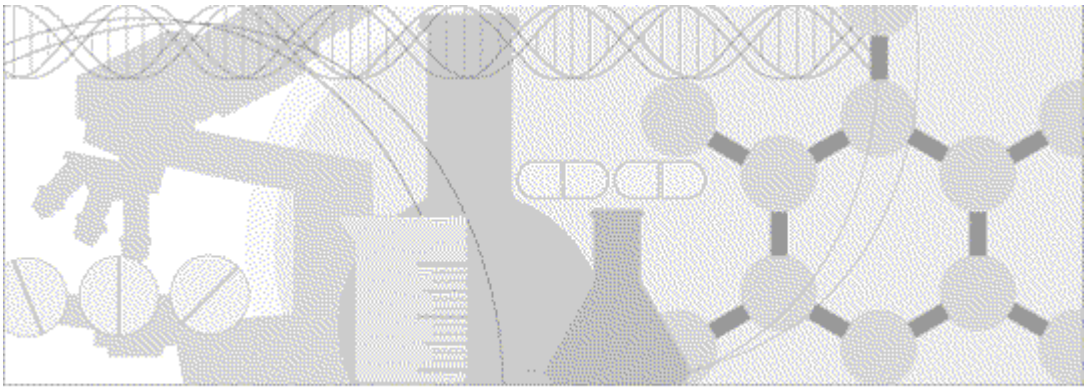
Sponsor User Guide

Oracle® Health Sciences InForm CRF Submit Release 4.0.1.1



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About this guide

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Overview of this guide

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 and History reports from InForm study data, and a detailed description of the user interface.

This document is also available from the CRF Submit user interface. Click the Help icon () in the top line of the page and select **User Guide**.

Audience

This guide is for anyone who uses the CRF Submit application to generate submission, custom, and archival PDF files and History reports for clinical studies using the InForm software.

Related information

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (https://edelivery.oracle.com)—The complete documentation set.
- **My Oracle Support** (https://support.oracle.com)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (http://www.oracle.com/technetwork/documentation)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

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

Title	Description
Release Notes	The *Release Notes* document provides hardware and software requirements and describes the new features, enhancements, and fixed issues in this release.
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.
Sponsor User Guide and online Help	The *User Guide* and online Help provide an overview of the CRF Submit application, step-by-step instructions for sponsors using the CRF Submit application to generate PDF files and History reports of study data, and a detailed description of the user interface.
Site User Guide and online Help	The *User Guide* and online Help provide an overview of the CRF Submit application, step-by-step instructions for site users using the CRF Submit application to generate PDF files and History reports of study data, and a detailed description of the user interface.
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 CRF Submit software.

If you need assistance

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.

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 files (PDFs) and History reports from an InForm study. You can use the output created with the CRF Submit application for:

- Inclusion in submissions to regulatory authorities.
- Archiving of study data for retention by sponsors and investigative sites.

For each PDF request, the CRF Submit application creates PDF subject casebooks that include:

- CRFs.
- Visits.
- Audit trails (including queries).
- Comments.
- Signatures.

A self-service application

The CRF Submit application is self-service. Users initiate PDF and History report requests directly from the live InForm study database, via a portal page, and retrieve the requested data from the cloud.

1 An authorized user requests PDF or History report generation from within the InForm application portal.

2 The CRF Submit application extracts data from the InForm database and renders the data into regulatory-compliant PDFs and History reports.

3 The user retrieves the PDFs and History reports by downloading them to a local machine.

Accessing the CRF Submit application

1 Log into the InForm application.

2 On the InForm Home page, click the **Archive Generator** link.

The My Requests - Processing page appears.

Note: Because you log into a specific study, PDF and History report generation are performed by study.

Sponsor vs. site users

InForm users at sponsor organizations and sites use the CRF Submit application to generate and retrieve PDFs and History reports for a given study.

Sponsor users are typically CRAs, CDMs, CROs, and medical monitors, who review clinical data queries, perform source verification, transfer subjects from one site to another, run standard reports, and create ad hoc reports.

Sponsor users generate PDF output using several request types. Sponsor users with the Share with Sites right can share archival PDF output with sites for download and generate the PDF for a particular rights group. As in InForm, specific rights groups may see different items in the study. Sponsor users with the right to view the Site Confirmation report can monitor site actions related to shared archival PDFs. Sponsor users can also request Subject Audit History and User Assignment History reports based on site data and share these with sites.

Site users are typically CRCs or PIs, who register subjects into a study, enter and change clinical data in electronic case report forms, answer queries on clinical data, sign electronic case report forms, and prepare for monitoring visits.

Site users can generate PDFs for their subjects at their sites only, without relying on the sponsor user to provide this output. PDF request settings for site users are limited to the options most applicable to site users. The information included in the PDF file always matches what the user sees in the InForm application. Site users with the site confirmation right can signify that they have downloaded the archival PDFs and History reports that a sponsor has shared.

In addition to CRF Submit permissions, some CRF Submit users have authority to perform administrative functions, such as assigning CRF Submit rights to InForm rights groups.

Built-in information to guide you

The CRF Submit application includes features to guide you through the process of making requests.

For all PDF request types, you complete four pages of settings:

1 **Study Information**—PDF request name and description, selection of PDF request type, if you are a sponsor user, or site, if you are a site user.

2 **Form Options**—Heading and formatting settings that apply to the whole PDF output file.

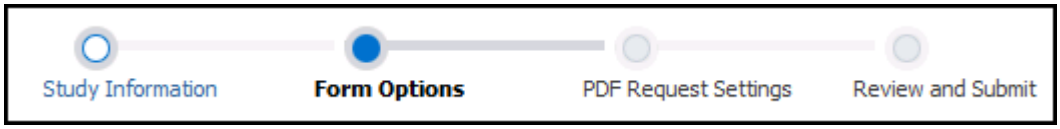
3 **Request Settings**—Options associated with the PDF request type selected.

4 **Review and Submit**—Summary of settings and PDF request actions.

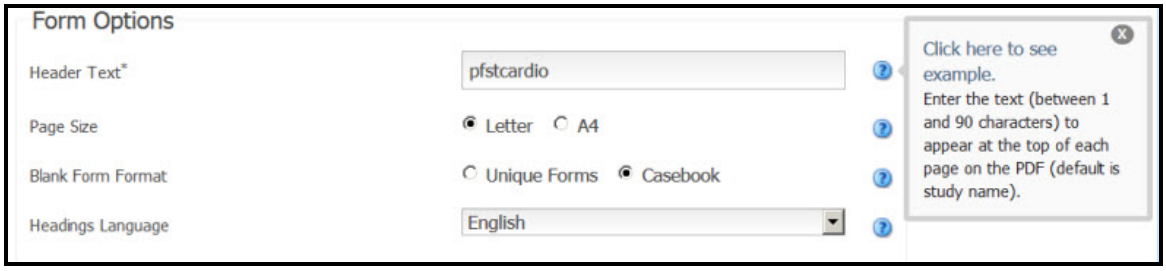
Sponsor requests for History reports include the Study Information, Request Settings, and Review and Submit pages.

Additionally, a number of user assistance devices are built into the CRF Submit application.

Progress indicator—As you complete each page, the corresponding box in the progress indicator at the top of the page is filled in:



Field-level help—To the right of most data entry fields is a Help icon (). Click it to see data entry requirements. Dismiss it by clicking the x in the upper right-hand corner. Select the **Click here to see example** link to view the effects of selecting the option.



User Guide—To view a user guide tailored to your user type, either sponsor or site, click the Help icon () in the top line of the page and select **User Guide**.

Videos—To view short video demonstrations of the main CRF Submit functions, click the Help icon () in the top line of the page and select **How-to videos.**

Rights and rights groups determine the data shown or hidden

A right is the permission to perform a specific activity. A rights group is a collection of rights. An InForm user can be a member of only one rights group and has been added to that rights group by their InForm administrator.

Associated with each InForm study is a set of rights and rights groups that are assigned by the sponsor to InForm rights groups to cover the activities that are typically restricted to specific roles in a study. When a new user is created in a study, an administrator with the right to modify user information assigns the user to a rights group, providing the user permissions to perform specific study activities. Depending on the rights group involved, particular data items might be hidden from users in that rights group. These limitations carry over to the CRF Submit application.

The CRF Submit application relies on the rights groups from the InForm application to manage the data included in the PDF and History report output. The same study data that is exposed in the InForm application to a user in a rights group is included on the PDFs and History reports. The rights group controls what data will and will not appear. What are not included in the output are any hidden items in the user's assigned rights group. For example, these could include study arms or coding status.

Hiding items

The items included in the PDF output and on the History reports depend on the selection the user makes on the Form Options or Request Settings page from the **Select the rights group to control content** drop-down list.

- For sponsor users, the default selection is the rights group of the user. For site users, this option is not provided.
- Choosing a different rights group than your own results in including a subset of the items your rights group and the selected rights group are able to see in the PDF output. The items included in the output are any the logged-in rights group are able see. Any items the selected rights group are not able to see are removed.
- To include all data items, you must be logged in with a rights group that has been set up to see all items present in the study design. The rights group needs Read-Only or Editable display overrides to any item that is hidden by design default.

In the InForm application, after you create an item group, you can assign it to a rights group as a Read-Only, Editable, or Hidden display override. Each of these specifications overrides for all items in the item group the access conferred by membership in a rights group and the access conferred by the definition of an item-level display override.

When a rights group has a display override assigned to it, a user who is a member of the rights group has the type of access defined by the display override to the items in the item group. Display overrides overrule the access rights of the rights group and the access rights determined by item definitions (design defaults).

For example, if an item group contains an item called dose_missed_rsn, and that item group is assigned to the CDMGrp with a hidden override, a member of the CDMGrp rights group cannot see the dose_missed_rsn item even if the design default is Read-Only or Editable.

Multilingual study support

The InForm CRF Submit 4.0.1.1 application is Unicode-based and supports PDF and History report generation for multilingual studies.

You can generate PDF files and History reports in either English or Japanese by specifying a submission language in the **Headings Language** field on the Form Options page. When you specify a submission language, you are choosing a language for the structure of the PDF file or History report, including headers, headings, and labels. The study content remains in the language it was entered in the InForm study.

You also have the option to generate linking blank forms in a different study language than the one selected as the submission language. A reviewer not fluent in the original language can link to the associated blank form in a different language.

CHAPTER 2

PDF requests

In this chapter

CRF Submit workflow

Step	Action	Procedure
1	Access the CRF Submit application.	1 Log into the InForm application. 2 Click the **Archive Generator** link. The My Requests - Processing page appears.
2	Create a request.	From the Create Requests drop-down list, click **Create New PDF Request**. The Create New PDF Request screen appears. As you create your request, the application displays your progress by highlighting the step in the process you are completing in the progress bar at the top of the page.
	Step 1: Enter the study information.	Enter study information: • **PDF Request Name**—Name for the PDF request. You can accept the application-generated name or enter a name. Spaces are allowed in the name. • **PDF Request Description**—Description of the request (optional). • **PDF Request Type**—Select the request type: ▪ Submission PDF ▪ Archival PDF ▪ Blank Forms Only ▪ Custom PDF ▪ Custom Blank Forms For more information, see *Types of PDFs* (on page 14).
	Step 2: Specify the form options.	Select the options to apply to this request. • Header Text • Page Size • Rights group to control content (only visible with certain rights) • Blank Form Format • Headings Language
	Step 3: Specify the PDF request settings.	PDF request settings that appear depend on the type of request. Note that passwords you specify here are not recoverable.

Step	Action	Procedure
	Step 4: Review the request options and submit the PDF request.	1 Review the options you selected. You can return to a previous page to make changes by clicking **<Back**. 2 Click **Submit**. The application acknowledges the submission and asks if you would like to create another PDF request or continue to the My Requests - Processing page. ▪ **Yes** returns you to the first Create New PDF Request page for you to specify study information for another PDF request. ▪ **No** displays the My Requests - Processing page. If you select **No**, the application extracts the requested data from the study database, transforms the data to XML, and generates the PDFs. You can monitor the progress on the My Requests - Processing page. Click **Refresh** to update the page. When the request disappears from the My Requests - Processing page, it is complete. If email is enabled and the sponsor user has an email address listed in the user profile, the application sends a message to this email address. If there is no email address in the sponsor profile, the application sends a message to the default email address. 3 To view the completed request, click the **Completed** link.
3	Download the PDFs.	1 From the My Requests - Complete page, select the checkbox of the PDF request. 2 Click **Download**. 3 Open or save the ZIP file.

Types of PDFs

You determine the PDF type on the Study Information page when you create a new PDF request.

These PDF request types include a lot of predefined settings:

- **Submission PDFs**—PDFs generated from an InForm study that will be used in submissions to regulatory authorities for drug or device approval. Typically, these requests include a subset of study subjects.
- **Archival PDFs**—PDFs generated from an InForm study that form the permanent record of the study and are available for review after the study database has been locked or decommissioned. Typically, these requests include all sites and subjects. Sometimes only subjects of a closed site are generated.
- **Blank Forms Only PDFs**—PDFs that describe the forms, including the set of potential answers for each form item. No subject data is included.

These PDF request types give you complete control over all settings:

- **Custom PDFs**—PDFs based on settings provided by a sponsor user to create customized clinical and blank PDFs.
- **Custom Blank Forms PDFs**—PDFs based on settings provided by a sponsor user that include blank forms only (no clinical data).

Creating a new request

1 On any My Requests page, from the **Create Requests** drop-down menu, select **Create New PDF Request**.

The Create New PDF Request page appears, displaying the Study Information fields.

As you create your request, the application displays your progress by highlighting the step in the process you are completing in the progress indicator bar at the top of the page.

2 Enter the study information. For more information, see Step 1: Enter the study information.

3 Enter the form options. For more information, see *Step 2: Enter the form options* (on page 15).

4 Enter the PDF request settings. For more information, see *Step 3: Enter the PDF request settings* (on page 16).

5 Review and confirm the request options and settings, then submit the request. For more information, see *Step 4: Review the request options and submit the PDF request* (on page 31).

Step 1: Enter the study information

1 On the **Study Information** page, in the **PDF Request Name** field, accept the application-generated name or enter a name for the request.

The PDF Request Name appears on lists of Processing, Completed, Saved, and Purged PDF requests. The application-generated name is comprised of the study name and the current date-time string concatenated together. The name can contain blank spaces, but no special characters. For example, Mass General Blank Forms.

2 In the **PDF Request Description** field, write a short description of the request (optional).

3 Select the request type.

- **Submission PDF**—Generate submission-ready PDF files and blank forms.
- **Archival PDF**—Generate archival PDF files and blank forms. Optionally, share the archival PDF with sites.
- **Blank Forms Only**—Create blank PDFs (no clinical PDFs).
- **Custom PDF**—Create customized clinical and blank PDFs.
- **Custom Blank Forms**—Create customized blank PDFs (no clinical PDFs).

4 Click **Next**.

The Form Options page appears.

Step 2: Enter the form options

1 On the **Form Options** page, in the **Header Text** field, enter the text to appear in the header box above each form in the PDF output. The default is the study name.

2 Select the **Page Size** radio button. Select **Letter** for an 8-1/2 " by 11" page or **A4**, the standard European letter size (210 x 297 mm).

3 Sponsor users with the Share with Sites right can select the rights group with control over the

content of the request type from the **Select the rights group to control content** drop-down list. The default is the logged-in user's rights group. Sponsor users without the Share with Sites right will not see this option.

The rights group controls what data will and will not appear on the PDF. Hidden in the PDF output are the hidden items in the selected user's rights group defined in the InForm application.

Your organization might have set up one or more specific rights groups in the InForm application for use with the CRF Submit application.

4 Select the **Blank Form Format** to determine how blank forms are presented.

- To include each unique form in alphabetic order, select **Unique Forms**. Selecting Unique Forms produces blank forms more efficiently than by casebook.
- To include all forms within the visit structure, corresponding to the order in which the forms appear in the study design, regardless of whether the form was ever started, select **Casebook**.
- To simulate an actual subject casebook, select **Casebook**. Within a visit, all forms are represented, even if the same form is used in multiple visits. For example, almost every visit includes a DOV form. If you select the Unique Forms choice, the DOV form appears once. With the Casebook choice, the DOV form appears under each visit in which the form is used.

  It is also not uncommon to see what appears to be the same form repeated. These are actually separately defined forms with the same form name.

5 From the **Headings Language** drop-down list, select the language to use for bookmarks, headers, and labels.

6 Click **Next**.

Step 3: Enter the PDF request settings

Which settings you see on the PDF Request Settings page depend on the PDF request type you selected on the Study Information page.

- **Submission PDF**—This option has predefined settings most suitable for PDF files that will be included in submissions to a regulatory authority. Blank forms are also generated. For more information, see *Submission PDF request settings* (on page 16).
- **Archival PDF**—This option has predefined settings most suitable for PDFs that will represent study contents for archival purposes. Blank forms are also generated and the archival PDF can be shared with sites. For more information, see Archival PDF request settings.
- **Blank Forms Only**—This option produces blank forms only (no completed subject forms). For more information, see *Blank Forms Only request settings* (on page 20).
- **Custom PDF**—This option gives you complete control over all settings. For more information, see Custom PDF request settings.
- **Custom Blank Forms**—This option produces blank forms only, but allows you complete control over all settings that relate to blank forms. For more information, see *Custom Blank Forms request settings* (on page 27).

Submission PDF request settings

The Submission PDF type is most suitable for PDF files to be included in submissions to a

regulatory authority. Blank forms are also generated. Password protection is not permitted for submission PDFs and does not appear as an option.

1 On the **PDF Request Settings** page, enter the Submission PDF request settings.

Setting	Choices	Notes
Enable eTMF integration	Yes or No	Makes the PDF output available where someone with the eTMF right can access it. Appears only if eTMF integration has been enabled on the Settings page. For more information, see *Specifying trial, email, and storage settings* (on page 73).
Export Selection Criteria	All Subjects By Subject By Site	The default is **All Subjects**. This choice includes everything in the study. You can select subjects from multiple sites and *bulk load subjects from a file* (on page 29). If you select **By Subject**, the Select Subjects dialog box appears. 1 From the **Select a site to filter** drop-down list, select a site. The subjects associated with the selected site appear in the subjects list. 2 (Optional) In the **Select subjects from list below** text box, search for subjects by typing at least three characters of the subject ID. The subjects that match the filter appear in the list. 3 Using the **Shift** and **CTRL** keys, highlight the subjects you want to include, and click the **right arrow**. The selected subjects move to the Selected List. 4 To scroll through the subjects list, click the **Get Next 500** link. If there are no more records, this link does not appear. 5 Continue selecting subjects. 6 To select subjects from another site, from the **Select a site to filter** drop-down list, select the site. 7 Follow the instructions in steps 2 through 6. 8 Click **Save**.

Generate Linking Blank Forms	Yes or No	If the study is not multilingual, accept the default, **No**. **Yes** allows you to link a blank form associated with a study version in a different language. This enables a reviewer who is unfamiliar with the language on the original form to view the form structure in another language. The actual clinical data, however, is always in the entered language. For example, if a form is designed in Spanish and this setting has been selected, the user can click a link to view an equivalent form in another language. To generate linking blank forms, select **Yes**. Then select the study from the drop-down list.

2 Click **Next**.

Archival PDF request settings

The Archival PDF request type is most suitable for PDFs that will represent study contents for archival purposes. Blank forms are also generated by default.

Use this request type to create a mid-trial archive or final archive and share the archive with one or more sites. The sites can download their PDFs, examine them, and confirm that they have downloaded and reviewed the PDFs.

1 Enter the Archival PDF request settings.

Setting	Choices	Notes
Enable eTMF integration	Yes or No	Makes the PDF output available where someone with the eTMF right can access it. Appears only if eTMF integration has been enabled on the Settings page. For more information, see *Specifying trial, email, and storage settings* (on page 73).
Share with sites	Yes or No	**No** is the default. Select **Yes** to allow sites to download the archival PDF files. Sponsor users without the Share with Sites right will not see this option.
Site Confirmation Required	Yes or No	This field appears if you select **Share with sites**. If these PDFs are meant for final archival, or MHRA submittal, select **Yes** to require sites to confirm download of this request. Select **No** to make confirmation optional.

Setting	Choices	Notes
Export Selection Criteria	All Subjects By Subject By Site	The default is **All Subjects**. This choice includes everything in the study. To select subjects from one or more sites, select **By Subject**. This option does not appear if you select the **Share with sites** option. You can select subjects from multiple sites and *bulk load subjects from a file* (on page 29). If you select **By Subject**, the Select Subjects dialog box appears. 1 From the **Select a site to filter** drop-down list, select a site. The subjects associated with the selected site appear in the subjects list. 2 (Optional) In the **Select subjects from list below** text box, search for subjects by typing at least three characters of the subject ID. The subjects that match the filter appear in the list. 3 Using the **Shift** and **CTRL** keys, highlight the subjects you want to include, and click the **right arrow**. The selected subjects move to the Selected List. 4 To scroll through the subjects list, click the **Get Next 500** link. If there are no more records, this link does not appear. 5 Continue selecting subjects. 6 To select subjects from another site, from the **Select a site to filter** drop-down list, select the site. 7 Follow the instructions in steps 2 through 6. Click **Save**. To include all subjects from the selected site, select **By Site**. If you select **By Site**, the Select Sites dialog box appears. 8 In the **Select sites from list below** text box, search for a site by typing at least three characters of the site name. The sites that match the filter appear. Or

Setting	Choices	Notes
Generate Blank Forms	Yes or No	Select **Yes**, the default value, to include blank forms (without clinical data).
Require Password to Change Document Require Password to Change Form Comments Require Password to Extract or Copy Contents	Yes or No	Password protection is selected by default. 1 Type the password. 2 Re-type the password to confirm it. The same password is applied to these three options. You can select any or all of them to be password-protected.
Require Password to extract zip file	Yes or No	By default, password protection is not selected. To include password protection: 1 Click the **Yes** radio button. 2 Type the password. 3 Re-type the password to confirm it.

2 Click **Next**.

Blank Forms Only request settings

The Blank Forms Only request type produces a PDF containing the blank forms (no eCRFs).

1 Enter the Blank Forms Only PDF request settings.

Option	Choices	Notes
Enable eTMF integration	Yes or No	Makes the PDF output available where someone with the eTMF right can access it. Appears only if eTMF integration has been enabled on the Settings page. For more information, see *Specifying trial, email, and storage settings* (on page 73).

Study Version	All or Select from list	To include all study versions, select **All**. To select study versions, select **Select from list**. If you select **Select from list**, the Select Study Versions dialog box appears. 1 In the **Select study versions from list below** text box, search for a study version by typing at least three characters of the study version name. The study versions that match the filter appear. Or 2 From the list below the **Select study versions from list below** text box, use the **Shift** and **CTRL** keys to highlight the study versions you want to include. 3 Click the **right arrow**. The study versions appear in the **Selected List**. 4 To scroll through the study versions list, click the **Get Next 500** link. If there are no more records, this link does not appear. 5 Continue selecting study versions. 6 Click **Save**. To save your choices, click **Save**.

2 Click **Next**.

Custom PDF request settings

The PDF Request Settings page appears after you have specified the study information and form options. It provides control over settings grouped into the following categories:

- eTMF Integration
- Data Format
- Subject and Site Selection Options
- Form Selection Options
- Visit Selection Options
- Study Content
- Additional Content
- Security Options

1 Enter the Custom PDF request settings:

Option	Choices	Notes

eTMF Integration: Enable eTMF integration	Yes or No	Makes the PDF output available where someone with the eTMF right can access it. Appears only if eTMF integration has been enabled on the Settings page. For more information, see ***Specifying trial, email, and storage settings*** (on page 73).
Data Format: Include Bookmark Prefixes	Yes or No	Adds a prefix (for example, CRF, Form, Visit, Study) to PDF bookmarks.
Data Format: Audit Location	After Each Form or End of PDF	Identifies the location of the audit trail history information in the PDF output.

Subject and Site Selection: Export Selection Criteria	All Subjects By Subject By Site	The default is **All Subjects**. This choice includes everything in the study. You can select subjects from multiple sites and *bulk load subjects from a file* (on page 29). If you select **By Subject**, the Select Subjects dialog box appears. 1 From the **Select a site to filter** drop-down list, select a site. The subjects associated with the selected site appear in the subjects list. 2 (Optional) In the **Select subjects from list below** text box, search for subjects by typing at least three characters of the subject ID. The subjects that match the filter appear in the list. 3 Using the **Shift** and CTRL keys, highlight the subjects you want to include, and click the **right arrow**. The selected subjects move to the Selected List. 4 To scroll through the subjects list, click the **Get Next 500** link. If there are no more subjects, this link does not appear. 5 Continue selecting subjects. 6 To select subjects from another site, from the **Select a site to filter** drop-down list, select the site. 7 Follow the instructions in steps 2 through 6. 8 Click **Save**. If you select **By Site**, the Select Sites dialog box appears. 9 In the **Select sites from list below** text box, search for a site by typing at least three characters of the site name. The sites that match the filter appear. Or 10 From the list below the **Select sties from list below** text box, use the **Shift** and **CTRL** keys to highlight the sites you want to include. 11 Click the **right arrow**. The sites appear in the **Selected List**. 12 To scroll through the sites list, click the **Get Next 500** link. If there are no more records, the link does not appear. 13 Continue selecting sites. 14 Click **Save**.

Form Selection: Forms	All or Select from list	Include all study forms or selected forms in a clinical study. If you include selected forms, you cannot limit the PDF to selected visits. If you select **Select from list**, the Select Forms dialog box appears. 1 In the **Select forms from list below** text box, search for a form by typing at least three characters of the form name. The forms that match the filter appear. Or 2 From the list below the **Select forms from list below** text box, use the **Shift** and **CTRL** keys to highlight the forms you want to include. 3 Click the **right arrow**. The forms appear in the **Selected List**. 4 To scroll through the forms list, click the **Get Next 500** link. If there are no more records, the link does not appear. 5 Continue selecting forms. 6 Click **Save**.

Visit Selection: Visits	All or Select from list	Include all study visits or selected study visits in a clinical PDF. If you include selected visits, you cannot include selected forms. If you select **Select from list**, the Select Visits dialog box appears. 1 In the **Select visits from list below** text box, search for a visit by typing at least three characters of the visit name. The visits that match the filter appear. Or 2 From the list below the **Select visits from list below** text box, use the **Shift** and **CTRL** keys to highlight the visits you want to include. 3 Click the **right arrow**. The visits appear in the **Selected List**. 4 To scroll through the visits list, click the **Get Next 500** link. If there are no more records, the link does not appear. 5 Continue selecting visits. 6 Click **Save**.
Study Content: Transferred Subjects in Current Site Only	Yes or No	Select **Yes** to create a PDF for a transfer patient in just the current site. Select **No** to create a PDF for both the originating and the current site.
Study Content: Suppress Empty Clinical Forms	Yes or No	Select **Yes** to omit forms without data. Choose **No** to include all forms, even if they contain no data.
Study Content: Suppress Empty Clinical Visits	Yes or No	Select **Yes** to omit visits without data. Select **No** to include all visits, even if they contain no data.
Study Content: Candidate Queries	Yes or No	Select **Yes** to include candidate queries.
Additional Content: Generate Blank Forms	Yes or No	Select **Yes** to include blank forms (without clinical data). If **Yes**, The Study Version field appears. To include all studies, select **All**. To select the study version from a list of studies, select **Select from list**.

Additional Content: Generate Linking Blank Forms	Yes or No	**Yes** allows you to link a blank form associated with a study version in a different language. This enables a reviewer who is unfamiliar with the language on the original form to view the form structure in another language. The actual clinical data, however, is always in the entered language. For example, if a form is designed in Spanish and this setting has been selected, the user can click a link to view an equivalent form in another language. Select **Yes**, then select the study from the drop-down list.
Additional Content: Generate TOC	Yes or No	Select **Yes** to create a table of contents as a separate file with links to all generated patient PDFs in the request.
Additional Content: Protocol Guide	Yes or No	Select **Yes** to include the Protocol Guide and the CRF Help in the PDF.
Security: Require Password to Change Document Password to Change Form Comments Password to Extract or Copy Contents	Yes or No	Password protection is turned off by default. To include password protection on any or all of these options: 1 Click the **Yes** radio button. 2 Type the password. 3 Re-type the password to confirm it.
Security: Require Password to extract zip file	Yes or No	Password protection is turned off by default. To include password protection: 1 Click the **Yes** radio button. 2 Type the password. 3 Re-type the password to confirm it.

2 Click **Next**.

Including cross visits

When you have selected specific study visits, to include common forms across visits you must select the cross visit entry in the Visits PDF request settings, or the forms will be missing from the output.

1 On the **Custom PDF Request Settings** page, in the **Visit Selection Options** section, select the **Select from list** radio button.

The Select Visits dialog box appears.

2 From the **Select visits from list below** list, select the cross-trial visit. It might be labeled something similar to **Common (Cross Trial)**.

3 Use the right-arrow to move it to the **Selected List**.

4 Click **Save**.

5 Finish entering the PDF request options, review the request, and submit it.

Custom Blank Forms request settings

The Custom Blank Forms request type produces blank forms only, but allows the user control over all settings that relate to blank form output.

1 Make sure on the **Settings** page in the **Trial Settings** section that you have selected **Enable eTMF integration**.

2 Enter the Custom PDF request settings.

Option	Choices	Notes
eTMF Integration: Enable eTMF integration	Yes or No	Makes the PDF output available where someone with the eTMF right can access it. Appears only if eTMF integration has been enabled on the Settings page. For more information, see *Specifying trial, email, and storage settings* (on page 73).
Data Format: Include Bookmark Prefixes	Yes or No	Adds a prefix (for example, CRF) to PDF bookmarks.

Additional Content: Study Version	All or Select from list	If you choose **Select from list**, from the drop-down list select one, multiple, or all versions. To save your selection, click **Save**. If you select **Select from list**, the Select Study Versions dialog box appears. 1 In the **Select study versions from list below** text box, search for a study version by typing at least three characters of the study version name. The study versions that match the filter appear. Or 2 From the list below the **Select study versions from list below** text box, use the **Shift** and **CTRL** keys to highlight the study versions you want to include. 3 Click the **right arrow**. The study versions appear in the **Selected List**. 4 To scroll through the study versions list, click the **Get Next 500** link. If there are no more records, this link does not appear. 5 Continue selecting study versions. 6 Click **Save**.
Security: Require Password to Change Document Require Password to Change Form Comments Security: Require Password to Extract or Copy Contents	Yes or No	Password protection is selected by default. 1 Click the **Yes** radio button. 2 Type the password. 3 Re-type the password to confirm it. The same password is applied to these three options. You can select any or all of them to be password-protected.
Security: Require Password to extract zip file	Yes or No	Password protection is turned off by default. To include password protection: 1 Click the **Yes** radio button. 2 Type the password. 3 Re-type the password to confirm it.

3 Click **Next**.

eTMF integration

eTMF integration makes the PDF output available for use in an Electronic Trial Master File (eTMF) system. A user with the eTMF right can retrieve the output and then load it into the eTMF.

Note: A user with the right to retrieve output for use in an eTMF does not have rights to perform any other CRF Submit-related activity and does not have any other access to the study.

You can request eTMF integration for Submission, Archival, Blank Forms Only, Custom PDF, and Custom Blank Forms PDF requests on the PDF Request Settings page. For more information, see Custom PDF request settings. The option appears only if eTMF integration has been enabled on the Settings page within the administration function. For more information, see *Specifying trial, email, and storage settings* (on page 73).

Importing bulk subjects from a file

Note: To use the bulk import feature, you must use Microsoft Internet Explorer 10 or higher, or another browser supported by the InForm application.

Selecting a large number of subjects through the CRF Submit user interface may be time-consuming. This feature allows a user to point to a file containing the subject, associated site, and subject initials (if necessary) in a required format and import all the subjects at once.

This option is available for the following request types:

- Submission PDF
- Archival PDF
- Custom PDF

1 On the **PDF Request Settings** page, in the **Export Selection Criteria** field, select **By Subject**.

The Select Subjects dialog box appears.

2 Click the Import Subjects tab.

3 Select the file to import from your PD by clicking **Browse** and locating the file.

This feature imports CSV files. CSV stands for *comma-separated value* and is an industry-standard format for importing and exporting data. The CSV file cannot be greater than 1MB.

To create the CSV file:

- Use Microsoft Excel and save it as file type .csv.
- Enter each entry on a separate line.
- Separate the fields by commas.
- Save the file with the extension .csv.

For example, an entry that includes Subject ID and Subject number string is, as follows:

100012,LLL

Shown below are entries from a CSV file generated from an InForm study:

11510,2333

2333,012-001

22486,012-003

4 Click **Import**.

5 Click **Save**.

The application adds the subjects to the list. To select the subjects, see *CRF Submit workflow* (on page 12).

Performing a bulk import

The bulk import feature applies to Submission PDF, Archival PDF, and Custom PDF requests.

1 On the **PDF Request Settings** page, in the **Export Selection Criteria** field, select **By Subject**.

The Select Subjects dialog box appears.

2 Click the **Import Subjects** tab.

3 Click **Browse** to locate the CSV file with the Patient ID and Patient Subject Number for each subject to upload. This is likely to be stored on your server or locally on your PC.

4 Click **Import**.

The number of subjects successfully loaded appears.

5 Click **Save**.

6 Complete the PDF request.

Step 4: Review the request options and submit the PDF request

After you select the PDF request settings, the application displays a summary of your selections, including:

- Study information
- PDF request type
- Form options
- PDF request settings

If you selected specific subjects, visits, or forms, an underlined link allows you to view these selections.

At this point, you have a number of choices:

- To submit the request for processing, click **Submit**. For more information, see *Submit the PDF request* (on page 31).
- To return to a previous page and change study information, form options, or PDF request settings, click **<Back**.
- To save the selections as a template, click **Save as New Template**. For more information, see *Creating a template* (on page 38).
- To save the request without submitting it, click **Save**.
- To print a copy of the summary, click **Print**.

Submit the PDF request

1 On the **Review and Submit** page, after reviewing the PDF request, click **Submit.**

The PDF Request Submitted dialog box appears, confirming that the request has been submitted and offering you the opportunity to create another PDF request or go to the My Requests - Processing page.

2 To create another new PDF request, click **Yes, Create Another**.

The Create New PDF Request page appears, for you to enter the study information for the new PDF request, followed by the form options and PDF request settings. You can then submit this PDF request.

or

To complete this request, click **No, Go to Processing Page**.

The My Requests - Processing page appears. You can monitor the processing progress by observing the value in the **% Complete** column.

3 To update the processing details, click **Refresh**.

When processing is complete (100%), the PDF request disappears from the Processing page and appears on the Complete page.

If the **Send email on request completion** option has been selected on the **Trial Settings** section of the **Settings** page, when the request is complete, an email message is sent to the sponsor's default mailbox or the site user's email address.

4 To display the My Requests - Complete page, click the **Completed** link.

Saving the request without submitting it

If you get interrupted while creating the request or decide not to submit a PDF request, you can save it without submitting it. A saved-but-not-submitted PDF request is visible only to the user who created it and persists across sessions.

1 On the Review and Submit page, click **Save**.

The PDF Request Saved dialog box appears, confirming that the request has been saved and giving you the opportunity to create another PDF request.

2 To create another PDF request, click **Yes, Create Another.**

The Create New PDF Request page appears, for you to enter the options for the new PDF request.

or

To view your PDF requests, click **No, Go to Saved Page.**

The My Requests - Saved page appears.

3 From the **Date Range** drop-down list, select **All** to include all requests.

or

select a date range to limit the requests shown.

For each saved PDF request, the application lists the request name, the request type, the date and time that the request was last modified, and whether or not this was a test run. Only sponsor users can submit test run PDF requests.

Create an archival PDF request to share with sites and require download confirmation

1 From the **Create Requests** drop-down menu on any My Requests page, select **Create New PDF Request**.

The Create New PDF Request page appears, displaying the Study Information fields.

2 On the **Study Information** page, enter the **PDF Request Name** and **PDF Request Description**.

3 Select the **Archival PDF** request type.

4 Click **Next**.

5 On the **Form Options** page, select the formatting options.

6 Make sure that you select the rights group with control over the content of the archival request type in the **Select the rights group to control content** drop-down list. The default is the logged-in user's rights group, but a sponsor user with the Share with Sites right can select additional rights groups.

The rights group controls what data will and will not appear on the PDF. What are hidden in the PDF output are the hidden items in the selected user's rights group and the rights group of the user downloading the PDF.

Your organization might have set up one or more specific rights groups in the InForm application for use with the CRF Submit application.

7 Click **Next**.

The PDF Request Settings page appears.

8 In the **Share with sites** field, select the **Yes** radio button. This option appears only if the sponsor user has been assigned the Share with Sites right.

The **Site Confirmation Required** field appears if the Share with Sites option is selected.

9 To require the site to confirm receipt and download of the archival PDF, select **Yes**.

10 In the Export Selection Criteria field, select **All Subjects** or **By Site**.

If you selected **By Site**, the Select Sites dialog box appears.

11 From the **Select sites from list below** list, select all or some of the sites and click the right-arrow (>) to move them to the **Selected List**.

12 Click **Save**.

You return to the PDF Request Settings page.

13 To require the site to confirm they have downloaded the archival PDF, in the **Site Confirmation Required** field, select the **Yes** radio button.

14 In the **Generate Blank Forms** field, specify whether or not to include blank forms in the PDF output. **Yes** is the default value.

15 Enter and confirm passwords as required.

16 Click **Next**.

The application displays a summary of your selections.

17 Click **Submit**.

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.

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.

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 file name containing the transfer history is the subject number with **-prth** appended to it. 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.

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.

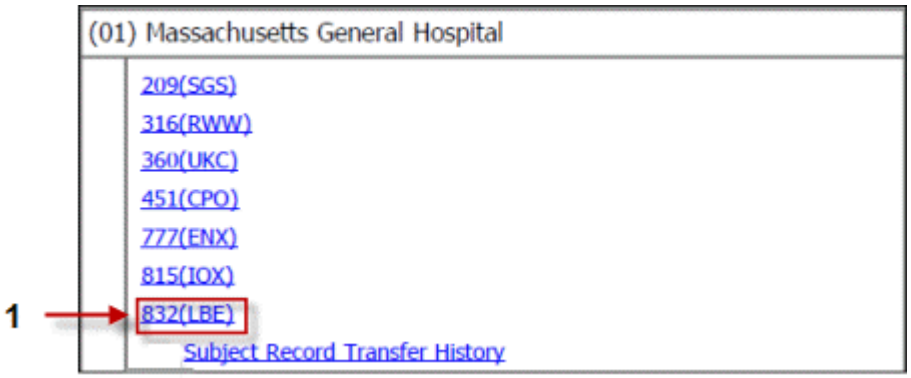
Transferred Subjects in Current Site Only

By default, data for transferred subjects is included in the PDFs for every site with which the subject was associated. If a sponsor user selects the **Transferred Subjects in Current Site Only** option on the PDF Request Setting page of a Custom PDF request, information is limited to only the PDF in the destination site associated with the study.

For more information, see *Custom Blank Forms request settings* (on page 27).

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 and the PDF generated.

Destination site (01):



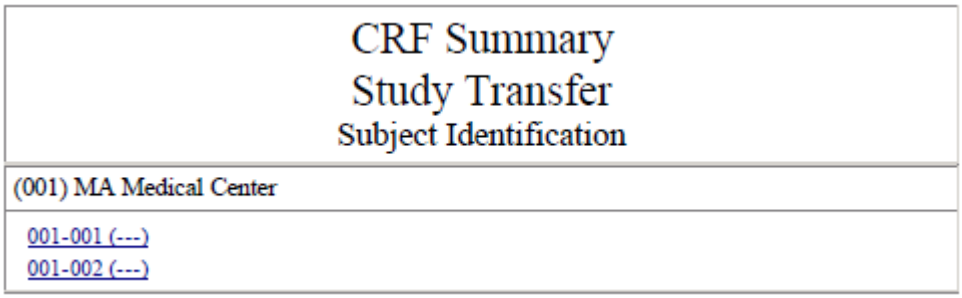
1 Link goes to the subject PDF at the destination site.

Origination site (11):

2 Link goes directly to the **Subject Record Transfer History**.

Finding Patient Record Transfer History in the table of contents

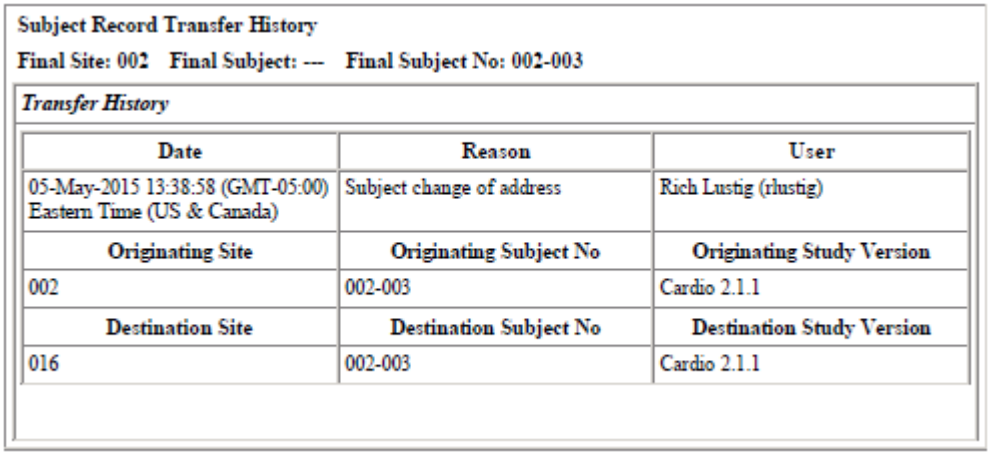
Links to the patient Record Transfer History are in the **crftoc.pdf** file.


CRF Summary
Study Transfer
Subject Identification

(001) MA Medical Center

001-001 (---)
001-002 (---)

Subject Record Transfer History link—Appears below the subject number for a transferred subject in the table of contents. Click to view the Subject Record Transfer History.


Subject Record Transfer History

Final Site: 002 Final Subject: --- Final Subject No: 002-003

Transfer History

Date	Reason	User
05-May-2015 13:38:58 (GMT-05:00) Eastern Time (US & Canada)	Subject change of address	Rich Lustig (rlustig)
Originating Site	**Originating Subject No**	**Originating Study Version**
002	002-003	Cardio 2.1.1
Destination Site	**Destination Subject No**	**Destination Study Version**
016	002-003	Cardio 2.1.1

Subject Record Transfer History—Includes subject data that is always generated unless the output is for the current site only.

CHAPTER 3

Working with PDF request templates

In this chapter

Creating a template

On the Review and Submit page, if you have the appropriate rights, you can save PDF request options as a template. All saved templates appear on the Manage Templates page.

Creating templates for PDF requests saves time and increases consistency. Templates are especially useful when a dataset is used by multiple people. You can make the templates you create most useful by providing descriptive names and documenting for others why you made the choices you did.

1 On any My Requests page, from the **Create Requests** drop-down menu, select **Create New PDF Request**.

The Create New PDF Request page appears, displaying the Study Information fields.

As you create your request, the application displays your progress by highlighting the step in the process you are completing in the progress indicator bar at the top of the page.

2 Enter the study information. For more information, see Step 1: Enter the study information.

3 Enter the form options. For more information, see *Step 2: Enter the form options* (on page 15).

4 Enter the PDF request settings. For more information, see *Step 3: Enter the PDF request settings* (on page 16).

5 Review and confirm the request. For more information, see *Step 4: Review the request options and submit the PDF request* (on page 31).

6 On the Review and Submit page, click **Save as New Template**.

The Template dialog box appears.

7 In the **Template Name** text box, enter a unique name for the template.

8 In the **Description** text box, type a description of the template.

9 Click **Save**.

The application adds the template to the Manage Templates page.

Creating a new PDF request from a template

1 From the **Create Requests** drop-down menu on any My Requests page, select **Create from Templates**.

The Create from Templates page appears, displaying the Study Information fields.

2 Enter the PDF request name and description.

3 From the **Select Custom Template** drop-down list, select a template.

4 If you are a site user, you must select a site from the **Select the site for the request** drop-down list.

5 Click **Next**.

6 Step through the **Forms Options** and **PDF Request Settings** pages.

These have been prepopulated with the values from the template you selected. Note that the password option defaults have been restored on the PDF Request Settings page.

7 Click **Next**.

8 On the Review and Submit page, click **Submit**.

Editing or deleting a template

An authorized sponsor user can edit and delete any sponsor template, including templates created by other sponsors. Site users can only edit and delete templates they created.

1 Under the **Templates** section of the navigation pane, click **Manage Templates**.

The Manage Templates page appears, displaying a list of saved templates, including the template name and who it was created by.

2 To find a specific template, type its name in the **Template Name** search field or the name of the user who created the template in the **Created By** field.

The templates that match your search criteria appear.

3 To delete a template, select the checkbox associated with the template, and click **Delete**.

The application deletes the template.

4 To edit the template, select the checkbox associated with the template, and click **Edit**.

If the template was created by another user, the application asks you to confirm that you want to edit the template.

The Edit Template page appears.

The application has populated the Study Information, Form Options, and PDF Request Settings pages with the settings from the selected template.

5 Modify the settings as necessary.

6 To save the changes to the template, on the **Review and Submit** page, click **Save Template**.

The Template dialog box appears.

7 In the **Template Name** field, enter a name for the modified template.

8 In the **Description** field, type a description of the modified template.

9 To save the template, click **Save**.

or

To make a copy of the template, click **Make a Copy**.

a Enter a unique name for the template and a description.

b Click **Save**.

CHAPTER 4

History requests

In this chapter

The Subject Audit History and User Assignment History reports

As part of a study decommissioning package, some regulatory agencies require the following two reports:

Subject Audit History —Includes the data changes and queries for a subject's casebook.

User Assignment History—Includes the user-to-site and user-to-rights group association. This report does not include any history associated with a sponsor user.

Sponsors generate these reports from the My Requests menu. By selecting the **Share with Sites** option and **Site Confirmation Required** option, the sponsor can request the sites to acknowledge the receipt of the file.

The file is in csv format for import into MS Excel. For the Subject Audit History report, one CSV file is created per subject. The files are then zipped per site and the entire request can be downloaded as one zipped file. For the User Assignment History report, one CSV file is generated per site and the entire request can be downloaded as one zipped file.

Creating a History request

1 On any My Requests page, from the **Create Requests** drop-down menu, select **Create History Request**.

The Create History Request page appears, displaying the Study Information fields.

As you create your request, the application displays your progress by highlighting the step in the process you are completing in the progress indicator bar at the top of the page.

2 In the **Request Name** field, accept the application-generated name or enter a name for the request.

The Request Name appears on lists of Processing, Completed, Saved, and Purged requests. The application-generated name is comprised of the study name and the current date-time string concatenated together. The name can contain blank spaces. For example, Mass General Subject Audit History.

3 In the **Request Description** field, write a description of the request (optional).

4 Select the request type:

a To view the data changes and queries for a subject, select the **Subject Audit History** radio button.

Or:

b To view user-to-site and user-to-rights group associations, select the **User Assignment History** radio button.

5 Click **Next**.

The Request Settings page appears.

6 Enter the request settings.

Setting	Choices	Notes
Select the rights group to control content	The rights group controls what data will and will not appear on the report.	Applicable only to the Subject Audit History report. The default is the logged-in user's rights group, but a sponsor user with the Share with Sites right can select a different rights group.
Headings Language	The language to use for bookmarks, headers, and labels.	NA
Share with sites	Yes or No	**Yes** is the default. Select **No** to prevent sites from downloading the report. Sponsor users without the Share with Site right will not see this option.
Site Confirmation Required	Yes or No	Appears if you select **Share with sites**. If you select **Yes**, the sites must confirm download and review of this request. Select **No** to make confirmation optional.

Setting	Choices	Notes
Generate TOC	Yes or No	Create a table of contents as a separate file with links to all generated records in the request. The default is **Yes**.
Export Selection Criteria	All Sites By Site	The default is **All Sites**. This choice includes all sites in the study. To select one or more sites, select **By Site. [** The Select Sites dialog box appears. 1 In the **Select sites from list below** text box, search for a site by typing at least three characters of the site name. The sites that match the filter appear. Or 2 From the list below the **Select sites from list below** text box, use the **Shift** and **CTRL** keys to highlight the sites you want to include. 3 Click the **right arrow**. The sites appear in the **Selected List**. 4 To scroll through the sites list, click the **Get Next 500** link. If there are no more records, the link does not appear. 5 Continue selecting sites. 6 Click **Save**.
Require Password to extract zip file	Yes or No	By default, password protection is set to **Yes**. 1 Type the password. 2 Re-type the password to confirm it.

7 Click **Next**.

The Review and Submit page appears and summarizes your study information selections and request settings.

8 If you selected specific sites, to see those sites, click the **View Selected Sites** link. To close the Select Sites dialog box, click **Close**.

9 To submit the request for processing, click **Submit**.

The Request Submitted dialog box appears, confirming that the request has been submitted and offering you the opportunity to create another request or go to the My Requests - Processing page.

10 To create another request, click **Yes, Create Another**.

The Create History Request page appears, for you to enter the study information for the new

request, followed by the form options request settings. You can then submit this request.

or

To complete this request, click **No, Go to Processing Page**.

The My Requests - Processing page appears. You can monitor the processing progress by observing the value in the **% Complete** column.

11 To update the processing details, click **Refresh**.

When processing is complete, the request disappears from the Processing page and appears on the Complete page.

12 To display the My Requests - Complete page, click the **Completed** link.

The My Requests - Complete page appears and includes all completed requests, including the History requests.

13 You can perform the same functions on the History requests as you can on PDF requests. For more information, see *Working with submitted requests* (on page 49).

Viewing and downloading history requests

Sponsor users make History report requests and can view and download the output of these requests in the same way as they view and download PDF request output. For more information, see *Working with submitted requests* (on page 49).

When defining the History request, the sponsor has the option of sharing the History report with sites. If a History request is shared with sites, the request appears on the My Requests - Complete page, along with PDF requests created by sites and archival requests shared with the site by a sponsor user.

For more information, see *Downloading the output from a request* (on page 64). You can sort these report by date and time by clicking a column heading. The time is shown in both the site location's time zone and using the 24-hour clock.

The Subject Audit History report includes the following information:

- Study Name
- Site ID
- Site Name
- Subject ID
- Visit ID
- Form ID
- Form Index
- Itemset index
- Item Question
- Entry Type
- Entered Reason
- Current Value
- Current Value Date/Time
- Current Value Date/Time (UTC)
- Query Text
- Previous Value
- Previous Value Date/Time
- Previous Value Date/Time (UTC)
- Rights Group
- Username
- User Type

The User Assignment History report includes the following information:

- Study Name

- Site ID
- Site Name
- Username
- Change Type
- Change Time
- Change Time (UTC)
- User Change
- Change Rights Group Type
- Group Name
- Changing Username

Verifying that the site has downloaded and confirmed the History report

To confirm that the site has confirmed that it has downloaded and reviewed the History request, use the Site Confirmation report.

For more information, see *Viewing and downloading the Site Confirmation report* (on page 78).

CHAPTER 5

Working with submitted requests

In this chapter

Viewing request notices

The CRF Submit application logs the email notification made reporting the progress of requests.

1 In the navigation pane, in the Notifications section, click the **Request Notices**.

The Request Notices page appears, providing a log of the email notifications sent when requests have been completed or downloaded.

> **Note:** This feature must be activated by an administrator on the Admin Settings page.

2 Filter the list by column headings:

- **Request Name**—Application-generated or user-defined name for the request. Click the **Request Name** to display the request.
- **Notification Type**—Status or action with which the email notification is associated (for example, Completed or Failed).
- **Email Sent (GMT)**—The date and time when the email notification was sent.
- **Email Status**—Message status. For example: Success means the email notification was sent successfully.
- **Details**—Click this link to display details of the email message.

a Click the heading to sort in ascending or descending order.

or

b Begin typing the value in the search box associated with the column heading.

The notifications that match your search criteria appear.

3 To view the notification details, click the **Details** link in the Details column.

The Details window appears and provides the detail of the email notification, including:

- **Subject**—Subject line of the email message.
- **Body**—Content of the message.
- **Email Sent (GMT)**—Date and time the notification was sent.
- **Sender**—The email address of the sender.
- **Recipient**—The email address of the person who received the message.
- **Sent**—Status of the notification. For example, Sent or Failed.

4 To close the Details window, click the **X** in the upper-right corner.

Viewing sponsor-created requests shared with sites

On the Admin Settings page, when the **Send email on request completion** option is selected and a default email address is specified, sponsors can access site notices to view all requests made and completed by site users.

The Site Notices page lists each notification to a sponsor that a site request has been completed. The CRF Submit application updates the page only when email notification has been enabled on the Admin Settings page. If email is not enabled, no email notification occurs. For more information, see *Specifying trial, email, and storage settings* (on page 73).

Oracle recommends that you always enable email notification.

1 In the navigation pane, from the Notifications section, click **Site Notices**.

The Site Notices page appears, listing notifications for completed PDF requests and History reports.

2 Filter the list by column headings:

- **Request Name**—Application-generated or user-defined name for the request.
- **Notification Type**—Status of the associated request. For example, Create or Download.
- **Site Name**—Site that initiated the request or performed the download.
- **Site User Name**—User name of the person who generated the request.
- **Email Sent (GMT)**—Date and time the notification was sent.
- **Email Status**—Notification status. For example, Success or Failed.
- **Source**—How the request was created: Created by site or sponsor.
- **Details**—Link to display email message.

3 To view the notification details, click the **Details** link in the Details column.

The Details window appears and provides the detail of the email notification, including:

- **Subject**—Subject line of the email message.
- **Body**—Content of the message.
- **Email Sent (GMT)**—Date and time the notification was sent.
- **Sender**—The email address of the sender.
- **Recipient**—The email address of the person who received the message.
- **Sent**—Status of the notification. For example, Sent.

4 To close the Details window, click the **X** in the upper-right corner.

Filtering the requests to be displayed

1 From the **My Requests** section of the navigation pane, select a category of requests:

- Processing
- Completed
- Saved
- Purged

The selected My Requests page appears listing the requests of the category selected.

2 Optionally, select a date range from the drop-down list. The application refreshes the list with the requests that match the selected date range.

3 Filter the list by entering or selecting values for the columns shown. Which columns appear depends on the Request category.

- **Request Name**—Type all or part of the request name.
- **Request Type**—The PDF request type or History report request.
- **Created By**—Type all or part of the user who created the request.
- **Status**—From the drop-down list, select **All** statuses, or:
  - Saved
  - Created
  - Processing
  - Complete
  - Failed
  - Canceled
  - Purged
  - Paused
  - Zip in progress
- **Start Time**—The date and time on which the request was started.
- **Last Modified Time**—The date and time on which the request was last modified by creating, processing, pausing, or zipping the output. Most significant for very large PDF requests.
- **Estimated Complete Time**—After the request has started, the CRF Submit application analyzes the request progress and provides the date and time when the request is expected to be complete. The estimate becomes more accurate as the request progresses. When the request is complete, the actual end time appears in the Completed Time column.
- **Completed Time**—The date and time the request was completed.
- **Purged Time**—The date and time the request was purged.
- **% Complete**—Percentage of the request completed so far. A request that reaches 100% is moved from the Processing page to the Completed page.

- **Data Changed**—Indicates whether any subject data was changed after the request was submitted. Use the InForm Data Viewer to review the changes. For more information, see the *InForm User Guide*.
- **File Size (in MB)**—Include requests that generate files of the specified size.
- **Test Run**—Include all test run requests or none.
- **Source**—For site users, the My Requests - Complete page includes a column indicating the source of the request:
  - **Sponsor**—The request was initiated by a sponsor user.
  - **Site**—The request was initiated by the site user.

The application saves your preferences and filters the list based on these preferences until you change the filtering options or click **Clear Filter** to restore the defaults.

Displaying processing, completed, saved, and purged requests

1 From the **My Requests** section of the navigation pane, select a category of requests:

- Processing
- Completed
- Saved
- Purged

The selected My Requests page appears listing the requests of the category selected.

2 Optionally, select a date range from the drop-down list. The application refreshes the list with the requests that match the selected date range.

3 Review the information displayed. Which columns appear depends on the Request category.

- **Request Name**—The system-generated or custom request name. The Request Name is a link that, when clicked, displays request details.
- **Request Type**—The PDF request type or History report request.
- **Created By**—The user who created the request.
- **Status**—The status of the request:
  - Saved
  - Created
  - Processing
  - Complete
  - Failed
  - Canceled
  - Purged
  - Paused
  - Zip in progress
- **Start Time**—The date and time on which the request was started.
- **Last Modified Time**—The date and time on which the request was last changed.
- **Estimated Complete Time**—The date and time when the request is expected to be complete. The estimate becomes more accurate as the request progresses. When the request is complete, the actual end time appears in the Completed Time column.
- **Completed Time**—The date and time the request was completed.
- **Purged Time**—The date and time the request was purged.
- **System Purge**—For autopurged requests, the column is set to Yes.
- **% Complete**—Percentage of the request completed so far. A request that reaches 100% is moved from the Processing page to the Complete page.

- **Data Changed**—Whether any subject data was changed after the request was submitted. Use the InForm Data Viewer to review the changes. For more information, see the *InForm User Guide*.
- **File Size (in MB)**—The size of the file generated.
- **Test Run**—Whether or not the request is a test run.
- **Source**—For site users, the My Requests - Complete page includes a column indicating the source of the request:
  - **Sponsor**—The request was initiated by a sponsor user.
  - **Site**—The request was initiated by the site user.

Viewing the details of a request

1 On the **My Requests - Complete** or **My Requests - Purged** page, click the **Request Name**.

The Request Details page appears and lists the following information about the request:

- **Start Time**—Date and time processing of the request started.
- **Complete Time**—Date and time processing of the request completed.
- **File Type**—Type of information included in the output. The file types include:
  - Blank CRF
  - Table of Contents (TOC)
  - Protocol Guide
  - Subject CRF
  - Transferred Subject Archive CRF
  - Subject Audit History
  - Subject Transfer History
  - User Assignment History
- **File Name**—Name of the file generated for the request.
- **Data Changed**—Whether or not the subject data changed in the InForm application after the request was submitted.
- **State**—Status of the request. The states include:
  - Connector Started
  - Connector Submitted
  - Connector Complete
  - Connector Failed
  - DocGen Started
  - DocGen Complete
  - DocGen Failed
  - Storage Started
  - Ready for Download
  - Storage Failed

2 To return to the My Requests page, click **Return**.

Printing the request settings

You can print a copy of the PDF request settings from the Review and Submit page when you create a PDF request or from the Show Settings page after the request is complete.

1 On any My Requests page, from the **Create Requests** drop-down menu, select **Create New PDF Request**.

2 Enter the study information, form options, and PDF request settings.

3 Click **Next**.

The Review and Submit page appears.

Or:

On the My requests - Complete or Saved pages, select the request and click **Show Settings**.

The Request Settings dialog box appears

4 Click **Print**.

The Print dialog box for your PC or network appears.

5 Specify your printing options.

6 Click **Print**.

If you selected specific subjects, visits, or forms, the printed request settings include these selections.

Pausing and resuming a request

You may or may not be able to perform this activity, depending on the rights assigned to you.

1 On the **My Request - Processing** page, select the checkbox of one or more requests.

2 Click **Pause**.

The status of selected requests changes to **Paused**.

3 To resume processing, select the paused request and click **Resume**.

The status of the resumed request changes to **Processing**.

Cancelling a request

1 On the **My Request - Processing** page, select the checkbox of one or more requests.

2 To cancel the request, click **Cancel**.

3 Confirm the cancellation.

The application moves the request to the My Requests - Complete page and changes the status to **Canceled**.

The application removes any files created prior to cancellation.

Displaying the settings

1 On the **My Requests - Complete** or **My Requests - Saved** page, select the request checkbox and click **Show Settings**.

The Request Settings dialog shows the form options and request settings applied to the request.

2 To return to the My Requests page, click **Close Window**.

If data has changed since processing began...

Because the CRF Submit application generates output from a live study, there is a small possibility that data might be updated during the extract phase of the request. The CRF Submit application notes in the Data Changes column of the My Requests - Complete page whether the data has changed since the PDF or History report request was submitted. For PDF requests, you can use the InForm Data Viewer to identify those changes.

1 On the **My Requests - Complete** page, check to see if the data has changed.

   If the data has changed between the time the data extract started for the first subject in the PDF request and the time the extract completed for the last subject, **Yes** appears in the **Data Changed** column.

2 Make a note of the request **Start Time**.

3 To see the details, click the request in the **Request Name** column.

   The application displays the list of subjects.

4 At the top of the page, from the InForm Home menu bar, click **Review**.

5 In the **Filters** panel, add the subject numbers in the **Subject(s)** text box.

6 In the **Updated since date** field, select the request start time as the date and time.

7 Click **Apply**.

   The InForm Data Viewer opens and displays the forms containing the changed data.

   For more information, about the Data Viewer, see the *InForm User Guide*.

8 To return to the CRF Submit application, click **Home** and then **Archive Generator**.

Resubmitting a failed request

When a request fails, the status on the My Requests - Complete page becomes **Failed**. The email sent upon completion indicates that the request failed. In many instances, resubmitting the request will correct the error.

1 On the **My Requests - Complete** page, locate a request with a **Failed** status.

2 Click the **Request Name**.

The Request Details page for the request appears. The reason for failure appears in red in the **State** column. For example, DocGen Failed.

3 For more information about the error, click the value in the **State** column.

The error dialog box provides a number corresponding to the error, which you will be asked to provide if you contact Oracle Support about this problem.

4 To dismiss the dialog box, click **Ok**.

5 To return to the My Requests - Complete page, click **Return**.

6 Select the checkbox of the failed request.

7 Click **Resubmit**.

The Resubmit dialog box appears.

Note: If the Resubmit button does not appear, click anywhere else on the page and it will appear.

8 Choose a resubmit option. The study data might have changed since the original request was processed, impacting the content of the PDFs.

- To include any new information, select **Yes, generate the subset of PDFs that were not generated in the previous run**.
- To regenerate the entire request, select **Yes, generate a completely new set of PDFs**.
- To cancel the resubmitted request and return to the My Requests - Complete page, select **No, go back to the previous page**.

9 Click **OK**.

If resubmission is successful, the application displays an Operation successful message.

10 Click **OK**. The application moves the request to the My Requests - Processing page.

- The application reprocesses the PDF request. When processing is complete, the request moves to the My Requests - Complete page and, if successful, the status changes to **Complete**.
- If the PDF request fails again, note the reason for failure (see steps 2 and 3) and contact Oracle Support.

Purging a request

1 On the **My Requests - Complete** page, select the checkbox of one or more requests.

2 Click **Purge**.

3 Confirm that you want the request deleted by clicking **OK**.

The application removes all stored output from the request. The information used to generate the output is not removed from the database.

The request moves to the My Requests - Purged page. Purged requests cannot be resubmitted.

Purged requests include those that you explicitly select and purge as well as autopurged requests. The application automatically purges requests that are 60 days or older.

Downloading the output from a request

You can download the complete output from a request from the My Requests - Complete page and the Request Details page.

For PDF requests, you can download individual subjects from the Request Details page associated with a PDF request with the status **Complete**. If the output exceeds 500 MB, the application chunks the output into 500 MB files. Requests are kept for 60 days after they are generated and then purged from the data store.

For History requests, you can download the request output as a CSV format spreadsheet.

1 On the **My Requests - Complete** or a **Request Details** page, select the request checkbox and click **Download**.

The browser prompts you to **Open** or **Save** the file. Oracle recommends that you save the file(s) to a local machine and then extract the output from the downloaded ZIP file.

Note: If you view files without extracting them in the Zip tool, the hyperlinks in the files might not work correctly.

2 Click **Save**.

The output is saved to your local machine at the designated location. The name of the ZIP file matches the request name.

3 Extract the output from the ZIP file.

If you password protected the ZIP file, you will have to enter the password you set up.

PDF output details

The CRF Submit application produces PDF output that conforms to PDF format version 1.7.

Page orientation—By default, output is printed in portrait orientation. The CRF Submit application automatically creates line-wraps in most text data. If the form data requires more space than the width of the page, the font is reduced by up to 70% of the initial font size.

Margins—Left margins are at least 3/4 inch. Top, bottom, and right margins are at least 3/8 inches. Headers and footers do not appear in the margin areas.

Fonts—Fonts are embedded and restricted to 9 to 12 points.

Text color—Text is presented in black type.

Hyperlinks—Both visited and non-visited hyperlinks are blue.

Optimized output—Output is optimized for fast web view automatically.

Compression—The CRF Submit application compresses individual PDF files to fit within regulatory standards.

CHAPTER 6

Performing a test run

In this chapter

Creating a test run PDF request

To provide the opportunity to confirm that the selected settings result in the desired output, a sponsor user can create a test run. A test run is identical to a regular PDF request, except that the test run is limited to one subject and one study version.

Once the PDF output is complete, the application gives you the option to either create a real PDF request or perform another test run.

1 On any My Requests page, from the **Create Requests** drop-down menu, click **Create Test Run**.

The Create Test Run PDF Request page appears.

2 On the **Study Information** page, specify the PDF request name and description and select the PDF request type.

3 Click **Next**.

4 Complete the **Forms Options** page. Enter:

- Header text
- Page size
- Rights group to control the content
- Blank form format
- Headings language

For more information, see *Enter the form options* (on page 15).

5 Click **Next**.

6 Depending on the request type, you must select a subject, site, or study version from the dialog box that appears. For example:

a To select a subject, from the **Select a site to filter** drop-down list, select a site.

b From the **Select subjects from list below** list, select one subject and use the single right-arrow to move it to the **Selected List**.

c Click **Save**.

Note: You can include only one site, one study version, or one subject in a test run.

The Create Test Run PDF Request page appears. The options include depend on the PDF request type you selected on the Study Information page.

7 Specify the PDF request settings.

8 Click **Next**.

The Review and Submit page appears.

9 Review your settings and click **Submit Test Run**.

The PDF Request Submitted dialog box appears.

10 To process the test run, click **No, Go to Processing Page**.

The My Requests - Processing page appears. Note that **Yes** appears in the **Test Run** column to identify the request as a test run.

11 To monitor the progress of the test run PDF request, click **Refresh**.

When complete, the test run PDF request moves to the My Requests - Complete page.

In the **Test Run** column, you will see **Yes**.

- To view the processing details, click the test run **PDF request name**. Review the PDF Request Details page, then click **Return**.
- To view the PDF output, click **Download**.

Editing test run PDF request settings

You have three opportunities to edit the test run PDF request settings:

- From the **Review and Submit** page, using the **<Back** button to return to a previous settings page.
- From the **My Requests - Complete** page, by selecting the checkbox of a test run PDF request and clicking **Edit Test Run**.
- From the **My Requests - Saved** page, by selecting the checkbox of the test run PDF request and clicking **Edit**.

Each procedure ends at the Review and Submit page, where you have the option of saving, printing, or submitting the test run PDF request.

Running the test run request as a PDF request

1. On the **My Requests - Complete** page, select the checkbox of a PDF request with **Yes** in the Test Run column.
2. Click **Proceed With PDF Request**.

   The application populates the Study Information, Form Options, and PDF Request Settings pages with the values in the test run request.
3. Edit the settings as desired.
4. On the **Review and Submit** page, click **Submit**.

Working with saved test run PDF requests

1 On the **My Requests - Saved** page, select the checkbox of a PDF request with **Yes** in the **Test Run** column.

2 To edit the test run PDF request, select the test run request checkbox and click **Edit**.

or

To turn the test run PDF request into a PDF request, click **Proceed with PDF Request**.

The Edit PDF Request page appears. For more information, see *Running the test run request as a PDF request* (on page 69).

3 Edit the settings as desired. The settings you specified in the test run PDF request are your starting point.

4 On the **Review and Submit** page, click **Submit**.

CHAPTER 7

Administrative activities

In this chapter

Overview of administrative activities

If a user has administrative rights, an administrative section appears in the navigation pane. If you only have administrative rights, the Admin page appears upon logging into the InForm application and you cannot generate a PDF file.

Administrative activities include:

- Associating rights groups with CRF Submit-related rights.
- Assigning archiving-related rights to groups.
- Specifying study settings.
- Setting up email notifications.
- Running reports, including the Request Overview report.

Specifying trial, email, and storage settings

1 From the **Manage** section of the navigation pane, select **Settings**.

The Settings page appears.

2 Accept or change the settings in the **Trial Settings** section:

Setting	Description	Notes
Maximum No. of Subject PDFs per PDF Request by site user	Maximum number of subject PDF files that can be generated in a single PDF request by a site user.	Required. The default setting is 5 subjects, the minimum setting is 1, and the maximum setting is 25. If the maximum is set to 1, only the **By Subject** choice appears for the **Export Selection Criteria** field on the site user's PDF Request Settings page.
Send email on request completion	Activates the notification function for the default email address provided.	Recommended. Required for the Notifications reports.
Default Email Address	Email address for request notifications.	Required, if **Send email on request completion** is checked.
Enable eTMF Integration	If checked, enables a rights group with the eTMF right to retrieve output for loading into an eTMF application.	Select only to integrate with an eTMF system.
Give priority to InForm	Check if the study is not locked and priority needs to be given to InForm users who are still entering study data.	When checked, the CRF Submit application will limit the concurrent data generation of output for that trial so that InForm activities take priority.

3 Click **Save**.

Rights groups in CRF Submit

Access to CRF Submit functions is governed by rights and the association of those rights with an InForm rights group. Assignment and management of rights are performed within the CRF Submit application on the Rights Group page. Establishment of the rights groups is done in the InForm application.

A right must be granted to:

- Generate a PDF.
- Perform administrative functions and run reports.
- Pause or restart a PDF request.
- Purge or cancel a PDF request.
- Retrieve output generated by another sponsor user from the same trial.
- Edit and delete templates created by other users.
- Allow a site user to confirm download of archival PDFs shared by a sponsor.
- Allow a sponsor user to share PDF and History output with sites.
- Allow a sponsor user to view the Confirmation report.
- Retrieve a PDF for eTMF usage.

Users with generate PDF rights see the My Requests page when they log in. Users with administrative rights only see the Admin page.

Adding a rights group and assigning it rights

1 From the **Manage** section of the navigation pane, select **Rights Group**.

The Rights Group page appears.

2 Click **Associate Rights Group**.

A new line is added to the top of the rights group list.

3 From the **Rights Group Name** drop-down list, select the rights group to add. This drop-down list includes all the rights groups available in the InForm application.

4 Select and deselect the checkboxes of the rights as desired.

5 Click **Save**.

Editing the CRF Submit rights associated with a rights group

1 From the **Manage** section of the navigation pane, select **Rights Group**.

The Rights Group page appears.

2 To view the rights associated with a specific rights group, begin typing the rights group name in the **Rights Group Name** text box.

The matching rights groups appear in the list.

3 Select the radio button of the rights group whose rights you want to edit.

4 Click **Edit**.

5 Select and deselect the rights as necessary.

6 Click **Save**.

Assigning the Confirm Archival right to a rights group

Sponsor users can share archival PDFs with site users. To confirm receipt and review of the archive, site users must be in a rights group associated with the Confirm Archival right.

1 From the **Manage** section of the navigation pane, select **Rights Group**.

The Rights Group page appears, listing, by default, the rights groups in the InForm application with which CRF Submit rights are associated.

2 To view the rights associated with a specific rights group, begin typing the rights group name in the **Rights Group** text box.

The matching rights groups appear in the list.

3 Select the radio button of the rights group to which you want to add the Confirm Archival right, and click **Edit**.

Or

a To add a rights group, click **Associate Rights Group**.

A new line is added to the top of the rights group list.

b From the **Rights Group Name** drop-down list, select the rights group to add. This drop-down list includes all the rights groups available in the InForm application.

4 Select **Confirm Archival**, as well as any other rights you want to select or deselect.

5 Click **Save**.

Assigning the View Confirmation right to a rights group

To view the Site Confirmation report, a sponsor user must be assigned to a rights group with the View Confirmation right.

1 From the **Manage** section of the navigation pane, select **Rights Group**.

The Rights Group page appears.

2 Select the radio button of the rights group whose rights you want to edit, and click **Edit**.

Or

To add a new rights group and assign the View Confirmation report right:

a Click **Associate Rights Group**.

A new line is added to the top of the rights group list.

b From the **Rights Group Name** drop-down list, select the rights group to add. This drop-down

list includes all the rights groups available in the InForm application.

3 Select **View Confirmation Report**, as well as any other rights you want to select or deselect.

4 Click **Save**.

Deleting a rights group from CRF Submit

1 From the **Manage** section of the navigation pane, select **Rights Group**.

The Rights Group page appears.

2 To view the rights associated with a specific rights group, begin typing the rights group name in the **Rights Group** text box.

The matching rights groups appear in the list.

3 Select the radio button of the rights group you want to delete.

4 Click **Delete**.

5 Confirm the deletion by clicking the **Delete** button.

CHAPTER 8

Working with reports

In this chapter

Viewing and downloading the Site Confirmation report

The report lists all requests shared with sites where a site confirmation was requested. You can also download and store the report as historical evidence that sites confirmed receipt of PDFs and History reports.

1 From the **Reports** section of the navigation pane, select **Site Confirmation.**

The Reports - Site Confirmation page appears.

2 Filter the list by typing a specific value in the text boxes associated with the column headers. For example, type a specific request name in the **Request Name** text box.

The application displays the site confirmations that meet your criteria. For each confirmation, the application displays the:

- **Request Name**—Application-generated or user-defined name for the request.
- **Request Type**—The type of request: archival PDF, Subject Audit History, or User Assignment History.
- **Published Time (GMT)**—Date and time the report was published.
- **Site Name**—Site that initiated the request or performed the download.
- **Confirmed By**—User name of the person who confirmed that the document was received and reviewed.
- **Confirmation Time (GMT)**—Date and time the confirmation was completed by the site.

3 To download the report, click **Download as CSV** (Excel spreadsheet) or **Download as PDF**.

4 The browser prompts you to **Open** or **Save** the file. Oracle recommends that you save the report to a local machine.

5 Click **OK**.

The output is saved to your local machine at the designated location.

Viewing the Request Overview report

The Request Overview report is an operational report that provides usage statistics across studies that are serviced by one of the instances of the CRF Submit application.

1 From the **Reports** section of the navigation pane, select **Request Overview.**

The Reports - Request Overview page appears.

2 Filter the list by date range, type a specific study in the **Study Name** text box, or click a column header to sort the requests by that statistic.

The application displays the requests that meet your criteria. For each study, the application displays the:

- Study name.
- Number of requests that were submitted.
- Number of the submitted requests that were successful.
- Number of submitted requests that failed.
- Average size of the requests (in MB).
- Average time it took to complete a request (in minutes).
- Total number of files submitted.