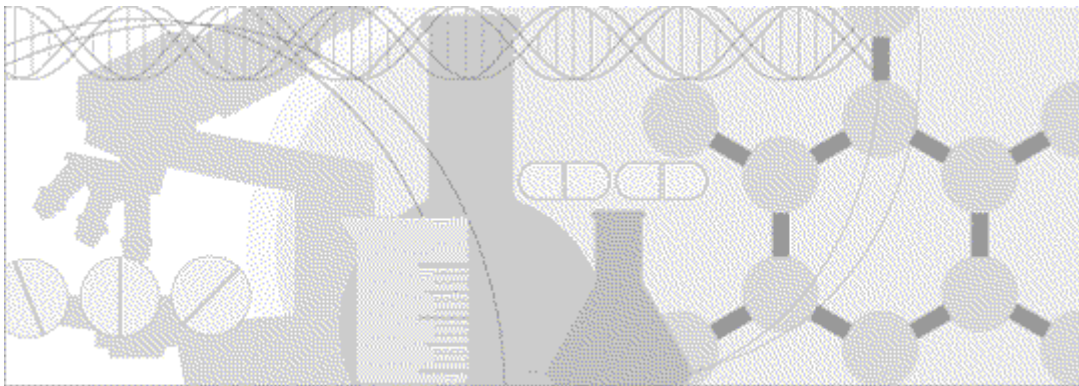


Installation Guide

Oracle[®] Health Sciences InForm CRF Submit
Release 3.1.2



ORACLE[®]

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Overview of this guide

The *Installation Guide* provides an architectural overview of the CRF Submit application and step-by-step instructions for installing, upgrading, and uninstalling the CRF Submit software. This guide describes how to configure the environment for the CRF Submit application and manage the CRF Submit software.

Audience

This guide is for IT professionals, database administrators, and data managers who need to install and manage the CRF Submit software.

Related information

Documentation

All documentation is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) and the Download Center (<https://extranet.phaseforward.com>).

All documents may not be updated for every CRF Submit release. Therefore, the version numbers for the documents in a release may differ. For a complete list of the documents in this CRF Submit release, their release version numbers, and part numbers, see the *Release Notes*.

Title	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	<p>The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.</p> <p>The most current list of known issues is available on the Extranet. To sign in to the Extranet, go to https://extranet.phaseforward.com.</p>
<i>Installation Guide</i>	<p>The <i>Installation Guide</i> describes how to install the CRF Submit software and the CRF Submit Adapter server.</p> <p>This document is also available from the Documentation CD.</p>
<i>User Guide</i> and online Help	<p>The <i>User Guide</i> and online Help provide an overview of the CRF Submit application, step-by-step instructions for using the CRF Submit application to generate PDF files of study data, and a detailed description of the user interface.</p> <p>This document is also available from the Documentation CD and the CRF Submit user interface.</p>
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Oracle® Health Sciences CRF Submit application, including details about the general principles of application security, and how to install, configure, and use the CRF Submit application securely.
<i>PDF Quick Reference</i>	The <i>PDF Quick Reference</i> provides an overview of the PDFs generated by the CRF Submit software and instructions for viewing PDFs.

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info>, or if you are hearing impaired, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs>.

CHAPTER 1

CRF Submit overview

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About the CRF Submit application

The InForm CRF Submit application is an InForm application add-on that you use to create Portable Document Format (PDF) files from an InForm study. The PDFs created with the CRF Submit application can be used for:

- Regulatory submissions under ICH or FDA guidance.
- Archived clinical data for investigative sites.

For each study, the CRF Submit application creates PDFs for subjects and visits that include:

- CRFs
- Audit trails
- Comments
- Signatures

General concepts

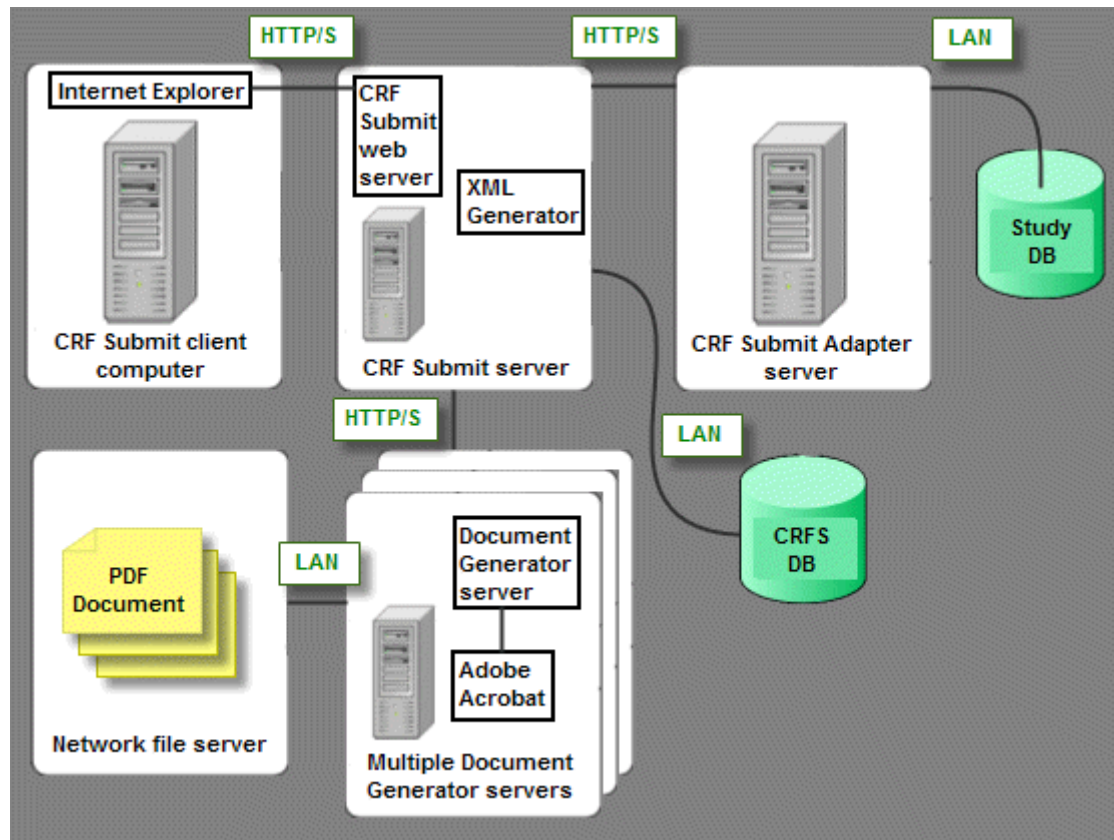
The CRF Submit software generates output based on:

- **Work orders**—The CRF Submit tasks that must be completed to fulfill a generation request.
- **Jobs**—The logical breakdown of a work order into the tasks that must occur to generate the PDF and XML files for a single subject or site.

CRF Submit software components

Overview of the CRF Submit system architecture

The following diagram shows the components that convert InForm study data into PDF files.



Component	Description
CRF Submit client computer	The computer on which you use Internet Explorer to access the CRF Submit server to create and monitor work orders.
CRF Submit server	<ul style="list-style-type: none"> Generates XML and includes the CRF Submit web server. You can use a centralized location for the storage and retrieval of the XML information that is to be converted into HTML and subsequently into PDF files.

Component	Description
CRF Submit database	<p>An Oracle database that:</p> <ul style="list-style-type: none"> • Tracks CRF Submit processes including: <ul style="list-style-type: none"> ▪ Time a work order is submitted. ▪ Time a work order is started and finished. ▪ Names of the CRF Submit computers. ▪ Error messages. ▪ The status of work orders. • Stores the queue of Document Generator jobs until they are completed. Work orders and completed jobs remain in the database until an administrator purges them. • Stores the XML that is received from the CRF Submit Adapter server and later turned into PDFs.
Document Generator server	Performs final conversion to PDF files.
Network file server	Repository to hold the final PDF output.
CRF Submit Adapter server	Processes requests from the CRF Submit web server and retrieves clinical data from the InForm database and converts it into XML format.
Study database	<p>Maintains and controls study data as it is entered into the InForm application. Contains the source data for the PDF, XML, and HTML files generated by the CRF Submit application.</p> <p>Note: The CRF Submit application does not modify the InForm data.</p>

How the components work together

- 1 The XML data is processed and stored as XML in the CRF Submit database.
As each XML job is processed by the Document Generator server, PDF jobs are created.
- 2 The Document Generator server retrieves jobs from the PDF job queue on the CRF Submit server and starts Adobe Acrobat.
- 3 The CRF Submit server transforms the requested XML into HTML and sends it back to Adobe Acrobat.
- 4 Adobe Acrobat processes the HTML by expanding each link that points to the CRF Submit server.
- 5 Adobe Acrobat generates a PDF file from the HTML.

The resulting PDF and XML files are stored in the directory specified in the work order.

Processing considerations and options

Generally, PDF generation is a lengthy process. Therefore, before you begin the PDF generation process, consider the following:

- The amount of time it will take to create PDFs.
- The amount of disk space required.

The amount of time required to create PDFs depends on:

- The number of CRFs in the study.
- The number of visits.
- The number of itemset entries, such as adverse events and lab data, entered for each subject.
- The length of the audit trails.
- Whether you suppress blank forms and visits.
- Whether you create PDFs by subject or by visit.
- The number of computers that are used and the processing power of those computers.

If you have a large amount of information to process, consider setting up several CRF Submit and Document Generator servers. For more information, see *Using multiple servers* (on page 5).

Using multiple servers

To make work order processing more efficient and to achieve optimal performance, the system can distribute processing among multiple CRF Submit and Document Generator servers.

- The work orders from all of the CRF Submit servers access one database server and are visible on all of the CRF Submit servers.
- A group of CRF Submit servers can retrieve data from a study and generate the XML for one work order.
- A group of Document Generator servers can generate the HTML and then the PDF files for one work order.
- Each server must have access to the shared directory to ensure that the PDF, XML, and HTML files are stored in the same location. For more information, see *Verifying the PDF Output Directory for multiple servers* (on page 28).

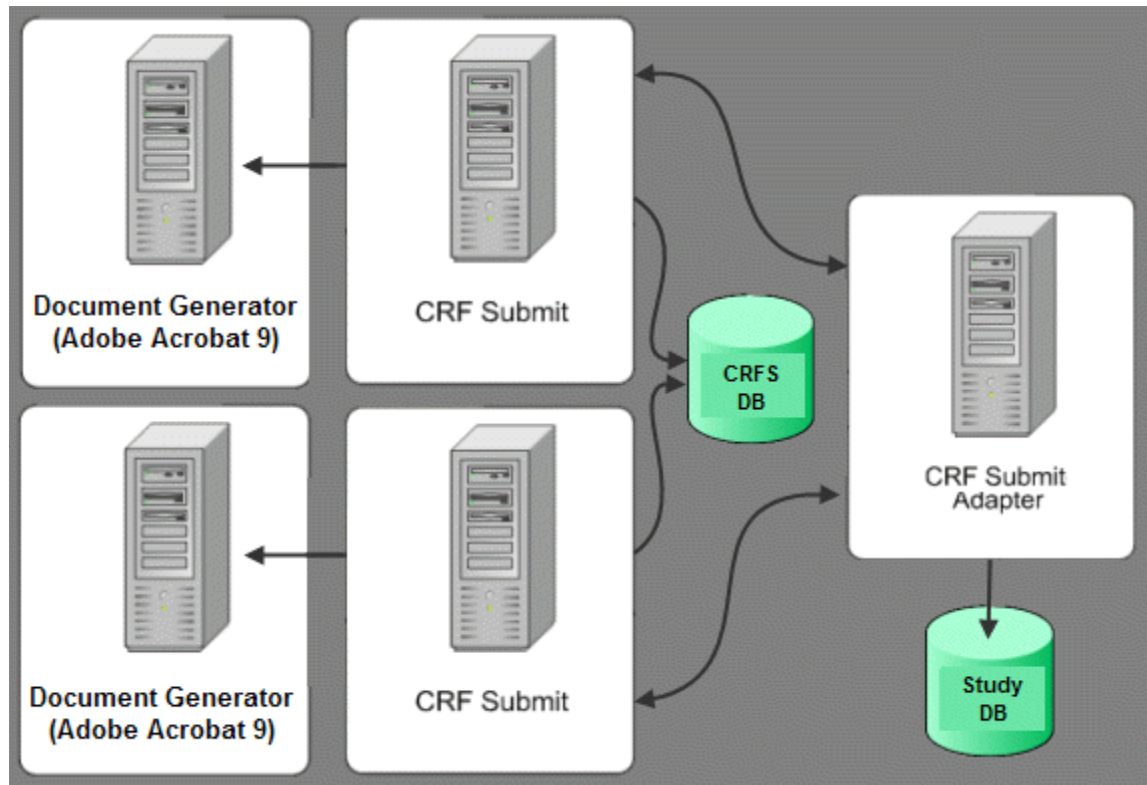
You can configure the servers during installation or you can configure the servers after installation using the options in the user interface. For more information, see *Configuration requirements for multiple servers* (on page 8).

Examples of using multiple servers

Basic environment with multiple servers

In the following example:

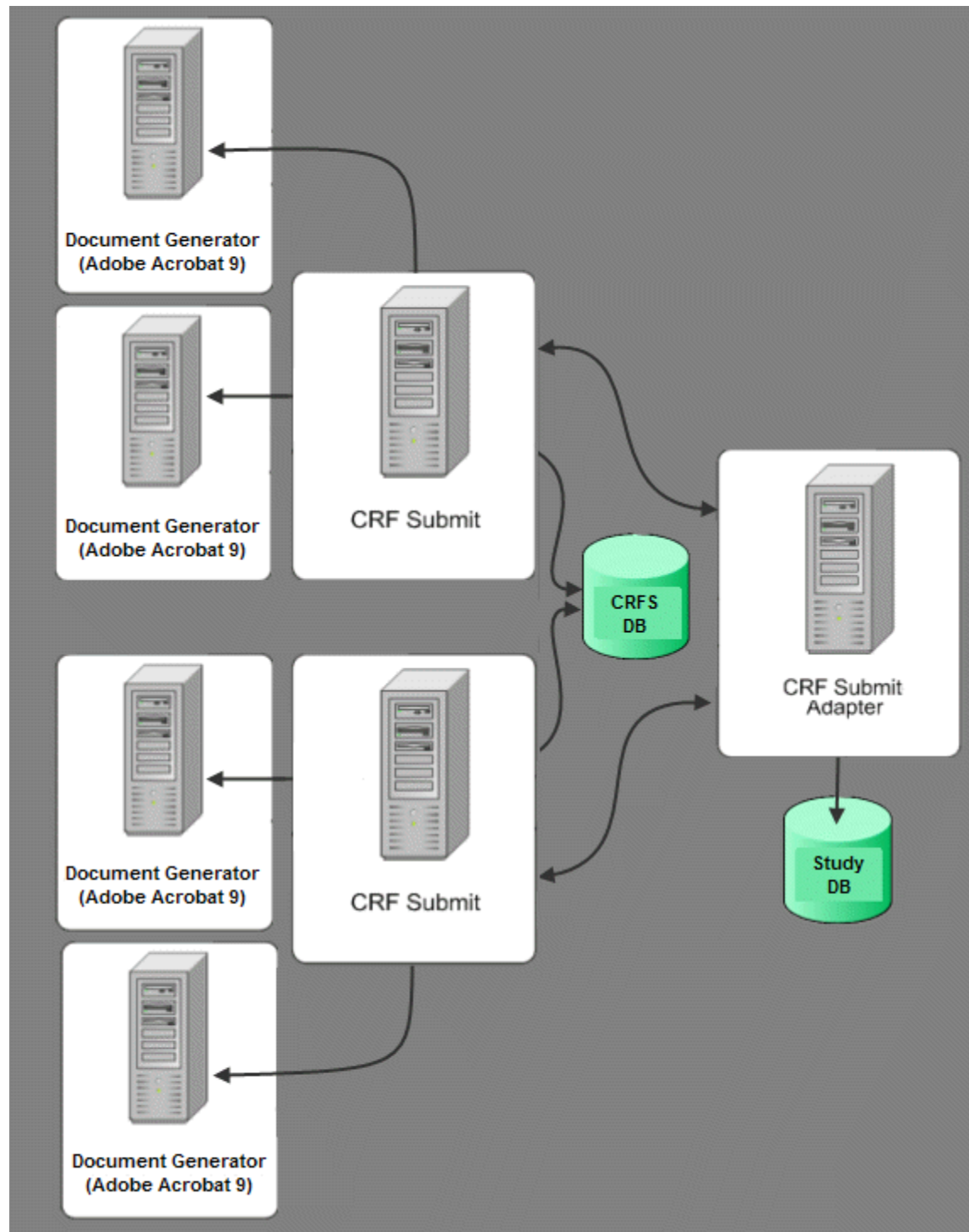
- XML processing is distributed between two CRF Submit servers.
- PDF job processing is distributed between two Document Generator servers.



Extended environment with multiple servers

The following example shows how a basic 4-server environment can be extended by the addition of two more Document Generator servers:

- XML processing is distributed between two CRF Submit servers.
- PDF job processing is distributed between four Document Generator servers.



Configuration requirements for multiple servers

- All of the CRF Submit servers should point to the same CRF Submit server database. When you install each CRF Submit server, make sure the same information is entered for the following fields:
 - **Database Connection String**—Oracle connection string used to connect to the CRF Submit database.
 - **CRFSubmit DB User**—Oracle user name used to access the CRF Submit database.
 - **CRFSubmit DB Password**—Password used to connect to the Oracle database.

You can change these settings in the CRF Submit application on the Configuration Options pages. For more information, see *Installing the CRF Submit software* (on page 15) and *Verifying the Oracle connection string for multiple servers* (on page 28).

- Each Document Generator server must point to the correct web server. After installation, set the CRF Submit server URL to point to the correct web server. For more information, see *Verifying the CRF Submit server field for multiple servers* (on page 28).
- The Document Generator servers must point to the same shared folder on all the computers to ensure that the work order data and the PDF, XML, and HTML files go to the correct location. For more information, see *Verifying the PDF Output Directory for multiple servers* (on page 28).

CHAPTER 2

Preparing to install

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Recommended configurations

Before you begin, verify that all hardware and software requirements are met.

For more information, see the *Release Notes*.

Note: You must install the Oracle database client on the CRF Submit server and the CRF Submit Adapter server. For more information, see your Oracle database documentation.

Oracle recommends that the CRF Submit software be deployed to at least three computers:

- CRF Submit server.
- Document Generator server.
- CRF Submit Adapter server.

If you have a large amount of information to process, consider setting up multiple CRF Submit and Document Generator servers.

For more information, see *Using multiple servers* (on page 5).

The following configurations are supported:

- Dedicated server for each component.
- CRF Submit server and Document Generator server on the same computer.
- CRF Submit server and CRF Submit Adapter server on the same computer.
- CRF Submit server, Document Generator server, and CRF Submit Adapter server on the same computer.
- One server for all components.

Oracle database settings

This section describes suggested Oracle database settings for configuring the CRF Submit database.

Required tablespaces

Before you install the CRF Submit software set up the following tablespaces in the Oracle database:

- **INFORM**—The default tablespace for the CRF Submit Oracle user.
- **TEMPBIG**—The temporary tablespace for the CRF Submit Oracle user.

Recommended settings

Tablespace settings

Tablespace	Size (MB)	Extend (MB)	Max extends	Autoextend
INFORM	2048	100	8 GB	YES
TEMPBIG	800	200	8 GB	YES
SYSTEM	800	N/A	N/A	NO
TEMP (optional)	350	5	2 GB	YES
UNDOTBS	500	100	8 GB	YES

Redo log settings

Include at least four redo log groups in the Oracle instance. Each group should have a redo log file that is at least 400 MB. This helps to reduce disk IO time by minimizing redo log file switching when large work orders are purged.

InitSID.ORA file parameters

Parameters	Recommended Specification Values
compatible	Must correspond to the installed Oracle 10g or 11g Client version
db_block_size	16384
cursor_sharing	SIMILAR
open_cursors	1000
java_pool_size	33554432
large_pool_size	1048576
processes	250

Parameters	Recommended Specification Values
undo_management	AUTO
undo_tablespace	UNDOTBS
_optimizer_cost_based_transformation	ON
_no_or_expansion	TRUE
db_writer_processes	4 (32-bit) 6 (64-bit)
db_file_multiblock_read_count	32 (32-bit) 64 (64-bit)
log_buffer	4194304 (32-bit) 10485760 (64-bit)
streams_pool_size	50 MB
sga_target	1750 MB (32-bit) 12000 MB (64-bit)
log_archive_max_processes	4 (32-bit) 6 (64-bit)
pga_aggregate_target	750 MB (32-bit) 3000 MB (64-bit)
recyclebin	OFF
undo_retention	3600 (32-bit) 9000 (64-bit)

CHAPTER 3

Installing the CRF Submit server

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Overview of the CRF Submit server installation

- 1 Install the CRF Submit software.

If this is the first time you are installing the CRF Submit software on this computer, see *Installing the CRF Submit software* (on page 15).

If you are upgrading from a previous version of the of the CRF Submit software, see *Upgrading the CRF Submit server* (on page 19).

- 2 Configure the CRF Submit software.

For more information, see *Configuring the CRF Submit software* (on page 17).

Installing the CRF Submit software

Note: If you try to install the CRF Submit software on a system that already has the Document Generator software installed, you receive an error message. To continue with the installation, click **Ignore**.

- 1 Log on to Windows as the user under which you want the CRF Submit software services to run.

Note: This must be an account that has local administrator rights.

- 2 Navigate to the CRF Submit ISO image.
- 3 In the CRF Submit folder, double-click **setup.exe**.
The Choose Setup Language page appears.
- 4 Select the language for the installation, and click **Next**.
The Welcome page appears.
- 5 Click **Next**.
The Customer Information page appears.
- 6 Enter the user name and company name, and click **Next**.
The Choose Destination Location page appears.
- 7 Verify the location in which the software will be installed. To change the location, use the **Browse** button to select another folder.
- 8 Click **Next**.
The Oracle CRF Submit Setup Dialog page appears.

Oracle CRF Submit Setup Dialog

Please fill in the requested information.

Database Connection String:

CRFSubmit DB Username:

CRFSubmit DB Password:

Admin Database Username:

Admin Database Password:

Install Clean Database

InstallShield

< Back Next > Cancel

- 9 Complete the fields using the information in the following table:

Field	Description
Database Connection String	Oracle connection string used to connect to the CRF Submit server database. If you plan to distribute processing among multiple servers, the connection string should be the same on all servers.
CRFSubmit DB Username	Oracle user name used to access the CRF Submit database. If you plan to distribute processing among multiple servers, the DB Username should be the same on all servers. Note: A clean database is automatically created. During a reinstall, the previously installed database is overwritten and you lose any information that was stored there. If you use an existing user, the user is dropped and then recreated.
CRFSubmit DB Password	Password used to connect to the Oracle database. If you plan to distribute processing among multiple servers, the password should be the same on all servers.
Admin Database Username	Name of the DBA in the Oracle instance.
Admin Database Password	Password that goes with the administrator user name.

- 10 Click **Next**.

The InstallShield Wizard review page appears.

- 11 Review the information provided to make sure it is what you intend to install. If you are not satisfied with the choices, click **Back**. When you are ready to proceed, click **Next**.

When the installation has completed, the InstallShield Wizard Complete page appears.

- 12 Click **Finish**.

Configuring the CRF Submit software

Enabling IIS 7.0 authentication for the CRF Submit server

You must enable ASP.NET Impersonation in IIS 7.0 for the CRF Submit server:

- 1 Select **Start > Administrative Tools > Server Manager**.
- 2 Select **Roles > Web Server (IIS) > Internet Information Services (IIS) Manager**.
- 3 On the Connections pane, select **<Machine Name> > Sites > Default Web Site > CRFSubmit**.
- 4 On the /CRFSubmit Home page, double-click **Authentication**.
- 5 On the Authentication pane:
 - a Select **ASP.NET Impersonation**.
 - b On the Actions pane, click **Enable**.
 - c Select **Windows Authentication**.
 - d On the Actions pane, click **Enable**.

Granting access to the CRF Submit software

Access to the CRF Submit software is controlled by Windows user groups. The following groups are created during installation. You must add users to the following groups to grant them access.

- **CRF Submit User Group**—Windows user group that defines the users who can access the CRF Submit application on a user level.
- **CRF Submit Admin Group**—Adds new work orders, monitors existing work orders, stops and restarts work orders, and maintains configuration settings.

For more information on user administration, see the Microsoft documentation.

If you use different names for your user groups, you must update the **PhaseForward.CRFS.Enterprise.config.xml** file.

Enabling integrated logging

When integrated logging is enabled, messages for the CRF Submit server and Document Generator server are combined in one log file located in the installation directory. Integrated logging is turned off by default.

To change the value for integrated, edit the **PhaseForward.CRFS.Enterprise.config.xml** file located in the installation directory.

```
<LEVEL>Level<LEVEL>
```

where *Level* is:

- **Off**—No logging.
- **Terse**—Log events without parameters. Recommended.
- **Full**—Log events with parameters.

Stop and restart the IIS and CRF Submit services for the changes to take effect.

Shared directory

The user who starts the Document Generator server must have write access to the shared directory where PDFs and XML files are stored. If the user does not have that access, the document generation jobs initiated by the user result in errors.

Password expiration

Oracle recommends that you use periodic password expiration for the CRF Submit User and CRF Submit Admin Groups for added security.

Upgrading the CRF Submit server

If you are upgrading from an older release of the CRF Submit software, you must:

- 1 Fully uninstall the current version of the CRF Submit software.
For more information, see *Uninstalling the CRF Submit software* (on page 20).
- 2 Verify that the software and hardware meet the CRF Submit requirements.
For more information, see the *Release Notes*.
- 3 Install the CRF Submit 3.1 software.
For more information, see *Installing the CRF Submit software* (on page 15).

Uninstalling the CRF Submit software

Note: Oracle recommends that you stop the CRF Submit XML Generator service before uninstalling the CRF Submit software.

- 1 Select **Start > Settings > Control Panel > Programs > Programs and Features**.
- 2 Select **CRF Submit Server** and click **Change/Remove**.
The Install Shield Wizard appears.
- 3 Select **Remove**, and click **Next**.
- 4 To confirm the uninstallation, click **Yes**.
- 5 Click **Finish**.

The CRF Submit software is uninstalled from the computer.

Note: After completing the uninstall wizard, you must manually delete the CRF Submit installation folder and all subfolders to make sure all the files have been removed from the system.

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Installing the Document Generator server

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Before you begin

You can install the Document Generator software on any server with HTTP access to the CRF Submit server. Oracle recommends that the server on which you install the Document Generator software is designated as a processing server only. If this is not possible, the CRF Submit Document Generator software should run on a dedicated computer that can invoke the Adobe Acrobat interface without being interrupted by user input.

Before you install the Document Generator software:

- 1 Install the CRF Submit software.

For more information, see *Installing the CRF Submit software* (on page 15).

Note: You can install the Document Generator software on the same computer or on a remote computer. Oracle recommends that you use two computers, one each for the Document Generator server and the CRF Submit server.

- 2 Verify that you have met the Document Generator hardware and software requirements listed in the *Release Notes*.
- 3 Verify that you have access to the CRF Submit server.

If you are upgrading from a previous release, see *Upgrading the Document Generator server* (on page 26).

Installing the Document Generator software

- 1 After you have installed the CRF Submit software, open a browser and type:

```
http://<CRFSubmit_server_name>/pdfgen/setup
```

where *CRFSubmit_server_name* is the name of the computer on which you installed the CRF Submit software.

The link to set up the Document Generator server appears.

- 2 Click the **Setup PDF Document Generator Client** link.

The Install Shield Wizard appears, displaying the status of the system check.

If all required software is found, the Choose Setup Language page appears.

If any required software is missing, the installation stops and an error message listing the missing software appears.

Note: After you install the missing software, restart the Document Generator server installation.

The Choose Setup Language page appears.

- 3 Select the language for the installation and click **Next**.

The Choose Destination Location page appears.

- 4 Verify the location in which the software will be installed. To change the location, click **Browse** and select another folder.
- 5 Click **Next**.
- 6 Click **Finish**.

When the install has completed, the InstallShield Wizard Complete page appears.

Setting up multiple Document Generator computers

If you have a large amount of information to process, consider setting up several Document Generator servers. Each computer must have access to the shared directory to ensure that the PDF, XML, and HTML files are stored in the same location. For more information, see *Using multiple servers* (on page 5).

Installing and configuring Adobe Acrobat Professional

Note: For information about Adobe Acrobat versions supported in this release, see the *Release Notes*.

When you install Adobe Acrobat:

- 1 Select the **Custom** installation option.
- 2 Select **View Adobe PDF > Asian Language Support** and then select the following options:
 - **Japanese Language Support.**
 - **Traditional Chinese Language Support.**
 - **Simplified Chinese Language Support.**
- 3 Select **Create Adobe PDF > Asian Language Support.**

Note: You need to install Asian Language Support for multilingual studies only when the Document Generator software is installed on an English operating system.

After you install the Document Generator software, you must:

- 1 Start Adobe Acrobat so that Adobe Acrobat can automatically create a set of subdirectories.
- 2 Modify the Adobe Acrobat update settings.
- 3 Turn off the Adobe Acrobat show overflow text indicator.

CRF Submit subdirectories in Adobe Acrobat

When Adobe Acrobat is opened, the subdirectories the CRF Submit application needs are created. These must be set up before you use the Document Generator server. Otherwise, PDF generation fails.

Modifying Adobe Acrobat update settings

After you have installed the Document Generator server and Adobe Acrobat, modify the update settings before you create any work orders.

- 1 Open Adobe Acrobat and select **Edit > Preferences.**
- 2 In the list box, click **Updater.**
- 3 Make sure **Do not download or install updates automatically** is selected.
- 4 Click **OK.**
- 5 Close Adobe Acrobat.

Configuring the show text field overflow indicator

The CRF Submit application shows all data in every field. However, if the text approaches the limit of a text box, the Adobe Acrobat software automatically inserts a plus sign to show that more data is available but not visible. You must turn this feature off to prevent the Adobe Acrobat software from adding the indicator.

- 1 Select **Edit > Preferences > Forms**.
- 2 Deselect **Show text field overflow indicator**.
- 3 Click **OK**.

Upgrading the Document Generator server

To upgrade the Document Generator software, uninstall the current version and reinstall the latest version.

- 1 To stop the Document Generator server, on the **PDF Document Generator - Detail** window, click **Exit**.
- 2 Fully uninstall the current version of the Document Generator software.
For more information, see *Uninstalling the Document Generator software* (on page 29).
- 3 Verify that the software and hardware meet the Document Generator requirements.
For more information, see the *Release Notes*.
- 4 Verify that you are using a supported version of Adobe Acrobat.
For more information, see the *Release Notes*.
- 5 Install the new Document Generator software.
For more information, see *Installing the Document Generator software* (on page 23).

Starting the CRF Submit application

- Open Internet Explorer and type the path to the CRF Submit server. For example:


http://<computer_name>/crfsubmit/

The Monitor page appears.

Configuring multiple servers

Verifying the Oracle connection string for multiple servers

Note: All CRF Submit servers must use the same CRF Submit database.

- 1 Click **Configuration** (.
- 2 In the following fields, make sure the same information is entered for all CRF Submit servers.
 - **DB Connection**—Oracle connection string used to connect to the CRF Submit server database.
 - **DB User**—Oracle user name used to access the CRF Submit database.
 - **DB Password**—Password used to connect to the Oracle database.
- 3 Click **Save Settings**.

Verifying the CRF Submit server field for multiple servers

- 1 Select **Start > Programs > Oracle® Health Sciences > Document Generator Client**.
- 2 If prompted, type your network user ID and password.
The PDF Document Generator - Detail window appears.
- 3 In the **CRF Submit server** field, make sure the URL points to the correct web server.

Verifying the PDF Output Directory for multiple servers

- 1 Start the CRF Submit application.
- 2 Click **Create Work Order**.
- 3 Make sure that all of the Document Generator servers have read/write access to the shared folder entered in the **PDF Output Directory** field.

Uninstalling the Document Generator software

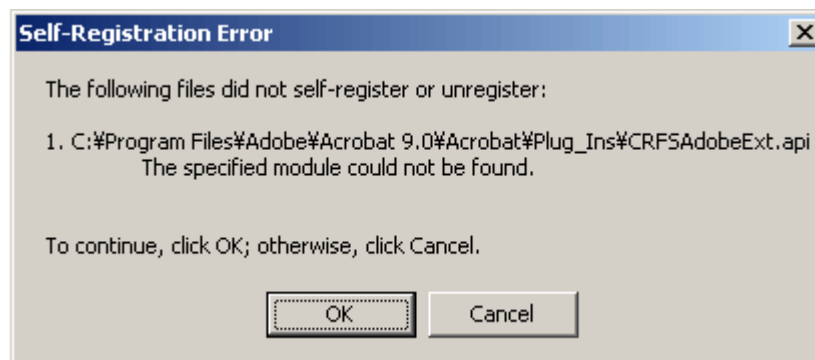
Note: Oracle recommends that you stop the CRF Submit XML Generator service before uninstalling.

- 1 Select **Start > Settings > Control Panel > Programs > Programs and Features**.
- 2 Select **DocGenClient** and click **Change/Remove**.

The Install Shield Wizard appears.

- 3 Select **Remove** and click **Next**.
- 4 To confirm the uninstallation, click **Yes**.

If the following error message occurs, click **OK** and continue.



The Document Generator software uninstalls successfully.

- 5 Click **Finish**.

The Document Generator software is uninstalled from the computer.

Note: After completing the uninstall wizard, you must manually delete the CRF Submit installation folder and all subfolders to make sure all the files have been removed from the system.

CHAPTER 5

Installing the CRF Submit Adapter server

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Before you begin

Before you install the CRF Submit Adapter software:

- 1 Install the CRF Submit software.

For more information, see *Installing the CRF Submit software* (on page 15).

- 2 Install the Document Generator software.

For more information, see *Installing the Document Generator software* (on page 23).

- 3 Verify that you have met the CRF Submit Adapter hardware and software requirements listed in the *Release Notes*.

Note: You must install the Oracle database client. For more information, see your Oracle database documentation.

If you are upgrading, see *Upgrading the CRF Submit Adapter server* (on page 37).


Installing the CRF Submit Adapter software

- 1 Navigate to the CRF Submit Adapter ISO image.
- 2 In the CRF Submit Adapter folder, double-click **setup.exe**.
The Choose Setup Language page appears.
- 3 Select the language for the installation and click **Next**.
The Welcome page appears.
- 4 Click **Next**.
The Required System Components page appears.
The installation wizard verifies that the server has all the necessary software components, including the operating system, IIS, and the Oracle client.
If required components are missing or are the wrong version, installation stops. The names of missing and invalid components appear on the Required System Components page. You must install them before continuing the installation.
- 5 Click **Next**.
The Setup Type page appears.
- 6 Select **Complete**, and click **Next**.
- 7 Click **Next**.
The CRF Submit Adapter Virtual Directory page appears.
- 8 Enter the virtual directory for this CRF Submit Adapter instance, and click **Next**.

Note: Virtual directories are used to uniquely identify a specific instance of the CRF Submit Adapter software.
- 9 Click **Next**.
The Ready to Install the Program page appears.
- 10 Click **Install**.
- 11 When the installation is complete, click **Finish**.




Configuring the CRF Submit Adapter server

You can modify the default CRF Submit Adapter configuration using options in the CRF Submit user interface.

- 1 Start the CRF Submit application.
- 2 Click **Configuration** ()
- 3 Click **Configure CRF Submit Adapter**.
- 4 To add, edit, or delete CRF Submit Adapter servers, next to the **CRF Submit Adapter** field, use the **Add**, **Edit**, or **Delete** buttons.
- 5 To add, edit, or delete CRF Submit Adapter studies, next to the **Studies** field, use the **Add**, **Edit**, or **Delete** buttons.
- 6 To return to the **Configuration** page, click **Back to Configuration**.

Setting the default CRF Submit Adapter URL

After the CRF Submit software is installed, you can specify a URL address to automatically appear on the Create Work Order page.

- 1 On the **Monitor** page, click **Configuration** ()
- 2 Click **Configure CRF Submit Adapter**.
- 3 Do one of the following:
 - To create a new CRF Submit Adapter URL and set it as the default, next to the **CRF Submit Adapter** field, click **Add** () and type:
`http://<computer_name>/CRFSAdapter/TrialInfoConfig/TrialConfig.aspx`
 - To set an existing CRF Submit Adapter URL as the default, from the CRF Submit Adapter drop-down list, select a CRF Submit Adapter server and click **Edit** ()
- 4 Select the **Default Adapter** checkbox.
- 5 Do one of the following:
 - To save the new CRF Submit Adapter server as the default server, click **Add Adapter**.
 - To save the changes to a CRF Submit Adapter server, click **Edit Adapter**.

Entries in the tnsnames.ora file.

The **tnsnames.ora** file contains network configuration parameters that enable the Oracle client to connect with the database server by using an alias. The file is located in the ORACLE_HOME/network/admin directory.

The Oracle installation that runs on the CRF Submit Adapter computer must have an entry in the **tnsnames.ora** file for each Oracle instance that contains an InForm study that the CRF Submit application needs to access.

Patient data cache settings

You can set the subject data cache to control the amount of time data is stored in cache before new data is returned from the CRF Submit interface.

- Edit the **CRFSAdapter.WebService.config** file entry:

```
<PatientCache cache="true" expiration="30">
```

The default expiration setting (30) indicates that new data will be returned after 30 minutes. You can edit this value to suit your business needs. For updated data to be returned immediately, specify **expiration="0"**.

Enabling IIS 7.0 authentication for the CRF Submit Adapter server

You must enable Anonymous Authentication in IIS 7.0 for the CRF Submit Adapter server:

- 1 Select **Start > Administrative Tools > Server Manager**.
- 2 Select **Roles > Web Server (IIS) > Internet Information Services (IIS) Manager**.
- 3 On the **Connections** pane, select **<Machine Name> > Sites > Default Web Site > CRFSAdapter**.
- 4 On the **/CRFSubmit Home** pane, double-click **Authentication**.
- 5 On the **Authentication** pane:
 - a Select **Anonymous Authentication**.
 - b On the **Actions** pane, click **Enable**.

Note: Make sure that all other authentication settings are disabled on the CRF Submit Adapter server.

Upgrading the CRF Submit Adapter server

If you are upgrading from an older release of the CRF Submit Adapter software:

- 1 Fully uninstall the current version of the CRF Submit Adapter software.
For more information, see *Uninstalling the CRF Submit Adapter software* (on page 38).
- 2 Verify that the software and hardware meet the CRF Submit Adapter requirements.
For more information, see the *Release Notes*.
- 3 Install the CRF Submit Adapter software.
For more information, see *Installing the CRF Submit Adapter software* (on page 33).

Uninstalling the CRF Submit Adapter software

Note: Oracle recommends that you stop the CRF Submit XML Generator service before uninstalling.

- 1 Select **Start > Settings > Control Panel > Programs > Programs and Features**.
- 2 Select **CRF Submit Adapter Server** and click **Change/Remove**.
The Install Shield Wizard appears.
- 3 Select **Remove** and click **Next**.
- 4 To confirm the uninstallation, click **Yes**.
- 5 Click **Finish**.

The CRF Submit Adapter software is uninstalled from the computer.

Note: After completing the uninstall wizard, you must manually delete the CRF Submit Adapter installation folder, subfolders, and the IIS virtual directory to make sure all the files have been removed from the system.

CHAPTER 6

Troubleshooting

In this chapter

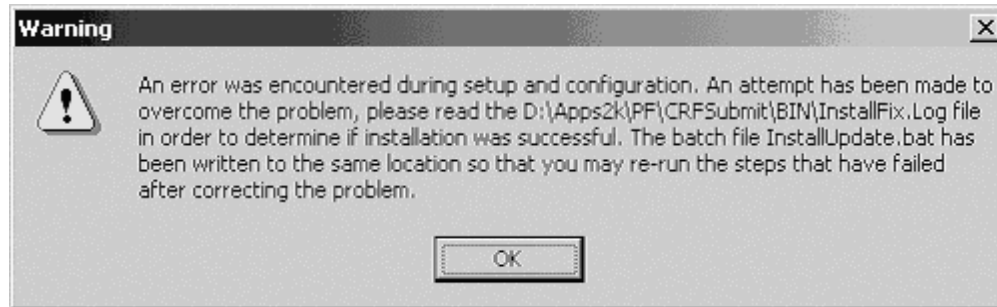
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Configuration issues

Installation consists of two processes:

- Copying the files to your system.
- Configuring the software based on the options you set in the wizard.

If an error occurs during the configuration process, the installation program attempts to diagnose and fix the issue. If the issue cannot be fixed, the following window appears.



The following files are created and saved in the BIN directory after an installation fails:

- **InstallFix.log**—Lists the settings that you specified during the installation. Review these settings to see if an error was made here. For example:
 - Typing mistakes in database names, user IDs, and passwords.
 - Incorrect connection strings.
- **InstallUpdate.bat**—Reruns the steps that failed.

Note: When an installation fails, Install Shield reports an unsuccessful installation but has a Finish button on it. Also, the software appears in the Add/Remove Programs list.

Virtual directories and IIS 6.0 Management Compatibility

If the virtual directories cannot be deployed and the IIS 6.0 Management Compatibility installation does not complete successfully:

- 1 Run the Server Manager.
- 2 Select **Roles**.
- 3 Right-click **Web Server (IIS)**.
- 4 Select **Add Role Services**.
- 5 Select **IIS 6.0 Management Compatibility** and all of its sub items.
- 6 Restart the CRF Submit software installation.

For more information, see *Installing the CRF Submit software* (on page 15).

The PDFGen Virtual directory and Application Development options

While installing Application Development options, if the PDFGen Virtual directory does not deploy and the CRF Submit installation fails:

- 1 Run the Server Manager.
- 2 Select **Roles**.
- 3 Right-click **Web Server (IIS)**.
- 4 Select **Add Role Services**.
- 5 Select **Application Development** and all of its sub items.
- 6 Restart the CRF Submit software installation.

For more information, see *Installing the CRF Submit software* (on page 15).