

Oracle Clinical Upgrade Guide



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Preface

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- [Documentation accessibility](#)
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- [Access to Oracle Support](#)

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>.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Oracle Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab> if you are hearing impaired.

Audience

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

Database Administrators

Upgrading 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

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

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

1

Prepare to Upgrade Oracle Clinical

Note:

During upgrade you see references to OLSA and OPA in the software (such as in directory names, file names, and screen text). They stand for earlier organization names Oracle Life Sciences Applications (OLSA) and Oracle Pharmaceutical Applications (OPA). Oracle Clinical and Oracle Clinical Remote Data Capture (RDC) are now part of the Oracle Life Sciences Global Industry Unit (LSGIU).

Note:

RDC and Oracle Clinical Licenses 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.

For more information, see:

- [Supported Upgrade Paths](#)
- [Check Supplementary Installation Documentation](#)
- [Architecture](#)
- [Software Requirements](#)
- [Supported Configurations with Oracle Data Guard and RAC](#)
- [Download the Software](#)
- [Use the Silent Installer \(Optional\)](#)
- [Choose a Character Set](#)
- [Apply the Latest Oracle Clinical Patches](#)
- [Integrating Oracle Clinical with Other Products and Options](#)

Supported Upgrade Paths

This chapter describes the recommended approach to upgrading an existing Oracle Clinical installation to Release 5.4.1.

The supported upgrade paths come from the following releases:

- Release 4.6.6

- Release 5.0 or 5.0.1
- Release 5.1
- Release 5.2
- Release 5.2.1
- Release 5.2.2
- Release 5.4

Check Supplementary Installation Documentation

Check these additional resources:

- [My Oracle Support Articles](#)
- [User Documentation](#)

My Oracle Support Articles

Visit the My Oracle Support website at <https://support.oracle.com> for the most up-to-date installation information, including:

- Performance Behavior and System Recommendations for Oracle Clinical Oracle Clinical Remote Data Capture Onsite 5.4.x (Document ID 2854275.1). Ensure to review this document prior to install/upgrade, and implement the configurations it details as applicable to your environment during your install/upgrade.
- Oracle Clinical (5.4) and Remote Data Capture (5.4) Installation Verification Tests (Document ID 2854557.1)
- Oracle Clinical 5.4.1 Release Notes (Document ID 2922551.1)
- Known Installation and Configuration Issues for Oracle Health Sciences products Oracle Clinical, RDC Onsite, and TMS version 5.x (Document ID 1572864.1)
- Oracle Life Sciences Applications Supported Technology Stack (Document ID 180430.1)
- Oracle Clinical Versions 5.4.x, 5.2.x, 5.1.0, 5.0.1, 4.6.6, and 4.6.0 Summary of Patches Available (Document ID 121863.1)
- Oracle Clinical/RDC Product Information Center (Document ID 1331795.1): Check here for continually refreshed content including new notes and white papers and product notifications.

User Documentation

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

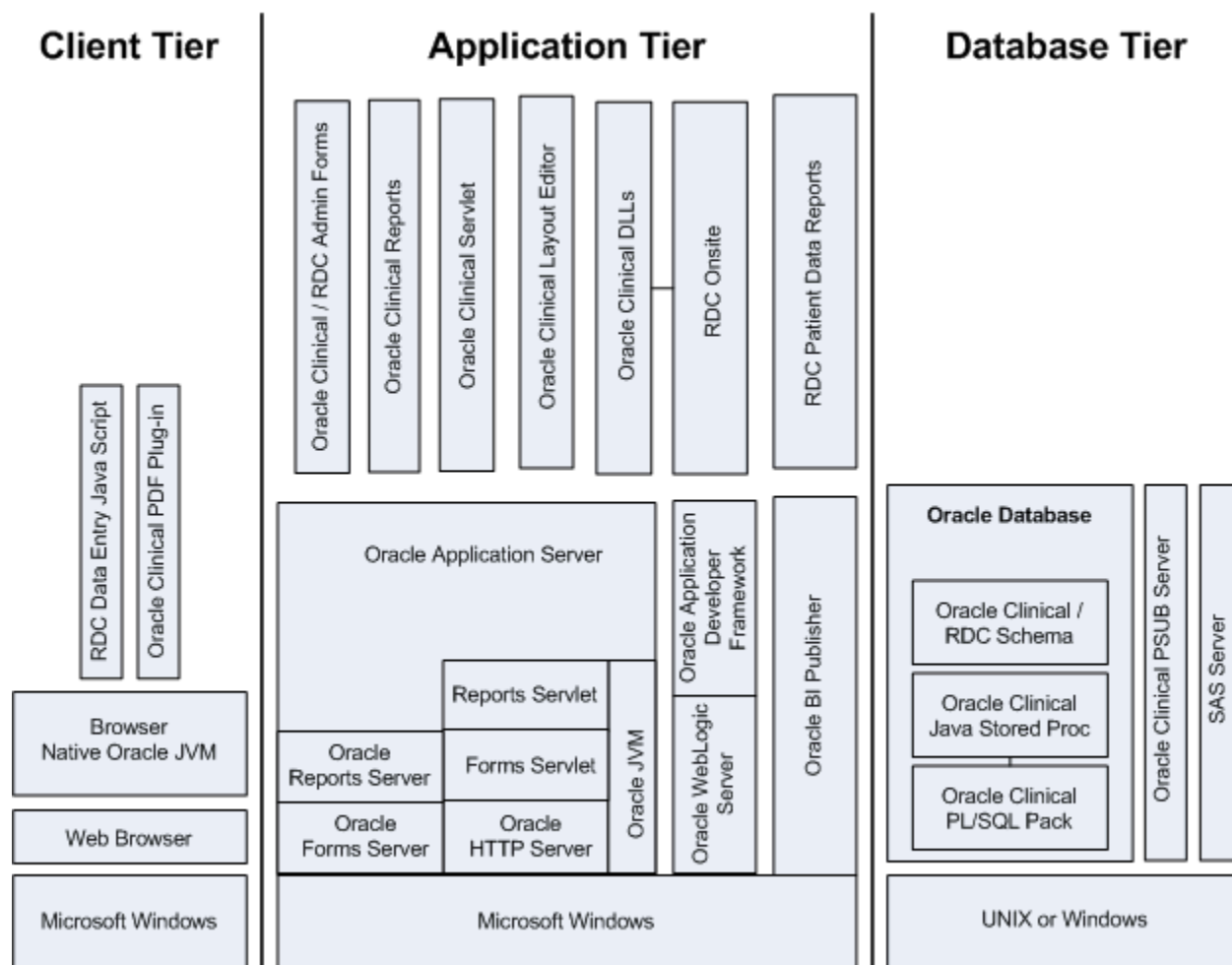
<https://docs.oracle.com/en/industries/health-sciences/clinical-remote-capture/5.4.1/index.html>

Architecture

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

The image below 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 parametrized 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 [Make the Oracle Clinical PDF Plug-in Available to Users](#) for more information.

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

Software Requirements

Check the following links for the latest software requirements:

- [Table 1-1](#)
- [Table 1-2](#)
- [Table 1-3](#)

Oracle technology stack components, such as Oracle Database and Oracle Fusion Middleware are certified for use with Oracle Virtual Machine (OVM). For further information including a complete list of products/versions certified on OVM, see *Oracle VM: Software Certified On OVM* (Doc ID 464754.1) on My Oracle Support.

Upon release, Oracle Clinical 5.4.1 and Oracle Remote Data Capture 5.4.1 are certified for use with the latest CPU certified for release 5.4.1. For information on the latest certified CPU, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support > section Oracle Life Sciences Critical Patch Updates (CPU) Notes in the PDF file.

Note:

You must apply the latest CPU certified for release 5.4.1 after installing Oracle Clinical 5.4.1. If the latest CPU is already applied, remove it, install Oracle Clinical 5.4.1, and then apply the latest CPU.

Table 1-1 Oracle Clinical Database Tier Technology Stack

Component	Supported Version
Operating System	Oracle Linux 7.6, 7.7, and 8.1 to 8.7 with the Unbreakable Enterprise Kernel (UEK), 64 bit (US English) Oracle Solaris SPARC 11.4, 64-bit architecture (US English) HP Itanium 11.31; 64-bit architecture (US English) Microsoft Windows Server 2019 (US English)
Oracle Database	Oracle Database 19c Release (19.3.0.0) Enterprise Edition, 64-bit
Compiler	For Oracle Linux 7.6 or 7.7: GCC-4.8.5 or later; command to identify compiler is <code>gcc -v</code> For Oracle Linux 8.1 to 8.7: GCC-8.5.0; command to identify compiler is <code>gcc -v</code> For Oracle Solaris SPARC 11: Oracle Solaris Studio 12.6 Sun C 5.15; command to identify compiler is <code>cc -V</code> For HP-UX Itanium: HP-UX 11.31 September 2014 B.11.31.1409 or later ; command to identify compiler is <code>'which cc'</code> and <code>'cc -v'</code>
Optional Software	SAS 9.4—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

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

Component	Supported Version
Operating System	Microsoft Windows Server 2016 and 2019
Oracle WebLogic Server	Oracle WebLogic Server 12c Release 2 (12.2.1.4)
Oracle Fusion Middleware Infrastructure	Oracle Fusion Middleware Infrastructure 12c Release 2 (12.2.1.4)
Oracle Application Development Framework	Oracle Application Development Framework 12c Release 2 (12.2.1.4) Note: Included with Oracle Fusion Middleware Infrastructure.
Oracle Forms and Reports	Oracle Forms and Reports 12c Release 2 (12.2.1.19)
Oracle Java Development Kit (JDK)	Oracle Java Development Kit 1.8 Update 391 or later (JDK 1.8 is also known as JDK 8)
Oracle Java Runtime Environment (JRE)	Oracle Java Runtime Environment (JRE) 1.8 update 391, also known as JRE 8
Microsoft Visual Studio	Visual C++ in Microsoft Visual Studio 2015-2022 (x64 distributed)—Required for Oracle WebLogic Server 12c (12.2.1.4) and Oracle Forms and Reports 12c (12.2.1.19). Also, can be used to invoke Data Capture API methods from custom clients.

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

Component	Supported Version
Operating Systems	Microsoft Windows 11; 32-bit or 64-bit architecture (US English)

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

Component	Supported Version
Mobile Operating Systems	iOS 15.0 (iPad) - for RDC Onsite only macOS Big Sur Version 11.6 (MacBook) - for RDC Onsite only
Supported Browsers	The following Microsoft browser and operating system combinations are supported: <ul style="list-style-type: none"> Microsoft Windows 11: Microsoft Edge v96 and Chrome v96 Safari versions depend on the operating system: <ul style="list-style-type: none"> iPad (iOS 15.0): Safari 15.0 for Oracle RDC Onsite only MacBook (macOS Big Sur Version 11.6): Safari 15.0 for Oracle RDC Onsite only
Adobe Reader	Adobe Acrobat Reader DC 21 or Adobe Acrobat Reader 2020 (Classic Track) are required for viewing reports, including Patient Data Reports (PDRs)
Adobe Acrobat	Adobe Acrobat Standard DC 21 or Adobe Acrobat 2020 (Classic Track) are required for creating annotated layouts
Oracle Java Runtime Environment (JRE)	JRE 1.8 update 391 or later, also known as JRE 8

For more information, see:

- [Database Tier Operating System Requirements](#)

Database Tier Operating System Requirements

To verify that your system fits the requirements listed in [Table 1-1](#) do the following in UNIX or Windows:

UNIX

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

```
uname -a
```

In addition, for Linux, enter the following command:

```
more /etc/*release*
```

Windows

To verify Windows operating system details, navigate to the Control Panel, then System and Security, then System.

Supported Configurations with Oracle Data Guard and RAC

Oracle Clinical supports a distributed environment over a network or within an Exadata machine.

For more information, see:

- [Supported Configurations with Oracle Real Application Clusters \(RAC\)](#)
- [Supported Configurations with Oracle Data Guard](#)

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](#)
- [Node 2: Install the Minimum Required as a RAC Node](#)
- [Node 3: Install Everything Required for Oracle Clinical as Backup](#)

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

- 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 9.4 (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. For more information, see [Set Up the Parametrized Submission Process](#).

 **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).

Recommended Options for RAC

Oracle Clinical 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® Database 2 Day + Real Application Clusters Guide* both at <https://docs.oracle.com/en/database/oracle/oracle-database/19/clustering.html>
- *Grid Infrastructure Single Client Access Name (SCAN) Explained* (My Oracle Support Article ID 887522.1).

- Oracle Data Guard and other high availability documentation at <https://docs.oracle.com/en/database/oracle/oracle-database/19/sbydb/index.html>

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

Oracle Data Guard is included in Oracle Database Enterprise Edition.

Download the Software

In this section:

- [Create Staging Areas](#)
- [Download the Oracle Clinical 5.4.1 Media Pack](#)
- [Download Patches from My Oracle Support](#)
- [Download Oracle Java Development Kit](#)
- [Download the Java Runtime Environment](#)
- [Download Adobe Reader](#)
- [Download JSpell \(Optional\)](#)

Create Staging Areas

1. Create one staging area each on the database server and on the application server.
2. Create one directory, in each staging area, for each media pack disk, patch, or other software unit, and give the directory a logical name.

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

Disk or Patch Name	Source
Oracle Clinical Release 5.4.1 Documentation	Select the latest release: https://docs.oracle.com/en/industries/health-sciences/clinical-remote-capture/5.4.1/index.html
Oracle Clinical Release 5.4.1	Media Pack
Oracle Database 19c (19.3.0.0) — Linux x86-64	Media Pack – Oracle Database 19.3.0.0.0
Oracle Database 19c (19.3.0.0) — Solaris Sparc 64	Media Pack – Oracle Database 19.3.0.0.0
Oracle Database 19c (19.3.0.0) — HP IA	Media Pack – Oracle Database 19.3.0.0.0
Oracle Database 19c (19.3.0.0) — Windows x64	Media Pack – Oracle Database 19.3.0.0.0

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

Disk or Patch Name	Source
Oracle Clinical Release 5.4.1 Documentation.	Select the latest release: https://docs.oracle.com/en/industries/health-sciences/clinical-remote-capture/5.4.1/index.html
Oracle Clinical Release 5.4.1	Media pack
Oracle WebLogic Server 12c (12.2.1.4)	Media Pack – Oracle WebLogic Server 12.2.1.4.0
Oracle Fusion Middleware 12c Infrastructure	Media Pack – Oracle Fusion Middleware 12c Infrastructure 12.2.1.4.0
Oracle Forms and Reports (12.2.1.19)	Media Pack – Oracle Forms and Reports 12.2.1.19
Oracle Java Development Kit 1.8, also known as JDK 8; see Download Oracle Java Development Kit	My Oracle Support
Java Runtime Environment (JRE) 1.8	https://www.oracle.com
Note: JRE is not a required component of the Application Server Technology Stack. However, it can be made available for the client download from the application server; see Download the Java Runtime Environment	
Adobe Reader; see Download Adobe Reader	http://www.adobe.com
JSPELL Spell Checker SDK for J2EE; see Download JSPELL (Optional)	http://www.jspell.com
Microsoft Visual C++ 2015-2022 redistributable - 14.38.33135.0	https://learn.microsoft.com/en-US/cpp/windows/latest-supported-vc-redist?view=msvc-170#visual-studio-2015-2017-2019-and-2022

Download the Oracle Clinical 5.4.1 Media Pack

To download the software:

1. Go to <https://edelivery.oracle.com> and log in.
2. From the drop-down next to the search field, select **Download Package**.
3. In the search field, type *Oracle Clinical*.
4. From the search result, select **Oracle Clinical 5.4.1.0.0**.
5. Click **Continue**.
6. Select the appropriate platform for which you want to download the media pack, and click **Continue**.
7. Read the license agreement and select the checkbox to accept the license agreement.
8. Click **Continue**.
9. Review the media pack components you want to download, and click **Download**.
10. Select the location where you want to save the `Oracle_SSN_DLM_*.exe` file, and execute the file.

11. Select a location in the appropriate staging area to download the zip files of the media pack, and click **Next**.
12. Extract each part_number.zip file into a meaningfully named directory.
13. 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 oc_middleware_installer.zip.

Download 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.

Download Oracle Java Development Kit

To download 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 *Supported Java SE and Java Component Downloads on MOS* (Document ID 1439822.1).
4. Scroll down the list of JDK versions to **Oracle JDK 8 Update 391** (Patch 35854934).

Note:

Check Oracle Clinical Versions 5.4.x, 5.2.x, 5.1.0, 5.0.1, 4.6.6, and 4.6.0 Summary of Patches Available (Document ID 121863.1) on My Oracle Support to see if a more recent version is supported.

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.

To install JDK, see [Install Oracle Java Development Kit](#).

Download the Java Runtime Environment

Oracle Clinical and the RDC Administration application require that Java Standard Edition (SE) Runtime Environment (JRE) 1.8.0.311—also known as JRE 8 Update 311—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 [Make the Java Runtime Environment Available for Download](#).

To download JRE:

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 My Oracle Support (Document ID 1439822.1).
4. Scroll down the list of JRE versions to **Oracle JRE 8 Update 391 (Public) or later version**.
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.

Download Adobe Reader

Adobe Reader is required on the Reports Server and on client computers.

- Download Adobe Reader from <http://www.adobe.com>.

Download 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 [Install and Configure JSpell Spell Checker SDK \(Optional\)](#).

Use the Silent Installer (Optional)

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 5.4.1 media pack disk under `Disk1\stage\Response` in the `.zip` file for the application server or for the appropriate database operating system.

The table below 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	Response File	Parameter Information
Oracle Clinical Database Server for Linux	oracle.pharma.oc.server.unix.Complete.rsp	Gather Required Information for Oracle Clinical Database Server
Oracle Clinical Database Server for Solaris	oracle.pharma.oc.server.unix.Complete.rsp	Gather Required Information for Oracle Clinical Database Server
Oracle Clinical Database Server for HP	oracle.pharma.oc.server.unix.Complete.rsp	Gather Required Information for Oracle Clinical Database Server
Oracle Clinical Database Server for Windows	oracle.pharma.oc.server.windows.Complete.rsp	Gather Required Information on Oracle Clinical Database Server for Windows
Oracle Clinical Database—fresh installation	oracle.pharma.oc.db.install.Complete.rsp	Gather Required Information for Oracle Clinical Database
Oracle Clinical Database—upgrade and configure	oracle.pharma.db.upgrade.install_type_1.rsp	Gather Required Information for Oracle Clinical Database
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	Gather Required Information for Oracle Clinical Database
Oracle Clinical Front End	oracle.pharma.oc.frontend.Custom.rsp	Gather Required Information for Oracle Clinical Front End
Oracle Clinical Reports Server	oracle.pharma.oc.reportserver.Complete.rsp	Gather Required Information for Oracle Clinical Reports Server

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/19.3.0.0/dbhome_1/  
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 19.3.0 *Oracle Database Installation Guide* for your operating system:

- **Linux:** <https://docs.oracle.com/en/database/oracle/oracle-database/19/ladbi/using-response-files.html>
- **Solaris:** <https://docs.oracle.com/en/database/oracle/oracle-database/19/ssdbi/using-response-files.html>
- **HP-UX Itanium:** <https://docs.oracle.com/en/database/oracle/oracle-database/19/hpdbi/using-response-files.html>
- **Windows:** <https://docs.oracle.com/en/database/oracle/oracle-database/19/ntdbi/using-response-files.html>

Choose a Character Set

For Oracle Clinical and RDC, Oracle strongly recommends that you use the AL32UTF8 character set. However, 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/opasettings.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.

Restrictions:

- You must use the **same character set on the database tier and the application tier**. Otherwise Oracle Clinical may store some special characters incorrectly in the database.
- 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**.

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

Apply the Latest Oracle Clinical Patches

- Check My Oracle Support article *Oracle Clinical Summary of Patches Available* (Article ID 121863.1) for the latest patch set and patches, and apply it/them.

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.

For more information, see:

- [Oracle Clinical Remote Data Capture Onsite](#)
- [Oracle Thesaurus Management System](#)
- [Oracle Life Sciences Data Hub](#)
- [SAS](#)
- [Custom Applications for Oracle Clinical](#)

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 [RDC and Oracle Clinical Licenses](#).

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*.

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.

SAS

Oracle Clinical supports integration with the statistical software application SAS 9.4 for data extract.

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 Life Sciences 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.

2

Upgrade to Release 4.6.6 (If Needed)

If you are currently using a release of Oracle Clinical earlier than Release 4.6.6, you must first upgrade Oracle Database, the Oracle Clinical database server and Oracle Clinical databases to Release 4.6.6.

For more information, see:

- [Upgrade to Release 4.6.2](#)
Upgrade to Release 4.6.2, if you are using a release prior to 4.6.2.
- [Upgrade to Release 4.6.6](#)
Upgrade to Release 4.6.6 after upgrading to 4.6.2, or if you are using a release higher than 4.6.2 and lower than 4.6.6.
- [Upgrade to Release 5.2.2](#)

Upgrade to Release 4.6.2

Upgrade to Release 4.6.2, if you are using a release prior to 4.6.2.

If you are currently using a release of Oracle Clinical prior to Release 4.6.2, you must first upgrade Oracle Database, the Oracle Clinical database server and Oracle Clinical databases to Release 4.6.2.



Note:

You do NOT need to install the 4.6.2 application tier because the technology stack is new in Release 5.x and you must do a fresh install of the whole application tier.

If you are already using Release 4.6.2 or higher, you can skip this section.

1. Open a Service Request (SR) on My Oracle Support at <https://support.oracle.com> to download the Release 4.6.2 media, which are no longer publicly available.
2. Download the most recent version of the 4.6.2 *Installation Guide* from <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>.
3. Read Chapter 1 of the Release 4.6.2 *Installation Guide* to plan your installation.
4. In the Release 4.6.2 *Oracle Clinical Installation Guide* Chapter 12, *Upgrading an Oracle Clinical Installation to Release 4.6.2* perform the tasks in Section 12.2, "Completing Other Pre-Upgrade Tasks."
5. Do Section 12.4, "Installing Oracle Clinical 4.6.2 on the database server." This step is needed to upgrade databases to 4.6.2.
6. Do Section 12.5, "Upgrading Oracle Clinical 4.6.2 to the New Oracle 11gR2 Oracle Home" to upgrade your databases to the new Oracle Home.

7. Do Section 12.6, "Upgrading Database Objects to Oracle Clinical 4.6.2"

 **Note:**

Do **NOT** follow the other instructions in Section 12.7 "Installing and Configuring Other Components for Oracle Clinical".

8. Check section 12.9, "Repairing Oracle Clinical Data." If you have not already run the Find and Fix scripts that are available, run them now.
9. Next, follow instructions below to upgrade to Release 4.6.6.

Upgrade to Release 4.6.6

Upgrade to Release 4.6.6 after upgrading to 4.6.2, or if you are using a release higher than 4.6.2 and lower than 4.6.6.

1. If you are on Release 4.6.2, 4.6.3, 4.6.4, or 4.6.5, upgrade to Release 4.6.6 following instructions in the Release 4.6.6 release notes on My Oracle Support, document ID 1459178.1.

 **Note:**

You do NOT need to install the 4.6.6 application tier because the technology stack is new in Release 5.x and you must do a fresh install of the whole application tier.

2. In addition:
 - If you are upgrading from Oracle Clinical 4.5.x, follow instructions in the *Oracle Clinical Administrator's Guide* "Troubleshooting" chapter, "Managing High Sequence Numbers" section.
 - If you are upgrading from Oracle Clinical 4.6.x check the same documentation to proactively determine whether you need to reseed any sequences.

Upgrade to Release 5.2.2

- If you are on Release 4.6.6, upgrade to Release 5.2.2 by following instructions in the *Oracle Clinical Upgrade Guide Release 5.2.2*.

 **Note:**

You do NOT need to install the 5.2.2 application tier because the technology stack is new in Release 5.4 and you must do a fresh install of the whole application tier.

3

Upgrade Oracle Database Server Code and Databases

In this chapter:

- [Stop Processes](#)
- [Back Up Your Database\(s\)](#)
- [Upgrade Oracle Database](#)
- [Set Initialization Parameters](#)
- [Create a Secret Store Directory](#)

Stop Processes

Before you start to upgrade your system to Oracle Clinical 5.4.1, complete the preliminary tasks described in this section:

- [Stop PSUB](#)
- [Prevent Access to Oracle Clinical Databases](#)

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 rxcprod account.
2. Set the environment variables for the database and code environment.
3. Enter the following command:

```
stop_psub database_name code_environment
```

Note:

Enter *rxcprod_password*, if prompted.

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 $OPA_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**.

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:

1. Place the database in restricted mode.
2. Provide restricted session access to the following accounts:
 - OPA
 - RXC
 - RXA_DES
 - RXC_SERVLETST
 - SYSTEM
3. After you complete the upgrade, remove the restricted access from the databases and user accounts.

Back Up Your Database(s)

- Back up your database(s).

Upgrade Oracle Database

In this section:

- [Upgrade the Database to Oracle Database 19c \(19.3.0\)](#)

Upgrade the Database to Oracle Database 19c (19.3.0)

If your Oracle database version is 11.2.0.4 or 12.1.0.2, you can upgrade the database to the 19c version.

Do one of the following:

For more information, see:

- [Upgrade in Place from Oracle Database 11.2.0.4 or 12.1.0.2 to 19c](#)
- [Clone Your Database on a Oracle Database 19c](#)

Upgrade in Place from Oracle Database 11.2.0.4 or 12.1.0.2 to 19c

Follow instructions in the *Oracle Database Upgrade Guide - 19c* at <https://docs.oracle.com/en/database/oracle/oracle-database/19/upgrd/> using the Database Upgrade Assistant (DBUA) option.

For more information, see Method 1 in the *Upgrade and Migrate to Oracle Database 19c* White Paper at <https://www.oracle.com/a/tech/docs/twp-upgrade-oracle-database-19c.pdf>.

Clone Your Database on a Oracle Database 19c

To clone your database on a Oracle Database 19c:

1. Install Oracle Database 19c.
2. Create an Oracle Database Container Database (CDB) to use one or more pluggable databases.

 **Note:**

If you are upgrading multiple databases, you still need only one CDB.

3. Update the listener and tnsnames.ora.
4. Clone your database. For instructions, see *Cloning Oracle Clinical and TMS Databases* White Paper (Doc ID 883213.1) on My Oracle Support.

Set Initialization Parameters

After the upgrade completes:

1. Set the init.ora parameters. See [Table 3-1](#) for parameter values.
2. Stop and then start the database to activate the modified init.ora parameters.

 **Note:**

Do NOT SET the DB_DOMAIN parameter. In Release 5.1 onward, this causes problems with the Patient Data Report generation.

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 [Table 3-1](#) 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.

Table 3-1 Required and Recommended Initialization Values in the init.ora File

Parameter	Value	Comments
COMPATIBLE	19.3.0	Specifies the release with which the Oracle server must maintain compatibility.
DB_BLOCK_SIZE	16384 bytes	You cannot change this value after you create the database.
DB_CACHE_SIZE	150 MB	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
DB_DOMAIN	null	DO NOT set this value. In Release 5.1 onward, setting this value causes problems with the Patient Data Report generation.
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 this parameter to a value as per the number of concurrent users accessing the system.
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_ADAPTIVE_PLANS	FALSE	Controls adaptive plans. Adaptive plans are execution plans built with alternative choices that are decided at run time based on statistics collected as the query executes.
OPTIMIZER_ADAPTIVE_STATISTICS	FALSE	Controls adaptive statistics. Some query shapes are too complex to rely on base table statistics alone, so the optimizer augments these statistics with adaptive statistics.
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	19.1.0	Acts as an umbrella for enabling a series of optimizer features based on an Oracle release number.
PGA_AGGREGATE_TEMPORARY_SIZE	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.

Table 3-1 (Cont.) Required and Recommended Initialization Values in the init.ora File

Parameter	Value	Comments
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.

Create a Secret Store Directory

- Create a directory that is accessible to the `opapps` user and different from the Oracle Wallet location.

Example location: `opa_home/sec_store/db_name`

The Installer fails if this directory is not created before running the Installer.

4

Upgrade Oracle Clinical Database Components on UNIX

This chapter describes how to upgrade the Oracle Clinical database server on a UNIX computer.



Note:

See [Use the Silent Installer \(Optional\)](#) for instructions for running the Installer as a file with pre-entered parameter values.

For more information, see:

- [Upgrade the Oracle Clinical Database Server](#)
- [Upgrade Oracle Clinical Databases](#)
- [Preserve Your Database Customizations](#)

Upgrade the Oracle Clinical Database Server

To complete to upgrade on UNIX database servers, perform the following tasks:

- [Grant Access for the opapps Account](#)
- [Set Permissions](#)
- [Check for an ORA-29548 Error](#)
- [Gather Required Information for Oracle Clinical Database Server](#)
- [Prepare to Install the Oracle Clinical Database Server Software](#)
- [Upgrade the Oracle Clinical Database Server Software](#)
- [Perform Post-Upgrade Tasks](#)

Grant Access for the opapps Account

- Grant write access for the opapps account to the ORACLE_HOME directory and its contents.

Set Permissions

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.

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](#)

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
```

Grant Access to the `ORACLE_HOME` Directory

You must change the access settings for this directory before you install Oracle Clinical, because the Oracle Clinical Installer checks if the `ORACLE_HOME` directory exists and if it has write access.

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 19c Release (19.3.0.0.0) installation.

Note that the oraenv script gives an error if run by a non-Oracle user. To avoid this error, see [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.

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.

Check for an ORA-29548 Error

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

```
opa_setup database_name code_environment
```

3. Connect to SQL*Plus as the SYS user:

```
sqlplus sys/password
```

4. Run the following command to check for the ORA-29548 error:

```
select dbms_java.get_jdk_version() from dual;
```

If no error appears and the command retrieves the JDK version, skip to [Gather Required Information for Oracle Clinical Database Server](#).

If you see the following error, continue with the next step to fix it:

```
ERROR at line 1:  
ORA-29548: Java system class reported: release of classes.bin in the database  
does not match that of the oracle executable
```

5. To correct the ORA-29548 error, run the following script:

```
start update_javavm_db.sql
```

Gather Required Information for Oracle Clinical Database Server

Have the following information ready to enter in the Installer:

- 1. Home Details:** The `ORACLE_HOME` location where you installed Oracle Database 19c (19.3.0.0).
For example: `root:/app/oracle/product/19.3.0.0/dbhome_1`
- 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:
`/pharm/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_USER:** Choose directory for `RXC_USER`; Oracle recommends:
`/pharm/home/opapps`
- 7. Oracle Wallet location and password:** The Installer uses these to create the database Wallet in the location you specify. If you are upgrading, you can enter the existing location and password.
The database Wallet stores the password for:
 - The OCPSUB proxy account, which is used for database access for parametrized submission (PSUB) jobs. Its credentials are created in this Wallet by the Installer.

Prepare to Install the Oracle Clinical Database Server Software

Note:

Verify that the `libnsl.so` library or a soft link `libnsl.so` exists in the user libraries directory. Check the following locations with the `"ls -lrt libnsl*"` command to see which location returns results for `libnsl.so.1` or `libnsl.so.2.:`

```
/usr/lib  
/usr/lib64
```

Under this location, if `libnsl.so` does not exist, then create a soft link by using one of the existing soft links, that is, `"ln -s libnsl.so.2 libnsl.so"` or `"ln -s libnsl.so.1 libnsl.so"`.

- 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`.

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 [Download the Software](#).
5. Open the `ldflags` file at `root: app/oracle/product/19.3.0.0/dbhome_1/lib` and add the `-lnnz19` flag.

Upgrade the Oracle Clinical Database Server Software

1. Log in to the server computer using the `opapps` account.
2. In the staging area, locate the directory where you downloaded Oracle Clinical and extract the `.zip` file for your database 19c 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 nor 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/19.3.0.0/dbhome_1/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/19.3.0.0/dbhome_1/  
oraInst.loc
```

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

 **Note:**

See [Use the Silent Installer \(Optional\)](#) 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 **OC Server for UNIX 5.4.1.0.x**.
7. Follow the instructions on the installation screens, providing the information you assembled in [Gather Required Information for Oracle Clinical Database Server](#).
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/541/relink_rxc.log
```
 - c. Open the `installActionstimestamp.log` in the `oraInventory/logs` directory.

Perform Post-Upgrade Tasks

 **Note:**

To perform the required changes done for PDR hyperlinks during DCI form version generation, follow the instruction in Doc ID 2763299.1 on My Oracle Support.

This section describes the following tasks that you perform to complete the upgrade of Oracle Clinical database server on a UNIX computer:

- [Complete the Setup of the opapps Account](#)
- [Limit Permissions on the XMLTEMP Folder](#)
- [Review the opa_settings File](#)
- [Check for Oracle Clinical Databases on a UNIX Server](#)

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 19c (19.3.0.0.0).

`OPA_HOME` is the directory where you installed Oracle Clinical database server.
 - c. Source the `.cshrc` file when you finish editing it:

```
source .cshrc
```
 - d. For HP-UX Port, copy `$ORACLE_HOME/bin/oraenv` to `$OPA_BIN/oraenv_opa`.
For example,
`$ORACLE_HOME/bin/oraenv` becomes `$OPA_BIN/oraenv_opa`
`ORACLE_HOME: Oracle 19c Home`
`OPA_BIN: <OPA Home>/bin`

Limit Permissions on the XMLTEMP Folder

To reduce security risks, you should limit permissions on the XMLTEMP folder for all database server installations.

1. Log in as `opapps`.
2. Go to the `OPA_HOME` directory.
3. Modify `chmod <permission> xmltemp` as follows:

```
chmod 777 xmltemp
```

Review the opa_settings File

The Installer creates the `opa_setting` file and enters all necessary entries and default values for the Oracle Clinical environment.

1. Review the `opa_settings` file in the following directory:
`OPA_HOME/bin`
2. Adjust the default values for the Oracle Clinical environment., if necessary.

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

 **Note:**

- The `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 [Choose a Character Set](#) .
- `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`.

Check for Oracle Clinical Databases on a UNIX Server

As part of the implementation of the PDR hyperlinks on superscripts, a new script post-processes DCI Form Version templates to insert hyperlink placeholders. This process can fail with error `ORA-27369`, when a database post-install step has not been completed. For example, for a database on HP-UX, refer to <https://docs.oracle.com/en/database/oracle/oracle-database/19/hpdbi/oracle-database-postinstallation-tasks.html#GUID-FCF693BF-FB7F-4FA6-81BD-DF669675D401>. You can also refer to My Oracle Support Article ID 391820.1, Scheduled Job Running Shell.

Upgrade Oracle Clinical Databases

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.

If you are upgrading your database using export and import, do the following:

1. Perform one of the following:
 - If you are upgrading your database through export and import:
 - a. Make sure `GLOBAL_NAME` does not include the domain name. To do so, leave `DB_DOMAIN` null when you create the target database instance.
 - If you are upgrading an existing database:

You can successfully install Oracle Clinical in a pluggable database only if the database is configured to receive connections as `SERVICE` rather than the `SID`. The `DB_NAME` in `OCL_STATE` reference codelist must match the service name. Further, the `OWNING_LOCATION` and `LOCATION_CODE` in several tables must match the `DB_NAME`. The `OWNING_LOCATION` and `LOCATION_CODE` have a limit of maximum 15 characters. Therefore, the

SERVICE name and DB_NAME also have a limit of maximum 15 characters. To satisfy this limitation, remove the domain name from the GLOBAL_NAME and DB_NAME. To do so:

a. Back up your database.

b. Connect to SQL*Plus as the SYS user:

```
sqlplus sys/password
```

c. Check the current database global name:

```
select * from global_name;
```

d. Update the props\$ table to update the global_name:

```
update props$ set value$='New name without domain' where name =  
'GLOBAL_DB_NAME';  
commit;
```

e. Verify that the global database name does not include the domain name:

```
select * from global_name;
```

2. Reset the OWNING_LOCATION and LOCATION_CODE so that they match. For instructions, see *Cloning Oracle Clinical and TMS Databases* (Doc ID 883213.1) on My Oracle Support.

For more information, see:

- [Gather Required Information](#)
- [Run the Installer](#)
- [Review the Log Files for Upgrade Results and Errors](#)
- [Compile Invalid Objects](#)
- [Perform Post-Upgrade Database Tasks](#)

Gather Required Information

Make sure you have the information below 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 have the option to skip the upgrade but rerun all recreatable object scripts (views, packages, functions, and so on) against the database.

1. Home Details: The ORACLE_HOME location where you installed Oracle Database 19c (19.3.0.0).

For example: `/app/oracle/product/19.3.0.0/dbhome_1/`

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

Drive: `/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. Enter the service name for the database to be installed
5. Enter the database server name and database port.
6. Know if you plan to use either Automatic Storage Management (ASM) or Real Application Clusters (RAC). This affects the Installer behavior for validating tablespaces.
7. Location for tablespace datafiles. You can change the default sizes by editing the script before running the Installer.

If you had selected Yes in the previous step, prefix the location for tablespace datafiles with "<ASM disk group name>". For example, <ASM disk group name>/<location for tablespace datafiles>.

To get the location for tablespace datafiles, execute the following command:

```
show parameter db_create_file_dest
```

8. Provide the database configuration parameter.
9. Location and password for the Wallet created during Oracle Clinical database server installation to store credentials for OCPSUB and RXC_DISC_REP.
10. You will need to enter passwords for the following:
 - 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.

- 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*.

11. 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.
12. Database host name and port number
13. 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 have multiple databases, enter the host name for the database designated as the Global Library location.
14. Location of the secret store folder you created in [Create a Secret Store Directory](#).

Run the Installer

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 19c Release (19.3.0.0.0) 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 [Download 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/19.3.0.0/dbhome_1/  
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/19.3.0.0/dbhome_1/  
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 5.4.1.0.x**. Follow instructions on screen, entering the information indicated in [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.

Review the Log Files for Upgrade Results and Errors

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

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

For example:

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

The rest of this section describes finding errors in the log files (as *logfile*), and descriptions of known errors.

For more information, see:

- [Find Errors](#)
- [Reencrypt Account Passwords](#)

Find 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 541  
cd $RXC_INSTALL  
/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

- **Oracle Solaris SPARC:** From the command line, enter:

```
opa_setup database 541
cd $RXC_INSTALL
/usr/xpg4/bin/grep -E '^ORA-|^PLS-|^SP2-' logfile | more
```

- **HP-UX Itanium:** From the command line, enter:

```
opa_setup database 541
cd $RXC_INSTALL
/usr/bin/grep -n -E '^ORA-|^PLS-|^SP2-' logfile | more
```

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."

1. Check if the "Passwords for the following schema accounts were not converted" section exists and if it lists any accounts.
2. If there are any accounts, reencrypt them using the `set_pwd` command.

For instructions, see the *Oracle Clinical Administrator's Guide*.

Normally, if you are upgrading from 5.0 or higher and have not changed the location of the Secret Store directory, you do not need to rerun `set_pwd`.

Compile Invalid Objects

When upgrading the Oracle Clinical database, the Installer calls and runs `compile_all_invalid.sql` to compile invalid objects. 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.

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, use instructions in the following sections:

- [Compile PL/SQL Code Before Running the Script](#)
- [Run the `compile_schema_invalid.sql` Script](#)

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, first run:

```
compile_schema_invalid.sql X
```

Then run:

```
compile_schema_invalid.sql RXC_PD
```

Run the compile_schema_invalid.sql Script

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 5.4.1, the default value is 541.

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 as shown in [Table 4-1](#).

Table 4-1 SQL Commands for Compiling Specific Types of Invalid Objects

To...	Enter this SQL Command...
Compile any invalid objects in <code>RXC_PD</code>	<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 <code>OPPS\$</code> 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 <code>RXC</code> and <code>RXA_DES</code> . 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
```

Perform Post-Upgrade Database Tasks

Note:

Make sure that you have installed the latest CPU certified for release 5.4.1 before performing any of the instructions below. For information on the latest certified CPU, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support > section Oracle Life Sciences Critical Patch Updates (CPU) Notes in the PDF file.

Perform each of the following tasks:

- [Set the Database Time Zone](#)
- [Pin Database Packages](#)
- [Migrate Users](#)
- [Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer](#)
- [Regenerate DCI Forms to Access from Microsoft Edge Browser](#)

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';
```

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 `rxcl_install` directory to pin the 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 `rxo` user:

```
sqlplus rxo/password
```

5. Run the `rxodbinit.sql` script:

```
start rxodbinit.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 `rxodbinit.sql` automatically.

Migrate Users

The requirements for users who need to run PSUB jobs changed in Release 5.0.

- Run a script to migrate user accounts to the new model, if you have not already done so.

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

Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer

After upgrading to Oracle Clinical 5.4.1 and setting initialization parameter **optimizer_features_enable** (see [Set Initialization Parameters](#)):

- Run scripts **ocstats.sql** and **opastats.sql** to gather statistics required for the Oracle Database Optimizer to be effective for internally used accounts.

Failure to execute these scripts can negatively impact performance.

For more information on gathering statistics and using dynamic sampling to improve performance, see the *Oracle Clinical Administrator's Guide*.

Regenerate DCI Forms to Access from Microsoft Edge Browser

For information, see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

Preserve Your Database Customizations

Since the 19.3.0.0 database server code will be in a different directory from the 11g/12c 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 Release 5.4.1 version of the file.

All customizable scripts are located in the same directories in Release 5.4.1 as in Release 4.6.2 or later. For information about customizing them, see the *Oracle Clinical Administrator's Guide*.

Table 4-2 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, 5.1, and 5.4
ocstats.sql	\$RXC_INSTALL	Gather statistics; see Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer .	New in 5.0, unchanged in 5.1, 5.2, or 5.4
opastats.sql	\$RXC_INSTALL	Gather statistics; see Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer .	New in 5.0, unchanged in 5.1, 5.2, or 5.4
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
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, not changed in 5.2 or 5.4

5

Upgrade the Oracle Clinical Database Server on Windows

In this section:

- [Upgrade the Oracle Clinical Database Server](#)
- [Upgrade Oracle Clinical Databases](#)

Upgrade 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
- 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

For more information, see:

- [Gather Required Information on Oracle Clinical Database Server for Windows](#)
- [Upgrade the Oracle Clinical Database Server Software](#)
- [Review the Log Files](#)
- [Oracle Clinical Database Server Directory Structure for Windows](#)
- [Perform Post-Upgrade Tasks](#)

Gather Required Information on Oracle Clinical Database Server for Windows

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

1. **Home Details:** The *ORACLE_HOME* location where you installed Oracle Database 19c (19.3.0.0.0).

For example: *drive:\app\oracle\product\19.3.0.0\dbhome_1*

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:
 - The OCPSUB proxy account, which is used for database access for parametrized submission (PSUB) jobs. Its credentials are created in the Wallet on the database server during Oracle Clinical database installation.

 **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.

Upgrade the Oracle Clinical Database Server Software

1. Log in to the server computer using the opapps account.
2. In the staging area, locate the directory where you downloaded Oracle Clinical and extract the .zip file for your database 19c if you have not already done so.
3. Run the following file as an administrator:

`Disk1\install\setup.exe`

The Installer opens to the Welcome screen.

 **Note:**

See [Use the Silent Installer \(Optional\)](#) 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 5.4.1.0.x**.
5. Follow the instructions on the installation screens, providing the information you assembled in [Gather Required Information on Oracle Clinical Database Server for Windows](#).

Review the Log Files

- Review the generated log files located at:

```
\Oracle\Inventory\logs
```

For example:

```
C:\Program Files\Oracle\Inventory\logs
```

Oracle Clinical Database Server Directory Structure for Windows

The Installer creates the following directory structure:

```
OPA_HOME
  \bin
  \xmltemp
  \oc
    \541
      \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 Life 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*.

Perform Post-Upgrade Tasks

To complete the upgrade of Oracle Clinical database server on a Windows computer, perform the following tasks:

- [Limit Permissions on the XMLTEMP Folder](#)
- [Review the opa_settings.bat File](#)

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, limit permissions on the XMLTEMP folder for all Windows database server installations.

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.

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.

1. Review the opa_settings.bat file in the following directory:

Drive:\opapps\bin

2. Adjust the default values, if necessary.

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

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 [Choose 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`.

Upgrade Oracle Clinical Databases

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.

If you are upgrading your database using export and import, do the following:

1. Perform one of the following:
 - If you are upgrading your database through export and import:
 - Make sure `GLOBAL_NAME` does not include the domain name. To do so, leave `DB_DOMAIN` null when you create the target database instance.
 - If you are upgrading an existing database:

You can successfully install Oracle Clinical in a pluggable database only if the database is configured to receive connections as SERVICE rather than the SID. The DB_NAME in OCL_STATE reference codelist must match the service name. Further, the OWNING_LOCATION and LOCATION_CODE in several tables must match the DB_NAME. The OWNING_LOCATION and LOCATION_CODE have a limit of maximum 15 characters. Therefore, the SERVICE name and DB_NAME also have a limit of maximum 15 characters. To satisfy this limitation, remove the domain name from the GLOBAL_NAME and DB_NAME. To do so:

- a. Back up your database.
- b. Connect to SQL*Plus as the SYS user:

```
sqlplus sys/password
```

2. Check the current database global name: `select * from global_name;`

3. Update the props\$ table to update the global_name:

```
update props$ set value$ = 'New name without domain'  
where name = 'GLOBAL_DB_NAME';  
commit;
```

4. Verify that the global database name does not include the domain name: `select * from global_name;`
5. Reset the OWNING_LOCATION and LOCATION_CODE so that they match. For instructions, see *Cloning Oracle Clinical and TMS Databases* (Doc ID 883213.1) on My Oracle Support.

For more information, see:

- [Check for an ORA-29548 Error](#)
- [Gather Required Information for Oracle Clinical Database](#)
- [Run the Installer](#)
- [Review the Log Files for Upgrade Results and Errors](#)
- [Compile Invalid Objects](#)
- [Perform Post-Upgrade Database Tasks](#)

Check for an ORA-29548 Error

1. Log in to the server computer.
2. Set environment variables:

```
set p1=database_name  
set p2=541  
opa_setup
```

3. Connect to SQL*Plus as the SYS user:

```
sqlplus sys/password
```

4. Run the following command to check for the ORA-29548 error:

```
select dbms_java.get_jdk_version() from dual;
```

If no error appears and the command retrieves the JDK version, skip to [Gather Required Information for Oracle Clinical Database](#).

If you see the following error, continue with the next step to fix it:

```
ERROR at line 1:  
ORA-29548: Java system class reported: release of classes.bin in the database  
does not match that of the oracle executable
```

5. To correct the ORA-29548 error, run the following script:

```
start update_javavm_db.sql
```

Gather Required Information for Oracle Clinical Database

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.

You have the option to skip the upgrade but rerun all recreatable object scripts (views, packages, functions, and so on) against the database.

Note:

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

1. **Home Details:** The *ORACLE_HOME* location where you installed Oracle Database 19c (19.3.0.0.0).
For example: Drive:\app\oracle\product\19.3.0\dbhome_1
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:
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.
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:
 - 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.

- 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 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 [Create a Secret Store Directory](#).

Run the Installer

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 [Download 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 5.4.1.0.x**. Follow instructions on screen, entering the information indicated in [Gather Required Information on Oracle Clinical Database Server for Windows](#).

Review the Log Files for Upgrade Results and Errors

- Review the generated log files located at:

```
OPA_HOME\oc\541\install
```

The rest of this section describes finding errors in the log files (as *logfile*), and descriptions of known errors.

For more information, see:

- [Find Errors](#)
- [Reencrypt Account Passwords](#)

Find Errors

To simplify reviewing upgrade results, run these commands for each of the database upgrade log files:

- Open a DOS window as an administrator and enter:

```
set p1=database
set p2=541
opa_setup
cd %RXC_INSTALL%
find /i "error" logfile | find /v "No error"
```

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."

1. Check if the "Passwords for the following schema accounts were not converted" section exists and if it lists any accounts.
2. If there are any accounts, reencrypt them using the `set_pwd` command.

For instructions, see the *Oracle Clinical Administrator's Guide*.

Normally, if you are upgrading from 5.0 or higher and have not changed the location of the Secret Store directory, you do not need to rerun `set_pwd`.

Compile Invalid Objects

When upgrading the Oracle Clinical database, the Installer calls and runs `compile_all_invalid.sql` to compile invalid objects. 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.

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 use instructions in the following sections. For more information, see:

- [Compile PL/SQL Code Before Running the Script](#)
- [Run the `compile_schema_invalid.sql` Script](#)

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, first run:

```
compile_schema_invalid.sql X
```

Then run:

```
compile_schema_invalid.sql RXC_PD
```

Run the `compile_schema_invalid.sql` Script

1. Open a DOS window as an administrator and enter:

```
set p1=database
set p2=541
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 as shown in [Table 5-1](#).

Table 5-1 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 OPSS\$ accounts	<code>start compile_schema_invalid OPSS\$%</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:**

This command compiles *all* invalid objects, including those in other schemas such as RXC and RXA_DES. However, the `compile_all_invalid.sql` script that the 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`

Perform Post-Upgrade Database Tasks

 **Note:**

Make sure that you have installed the latest CPU certified for release 5.4.1 before performing any of the instructions below. For information on the latest certified CPU, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support > section Oracle Life Sciences Critical Patch Updates (CPU) Notes in the PDF file.

Perform each of the following tasks:

- [Set the Database Time Zone](#)
- [Pin Database Packages](#)
- [Migrate Users](#)
- [Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer](#)
- [Regenerate DCI Forms to Access from Microsoft Edge Browser](#)

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';
```

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.

To pin the database packages located on a Windows server:

1. Log in to the Windows server computer as an administrator.
2. Set the Windows environment:

```
set p1=database
set p2=541
opa_setup
```

where `database` is the name of this database instance, and 541 is the alias for the version of Oracle Clinical.

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

```
cd %RXC_INSTALL%
```

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

```
sqlplus rxc/password
```

5. Run the `rxcdbinit.sql` script to pin the database packages:

```
start rxcdbinit.sql
```

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

Migrate Users

The requirements for users who need to run PSUB jobs changed in Release 5.0.

- Run a script to migrate user accounts to the new model, if you have not already done so.

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

Run Scripts to Gather Schema Statistics for the Oracle Database Optimizer

After upgrading to Oracle Clinical 5.4.1 and setting initialization parameter **optimizer_features_enable** (see [Set Initialization Parameters](#)):

- Run scripts **ocstats.sql** and **opastats.sql** to gather statistics required for the Oracle Database Optimizer to be effective for internally used accounts.

Failure to execute these scripts can negatively impact performance.

For more information on gathering statistics and using dynamic sampling to improve performance, see the *Oracle Clinical Administrator's Guide*.

Regenerate DCI Forms to Access from Microsoft Edge Browser

For information, see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

6

Set Up the Parametrized 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.

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

For more information, see:

- [Set Up PSUB](#)
- [Start and Stop the PSUB Service](#)
- [Test the PSUB Installation](#)
- [Customize the PSUB Service](#)
- [Run PSUB in a RAC Environment](#)
- [Manually Start the Advanced Queue Process \(If You Cloned a Database\)](#)

Set Up PSUB

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

- [Create Directories and Enter Values in OCL_STATE Local Reference Codelist](#)
- [Enable Users to Submit PSUB Jobs](#)
- [Enable opapps to Use the at Command \(UNIX Only\)](#)
- [Set Up Active Directory \(Windows Only\)](#)

Create Directories and Enter Values in OCL_STATE Local Reference Codelist

1. Create several directories on the PSUB server.
2. Enter paths of the new directories 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 [Set Up SAS](#) for information about new OCL_STATE settings related to SAS configuration.

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 under their own OS account home. (Instead PSUB outputs are stored temporarily in a user specific directory under PSUB root folder specified in PSUB_LOGS_DIR entry of the OCL_STATE local reference codelist. Then they are uploaded into database and can be viewed.)

New Users

To add new users:

1. Use the ocl_add_user.sql script, indicating which new users need to run PSUB jobs.
See the *Oracle Clinical Administrator's Guide* for more information.

Existing Users

If you are upgrading from a pre-5.0 version of Oracle Clinical, to give users who need to run PSUB jobs access to the opapps account:

- Use the migration script oclupg50migrateusers.sql.
See the *Oracle Clinical Administrator's Guide* for more information.

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.

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-UX:** /usr/lib/cron/at.allow
2. Add the following line to the **at.allow** file:
opapps

Set Up Active Directory (Windows Only)

If you are running PSUB on a Windows server that is a primary domain controller running Active Directory:

1. Add the PSUB account (typically opapps) to the domain.
2. 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

Start and Stop the PSUB Service

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

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

For more information, see:

- [Start and Stop PSUB Automatically in UNIX and Windows](#)
- [Start PSUB Manually in UNIX](#)
- [Start PSUB Manually in Windows](#)

Start and Stop PSUB Automatically in UNIX and Windows

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

For more information, see:

- [Start PSUB Automatically in UNIX](#)
- [Stop PSUB Automatically in UNIX](#)
- [Start PSUB Automatically in Windows](#)

Start 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/19.3.0.0/dbhome_1
```

```
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 541 venus
# Start database 2
start_psub pluto 541 pluto
```

where the database names are venus and pluto and your code environment is 541.

Stop 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/19.3.0.0/dbhome_1
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 541 wallet_alias
# Stop database 2
stop_psub pluto 541 wallet_alias
```

where the database names are venus and pluto and your code environment is 541.

Start PSUB Automatically in Windows

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\541\log* directory):

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

Perform the following actions:

- [Create a System Environment Variable](#)
- [Create a Batch File](#)
- [Schedule the Batch File and Testing the Setup](#)
- [Add a Shortcut](#)
- [Create a System Environment Variable](#)
- [Schedule the Batch File and Testing the Setup](#)
- [Create a Batch File](#)
- [Add a Shortcut](#)

Create 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 541 verbose t:\opapps\loc\541 wallet_alias
```

where `pluto` is the database ID and `RXC_ROOT` is `t:\opapps\loc\541`.

 **Note:**

If your entry requires a backslash (\), you must enter two (\\). Alternatively, you can enter the path using single forward slashes, for example, `t:/opapps/oc/541`.

Schedule 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.

Create a Batch File

- Create a batch file called 'psub_start1.bat' in the %RXC_ROOT%/log directory (for example, D:\opapps\loc\541\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
```

Note:

- "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.

Add a Shortcut

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

Start PSUB Manually in UNIX

To start the PSUB service on UNIX:

1. Log in as the opapps user. By default, the opapps user 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 541
```

3. Go to the PSUB location:

```
cd $RXC_PSUB
```
4. 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 541 prod
```

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

where 541 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.

5. If there are any errors, check the following log files in the \$RXC_CENTRAL_LOG directory:
 - rxcpsd_instance_environment_1.log
 - rxcpsd_instance_environment_2.log

Start 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 541 verbose c:\opapps\oc\541 <wallet_alias>`

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

where *541* 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:/opapps/oc/541`.

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.

Test the PSUB Installation

To test your PSUB installation:

1. Open Oracle Clinical.
2. Submit a 3GL job such as Batch Validation or a PL/SQL job such as Study Unfreeze.

3. Verify that Oracle Clinical creates the log and output files 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

Customize the PSUB Service

- 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*.

Run 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.

For more information, see [Supported Configurations with Oracle Real Application Clusters \(RAC\)](#).

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.STOP_QUEUE ('RXC.PSUB_REPLY_QUEUE', TRUE, TRUE);
EXEC DBMS_AQADM.STOP_QUEUE ('RXC.PSUB_SEND_QUEUE', TRUE, TRUE);
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.

7

Set Up SAS

Oracle Clinical supports the following configurations with SAS:

- SAS and Oracle Clinical on the same UNIX or Windows computer
- SAS on a separate UNIX 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.

The SAS/ACCESS Interface to Oracle requires Oracle SQL*NET on the computer with the SAS software installation. For this statistics application to function with Oracle Clinical Data Extract, you must install these SAS components:

- Base SAS
- SAS/ACCESS

For more information, see:

- [Set Up SAS Data Extract](#)
- [Install SAS on a UNIX Computer](#)
- [Install SAS on a Windows Computer](#)

Set Up SAS Data Extract

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

For more information, see:

- [Give Users Access to the opapps Account](#)
- [Add the opapps Account to the oclsasr User Group](#)
- [Give opapps Access to the Directory Specified in the RXC_SAS_VIEW Environment Variable](#)
- [Set Up SAS User Authentication and Set OCL_STATE Reference Codelist Values](#)
- [Changes in SAS Data Extract Implementation](#)

Give Users Access to the opapps Account

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

Add the opapps Account to the oclsascr User Group

- Add the opapps user to the oclsascr user group. It is the only user required to be in this group.

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

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

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

Set Up SAS User Authentication and Set OCL_STATE Reference Codelist Values

1. Choose one of the following user authentication methods:
 - Oracle Wallet
 - SAS password encryption with a proxy user
2. 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* for more information.

Changes in SAS Data Extract Implementation

If you are upgrading Oracle Clinical from any release prior to 5.0, SAS files generated in earlier releases of Oracle Clinical cannot be re-used in Release 5.0 or later because they contain a database connection string that is no longer usable.

You must re-run Data Extract job or gen_views utility to create new *.sas files. For more information and other options, see *Data Extract batch jobs fail in INCREMENTAL mode (after upgrading from OC 4.6.x to 5.x.x)* (Doc ID 2029953.1) on My Oracle Support (Doc ID 2029953.1).

Install SAS on a UNIX Computer

In this section:

- [Modify SAS 9.4 and opa_settings on UNIX](#)
- [Install SAS on the Same UNIX Computer as Oracle Clinical](#)
- [Install SAS on a Different UNIX Computer from Oracle Clinical](#)

Modify SAS 9.4 and opa_settings on UNIX

Oracle Clinical supports SAS 9.4. You can validate your Oracle Clinical installation, and then upgrade to SAS 9.4 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. See:

- [Prepare the SAS Template File](#)

Prepare the SAS Template File

Make the following modifications to the SAS template file:

1. Copy the SAS template file from `OPA_HOME/oc/541/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:

```
/usr/local/SASHome/SASFoundation/9.4/sas $*
```

Note:

For SAS 9.4, there is no need to use `$ORACLE_HOME/lib32` in `LD_LIBRARY_PATH` in the SAS script. Comment out the line that sets `LD_LIBRARY_PATH` to point to 32-bit libraries.

4. Save your work.

Install 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:

- [Set REMOTE_OS_AUTHENT to FALSE](#)
- [Set Up a SAS Connection](#)

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 [Set Initialization Parameters](#) for more information.

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`.

Oracle Wallet

This is the default option. The SAS connection is set up automatically.

SAS Encryption

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 connect 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;
```

Where, password is the database password of the user sas_proxy_user.

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 6.

For example, pwd.sas

8. Run the SAS files.

Install 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.

For more information, see:

- [Establish the Connection to SAS on a Different Computer](#)
- [Set Up SAS Security on a Different Computer](#)
- [Configure Private and Public Keys for Using SSH with SAS](#)

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.

NFS

1. 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.
2. 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.

Create opapps on the SAS Server

1. Create the opapps UNIX user account on the SAS server.
2. Create a group for opapps and put it in the group.
3. Link /etc/group with /etc/login/group on the SAS server if it is not the primary group for opapps.

Check init.ora

1. Open the init.ora file.
2. 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 [Set Initialization Parameters](#) for more information.

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/19.3.0.0/dbhome_1;cd $$SASDIR ;
/home/opapps/bin/sas -log $LOGNAME $3 $4 $5 $6 "
```

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`.

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 [Complete the Setup of 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. 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: `/pharm/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/wallet))) SQLNET.WALLET_OVERRIDE = TRUE
```

where `/pharm/home/opapps/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.

SAS Encryption

To set up a SAS connection using SAS encryption, follow instructions in [Set Up a SAS Connection](#).

Configure Private and Public Keys for Using SSH with SAS

If you are installing SAS on a different server on an intranet, do the following to establish an SSH connection from the PSUB server to the 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.

Install SAS on a Windows Computer

In this section:

- [Modify the opasettings.bat file](#)
- [Install SAS on the Same Windows Server Computer](#)
- [Install SAS on a Different Windows Server Computer](#)

Modify the opasettings.bat file

To use SAS 9.4 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
```

Install 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 [Install SAS on a Different Windows Server Computer](#).

In this section:

- [Set REMOTE_OS_AUTHENT to FALSE](#)
- [Set System Path](#)
- [Edit the SAS Config File and Grant Permissions](#)

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 [Set Initialization Parameters](#) for more information.

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 9.4 is installed in `C:\Program Files`):

```
C:\Program Files\SAS94\SharedFiles\Formats;C:\Program Files\SAS94\SASFoundation\9.4;
```

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\SAS94\SharedFiles\Formats;C:\Program Files\SAS94\SASFoundation\9.4;`

- 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.

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 location where you have installed SAS 9.4. In this following example: SAS 9.4 is installed in C:\Program Files:

```
C:\Program Files\SAS94\SASFoundation\9.4\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\9.4"*/
-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.

Install 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.

In this section:

- [Set REMOTE_OS_AUTHENT to FALSE](#)
- [Enable Executing Data Extract PSUB Jobs](#)
- [Edit the SAS Config File and Grant Permissions](#)

- [Set Values in OCL_STATE Reference Codelist](#)

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 [Set Initialization Parameters](#) for more information.

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.

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 9.4 is installed in C:\Program Files):

```
C:\Program Files\SAS94\SASFoundation\9.4\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.

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

8

Upgrade and Configure the Oracle Application Tier

If you are upgrading or migrating from an Oracle Clinical Remote Data Capture release other than version 5.2.1 or later, you cannot upgrade the application tier. You must complete a new install because releases 5.2.1 or later, 5.4, and 5.4.1 use a different technology stack compared to prior releases. See *Oracle Clinical Installation Guide* for more information.

For the upgrade from release 5.2.1, upgrade the application tier technology stack from version 12.2.1.3 to 12.2.1.4.

- Oracle Application Server 12c R2, which includes the Oracle Forms Server and the Oracle Reports Server. Both are required for Oracle Clinical.
- WebLogic Server 12c R2 and Oracle Application Developer Framework 12c R2. These are required for RDC.

You can install all components on the same machine or 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*.

This chapter describes how to upgrade Oracle Application Server, which includes the Oracle WebLogic Server, Oracle Fusion Middleware Infrastructure Software, Oracle Forms Server, and the Oracle Reports Server.

For more information, see *Oracle Fusion Middleware - Upgrade Common Tasks 12.2.1.4.0* at <https://docs.oracle.com/en/middleware/fusion-middleware/12.2.1.4/upgrade-tasks.html> and *Upgrading Oracle Forms from a Previous 12c Release* at <https://docs.oracle.com/en/middleware/developer-tools/forms/12.2.1.4/install-fnr/upgrading-oracle-forms.html#GUID-E9D8E1FF-A680-4D68-A8C5-780350309EDD>.

For more information, see:

- [Before You Start](#)
- [Gather Required Information](#)
- [Restart Computer and Stop All Servers](#)
- [Install Oracle Java Development Kit](#)
- [Install Oracle WebLogic Server 12.2.1.4](#)
- [Install the Oracle Fusion Middleware Infrastructure Software](#)
- [Install the Oracle Forms and Reports Servers](#)
- [Run Pre-Upgrade Readiness Check](#)
- [Upgrade the Domain Schema](#)
- [Run the Reconfiguration Wizard](#)

- [Upgrade the Forms Server](#)

Before You Start

In this section:

- [Identify a Single Account to Perform All Application Tier Installation Tasks](#)

Identify a Single Account to Perform All Application Tier Installation Tasks

Install all application tier components using the same user account you had when you installed version 12.2.1.4.

The account must have administrator privileges on the server computer.

Gather Required Information

Have the following information ready.

Note:

A new ORACLE_HOME needs to be created, the 12.2.1.19 upgrade is an out-of-place upgrade. The existing domains remain in the same place, FRDomain and OPADomain do not change their paths. The domain and component upgrade are in-place as the domain directory remains the same in the initial 12.2.1.4 ORACLE_HOME.

Note:

For OHS 12.2.1.19 on Windows, it is required to have Microsoft Visual C++ 2017 Redistributable. Otherwise, there will be errors when starting the ohs component and trying to access forms. For more information, see *Oracle HTTP Server Start Failed With 'exit status = -1073741515' In New Installation of FMW 12.2.1.3 on Windows Server* (Doc ID 2314112.1) on My Oracle Support. These libraries may already be installed, In this case, there will be an error message when trying to install them.

Install the 12.2.1.4 Oracle WebLogic Server:

- Home directory path for FMW 12.2.1.19; for example:
C:\Oracle122119\Middleware\Oracle_Home
- Email address to receive the security updates specific to your installation
- My Oracle Support password if you wish to receive the security updates through My Oracle Support

Install the Oracle Fusion Middleware Infrastructure Software:

- Home directory path for FMW 12.2.1.19; for example: C:\Oracle122119\Middleware\Oracle_Home
- Email address to receive the security updates specific to your installation
- My Oracle Support password if you wish to receive the security updates through My Oracle Support

Install the Oracle Forms and Reports Servers:

- Home directory path for Forms and Reports 12.2.1.19; for example: C:\Oracle122119\Middleware\Oracle_Home

Restart Computer and Stop All Servers

1. Restart the computer before starting the upgrade to 12.2.1.19.
2. Before starting the upgrade to 12.2.1.19, stop all servers and components.

For FRDomain, make sure Admin Server, WLS_FORMS, WLS_REPORTS, OHS, report server instance, and Node Manager are stopped.

For OPADomain, make sure Admin Server, managed server, and Node Manager are stopped.

Install Oracle Java Development Kit

To install Oracle Java Development Kit (JDK):

1. [Download Oracle Java Development Kit](#), if not already done.
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\jdk. "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\jdk.

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

Install Oracle WebLogic Server 12.2.1.4

1. In the staging area where you downloaded the media pack (see [Download the Software](#)), locate the directory where you downloaded Oracle WebLogic Server 12.2.1.4 Generic and Coherence and extract the WebLogic Server .zip file (V983364-01) if you have not already done so.
2. Log in as the user you selected in [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; `fmw_12.2.1.4.0_wls.jar`. For instructions, see *Oracle® Fusion Middleware Installing and Configuring Oracle WebLogic Server and Coherence for Release 12.2.1.4*, at <https://docs.oracle.com/en/middleware/fusion-middleware/12.2.1.4/wlsig/installing-oracle-weblogic-server-and-coherence-software.html#GUID-11F2824A-997D-4EDC-85EC-D0E3D1F0617A>.

The complete documentation set for Oracle WebLogic Server 12.2.1.4 is available at: <https://docs.oracle.com/en/middleware/fusion-middleware/weblogic-server/12.2.1.4/index.html>.

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 `wlserver` and `oracle_common`.

 **Note:**

Make sure you have installed Microsoft Visual C++ Redistributable for Visual Studio 2017 (x64). This is required for Oracle WebLogic Server 12c (12.2.1.4) and Oracle Forms and Reports 12c (12.2.1.19) Servers to invoke Data Capture API methods from custom clients.

Choose the WebLogic Server Install Type

1. Select **WebLogic Server**.
This is required in order to create a Node Manager.

Security Updates

 **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.

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

 **Note:**

Continue to click **Next** until you are finished. After the Installation Summary, the processing may take a few minutes. Deselect the Automatically Launch Configuration Wizard check box and click Finish to complete the 12c WebLogic Server installation.

Install the Oracle Fusion Middleware Infrastructure Software

1. In the staging area where you downloaded the media pack (see [Download the Software](#)), locate the directory where you downloaded the Oracle Fusion Middleware Infrastructure Software and extract the .zip file (V983368-01) if you have not already done so.
2. Log in as the user you selected in [Identify a Single Account to Perform All Application Tier Installation Tasks](#).
3. Install the Oracle Fusion Middleware Infrastructure Software using a Generic Package installer—This type of installer is a .jar file; `fmw_12.2.1.4.0_infrastructure.jar`.

 **Note:**

Use the same install directory that you specified when you installed WebLogic Server in [Install Oracle WebLogic Server 12.2.1.4](#).

Select "Fusion Middleware Infrastructure" as the installation type.

For instructions, see *Installing and Configuring the Oracle Fusion Middleware Infrastructure*, at <https://docs.oracle.com/en/middleware/fusion-middleware/12.2.1.4/infin/installing-infra-structure-software.html#GUID-943F11B4-DD9E-4631-8F5F-80B3ADC06F26>.

Install the Oracle Forms and Reports Servers

1. In the staging area where you downloaded the media pack (see [Download the Software](#)), locate the directory where you downloaded Oracle Forms and Reports 12c (12.2.1.19) for Microsoft Windows (64-bit) and extract the .zip file (V1033711-01) if you have not already done so.
2. Log in as the user you selected in [Identify a Single Account to Perform All Application Tier Installation Tasks](#).
3. Install the Oracle Forms and Reports 12c (12.2.1.19) using a Generic Package installer—This type of installer is an .exe file; `setup_fmw_12.2.1.19.0_fr_win64.exe`.

When asked, to choose an installation type, select **Forms and Reports Deployment**.

 **Note:**

Use the same install directory that you specified when you installed WebLogic Server in [Install Oracle WebLogic Server 12.2.1.4](#).

For instructions, see *Oracle® Fusion Middleware Upgrading to Oracle Forms and Reports* for Release 12.2.1.19, at <https://docs.oracle.com/en/middleware/developer-tools/forms/12.2.1.19/install-fnr/upgrading-oracle-forms.html#GUID-20AC6348-AA11-4D36-A460-8C06A0218A66>.

Run Pre-Upgrade Readiness Check

To identify potential issues with the upgrade, Oracle recommends that you run a readiness check before you start the upgrade process. Be aware that the readiness check may not be able to discover all potential issues with your upgrade. An upgrade may still fail, even if the readiness check reports success.

The Upgrade Assistant readiness check performs a read-only, pre-upgrade review of your Fusion Middleware schemas and WebLogic domain configurations that are at a supported starting point. The review is a read-only operation.

The readiness check generates a formatted, time-stamped readiness report so you can address potential issues before you attempt the actual upgrade. If no issues are detected, you can begin the upgrade process. Oracle recommends that you read this report thoroughly before performing an upgrade.

Once the new 12.2.1.4 ORACLE_HOME is created and Oracle WebLogic Server, Oracle Fusion Middleware Infrastructure Software, and Oracle Forms and Reports Servers are installed, run a pre-upgrade readiness check. You must run this check separately for FRDomain and OPADomain.

1. Run the following command to start the pre-upgrade readiness check:

```
<12.2.1.4_Oracle_Home>\oracle_common\upgrade\bin\ua.bat -readiness
```

- a. Select the **Domain Based** option and enter the domain location.
 - b. Select the **Include checks for all schemas** and **Include checks for all configurations** check boxes.
2. Enter the WebLogic domain directory where schemas and configurations will be checked. This will be the path to the domains directory from <12.2.1.3_Oracle_Home>. For example, C:\Oracle\Middleware\Oracle_Home\user_projects\domains\FRDomain.
 3. Check schemas and configuration in FRDomain.
Schemas to be checked:

- Oracle Platform Security Services – OPSS
- Oracle Audit Services – IAU
- Common Infrastructure Services – STB
- Oracle WebLogic Server - WLS_RUNTIME

Configuration to be checked:

- System Components Infrastructure
- Oracle HTTP Server
- Oracle JRF
- Common Infrastructure Services
- Oracle Forms Services

- Oracle Reports Services
4. Check schemas and configuration in OPADomain.
Schemas to be checked:
 - Oracle Platform Security Services – OPSS
 - Oracle Audit Services – IAU
 - Common Infrastructure Services – STB
 - Oracle WebLogic Server - WLS_RUNTIMEConfiguration to be checked:
 - System Components Infrastructure
 - Oracle HTTP Server
 - Oracle JRF
 - Common Infrastructure Services
 - Oracle Forms Services
 5. Enter the administrator database account credentials for checking the RCU OPSS schema. The account need to have DBA privileges (can be system account).

 **Note:**

Click **Connect** to make sure the credentials you entered are valid.

6. Enter the administrator database account credentials for checking account credentials for the RCU IAU and STB schemas. The account need to have DBA privileges (can be system account).
7. In the Readiness Progress screen, check that all the components should have a green status – upgrade not necessary or ready for upgrade.

For OPADomain in the Readiness Progress screen all the components should have a green status – upgrade not necessary or ready for upgrade; except for Oracle Forms Services. The Oracle Forms Service component for OPADomain will be marked as Failure but this can be ignored as Oracle Forms Service is not a part of OPADomain.

Upgrade the Domain Schema

When upgrading the application technology stack from 12.2.1.3 to 12.2.1.4 version the upgrade of the domain schema is not needed.

Run the Reconfiguration Wizard

Run the Reconfiguration Wizard For FRDomain

1. Open a DOS prompt and run:

```
<12.2.1.4_Oracle_Home>\oracle_common\common\bin\reconfig.cmd -log  
<path_to_log_file>\FRDomain_log.txt -log_priority=ALL
```

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

Select Domain

1. Select the FRDomain location; for example:
C:\Oracle\Middleware\Oracle_Home\user_projects\domains\FRDomain

Database Configuration Type

1. Select the **RCU data** check box under Specify AutoConfiguration Options Using.
2. Make sure the RCU database is correct.
3. Click **Get RCU Configuration**.

Component Datasources

1. Select all RCUs.
2. Click **Next**.

Advanced Configuration

1. Select only the **Topology** check box in the Advanced Configuration in the Reconfiguration Wizard.
Do not select the System Components check box. Those are automatically configured/upgraded by the Upgrade Assistant in the next steps.

Make a note of the FRDomain defaultCoherenceCluster port because for OPADomain a different port needs to be used. By default, it is 7574.

Run the Reconfiguration Wizard For OPADomain

1. Open a DOS prompt and run:

```
<12.2.1.4_Oracle_Home>\oracle_common\common\bin\reconfig.cmd -log  
<path_to_log_file>\OPADomain_log.txt -log_priority=ALL
```

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

Select Domain

1. Select the OPADomain location; for example:
C:\Oracle\Middleware\Oracle_Home\user_projects\domains\OPADomain

Datasources

1. Select the existing data sources.

Database Configuration Type

1. Select the **RCU data** check box under Specify AutoConfiguration Options Using.
2. Make sure the RCU database is correct.
3. Click **Get RCU Configuration**.

Component Datasources

1. Select all RCUs.
2. Click **Next**.

Advanced Configuration

1. Select all check boxes.

Default Coherence Cluster

1. Use a different port number other than the one used for FRDomain. For example, 7575.

Domain Frontend Host

- Deselect the **Configure Domain Frontend Host** check box.

Upgrade the Forms Server

Start the upgrade assistant in the new 12.2.1.4 Oracle Home to upgrade the Forms installation.

1. Run the following command:

```
<12.2.1.4_Oracle_Home>\oracle_common\upgrade\bin\ua.bat
```

2. Select the **All Configurations Used by a Domain** check box, and provide the FRDomain location.
3. Upgrade the components in FRDomain:
 - System Components Infrastructure
 - Oracle HTTP Server
 - Oracle JRF
 - Oracle Forms Services
 - Oracle Reports Services
4. In the Prerequisites screen, select all the check boxes.
5. In the Examine screen, make sure all the checks have the status "ready for upgrade" or "upgrade not necessary".
6. Click **Upgrade**.
7. Start all components for FRDomain, except the report server you created for OC 5.2.1 or TMS 5.3.

If OHS fails to start with exit status = 1 (startComponent ohs1), there is an issue in the httpd.conf files in the FRDomain.

The httpd.conf files can be found under:

- <12.2.1.3_Oracle_Home>\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\instances\ohs1\
- <12.2.1.3_Oracle_Home>\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1\

 **Note:**

Make sure the httpd.conf files have only one Listen directive for one specific port.

Listen <machine_name>:<port_number>

9

Upgrade the Oracle Clinical Front End

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, and WebLogic Server Domain (OPADomain).

The Oracle Application Server technology stack must be upgraded before you upgrade the Oracle Clinical Front End. See [Upgrade and Configure the Oracle Application Tier](#) for instructions.

For Oracle Clinical 5.4.1 Front End upgrade, OPADomain Admin Server and managed server must be running.

For more information, see:

- [Gather Required Information for Oracle Clinical Front End](#)
- [Install the Oracle Clinical Front End Components](#)
- [Make the Java Runtime Environment Available for Download](#)
- [Make the Oracle Clinical PDF Plug-in Available to Users](#)
- [Share the RDC Directory for Image Access](#)
- [Install and Configure JSpell Spell Checker SDK \(Optional\)](#)
- [Verify and Fix Environment Variables](#)
- [Set Up Automatic Startup](#)
- [Start Servers Manually](#)
- [Verify the Application Tier Installation](#)
- [Stop Servers](#)

Gather Required Information for Oracle Clinical Front End

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

- Home Details: Enter the following:
 - Name: OPA_HOME
 - Path: C:\opapps52

 **Note:**

Use the same location used for Oracle Clinical 5.2.1 or later installation.

 **Note:**

If Oracle Clinical 5.2.1 or later, or TMS 5.3.x has already been installed on this application server, OPA_HOME may already be set to C:\opapps52 or similar path and you must use this for Oracle Clinical 5.4.1 too. Do not create a new OPA_HOME if this was already created. The Oracle Clinical 5.2.x components will be placed by the installer under this OPA_HOME at the specified location for the Oracle Clinical 5.4.1 release.

- Java Home is the location where JDK 1.8.0_391 or higher was installed
- Oracle Fusion Middleware home directory:
 - If the technology stack has been upgraded from version 12.2.1.3 to 12.2.1.4, use the new 12.2.1.4 Oracle Home (post upgrade one). The upgrade to 12.2.1.4 is an out-of-place upgrade and a new oracle_home is created; for example, C:\Oracle12214\Middleware\Oracle_Home.
 - If the technology stack was fresh installed at version 12.2.1.4, for example if OC 5.2.2 Front End was already installed use the Oracle Home you had at the time of technology stack installation; for example, C:\Oracle\Middleware\Oracle_Home.
- Oracle Fusion Middleware User Projects directory:
 - If the technology stack has been upgraded from version 12.2.1.3 to 12.2.1.4, use the initial 12.2.1.3 Oracle Home (pre upgrade one) to select the user projects directory. The upgrade to 12.2.1.4 is an out-of-place upgrade and the domains reside in the 12.2.1.3 oracle home; for example, C:\Oracle\Middleware\Oracle_Home\user_projects.
 - If the technology stack was fresh installed at version 12.2.1.4, for example if OC 5.2.2 Front End was already installed, use the Oracle Home you had at the time of technology stack installation; for example, C:\Oracle\Middleware\Oracle_Home\user_projects.
- OPA home directory: By default, it is C:\opapps52.

 **Note:**

Use the same location used for OC 5.2.1 or later installation.

- OPADomain Administration Server configuration details:
 - Listen address
 - OPADomain Listen port number
 - OPADomain SSL listen port number
 - OPADomain WebLogic username
 - OPADomain WebLogic password
- OPADomain Node Manager configuration details:
 - Listen address
 - OPA Domain NodeManager Listen port number

- WebLogic username
- WebLogic Server password
- Database details (database used for data source created under OPADomain):
 - Server.Domain: for example, *servername.your_company.com*
 - Port number
 - Database service name
 - RDC Proxy Password (*rdc_midtier_proxy*)—the password you created when installing Oracle Clinical database objects.
- Managed Server configuration details:
 - Number of Managed Servers
 - Listen port start index
- Online help URL: If you have customized the online help, the URL where the customized online help is located.

Install the Oracle Clinical Front End Components

To install the Oracle Clinical Front End components:

1. Log in as the user you selected in [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 [Download the Software](#)).
3. Run the following file as an administrator:

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

The Installer opens to the Welcome screen.

Note:

See [Use the Silent Installer \(Optional\)](#) 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 5.4.1.0.x**.
5. Choose Install Type, select **No**.
6. Follow the instructions on the installation screens, providing the information you assembled in [Gather Required Information for Oracle Clinical Front End](#).
7. If the Installer detects that you have already installed Release 5.4.1 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.

8. **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**.

9. **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.

10. **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:
`\opapps52\log\setup.txt`

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

For more information, see:

- [Review the Installation Log Files](#)
- [Set Remote Method Invocation \(RMI\) JDBC Security to Secure](#)
- [Restart the Computer](#)
- [Add WebLogic Data Sources If Using Multiple Databases](#)

Review the Installation Log Files

- Review the generated installation log file, `installActionstimestamp.log`, located at:

`\Oracle\Inventory\logs`

For example:

`C:\Program Files\Oracle\Inventory\logs`

All generated log files have a timestamp appended to the name. For example:

`installActions2022-02-24_11-22-52AM.log`

Also, review the log files located in the `C:\opapps52\log` folder.

If you encounter any error, contact Life Sciences Support.

Set Remote Method Invocation (RMI) JDBC Security to Secure

1. Log in to the OPADomain WebLogic Server.
2. Go to **Summary of Servers**, select **Managed Server of OPADomain**, select **General**, and click **Advanced**.

3. Change the **RMI JDBC Security** setting to **Secure**.
4. Click **Save**.
5. Click **Activate Changes**.

Restart the Computer

To ensure that all configuration changes are initialized:

- Restart the computer before you continue with the next task in the installation process or before you install Oracle Clinical Reports Server.

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:

1. Create a WLS data source for RDC for each additional database.

If you also are using TMS on multiple databases:

- Create additional data sources for OPA.

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*.

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 [Download 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`.

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.



Note:

You should already have downloaded the plug-in, following instructions in [Download the Software](#).

1. Download the PDF plug-in from the link on the Oracle Clinical launch page.
The link on the launch page resolves to: `https://machine/opa54/rdc/opapdf.exe`.
2. To make the plug-in available from the launch page, follow the instructions in the readme file, located in the `opa_home\html\rdc` directory, to install the PDF plug-in on the client machine.

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 `opapps52\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.

For more information, see:

- [Share the Directory Across Multiple Computers](#)
- [Set Up the Image Directory on a Single Computer](#)

Share 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:\opapps52\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` (`opapps52\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/opa54/rdc/dcif_images`
 - RDC_DCIF_IMAGES_BROWSE: Set to Y to enable image browsing or N to disable image browsing.
 - RDC_DCIF_IMAGES_VALIDATE: If this registry variable is set to Y, you must have access to the network location for the directory specified in the RDC_DCIF_IMAGES variable and you must select a file from that directory. In addition, the network location must be inside the firewall.
7. Put the images that should be available for the Patient Data Report and graphic layouts in the image directory; by default, `dcif_images`.

Set Up the Image Directory on a Single Computer

If you have a single Forms server:

- Perform the setup in [Share the Directory Across Multiple Computers](#) except skip sharing the directory (steps 3 and 4 above) and set the RDC_DCIF_IMAGES registry entry to the full path; for example, `C:\opapps52\html\rdc\dcif_images`.

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.

For more information, see:

- [Install JSpell on Oracle Application Server](#)
- [Install the JSpell WAR File on the WebLogic Server](#)
- [Update the mod_wl_ohs.conf File for JSpell](#)
- [Stop and Start Oracle HTTP Server \(OHS\)](#)
- [Test the JSpell Servlet](#)
- [Update the formsweb.cfg File for JSpell](#)
- [Update the Windows System Registry for JSpell](#)
- [Test JSpell in the Graphic Layout Editor](#)

Install JSpell on Oracle Application Server

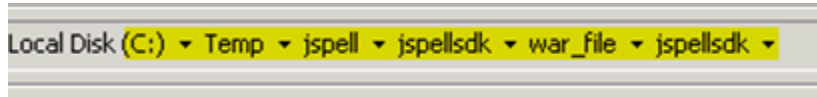
To install the JSpell on Oracle Application Server:

1. If you have not already done so, download and extract JSpell, following instructions in [Download 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*.

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\Server.Domain_OPA_1\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 **Managed Server Name** under **OPADomain** 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 Managed Server of OPADomain process; see [Start the Managed Server of OPADomain](#).
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.

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\Oracle_Home_FR\user_projects\domains\FRdomain\config\fmwconfig\components\OHS\instances\ohs1\moduleconf`

2. Open the **fmod_wl_ohs.conf** file.

3. Add the following entry:

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

Stop and Start Oracle HTTP Server (OHS)

To restart OHS:

1. Open a DOS prompt.
2. To stop OHS enter:

```
drive:\Oracle\Middleware\Oracle_Home_FR\user_projects\domains\FRdomain\bin\stopComponent.cmd ohs1
```

3. To start OHS enter:

```
drive:\Oracle\Middleware\Oracle_Home_FR\user_projects\domains\FRdomain\bin\startComponent.cmd ohs1
```

Test the JSpell Servlet

To test the JSpell Servlet:

1. Open a 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.

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_F  
ORMS\applications\formsapp_12.2.1\config
```

2. Open the **formsweb.cfg** file.
3. Find the **[opa54]** text section.
4. Append the following text string to the end of the **archive** parameter value:

```
jspellsdks.jar,jspellsdkn.jar
```

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.

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*.

Verify and Fix Environment Variables

Check values and correct them, if required, as mentioned below:

- [Check Values](#)
- [Correct Values](#)

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 [Download 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 [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 [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 [Correct Values](#).

Correct Values

To correct any of the above problems:

1. Navigate to `middleware_home\Oracle_Home_FR\oracle_common\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\jdk
```

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 [Check Values](#).

Set 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 [Start Servers Manually](#).

In this section:

- [Create boot.properties](#)
- [Increase the Delay for Auto Start OPADomain and FRDomain](#)
- [Set Up Scripts to Execute Automatically at Machine Startup](#)
- [Test Autostart](#)

Create boot.properties

Check if the boot.properties file exists in `Oracle_Home\user_projects\domains\FRDomain\servers\AdminServer\security`.

If not, create it as a plain text file with the following contents:

```
username = weblogic_username  
password = weblogic_user_password
```

By default, the WebLogic username is `weblogic`. This username and password will get encrypted after all services are started.

Increase the Delay for Auto Start OPADomain and FRDomain

For the OPADomain and FRDomain to start successfully, depending on the performance in your environment, you may want to increase the delay by which OPADomain and FRDomain start to allow time for Node Manager to start first.

1. Go to `OPA_HOME\config\opa_setup_scripts\` directory.
2. Open the `autostartfrdomain.cmd` and `autostartopadomain.cmd` files.
3. In each file, find the line `PING 127.0.0.1 -n x` and change the value of `x` to 300.
4. Save and close the files.

Set Up Scripts 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 **System and Security**, 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 FRDomainNM Autostart
Trigger: When the computer starts
Action: Start a program
Select: `opa_home\config\opa_setup_scripts\autostartfrdomain.cmd`
4. Click **Next** and then **Finish** to complete creation of the scheduled task.
5. Find the task **Oracle FRDomainNM Autostart** under the Task Scheduler Library list. Right-click on the task you just created and select **Properties**.
6. On the **General** tab, select **Run whether user is logged on or not**.
7. On the **Settings** tab, deselect the **Stop the task if it runs longer than** : check box.
8. Click **OK**.
9. When prompted, enter the user name and password.
10. Repeat the above steps for OPADomain Node Manager, OPADomain, and FRDomain, except for step 3 enter:
 - For OPADomain Node Manager:
Name: Oracle OPADomainNM Autostart
Select: `opa_home\config\opa_setup_scripts\autostartopadomainNM.cmd`
 - For OPADomain:
Name: Oracle OPADomainMS Autostart
Select: `opa_home\config\opa_setup_scripts\autostartOPADomain.cmd`
 - For FRDomain:
Name: Oracle FRDomainMS Autostart
Select: `opa_home\config\opa_setup_scripts\autostartfrdomain.cmd`
11. Back up the `autostartfrdomainscript.py` and `autostartopadomainscript.py` files from `<OPA_HOME>\config\opa_setup_scripts\domain\lifecycle`.
12. Update both the `autostartfrdomainscript.py` and `autostartopadomainscript.py` files by replacing the upgraded Oracle home path with the old Oracle home path. For example, replace `C:\<upgraded_oracle_home>` with `C:\<old_oracle_home>`.

Test Autostart

To test:

1. Restart the computer.
2. Allow some time for the services to start.

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

- Oracle Clinical: `https://server.domain/opa54/launch.htm`
- RDC: `https://server.domain/rdcadfsrnd/faces/Login`

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

For FRDomain:

- `autostartfrdomainNM.log`
- `autostartfrdomainNM.err`
- `autostartfrdomain2.log`
- `autostartfrdomain2.err`

For OPADomain:

- `autostartopadomainNM.log`
- `autostartopadomainNM.err`
- `autostartopadomain2.log`
- `autostartopadomain2.err`

Start 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, see [Architecture](#).

In this section:

- [Start the FRDomain Node Manager](#)
- [Start the FRDomain Admin Server](#)
- [Start the Forms Server](#)
- [Start the Reports Server](#)
- [Start the OPADomain Node Manager](#)
- [Start the OPADomain Admin Server](#)
- [Start the Managed Server of OPADomain](#)
- [Start the OHS Server](#)

Start the FRDomain Node Manager

To start the FRDomain Node Manager:

- Go to `ORACLE_HOME\user_projects\domains\FRDomain\bin` and run `startNodeManager.cmd`.

Start 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.

At the DOS command prompt, do the following:

- Go to `ORACLE_HOME\user_projects\domains\FRDomain\bin` and run the `startWebLogic.cmd`.

**Note:**

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

Start the Forms Server

The Oracle Forms Server is located on the WebLogic Server domain that must be named FRDomain. You must start the FRDomain Admin Server before the Forms Server.

To start the Forms Server:

- Open a DOS prompt, and run the following:

```
ORACLE_HOME\user_projects\domains\FRDomain\bin\startManagedWeblogic WLS_FORMS
```

Start the Reports Server

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

- Open a DOS prompt, and run the following:

```
ORACLE_HOME\user_projects\domains\FRDomain\bin\startManagedWeblogic WLS_REPORTS
```

Start the OPADomain Node Manager

To start the OPADomain Node Manager:

- Go to `ORACLE_HOME\user_projects\domains\OpaDomain\bin` and run `startNodeManager.cmd`.

Start the OPADomain Admin Server

The Oracle OPADomain Admin Server is located on the WebLogic Server domain that the Installer names OPADomain. You must start the Admin Server before you can start the Managed Server of OPADomain.

To start the OPADomain Admin Server:

- Go to `ORACLE_HOME\user_projects\domains\OpaDomain\bin` and run `startWebLogic.cmd`.

**Note:**

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

Start the Managed Server of OPADomain

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

You must start the OPADomain Admin Server before the Managed Server of OPADomain.

OPADomain Managed Server is auto started on starting NodeManager of OPADomain and Admin Server of OPADomain. If managed server is not auto started, to start the Managed Server of OPADomain, use the Admin Console at either:

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

Start the OHS Server

To start the OHS Server:

- Go to `ORACLE_HOME\user_projects\domains\FRDomain\bin` and run the `startComponent.cmd` for ohs1.

Verify the Application Tier Installation

- Verify that these URLs work and you can log into the application:
 - <https://host/opa54/launch.htm>
 - <https://host/rdcadfsrnd/faces/Login>
- The `OPA_XMLTEMP_HTTP` registry URL is used to communicate from the database server to the application server in order to retrieve the Patient Data Report PDF template created as part of DCI form generation. Ensure that this port is open on any firewall that exists between the application server and database server.

To confirm if the port is open:

 1. Follow instructions in My Oracle Support Article ID 1942747.1, 24311: 100501: *Non-ORACLE Exception Error When Performing DCI Form Generation*.

Stop Servers

You can stop each server either in the appropriate WLS Admin Console or from the Windows **Start** menu.

**Note:**

These instructions are provided for your information; you do not need to do them now.

In this section:

- [Stop the Forms Server](#)
- [Stop the Reports Server](#)
- [Stop the FRDomain Admin Server](#)
- [Stop the Managed Server of OPADomain](#)
- [Stop the OPADomain Admin Server](#)

Stop 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 one of the following:

- Open a DOS prompt, and run the following:

```
ORACLE_HOME\user_projects\domains\FRDomain\bin\stopManagedWeblogic WLS_FORMS
```
- Use the Admin Console at <http://host:7001/console>.

**Note:**

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

Stop 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, use the Admin Console at <http://host:7001/console>.

**Note:**

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

Stop 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:

- Go to `ORACLE_HOME\user_projects\domains\FRDomain\bin` and run `stopWebLogic.cmd`.

Stop the Managed Server of OPADomain

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

To stop the Managed Server of OPADomain, 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.

Stop 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:

- Go to `ORACLE_HOME\user_projects\domains\Opadomain\bin` and run the `stopWebLogic.cmd`.

10

Upgrade the Oracle Clinical Reports Server

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 [Upgrade and Configure the Oracle Application Tier](#) for installation instructions.

For more information, see:

- [Gather Required Information for Oracle Clinical Reports Server](#)
- [Restart the Computer](#)
- [Start the WebLogic FRDomain Admin Server](#)
- [Install the Oracle Clinical Reports Server](#)
- [Restart the Computer](#)
- [Set Up the Reports Server for Access and File Viewing](#)
- [Add the Reports Server to the Database Reference Codelist](#)
- [Test the Reports Server Installation](#)
- [Set Up Automatic Startup of Services](#)

Gather Required Information for Oracle Clinical Reports Server

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

- Home Details: Enter the following:
 - Name: OPA_HOME
 - Path: c:\opapps52

Note:

Use the same location used for OC 5.2.1 or later installation.

- Your Oracle Fusion Middleware home directory; for example:

C:\Oracle\Middleware\Oracle_Home

- Oracle Fusion Middleware User Projects directory; for example:
C:\Oracle\Middleware\Oracle_Home\user_projects
- Your OPA home directory; for example:
C:\opapps52

 **Note:**

Use the same location used for OC 5.2.1 or later installation.

- WebLogic username and password
- Report Server name
- Report Server output directory

 **Note:**

The Report Server output directory must be entered as the Oracle Clinical user Report Server output directory for example:
C:\opapps52\log

Restart the Computer

- Restart the computer.

Start the WebLogic FRDomain Admin Server

The WebLogic FRDomain Admin Server must be running when you install the Reports Server.

1. At the DOS command prompt, do one of the following:
 - Go to ORACLE_HOME\user_projects\domains\FRDomain\bin and run the startWebLogic.cmd.
 - Go to C:\ProgramData\Microsoft\Windows\Start Menu\Programs\Oracle FMW 12c Domain-FRDomain - 12.2.1.4.0 and run Start Weblogic Admin Server.
2. Go to ORACLE_HOME\user_projects\domains\FRDomain\bin and run startNodeManager.cmd.

Install the Oracle Clinical Reports Server

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

 **Note:**

You must 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 [Download the Software](#).
3. Run the following file as an administrator:

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

The Installer opens to the Welcome screen.

 **Note:**

See [Use the Silent Installer \(Optional\)](#) 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 5.4.1.0.x**.
5. For Choose Install Type, select **No**.
6. Follow instructions on screen, entering the information you have gathered; see [Gather Required Information for Oracle Clinical Reports Server](#).

 **Note:**

For the question "Do you want to create Report Server Component?":

- If you select **Yes**, a new report server will be created, and you must provide a new name for the report server.
- If you select **No**, provide the existing reports server name. The existing reports server will be deleted and then recreated.

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**.

 **Note:**

After completing these steps, install the latest CPU certified for release 5.4.1. For information on the latest certified CPU, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support > section Oracle Life Sciences Critical Patch Updates (CPU) Notes in the PDF file.

For more information, see:

- [Review the Installation Log File](#)

Review the Installation Log File

- Review the generated installation log file, `installActiontimestamp.log`, for errors.

This is the name of the most current log file. Earlier files have a timestamp appended to the name.

Location: `\Oracle\Inventory\logs`

For example:

```
C:\Program Files\Oracle\Inventory\logs
```

If you encounter any error, contact Life Sciences Support.

Restart the Computer

To ensure that all configuration changes are initialized:

- Restart the computer before you continue with the next task in the installation process.

Set Up the Reports Server for Access and File Viewing

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

- [Create the Reports Server Root Directory](#)
- [Share and Grant Access to Each Reports Server Root Directory](#)
- [Configure the Reports Server and Forms Server for DCI Form Generation](#)

- [Configure the Reports Server to Send Output to a Printer](#)

Create the Reports Server Root Directory

If your Oracle Clinical environment includes any standalone Reports Servers and/or File Servers, select the single computer where you will locate your Reports Server root directory. The directory can reside on the Forms Server, on any of the Reports Servers, or any other computer. Otherwise, you will locate the Reports Server root directory on the single computer comprising your entire Oracle Clinical installation.

- Create the Reports Server Root directory, making sure it is accessible by the user that started up the auto process; see [Set Up Automatic Startup](#).

Share and Grant Access to Each Reports Server Root Directory

If your Oracle Clinical environment includes multiple servers, you must make your Report Server root directory shareable on every server (Forms Server and Reports Server). Otherwise, all of your Oracle Clinical components and your Report Server root directory reside on a single computer, and you can skip the following steps.

1. Share the Reports Server root directory:
 - a. Log on to Windows with an administrator account.
 - b. Use Windows Explorer to select the Reports Server root directory.
 - c. Right-click on the folder, and select **Properties**.
 - d. Click the **Sharing** tab.
 - e. Select **Shared This Folder**, and then enter a value in the Share Name field.
 - f. Click **OK** to save your changes.
2. On each Forms and Reports Server, map a drive to the shared directory.
 - a. You must use the same drive letter in each server's mapping, for example 't'. This allows for a unified specification of the output directory in Oracle Clinical.
 - b. Even if the root directory is local to the Report Server, you must map a drive to allow for unified specification.

If you have already completed the Oracle Clinical Report Server installation and did not specify the correct Report Server root directory path, you can correct this by editing the `rwserver.conf` file, directly, as follows:

```
<folderAccess><read>%OPA_HOME%\oc;%OPA_HOME%\*;%REPORTS_LOG_DIR%\*</  
read><write>%OPA_HOME%\oc;%OPA_HOME%\*;%REPORTS_LOG_DIR%\*</write></folderAccess>
```

Configure the Reports Server and Forms Server for DCI Form Generation

Both the Reports Server and the Oracle Clinical application server must have read/write access to the directory (`\rdc\temp`) on the application server used to write temporary files during the DCI form generation process.

If you have any standalone Reports Servers, they must also have access to this directory.

On the Oracle Clinical (Forms) Server:

1. Confirm that the OUI has the specified values for the registry settings `OPA_XMLTEMP_UNC` and `OPA_XMLTEMP_HTTP`. During the installation, if you

correctly indicated that there is a standalone report server, the value of the key(s) is set to:

- OPA_XMLTEMP_UNC:
C:\opapps52\html\rdc\temp
- OPA_XMLTEMP_HTTP:
https://<serverName>:port/opa54/rdc/temp

2. To provide access to the remote Report Server, share the directory with the share name "RDC", providing read/write privileges to the domain/account on the report server.

On the Reports Server used in DCI Form Generation

1. By default, OUI will have updated RWSERVER.conf, specifying a value of %OPA_HOME%\oc;%OPA_HOME%*;%REPORTS_LOG_DIR%* under folder access.

For example:

```
<folderAccess>
<read>%OPA_HOME%\oc;%OPA_HOME%\*;%REPORTS_LOG_DIR%\*</read>
<write>%OPA_HOME%\oc;%OPA_HOME%\*;%REPORTS_LOG_DIR%\*</write>
</folderAccess>
```

2. Map a drive to the RDC share on the application server.
3. Update the registry values. For example:

- OPA_XMLTEMP_UNC:
z:\rdc\temp

The Z drive is mapped to \\SharedAPPSERVERNAME\OPA_HOME\html.

- OPA_XMLTEMP_HTTP:
https://servername(same as Z drive):port/opa54/rdc/temp

If the only report server that you use to generate DCI forms co-exists on the same computer with the application server, there is no need to share the xmltemp directory and the path specification can be a simple local directory name, such as,

```
C:\opa_home\html\rdc\temp
```

Configure the Reports Server to Send Output to a Printer

If you run the PDR, and you send the output directly to a printer:

- Set value for the RDC_PDF_PRINT_TOOL key.
The value assigned to the RDC_PDF_PRINT_TOOL key determines the location of the Adobe Acrobat or Reader executable, which allows users to run PDF patient data reports with "PRINTER" specified as the output type. This value must be in the form:

```
"<acrobat-reader_path>" /t
```

Note that the double-quotation marks around the path and the "/t" switch are required. A typical example of a value is:

```
"C:\Program Files\Adobe\Acrobat <version>\Acrobat\Acrobat.exe" /t
```

In addition to setting this key correctly, ensure that the Adobe Acrobat or Reader application is running on the Reports Server prior to users initiating this type of report job, that is, a job that specifies the output type as "PRINTER".

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 10-1](#), 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 10-1 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**.

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.

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 [Set 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\opa_setup_scripts\domain\lifecycle`:

```
nmConnect(userConfigFile=configfile, userKeyFile=keyfile,  
nmPort=port,  
domainName='OPADomain', domainDir='your_middleware_home/USER_P~1/  
domains/OPADomain', nmType='ssl')
```

11

Set Up Clients

This chapter describes how to set up client computers in your Oracle Clinical/RDC Onsite installation.

For client technical requirements, see [Software Requirements](#).

For more information, see:

- [Configure Personal Firewall](#)
- [Use Safari on an iPad](#)
- [Set Up for Proxy Usage on Fully Qualified Application Tier Names](#)
- [Download Required Applications for Clients](#)
- [Map Network Drive for Image Browsing](#)
- [Enable Report Generation from the Command Line](#)
- [Log in to the Application](#)

Configure Personal Firewall

If the client computer has a personal firewall:

- Disable the firewall or configure it for RDC to function correctly.
See your firewall documentation or ask your system administrator for assistance.

Use 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

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 Windows client proxy settings:

1. In Windows, open Settings.
2. Search and open Proxy Settings.
3. Under Manual proxy setup, turn on the **Use a proxy server** toggle.
4. Enter the address and port number, and click **Save**.

 **Note:**

Similar proxy settings may be required on Macbook and ipad.

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 [Make the Java Runtime Environment Available for Download](#) and [Make the Oracle Clinical PDF Plug-in Available to Users](#).

In this section:

- [Download the Java Runtime Environment](#)
- [Configure Java Security Settings for Oracle Clinical](#)
- [Download the Oracle Clinical PDF Plug-in](#)
- [Download Adobe Reader](#)

Download the Java Runtime Environment

Oracle Clinical and RDC Administration require the Java Runtime Environment (JRE) version 8 (1.8.0.391 or above).

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 Life Sciences application:

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

To download and install the JRE onto a client:

1. Open a browser and enter the URL to open the Launch page for the Oracle Clinical application. For example:

```
https://server.domain:port/opa54/launch.htm
```

2. Click **Install JRE Plug-in** 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 [Make the Java Runtime Environment Available for Download](#) for more information.

Configure Java Security Settings for Oracle Clinical

If Java is not configured properly, you may encounter an error when launching the application. To avoid this error, follow the instructions below:

1. Go to Control Panel, and click **Java**.
2. Click the Advanced tab.
3. Under Advanced Security Settings:
 - Deselect the **Use TLS 1.0** check box.
 - Select the **Use TLS 1.1** and **Use TLS 1.2** check boxes.
4. Click **OK**.

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/opa54/launch.htm`
2. Click **Download PDF Plug-in** on the Launch page.
3. Run the plug-in installer `opapdf.exe`, which extracts the following to the specified directory:
 - The library file `OCLN.api`.
 - The ReadMe file.
4. Follow the instructions in the ReadMe file to 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 [Make the Oracle Clinical PDF Plug-in Available to Users](#) for more information.

Download Adobe Reader

Oracle Clinical and RDC support Adobe Acrobat Reader DC 21 or Adobe Acrobat Reader 2020 (Classic Track), 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.

Map 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 [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**.

Enable 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.

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.

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.

Log in to the Application

To log in to the Oracle Clinical, RDC Onsite, or the RDC Administration application:

1. Open a supported browser.
2. Enter the appropriate URL:

Table 11-1 URLs to Start Oracle Clinical and RDC Applications

Application	URL
Oracle Clinical	<code>https://computer_name.domain/opa54/launch.htm</code>
RDC Onsite	<code>https://computer_name.domainrdcadfsrnd/faces/Login?</code>
RDC Administration	<code>https://computer_name.domain/opa54/rdcadmin.htm</code>
RDC Administration (in Test Mode)	<code>https://computer_name.domain/opa54/rdcadmint.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.