Installation and Maintenance Guide

Oracle[®] Health Sciences InForm CRF Submit
Release 3.1.6

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CRF Submit overview

In this chapter

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.
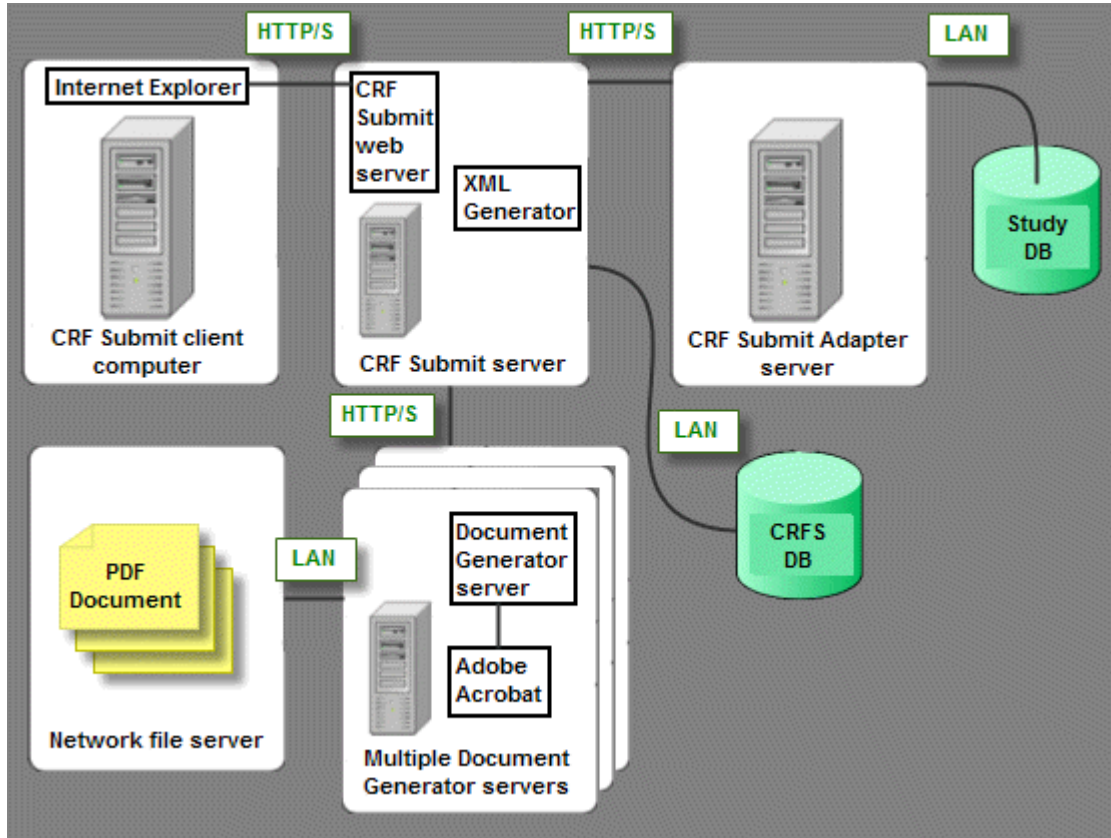
Component	Description
CRF Submit client computer	The computer on which you use Internet Explorer to access the CRF Submit server to create and monitor work orders.
CRF Submit server	• Generates XML and includes the CRF Submit web server. • You can use a centralized location for the storage and retrieval of the XML information that is to be converted into HTML and subsequently into PDF files.

Component	Description

CRF Submit database	An Oracle database that:
	
	• Tracks CRF Submit processes including:
	
	  ▪ 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	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. **Note:** The CRF Submit application does not modify the InForm data.

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 30).

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.

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.

- The Document Generator must have Adobe Acrobat 11 installed.
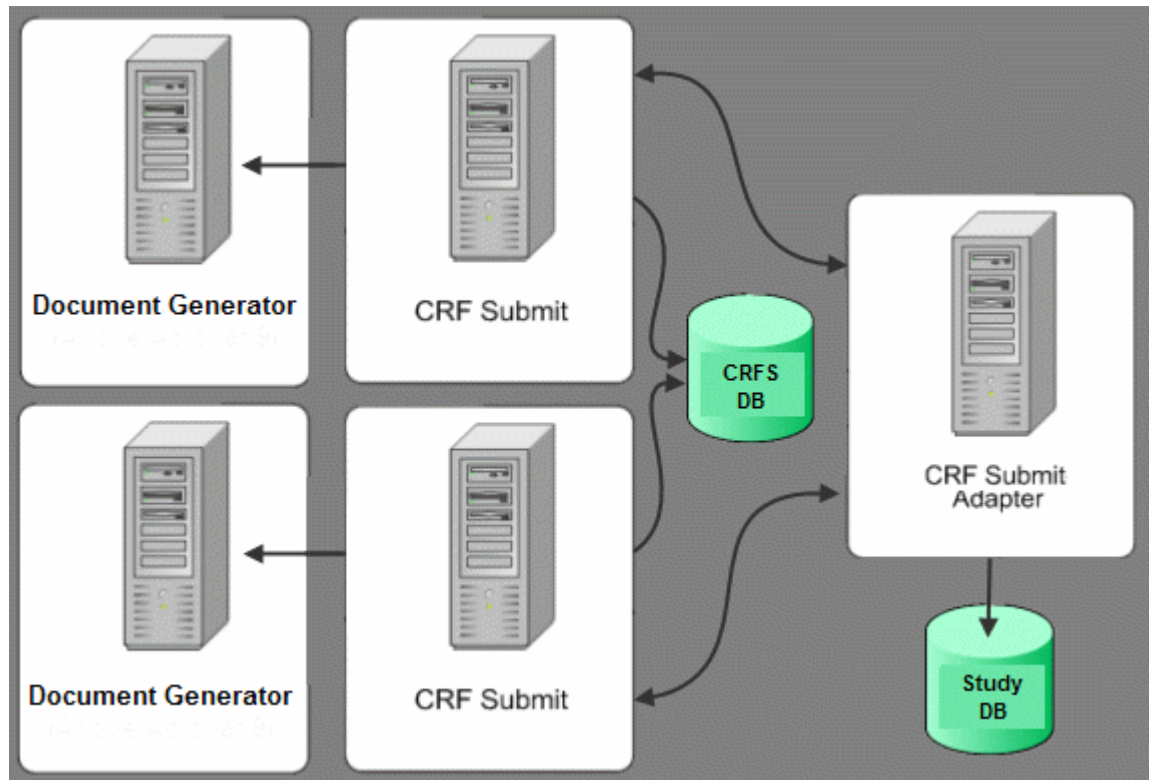
Extended environment with multiple servers

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.

- The Document Generator must have Adobe Acrobat 11 installed.
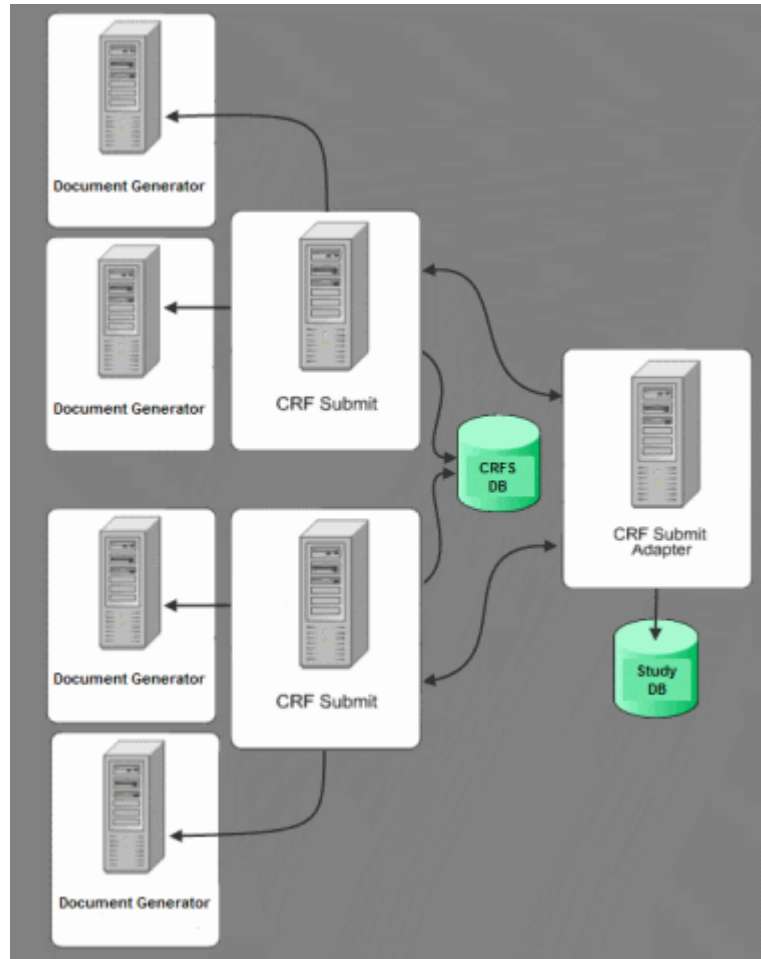
Configuration requirements for multiple servers

- 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 30).

- 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 30).

C H A P T E R   2

Preparing to install

In this chapter

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)

C H A P T E R 3

Installing the CRF Submit server

In this chapter

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.

2 Configure the CRF Submit software.

For more information, see *Configuring the CRF Submit software* (on page 18).

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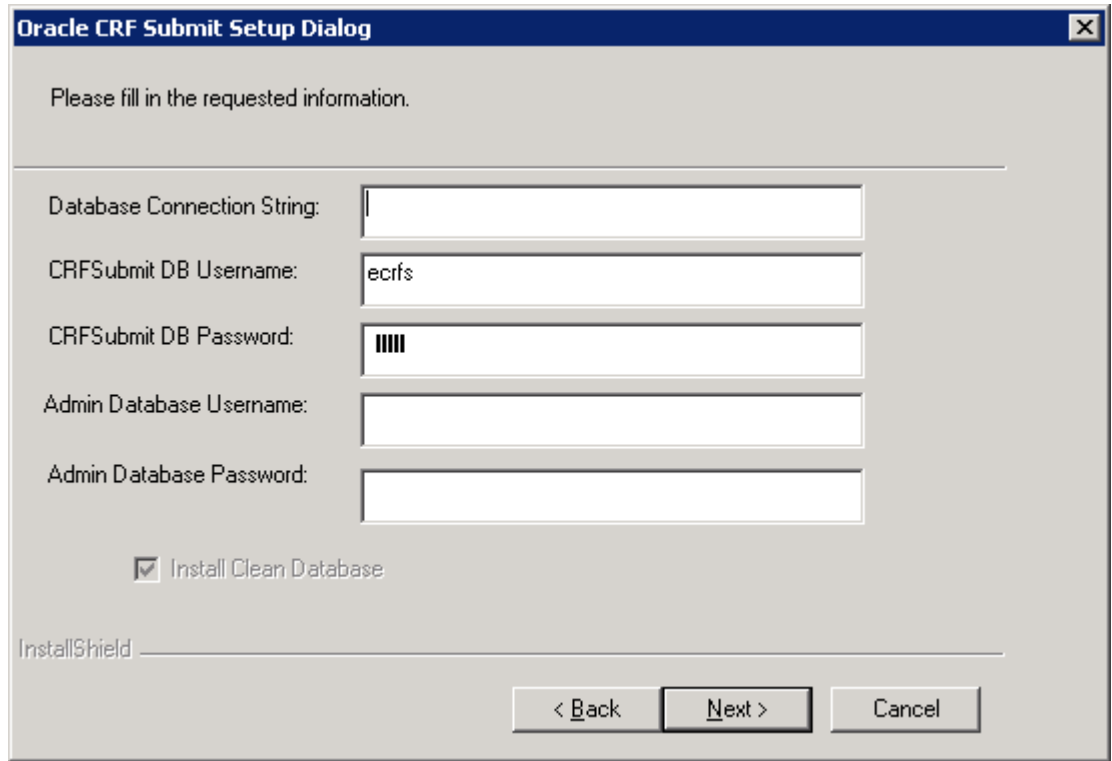
9   Complete the fields using the information in the following table:

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**.

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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 pane, 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.

2   Verify that the software and hardware meet the CRF Submit requirements.

     For more information, see the *Release Notes*.

3   Install the CRF Submit 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 **Uninstall**.

   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.

C H A P T E R 4

Installing the Document Generator server

In this chapter

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 28).

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**.

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

6   Click **Finish**.

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 **Expand Languages** and then select the following options:

- **English**

- **Japanese**

- **Korean**

- **Chinese Simplified**

- **Chinese Traditional**

> **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. See *Modifying Adobe Acrobat update settings* (on page 26).

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 31).

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 25).

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.
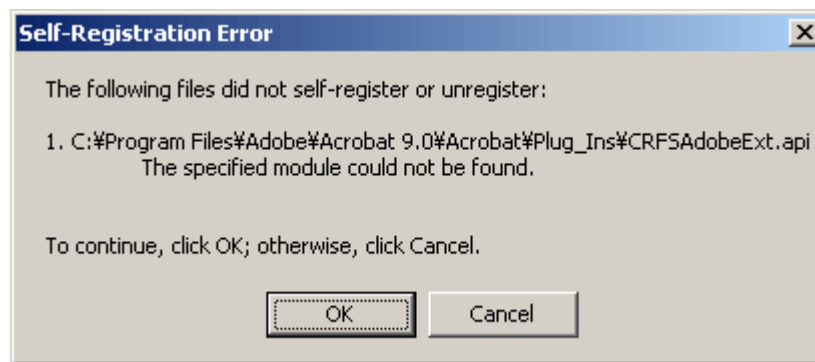
    The Document Generator software uninstalls successfully.

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.

C H A P T E R 5

Maintaining the Document Generator server

In this chapter

Starting the Document Generator server

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, confirm that the URL of the computer matches the HTTP URL on which the CRF Submit application is installed, and has the suffix **ecrfswsi.asmx**.

> **Note:** If you are using a secure server, use **https:** in the URL. Also, the computer name in the URL must match the **SSL certificate**.

4   Click **Start Polling**.

The Document Generator monitors the CRF Submit server for work order jobs to process.

The Download Statistics window appears, detailing the progress of the download from the CRF Submit database.

The information is converted into PDF and XML files and saved in the target directory that you specified in the work order.

Viewing and hiding the Document Generator - Detail window

To hide the Document Generator - Detail window:

*   On the **PDF Document Generator - Detail** window, uncheck **Start up with Detail Window Showing**.

To view the window:

*   Select **Start > Programs > Oracle**® **Health Sciences > Document Generator Client**.

Adjusting the polling increment time

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   Click **Stop Polling**.

4   In the **Queue Polling Increment (seconds)** field, type the number of seconds between when a work
     order completes and polling the CRF Submit server for another work order begins.

5   Click **Start Polling** to restart the Document Generator.

Generating multiple XML or HTML jobs simultaneously

You can generate multiple XML or HTML jobs simultaneously, in parallel with PDF generation.

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   Click **Stop Polling**.

4   In the **Number of concurrent non-PDF jobs** field, type the number of XML or HTML jobs to run simultaneously in parallel with PDF generation.

> **Note:** Defaults to **1**, which runs 1 XML or HTML job simultaneously in parallel with PDF generation. Set this field to 0 to run a single job at a time.

5   Click **Start Polling** to restart the Document Generator.

Monitoring the Document Generator activity

An icon in the system tray displays the status of the Document Generator activity.

Icon	Status of the PDF Generator
(Red)	Open and running, but not polling the CRF Submit server.
(Yellow blinking arrow)	Polling the CRF Submit server.
(Green blinking arrow)	Processing a work order.
Alternating red and yellow arrow	Not able to connect, but continuing to try for a connection.

Stopping and closing the Document Generator server

Stopping the Document Generator server

To stop the Document Generator from getting the next job, select one of the following:

- **Abort Processing**—Stop the Document Generator from processing.

- **Abort Processing After Current Job Completes**—Stop the Document Generator from getting a new job. The current job will complete, and then the Document Generator will stop.

Closing the Document Generator server

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   Click **Stop Polling** and click **Exit**.

C H A P T E R   6

Installing the CRF Submit Adapter server

In this chapter

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 25).

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 48).

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**.

Using the command line to add or remove an InForm study

You can add, update, or remove InForm studies using the **RegTrial.exe** command line utility, located in the *<Installation_Directory>*\Tools\RegTrial directory.

When you run the command, you must enter the command parameters in a text file. The format of the text file is a comma delimited file separating parameter=value pairs. The file must be located in the same directory as the utility. The files must contain the following parameters:

- To add or update a study, supply these parameters:

  TrialRegFile=<*path_to_trialreg_file*>**, TrialAlias=**<*alias*>**, TrialName=**<*name*>**, TrialDbUser=**<*user*>**, TrialDbPassword=**<*password*>**, TrialDbTns=**<*tns*>**, SILENT=**[*TRUE | FALSE*]

- To remove a study, supply these parameters:

  TrialRegFile=<*path_to_trialreg_file*>**, TrialAlias=**<*alias*>**, SILENT=**[*TRUE | FALSE*]

where:

- **path_to_trialreg_file**—Path to the trialreg.config file in which CRF Submit Adapter stores study registration information:

  <Installation_Directory>\CRFSAdapter\TrialInfoConfig\TrialConfig\bin\config\trialreg.config.

- **alias**—Alias of the InForm study from which to collect data to generate PDFs.

- **name**—Name of the InForm study from which to collect data to generate PDFs.

- **user**—InForm study user name to log into the Oracle database.

- **password**—InForm study password to log into the Oracle database.

- **tns**—Connection string for the Oracle database instance where the InForm study data is stored; defined in the tnsnames.ora file.

- **SILENT**—Option for displaying or hiding the output of the command on the console.

Adding a study using the command line utility

1   Open a command prompt window and change the directory to

<Installation_Directory>\CRFSAdapterTools\RegTrial.

2   Run the following command:

RegTrial /AddTrial:*<parameter_file>*

For example:

RegTrial /AddTrial:parameter.txt

Removing a study using the command line utility

1   Open a command prompt window and change the directory to
    <Installation_Directory>\CRFSAdapterTools\RegTrial.

2   Run the following command:

RegTrial /RemoveTrial:*<parameter_file>*

For example:

RegTrial /RemoveTrial:parameter.txt

Related procedures	For more information
Configuring the CRF Submit Adapter server	Add or edit Study options
Using the Create Work Order page to add an InForm study	Configure CRF Submit Adapter page
	Configuration Options page
Using the Configure CRF Submit Adapter page to add or edit a CRF Submit Adapter server	Step 4 - Configure the CRF Submit software and the CRF Submit Adapter server

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.asmx

   • 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 49).

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 43).

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 7
Troubleshooting

In this chapter

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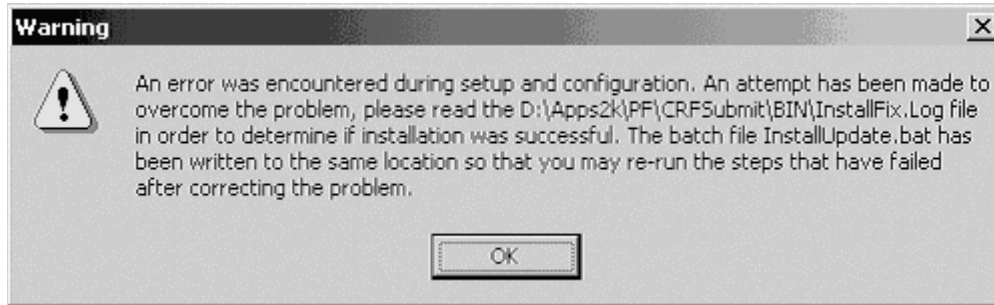
The following files are created and saved in the BIN directory after an installation fails:

- **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).

CRF Submit server troubleshooting

Selecting the correct IIS ASP.NET version

If you receive an application error the first time you try to access the CRF Submit URL you may need to specify the correct ASP.NET version for the CRF Submit web server.

To change the ASP.NET version for the CRF Submit web site:

1   Click **Start > All Programs > Administrative Tools > Internet Information Services (IIS) Manager**.

The Internet Information Services (IIS) Manager window appears.

2   Expand the **Web Sites** folder.

3   Right click on **CRF Submit** and select **Properties**.

The CRF Submit Web Site Properties window appears.

4   Select the **ASP.NET** tab.

5   Select version 3.5 from the **ASP.Net version** drop-down list.

6   Click **OK**.

Starting the CRF Submit server immediately after a reinstallation

If you cannot start the CRF Submit server immediately after reinstallation, make sure that the default Web Service is running. If it is stopped, restart the Web Service and then try to open the CRF Submit server.

Stopped jobs

Threads occasionally stop, causing jobs to stop. If a job has stopped, check the Configuration Options page to see if threads are still running. If they are not, restart the threads.

Subjects with the same subject number

If you have two subjects at the same site with the same subject number and you export by subject, -1 and -2 are added to their subject numbers.

Note: Requiring a unique subject ID and date of birth on the Configuration Options page in the InForm application prevents this situation.

Updating thread options

If you update thread options, and restart the threads, and the CRF Submit server appears to stop indefinitely, reboot the CRF Submit server. In this situation, a server error might appear in the Event Log. If stopping the threads takes longer than 15 minutes, a reboot may be necessary.

Work order taking a long time to complete

If a work order takes longer than expected to complete, other work orders that other people have submitted might be queued up before yours. If you do not have administrator rights, you can only see the work orders you created.

Document Generator troubleshooting

Displaying error messages on the remote client

If you want to display web service error messages on the client browser, you must edit the **web.config** file.

- Change the **customErrors** entry to:

   <customErrors mode="RemoteOnly"/>

Document Generator checking for Adobe Acrobat updates

If you have a Document Generator computer that seems to stop during the Adobe processing, select the Adobe process in the task bar and make sure that it is not looking for updates.

To prevent this issue in the future:

1   Open Adobe Acrobat and select **Edit > Preferences**.

2   In the list box, click **Updater**.

3   Change **Check for Updates** to **Do not download or install updates automatically**.

Document Generator loses the connection to Acrobat

If you receive the error **Connection to Acrobat was closed unexpectedly**, try the following:

- Restart the Document Generator client and rerun the failed job.

- In the **PDFDocGen** section of the **PhaseForward.CRFS.Enterprise.config.xml** file, increase the **Retries** value.

Site without subjects does not appear in the work order details

If you generate a work order for a site with no subjects, the site does not appear in the list of sites on the **Work Order Details** page. However, the site does appear in the resulting PDF and the table of contents.

Summary of CRF Submit error text

The following is a summary of error text that might occur during the CRF Submit PDF and XML generation process. In many cases, these error messages appear in combination with each other or with error messages that are generated by external sources such as OS, OleDB, network, Adobe Acrobat, and InForm application.

The CRF Submit server

InForm connection error messages

Error message	Reason and resolution
An error occurred while connecting with the InForm trial: The underlying connection was closed: The remote name could not be resolved.	The server name in the URL could not be found or is not available. Make sure that you entered the server name correctly and that you have access rights to the server.
An error occurred while connecting with the InForm study: Invalid URL: The format of the URL could not be determined.	The URL is not in the required format or syntax. The most likely reason is that the URL is missing an **http://** or **https://**.

XML Generator errors

Error message	Reason and resolution
XMLGEN ERROR 1: There is an error in XML document (0, 0).:XML.	An error occurred during the downloading of XML data from the InForm study. Confirm that the InForm study is still available and rerun the failed Document Generator job.
XMLGEN ERROR 2: The underlying connection was closed: Unable to connect to the remote server.	The connection with the InForm study was closed or interrupted. Confirm that the InForm study is still available, and rerun the failed Document Generator job.

Error message	Reason and resolution
XMLGEN ERROR 3: Thread was aborted.	There are two possible causes:
	• CRF Submit server threads were stopped or the CRF Submit service was stopped while the XML Gen job was still running.
	Confirm that the CRF Submit service and thread are running and rerun the failed XML Gen Job.
	• The Job thread timeout limit was reached before the XML Gen job could complete.
	Increase the XML Gen Job timeout in the enterprise configuration file. Restart the CRF Submit service and threads. Rerun the failed XML Gen job.
XMLGEN ERROR 4: Operation timed out.	Increase the XML Gen Job and Download Task timeout in the enterprise configuration file. Restart the CRF Submit service and threads. Rerun the failed XML Gen job.

Document Generator errors

Error message	Reason and resolution
DOCGEN ERROR 1: The process cannot access the file "C:\Documents and Settings\Administrator\Application Data\Adobe\Acrobat\Preferences\WebCaptr.prefs" because it is being used by another process.	A previous Acrobat process was not terminated by the Document Generator prior to the execution of the failing job. Stop and shut down the failing Document Generator client. Cancel any Acrobat processes that are still running using the Windows Task Manager. Rerun the failed job.
DOCGEN ERROR 2: Could not find a part of the path "C:\Documents and Settings\Administrator\Application Data\Adobe\Acrobat\Preferences\WebCaptr.prefs".	Acrobat was not run once as the currently logged in user. Follow the installation procedures for the Document Generator client, making sure to open Acrobat and change the Update preferences from Automatic to Manual. Rerun the failed job.
DOCGEN ERROR 3: Connection to Acrobat was closed unexpectedly.	The Document Generator client lost its connection with the Acrobat API. Restart the Document Generator client and rerun the failed job.
DOCGEN ERROR 6: Access is denied.	Document Generator client does not have access to the target directory where PDFs are to be saved. Resolve the access issue for the user running the Document Generator client, and rerun the failed job.

Error message	Reason and resolution
DOCGEN ERROR 7: Unhandled Error.	Unknown.
	Exit and restart the Document Generator client. Rerun the failed job.
DOCGEN ERROR 8: Cannot process request because the process (2220) has exited.	Acrobat was terminated while the Document Generator client was still processing the Doc Gen job.
	Exit and restart the Document Generator client. Rerun the failed job.
DOCGEN ERROR 9: Lost Adobe window focus, could not open Web Page Dialog.	The Document Generator client could no longer locate the Acrobat window.
	Exit and restart the Document Generator client. Rerun the failed job.

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- **My Oracle Support** (https://support.oracle.com)—*Release Notes* and *Known Issues*.

- **Oracle Technology Network** (http://www.oracle.com/technetwork/documentation/hsgbu-154445.html)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

If the software is available for download, the complete documentation set is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com).

All documents may not be updated for every CRF Submit release. Therefore, the version numbers for the documents in a release may differ.

Documentation accessibility

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

Access to Oracle Support

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

Documentation

Title	Description	Part Number	Last Updated
Release Notes	The *Release Notes* document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.	E78059-01	3.1.6
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.	E78060-01	3.1.6

Title	Description	Part Number	Last Updated
Installation and Maintenance Guide	The *Installation and Maintenance Guide* describes how to install the CRF Submit software and the CRF Submit Adapter server.	E78511-01	3.1.6
User Guide and online Help	The *User Guide* 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. This document is also available from the CRF Submit user interface.	E78512-01	3.1.6
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the CRF Submit application, including details about the general principles of security, and how to install, configure, and use the CRF Submit application securely.	E78513-01	3.1.6
PDF Quick Reference	The *PDF Quick Reference* provides an overview of the PDFs generated by the CRF Submit software and instructions for viewing PDFs.	E40031-01	3.1.2
Third Party Licenses and Notices	The *Third Party Licenses and Notices* document includes licenses and notices for third party technology that may be included with the InForm software.	E78514-01	3.1.6

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