Oracle Clinical Installation Guide



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ORACLE

Oracle Clinical Installation Guide, Release 5.4.1

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Preface

- Audience
- Documentation accessibility
- Related resources
- Diversity and Inclusion
- 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/lifesciences/support/ or visit https://www.oracle.com/corporate/accessibility/learningsupport.html#support-tab if you are hearing impaired.



Audience

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

Database Administrators

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

System Administrators

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

- UNIX operating systems
 - Creating and managing user accounts and groups
 - Installing Oracle database software and patches
 - Identifying space on a file system for Oracle database tablespaces
 - Setting and using environment variables
- Microsoft Windows operating systems
 - Creating and managing user accounts and groups
 - Installing Oracle software
 - Managing settings through the Control Panel and Administrative Tools
 - Managing network printers
 - Creating services



1 Prepare to Install Oracle Clinical

Note:

During installation 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.

In this chapter:

- 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

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 upto-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 available 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.



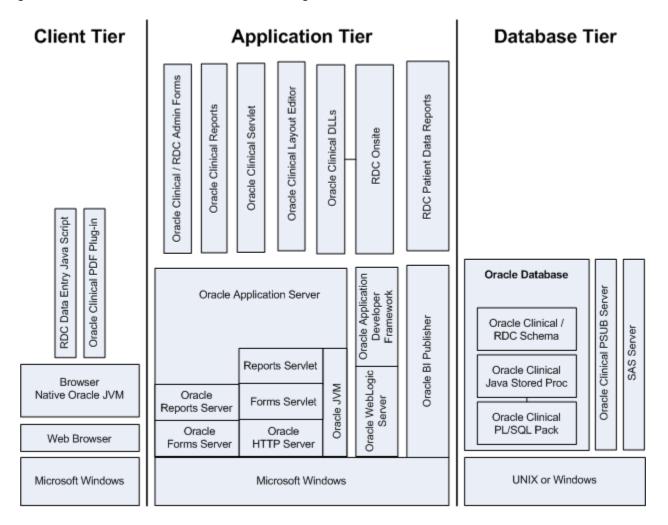


Figure 1-1 Oracle Clinical and RDC Onsite Logical Architecture

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 for Oracle Clinical Forms Application. 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

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 and versions certified on OVM, see *Oracle VM: Software Certified On OVM* (Document 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.

Note:

After release, Oracle Clinical 5.4.1 will continually be certified for future CPUs. For the latest technology stack certification detail, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support.



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-UX 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 gcc -v
	For Oracle Linux 8.1 to 8.7: GCC-8.5.0; command to identify compiler is gcc $-v$
	For Oracle Solaris SPARC 11: Oracle Solaris Studio 12.6 Sun C 5.15; command to identify compiler is $cc -V$
	For HP-UX Itanium: HP-UX 11.31 September 2014 B.11.31.1409 or later; command to identify compiler is 'which cc' and cc -V
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 1-1 Oracle Clinical Database Tier Technology Stack

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 12 <i>c</i> 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 or later, 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.		



Component	Supported Version	
Operating Systems	Microsoft Windows 11; 32-bit or 64-bit architecture (US English)	
ipad/MacBook	iOS 15.0 (iPad) - for RDC Onsite only	
Operating Systems	macOS Big Sur Version 11.6 (MacBook) - for RDC Onsite only	
Supported Browsers	The following Microsoft browser and operating system combinations are supported:	
	 Microsoft Windows 11: Microsoft Edge v96 and Google Chrome v96 	
	Safari versions depend on the operating system:	
	 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)	
	Required for viewing reports, including Patient Data Reports (PDRs)	
Adobe Acrobat	Adobe Acrobat Standard DC 21 or Adobe Acrobat 2020 (Classic Track)	
	Required for creating annotated layouts	
Oracle Java Runtime Environment (JRE)	JRE 1.8 update 391 or later, also known as JRE 8	

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

To verify Linux operating system details, 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 Parametrized 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 Parameterized Submissions for UNIX, and Set Up Parameterized Submissions for Windows.

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).

For more information, see:

• Recommended Options for RAC

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 on My Oracle Support (Document 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

To create staging area:

- 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	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



Disk or Patch Name	Source
Oracle Clinical Release 5.4.1 Documentation.	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

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

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.
- 7. Click Continue.
- 8. Read the license agreement and select the checkbox to accept the license agreement.
- 9. Click Continue.
- **10.** Review the media pack components you want to download.
- 11. Click Download.
- **12.** Select the location where you want to save the <code>Oracle_SSN_DLM_*</code>.exe file.
- **13.** Run the Oracle_SSN_DLM_*.exe file.



- **14.** Select a location in the appropriate staging area to download the zip files of the media pack.
- 15. Click Next.
- **16.** Extract each *part_number*.zip file into a meaningfully named directory.
- 17. 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_middletier_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.
- 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 and install JDK:

- 1. Go to My Oracle Support at https://support.oracle.com and sign in.
- 2. In the Search Knowledge Base field in the upper right, enter: 1439822.1

A page appears with a list of documents.

- 3. Click the link 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:

To check if a more recent JDK version is supported, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support.

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

Installation instructions are in 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) 1.8.0.391—also known as JRE 8 Update 391—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 All Java SE Downloads on MOS link (Doc 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.
- 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-spellchecker.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 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.



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 the Oracle Clinical Front End
Oracle Clinical Reports Server	oracle.pharma.oc.reportserver.Complete.rsp	Gather Required Information for the Oracle Clinical Reports Server

Table 1-6 Response Files and Parameter Information



- 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/usingresponse-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.



You must select **AL16UTF16- Unicode UTF-16 Universal character set** as the National Character Set.

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:

- 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 Prepare to Install Oracle Clinical

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.



Part I Database Tier

Note:

Follow instructions for either UNIX or Windows.

This part contains the following chapters:

- Install Oracle Database
- Install Oracle Clinical Database Components on UNIX
- Install Oracle Clinical Database Components on Windows
- Integrate SAS (Optional)



2 Install Oracle Database

If you are upgrading Oracle Clinical, see the *Oracle Clinical Upgrade Guide*. If you are using Oracle Real Application Clusters (RAC) or Oracle Data Guard, see Supported Configurations with Oracle Data Guard and RAC.

For more information, see:

- Get the Oracle Database 19.3.0 Installation Guide
- Download and Extract the Oracle Database 19.3.0 Software
- Performing Prerequisite Tasks for Installing Oracle Database
- Install Oracle Database 19.3.0
- Install Oracle Database 19.3.0 Examples
- Install Oracle Critical Patch Update

Get the Oracle Database 19.3.0 Installation Guide

- Open or download the installation guide for your operating system:
 - Linux: https://docs.oracle.com/en/database/oracle/oracle-database/19/ ladbi/index.html
 - Solaris: https://docs.oracle.com/en/database/oracle/oracle-database/19/ ssdbi/index.html
 - HP-UX Itanium: https://docs.oracle.com/en/database/oracle/oracledatabase/19/hpdbi/index.html
 - Windows: https://docs.oracle.com/en/database/oracle/oracle-database/19/ ntdbi/index.html

Download and Extract the Oracle Database 19.3.0 Software

To download and extract the Oracle Database 19.3.0 software:

• Follow instructions in the Oracle Database Installation Guide.

Oracle Clinical requires Oracle Database Enterprise Edition.

Oracle Database Grid Infrastructure is optional.

Performing Prerequisite Tasks for Installing Oracle Database

To ensure that your platform meets the minimum requirements for installing Oracle Database 19c (19.3.0.0), you must perform the following preparatory tasks:

Create Owners, Groups, and Mount Points



- Configure Kernel Resources and Adjust Operating System Environment
- Test the C Compiler Installation
- Install Latest Operating System Patches

Create Owners, Groups, and Mount Points

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

- 1. Create the software owner and groups:
 - Create a UNIX user to own the Oracle software. Typically, the user name is oracle.
 - Create two groups: one is the Oracle Inventory group; the other is the operating system DBA group. Typically, the group names are **oinstall** and **dba**, respectively.
- 2. Create mount points owned by the oracle user:
 - Create a software mount point of at least 10 GB.
 - Create mount points to hold the database files, control files, and log files, respectively.
- **3.** Test permissions. Ensure that the oracle user can write to the new mount points and all subdirectories.

Configure Kernel Resources and Adjust Operating System Environment

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

Test the C Compiler Installation

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

- 1. Log in to the database server as the opapps user.
- 2. Test for the C compiler type:

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

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

3. Compare your results to the correct responses listed in the following table:

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

Operating System	Response	Symbolically Links To
Oracle Linux x86-64	/usr/bin/gcc	(Not applicable)
Oracle Solaris SPARC	/opt/SUNWspro/bin/cc/prod/bin/cc	

4. Test that the make command is accessible:



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

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

5. Compare your results to the correct responses listed in the following table:

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

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

Install Latest Operating System Patches

Download and install the latest operating system patches required for Oracle, if necessary. Review the latest platform-specific install bulletins for Oracle Database 19c (19.3.0.0).

Install Oracle Database 19.3.0

To install Oracle Database 19.3.0, follow instructions in the *Oracle Database Installation Guide*, making selections appropriate for Oracle Clinical as noted in the following sections.

You can configure database(s) as part of the database software installation or after, using the Database Configuration Assistant (DBCA).

Oracle Clinical supports installation on either a Container Database (CDB) containing a Pluggable Database (PDB) or a non-CDB database.

Note:

For information on pluggable and container databases, see:

- Oracle Database New Features Guide for 19c at https://docs.oracle.com/en/ database/oracle/oracle-database/19/newft/index.html
- Oracle Database Concepts for 19c at https://docs.oracle.com/en/database/ oracle/oracle-database/19/cncpt/index.html

For an explanation of which options require an additional license, see the Database Licensing Information User Manual at https://docs.oracle.com/en/database/oracle/oracle-database/19/dblic/index.html:

For more information, see:

- Install and Configure Oracle Database
- Modify the tnsnames.ora File on the Database Server
- Create the oinstall User Group
- Check Required Tablespaces



Install and Configure Oracle Database

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

When you configure the database, select the following options for Oracle Clinical:

- Custom Database template (recommended)
- Oracle JVM (required)
- Oracle Text (required for TMS only)
- Service name requirements for Oracle Clinical include:
 - The service name must be less than 15 characters long.
 - It must not include the domain.
 - It must be **all lowercase**.
- Check that required tablespaces exist, and have Autoextend on:
 - SYSTEM
 - TEMP
 - UNDOTBS1
 - USERS
 - SYSAUX
- Initialization Parameters. The Table 2-3 table below shows the required or recommended values for Oracle Clinical. For parameters that accept a value within a range, the minimum values are given.

🔷 Tip:

Parameters are listed in alphabetical order. In the Database Configuration Assistant, you can click the Parameter column to display the parameters in the same order. You may need to select Advanced Parameters to see all of them.

Note:

For an existing database, if you make any changes to the initialization parameters, restart the database for the new settings to take effect.

- Automatic Memory Management (recommended): For more information, see Performance Behavior and System Recommendations for Oracle Clinical, Oracle Clinical Remote Data Capture Onsite 5.4 (Doc ID 2854275.1).
- Sizing: From the Block Size drop-down, select 16384 Bytes.
- Character Set: See Choose a Character Set .



The following get installed by default in Oracle Database 19.3.0 with the Custom Database template selected:

- Distributed Database Option
- Oracle Partitioning
- Oracle XML DB
- Oracle Text, Java Virtual Machine (JVM), and Oracle XML DB are configured automatically if you select the Custom Database template.

Table 2-3 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 . From 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	Required for HTML generation.
	context forever, level 0x100	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_PROCESS ES	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_TARGE T	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_SEMANTI CS	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.

Parameter	Value	Comments
OPTIMIZER_DYNAMIC_ SAMPLING	2 or greater	The default setting is 2. Oracle recommends using dynamic sampling for Batch Data Load temporary tables; see the Oracle Clinical Administrator's Guide.
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_TAR GET	200 MB	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
REMOTE_LOGIN_PASS WORDFILE	EXCLUSIVE	The database must be set up to use password file authentication.
SEC_CASE_SENSITIVE _LOGON	FALSE	Lets you enter passwords without case sensitivity.
SESSIONS	500 or greater	You can change the value of this parameter after installation.
SGA_MAX_SIZE	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
SGA_TARGET	600 MB (minimum)	Recommended value for 50 to 60 concurrent users. Adjust this value according to your organization's needs.
SHARED_POOL_SIZE	150 MB (minimum)	Recommended value for 50 to 60 concurrent users. You can change the value of this parameter after installation.
UNDO_MANAGEMENT	AUTO	Specifies which undo space management mode the system uses. When set to AUTO, the instance starts in Automatic Undo Management (AUM) mode.

Table 2-3 (Cont.) Required and Recommended Initialization Values in the init.ora File

Modify the tnsnames.ora File on the Database Server

There is a tnsnames.ora file in at least two locations in the installation. Oracle recommends maintaining a master file and copying it to each location whenever you add a database. See Modify the tnsnames.ora File on the Application Server for the application server locations.

- Navigate to the tnsnames.ora file in the following directory on the database server: Oracle_Home/network/admin
- 2. Enter a connect string for each database that matches the database's service name.
- 3. If there are multiple Oracle homes, maintain the entries for all databases in a central location; for example: /etc/thenames.ora.

Create the oinstall User Group

Use instructions in the Oracle Database 19.3.0 Installation Guide chapter "Configuring Users, Groups and Environments for Oracle Database."

- 1. Check if the **oinstall** user group exists.
- 2. If it does not exist, create it.



Check Required Tablespaces

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

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

Table 2-4 Required Tablespaces and Sizes

Tablespace	Minimum Size
SYSTEM	900 MB
ТЕМР	100 MB
UNDOTBS1	700 MB
USERS	500 MB
SYSAUX	600 MB

Install Oracle Database 19.3.0 Examples

Oracle Database Examples includes the following items:

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

Note:

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

To install Oracle Database Examples:

- 1. Extract the zip file containing Oracle Database Examples in the examples directory.
- 2. Start Oracle Universal Installer from the examples directory.

```
./runInstaller
```

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

./runInstaller -invPtrLoc ORACLE_HOME/oraInst.loc

3. Accept all the default values during the installation.

For more information, see the Oracle Database Examples Installation Guide at https://docs.oracle.com/en/database/oracle/oracle-database/19/exmpl/index.html#EXMPL-GUID-84DCE7DB-ED03-47DB-8C05-1B2B5618A2E9.



Install Oracle Critical Patch Update

- 1. For the latest quarterly Oracle CPU patches tested with Oracle Life Sciences applications, see *Oracle Life Sciences Applications Supported Technology Stack* (Document ID 180430.1) on My Oracle Support.
- 2. Install these patches on every computer with an Oracle Home.



3

Install Oracle Clinical Database Components on UNIX

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

If you are upgrading Oracle Clinical, see the *Oracle Clinical Upgrade Guide*. If you are using Oracle Real Application Clusters (RAC) or Oracle Data Guard, see Supported Configurations with Oracle Data Guard and RAC.

For more information, see:

- Set Up the opapps User Account and oclsascr User Group
- Set Permissions
- Install the Oracle Clinical Database Server
- Perform Server Post-Installation Tasks
- Install Oracle Clinical Database Objects
- Perform Database Post-Installation Tasks
- Set Up Parameterized Submissions

Set Up the opapps User Account and oclsascr User Group

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

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

For more information, see:

- Create the oclsascr User Group for SAS
- Create the opapps Account and Add It to Groups

Create the oclsascr User Group for SAS

If you use SAS integrated with Oracle Clinical, you must create the **oclsascr** user group, which controls access to the files Oracle Clinical generates on the database server for SAS. These include SAS data extract files, which contain patient data.

- 1. Create a user group named oclsascr by adding it to the /etc/group file.
- The preferred method for group authentication is that all groups assigned to a user should become the user's default group at login. If this method is acceptable, link the /etc/logingroup file to the /etc/group file.



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

To create the symbolic link, enter these commands:

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

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

Create the opapps Account and Add It to Groups

Create the **opapps** operating system account that owns Oracle Clinical. This account also has the privileges to run the parameterized submission (PSUB) service RXCPSDPS and the PSUB Launcher (PSLAUNCH). The opapps home directory on the database server, for example /pharm/home/opapps, is referred to as *OPA_HOME* in Oracle Clinical documentation.

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

/bin/csh

- 2. Make the opapps account a member of these user groups:
 - oclsascr
 - oinstall
 - dba

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

Set Permissions

Note:

You might have to perform these steps whenever you apply an HSGBUapproved 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

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

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

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

These shell scripts are located under your Oracle Database 19c (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 (oralnventory) directory:

- **1.** Log in to the server as the oracle user.
- Locate the path for the oralnventory directory. The location is defined in the inventory_loc parameter in the /var/opt/oracle/oralnst.loc file.

For example, suppose you enter: more /var/opt/oracle/oraInst.loc

The system might return the oralnventory location as:

inventory loc=/u01/app/oraInventory

3. Give recursive read and write permission for the oralnventory 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 oralnventory 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.

Install the Oracle Clinical Database Server

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

In this section:

- Gather Required Information for Oracle Clinical Database Server
- Prepare to Install the Oracle Clinical Database Server Software
- Install the Oracle Clinical Database Server Software
- Save the Installation Information
- Review the Installation Log Files
- Oracle Clinical Database Server Directory Structure for UNIX
- Remove Group Privileges from this Session

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 (19.3.0.0.0).

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

 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.

ORACLE

The database Wallet stores the password for the OCPSUB proxy account, which is used for database access for parameterized submission (PSUB) jobs. Its credentials are created in the 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, "In -s libnsl.so.2 libnsl.so" or "In -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:



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 <code>oinstall</code>. See Create the opapps Account and Add It to Groups.

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.

5.1: Removed "and add ":0" to the end of the address." 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.
- Open the ldflags file at *root*: app/oracle/product/19.3.0.0/dbhome_1/lib (ORACLE_HOME/ lib) and add the -lnnz19 flag.



Install the Oracle Clinical Database Server Software

- 1. Log in to the server computer using the opapps account.
- In the staging area, locate the directory where you downloaded Oracle Clinical (see Download the Software) and extract the .zip file if you have not already done so.
- 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 oralnventory/logs directory.

Save the Installation Information

- Save the following information displayed in the Installer. You need it for several postinstallation tasks.
 - Location of the OPA_HOME directory
 - Location of the OPA_HOME/bin directory
 - Name of the code environment

Review the Installation Log Files

Review the generated installation log files located at:

```
$ORACLE_BASE/oraInventory/logs
For example:
```

/u01/app/oraInventory/logs

Work with Life Sciences Support, if necessary, to resolve any errors.

Oracle Clinical Database Server Directory Structure for UNIX

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

OPA HOME

/bin /xmlte	emp	
/oc		
/54	41	
	/bin	(Symbolic links to the executables)
	/common	(Common files)
	/dcd	(Data Collection Definition)
	/des	(Design)
	/dm	(Data Management)
	/dx	(Data Extract)
	/glib	(Global Library)
	/install	(Install and upgrade scripts)
	/log	(PSUB log files)
	/lr	(Lab Ranges)
	/patch	(Patches to Oracle Clinical)
	/pd	(Procedure Definition)
	/psub	(Parameterized Submission process)
	/release	(Server code release marker)
	/sec	(Security tools)
	/tools	(Miscellaneous tools)



Remove Group Privileges from this Session

Undo the temporary change you made in Prepare to Install the Oracle Clinical Database Server Software:

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

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

Perform Server Post-Installation Tasks

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

- Complete the Setup of the opapps Account
- 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

- 1. Create the log directory for opapps in the following location: *OPA_HOME/*log
- 2. Define the environment variables for the opapps user:
 - 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.

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

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



Note:

For HP-UX Port, copy \$ORACLE_HOME/bin/oraenv to \$OPA_BIN/ oraenv_opa. For example: cp \$ORACLE_HOME/bin/oraenv \$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:

```
Example:
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.

Install Oracle Clinical Database Objects

To add Oracle Clinical database objects to this database, follow the instruction mentioned below:

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 Health Sciences Critical Patch Updates (CPU) Notes in the PDF file.

- Customize the Installation
- Check for an ORA-29548 Error
- Gather Required Information
- Start Installing the Oracle Clinical Database
- Remove Group Privileges from this Session
- Review the Installation Log Files

Customize the Installation

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

 Edit the Tablespace Size Scripts: The Installer creates several new tablespaces with default sizes. To create larger databases, you can edit two scripts. The default value is an autoextend of 1MB and an unlimited maximum size. To create larger databases in UNIX, edit the following scripts:

OPA_HOME/oc/541/install/opadba2.sql

OPA HOME/oc/541/install/rxcdba2.sql

 Edit the User Account Creation Script: The Installer prompts to create accounts in this database. If you select Yes, the Installer runs a script that creates default guest accounts.

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



```
OPA HOME/oc/541/install/rxcdba4.sql
```

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

Create a Secret Store Directory

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

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

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

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.

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

Have the following information ready to enter in the Installer:

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: /app/oracle/product/19.3.0.0/dbhome_1/

- OPA Home: the directory where Oracle Clinical will be installed; Oracle recommends: /pharm/home/opapps
- 3. SAS View: the directory where Oracle Clinical will generate SAS views; Oracle recommends:



- UNIX: \$OPA_HOME/sas_view
- Windows: %OPA_HOME%\sas_view

Note:

The upgrade Installer does not prompt for this value.

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

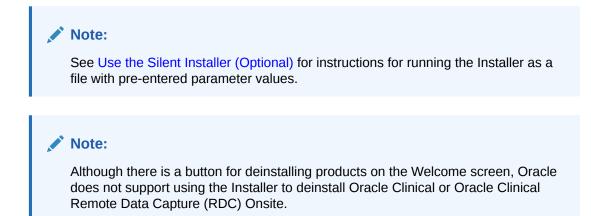


Note:

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.

Start Installing the Oracle Clinical Database



For more information, see:

Start the Installer on a UNIX Server

Start the Installer on a UNIX Server

To start installing the Oracle Clinical database:

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

Note:

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

```
newgrp inst_group
```



where *inst_group* is the name of the group that owns the Oracle Inventory. You specified the name during the Oracle Database 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
```

- In the staging area, locate the directory where you downloaded Oracle Clinical (see Download the Software) and extract the .zip file if you have not already done so.
- 5. Navigate to this location:

server_code_platform\Disk1\install

6. Change protections on files to 755.

chmod 755 *

- 7. Start the Installer:
 - Non-RAC Installation:

./runInstaller

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

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

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/19.3.0.0/dbhome_1/
oraInst.loc
```

RAC Installation:

./runInstaller -local

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

./runInstaller -local -invPtrLoc ORACLE HOME/oraInst.loc

For example:

```
./runInstaller -invPtrLoc /u01/app/oracle/product/19.3.0.0/dbhome_1/
oraInst.loc
```

- 8. In the Select a Product to Install page, select OC Database Install 5.4.1.0.x.
- **9.** Follow the instructions on the installation screens, providing the information you assembled in Gather Required Information.

Remove Group Privileges from this Session

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



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

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

Review the Installation Log Files

During the installation of a component, the Oracle Universal Installer generates a log file named installActions.log. Earlier files have a timestamp appended to the name.

1. Review the generated installation log files located at:

```
$ORACLE_BASE/oraInventory/logs
For example:
```

/u01/app/oraInventory/logs

- 2. Check the following log files for error messages and invalid objects:
 - oclinst_database_service.log
 - reall_database_service.log
 - oclconfig_database_service.log
 - flt_seeddata_database_service_timestamp.log
 - html_dialg_templ_database_service_timestamp.log
 - html blob seeddata database service timestamp.log
 - xmlp clob seeddata database service timestamp.log
 - xml clob seeddata database service timestamp.log
 - compile_all_invalid_database_service.log
 - load olsardcstatemachine jar database service.log
 - install_database_service_timestamp.log
 - opaconnectcheck_system_database_service.log

Perform Database Post-Installation 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 for completing the installation of your Oracle Clinical database:

- Set the Database Time Zone
- Pin Database Packages
- Consider Implementing Partitioning



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 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 rxc user:

sqlplus rxc/password

5. Run the rxcdbinit.sql script:

start rxcdbinit.sql

The script pins the database packages and exits upon completion.



Note:

You must rerun this script *each* time you restart the database. Consider creating an entry in the database startup script that runs <code>rxcdbinit.sql</code> automatically.

Consider Implementing Partitioning

• Partition the Oracle Clinical RESPONSES table, which contains all patient data entered for all studies in an Oracle Clinical installation.

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

Set Up Parameterized Submissions

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:

- Create Directories and Enter Values in OCL_STATE Local Reference Codelist
- Enable Users to Submit PSUB Jobs
- Enable opapps to Use the at Command
- Start the PSUB Service
- Customize the PSUB Service (Optional)
- Test the PSUB Installation

Create Directories and Enter Values in OCL_STATE Local Reference Codelist

- 1. Create several directories on the PSUB server.
- 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 Integrate SAS (Optional) 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 inPSUB_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:

 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

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

opapps

Start the PSUB Service

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

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

To start the PSUB service on UNIX:

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

opa_setup <database_name> <code_environment>

For example, where prod is the database name:

opa_setup prod 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.

- 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

Customize the PSUB Service (Optional)

- 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.

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:

\$RXC_ROOT/log



4

Install Oracle Clinical Database Components on Windows

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

Note:

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

If you are upgrading Oracle Clinical, see the Oracle Clinical Upgrade Guide.

Note:

If you install the Oracle Clinical database on Windows and use SAS, you must also install SAS on Windows; see Integrate SAS (Optional).

For more information, see:

- Set Up the opapps User Account and the oclsascr User Group
- Set Up Local Policy Security Options
- Install the Oracle Clinical Database Server
- Perform Server Post-Installation Tasks
- Install Oracle Clinical Database Objects
- Perform Database Post-Installation Tasks
- Set Up Parameterized Submissions

Set Up the opapps User Account and the oclsascr User Group

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

- Create the oclsascr User Group
- Create the opapps Account and Add It to Groups



Create the oclsascr User Group

If you use SAS integrated with Oracle Clinical, you must create the **oclsascr** user group, which controls access to the files Oracle Clinical generates on the database server for SAS. These include SAS data extract files, which contain patient data.

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

See the Oracle Database 19.3.0 Installation Guide for Windows chapter "Configuring Users, Groups and Environments for Oracle Database" at https:// docs.oracle.com/en/database/oracle/oracle-database/19/ntdbi/configuring-usersgroups-and-environments-for-oracle-database.html.

Create the opapps Account and Add It to Groups

Create the **opapps** operating system account that owns Oracle Clinical. This account also has the privileges to run the parameterized submission (PSUB) service RXCPSDPS and the PSUB Launcher (PSLAUNCH). The opapps home directory on the database server, for example *Drive*:\opapps, is referred to as *OPA_HOME* in Oracle Clinical documentation.

- 1. Create the **opapps** operating system account.
- 2. Using Windows administrative tools, assign opapps to the following user groups:
 - ORA_INSTALL
 - ORA_DBA
 - ORA_ASMDBA
 - OCLSASCR

Note:

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

Set Up Local Policy Security Options

To set up the local policy security options:

- 1. In the Start menu, navigate to Administrative Tools.
- 2. Open Administrative Tools, and then Local Security Policy.
- 3. Expand the Local Policies folder and then select Security Options.
- 4. Set the following values:
 - Set Network security: Restrict NTLM: Outgoing NTLM traffic to remote servers to Allow All.
 - Set Network security: Restrict NTLM: Incoming NTLM traffic to Allow All.



- Set Network Security: Allow Local System to use Computer identity for NTLM to Enabled.
- Set Network Security: Allow Local System NULL session fallback to Enabled.
- 5. Enforce the policy by opening a command prompt and entering: gpupdate/force

Install the Oracle Clinical Database Server

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

The Oracle Universal Installer performs the following operations:

- Creates the Oracle Clinical directory structure (see Oracle Clinical Database Server Directory Structure for Windows for details).
- Installs the Oracle Clinical database server.
- Sets permissions on directories.
- Creates and modifies environment setup files.
- Creates an Oracle Wallet to store credentials for OCPSUB.
- Creates a directory for storing the SAS files.

For more information, see:

- Gather Required Information on Oracle Clinical Database Server for Windows
- Install the Oracle Clinical Database Server for Windows
- Save the Installation Information
- Review the Installation Log Files
- Oracle Clinical Database Server Directory Structure for Windows

Gather Required Information on Oracle Clinical Database Server for Windows

Have the following information ready to enter in the Installer:

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

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
- 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 parameterized 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.

Install the Oracle Clinical Database Server for Windows

- 1. Log in to the server computer using the opapps account.
- 2. In the staging area, locate the directory where you downloaded and extracted Oracle Clinical (see 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. 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.

Save the Installation Information

At the end of the installation, the installer screen displays the:

- Location of the OPA_HOME directory
- Location of the OPA_HOME\bin directory
- Name of the code environment

Make note of this information because you need it for several post-installation tasks.

Review the Installation Log Files

Review the generated installation log files located at:

```
\label{eq:constraint} $$ \oracle\Inventory\logs $$ For example: $$ $$ \end{tabular}
```



C:\Program Files\Oracle\Inventory\logs

Work with Life Sciences Support, if necessary, to resolve any errors.

Oracle Clinical Database Server Directory Structure for Windows

The Installer creates the following directory structure:

OPA_HOME

\bin		
\xmltem	p	
\oc		
\541		
\]	bin	(Executables)
\.	dcd	(Data Collection Definition)
1	des	(Design)
1	dm	(Data Management)
\.	dx	(Data Extract)
\.	glib	(Global Library)
\.	install	(Install and upgrade scripts)
\.	log	(PSUB log files)
\.	lr	(Lab Ranges)
\1	oatch	(Patches to Oracle Clinical)
\	od	(Procedure Definition)
\	osub	(Parameterized Submission process)
\:	release	(Server code release marker)
1	tools	(Miscellaneous tools)

Note that *OPA_HOME* refers to the root installation directory of Oracle Clinical, RDC, and TMS, which were formerly known as Oracle Pharmaceutical Applications (OPA). You specify the root installation directory when you install the Oracle Clinical database server. Oracle recommends *drive*:\opapps.

Perform Server Post-Installation Tasks

To complete the installation 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.
- 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.

Install Oracle Clinical Database Objects

To add Oracle Clinical database objects to this database, follow the instructions mentioned below:

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.

- Customize the Installation
- Check for an ORA-29548 Error
- Gather Required Information for Oracle Clinical Database



- Start Installing the Oracle Clinical Database
- Review the Installation Log Files

Customize the Installation

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

 Edit the Tablespace Size Scripts: The Installer creates several new tablespaces with default sizes. To create larger databases, you can edit two scripts. The default value is an autoextend of 1MB and an unlimited maximum size.

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

OPA_HOME\oc\541\install\opadba2.sql
OPA_HOME\oc\541\install\rxcdba2.sql

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

OPA HOME\oc\541\install\rxcdba4.sql

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

Create a Secret Store Directory

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

Example location: Drive:\opapps\sec_store\db_name

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

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 as SYSDBA

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

Have the following information ready to enter in the Installer.

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\19.3.0.0\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:
 - UNIX: \$OPA_HOME/sas_view
 - Windows: %OPA_HOME%\sas_view

Note:

The upgrade installer does not prompt for this value.

- 4. Service name for the database to be installed
- Know if you plan to use either Automatic Storage Management (ASM) or Real Application Clusters (RAC). This affects the Installer behavior for validating tablespaces.
- 6. Location for tablespace datafiles. You can change the default sizes by editing the script before running the Installer; see Customize the Installation.
- 7. Location and password for the Wallet created during Oracle Clinical database server installation to store credentials for OCPSUB.
- 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.

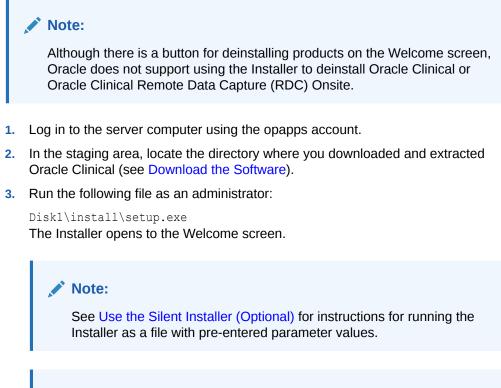
- 9. A database seed number between 1 and 99. Each database in an Oracle Clinical installation (or group of databases that are replicating with each other) must have a unique seed starting number.
- 10. Database host name and port number
- **11.** Global library code. There can be only one Global Library 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.

Start Installing the Oracle Clinical Database

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 Database Install 5.4.1.0.x.
- 5. Follow the instructions on the installation screens, providing the information you assembled in Gather Required Information for Oracle Clinical Database.

Review the Installation Log Files

During the installation of a component, the Oracle Universal Installer generates a log file named installActions.log. Earlier files have a timestamp appended to the name.

1. Review the generated installation log files located at:

```
\Oracle\Inventory\logs
For example:
```

C:\Program Files\Oracle\Inventory\logs

- 2. Check the log files for error messages and invalid objects.
 - oclinst_database_service.log
 - reall_database_service.log
 - oclconfig database service.log
 - flt_seeddata_database_service_timestamp.log
 - html dialg templ database service timestamp.log



- html blob seeddata database service timestamp.log
- xmlp_clob_seeddata_database_service_timestamp.log
- xml_clob_seeddata_database_service_timestamp.log
- compile all invalid database service.log
- load_olsardcstatemachine_jar_database_service.log
- install_database_service_timestamp.log
- opaconnectcheck_system_database_service.log

Perform Database Post-Installation Tasks

To complete the installation of your Oracle Clinical database, perform the following tasks:

- Set the Database Time Zone
- Pin Database Packages
- Consider Implementing Partitioning

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 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 Clincal 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 installation, note that you perform the next task in this environment.

Consider Implementing Partitioning

• Partition the Oracle Clinical RESPONSES table, which contains all patient data entered for all studies in an Oracle Clinical installation.

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

Set Up Parameterized Submissions

The Parameterized Submission process (PSUB) schedules and runs jobs, reports, and batch processing for Oracle Clinical. In order to support using Oracle Real Application Clusters (RAC), the implementation of PSUB changed in Oracle Clinical 5.0. See the 5.0.1 *Installation Guide* for more information.

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

For more information, see:

- Create Directories and Enter Values in OCL_STATE Local Reference Codelist
- Enable Users to Submit PSUB Jobs
- Set Up Active Directory
- Start the PSUB Service
- Customize the PSUB Service (Optional)
- Test the PSUB Installation

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 Integrate SAS (Optional) 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 inPSUB_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.



Set Up Active Directory

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 the PSUB Service

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

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

To start the PSUB service manually 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.
 - 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.

Customize the PSUB Service (Optional)

- 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.

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:

%RXC_ROOT%\log



5 Integrate SAS (Optional)

Oracle Clinical supports the following configurations with SAS statistics application:

- SAS and Oracle Clinical database server 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 Windows, SAS must also be installed on Windows.

• SAS installed locally and Oracle Clinical installed in a hosted environment

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

- Base SAS
- SAS/ACCESS

The SAS/ACCESS interface to Oracle requires Oracle SQL*NET on the computer where SAS is installed.

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 oclsascr 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

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 for UNIX and Enable Users to Submit PSUB Jobs for Windows.



Add the opapps Account to the oclsascr User Group

To 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 Create the oclsascr User Group for SAS.

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

See the Oracle Clinical Administrator's Guide for information.

Set Up SAS User Authentication and Set OCL_STATE Reference Codelist Values

To 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.

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.

- Prepare the SAS Template File
- Edit the opa_settings File
- Set Up a SAS Connection



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>

 Replace the string with the actual SAS executable path; for example: /usr/local/SASHome/SASFoundation/9.4/sas \$*



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.

Edit the opa settings File

To use SAS 9.3 with Oracle Clinical on a UNIX platform:

- 1. Navigate to the following directory: *OPA_HOME*/bin
- 2. Open the opa_settings file.
- 3. Change the value of the SASORA environment variable to V9. For example: db_env_setting:_DEFAULT_:SASORA:V9

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. During installation, the database Installer prompts you for the SAS_CONNECTION value and adds it to the OCL_STATE reference code list. The short value is SAS_CONNECTION and the long value can be either ORACLE_WALLET or SAS_ENCRYPTION.

Oracle Wallet

This is the default option.

If your SAS server is the same as the database server, and you set ORACLE_WALLET as the long value, the SAS connection is set up automatically.

If your SAS server is on a different machine from the database and you want to use ORACLE_WALLET, it is not necessary to install the Oracle Clinical server on the SAS server machine as long as you are able to connect to the database after you log in as opapps.

On the SAS server:

1. Log on as opapps.



- If the Oracle Clinical database server is not installed on the same machine, set the environment variables in .cshrc so you can connect to the database using SQL*Plus.
- If the Oracle Clinical database server is installed on the same machine,
- 2. Set up the Oracle Wallet on the SAS server. See Create an Oracle Wallet and Generate a Certificate Request.
- 3. Create an opapps account in the same was you did on Database Server with default shell C Shell. See Create the opapps Account and Add It to Groups.
- Enter the SAS server in the OCL_STATE reference codelist for short value REMOTE_SAS_SERV. See the Oracle Clinical Administrator's Guide for information.

SAS Encryption

To set up a SAS connection using SAS encryption:

1. Log in to the database as the system user and create a database account: create user sas proxy user

For example, *abc123*

- Grant proxy connection for the database user account: alter user <oc user> grant connect through <sas proxy user>;
- Log in to the PSUB server as RXC_SAS_VIEW owner and run the commands: opa_setup <dbname> <codenv>

cd \$RXC SAS VIEW

4. Create a SAS file named pwd.sas with the following content:

```
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.

- 5. Run the file created in Step 4. This creates the sas_proxy_password_encoded_file which stores the encrypted password of the sas_proxy_user db user.
- 6. Remove the file created in Step 4.
- 7. Run the SAS files.

The sas_proxy_user does not have *create session* privileges and so cannot be directly connected through an SQL*Plus session.

Other OS users can run SAS jobs from their accounts if they have *read* access to the path \$RXC_SAS_VIEW. In other words, if the OS user belongs to the oclsascr group.

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.

For more information, see:

- Set REMOTE_OS_AUTHENT to FALSE
- Set Up a SAS Connection



Set REMOTE_OS_AUTHENT to FALSE

To 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

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:

- Log in to the database as system user and create the sas_proxy_user database account: create user sas_proxy_user identified by <password>;
- 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;
```

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 5.
- 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

Note:

The procedures in this section uses secure shell (ssh) to establish the connection to SAS.

To set up SAS on a different UNIX server computer:

- Network File System (NFS)
- Create opapps on the SAS Server
- Check init.ora
- Create a Shell Script

Network File System (NFS)

- Use Network File System (NFS) protocol to make the directory on the Oracle Clinical server pointed to by the \$RXC_USER /sas_view visible to the SAS server.
- 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/logingroup on the SAS server if it is not the primary group for opapps.

Check init.ora

- **1.** Open the init.ora file.
- Verify that the REMOTE_OS_AUTHENT initialization parameter is set to FALSE for the Oracle Clinical database instance in the init.ora file: REMOTE OS AUTHENT=FALSE

See the Table 2-3 table 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/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 Create the opapps Account and Add It to Groups.
- 2. Log on as opapps.
- 3. Set the environment variables in .cshrc so you can connect to the database using SQL*Plus.
- 4. Set up the Oracle Wallet on the SAS server. See Create an Oracle Wallet and Generate a Certificate Request You may use the same Wallet password that you used during Oracle Clinical installation or a different one:

mkstore -wrl wallet_location -create -nologo

Example wallet location: /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 for **SAS Encryption** 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.

- Press Return to accept the default location. This process creates two files in the user's home directory:
 - ~I.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.
 - ~I.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, *I*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
- 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 Computer as Oracle Clinical
- Install SAS on a Different Windows Computer from Oracle Clinical

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 Computer as Oracle Clinical

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 Computer from Oracle Clinical.

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 the table in Install and Configure Oracle Database 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

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

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 the 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\9.2"*/
-SASUSER "D:\sasuser"
/* Setup the default SAS System user work folder */
/*-WORK "!TEMP\SAS Temporary Files"*/
-WORK "D:\sastemp"
```

- 5. Save the file.
- 6. Create directories D:\sasuser and D:\sastemp or your preferred equivalents. (In Windows Explorer, right-click and then select **New**, then **Folder**.)
- 7. Give full control directory permissions on these directories to the oclsaser group.

Install SAS on a Different Windows Computer from Oracle Clinical

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
- Edit the SAS Config File and Grant Permissions
- Set Values in OCL_STATE Reference Codelist

Set REMOTE_OS_AUTHENT to FALSE

To 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 the table in Install and Configure Oracle Database for more information.

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 location where you have installed SAS 9.4. In the 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\9.3"*/
-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



Part II Application Tier

Part II contains the following chapters:

- Install and Configure the Oracle Application Tier
- Install the Oracle Clinical Front End
- Install the Oracle Clinical Reports Server



6

Install and Configure the Oracle Application Tier

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

For more information, see:

- Before You Start
- Gather Required Information
- Install Adobe Reader
- Install Oracle Java Development Kit
- Install Oracle WebLogic Server
- Install the Oracle Fusion Middleware Infrastructure Software
- Install the Oracle Forms and Reports Servers
- Create the Repository Creation Utility
- Configure the FRDomain
- Enable SSL Between a Browser and Oracle HTTP Server
- Modify the tnsnames.ora File on the Application Server
- Configure Firewall on the Application Tier
- Test Connectivity to Databases for Forms and Reports Servers

Before You Start

In this section:

- Identify a Single Account to Perform All Application Tier Installation Tasks
- Get a CA Certificate for HTTPS
- Shared Directory
- Permanent IP Address

Identify a Single Account to Perform All Application Tier Installation Tasks

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



Get a CA Certificate for HTTPS

To support HTTPS:

- 1. Request a certificate from a Certificate Authority (CA) vendor, such as Thawte, Entrust, or Verisign.
 - a. Generate an encoded plain text certificate request file. See Create an Oracle Wallet and Generate a Certificate Request for more information.
 - Email the certificate request file to the CA vendor.
 The vendor will sign the file, and send you a Trusted Certificate and a User Certificate. Allow some time for the certificates to be issued.
- 2. Import the certificate into the Oracle Wallet for the Oracle Application Server.

Note:

If your intention is to install an environment that will never be taken into production, you can skip this step and create a self-signed demo certificate for testing purposes; see Enable SSL Between a Browser and Oracle HTTP Server With Self Signing.

Shared Directory

If you have multiple Oracle Clinical Forms and/or Reports Server computers:

- **1.** Select a shared directory to be accessible from all servers for storing report output and logs.
- 2. Map the shared directory as a network drive of same name in all the servers.

Permanent IP Address

• Make sure every computer on which either the Oracle Clinical Forms or Reports Server is installed has a permanent IP address.

Gather Required Information

Have the following information ready.

Install the Oracle WebLogic Server

- Home directory path; for example:
 C:\Oracle\Middleware\Oracle Home
- Email address to receive 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 example:
 C:\Oracle\Middleware\Oracle_Home



- · Email address to receive 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 example:

C:\Oracle\Middleware\Oracle Home

Create the Repository Creation Utility

- Database details:
 - Server.Domain; for example: servername.your_company.com
 - Port number
 - Database service name
 - Database administrator username and password
- RCU Schema password

Configure the FRDomain

- Domain home path; for example:
 C:\Oracle\Middleware\Oracle Home\user projects\domains\FRDomain
- Application location; for example: C:\Oracle\Middleware\Oracle_Home\user_projects\applications\FRDom ain
- WebLogic Domain administration username and password
- RCU Database connection:
 - DBMS/ Service name
 - Server.Domain; for example: servername.your_company.com
 - Port number
 - Schema owner name and password
- Node Manager credentials: Username and password
- Oracle HTTP Server details:
 - Administrator host's IP address
 - Administrator port number
 - Listen address
 - Listen port number
 - SSL listen port number
 - Server name



Install Adobe Reader

If you have not already downloaded Adobe Reader, following instructions in Download Adobe Reader, do so now.

• Install Adobe Reader on the Reports Server and on client computers.

Install Oracle Java Development Kit

To install Oracle Java Development Kit (JDK):

- 1. If you have not already done so, follow instructions in Download Oracle Java Development Kit.
- 2. Follow instructions in the release notes to apply the patch.

Note:

Do not use the default download location. By default, the download directory is C:\Program Files\java\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

- 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 for Microsoft Windows x64 (64-bit) and extract the V983364-01.zip file 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.
- 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-oracleweblogic-server-and-coherence-software.html#GUID-E4241C14-42D3-4053-8F83-C748E059607A.

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 want, 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++ 2015-2022 redistributable -14.38.33130. 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.

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

To 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



12.2.1.4 for Microsoft Windows x64 (64-bit) and extract the V983368-01.zip file 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.
- 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.

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-infrastructure-software.html#GUID-943F11B4-DD9E-4631-8F5F-80B3ADC06F26.

Install the Oracle Forms and Reports Servers

- In the staging area where you downloaded the media pack (see Download the Software), locate the directory where you downloaded Oracle Forms and Reports 12.2.1.19 for Microsoft Windows x64 (64-bit) and extract the V1033711-01.zip file 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 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.

For instructions, see Oracle® Fusion Middleware Installing 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/installing-and-configuring-oracle-forms1.html#GUID-EBBA8709-F563-469C-9D2F-F308AF4E60C5.

Create the Repository Creation Utility

For this task, you need the following database server details:

- Host name
- Port



- Service name
- Password for the SYS account

For instructions, see Oracle® Fusion Middleware Installing 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/installing-and-configuring-oracle-

forms1.html#GUID-26210D99-290E-446D-B972-A81EA5C90CF9. Run \$FMW_HOME/
oracle_common/bin/rcu.bat. Unless otherwise noted, click Next to continue to the next
screen.

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

Select Components

- 1. Select the option Oracle Platform Security Services.
- 2. Enter the prefix name for the domains in the following format: *servername*FR

Schema Password

 Provide a schema password and make note of the schema name and password because they are required to configure the FRDomain.

Configure the FRDomain

For instructions, see Oracle® Fusion Middleware Installing 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/installing-and-configuring-oracle-forms1.html#GUID-E3EC8981-780D-4D15-AA01-1FF91CDDCF59.

Make sure you type FRDomain (case-sensitive) in the desired domain home path.

When configuring the FRDomain, it is recommended to use the default port 7001 for Admin Server and 9001 or 9002 for managed servers (WLS_FORMS and WLS_REPORTS).

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

After completing the FRDomain configuration, follow instructions in Run ohs_updateInstances.

Templates

- 1. Select the check box for the following templates:
 - Oracle Forms [forms]
 - Oracle Reports Application [reports]
 - Oracle Enterprise manager [em]
 - Oracle HTTP Server (Collocated) [ohs]
 - Oracle Reports Tools [ReportsToolsComponent]
 - Oracle Reports Server [ReportsServerComponent]
 - Oracle Reports Bridge [ReportsBridgeComponent]
 - Oracle JRF [oracle_common]
 - Weblogic Coherence Cluster Extension [wlserver]



Add Administrator Account - Provide a password for the WebLogic user account and make note of this password because it is required to install Oracle Clinical and/or Oracle Thesaurus Management System.

Domain Mode and JDK - Select the Production option under Domain Mode.

Database Configuration Type

- 1. Provide the Repository Creation Utility schema name that you defined in Create the Repository Creation Utility and add _STB to this name. For example, if the schema name you defined was OCRDCDEV, provide OCRDCDEV_STB.
- 2. Provide the schema password that you defined in Create the Repository Creation Utility.
- 3. Click Get RCU Configuration to continue.

Advanced Configuration - Select all check boxes.

Administration Server - Select the Enable SSL check box.

Node Manager - Define the Node Manager username and password and make note of them because they are required to install Oracle Clinical and/or Oracle Thesaurus Management System.

Managed Servers - Select the Enable SSL check box for all managed servers.

Assign Servers to Machines - Move AdminServer from the Servers list to the Machines list.

System Components

- 1. Click Add to add the OHS component.
 - a. For System Component, specify ohs1.
 - b. For the Component Type, select OHS.

OHS Server

Note:

It is recommended to use the standard HTTP/HTTPS ports 80 or 443. If you plan to use other ports, these need to be modified accordingly during the installation process.

- **1.** For Listen Address, specify the machine name, including the domain.
- 2. Change the Listen Port value to 80.
- 3. Change the SSL Listen Port value to 443.

Domain Frontend Host

- 1. Copy the URL from the **Plain** field and paste it in the **SSL** field.
- 2. In the **SSL** field, change *http* to *https*, and add the SSL port if the non-standard port 443 is used.
- 3. Select the SSL as the default option.



Assign System Components - Move ohs1 from the System Component list to the Machines list.

Run ohs_updateInstances

Run ohs_updateInstances

Perform the following steps:

1. Start the Node Manager.

%ORACLE_HOME%
\user projects\domains\FRDomain\bin\startNodeManager.cmd

2. Start the admin server.

```
%ORACLE_HOME%
\user projects\domains\FRDomain\bin\startWebLogic.cmd
```

3. Run WLST.

%ORACLE HOME%\oracle common\common\bin\wlst.cmd

4. Connect to admin server.

connect('adminserver_username','adminserver_password','t3://
host_name:FRDomain_adminserver_port')
For example:

connect('weblogic','password1','t3://localhost:7001')

5. Run the following command:

ohs_updateInstances()

Enable SSL Between a Browser and Oracle HTTP Server

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

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

- Enable SSL Between a Browser and Oracle HTTP Server Using a Certificate Authority
- Enable SSL Between a Browser and Oracle HTTP Server With Self Signing

Enable SSL Between a Browser and Oracle HTTP Server Using a Certificate Authority

An Oracle Wallet is a container that stores your credentials, such as certificates, trusted certificates, certificate requests, and private keys.

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



Note:

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

For more information, see:

- Create an Oracle Wallet and Generate a Certificate Request
- Obtain Trusted Certificate and User Certificate from Certificate Authority
- Add the User Certificate and Trusted Certificate to an Oracle Wallet
- Edit the Oracle HTTP Server Configuration File

Create an Oracle Wallet and Generate a Certificate Request

To create an Oracle Wallet:

- 1. Create an Oracle Wallet: https://docs.oracle.com/en/middleware/fusionmiddleware/12.2.1.4/asadm/managing-keystores-wallets-andcertificates.html#GUID-DA49F413-AB8F-46E6-924C-EC4CD8F96AC1
- 2. Generate a Certificate Request: https://docs.oracle.com/en/middleware/ fusion-middleware/12.2.1.4/asadm/managing-keystores-wallets-andcertificates.html#GUID-70174F92-035D-4829-9DB8-8118964BFA9D

Obtain Trusted Certificate and User Certificate from Certificate Authority

Note:

Certificate signed using MD5 algorithm is no longer supported in Oracle HTTP Server (12.2.1.4). You must get the certificate signed using Secure Hashing Algorithm 2 (SHA-2).

 Obtain the certificates from the Certificate Authority as described in Get a CA Certificate for HTTPS.

Depending on the Certificate Authority, you will need to send either the certificate request file generated in the previous section or you will need to copy and paste the text in that file.

Add the User Certificate and Trusted Certificate to an Oracle Wallet

For information, see https://docs.oracle.com/en/middleware/fusion-middleware/ 12.2.1.4/asadm/managing-keystores-wallets-andcertificates.html#GUID-70174F92-035D-4829-9DB8-8118964BFA9D.



Edit the Oracle HTTP Server Configuration File

WebLogic Server installation creates a default, unsigned SSL wallet file for OHS. Its location is specified in the configuration file (ssl.conf) loaded at startup from the %ORACLE_HOME% \user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1 directory.

 Make a backup copy of ssl.conf, which is located where Fusion Middleware is installed in %ORACLE_HOME%:

```
%ORACLE_HOME%\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1
```

```
%ORACLE_HOME%
\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\instances\ohs1
```

- 2. Open ssl.conf in a text editor.
- 3. Find the string #Path to the wallet and comment out the default location that follows it.

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

4. Replace the above string (in bold) with the path to the directory you created:

```
SSLWallet %ORACLE_HOME%
\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1\keystores\defa
ult
```

- 5. Stop and start Oracle HTTP Server (OHS) to load the configuration change:
 - a. To stop OHS: %ORACLE_HOME%\user_projects\domains\FRDomain\bin\stopComponent ohs1
 - b. To start OHS:

Note:

Ensure that the FRDomain Node Managfer is running before you start OHS.

%ORACLE_HOME%\user_projects\domains\FRDomain\bin\startComponent ohs1

Note:

ohs1 is the name of OHS component provided while configuring FRDomain. %ORACLE_HOME% is the location of installed FMW.

6. Test that you can connect from a browser to your virtual host in HTTPS URL: https://host.your_company_domain



Enable SSL Between a Browser and Oracle HTTP Server With Self Signing

For more information, see *How to create a Self Signed Certificate to enable SSL between the Browser and HTTP Server in Oracle Clinical 5.2* (Document ID 2473240.1) on My Oracle Support.

For more information, see:

Edit the Oracle HTTP Server Configuration File

Edit the Oracle HTTP Server Configuration File

WebLogic Server installation creates a default, unsigned SSL wallet file for OHS. Its location is specified in the configuration file (ssl.conf) loaded at startup from the %ORACLE_HOME%

\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1 directory.

 Make a backup copy of ssl.conf, which is located where Fusion Middleware is installed in %ORACLE_HOME%:

```
%ORACLE_HOME%
\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1
%ORACLE_HOME%
\user_projects\domains\FRDomain\config\fmwconfig\components\OWS\instances
```

- $\label{eq:loss_loss} $$ loss \ FRDomain\ Config\ Mwconfig\ OHS\ loss \ \ loss \ \ loss \ loss \ loss \ \ los \ \ los \ \ los \ \ loss$
- 2. Open ssl.conf in a text editor.
- 3. Find the string #Path to the wallet and comment out the default location that follows it.

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

4. Replace the above string (in bold) with the path to the directory you created:

```
SSLWallet %ORACLE_HOME%
\user_projects\domains\FRDomain\config\fmwconfig\components\OHS\ohs1\keystore
s\default
```

5. Start Oracle HTTP Server (OHS) to load the configuration change:

Note:

Before starting ohs1, start the FRDomain Node Manager. Else, ohs1 will not start.

%ORACLE_HOME%\user_projects\domains\FRDomain\bin\startComponent *ohs1 ohs1* is the name of OHS component provided while configuring FRDomain. %ORACLE_HOME% is the location of installed FMW.

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



Modify the tnsnames.ora File on the Application Server

To modify the tnsnames.ora file on the application server:

- Go to the following tnsnames.ora location on the application server: middleware_home\user_projects\domains\FRDomain\config\fmwconfig
- 2. Make sure the tnsnames.ora file has an entry for each database that matches the database's service name.

Configure Firewall on the Application Tier

If you have a firewall in your environment:

- Open the following ports:
 - HTTP: 80 (or listen from httpd.conf)
 - HTTPS: 443 (or listen from ssl.conf)
 - RDC Onsite: 7221
 - Oracle Forms: 9001
 - Oracle Reports: 9002
 - Forms Admin Server: 7001
 - OPADomain Admin Server: 7101

Test Connectivity to Databases for Forms and Reports Servers

The Oracle Clinical database must be able to communicate with the application servers.

For more information, see:

- Test the Connection from the Application Servers to the Database
- Troubleshoot Network Connection Issues

Test the Connection from the Application Servers to the Database

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

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

sqlplus system/password@dbname

Troubleshoot Network Connection Issues

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

Possible causes of errors include:

• The computer is not physically connected to the network.



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



7 Install 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 installed before you install the Oracle Clinical Front End. See Install and Configure the Oracle Application Tier for instructions.

For more information, see:

- Gather Required Information for the Oracle Clinical Front End
- Restart Computer and Start All Services
- 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 the 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:\opapps54
- Java home is located in version JDK 1.8.0_391 or higher.
- Your Oracle Fusion Middleware home directory; for example: C:\Oracle\Middleware\Oracle_Home
- Your Oracle Fusion Middleware user project directory; for example: C:\Oracle\Middleware\Oracle_Home\user_projects
- Your OPA home directory; by default: C:\opapps54



Cluster Configuration:

Note:

Oracle Clinical installer supports cluster configuration. For configuring cluster environment:

- **1.** Identify the primary and secondary nodes of application servers which will be part of the cluster.
- 2. Install the technology stack in all nodes.
- 3. Configure FRDomain only on the primary node.
- **4.** After installing the technology stack, use the Oracle Clinical installer to install primary and secondary nodes by selecting the cluster options.
- For configuring the standalone server:
 Select the No option (default value) in the Cluster Configuration screen.
- For configuring the primary node cluster:
 Select the Yes option in the Cluster Configuration screen.

To install the primary node, select the **Yes** option in the Node Configuration screen, and enter the secondary node server details:

SecondaryNodeServer.Domain:Port Number; for example:

secondary_node_server_name.your_company.com:port_number

 For configuring the secondary node cluster: Select the Yes option in the Cluster Configuration screen.

To install the secondary node, select the **No** option in the Node Configuration screen, and enter the primary OPADomain Admin Server details in the Admin Server Configuration screen.

- WebLogic username: The account created when you installed the WebLogic Server.
- WebLogic Server Password: Enter a new password or use the password you created when installing WebLogic Server.
- Admin Server configuration details:
 - Listen address
 - Listen port number (default is 7101)
 - SSL listen port number (default is 7102)
 - WebLogic username
 - WebLogic Server password
- Node Manager configuration details: We recommend you to use the default values.
 - Listen address
 - Listen port number
 - WebLogic username



- WebLogic Server password
- Database details:
 - 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
- Your OPA backup directory: C:\opa_backup
- Oracle Fusion Middleware Repository Creation Utility (RCU) configuration details:
 - Schema prefix

Note:

For setting the schema prefix, we recommend you to:

- * Set a value which is not in use
- * Set a value that does not start with a number
- * Specify it in the format *HostName*OPA
- * Use only alphanumeric characters
- * Set a value that does not contain any special characters
- * Set a value of length not more than 12 characters
- Database administrator username and password
- RCU schema password
- Wallet location: for the Wallet you created in Enable SSL Between a Browser and Oracle HTTP Server. (You can browse for it on screen.)
- 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.

Restart Computer and Start All Services

Restart the computer and then start all services:

- **1.** Restart the computer.
- 2. Navigate to ORACLE_HOME\user_projects\domains\FRDomain\bin and run startNodeManager.cmd to start the FRDomain Node Manager.
- 3. Navigate to ORACLE_HOME\user_projects\domains\FRDomain\bin and run startWebLogic.cmd to start the FRDomain Admin Server.



- Open a DOS prompt, and navigate to ORACLE_HOME\user_projects\domains\FRDomain\bin.
- 5. To start the Forms and Reports server, use the Admin Console at http://host:port/ console.
- 6. To start OHS, enter:

startComponent ohs1

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. Follow instructions on the installation screens, providing the information you have gathered in Gather Required Information for the Oracle Clinical Front End.
- 6. If the Installer detects that you have already installed Release 5.2.2 or above and created the OPADomain, the Installer asks if you want to overwrite OPADomain or not.

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

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

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



8. **Install**: The Installer copies the files onto the server, completes the setup and configuration tasks, and generates a log file of this installation.

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

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

The Installer saves the URL information in the following file: \opapps54\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

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

Also, review the log files located in the C:\opapps54\log folder.

Work with Life Sciences Support, if necessary, to resolve any errors.

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.

To download and install the Oracle Clinical PDF plug-in onto the client, see Download the Oracle Clinical PDF Plug-in.

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 opapps54\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:

- Sharing the Directory Across Multiple Computers
- Setting Up the Image Directory on a Single Computer

Sharing the Directory Across Multiple Computers

To share the image directory across multiple machines:

- 1. Log in to the Forms Server computer as a user with system administrator privileges.
- 2. Select a directory to store the images. The default location is <OPA HOME>\html\rdc\dcif_images (for example C:\opapps54\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 (opapps54\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.

Setting Up the Image Directory on a Single Computer

If you have a single Forms server:



Perform the setup in Sharing 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:\opapps54\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
- Change the Lexicons Directory if Necessary
- 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
- 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:





- Copy the jspellsdk folder to default Admin Server upload location: middleware_home\user_projects\domains\OPADomain\servers\AdminServer\upload.
- Also copy the jspellsdk folder to the Target Server stage location. (middleware_home\user_projects\domains\OPADomain\servers\Server.Domain_OPA_1\s tage)



- 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 <code>jspellsdk</code> 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_HOME\user_projects\domains\FRdomain\bin\stopComponent.cmd ohs1

3. To start OHS enter:

drive:\ORACLE_HOME\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.

Change the Lexicons Directory if Necessary

If the Application Server and JSpell directories are located under the same parent directory; for example, C:/oracle and C:/jspell, then you can skip this step. If they aren't in the same parent directory, you must map JSpell's lexicons directory:

- Navigate to the following directory: ORACLE HOME\j2ee\opa\applications\jspellsdk \jspellsdk\WEB-INF
- 2. Open the web.xml file.
- 3. Find the following lines in the web.xml file:

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

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

Update the formsweb.cfg File for JSpell

To update the formsweb.cfg file:

1. Navigate to the following directory:

 $\label{eq:middleware_home} middleware_home \label{middleware_home} \label{eq:middleware_home} \end{tabular} $$ ORMS \end{tabular}$

- 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\KEY*number* 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 $\tt HTTP$ or $\tt HTTPS$, 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. For more information, see:

- 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 Install Oracle Java Development Kit .
 - b. Enter: dir %java_home%. You should see the directory specified as your JAVA_HOME containing a file called src.zip and four subdirectories: jre, lib, bin, and include.

If you do not see these things, you will need to add them as directed in 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\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.

Note:

Create the security folder, if not available.

If the boot.properties file does not exist, create it as a plain text file with the following contents:

```
username = weblogic_user_name
password = weblogic_user_password
```

By default, the WebLogic user name is weblogic. This user name 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

Set up the Task Scheduler to start the FRDomain and OPADomain at startup:

- 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 the following values:

Name: Oracle FRDomainNM Autostart Trigger: When the computer starts

Action: Start a program

Select: opa home\config\opa setup scripts\autostartfrdomainNM.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

Test Autostart

To test autostart:

- 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.



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.

To start 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.



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 the 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.



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

For more information, see:

- 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, do the following:



 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)



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.



8

Install the Oracle Clinical Reports Server

You can choose to install a *standalone* Reports Server on a computer that does not have a Forms Server installation. You can also set up and use more than one Reports Server on a subnet where they can access each other. If you have any standalone Report Servers, all Forms and Report Servers must map a drive (the same drive for each server) to the shared directory on whichever server you choose; see Set Up Reports Server and Forms Server for Access and File Viewing.

If you are installing the Reports Server on the same computer as the Forms Server, you must install the Oracle Application Server technology stack and Oracle Clinical Front End before you install the Oracle Clinical Reports Server.

If you are installing a standalone Reports Server, you must first install the Oracle Application Server technology stack on the same server.

For more information, see:

- Gather Required Information for the Oracle Clinical Reports Server
- Restart the Computer
- Start the WebLogic FRDomain Admin Server
- Install the Oracle Clinical Reports Server
- Restart the Computer
- Set Up Reports Server and Forms 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 the Oracle Clinical Reports Server

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

- Home Details: Enter the following:
 - Name: OPA_HOME
 - Path: c:\opapps54
- Your Oracle Fusion Middleware home directory; for example: C:\Oracle\Middleware\Oracle_Home
- Your Oracle Fusion Middleware User Project; for example: C:\Oracle\Middleware\Oracle_Home\user_projects
- Your OPA home directory; for example: C:\opapps54



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

You must enter the Report Server output directory as the Oracle Clinical user Report Server output directory. For example, C:\opapps54\log

- Adobe Reader location; for example: C:\Program Files (x86)\Adobe\Acrobat Reader DC\Reader\AcroRd32.exe
- If you select to store the DCIF images locally, you need the local DCIF images directory. Else, you need the location of the shared directory.

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. Go to ORACLE_HOME\user_projects\domains\FRDomain\bin and run startNodeManager.cmd.
- At the DOS command prompt, go to ORACLE_HOME\user_projects\domains\FRDomain\bin and run startWebLogic.cmd.

Install the Oracle Clinical Reports Server

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

Note:

It is required to 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. Follow instructions on the installation screens, providing the information you have gathered in Gather Required Information for the Oracle Clinical Reports Server.
- 6. **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**.

7. 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.

8. 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, installActionstimestamp.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

Work with Life Sciences Support, if necessary, to resolve any errors.

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 Reports Server and Forms 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 Each Reports Server Root Directory
- Provide Oracle Clinical and RDC Users Access to the 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 Forms, Reports, or standalone File Server, select a single server where you will locate your Reports Server root directory. 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 of Services.

Note:

(Optional) Either now or later you can create a separate subdirectory for each user. However, users do not require direct access to the directory, and when viewing reports and log files from the application, users can see only the files they generated.

Share 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.
 - 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.
 - 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>
```

Provide Oracle Clinical and RDC Users Access to the Root Directory

The Report Server root directory you created in the previous steps is the directory to specify for each user in Oracle Clinical. See the Oracle Clinical Administrator's Guide on setting up user accounts, sections "Running the Add User Script" and "Maintaining Oracle User and Group User Accounts."

Provide the Oracle Clinical and RDC user access to the root directory on the Forms server. If the directory is local to the Oracle Clinical Forms server, specify the full directory path, including the user directory name, if any. Otherwise, the specification will be the mapped directory path, optionally with a user-specific subdirectory, for example: t:\<user_name>

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



• On the Reports Server used in DCI Form Generation

On the Oracle Clinical (Forms) Server

- 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:\opapps54\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

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 the table below, 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 8-1	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\opa_setup_scripts\domain\lifecycle, comment out the following line:

start ('WLS_FORMS')

- To autostart the reports server:
 - Update the autostartfrdomainscript.py file located in the opa_home\config\opa_setup_scripts\domain\lifecycle directory with the following command:

```
nmStart(serverName='<ReportsServerName>',
serverType='ReportsServerComponent')
```

- 2. Save and close the file.
- Restart the computer to apply the changes. Allow some time for all the services which includes Reports server to start.



 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')
```

Part III Client Tier

Part III contains the following chapter:

• Set Up Clients



9 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
- About Using Safari on an iPad
- Set Up for Proxy Usage on Fully Qualified Application Tier Names
- Download Required Applications
- Map Network Drive for Image Browsing (Optional)
- Enable Report Generation from the Command Line (Optional)
- 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.

About Using Safari on an iPad

On an iPad, which is supported for RDC Onsite, some functionality available on a personal computer using a mouse is not available, including:

- Right-click and double-click options.
- Selecting multiple records using Ctrl+click

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.
- 5. Click Save.

Similar proxy settings may be required on Macbook and ipad.

Download Required Applications

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.

For more information, see:

- 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 higher).

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

Please verify the instructions below are completed to avoid encountering an erro while launching the Oracle Clinical Application.

- **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.

(Optional) Enter the result of the procedure here.

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, graphicbased 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 (Optional)

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 (Optional)

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 9-1 URLs to Start Oracle Clinical and RDC Applications

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

where:

- *computer name* is the network name for the application server
- *domain* is the network domain name for your organization
- 3. Click Login.
- 4. Enter your user name, your password, and the database name.
- 5. Click **Connect** to start the 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.

