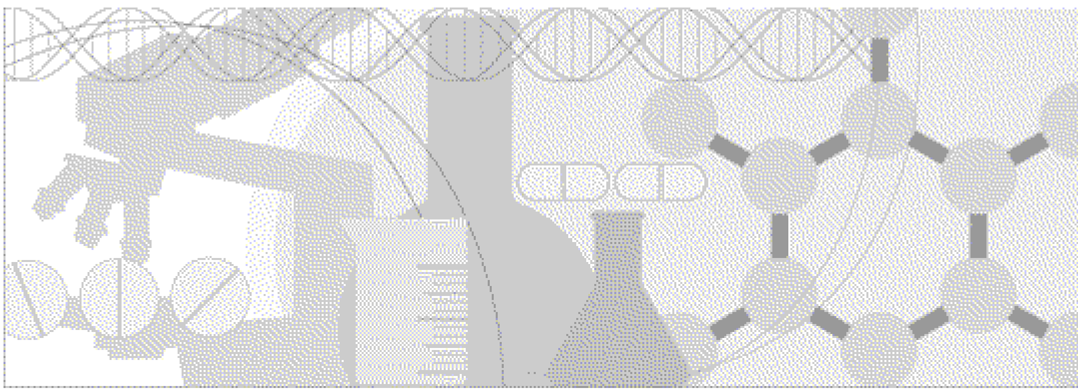
User Guide

Oracle® Health Sciences InForm CRF Submit
Release 3.1.6



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CHAPTER 1

Introduction

In this chapter

Overview of 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

Multilingual study support

The InForm CRF Submit 3.1.6 application is Unicode-based and supports PDF generation for multilingual studies in InForm 4.7 and higher.

You can generate PDF files in either English or Japanese by specifying a submission language. When you specify a submission language, you are choosing a language for the structure of the PDF file—headers, footers, headings, and labels. The study content included in the file remains in the language it was entered in the InForm study.

You also have the option to generate blank forms in a different language than the one selected as the submission language. Typically, linking blank forms are used as reference by an auditor reviewing submission PDF forms in a language in which the auditor has limited fluency.

Regulatory compliance

The InForm CRF Submit 3.1.6 application is designed for deployment as part of a validated system that is compliant with GCP predicate rule requirements, laws, and regulations applicable to the conduct of clinical studies, and FDA 21 CFR Part 11 pertaining to the use of electronic records and signatures.

The PDF output of the CRF Submit application is designed according to ICH eCTD guidance. Oracle solicited feedback from the FDA to ensure that the PDF file output is organized and navigable according to both CBER and CDER preferences. The user of the CRF Submit application is ultimately responsible for the success of the submission with regulatory agencies.

Overview of the CRF Submit user interface

The main CRF Submit user interface appears in a browser window that displays all the features to which you have access, based on your rights and rights groups. The Monitor page is the main page of the CRF Submit user interface and it is the first page to appear when you start the CRF Submit application.

The Configuration and Help icons appear in the upper-right corner of all pages in the CRF Submit user interface.

Use the Configuration icon ( ) to navigate to the Configuration Options page.

You can access the CRF Submit Adapter page from the Configuration Options page.

If you have administrator rights, you can:

- Use the Configuration Options page to modify the configuration options that were set during installation.
- Use the CRF Submit Adapter page to modify the CRF Submit Adapter settings.

Getting Help

Use the Help icon ( ) to open the context-sensitive Help. There is a small arrow ( ) to the right of the Help icon. If you click the arrow, a drop-down menu appears with the following options:

- **Help about this page**—Opens the context-sensitive Help, which describes the page function(s) and fields for the current page. The page-level help is part of the *User Guide* and opens in a browser window that you can resize and move for easy side-by-side viewing with other pages.
- **CRF Submit User Guide**—Opens the *User Guide* to the title page. The guide appears in a browser window that you can resize and move for easy side-by-side viewing with other pages.
- **PDF Quick Reference—**Opens the *PDF Quick Reference,* which provides an overview of the PDF files generated by the CRF Submit application and instructions for viewing PDFs.

The CRF Submit user interface also includes hover help. When you hover over a field that has hover help, a question mark and a brief description of the field appear. Some descriptions include links to PDF examples or topics in the *User Guide*. When you move your cursor off the field, the hover help disappears.

The CRF Submit workflow

Step 1 - Install the CRF Submit software

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

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

The installation is divided into two processes:

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

For instructions, see the *Installation and Maintenance Guide*.

Step 2 - Create a work order

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.

Use the Create Work Order page to:

- Select a CRF Submit Adapter server and InForm study.

  > **Note:** If the administrator has already set up a default CRF Submit Adapter URL, you only need to select an InForm study.

- Add CRF Submit Adapter servers or InForm studies.
- Specify the:
  - Work Order Name.
  - Submission Language.
  - PDF Output Directory.
- Select a saved custom template to apply to the work order. You can save work order options as a template on the confirmation page.

Step 3- Specify the work order options

Select a work order type. The application steps you through specifying options and settings.

- **Submission with Blank Forms**—Generate submission-ready PDF files and blank forms for all visits.
- **Archive with Blank Forms**—Generate archival PDF files and blank forms for all visits.
- **Blank Forms Only**—Generate a set of form templates that do not contain any data.
- **Custom PDF with Subject Data and Optional Blank Forms**—Customize a work order for forms that contain data.
- **Custom Blank Forms**—Customize the format, study versions, and security settings for a set of form templates that do not contain data.

> **Note:** If you apply a saved template to a work order, the application takes you directly to the Confirmation page.

Step 4 - Confirm the work order options and optionally save them as a template

Use the Confirm Work Order Settings page to:

- Review and edit the work order options you selected.
- View the preselected options for the work order.
- Save the selected work order options as a template to be used for other work orders. Use the Create Work Order page to apply a saved template to a work order.
- Submit the work order options for PDF generation.

Step 5 - Monitor work orders

Use the Monitor page to track the work orders submitted on the CRF Submit server. You can display the progress of all work orders that you have submitted. The Monitor page gives you sortable details about each work order.

If you have user rights, you see only the work orders that you submitted.

If you have administrator rights, you can:

- See the work orders that were submitted by other users in addition to the work orders that you submitted.
- Pause and resume processing of work orders.
- Restart or rerun work orders that have stopped.
- Purge work orders from the database.

All users can view the estimated end time for work orders being processed that appear on the Monitor page along with the percentage of complete jobs. The estimate becomes more accurate as the work order progresses. When a work order is complete, the actual end time appears in the End Time column.

> **Note:** To sort the list of work orders, click the column headings.

Step 6 - View jobs

Use the Work Order Jobs page, accessed by clicking the work order name on the Monitor page, to view information about the jobs in the work order.

> **Note:** If it is a PDF job, there is a link to view the content of the job (except for CRF Help, index, or table of contents).

Step 7 - Prepare PDFs in Adobe Acrobat

Use Adobe Acrobat to:

- View PDFs.
- Search PDFs.
- Create hyperlinks.
- Change the security settings.

> **Note:** Oracle recommends that you use the most recent version of Adobe Acrobat. For information about Adobe Acrobat versions supported in this release, see the *Release Notes*.

For more information about working with PDFs, see the *PDF Quick Reference*.

CHAPTER 2

Configuring the CRF Submit software and the CRF Submit Adapter server

In this chapter

Configuring the CRF Submit software

About configuring the CRF Submit software

On the Configuration Options page, some of the modifiable options include:

- User group names.
  - CRF Submit User Group.
  - CRF Submit Admin Group.
- Default target directory and the template directory.
- When to delete metrics.
- Processor threads settings and time out values.

  The CRF Submit application uses threads to distribute the XML generation efficiently among processors using three types of thread settings:
  - Number of work orders.
  - Number of job processing threads.
  - Number of CRF download threads.

  Thread tuning is designed to optimize throughput. Processing efficiency is dependent on several factors, including:
  - Hardware speed and memory.
  - Network traffic.
  - Volume and type of data being generated.

> **Note:** Do not change the configuration settings while work orders are processing.

Starting the CRF Submit application

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

  http://<computer_name>/crfsubmit/

  > **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.

  The Monitor page appears.

Updating user group names

You may choose to use user group names other than **CRF Submit User Group** and **CRF Submit Admin Group**.

To use other group names, you must:

1 Update the **PhaseForward.CRFS.Enterprise.config.xml** file.

2 On the **Configuration Options** page, update the user group names.

To update the Windows user group names on the Configuration Options page:

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ().

3 In the **CRF Submit User Group** field, type the name of the updated user group that can access the CRF Submit application on a user level.

4 In the **CRF Submit Admin Group** field, type the name of the updated user group that can access the CRF Submit application on an administrator level.

5 In the **DB Password** field, type your database password.

6 Click **Save Settings**.

Specifying a default target directory

Specify a folder to automatically appear on the **Create Work Order** page in the **PDF Output Directory** field. Setting a default directory ensures that the PDF and XML files that you create are saved in the same location.

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ().

3 In the **Default Target Directory** field, type the shared path of the folder.

> **Note:** If you install the CRF Submit application on more than one computer, the Default Target Directory 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.

4 In the **DB Password** field, type the password for the CRF Submit database.

5 Click **Save Settings**.

6 To verify that the specified directory is saved, click **Create Work Order**.

The specified directory appears as the default for the PDF Output Directory field.

Stopping and starting threads

To stop threads:

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ().

3 Click **Stop Threads**.

To start threads:

1 Click **Configuration** ( ).

2 Click **Start Threads**.

3 Click **Return to Monitor**.

4 Select the paused work orders and click **Resume**.

Changing the database on which CRF Submit data is stored

The DB Connection field allows you to define the connection to the database where the work orders generated by the CRF Submit application are stored. The Document Generator uses these work orders to process data into PDF and XML files.

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ( ).

3 In the **DB Connection** field, type a new Oracle connection string used to connect to the CRF Submit server database.

4 In the **DB Password** field, type your database password.

5 Click **Save Settings**.

6 Click **Start Threads**.

7 Click **Return to Monitor**.

8 Select the paused work orders and click **Resume**.

Viewing work order statistics

1 Click **Configuration** ( ).

The Configuration Options page appears.

2 Click **View Statistics**.

The View Statistics page appears.

> **Note:** You can also navigate to the View Statistics page from the Configure CRF Submit Adapter page.

3 To view additional information about each work order, hover over the **Information** icon ( ).

Work order statistics

Use the View Statistics page to view averages and the following overall work order metrics:

- **Work order completion**—Amount of time between the start of the work order and its completion.
- **CRF completion**—Amount of time to complete patient data generation. The amount of time to generate the table of contents, index, and other jobs is excluded from this metric.
- **Processing time**—Amount of time spent processing. Idle time is excluded from this metric.
- **PDF / Data Generation**—Ratio of time spent on PDF generation verses data generation.

You can view specific metrics including elapsed time, average time, and processing time for:

- CRF data generation.
- CRF PDF generation.
- CRF XML generation.

Hover over the Information icon () to view additional information about each work order, including the number of:

- CRF Threads.
- Job Threads.
- Runs.
- Doc Gen Servers.

Note: This information is captured at the time the work order is submitted.

You can use these statistics when you set the configuration options to help maximize efficiency.

Adjusting when metrics are deleted

1 Click **Configuration** ().

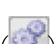
2 In the **DB Password** field, type your database password.

3 In the **Delete metrics older than (days)** field, enter the number of days after which metrics on the View Statistics page are deleted. Default is 180.

4 Click **Save Settings**.

Increasing or decreasing sleep time

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ().

3 Click **Stop Threads**.

4 Click **Return to Monitor** and verify that the work orders are paused by viewing the work order details.

> **Note:** Pausing work orders can take up to 15 minutes while jobs finish.

5 Click **Configuration** and update the following fields as necessary:

- **Work Order Processing Sleep Time (secs)**.
- **XML Gen Job Process Sleep Time (secs)**.
- **CRF Download Thread Sleep Time (secs)**.

6 Enter your password and click **Save Settings**.

7 Click **Start Threads**.

8 Click **Return to Monitor**.

9 Select the paused work orders and click **Resume**.

Increasing or decreasing the number of threads

1 On the **Monitor** page, select all work orders that are processing and click **Pause**.

2 Click **Configuration** ().

3 Click **Stop Threads**.

4 Click **Return to Monitor** and verify that the work orders are paused by viewing the work order details.

> **Note:** Pausing work orders can take up to 15 minutes while jobs finish.

5 Click **Configuration** and update the following fields:

- **XML Gen Job Process Thread Count**.
- **CRF Download Thread Count**.

6 In the **DB Password** field, type your database password.

7 Click **Save Settings**.

8 Click **Start Threads**.

9 Click **Return to Monitor**.

10 Select the paused work orders and click **Resume**.

Configuring the CRF Submit Adapter server

You can configure the CRF Submit Adapter server on the:

- Configure CRF Submit Adapter page.
- Create Work Order page.

About configuring the CRF Submit Adapter server

Before creating a work order, a CRF Submit administrator must create a study connection through the CRF Submit Adapter Trial Configuration.

After a connection is established, the following information is required:

- Name of the CRF Submit Adapter server.
- Name of the study to use.

Use the Configure CRF Submit Adapter page to set the default parameters used when the CRF Submit application accesses the CRF Submit Adapter server.

There are two ways to modify CRF Submit Adapter settings:

- Use the Configure CRF Submit Adapter page to add, edit, or delete CRF Submit Adapter servers or studies.
- Use the Create Work Order page to add CRF Submit Adapter servers or studies.

Adding or editing a CRF Submit Adapter server

Using the Configure CRF Submit Adapter page to add or edit a CRF Submit Adapter server

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, next to the **CRF Submit Adapter** field, click **Add** ( ) and type:

     http://<*computer_name*>**/CRFSAdapter/TrialInfoConfig/TrialConfig.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.

   - To edit a CRF Submit Adapter URL, from the CRF Submit Adapter drop-down list, select a CRF Submit Adapter server and click **Edit** ( ).
4. In the **Adapter Name** field, type or edit an alias for the CRF Submit Adapter URL.
5. In the **Adapter URL** field, type or edit a CRF Submit Adapter URL.
6. To make this the default adapter, select the **Default Adapter** checkbox.

7 Do one of the following:
   - To save a new CRF Submit Adapter server, click **Add Adapter**.
   - To save the changes to a CRF Submit Adapter server, click **Edit Adapter**.

Using the Create Work Order page to add a CRF Submit Adapter server

1. On the **Monitor** page, click **Create Work Order**.
2. Next to the CRF Submit Adapter field, click **Add** ( ).
3. In the **Adapter Name** field, type an alias for the CRF Submit Adapter URL.
4. In the **Adapter URL** field, type:

   http://<*computer_name*>/CRFSAdapter/TrialInfoConfig/TrialConfig.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.

5. Click **Add Adapter**.

Adding or editing an InForm study

Using the Configure CRF Submit Adapter page to add or edit an InForm study

1. On the **Monitor** page, click **Configuration** ( ).
2. Click **Configure CRF Submit Adapter**.
3. Do one of the following:
   - To add a new InForm study, next to the **Studies** field, click **Add** ( ).
   - To edit an InForm study, from the **Studies** list, select an InForm study and click **Edit** ( ).
4. Specify or edit the following fields:
   - **Study Name**—Name of the InForm study from which to collect data to generate PDFs. The study name must be unique. Required.
   - **Oracle DB**—Connection string for the Oracle database instance where the InForm study data is stored; defined in the **tnsnames.ora** file. Required.
   - **Username**—InForm study user name to log into the Oracle database. Required.
   - **Password**—InForm study password to log into the Oracle database. Required.
   - **Re-enter Password**.
5. Do one of the following:
   - To save a new InForm study, click **Add Study**.
   - To save the changes to an InForm study, click **Edit Study**.

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.

For more information, see the *Installation and Maintenance Guide*.

Using the Create Work Order page to add an InForm study

1 On the **Monitor** page, click **Create Work Order**.

2 From the **CRF Submit Adapter** drop-down, select an adapter.

3 Next to the **Study Name** field, click **Add** ().

4 Specify the following fields:

- **Study Name**—Name of the InForm study from which to collect data to generate PDFs. The study name must be unique. The InForm studies added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
- **Oracle DB**—Connection string for the Oracle database instance where the InForm study data is stored; defined in the **tnsnames.ora** file. Required.
- **Username**—InForm study user name to log into the Oracle database. Required.
- **Password**—InForm study password to log into the Oracle database. Required.
- **Re-enter Password**.

5 Click **Add Study**.

Setting the default CRF Submit Adapter URL

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

  > **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.

- 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**.

-

Setting up multiple CRF Submit and Document Generator 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 output directory to ensure that the PDF, XML, and HTML files are stored in the same location.

For more information, and examples of multiple server configurations, see the *Installation and Maintenance Guide*.

Configuring multiple servers

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 CRF Submit server.

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 PDF Output Directory for multiple servers

1. Click **Create Work Order**.
2. Make sure that all of the Document Generator servers have read/write access to the shared

folder entered in the **PDF Output Directory** field.

CHAPTER 3

Creating work orders and specifying the work order options

In this chapter

Creating a work order

1. On the **Monitor Page**, click **Create Work Order**.

   The Create Work Order page appears.

2. If the administrator has not set up a default CRF Submit Adapter URL, select or add a CRF Submit Adapter server.
3. In the **Study Name** field, select or add an InForm study.
4. In the **Work Order Name** field, type a name for the work order or accept the name automatically generated.
5. Select a **Submission Language** from the drop-down.
6. In the **PDF Output Directory** field, type a directory where the PDF or XML files will be saved.

   > **Note:** The Default Target Directory specified on the Configuration Options page automatically populates this field.

7. If applicable, specify a custom template to apply to the work order.
8. Select the **Use Custom Template** checkbox.

   > **Note:** You can save work order options as a template on the confirmation page.

9. Click **Next**.

   The Work Order Types page appears.

10. Select a work order type and click **Next**.
11. Specify the options for the work order type selected and click **Next**.

    > **Note:** If you select the **Reduce File Size** option, the PDF files are only viewable with Adobe Acrobat version 6.0 and higher.

    The confirmation page appears.

12. Click **Submit Work Order**.

Specifying custom work order options

Suppressing blank forms, visits, and forms in dynamic visits

1. On the **Monitor** page, click **Create Work Order**.
2. Specify the work order options. For more information, see *Creating a work order* (on page 20).
3. Click **Next**.
4. On the **Work Order Types** page, select **Custom PDF with Subject Data and Optional Blank Forms**.
5. Click **Next**.
6. On the **Custom PDF with Subject Data and Optional Blank Forms** page, select the options to apply to the custom work order. For more information, see the page-level help.
7. To suppress blank forms, In the **StudyContent to Include** section, select **Suppress Blank Forms**.
8. To suppress blank visits, select **Suppress Blank Visits**.
9. In the **Additional Content** section, specify whether or not to generate the index.
10. Click **Next** to display the Confirm Work Order Settings page.
11. Click **Submit Work Order**.

Creating a table of contents

1. On the **Monitor** page, click **Create Work Order**.
2. Specify the work order options. For more information, see *Creating a work order* (on page 20).
3. Click **Next**.
4. On the **Work Order Types** page, select **Custom PDF with Subject Data and Optional Blank Forms**.
5. Click **Next**.
6. On the **Custom PDF with Subject Data and Optional Blank Forms** page, select the options to apply to the custom work order. For more information, see the page-level help.
7. In the **Additional Content** section, specify whether or not to generate the index.
8. To create a table of contents, in the **Additional Content** section, select **Generate TOC**.
9. Click **Next** to display the Confirm Work Order Settings page.
10. Click **Submit Work Order**.

    The resulting file is named **crftoc.pdf** and is located in the Study folder.

Destination site output

The PDFs that are generated for destination sites contain the data for the given subject, as well as a Subject Record Transfer History PDF. The PDFs generated for the site with which the subject is currently associated include all subject data regardless of which site entered or modified the data.

Specifying site output for transferred subjects

The subject record transfer feature of the InForm application allows you to transfer a subject's information from one site to another. When a subject is transferred, the InForm application transfers the subject data that is associated with the originating site to the destination site. For more information, see ***How the CRF Submit software handles data for transferred subjects*** (on page 22).

To determine which sites display data for transferred subjects:

1. On the **Monitor** page, click **Create Work Order**.
2. Specify the work order options. For more information, see ***Creating a work order*** (on page 20).
3. Click **Next**.
4. On the **Work Order Types** page, select **Custom PDF with Subject Data and Optional Blank Forms**.
5. Click **Next**.
6. On the **Custom PDF with Subject Data and Optional Blank Forms** page, select the options to apply to the custom work order. For more information, see the page-level help.
7. In the **Study Content to Include** section, select or deselect the **Transferred Subjects in Current Site Only** checkbox.
   - **Selected**—Data for only the subjects who are currently associated with a site appears in the PDF output for that site.
   - **Unselected**—The PDF for a site lists data for every subject that was ever associated with that site.

   > **Note: The data in the PDF for every previous site to which the subject was associated represents a snapshot of the subject data at the moment the subject was most recently transferred from that site. This ensures that the originating site does not receive confidential subject data that was entered at a more recent site. The destination (current) site for the subject contains complete data for the subject.**
8. In the **Additional Content** section, specify whether or not to generate an index.
9. Click **Next** to display the Confirm Work Order Settings page.
10. Click **Submit Work Order**.

How the CRF Submit application handles data for transferred subjects

If a study includes subjects who have moved from one site to another site, a document named the **Subject Record Transfer History** is generated in the folder for each of the sites. This document contains information about all transfers that the subject has undergone.

The subject number with **-prth** appended to it comprise the file name. For example, for Subject 01-001, the PDF file is named **01-001-prth.pdf**.

Subject transfer history is located in two places:

- **Audit trail**—The primary source to locate transfer history.

  For each audit trail item in the PDF, you can see the site where the action occurred.

  The CRF Submit application also displays all subject record transfers as line items in the audit trails.

- **Subject Record Transfer History PDF**—Contains complete, detailed transfer history information.

Audit trail information for transferred subjects

If a subject has been associated with more than one site, time zone information corresponds to the time zone of the site where the data was entered. This might cause an audit trail to appear to be out of order.

Working with templates

Saving work order options as a template

1. On the **Monitor** page, click **Create Work Order**.
2. Specify the **Work Order Options** and click **Next**.
3. Specify a **Work Order Types** option and click **Next**.
4. Complete the fields for the selected work order type and click **Next**.

   The confirmation page appears. It displays the settings specified for the template.
5. To the right of the **Save Settings** button, type a name for the template.
6. Click **Save Settings**.

   The work order is saved. The name for the template is added to the **Use Custom Template** drop-down list.

   > **Note:** You specify a shared folder for the saved templates in the **Template Directory** field on the **Configuration Options** page. For more information, see Configuration Options page.

Applying a saved template to a work order

You can save work order options as a template on the confirmation page. You apply the template to a work order on the Create Work Order page.

1. On the **Monitor** page, click **Create Work Order**.
2. Enter the work order options.
3. Select the **Use Custom Template** checkbox.
4. From the **Use Custom Template** drop-down list, select a previously saved template.
5. Click **Next**.
6. On the work order page, review your settings and click **Next**.
7. On the **Confirm Work Order Settings** page, click **Submit Work Order**.

CHAPTER 4

Monitoring work orders

In this chapter

Managing a work order

On the **Monitor** page, select one or more work orders and perform the actions described below.

Pausing and resuming work orders

1 To pause a work order that is in the **Processing** state, click **Pause**.

The currently running jobs complete.

The status of selected work order changes to **Paused**.

> **Note:** When you pause a work order, jobs that are currently running complete and no new jobs start. Check the work order to verify that the jobs have completed. Pausing work orders can take up to 15 minutes while jobs finish.

2 To resume a paused work order, select it and click **Resume**.

The status of the selected work orders changes to processing.

Rerunning a selected work order

Click **Rerun**.

Any saved results including completed PDF output are deleted.

> **Note:** Only work orders that are in an **error** or **completed** state can be rerun.

Removing a selected work order

Click **Purge**.

Viewing work order details:

Click **View Work Order Details** ( ).

Exporting work order settings

You can export work order settings to the Microsoft Excel spreadsheet software.

1 On the **Monitor** page, Select the checkbox of a work order and click **View Work Order Details** ( ).

The Work Order Details page appears.

2 Click **Export**.

> **Note:** When you open the XLS file, a dialog box appears asking you to confirm whether to open the file. Click Yes.

Displaying job status details and rerunning jobs

1 On the **Monitor** page, find the row for the work order you want to view.

2 To display job status details, click the underlined text.

The Work Order Jobs page appears.

3 If there is more than one page, select the page numbers or click the arrows to look at other rows.

> **Note:** To quickly find jobs, you can sort the columns by selecting the column headers.

To rerun selected jobs:

1 Select the jobs to rerun.

2 Click **Run Selected Jobs**.

> **Note:** To select all jobs, click the Checkmark icon.

To rerun all failed jobs:

- Click **Run All Failed Jobs**.

To view CRF content:

- In the **View** column of a PDF job, select the link.

CHAPTER 5
Preparing PDFs in Adobe Acrobat

In this chapter

Earlier versions of Adobe Acrobat

The CRF Submit application saves PDF output as PDF Level 1.5, the file format that corresponds to Adobe Acrobat 5.0 and higher. This allows users of Adobe Reader 5.0 and higher to review the output.

Note: Oracle recommends that you use the most recent version of Adobe Reader. For information about Adobe Reader versions supported in this release, see the *Release Notes*.

Japanese linking blank forms

You must use Adobe Reader version 6.0 or higher to view linking blank forms that have Japanese file names.

Thumbnails tab, Comments tab, and Signatures tab

The Thumbnails tab, Comments tab, and Signatures tab visible on the left side of the PDF file are provided by Adobe Acrobat. These tabs are a part of the standard Adobe Acrobat functionality and do not apply to the CRF Submit application or PDFs produced by the CRF Submit application.

Searching PDFs using Adobe Acrobat indexing

If you created a PDF index file, use the Adobe Acrobat search feature to search the PDFs by keyword. Before you use the Search feature, you must identify the PDX (index) file that is associated with the PDF output.

To identify the index file in Adobe Acrobat:

1 Open **Adobe Acrobat**.

2 Select **Edit > Search**.

The Search window appears.

3 At the bottom of the window, select **Use Advanced Search Options**.

4 In the **Look In** field, select **Select Index**.

The Index selection window appears.

5 Select the **crfindex.pdx** file to use.

> **Note:** If the **crfindex.pdx** file is not displayed, click Add and navigate to the **crfindex.pdx** file.

6 Click **OK**.

The file is added to the list of available indexes.

Changing the security settings in Adobe Acrobat

You can use Adobe Acrobat to change the security settings for the PDF. If the PDF currently has security options set, you must provide the password that was specified in the work order.

1 Open the PDF in Adobe Acrobat.

2 Select **File** > **Properties**.

3 Select the **Security** tab.

4 Make changes and provide the password if necessary.

5 Click **OK**.

Guidelines for security settings

Purpose	Type of form	Security setting
Submission	Forms with data	No security.
	Blank forms	No security.
Archive	Forms with data	Security settings according to Sponsor guidelines.
	Blank forms	Security settings according to Sponsor policy.

Note: Do not select **Require Password to Extract or Copy Contents** for any PDF for which you want to create an index.

CHAPTER 6

PDF output examples

In this chapter

Overview of the PDF output

This chapter includes examples of the PDF output for some of the work order options. Each example describes the work order types for which you can specify the work order option.

For example, you can generate linking blank forms for the following work order types:

- Submission with Blank Forms.
- Archive with Blank Forms.
- Custom PDF with Subject Data and Optional Blank Forms.

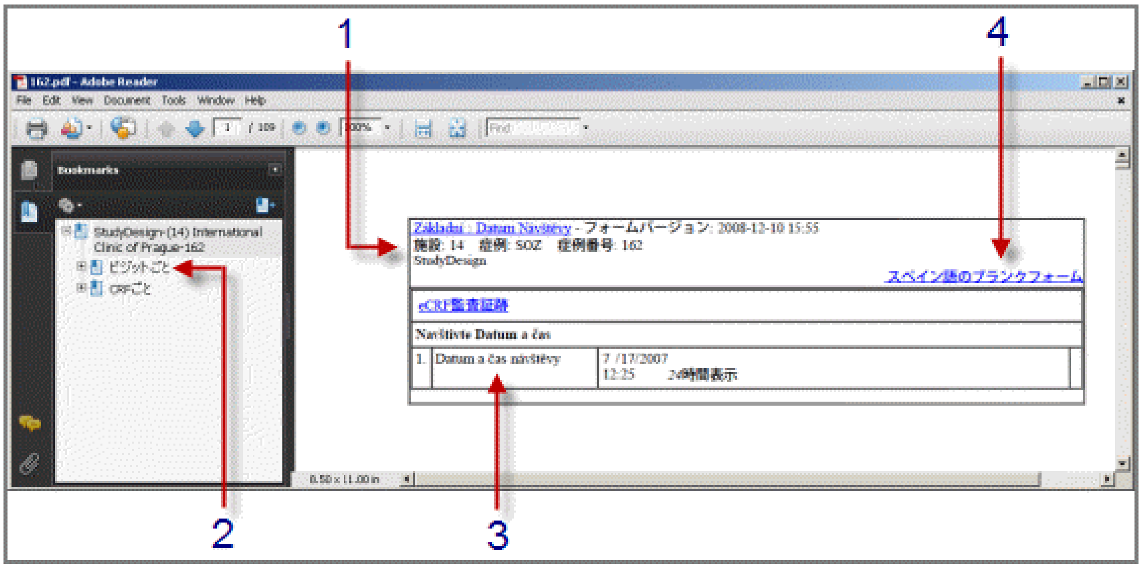
This chapter describes elements of the output that are affected by the specified work order option. Other factors that influence the output are also described, for example, the submission language that was chosen for the Linking Blank Forms example.

Submission Language

You select a submission language on the Create Work Order page.

In the following example:

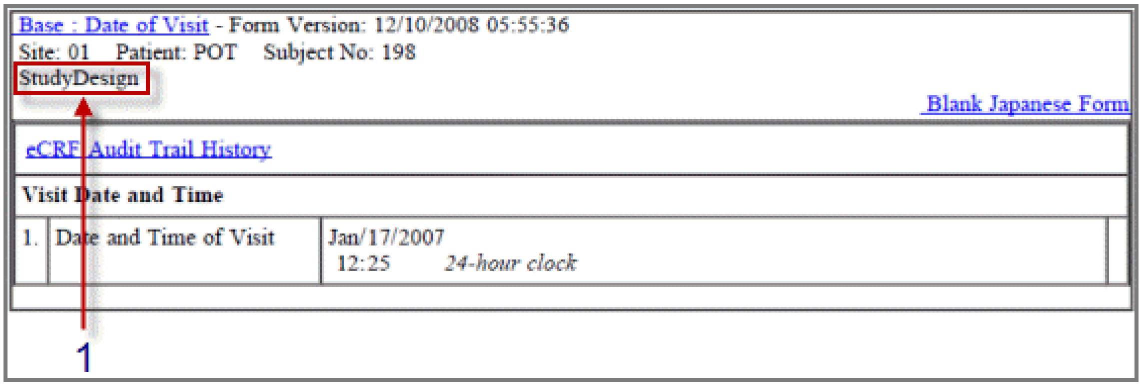
- The submission language is Japanese.
- The forms were created with Czech labels and data was entered at a Czech site.
- The forms link to Spanish blank forms.



1	**Header labels**	Appear in the Japanese submission language.
2	**Bookmarks**	Appear in the Japanese submission language.
3	**Form labels and data**	Labels appear in Czech. Information entered at the Czech site appears in the language in which it was entered into the InForm application.
4	**Link to blank form**	Appears in the Japanese submission language. Click to open the corresponding blank page.

Header Text

You can edit the Header Text field in the Work Order wizard for all work order types.

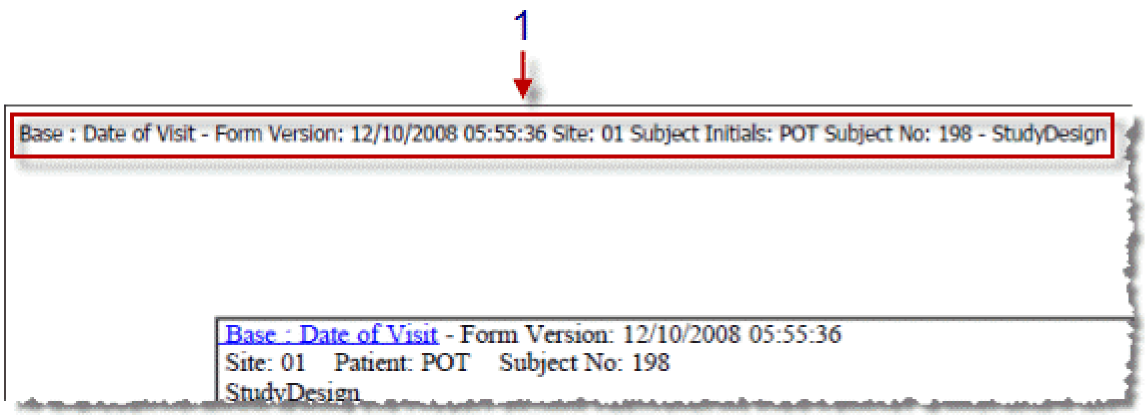


1	**Header Text**	The Header Text in this example is **StudyDesign**. The Header Text appears on every page in the table header.

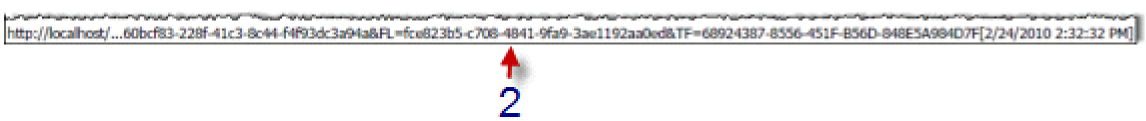
Include Supplementary Page Headers

You can include supplementary page headers and footers for the following work order types:

- Custom PDF with Subject Data and Optional Blank Forms.
- Custom Blank Forms.



1	**Page header**	Located in the upper left corner of every page. The supplementary page header includes the visit name, form version, subject initials, and subject number.

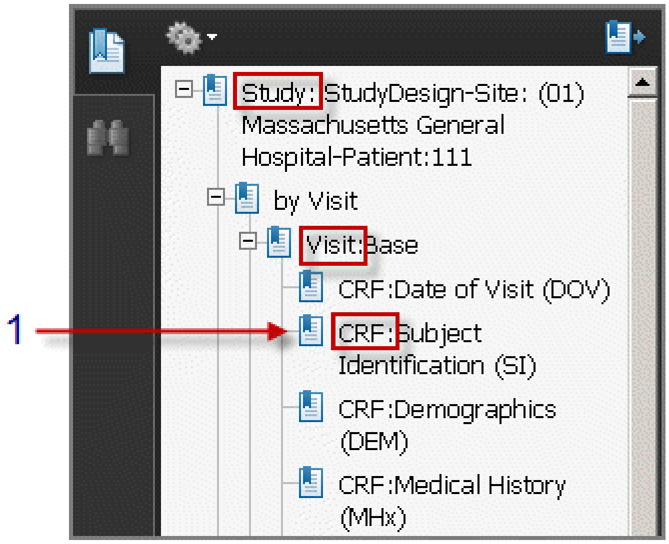


2	**Footer**	Includes the CRF Submit URL that was used when the page was generated. The footer only appears in the PDF output if you include supplementary page headers.

Include Bookmark Prefixes

You can include bookmark prefixes for the following work order types:

- Custom PDF with Subject Data and Optional Blank Forms.
- Custom Blank Forms.

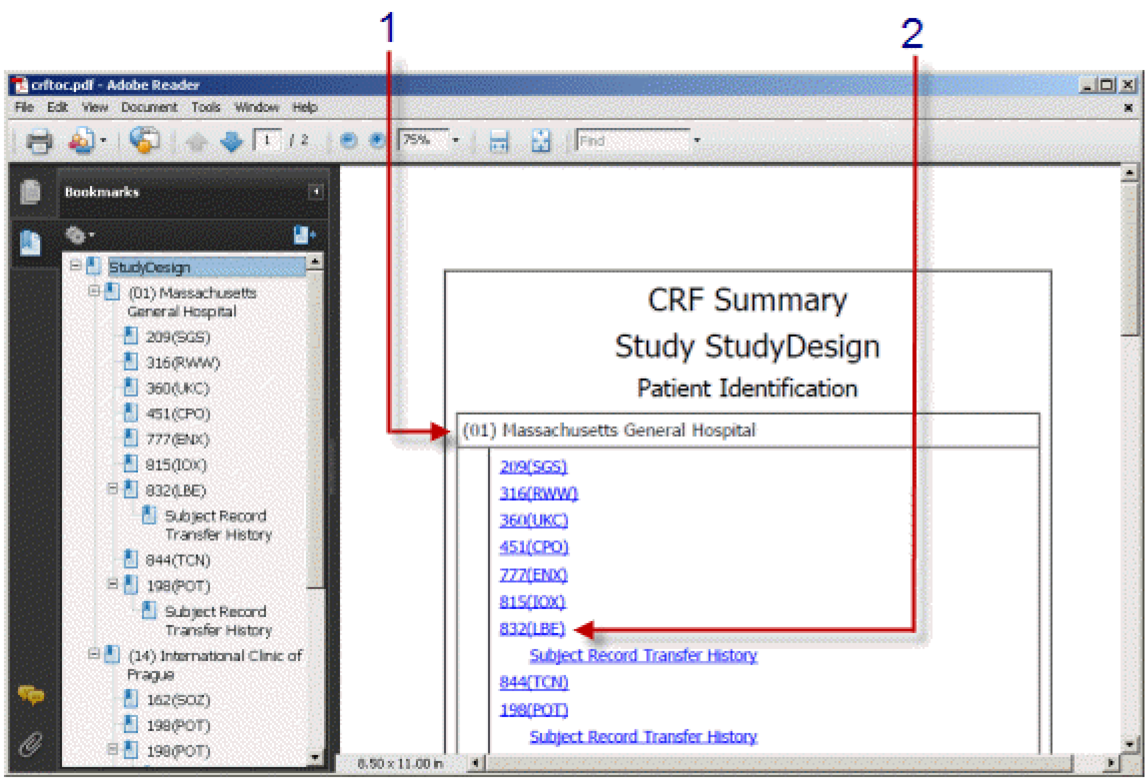


1	**Bookmark prefixes**	In the bookmark for CRF:Subject Identification (SI), **CRF:** is the bookmark prefix.

Generate TOC

A table of contents is automatically generated for all work order types except Custom PDF with Optional Blank Forms (table of contents optional), and Submission with Blank Forms (table of contents not available).

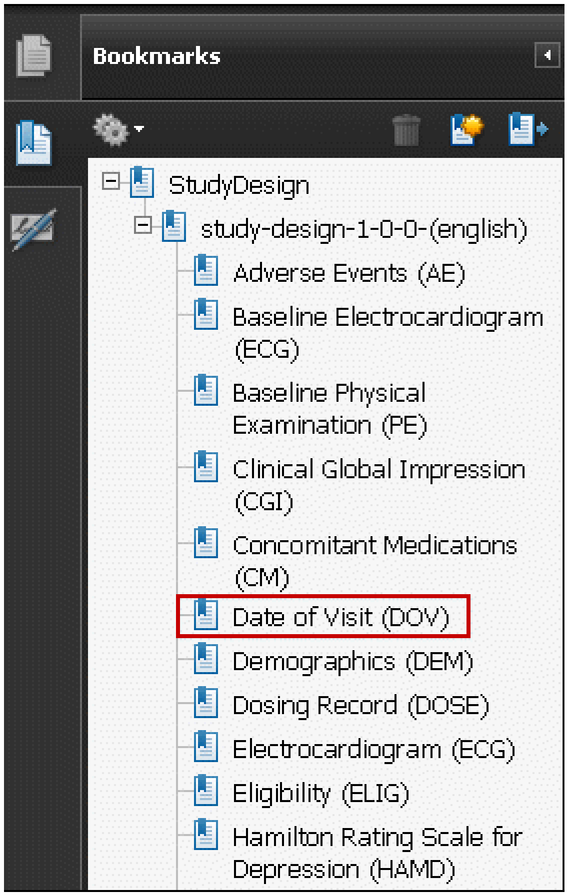
The <study name> folder contains a table of contents file (crftoc.pdf) for the study. This file provides a top-level organization of the subjects and sites included in the PDFs related to the study. It also links to the directory location for each file associated with the PDFs. For more information, see Creating a table of contents.

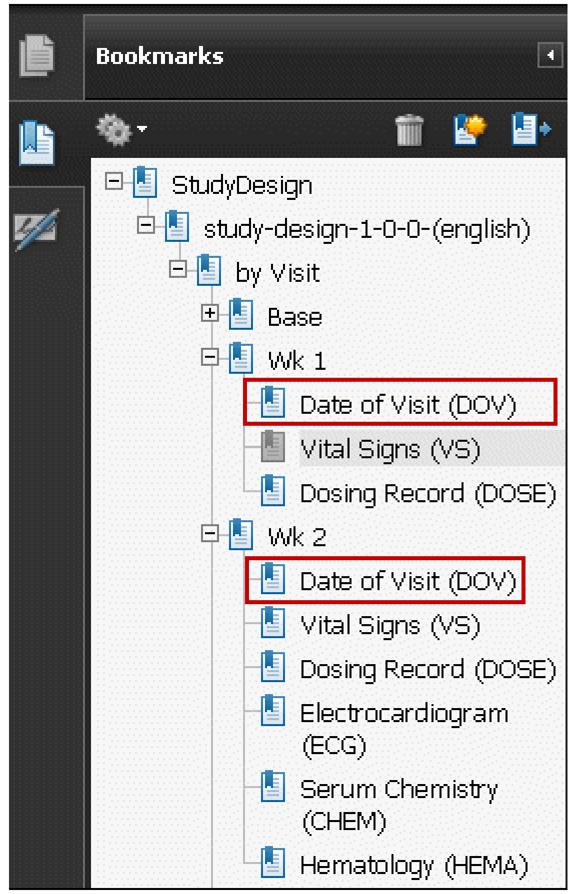


1	Sites	Subject links are organized under the associated sites in the table of contents.
2	Subject link	Click to navigate to the associated PDF.

Blank Form Format

You can edit the Blank Form Format field in the Work Order wizard for all work order types.





Unique Forms One copy of each unique form in the study version is arranged alphabetically. A single instance of the Date of Visit (DOV) blank form appears in this PDF.

Casebook Copies of all the forms in the study version are arranged by visit as they appear in the casebook. The Date of Visit (DOV) blank form appears multiple times in this PDF.

Hidden Item Selection

In the InForm application, you can control access to specific items by creating item groups, and making those items unavailable to users in a specific Rights group.

The CRF Submit application uses item groups to include or exclude items from the PDF output with the Hidden Item Options. You can select:

- Hide None.
- Hide All.
- Hide Selected.

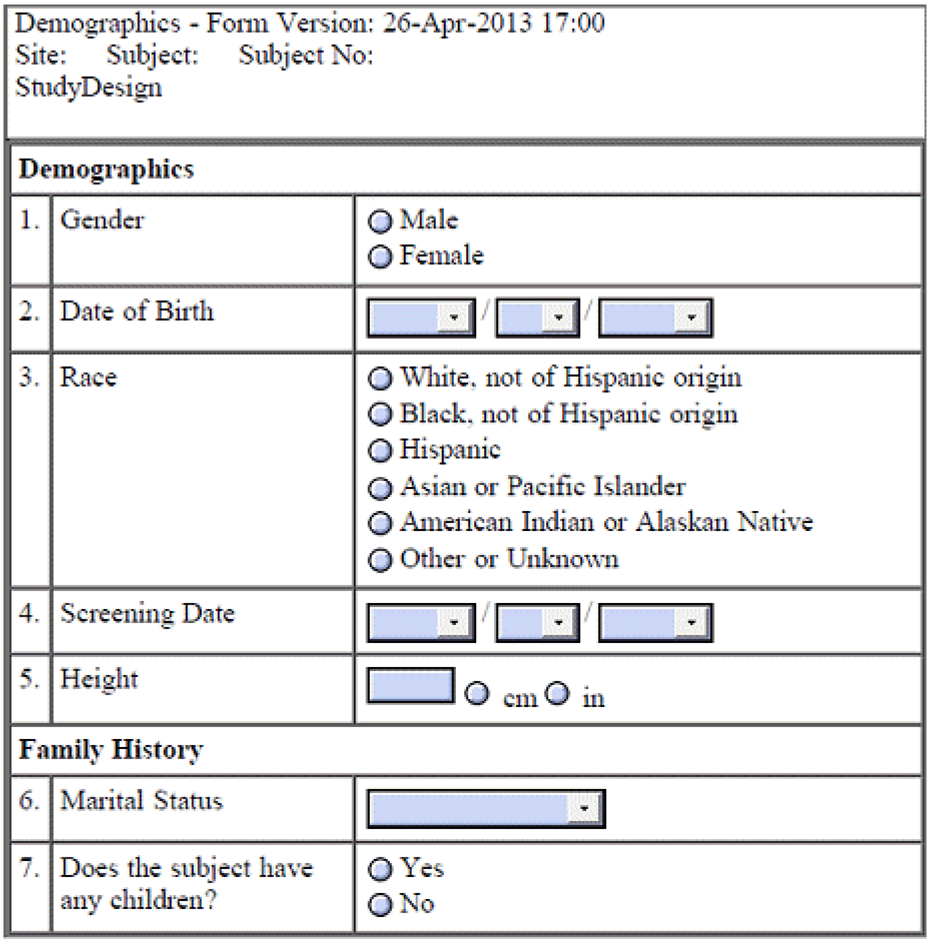
You can specify the hidden item selection for all work order types.

In the following example, two item groups and two rights groups have been created in the InForm application:

- One item group contains the Gender item from the Demographics form. The item group has been assigned the hidden display override for rights group A.
- One item group contains the Height and Race items from the Demographics form. The item group has been assigned the hidden display override for rights group B.

Hide None option

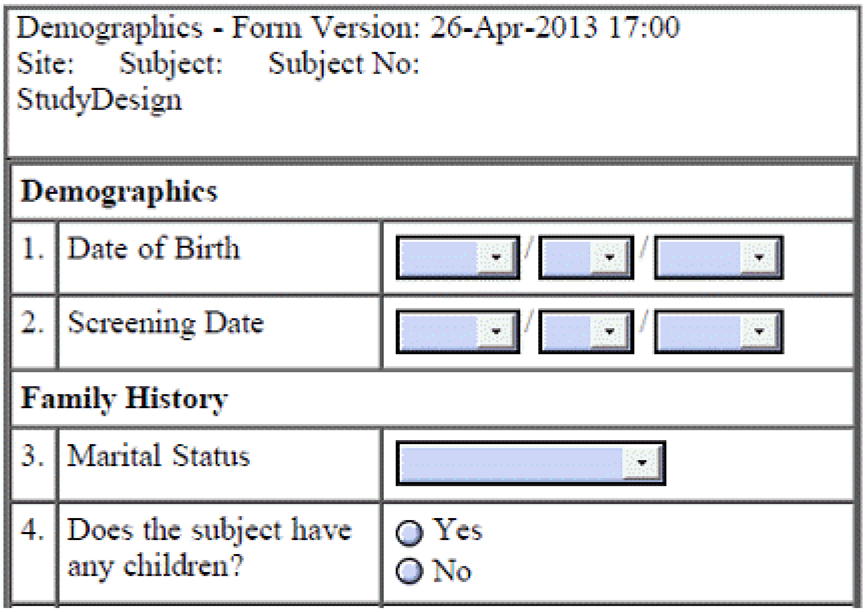
PDF output includes all items that are hidden to any rights group in the InForm study. Gender (hidden to rights group A), Race and Height (hidden to rights group B) are all included.


Demographics - Form Version: 26-Apr-2013 17:00
Site: Subject: Subject No:
StudyDesign

Demographics		
1.	Gender	Male Female
2.	Date of Birth	/ /
3.	Race	White, not of Hispanic origin Black, not of Hispanic origin Hispanic Asian or Pacific Islander American Indian or Alaskan Native Other or Unknown
4.	Screening Date	/ /
5.	Height	cm in
Family History		
6.	Marital Status	
7.	Does the subject have any children?	Yes No

Hide All option

PDF output excludes all items that are hidden to any rights group in the InForm study. Gender (hidden to rights group A), Race and Height (hidden to rights group B) are all excluded.

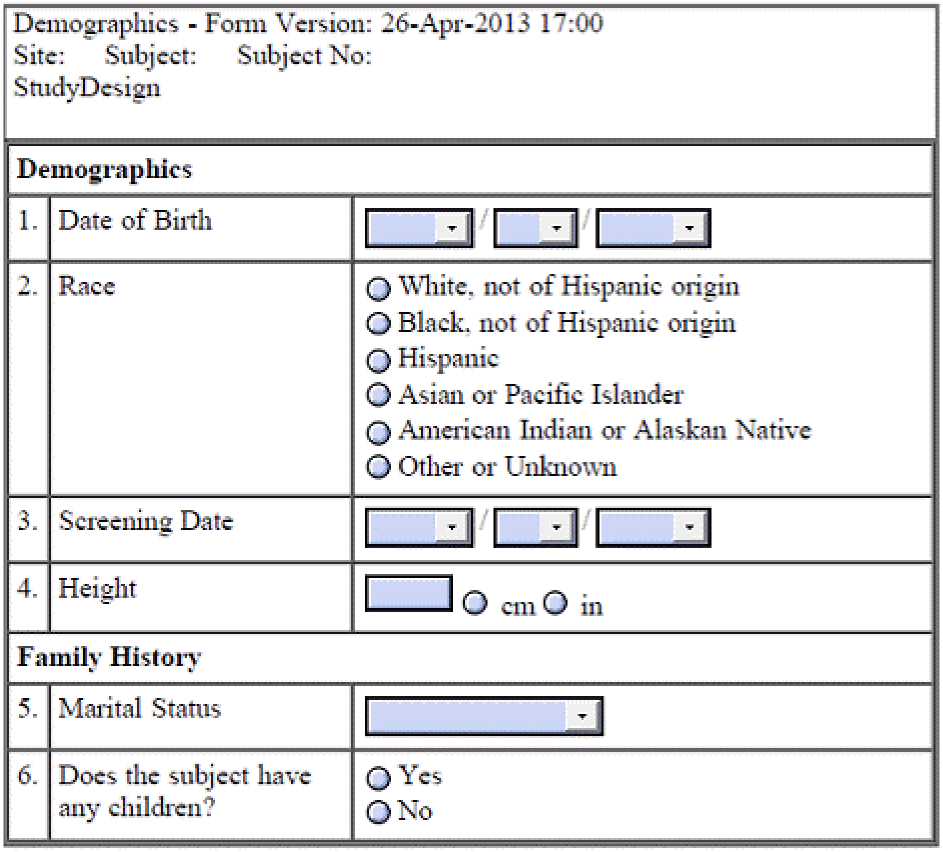


Demographics - Form Version: 26-Apr-2013 17:00
Site: Subject: Subject No:
StudyDesign

Demographics		
1.	Date of Birth	/ /
2.	Screening Date	/ /
Family History		
3.	Marital Status	
4.	Does the subject have any children?	Yes No

Hide Selected option

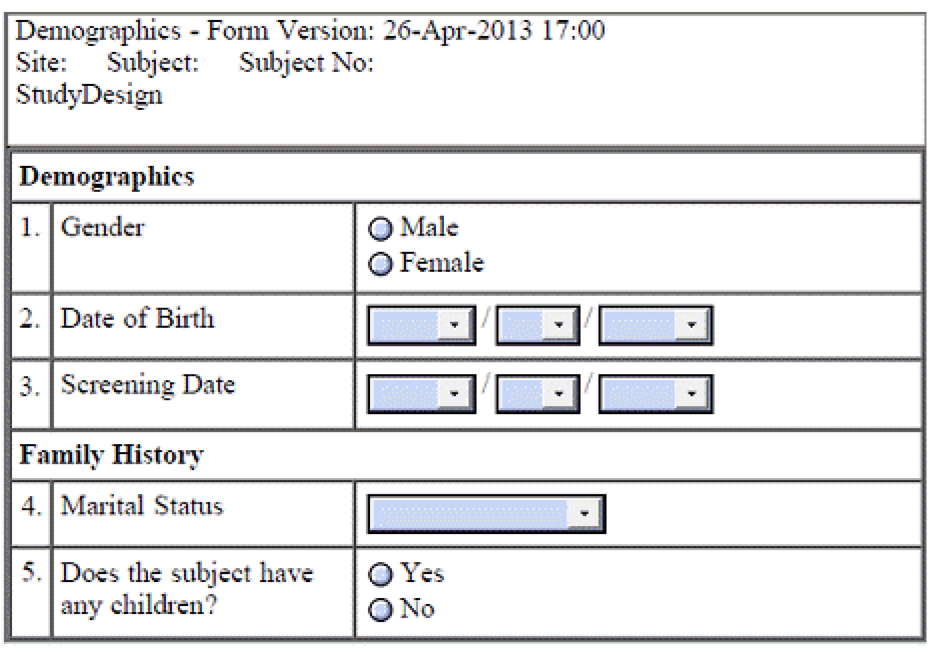
- **Rights group A**—PDF output excludes Gender, and includes Race and Height.



Demographics - Form Version: 26-Apr-2013 17:00
Site: Subject: Subject No:
StudyDesign

Demographics		
1.	Date of Birth	/ /
2.	Race	White, not of Hispanic origin Black, not of Hispanic origin Hispanic Asian or Pacific Islander American Indian or Alaskan Native Other or Unknown
3.	Screening Date	/ /
4.	Height	cm in
Family History		
5.	Marital Status	
6.	Does the subject have any children?	Yes No

- **Rights group B**—PDF output excludes Race and Height, and includes Gender.



Demographics - Form Version: 26-Apr-2013 17:00
Site: Subject: Subject No:
StudyDesign

Demographics		
1.	Gender	Male Female
2.	Date of Birth	/ /
3.	Screening Date	/ /
Family History		
4.	Marital Status	
5.	Does the subject have any children?	Yes No

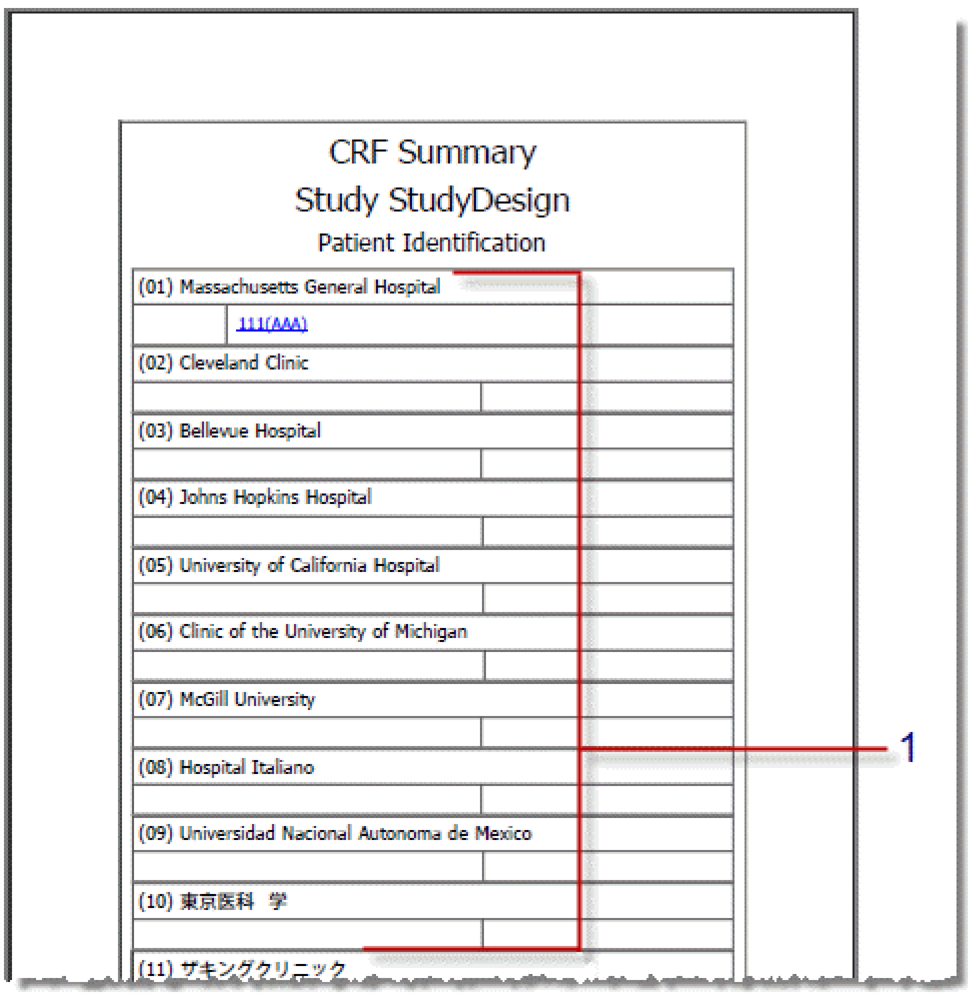
Selection Criteria

The selection criteria include the following export options:

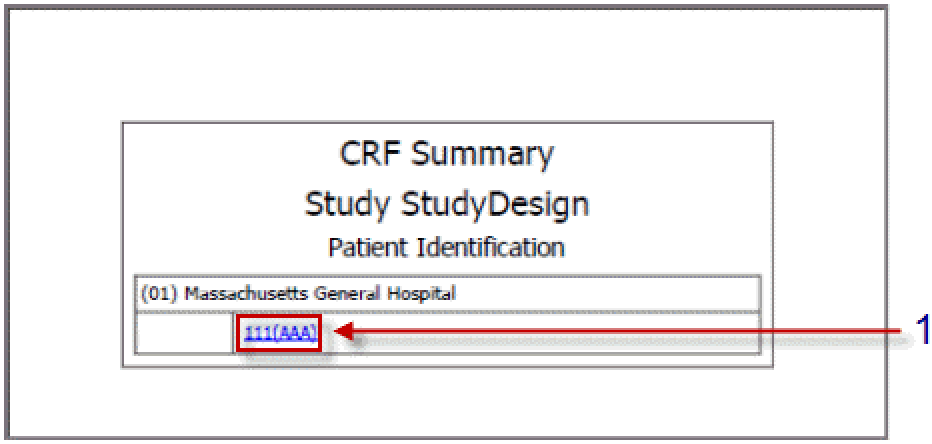
- Export All Subjects and Sites.
- Export by Subject.
- Export by Site.

You can specify the selection criteria for the following work order types:

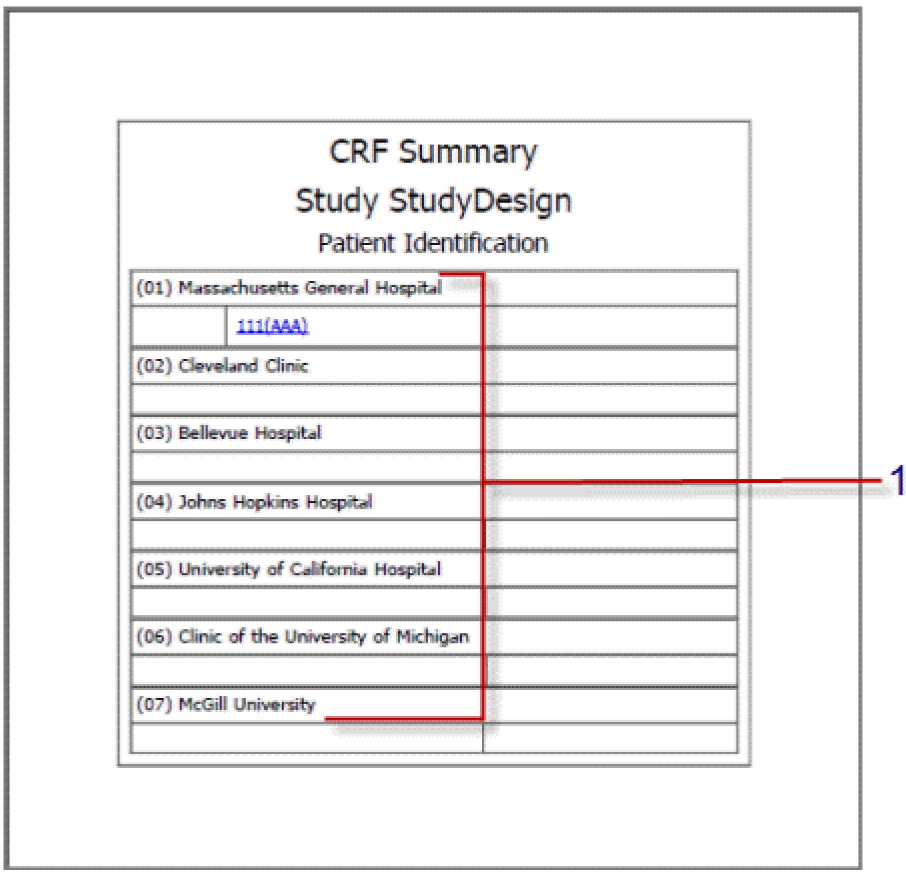
- Submission with Blank Forms.
- Archive with Blank Forms.
- Custom PDF with Subject Data and Optional Blank Forms.



1	**Export All Subjects and Sites**	The table of contents includes all subjects and sites.



1	**Export by Subject**	The table of contents includes the selected subjects.



1	**Export by Site**	The table of contents includes the selected sites.

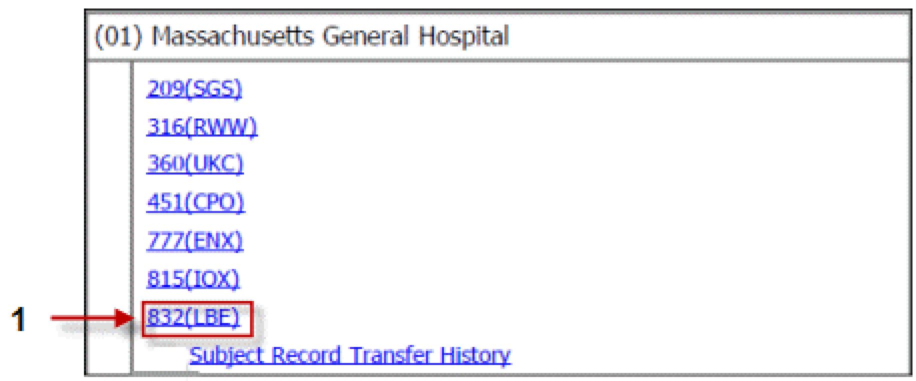
Transferred Subjects in Current Site Only

By default, data for transferred subjects is included in the PDFs for every site in which the subject was associated. If you select the **Transferred Subjects in Current Site Only** option, information is limited to only the PDF in the destination site associated with the study.

You can select the **Transferred Subjects in Current Site Only** option for a Custom PDF with Optional Blank Forms. For more information, see Specifying site output for transferred subjects.

The following example shows how the hyperlinks for subject 832(LBE), who was transferred from site 11 to site 01, would work in the table of contents when **Transferred Subjects in Current Site Only** is selected.

Destination site (01):



1 Link goes to the subject PDF at the destination site.

Origination site (11):

2 Link goes directly to the archived PDF..

Suppress Blank Forms and Visits

You can suppress blank forms or visits for a Custom PDF with Subject Data and Optional Blank Forms. For more information, see Suppressing blank forms, visits, and forms in dynamic visits.

Use the following table to determine whether blank forms or visits will appear in the PDF output.

Form or visit is	Suppress blank visits is	Suppress blank forms is	Visit appears in the PDFs
Not yet dynamically created.	Checked or unchecked	Checked or unchecked	No
Dynamically created, but not yet started.	Checked	Checked	No
	Unchecked	Checked	No
	Checked	Unchecked	No
	Unchecked	Unchecked	Yes
Dynamically created, data has been entered.	Checked	Checked or unchecked	Yes
	Unchecked	Unchecked	Yes
	Unchecked	Checked	Yes

Note: Blank forms do not contain subject data. Therefore, the bookmark for a blank form references the visit, but not the subject. For example, a repeating visit that appears as **Day 1 1** in a subject PDF will appear as **Day 1 0** in the blank study form.

Generate Linking Blank Forms

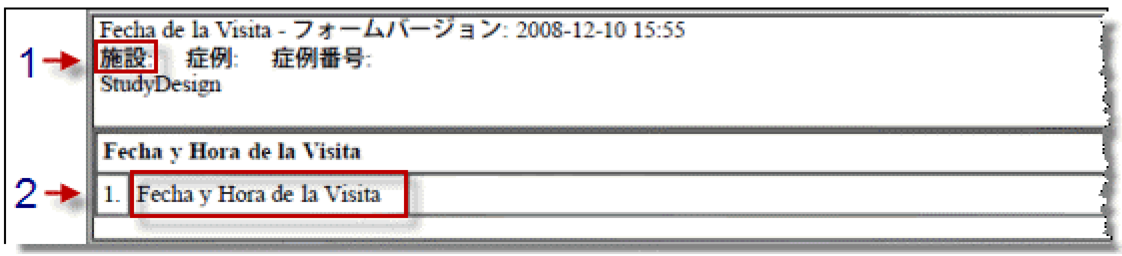
If blank forms were generated for a multilingual study, each page in the PDF file has a link to a corresponding blank page that contains labels in the language that was specified when the work order was created.

You can generate linking blank forms for the following work order types:

- Submission with Blank Forms.
- Archive with Blank Forms.
- Custom PDF with Subject Data and Optional Blank Forms.

In the following example:

- The submission language is Japanese.
- The linking blank form was generated in Spanish.

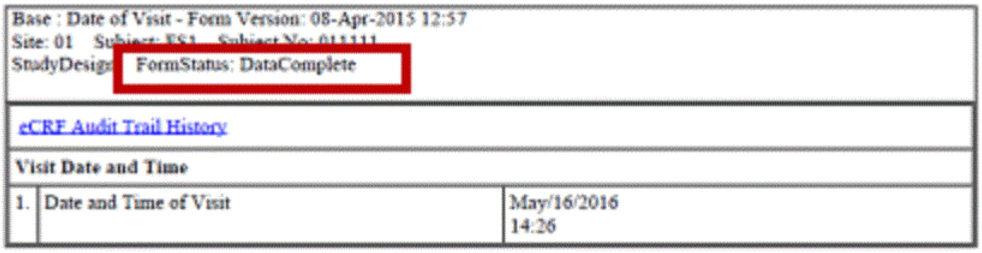


1	**Header labels**	Appear in the Japanese submission language.
2	**Form labels**	Appear in Spanish, the language specified for linking blank forms in the work order.

Include Form Status

You can include the form status for the following work order types:

- Custom PDF with Subject Data and Optional Blank Forms.



Base : Date of Visit - Form Version: 08-Apr-2015 12:57
Site: 01 Subject: FS1 Subject No: 011111
StudyDesign FormStatus: DataComplete

eCRF Audit Trail History

Visit Date and Time		
1.	Date and Time of Visit	May/16/2016 14:26

CHAPTER 7

Troubleshooting

In this chapter

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.

PDF troubleshooting

CRF bookmark links

If you can select CRF or audit trail bookmark links, or if the links point you to the last visit selected, there is an issue with the Adobe Acrobat settings. To resolve the issue, uninstall and reinstall Adobe Acrobat, and reboot the computer.

CRF Help and table of contents

If you are running a work order that includes a table of contents and the CRF Help and an issue occurs with the CRF Help, the job is assigned an error status. The work order does not complete and the table of contents is not generated.

To complete the work order, you must resolve the problem in the CRF Help and rerun the work order. You can also generate the CRF Help in a separate work order.

CRF Help is missing

The CRF Submit application gets the CRF Help and protocol information from the most recent study version. If the most recent study version does not have the protocol and help documents attached to it, a PDF of the CRF Help is not created.

Be sure to attach protocol and help documents to new study versions.

CRF images

Images in the CRF are not immediately visible in the PDF. In their place the word **Image** appears as a link. When you click the link, the image appears at the very end of the PDF.

Extra text in PDF

Certain HTML constructs are not visible in Internet Explorer but are visible when converted by Adobe Acrobat to PDF. Check the source HTML to find the extra hidden text.

Imported values in drop-down lists

If an invalid value was imported into a drop-down list in the InForm application, other than date/time fields, the value does not appear in the generated PDF. For example, if the drop-down list values are small, medium and large and the value **huge** is imported, the drop-down list appears blank in the PDF.

Protocol Help links

When you create a PDF and include the CRF Help or protocol guide, the hyperlinks in the Help might not work. If you want to follow help links to pages in the InForm study, open the Help through the InForm study.

Repeated generation of study data

If you generate two work orders using the same location, the following results may occur:

- Options could be different, some subjects will have comments, some will not.
- The table of contents will reflect only the most recent work order. If you generate tables of contents for two work orders, the second work order overwrites the first.

APPENDIX A

Page-level help reference

In this appendix

Configuration Options page

Field	Description
CRF Submit User Group	Windows user group that defines the users who can access the CRF Submit application on a user level. Required.
CRF Submit Admin Group	Windows user group that defines the users who can access the CRF Submit application on an administrator level. Required. For Domain user groups, specify DOMAIN/GROUP.
Default Target Directory	Shared directory where the PDF, XML, or HTML files are saved. Required. Default is c:\share\crfspdfs
Template Directory	Shared directory where templates are saved. Required.
DB Connection	Oracle connection string used to connect to the CRF Submit server database. Specified during the CRF Submit server installation.
DB User	Oracle user name used to access the CRF Submit database. Required.
DB Password	Password used to connect to the Oracle database. The Oracle password is defined during installation. Required. Changing the password requires: • Updating the password in Oracle. • Updating the password on the CRF Submit Configuration screen.
Delete Metrics Older Than (days)	Number of days after which metrics on the View Statistics page are deleted. Default is 180.
Work Order Processing Sleep Time (secs)	Amount of time between two work orders. Required. **Note:** The amount of tuning necessary is dependent on the computers that you are using, network traffic and the amount and type of data being processed.
XML Gen Job Process Thread Count	Number of jobs that can be processed simultaneously under a work order. Anything over the maximum number specified is queued. Required.
XML Gen Job Process Sleep Time	Amount of time between two job processes. Required. **Note:** The amount of tuning necessary is dependent on the computers that you are using, network traffic and the amount and type of data being processed.
CRF Download Thread Count	Number of CRF download threads the server can process simultaneously. Anything over the maximum number specified is queued. Required.
CRF Download Thread Sleep Time (secs)	Amount of time between two download threads. Required. **Note:** The amount of tuning necessary is dependent on the computers that you are using, network traffic and the amount and type of data being processed.

Field	Description
Work Order Thread	Displays the current status of threads • **Started**—The work orders and XML jobs are processing. • **Stopped**—No XML jobs are processing. **Note:** 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.
Number of running XML Gen Threads	Out of the number of XML Gen threads, the number that are actually running.

Button	Description
Start Threads	Processing is initiated and the status changes to **Started**. You must have administrator rights to start, stop and adjust threads.
Stop Threads	The current jobs finish and no other jobs are started. You must have administrator rights to start, stop and adjust threads.
Save Settings	Save the changes to the Configuration settings.
Cancel	Cancel the changes to the Configuration settings.
Create Work Order	Navigate to the Create Work Order page to specify work order options.
Return to Monitor	Navigate to the Monitor page.
Configure CRF Submit Adapter	Navigate to the Configure CRF Submit Adapter page to add or edit CRF Submit Adapter servers or InForm studies.
View Statistics	Navigate to the View Statistics page to view work order metrics.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Configure CRF Submit Adapter page

Field	Description
CRF Submit Adapter	CRF Submit Adapter server to connect to using the CRF Submit application. The CRF Submit Adapter servers added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
Studies	InForm studies for which to generate PDF files. Required.

Button	Description
Add	Add a CRF Submit Adapter server or InForm study.
Edit	Edit an existing CRF Submit Adapter server or InForm study.
Delete	Delete a CRF Submit Adapter server or InForm study.
Create Work Order	Navigate to the Create Work Order page to specify work order options.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
View Statistics	Navigate to the View Statistics page to view work order metrics.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Add or edit CRF Submit Adapter options

Field	Description
Adapter Name	Alias for the CRF Submit Adapter URL to connect to using the CRF Submit application. Required.
Adapter URL	CRF Submit Adapter URL to connect to using the CRF Submit application. Required. For example: **http://**<*computer_name*>**/CRFSAdapter/TrialInfoConfig/TrialConfig.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.
Default Adapter	Set a CRF Submit Adapter server as the default on the Create Work Order page.

Button	Description

Button	Description
Add Adapter	Save a new CRF Submit Adapter server to the CRF Submit Adapter drop-down list.
Edit Adapter	Save the changes to an existing CRF Submit Adapter server.
Cancel	Cancel the changes to a CRF Submit Adapter server.

Add or edit Studies options

Field	Description
Study Name	Name of the InForm study from which to collect data to generate PDFs. The study name must be unique. The InForm studies added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
Oracle DB	Connection string for the Oracle database instance where the InForm study data is stored; defined in the **tnsnames.ora** file. Required.
Username	InForm study user name to log into the Oracle database. Required.
Password	InForm study password to log into the Oracle database. Required.
Re-enter Password	Re-enter the password for password protected fields in order to confirm that the original password entered is correct.

Button	Description
Add Study	Save a new InForm study to the Studies drop-down list.
Edit Study	Save the changes to an existing InForm study.
Cancel	Cancel the changes to an InForm study.

View Statistics page

Button	Description
Create Work Order	Navigate to the Create Work Order page to specify work order options.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Configure CRF Submit Adapter	Navigate to the Configure CRF Submit Adapter page to add or edit CRF Submit Adapter servers or InForm studies.
Information icon	View additional work order metrics.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Create Work Order page

Field	Description
CRF Submit Adapter	CRF Submit Adapter server to connect to using the CRF Submit application. The CRF Submit Adapter servers added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
Study Name	Name of the InForm study from which to collect data to generate PDFs. The study name must be unique. The InForm studies added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
Work Order Name	Name for the request used to monitor the work order processing. Default is <study name>_<run date>. Required.
Submission Language	Specify the language to use for labeling in bookmarks, headers, and footers. Required. • English • Japanese The language of the data in the forms is the language in which study information was recorded in the InForm application.
PDF Output Directory	Directory where the PDF, XML, or HTML files are saved. Default is the Default Target Directory specified on the Configuration page. Required.
Use Custom Template	If applicable, specify a custom template to apply to the work order.

Button	Description
Add	Add a CRF Submit Adapter server or InForm study.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Add CRF Submit Adapter options

Field	Description
Adapter Name	Alias for the CRF Submit Adapter URL to connect to using the CRF Submit application. Required.

Field	Description
Adapter URL	CRF Submit Adapter URL to connect to using the CRF Submit application. Required. For example: **http://**<*computer_name*>**/CRFSAdapter/TrialInfoConfig/TrialConfig.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.

Button	Description
Add Adapter	Save a new CRF Submit Adapter server to the CRF Submit Adapter drop-down list.
Cancel	Cancel the changes to a CRF Submit Adapter server.

Add Study Name options

Field	Description
Study Name	Name of the InForm study from which to collect data to generate PDFs. The study name must be unique. The InForm studies added on the Configure CRF Submit Adapter page or the Create Work Order page automatically populate this drop-down menu. Required.
Oracle DB	Connection string for the Oracle database instance where the InForm study data is stored; defined in the **tnsnames.ora** file. Required.
Username	InForm study user name to log into the Oracle database. Required.
Password	InForm study password to log into the Oracle database. Required.
Re-enter Password	Re-enter the password for password protected fields in order to confirm that the original password entered is correct.

Button	Description
Add Study	Save a new InForm study to the Studies drop-down list.
Cancel	Cancel the changes to an InForm study.

Work Order Types page

Field	Description
Submission with Blank Forms	Generate submission-ready PDF files and blank forms for all visits. The CRF Submit software automatically generates an index, Protocol Guide, and CRF Help for the work order. When generation is complete, the blank CRFs are located in a folder named **blank-crfs**.
Archive with Blank Forms	Generate archival PDF files and blank forms for all visits. The CRF Submit application automatically generates a table of contents for the work order. When generation is complete, the blank CRFs are located in a folder named **blank-crfs**.
Blank Forms Only	Generate a set of form templates that do not contain any data. The CRF Submit software automatically generates a table of contents for the work order. The forms are based on the study version you select. When generation is complete, the blank CRFs are located in a folder named **blank-crfs**.
Custom PDF with Subject Data and Optional Blank Forms	Customize a work order for forms that contain data.
Custom Blank Forms	Customize the format, study versions, and security settings for a set of form templates that do not contain data. The CRF Submit application automatically generates a table of contents for the work order. When generation is complete, the blank CRFs are located in a folder named **blank-crfs**.

Button	Description
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Submission with Blank Forms Options page

The following fields appear on both the Submission with Blank Forms Options page and the Submission with Blank Forms confirmation page. Data entry occurs on the Submission with Blank Forms Options page. You cannot edit the following fields on the Submission with Blank Forms confirmation page, but you can view the options you selected.

Field	Description
Header Text	Custom text that appears in the table header. Default is the InForm study name. Required.
Page Size	Specify the page sizes for the PDF file. Required. • **Letter**—8.5 x 11 inches. Default. • **A4**—210 mm x 297 mm.
Blank Form Format	Specify the organization for the PDF files: • **Unique Forms**—One copy of each unique form in the study version arranged alphabetically. • **Casebook**—Copies of all the forms in the study version arranged as they appear in the casebook. Default.
Verify PDF After Generation	Run a post-processing script that verifies that the CRF Submit application generated a valid PDF file for every subject in the InForm study and that the bookmarks work correctly. Default.
Candidate Queries	Include candidate queries. **Note:** A candidate query is visible in InForm only to those users who have appropriate rights (for example a CRA).
Reduce File Size when >=	Run the Reduce File Size option in Adobe Acrobat. If selected, specify a minimum file size for the process to run. Default is 100 MB. **Note:** If you select this option, the PDF files are only viewable with Adobe Reader version 6.0 and higher.
Generate Linking Blank Forms	Generate a set of blank forms to use for reference with PDF files, typically for a multilingual study. If you select this option, specify the language for the blank forms. Typically, these forms are in a different language than the submission language. The **Generate Linking Blank Forms** drop-down list is automatically populated with the languages used in the InForm study. **Note:** The **Generate Linking Blank Forms** option only works with the InForm GTM (InForm 4.7, InForm 5.x, and InForm 6.x) releases. If you select the **Generate Linking Blank Forms** option for a study created in the InForm ITM (InForm 4.5 and InForm 4.6) release streams, the CRF Submit user interface displays an error message.

Field	Description
Hidden Item Selection	If you do not want to include items that are hidden to certain rights groups in the InForm study, select which hidden items to exclude. Use the search box to search for a rights group. • **Hide None**—Default. • **Hide All**—Exclude all items that are hidden to any rights group. • **Hide Selected**—A list of all the rights groups in the InForm study appears. Select a rights group to exclude items hidden to it. **Note:** To select more than one rights group, click multiple groups.
Selection Criteria	If you do not want to extract data from all subjects and sites, specify the subjects or sites whose data you want to export. Use the search box to search for a subject or site. • **Export All Subjects and Sites**—Default. • **Export by Subject**—A list of all the subjects in the InForm study appears. Select the subject for which you want to extract data. **Note:** To select more than one subject, click multiple subjects. • **Export by Site**—A list of all the sites in the InForm study that the InForm user has access to appears. Select the site for which you want to extract data. **Note:** To select more than one site, click multiple sites. Data is extracted for all subjects in the selected sites.

Button	Description
All	Selects all rights groups for hidden item selection. Selects all sites, subjects, forms, or visits when exporting by site, subject, form, or visit.
Reverse	Selects the unselected rights groups and deselects the selected rights groups for hidden item selection. Selects the unselected sites, subjects, forms, or visits and deselects the selected sites, subjects, forms, or visits when exporting by site, subject, form, or visit.
Right arrow icon	Move the selected rights groups to the Selected Rights Groups list. Move the selected sites, subjects, forms, or visits to the Selected Sites list, Selected Subjects list, Selected Forms list, or Selected Visits list

Button	Description
Left arrow icon	Remove the selected rights groups from the Selected Rights Groups list. Remove the selected sites, subjects, forms, or visits from the Selected Sites list, Selected Subjects list, or Selected Forms list, or Selected Visits list.
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Submission with Blank Forms confirmation page

Button	Description
Edit Settings	Navigate back to the previous page.
Save Settings	Save the selected work order options as a template to be used for other work orders.
Submit Work Order	Submit the work order options for PDF generation.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Help	Open the context-sensitive Help.

You cannot edit the following preselected fields for a Submission with Blank Forms.

Field	Preselected Output
PDF	True
XML	True
HTML	False
Require Password to Change Document	False
Require Password to Change Form Comments	False
Require Password to Extract or Copy Contents	False
Visits	All
Generate Subject Forms File per CRB or Visit	CRB

Field	Preselected Output
Generate Index	True
Generate Table of Contents	False
Protocol Guide and CRF Help	True
Transferred Subjects in Current Site Only	False
Suppress Blank Forms	False
Suppress Blank Visits	False
Candidate Queries	False
Audit Location	End of PDF
Include Supplementary Page Headers	False
Include Bookmark Prefixes	False

Archive with Blank Forms Options page

The following fields appear on both the Archive with Blank Forms Options page and the Archive with Blank Forms confirmation page. Data entry occurs on the Archive with Blank Forms Options page. You cannot edit the following fields on the Archive with Blank Forms confirmation page, but you can view the options you selected.

Field	Description
Header Text	Custom text that appears in the table header. Default is the InForm study name. Required.
Page Size	Specify the page sizes for the PDF file. Required. • **Letter**—8.5 x 11 inches. Default. • **A4**—210 mm x 297 mm.
Generate Index	Create a PDX (index) file for a set of PDFs. If you generate an index, you can use the Adobe Acrobat search feature to search PDFs by keyword. Required.
Blank Form Format	Specify the organization for the PDF files: • **Unique Forms**—One copy of each unique form in the study version arranged alphabetically. • **Casebook**—Copies of all the forms in the study version arranged as they appear in the casebook. Default.
Verify PDF After Generation	Run a post-processing script that verifies that the CRF Submit application generated a valid PDF file for every subject in the InForm study and that the bookmarks work correctly. Default.
Candidate Queries	Include candidate queries. **Note:** A candidate query is visible in InForm only to those users who have appropriate rights (for example a CRA).
Reduce File Size when >=	Run the Reduce File Size option in Adobe Acrobat. If selected, specify a minimum file size for the process to run. Default is 100 MB. **Note:** If you select this option, the PDF files are only viewable with Adobe Reader version 6.0 and higher.
Generate Linking Blank Forms	Generate a set of blank forms to use for reference with PDF files, typically for a multilingual study. If you select this option, specify the language for the blank forms. Typically, these forms are in a different language than the submission language. The **Generate Linking Blank Forms** drop-down list is automatically populated with the languages used in the InForm study. **Note:** The **Generate Linking Blank Forms** option only works with the InForm GTM (InForm 4.7, InForm 5.x, and InForm 6.x) releases. If you select the **Generate Linking Blank Forms** option for a study created in the InForm ITM (InForm 4.5 and InForm 4.6) release streams, the CRF Submit user interface displays an error message.

Field	Description
Require Password to Change Document	Prevent changes to the PDF file. If you are creating a site archive, it is recommended that you select this option.
Require Password to Change Form Comments	Prevent data from being added to the PDF file. If you are creating a site archive, it is recommended that you select this option. **Note:** If you select both the Require Password to Change Document and the Require Password to Change Form Comments options, active controls will not be enabled and their options will not be visible in generated blank form PDFs.
Password	Specifies a password. If you use any of the Adobe security options, you must specify a password. This allows access to the security options within the PDF so that changes can be made at a later date. **Note:** The security options have no effect on the ability to open and view a PDF file. Regulatory guidelines state that you should not include any security settings or password protection for submission PDF files.
Re-enter Password	Re-enter the password for password protected fields in order to confirm that the original password entered is correct.
Display passwords in plain text	Display the text entered in the Password and Re-enter Password fields.
Hidden Item Option	If you do not want to include items that are hidden to certain rights groups in the InForm study, select which hidden items to exclude. Use the search box to search for a rights group. • **Hide None**—Default. • **Hide All**—Exclude all items that are hidden to any rights group. • **Hide Selected**—A list of all the rights groups in the InForm study appears. Select a rights group to exclude items hidden to it. **Note:** To select more than one rights group, click multiple groups.

Field	Description
Selection Criteria	If you do not want to extract data from all subjects and sites, specify the subjects or sites whose data you want to export. Use the search box to search for a subject or site. • **Export All Subjects and Sites**—Default. • **Export by Subject**—A list of all the subjects in the InForm study appears. Select the subject for which you want to extract data. **Note:** To select more than one subject, click multiple subjects. • **Export by Site**—A list of all the sites in the InForm study that the InForm user has access to appears. Select the site for which you want to extract data. **Note:** To select more than one site, click multiple sites. Data is extracted for all subjects in the selected sites.

Button	Description
All	Selects all rights groups for hidden item selection. Selects all sites, subjects, forms, or visits when exporting by site, subject, form, or visit.
Reverse	Selects the unselected rights groups and deselects the selected rights groups for hidden item selection. Selects the unselected sites, subjects, forms, or visits and deselects the selected sites, subjects, forms, or visits when exporting by site, subject, form, or visit.
Right arrow icon	Move the selected rights groups to the Selected Rights Groups list. Move the selected sites, subjects, forms, or visits to the Selected Sites list, Selected Subjects list, Selected Forms list, or Selected Visits list
Left arrow icon	Remove the selected rights groups from the Selected Rights Groups list. Remove the selected sites, subjects, forms, or visits from the Selected Sites list, Selected Subjects list, or Selected Forms list, or Selected Visits list.
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.

Button	Description
Help icon	Open the context-sensitive Help.

Archive with Blank Forms confirmation page

Button	Description
Edit Settings	Navigate back to the previous page.
Save Settings	Save the selected work order options as a template to be used for other work orders.
Submit Work Order	Submit the work order options for PDF generation.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Help	Open the context-sensitive Help.

You cannot edit the following preselected fields for an Archive with Blank Forms.

Field	Preselected Output
PDF	True
XML	True
HTML	False
Require Password to Extract or Copy Contents	False
Visits	All
Generate Subject Forms File per CRB or Visit	CRB
Generate Index	False
Generate Table of Contents	True
Protocol Guide and CRF Help	False
Transferred Subjects in Current Site Only	False
Suppress Blank Forms	False
Suppress Blank Visits	False
Candidate Queries	False
Audit Location	End of PDF
Include Supplementary Page Headers	False
Include Bookmark Prefixes	False

Blank Forms Options page

The following fields appear on both the Blank Forms Options page and the Blank Forms confirmation page. Data entry occurs on the Blank Forms Options page. You cannot edit the following fields on the Blank Forms confirmation page, but you can view the options you selected.

Field	Description
Page Size	Specify the page sizes for the PDF file. Required. • **Letter**—8.5 x 11 inches. Default. • **A4**—210 mm x 297 mm.
Blank Form Format	Specify the organization for the PDF files: • **Unique Forms**—One copy of each unique form in the study version arranged alphabetically. • **Casebook**—Copies of all the forms in the study version arranged as they appear in the casebook. Default.
Verify PDF After Generation	Run a post-processing script that verifies that the CRF Submit application generated a valid PDF file for every subject in the InForm study and that the bookmarks work correctly. Default.
Reduce File Size when >=	Run the Reduce File Size option in Adobe Acrobat. If selected, specify a minimum file size for the process to run. Default is 100 MB. **Note:** If you select this option, the PDF files are only viewable with Adobe Reader version 6.0 and higher.
Study Versions	If you do not want to generate blank forms for all study versions, specify study versions for which to generate blank forms.
Hidden Item Option	If you do not want to include items that are hidden to certain rights groups in the InForm study, select which hidden items to exclude. Use the search box to search for a rights group. • **Hide None**—Default. • **Hide All**—Exclude all items that are hidden to any rights group. • **Hide Selected**—A list of all the rights groups in the InForm study appears. Select a rights group to exclude items hidden to it. **Note:** To select more than one rights group, click multiple groups.

Button	Description
All	Selects all rights groups for hidden item selection.
Reverse	Selects the unselected rights groups and deselects the selected rights groups for hidden item selection.
Right arrow icon	Move the selected rights groups to the Selected Rights Groups list.

Button	Description
Left arrow icon	Remove the selected rights groups from the Selected Rights Groups list.
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Blank Forms confirmation page

Button	Description
Edit Settings	Navigate back to the previous page.
Save Settings	Save the selected work order options as a template to be used for other work orders.
Submit Work Order	Submit the work order options for PDF generation.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Help	Open the context-sensitive Help.

You cannot edit the following preselected fields for Blank Forms.

Field	Preselected Output
PDF	True
XML	True
HTML	False
Require Password to Change Document	False
Require Password to Change Form Comments	False
Require Password to Extract or Copy Contents	False
Generate Subject Forms File per CRB or Visit	CRB
Generate Index	False
Generate Table of Contents	True

Field	Preselected Output
Protocol Guide and CRF Help	False
Suppress Blank Forms	False
Suppress Blank Visits	False
Include Supplementary Page Headers	False
Include Bookmark Prefixes	False

Custom PDF with Subject Data and Optional Blank Forms page

The following fields appear on both the Custom PDF with Subject Data and Optional Blank Forms page and the Custom PDF with Subject Data and Optional Blank Forms confirmation page. Data entry occurs on the Custom PDF with Subject Data and Optional Blank Forms page. You cannot edit the following fields on the Custom PDF with Subject Data and Optional Blank Forms confirmation page, but you can view the options you selected.

Field	Description
Header Text	Custom text that appears in the table header. Default is the InForm study name. Required.
Include Supplementary Page Header	Indicates whether to include a page header and footer. The header displays information taken from the InForm study, including: • Visit name • Form version • Subject initials • Subject number The footer includes the CRF Submit URL that was used when the page was generated.
Include Bookmark Prefixes	Include prefixes in the bookmarks. For example, in a bookmark for CRF:Date of Visit (DOV), **CRF:** is the bookmark prefix.
Include Form Status	Include the status of the form in the PDF.
Page Size	Specify the page sizes for the PDF file. Required. • **Letter**—8.5 x 11 inches. Default. • **A4**—210 mm x 297 mm.
One File per	Specifies how to arrange data and save the PDFs. • **CRB**—Data is arranged and saved on a subject by subject basis. One PDF is created per subject. • **Visit**—Data is arranged and saved on a visit by visit basis. One PDF is created per visit per subject. **Note:** This option only applies to forms with data. Blank forms are always generated by study version.
Audit Location	Specifies where in the PDF you want to format the Comments, Signatures, and Audit Trails: • After Each Form • At End of PDF

Field	Description
File Format	Specifies the formats in which to save the data. • PDF ▪ **Verify PDF After Generation**—Run a post-processing script that verifies that the CRF Submit application generated a valid PDF file for every subject in the InForm study and that the bookmarks work correctly. Default. ▪ **Reduce File Size**—Run the Reduce File Size option in Adobe Acrobat. If selected, specify a minimum file size for the process to run. Default is 100 MB. **Note:** If you select the Reduce File Size option, the PDF files are only viewable with Adobe Reader version 6.0 and higher. • XML • HTML
Require Password to Change Document	Prevent changes to the PDF file. If you are creating a site archive, it is recommended that you select this option.
Require Password to Change Form Comments	Prevent data from being added to the PDF file. If you are creating a site archive, it is recommended that you select this option. **Note:** If you select both the Require Password to Change Document and the Require Password to Change Form Comments options, active controls will not be enabled and their options will not be visible in generated blank form PDFs.
Require Password to Extract or Copy Contents	Prevent copying or exporting data from the PDF file. **Note:** This option prevents an index from being created. If you plan to generate an index for this PDF, do not select this option. Regulatory guidelines state that you should not include any security settings or password protection for submission PDF files.
Password	Specifies a password. If you use any of the Adobe security options, you must specify a password. This allows access to the security options within the PDF so that changes can be made at a later date. **Note:** The security options have no effect on the ability to open and view a PDF file. Regulatory guidelines state that you should not include any security settings or password protection for submission PDF files.
Re-enter Password	Re-enter the password for password protected fields in order to confirm that the original password entered is correct.
Display passwords in plain text	Display the text entered in the Password and Re-enter Password fields.
Transferred Subjects in Current Site Only	Indicates whether to include only those subjects in the current site who have been transferred between sites.

Field	Description
Suppress Blank Forms	Omit forms for which no data has been entered. If this is not selected, any forms that were dynamically created in the InForm application appear in the PDF. If a form was not created in the InForm application, it does not appear in the PDF. **Note:** If you are generating a set of blank forms, only those dynamic forms and visits that exist in the selected study version are included in the PDF.
Suppress Blank Visits	Omit visits for which no data has been entered. Otherwise, any visits that have been dynamically created in the InForm software will appear in the PDF. If a form has not yet been created in the InForm software, it will not appear in the PDF. **Note:** Blank forms do not contain subject data. Therefore, the bookmark for a blank form references the visit, but not the subject. For example, a repeating visit that appears as **Day 1 1** in a subject PDF will appear as **Day 1 0** in the blank study form.
Candidate Queries	Include candidate queries. **Note:** A candidate query is visible in InForm only to those users who have appropriate rights (for example a CRA).
Generate Index	Create a PDX (index) file for a set of PDFs. If you generate an index, you can use the Adobe Acrobat search feature to search PDFs by keyword. Required.
Protocol Guide and CRF Help	Generate the Protocol Guide and the CRF Help into separate PDF files.
Generate TOC	Create a table of contents for all the information generated in this work order.
Generate Linking Blank Forms	Generate a set of blank forms to use for reference with PDF files, typically for a multilingual study. If you select this option, specify the language for the blank forms. Typically, these forms are in a different language than the submission language. The **Generate Linking Blank Forms** drop-down list is automatically populated with the languages used in the InForm study. **Note:** The **Generate Linking Blank Forms** option only works with the InForm GTM (InForm 4.7, InForm 5.x, and InForm 6.x) releases. If you select the **Generate Linking Blank Forms** option for a study created in the InForm ITM (InForm 4.5 and InForm 4.6) release streams, the CRF Submit user interface displays an error message.
Generate Blank Forms	Extract a complete set of forms without subject data.
Blank Form Format	Specify the organization for the PDF files: • **Unique Forms**—One copy of each unique form in the study version arranged alphabetically. • **Casebook—**Copies of all the forms in the study version arranged as they appear in the casebook. Default.

Field	Description
Study Versions	If you do not want to generate blank forms for all study versions, specify study versions for which to generate blank forms.
Hidden Item Option	If you do not want to include items that are hidden to certain rights groups in the InForm study, select which hidden items to exclude. Use the search box to search for a rights group. • **Hide None**—Default. • **Hide All**—Exclude all items that are hidden to any rights group. • **Hide Selected**—A list of all the rights groups in the InForm study appears. Select a rights group to exclude items hidden to it. **Note:** To select more than one rights group, click multiple groups.
Form Selection Options	If you do not want to extract data from all forms, specify the forms whose data you want to export. Use the search box to search for a form. Hover over a form to view the RefName of the form.
Visit Selection Options	If you do not want to export data from all visits, specify the visits whose data you want to export. Use the search box to search for a visit.
Selection Criteria	If you do not want to extract data from all subjects and sites, specify the subjects or sites whose data you want to export. Use the search box to search for a subject or site. • **Export by Subject**—A list of all the subjects in the InForm study appears. Select the subject for which you want to extract data. **Note:** To select more than one subject, click multiple subjects. • **Export by Site**—A list of all the sites in the InForm study that the InForm user has access to appears. Select the site for which you want to extract data. **Note:** To select more than one site, click multiple sites. Data is extracted for all subjects in the selected sites.

Button	Description
All	Selects all rights groups for hidden item selection. Selects all sites, subjects, forms, or visits when exporting by site, subject, form, or visit.
Reverse	Selects the unselected rights groups and deselects the selected rights groups for hidden item selection. Selects the unselected sites, subjects, forms, or visits and deselects the selected sites, subjects, forms, or visits when exporting by site, subject, form, or visit.

Button	Description
Right arrow icon	Move the selected rights groups to the Selected Rights Groups list. Move the selected sites, subjects, forms, or visits to the Selected Sites list, Selected Subjects list, Selected Forms list, or Selected Visits list
Left arrow icon	Remove the selected rights groups from the Selected Rights Groups list. Remove the selected sites, subjects, forms, or visits from the Selected Sites list, Selected Subjects list, or Selected Forms list, or Selected Visits list.
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Custom PDF with Subject Data and Optional Blank Forms confirmation page

Button	Description
Edit Settings	Navigate back to the previous page.
Save Settings	Save the selected work order options as a template to be used for other work orders.
Submit Work Order	Submit the work order options for PDF generation.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Help	Open the context-sensitive Help.

Note: There are no preselected fields for a Custom Work Order.

Custom Blank Forms Work Order page

The following fields appear on both the Custom Blank Forms Work Order page and the Custom Blank Forms Work Order confirmation page. Data entry occurs on the Custom Blank Forms Work Order page. You cannot edit the following fields on the Custom Blank Forms Work Order confirmation page, but you can view the options you selected.

Field	Description
Header Text	Custom text that appears in the table header. Default is the InForm study name. Required.
Page Size	Specify the page sizes for the PDF file. Required. • **Letter**—8.5 x 11 inches. Default. • **A4**—210 mm x 297 mm.
Blank Form Format	Specify the organization for the PDF files: • **Unique Forms**—One copy of each unique form in the study version arranged alphabetically. • **Casebook**—Copies of all the forms in the study version arranged as they appear in the casebook. Default.
Include Supplementary Page Header	Indicates whether to include a page header and footer. The header displays information taken from the InForm study, including: • Visit name • Form version • Subject initials • Subject number The footer includes the CRF Submit URL that was used when the page was generated.
Include Bookmark Prefixes	Include prefixes in the bookmarks.
File Format	Specifies the formats in which to save the data. • PDF ▪ **Verify PDF After Generation**—Run a post-processing script that verifies that the CRF Submit application generated a valid PDF file for every subject in the InForm study and that the bookmarks work correctly. Default. ▪ **Reduce File Size**—Run the Reduce File Size option in Adobe Acrobat. If selected, specify a minimum file size for the process to run. Default is 100 MB. **Note:** If you select the Reduce File Size option, the PDF files are only viewable with Adobe Reader version 6.0 and higher. • HTML

Field	Description
Study Versions	If you do not want to generate blank forms for all study versions, specify study versions for which to generate blank forms.
Require Password to Change Document	Prevent changes to the PDF file.
Require Password to Change Form Comments	Prevent data from being added to the PDF file. **Note:** If you select both the Require Password to Change Document and the Require Password to Change Form Comments options, active controls will not be enabled and their options will not be visible in generated blank form PDFs.
Require Password to Extract or Copy Contents	Prevent copying or exporting data from the PDF file. **Note:** This option prevents an index from being created. If you plan to generate an index for this PDF, do not select this option. Regulatory guidelines state that you should not include any security settings or password protection for PDF files.
Password	Specifies a password. If you use any of the Adobe security options, you must specify a password. This allows access to the security options within the PDF so that changes can be made at a later date. **Note:** The security options have no effect on the ability to open and view a PDF file. Regulatory guidelines state that you should not include any security settings or password protection for submission PDF files.
Re-enter Password	Re-enter the password for password protected fields in order to confirm that the original password entered is correct.
Display passwords in plain text	Display the text entered in the Password and Re-enter Password fields.
Hidden Item Option	If you do not want to include items that are hidden to certain rights groups in the InForm study, select which hidden items to exclude. Use the search box to search for a rights group. • **Hide None**—Default. • **Hide All**—Exclude all items that are hidden to any rights group. • **Hide Selected**—A list of all the rights groups in the InForm study appears. Select a rights group to exclude items hidden to it. **Note:** To select more than one rights group, click multiple groups.

Button	Description
All	Selects all rights groups for hidden item selection.
Reverse	Selects the unselected rights groups and deselects the selected rights groups for hidden item selection.
Right arrow icon	Move the selected rights groups to the Selected Rights Groups list.

Button	Description
Left arrow icon	Remove the selected rights groups from the Selected Rights Groups list.
Back	Navigate back to the previous page.
Next	Navigate to the next page. You must enter all of the required fields before you can move on.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

Custom Blank Forms Work Order confirmation page

Button	Description
Edit Settings	Navigate back to the previous page.
Save Settings	Save the selected work order options as a template to be used for other work orders.
Submit Work Order	Submit the work order options for PDF generation.
Cancel	Cancel the work order and return to the Monitor page.
Return to Monitor	Navigate to the Monitor page.
Configuration	Navigate to the Configuration Options page.
Help	Open the context-sensitive Help.

You cannot edit the following preselected fields for Custom Blank Forms.

Field	Preselected Output
PDF	True
XML	False
HTML	False
Require Password to Extract or Copy Contents	False
Generate Subject Forms file per CRB or visit	CRB
Generate Index	False
Generate Table of Contents	True
Protocol Guide and CRF Help	False

Field	Preselected Output
Suppress Blank Forms	False
Suppress Blank Visits	False
Candidate Queries	False
Include Supplementary Page Header	False
Include Bookmark Prefixes	False

Monitor page

Button	Description
Pause	Pause a work order that is processing and continue to run it at a later time. For example, if you have a high priority work order, you can pause all other work orders and let the high priority one continue. **Note:** When you pause a work order, jobs that are currently running complete and no new jobs start. Check the work order to verify that the jobs have completed.
Resume	To restart a stopped or paused work order at the job where it stopped:
Purge	Remove a work order that is in an error state or a completed state.
Rerun	Recreate all the jobs in the work order, deletes any saved results including completed PDF output, and then runs the recreated work order. Only work orders that are in an error or completed state can be rerun.
View Work Order Details icon ( )	Display the details of a work order, including the work order settings and study versions.
View Work Order Jobs link	Click the underlined name of a work order to display a list of jobs in the work order.
Create Work Order	Navigate to the Create Work Order page to specify work order options.
Configuration ( )	Navigate to the Configuration Options page.
Help ( )	Open the context-sensitive Help.

Work Order Jobs page

Field	Description
Run All Failed Jobs	Rerun all failed jobs.
Run Selected Jobs	When you rerun a job, the results of the original job are deleted. The job status changes to **submitted** and will be picked up and processed by a Document Generator.
View Work Order Details	Display the details of a work order, including the work order settings and study versions.
View CRF Content	After a PDF job has been processed, an icon might appear in the far right column to indicate that a preview of the CRF is available. **Note:** This preview does not include all the CRF data, such as bookmarks for the CRF. It is intended to help you determine the contents of the data before the PDF is generated.
Create Work Order	Navigate to the Create Work Order page to specify work order options.

Field	Description
Return to Monitor	Navigate to the Monitor page.
Filter	Filter jobs by Job Name, Job State, or Job Type.
Configuration icon	Navigate to the Configuration Options page.
Help icon	Open the context-sensitive Help.

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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