluggable databases. (If you are upgrading multiple databases, you still need only one CDB.) **OR** create one non-CDB (11g-style) database.

Update the listener and tnsnames.ora either before or after the next step.

2. Clone your database. See Oracle White Paper *Cloning Oracle Clinical and TMS Databases*, article ID 883213.1 on My Oracle Support. See "[Finding Information on My Oracle Support](#)" on page xii.

11.4.4 Set Initialization Parameters

After the upgrade completes, set the init.ora parameters according to the instructions in [Section 4.1.8, "Set Initialization Parameters."](#)

You must stop and then start the database to activate the changed init.ora parameters.

Notes: Do NOT SET the DB_DOMAIN parameter. In Release 5.1 and above this causes problems.

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.

If your init.ora file includes the REMOTE_OS_AUTHENT parameter, make sure that it is not set to TRUE. It can be set to FALSE or be absent.

11.4.5 Create a Secret Store Directory

Create a directory that is accessible to the opapps user and different from the Oracle Wallet location. The Installer fails if this directory is not created before running the Installer.

Example location: `/home/opapps/sec_store/db_name`

11.4.6 Upgrade Databases to Oracle Clinical 5.1

This section describes how to run Installer to upgrade each database.

Note: If you are upgrading to a RAC environment, you must import your database(s) to a single RAC node before running the Installer to upgrade it.

11.4.6.1 Gather the Required Information

See [Section 4.2.2, "Gather Required Information"](#) before you start the Installer. The information is not in quite the same order as displayed in the Installer for upgrading databases but it is the same information.

You also have the option to skip the upgrade but rerun all recreatable object scripts (views, packages, functions, and so on) against the database.

11.4.6.2 Running the Installer in UNIX

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 12c Release 1 (12.1.0.1) 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, for example:

```
setenv DISPLAY 123.45.67.89
```

4. Navigate to this location in the folder where you extracted the server code; see [Section 1.5, "Downloading and Extracting the Software"](#):

```
server_code_platform\Disk1\install
```

5. Change protections on files to 755.

```
chmod 755 *
```

6. Start the Installer:

- For a non-RAC installation:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

- For a RAC installation:

```
./runInstaller
```

Or, if the database server has multiple Oracle Homes, then enter:

```
./runInstaller -local -invPtrLoc ORACLE_HOME/oraInst.loc
```

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/121010_qa/oraInst.loc
```

This ensures that the installation is performed only on the local node.

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

7. In the Select a Product to Install screen, select **OC Database Upgrade 5.1.0.0.x**. Follow instructions on screen, entering the information indicated in [Section 4.2.2, "Gather Required Information"](#).
8. Reset the privileges for the opapps account:

```
newgrp group
```

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

11.4.6.3 Running the Installer in Windows

To begin the installation:

1. Log in using an account with Windows system administrator privileges.
2. Navigate to this location in the folder where you extracted the server code; see [Section 1.5, "Downloading and Extracting the Software"](#).
3. Execute the following file as an administrator:

Disk1\install\setup.exe

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

4. In the Select a Product to Install screen, select **OC Database Upgrade 5.1.0.0.x**. Follow instructions on screen, entering the information indicated in [Section 4.2.2, "Gather Required Information"](#).

11.4.6.4 Review the Log Files for Upgrade Results and Errors

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

UNIX `OPA_HOME/oc/51/install`

Windows `OPA_HOME\oc\51\install`

After running the Installer, check the log files to confirm that the upgrade succeeded. Upgrading the Oracle Clinical database produces the following log files:

- `compile_all_invalid_database.log`
- `html_blob_seeddata_database_timestamp.log`
- `html_dialg_templ_database_timestamp.log`
- `load_olsardcstatemachine_jar_database.log`
- `oclconfig_database.log`
- `oclupg_database.log`
- `opaconnectcheck_system_database.log`
- `upgrade_database_timestamp.log`
- `xmlp_clob_seeddata_database_timestamp.log`
- `xml_clob_seeddata_database_timestamp.log`

The rest of this section describes finding errors in the log files (as *logfile*), and descriptions of known errors.

11.4.6.4.1 Finding Errors To simplify reviewing upgrade results, run these commands for each of the database upgrade log files:

Oracle Linux From the command line, enter:

```
opa_setup database 51
cd $RXC_INSTALL
/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

Oracle Solaris SPARC From the command line, enter:

```
opa_setup database 51
cd $RXC_INSTALL
/usr/xpg4/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

HP-UX Itanium. From the command line, enter:

```
opa_setup database 51
cd $RXC_INSTALL
/usr/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

Windows Open a DOS window as an administrator and enter:

```

set p1=database
set p2=51
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.

11.4.6.4.2 Known Error Messages See My Oracle Support Article ID 386941.1, *OLSA 4.6.x and 4.7.x Known Install and Configuration Issues*, for a description of any error messages.

11.4.6.4.3 Reencrypt 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 using the `set_pwd` command; instructions are in the *Oracle Clinical Administrator's Guide*.

Normally if you are upgrading from 5.0.x and have not changed the location of the Secret Store directory, you do not need to rerun `set_pwd`.

11.4.6.4.4 Check If You Need to Prepare and Migrate Data When you upgrade a database from Oracle Clinical 4.6.2 to Patch Set 4.6.3 or later, the Installer runs a validation script to ensure that all studies have been migrated to the enhanced approval and verification data model that was introduced in Oracle Clinical 4.5.3.11 and 4.5.3.12. If the database is in a replicated environment, within each study the Installer validates only patients that are owned by the current location.

Check the Installer log file:

- **If the validation succeeds**, the log file includes the message "Validation succeeded, database has been migrated to the new approval/verification data model. No further action is required." and the database upgrade process continues. However, if in the future you need to unfreeze a currently frozen study, you may need to migrate its data first.
- **If the validation fails**, the database upgrade process is terminated. The log file includes the error message that the migration has not been run on the database. Contact Oracle Support for further instructions.

11.4.6.5 Compile Invalid Objects

When upgrading the Oracle Clinical database, the 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 11-2](#)), 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.

11.4.6.5.1 Compile 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
```

11.4.6.5.2 Run the compile_schema_invalid.sql Script Follow the instructions appropriate for your operating system.

11.4.6.5.3 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 5.1, the default value is 51.

- 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 11-2](#) lists the options you can use to run the script depending on which invalid objects you want to compile.

Table 11-2 SQL Commands for Compiling Specific Types of Invalid Objects

To...	Enter this SQL Command...
Compile any invalid objects in RXC_PD	<code>start compile_schema_invalid RXC_PD</code>
Compile any invalid objects for the Data Extract views that belong to a study	<code>start compile_schema_invalid study_name\$%</code>

Table 11–2 (Cont.) SQL Commands for Compiling Specific Types of Invalid Objects

To...	Enter this SQL Command...
Compile any invalid objects in OPS\$ accounts	<code>start compile_schema_invalid OPS\$%</code>
Compile any invalid objects in any account that has the dollar symbol (\$) in the account name	<code>start compile_schema_invalid %\$\$</code>
Compile all invalid objects in all schemas	<code>start compile_schema_invalid %</code> Note that this command compiles <i>all</i> invalid objects, including those in other schemas such as RXC and RXA_DES. However, the <code>compile_all_invalid.sql</code> script that the Installer automatically runs after upgrading the Oracle Clinical database already compiles the invalid objects for those schemas.

6. Check the log file to verify that the script compiled the invalid objects successfully:
`$RXC_INSTALL\compile_schema_invalid_database.log`

11.4.6.5.4 Windows To run the `compile_schema_invalid.sql` script on Windows:

1. Open a DOS window as an administrator and enter:

```
set p1=database
set p2=51
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 11–3 lists the options you can use to run the script depending on which invalid objects you want to compile.

Table 11–3 SQL Commands for Compiling Specific Types of Invalid Objects

To...	Enter this SQL Command...
Compile any invalid objects in RXC_PD	<code>start compile_schema_invalid RXC_PD</code>
Compile any invalid objects for the Data Extract views that belong to a study	<code>start compile_schema_invalid study_name\$%</code>
Compile any invalid objects in OPS\$ accounts	<code>start compile_schema_invalid OPS\$%</code>
Compile any invalid objects in any account that has the dollar symbol (\$) in the account name	<code>start compile_schema_invalid %\$\$</code>
Compile all invalid objects in all schemas	<code>start compile_schema_invalid %</code> Note that this command compiles <i>all</i> invalid objects, including those in other schemas such as RXC and RXA_DES. However, the <code>compile_all_invalid.sql</code> script that the Installer automatically runs after upgrading the Oracle Clinical database already compiles the invalid objects for those schemas.

4. Check the log file to verify that the script compiled the invalid objects successfully:
`%RXC_INSTALL%/compile_schema_invalid_database.log`

11.4.6.6 Perform Post-Upgrade Database Tasks

Do each of the following tasks.

11.4.6.6.1 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. See [Section 4.4.1, "Set the Database Time Zone"](#) for instructions.

11.4.6.6.2 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. For details, see [Section 4.4.2.1, "Pin UNIX Database Packages"](#) or [Section 4.4.2.2, "Pin Windows Database Packages"](#).

11.4.6.6.3 Migrate Users The requirements for users who need to run PSUB jobs changed in Release 5.0 and you must run a script to migrate their accounts to the new model, if you have not already done so. See the *Oracle Clinical Administrator's Guide* for information.

11.4.6.6.4 Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer After upgrading to Oracle Clinical 5.1 and setting initialization parameter `optimizer_features_enable` to 11.2.0.4 (see [Section 4.1.8, "Set Initialization Parameters"](#)), you must manually run scripts—`ocstats.sql` and `opastats.sql`—to gather statistics required for the Oracle Database Optimizer to be effective for accounts used internally by Oracle Clinical, RDC Onsite, and TMS. Failure to execute these scripts can negatively impact performance.

Note: Oracle Clinical 5.1 is certified on the 11g Optimizer.

For more information on gathering statistics and using dynamic sampling to improve performance, see the *Oracle Clinical Administrator's Guide*.

11.4.7 Check Internal Sequence Numbers

Upgrading from 4.5.x If you are upgrading from Oracle Clinical 4.0.3 or 4.5.x, follow instructions in the *Oracle Clinical Administrator's Guide* "Troubleshooting" chapter, "Managing High Sequence Numbers" section, to assess the current value of internally generated IDs, reseed the sequence(s) if necessary, and ensure that the maximum value is properly set to avoid severe referential integrity bug 3718908. The affected sequences are the internal identifiers for:

- Received DCMs (RDCMs)
- Received DCIs (RDCIs)
- Discrepancies
- Responses

Upgrading from 4.6.x If you are upgrading from Oracle Clinical 4.6.x you may want to proactively determine whether you need to reseed any of these sequences. If the value of any of these internal IDs gets too close to the maximum, the system gives a warning message to a user attempting to use the relevant subsystem and exits the current screen. To avoid this, you can assess how close the highest current value is to the maximum and reseed the sequence in advance if necessary. For more information

see the *Oracle Clinical Administrator's Guide* "Troubleshooting" chapter, "Managing High Sequence Numbers" section.

11.4.8 Upgrade Installations that Use 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.

11.5 Application Tier

This section includes:

- [Section 11.5.1, "Copy Any Customized Application Tier Files"](#)
- [Section 11.5.2, "Install the Application Tier Technology Stack"](#)
- [Section 11.5.3, "Install the Oracle Clinical Front End and Reports Server"](#)
- [Section 11.1.4, "Reset Application Account Passwords Proactively"](#)
- [Section 11.5.5, "Preserve Your Customizations"](#)

11.5.1 Copy Any Customized Application Tier Files

If you have customized any application tier files, copy them into a location where they will not be overwritten by the new software. See [Section 11.5.5, "Preserve Your Customizations"](#) for a list of customizable files and their locations.

11.5.2 Install the Application Tier Technology Stack

11.5.2.1 Upgrading from a Release Earlier than 5.0

If you are upgrading from a release prior to 5.0, you cannot upgrade the application tier, you must install it fresh because Release 5.0 and later use a different technology stack:

- Oracle Application Server 11gR2, which includes the Oracle Forms Server and the Oracle Reports Server. Both are required for Oracle Clinical.
- WebLogic Server 11gR1 (10.3.6) and Oracle Application Developer Framework 11g R1. These are required for RDC Onsite.

You can install all components on the same machine, or install on multiple machines, but you must install all components on all machines and then disable services on the machine(s) where they are not needed.

To ensure high availability of the Reports Server, you can set up and use more than one Reports Server on a subnet and they can access each other. For more information see the *Oracle Clinical Administrator's Guide*.

Follow all instructions in [Chapter 5, "Installing and Configuring the Application Tier."](#)

11.5.2.2 Upgrading from Release 5.0.x

If you are upgrading from Oracle Clinical 5.0.x you can upgrade the application tier. You do not need to reinstall Oracle Application Server 11gR2, WebLogic Server 11gR1 (10.3.6), or Oracle Application Developer Framework 11g R1.

However, you do need to upgrade ADF and install a new version of Oracle Java Development Kit:

- [Section 5.3, "Install Oracle Java Development Kit"](#)—When prompted for a directory, specify the same directory you specified when you installed Oracle Clinical 5.0.x.
- [Section 5.7.2, "Upgrade ADF"](#)
- [Section 5.7.3, "Patch ADF to Support Internet Explorer 11"](#)

11.5.3 Install the Oracle Clinical Front End and Reports Server

Install the following:

- **Oracle Clinical Forms Server** — See [Chapter 6, "Installing the Oracle Clinical Front End."](#)
- **Oracle Clinical Reports Server** — See [Chapter 7, "Installing the Oracle Clinical Reports Server."](#)

If you are upgrading from 5.0.x, check that all entries that refer to `opa_home` refer to the correct `opa_home`. For example, if they say `C:\opapps50`, change to `C:\opapps51`.

11.5.4 Set Remote Method Invocation (RMI) JDBC Security to Secure

1. Log in to the WebLogic Server
2. Go to **Summary of Servers**, select **OpaServer1**, select **General**, and click **Advanced**.
3. Change the **RMI JDBC Security** setting to **Secure**.
4. Click **Save**.
5. Click **Activate Changes**.

11.5.5 Preserve Your Customizations

You may have customized Oracle Clinical and RDC Onsite files for various purposes. Due to changes in the underlying application tier technology stack, many of these files have been changed in Release 5.0 and/or 5.1. The application tier cannot be upgraded; it must be completely reinstalled.

To preserve your customizations:

1. Back up each file that you have customized before you install the new application tier. The following sections provide a list of customizable files and the actions required to preserve your changes.
2. From the Administration Console for the OPA domain (by default, port 7101), stop and delete the RDC Onsite application.
3. Install the new application tier technology stack, following instructions in [Chapter 5, "Installing and Configuring the Application Tier."](#)
4. Using information in the following sections, manually reenter your changes to the new versions of files that have changed in Release 5.0 or 5.1.
5. Redeploy these files and any files you have customized that have not changed in Release 5.0 or 5.1.
6. Restart the application for your changes to take effect.

The following sections contain information on customizable files:

- [Section 11.5.5.1, "Oracle Clinical Forms"](#)
- [Section 11.5.5.2, "Oracle Clinical Reports"](#)
- [Section 11.5.5.3, "Formsweb.cfg"](#)
- [Section 11.5.5.4, "RDC Onsite Customizable Files"](#)
- [Section 11.5.5.5, "Customizable HTML Files"](#)
- [Section 11.3.3, "Preserving Your Database Customizations"](#)

11.5.5.1 Oracle Clinical Forms

Affected Files: rxcuser.pll, rxcuser.fmb, rxcuser.mmb, rxclbcli.pll

Note: If you have customized rxclbcli.pll to integrate OC with an external workflow or imaging system, you must change user_password arguments in getimage and getimagedcf from encrypted_passwords.password%type to varchar2.

Required Action to Preserve Customization:

- Recompile rxcuser.fmb with Forms Builder 11g.
- Recompile rxcuser.mmb with Forms Builder 11g.
- Replace your recompiled rxcuser.fmb and rxcuser.mmb files on each Forms Server in your network.

Files marked Restored are backed up by the Installer in a location the user you specified during Oracle Clinical installation.

Table 11–4 Oracle Clinical Customizable Forms Files with 4.6.2 Locations

File Name	Location in 4.6.2	Purpose of Customization	Changed?
rxcuser.fmb (Restored)	opapps46\oc\admin	Customizing the Users and Roles menu	Changed in 5.0 and 5.1
rxcuser.mmb (Restored)	opapps46\oc\admin	Customizing the Users and Roles menu	Changed in 5.0 and 5.1
rxcuser.pll	opapps46\oc\admin	Customizing the Users and Roles menu	Changed in 5.0 and 5.1
rxclbcli.pll	opapps46\oc	Integration with other systems; see the <i>Oracle Clinical Application Programming Interface Guide</i> for information.	Changed in 5.0 and 5.1

11.5.5.2 Oracle Clinical Reports

Affected Files: rxcdrptl.rdf, rxcdrptp.rdf

Required Action to Preserve Customization: Recompile with Oracle Reports 11g and replace in opa_home\oc folder on the Oracle Reports server.

Table 11–5 Oracle Clinical Customizable Forms Files with 4.6.2 Locations

File Name	Location in 4.6.2	Purpose of Customization	Changed?
rxcdcf.bmp (Restored)	opapps46\oc\	Customizing the image on DCF reports.	Not changed
rxcdrptl.rdf (Restored)	opapps46\oc\admin	Customizing DCF reports landscape template.	Changed in 5.0 and 5.1
rxcdrptp.rdf (Restored)	opapps46\oc\admin	Customizing DCF reports portrait template.	Changed in 5.0 and 5.1
All files with extension .conf (Not Restored)	ORACLE_AS10gR2_HOME\reports\conf	Report Server parameter configuration.	Obsolete in 5.0

11.5.5.3 Formsweb.cfg

If you modified the DE_GRIDWIDTH and DE_GRIDHEIGHT parameters in formsweb.cfg, recreate your changes so your Data Entry screens have the correct appearance.

You may also have modified the file for file viewing purposes. These customizations are obsolete in Release 5.0; see [Section 11.1.3, "Changes to File and Image Viewing"](#).

In Release 4.6.2 this file was located at:

ORACLE_AS10gR2_HOME\forms\server.

The new version of the file is located at:

middleware_home\user_projects\domains\FRDomain\config\fmwconfig\servers\WLS_FORMS\applications\formsapp_11.1.2\config.

11.5.5.4 RDC Onsite Customizable Files

[Table 11–6, "RDC Onsite Customizable Files"](#) lists the RDC Onsite files that were customizable in Release 4.6.2 with their 4.6.2 location, the purpose of customization, and information about whether they have been changed or even made obsolete in Release 5.0 or 5.1, and their current location, if any.

Most of these files are now inside the olsardc.ear file, which contains the entire RDC Onsite application. You must reenter any customizations you have made and repackage the .ear file, then redeploy the application. Contact Oracle Support for help if necessary.

For more information on customizing these files, see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

Table 11–6 RDC Onsite Customizable Files

File Name	Location in Release 4.6.2	Purpose of Customization	Changed?	Location in Release 5.1
bc4j.xcfg	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\model\services\common	Performance configuration	Changed; no longer used by launch page	olsardc.ear\RdcSurroundAdfWebUIWebApp.war\WEB-INF\lib\rdcmodel.jar\oracle\pharma\rdc\model\services\common
dataentry-config.xml	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\	Performance configuration	Obsolete in 5.0; configurations moved to rdcConfig.properties	NA
dataentrylogger.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\	Specify the detail level of DE log file debug info	Changed in 5.0 and 5.1	olsardc.ear\RdcSurroundAdfWebUIWebApp.war\WEB-INF\
dcapi.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\	DCAPI log file generation, performance configuration	Changed in 5.0 and 5.1	\olsardc.ear\RdcSurroundAdfWebUIWebApp.war\WEB-INF\
de_external.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\de\resource\properties	Approval warning message, labels in data entry	Changed in 5.0 and 5.1	olsardc.ear\RdcSurroundAdfWebUIWebApp.war\WEB-INF\lib\rdcdataentry.jar\oracle\pharma\rdc\de\resource\properties
opalogger.properties	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\	~	Obsolete in 5.0	NA
rdcConfig.properties	~	Multiple settings; see the <i>Oracle Clinical Remote Data Capture Onsite Administrator's Guide</i> for information.	New in 5.0.	OPA_CONFIG folder at the location specified in the opa51 registry under HKEY_LOCAL_MACHINE > Software > Oracle
RdcLogos.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\view	Contact Us link	Changed in 5.0 and 5.1	OPA_CONFIG folder at the location specified in the opa51 registry under HKEY_LOCAL_MACHINE > Software > Oracle
RdcTexts.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\view\nls	Change Password link, text and messages in the RDC Surround	Changed in 5.0 and 5.1	OPA_CONFIG folder at the location specified in the opa51 registry under HKEY_LOCAL_MACHINE > Software > Oracle

Table 11–6 (Cont.) RDC Onsite Customizable Files

File Name	Location in Release 4.6.2	Purpose of Customization	Changed?	Location in Release 5.1
web.xml	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\olsardc\rdconsite\WEB-INF	Timeout interval, performance configuration	Changed in 5.0 and 5.1	Most functionality moved to rdcConfig.properties. Exists and located at: olsardc.ear\RdcSurroundAdfWebUIWebApp.war\WEB-INF\
orion-web.xml	ORACLE_AS10gR3_HOME\j2ee\rdc\application-deployments\olsardc\rdconsite\	Used in image viewing	Obsolete in 5.0	NA
orion-web.xml	ORACLE_AS10gR3_HOME\j2ee\opa\application-deployments\olsardc\rdcclassic\	Used in image viewing	Obsolete in 5.0	NA

11.5.5.5 Customizable HTML Files

If you customized any of the following files, to retain your changes you must reapply your customizations after upgrading.

In Release 5.1 these files reside in the opapps51 directory, not the opapps46 directory.

Table 11–7 HTML Customizable Files with 4.6.2 Locations

File Name	Location in 4.6.2	Purpose of Customization	Changed?
launch.htm	opapps46\html	Customize the launch page	Changed in 5.0 and 5.1
ocdcitemplate.htm	opapps46\html	Customize the launch page for the batch generator for HTML Data Entry Forms and Patient Data Report Templates	Changed in 5.0 and 5.1
rdcadmin.htm	opapps46\html	Customize the RDC Admin launch page	Changed in 5.0 and 5.1
rdcadmint.htm	opapps46\html	Customize the RDC Admin test mode launch page	Changed in 5.0 and 5.1
rdclaunch.htm	opapps46\html	Customize the RDC launch page	Obsolete in 5.0
rdclauncht.htm	opapps46\html	Customize the RDC test mode launch page	Obsolete in 5.0
All files	opapps46\html\xhelp	Customize online help content	Changed in 5.0 and 5.1

11.6 Postupgrade Steps

Set up the following:

- **PSUB** — See [Chapter 8, "Setting Up the Parameterized Submission Process."](#)
- **SAS** — See [Chapter 9, "Setting Up SAS."](#)
- **Clients** — See [Chapter 10, "Setting Up Clients."](#)
- Do the administrative tasks described in [Section 11.2, "Changes Introduced in Oracle Clinical and RDC 5.1."](#)
- [Section 11.6.1, "Update Environment Variables \(If Upgrading from 5.0.x\)."](#)

- [Section 11.6.2, "Manually Start the Advanced Queue Process \(If You Cloned a Database\)."](#)

11.6.1 Update Environment Variables (If Upgrading from 5.0.x)

If you upgrade from Release 5.0.x, the OC Front End and Reports Server Installers do not upgrade a few variables. Check these variables and update them from . . .50 to . . .51.

They are located on the SOFTWARE\ORACLE\KEY $number$ branch of the registry on the application tier server. The unchanged variables are:

- OC_PDF_REPORTS_TMP
- OC_REPORTS_TMP
- OPA_XHELP_DIR
- OPA_XML_LOC

11.6.2 Manually Start the Advanced Queue Process (If You Cloned a Database)

If you cloned a database, manually restart the AQ process:

1. Stop PSUB, see the *Oracle Clinical Administrator's Guide* for instructions.
2. Log in as sysdba.
3. Enter:

```
EXEC DBMS_AQADM.START_QUEUE('RXC.PSUB_REPLY_QUEUE',TRUE,TRUE);  
EXEC DBMS_AQADM.START_QUEUE('RXC.PSUB_SEND_QUEUE',TRUE,TRUE);
```

4. Start PSUB. See [Section 8.2, "Starting and Stopping the PSUB Service."](#)

