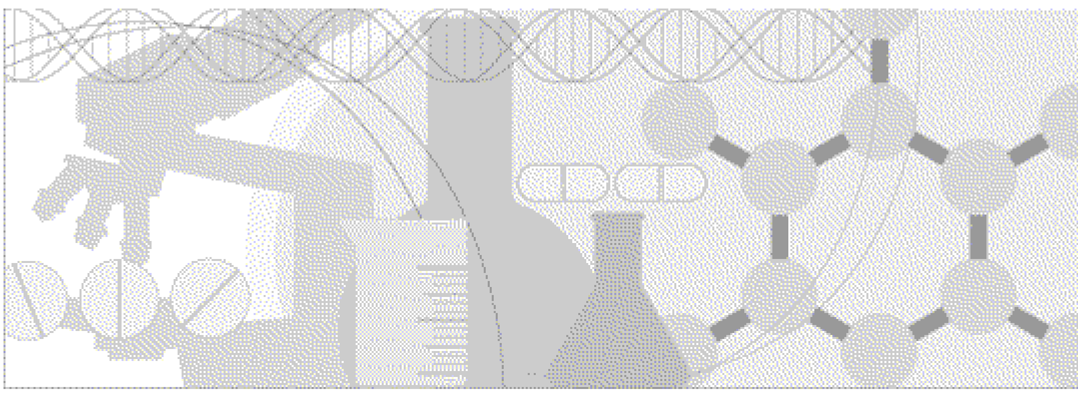
Site User Guide

Oracle® Health Sciences InForm CRF Submit
Release 4.0.1



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About this guide

In this preface

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 directly from within the InForm application.
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.

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 users have authority to perform administrative functions.

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.

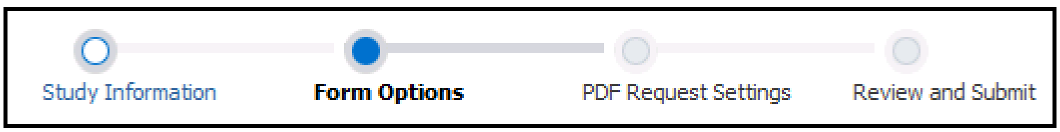
3 **Request Settings**—Options associated with the PDF request type selected.

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

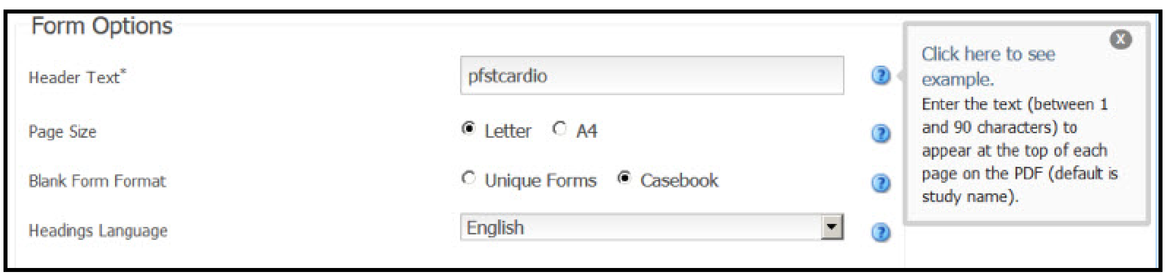
Sponsor requests for History reports include the Study Information, Request Settings, and Review and Submit pages.

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.

Multilingual study support

The InForm CRF Submit 4.0.1 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

Site requests

In this chapter

PDF output available to sites

Site users can generate PDF requests independent of the sponsor. The types of requests and PDF output settings available to sites are streamlined for sites.

Sponsors can also share the output from sponsor-generated archival requests and History report requests with a site. Requests shared with sites include a sponsor user name in the Created By column of the My Requests - Complete page.

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.	On any My Requests page, from the Create Requests drop-down list, select **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. There are five steps in the process: • Enter information about the study and select the site. • Enter form options. • Specify PDF request settings. • Review the request. • Submit the request for processing.
	Step 1: Enter the study information and select the site.	1 Enter basic 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). ▪ **Site**—From the **Select the site for the request** drop-down list, select the site for the request. You must select a site. 2 Click **Next**.
	Step 2: Specify the form options.	1 Select the form options to apply to this request. ▪ **Header Text**—To appear at the top of each page of the PDF. ▪ **Page Size**—Letter (US) or A4 (European) size. ▪ **Blank Form Format**— Unique Forms (one of each blank form) or Casebook (all forms by visit). ▪ **Headings Language**—Language to use for headers, bookmarks, and labels. 2 Click **Next**.

Step	Action	Procedure
	Step 3: Specify the PDF request settings.	1 Select additional options, including additional PDF generation options, as well as data format and security options. ▪ **Export Selection Criteria**—Select one or more subjects from a list. ▪ **Generate Blank Forms**—Include or exclude blank forms. They appear in a separate file. ▪ **Password options**—Restrict changes to PDFs by password-protecting changes to documents, form comments, copying output, and extracting the files from the zip file. 2 Click **Next**.
	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 PDF 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. If email is enabled and the user has an email address listed in the user profile, the application sends a "Completed" message to this email address. If there is no email address in the profile, the application sends a message to a default email address.
3	Download the PDFs.	1 From the My Requests - Complete page, select the PDF request. 2 Click **Download**. 3 Open the ZIP file or save it to a safe, secure, private location.

Creating a new request

1 On any My Requests page, from the **Create Requests** drop-down menu, click **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 ***Step1: Enter the study information*** (on page 13).

3 Enter the form options. For more information, see ***Step 2: Enter the form options*** (on page 13).

4 Enter the PDF request settings. For more information, see ***Step 3: Enter the PDF request settings*** (on page 14).

5 Review and confirm the request. For more information, see ***Step 4: Review and confirm the request options*** (on page 15).

6 Submit the PDF request. For more information, see ***Step 5: Submit the PDF request*** (on page 15).

Step1: 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.

2 In the **PDF Request Description** field, write an optional description of the request.

3 From the **Select the site for the request** drop-down list, select a site. This is a required field.

Site users are limited to generating the maximum number of PDFs per session defined in the **Maximum Number of Subject PDFs settings** field on the Admin Settings page, available to sponsor users and site users with admin rights.

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

3 Select the **Blank Form Format** to determine how blank forms are presented. To include one of each form in alphabetical order, select **Unique Forms.** To include all forms across visits, even if there are multiples of the same form, select **Casebook**.

4 From the **Headings Language** drop-down list, select the language to use for bookmarks, headers,

and form labels.

5 Click **Next**.

Step 3: Enter the PDF request settings

1 On the PDF Request Settings page, in the **Export Selection Criteria** field, select **All Subjects** or the **By Subject** radio button.

The Select Subjects dialog box appears.

> **Note:** On the Settings page, if the value in the Maximum No. of Subject PDFs per PDF Request by site user is set to 1, only the By Subject choice appears.

a (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.

b 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.

c To scroll through the subjects list, click the **Get Next 50** link.

d Continue selecting subjects.

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

f Click **Save**.

You return to the PDF Request Settings page.

2 In the **Generate Blank Forms** field, leave the default selection, **Yes**, to include blank forms (not containing clinical data). Select **No** to exclude blank forms from the output. If selected, the blank forms appear in a separate file.

3 Add security to your PDF output requests by requiring a password to:

- Edit a PDF.
- Add notes to a PDF.
- Copy the contents of the PDF.
- Extract files from any ZIP files generated by the PDF request.

Password protection is turned off by default. If you forget the password, you cannot recover it.

For each password-protection option:

a Select the **Yes** radio button.

b In the **Password** text box, enter the password.

c In the **Re-enter Password** text box., enter the same password.

4 Click **Next**.

The Review and Submit page appears.

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 15).
- 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 Saving the request as a template.
- 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.

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.

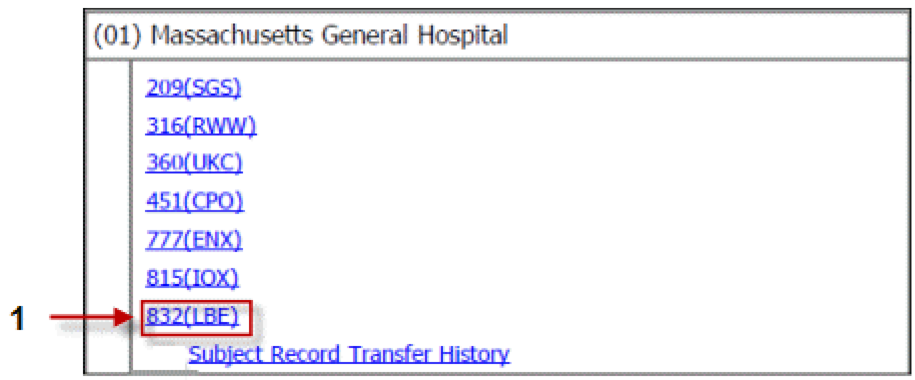
Transferred Subjects in Current Site Only

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.

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):



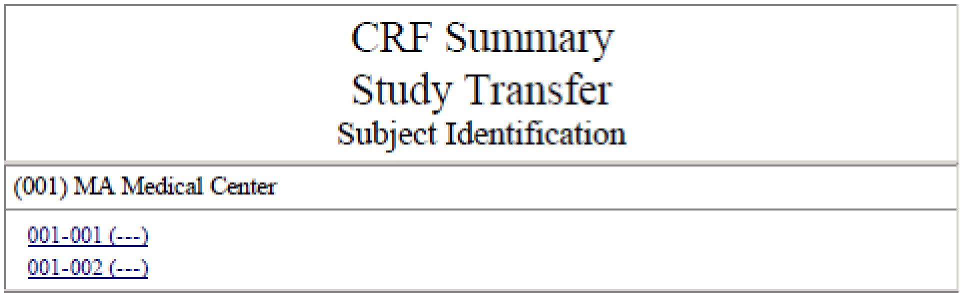
1 Link goes to the subject PDF at the destination site.

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.

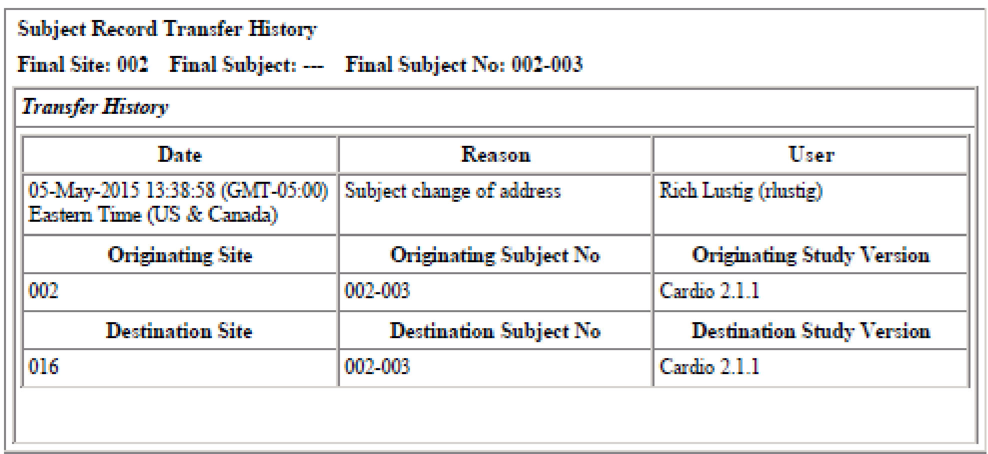


CRF Summary
Study Transfer
Subject Identification

(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.
4. Enter the PDF request settings. For more information, see Step 3: Enter the PDF request settings.
5. Review and confirm the request. For more information, see ***Step 4: Review and confirm the request options*** (on page 15).
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, the date and time it was last modified, 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

Working with submitted requests

In this chapter

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.

Viewing request notices

The CRF Submit application logs the email notifications corresponding to your completed and downloaded 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, typically a sponsor user, on their Admin Settings page.**

2 Filter the list by column headings:

- **Request Name**—Application-generated or user-defined name for the request. [this appears bold to imply a link, but it isn't a link]
- **Notification Type**—Status or action with which the email notification is associated (for example, Completed or Downloaded).
- **Email Sent Time (GMT)**—The date and time when the email notification was sent.
- **Email Status**—Message status. For example: Sent means the email notification was sent successfully.

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.

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**.

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.

CHAPTER 5

Working with archival requests and History reports

In this chapter

Downloading sponsor-created archival PDFs and History reports shared with sites

Archival PDF requests and history reports that a sponsor has marked to share with sites appear on the My Requests - Complete page. The Source column identifies sponsor-shared requests with the word Sponsor.

1 On the **My Requests – Complete** page, identify an archival PDF or History report. The value in the Request type column will be one of the following:

- Archival PDF
- Subject Audit History
- User Assignment History

The value in the Source column will be **Sponsor**.

2 Select the checkbox associated with the request, 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 from the downloaded ZIP file.

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

3 Click **Save**.

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

4 Extract the output from the ZIP file.

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

Confirming a sponsor-created archival PDF or History request has been received and reviewed

Site users can confirm receipt and download of sponsor-requested PDFs and History requests. The U.S. Food and Drug Administration requires evidence that sites have downloaded the archival data for all subjects as part of the process for study decommission. Confirmation of receipt of History requests is optional.

Both end-of-study archival PDF requests and History requests can only be made by a sponsor user. The sponsor user must specify that the output is to be shared with your site. Site users must be part of a group that has the Confirm Archival right to be able to confirm the downloads. This right cannot be assigned to a sponsor user.

1 From the **My Requests** section of the navigation pane, select **Confirmation Pending**.

   All the requests that are pending confirmation appear. For each request, the application displays the request name, the request type, who created the request, the date and time the request was completed, and the site name.

2 Select the checkbox for the request and click **Confirm Archival**.

   The application asks you to acknowledge that you have downloaded and reviewed the request output.

3 To confirm the download and approve the output, select the checkbox and click **Submit**.

   The application confirms that your confirmation operation was successful.

4 Click **Ok**.

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.

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 25).

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 26). 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