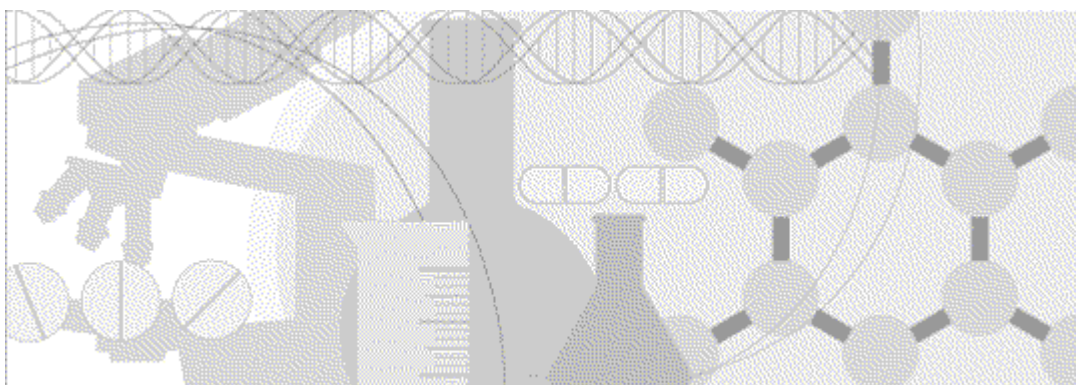


# Site User Guide

Oracle<sup>®</sup> Health Sciences InForm CRF Submit  
Release 4.0.2



ORACLE<sup>®</sup>

Part Number:E79080-01

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# Contents

<b>Chapter 1 Introduction</b>	<b>1</b>
Overview of the CRF Submit application .....	2
A self-service application .....	3
Accessing the CRF Submit application.....	4
Sponsor vs. site users.....	5
Built-in information to guide you .....	6
Rights and InForm rights groups determine the data shown or hidden.....	7
Multilingual study support.....	8
<b>Chapter 2 Site requests</b>	<b>9</b>
PDF output available to sites .....	10
CRF Submit workflow .....	11
Step 1: Enter the study information .....	13
Step 2: Enter the form options .....	14
Step 3: Enter the PDF request settings.....	14
Step 4: Review the request options and submit the PDF request.....	15
Transferred subjects .....	16
How the CRF Submit application handles data for transferred subjects .....	16
Audit trail information for transferred subjects.....	16
Destination site output.....	16
Finding Patient Record Transfer History in the table of contents.....	17
<b>Chapter 3 Working with submitted requests</b>	<b>19</b>
Displaying requests .....	20
Displaying request history.....	21
Filtering the requests to be displayed .....	22
Viewing the details of a request .....	23
Displaying the settings.....	24
Downloading the output from a request .....	25
PDF output details.....	25
Cancelling a request.....	26
Resubmitting a failed request .....	27
Deleting a request .....	28
<b>Chapter 4 Working with archival requests and History reports</b>	<b>29</b>
Downloading and confirming sponsor-created requests.....	30
The Subject Audit History and User Assignment History reports.....	31
<b>About the documentation</b>	<b>33</b>
Where to find the product documentation.....	33
Documentation accessibility.....	33
Access to Oracle Support .....	33
Documentation .....	34



# CHAPTER 1

## Introduction

### In this chapter

Overview of the CRF Submit application.....	2
A self-service application.....	3
Accessing the CRF Submit application.....	4
Sponsor vs. site users.....	5
Built-in information to guide you.....	6
Rights and InForm rights groups determine the data shown or hidden.....	7
Multilingual study support.....	8

## 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 or set of unique forms that include:

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

As part of a study decommissioning package, some regulatory agencies require the following two History 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.

## 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 site or sponsor user requests PDF report generation from within the InForm application portal. Sponsor users can also request History reports.
- 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, in csv format for use with a spreadsheet application, by downloading them to a local storage device.

## Accessing the CRF Submit application

- 1 Log into the InForm application.
- 2 On the InForm Home page, click the **Archive Generator** link.

The Site Archives page appears.

**Note:** Because you log into a specific study, PDF request generation is 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 (Clinical Research Associates), CDMs (Clinical Data Managers), CROs (Clinical Research Organizations), 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, custom PDF output, and Subject Audit History and User Assignment History reports with sites for download and generate the PDF or csv 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 (Clinical Research Coordinators) or PIs (Principal Investigators), 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 sponsor 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.

You complete four pages of settings:

- 1 **Study Information**—PDF request name, description, and site.
- 2 **Form Options**—Heading and formatting settings that apply to the whole PDF output file.
- 3 **Request Settings**—Options associated with the PDF request.
- 4 **Review and Submit**—Summary of settings and PDF request actions.

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.

**Form Options**

Header Text\*  🔍

Page Size  Letter  A4 🔍

Blank Form Format  Unique Forms  Casebook 🔍

Headings Language  🔍

Click here to see example. Enter the text (between 1 and 90 characters) to appear at the top of each page on the PDF (default is study name).

**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 for Sites**.

## Rights and InForm 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 4.0.2 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.

# CHAPTER 2

## Site requests

### In this chapter

PDF output available to sites .....	10
CRF Submit workflow .....	11
Transferred subjects .....	16

## PDF output available to sites

Site users can generate PDF requests independent of the sponsor. There is only one site request type and PDF output settings available to sites are streamlined.

With the appropriate permission, sponsors can share the output from 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 Site Archives page, as well as Request Name, File Type, Status, Status Date, and File Size, and Download and Confirmation links.

## CRF Submit workflow

Step	Action	Procedure
1	Access the CRF Submit application.	<ol style="list-style-type: none"> <li>1 Log into the InForm application.</li> <li>2 Click the <b>Archive Generator</b> link.</li> </ol> <p>The Site Archives page appears.</p> <p>To download a request listed on the Site Archives page, see <i>Downloading the output from a request</i> (on page 25).</p>
2	Create a request.	<p>On the Site Archives page, click <b>Create Site Request</b>.</p> <p>As you create your request, the application displays your progress by highlighting the step in the progress indicator at the top of the page. There are four steps in the process:</p> <ol style="list-style-type: none"> <li>1 Enter study information and select the site, if you are assigned to more than one site.</li> <li>2 Enter form options.</li> <li>3 Specify PDF request settings.</li> <li>4 Review the request options and settings and submit the request for processing.</li> </ol>
	1: Enter the study information and select the site.	<ol style="list-style-type: none"> <li>1 Enter basic study information: <ul style="list-style-type: none"> <li>▪ <b>PDF Request Name</b>—Name for the PDF request. You can accept the application-generated name or enter a name. Spaces are allowed in the name, but other characters are not.</li> <li>▪ <b>PDF Request Description</b>—Description of the request (optional).</li> <li>▪ <b>Site</b>—If you are assigned to more than one site, you must select a site. From the <b>Select the site for the request</b> drop-down list, select the site for the request.</li> <li>▪ For more information, see <i>Step 1: Enter the study information</i> (on page 13).</li> </ul> </li> <li>2 Click <b>Next</b>.</li> </ol>

Step	Action	Procedure
	2: Specify the form options.	<ol style="list-style-type: none"> <li>1 Select the form options to apply to this request. <ul style="list-style-type: none"> <li>▪ <b>Header Text</b>—This will appear at the top of each page of the PDF. The default is the study name.</li> <li>▪ <b>Page Size</b>—Letter (US) or A4 (European) size.</li> <li>▪ <b>Blank Form Format</b>— Unique Forms (one of each blank form) or Casebook (all forms by visit).</li> <li>▪ <b>Headings Language</b>—Language to use for bookmarks, headers, and footers.</li> <li>▪ For more information, see Step 2: Enter the form options.</li> </ul> </li> <li>2 Click <b>Next</b>.</li> </ol>
	3: Specify the PDF request settings.	<ol style="list-style-type: none"> <li>1 Select additional options, including additional PDF generation options, as well as data format and security options. <ul style="list-style-type: none"> <li>▪ <b>Include data as of date and time</b>—Displayed for the browser time zone. Select <b>Now</b> to include all eCRF data available at the current date and time. Use the <b>Select date/time</b> option to include data up to (as of) the date and time you enter.</li> <li>▪ <b>Export Selection Criteria</b>—Select <b>All</b> or select up to the maximum number of subjects defined on the Settings page by an administrator from a list or all subjects. The default value is 5; the maximum number of subjects is 25.</li> <li>▪ <b>Generate Blank Forms</b>—Include or exclude blank forms. They appear in a separate file.</li> <li>▪ <b>Prevent Form Comments Changes</b>—Select <b>Yes</b> to prevent comments from being added to the output PDF. Select <b>No</b> to allow comments and annotations in the PDF output.</li> <li>▪ <b>Prevent Content Extracts and Copying</b>—Select <b>Yes</b> to prevent the contents from being copied. Select <b>No</b> to allow text to be copied.</li> <li>▪ For more information, see <i>Step 3: Enter the PDF request settings</i> (on page 14).</li> </ul> </li> <li>2 Click <b>Next</b>.</li> </ol>



Step	Action	Procedure
	4: Review the request options and submit the PDF request.	<ol style="list-style-type: none"> <li>1 Review the options you selected. You can return to a previous page to make changes by clicking <b>&lt;Back</b>.</li> <li>2 Click <b>Submit</b>.</li> </ol> <p>The application acknowledges the submission and asks if you would like to create another PDF request or continue to the Site Archives page.</p> <ul style="list-style-type: none"> <li>▪ <b>Yes, Create Another</b> returns you to the Study Information page for the new request.</li> <li>▪ <b>No. Go to Site Archives</b> displays the Site Archives page.</li> <li>▪ For more information, see <i><b>Step 4: Review the request options and submit the PDF request</b></i> (on page 15).</li> </ul> <p>After your selection, the application extracts the requested data from the study database, transforms the data to XML, and generates the PDFs.</p> <p>You can monitor the progress on the Site Archives page. Click <b>Refresh</b> to update the page and see if the request status has changed to Available.</p>
3	Download the PDFs.	<ol style="list-style-type: none"> <li>1 From the Site Archives page, select a PDF request with the status <b>Available</b>.</li> <li>2 Click the underlined word, <b>Download</b>.</li> <li>3 Open the ZIP file or save it to a safe, secure, private location.</li> </ol>

## 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 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 if you are assigned to more than one site.

The sponsor has set a maximum number of PDFs you can generate per session, corresponding to the number of subjects you can select for each request. The number appears on the Select Subjects dialog box. The application generates a separate PDF for each subject.

- 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 specify how blank forms are presented.
  - To include one of each 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**.

Within a visit, all forms are represented, even if the same form is used in multiple visits. For example, almost every visit includes a Date of Visit (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.
- 4 From the **Headings Language** drop-down list, select the language to use for bookmarks, headers, and footers.
- 5 Click **Next**.

## Step 3: Enter the PDF request settings

- 1 On the PDF Request Settings page, in the **Include data as of date and time** field, select **Now** to include all eCRF data available at the current date and time. Use the **Select date/time** option to include data up to (as of) the date and time you enter.
- 2 In the **Export Selection Criteria** field, select **All Subjects** or the **By Subject** radio button.

The **All Subjects** option does not appear if there are more subjects than you are allowed to create at one time.
- 3 If you select **By Subject**, the Select Subjects dialog box appears.
  - a Highlight a subject and click the single right arrow to move the subject to the **Selected List**.

Or

Using the **Shift** and **CTRL** keys, highlight up to maximum number of subjects shown on the page, and click the **right arrow**.

The text under the question shows the site user the limit that the sponsor has placed on the number of subjects that can be selected.

The selected subjects move to the Selected List.
  - b (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.

- c (Optional) To scroll through a long subjects list, click the **Get Next 500** link.
- d Click **Save**.

You return to the PDF Request Settings page.

- 4 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.
- 5 In the **Prevent Form Comments Changes** field, specify whether or not per allow changes to comments on forms in the output PDF.
- 6 In the **Prevent Content Extracts and Copying** field, specify whether or not to permit text in the output PDF to be copied.
- 7 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. If you selected specific subjects, visits, or forms, an underlined link allows you to view these selections.

- To submit the request for processing, click **Submit**.
  - To return to a previous pages and change study information, form options, or PDF request settings, click **<Back**.
  - To print a copy of the summary, click **Print**.
- 1 If you submit the PDF request, 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 Site Archives 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 Site Archives**.

The Site Archives page appears. You can monitor the processing progress by observing the value in the Status column.

- 3 To update the processing status, click **Refresh**.  
When processing is complete, the status changes to **Available**.
- 4 To download the PDF output, click the **Download** link or the date of a previous download in the **Download** column.

## 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 **<studyname>-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.

## Finding Patient Record Transfer History in the table of contents

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

<p>CRF Summary Study Transfer Subject Identification</p>
(001) MA Medical Center
<a href="#">001-001 (---)</a> <a href="#">001-002 (---)</a>

**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.

<b>Subject Record Transfer History</b>		
Final Site: 002 Final Subject: --- Final Subject No: 002-003		
<i>Transfer History</i>		
<b>Date</b>	<b>Reason</b>	<b>User</b>
05-May-2015 13:38:58 (GMT-05:00) Eastern Time (US & Canada)	Subject change of address	Rich Lustig (rlustig)
<b>Originating Site</b>	<b>Originating Subject No</b>	<b>Originating Study Version</b>
002	002-003	Cardio 2.1.1
<b>Destination Site</b>	<b>Destination Subject No</b>	<b>Destination Study Version</b>
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.



# Working with submitted requests

## In this chapter

Displaying requests .....	20
Displaying request history .....	21
Filtering the requests to be displayed .....	22
Viewing the details of a request.....	23
Displaying the settings .....	24
Downloading the output from a request.....	25
Cancelling a request.....	26
Resubmitting a failed request.....	27
Deleting a request .....	28

## Displaying requests

Your requests and requests issued by other site users appear on the Site Archives page. All the information about a request is shown on this page. Click **Refresh** to update the page with the latest status of those requests.

- 1 Log into the InForm application.
- 2 On the InForm Home page, click the **Archive Generator** link.

The Site Archives page appears.

For each request, the page contains the following columns of information. All times are in the time zone of the current browser.

- **Select**—Checkbox to select to limit the action to be performed to the selected request.
- **Request Name**—The system-generated or custom request name. The Request Name is a link that, when clicked, displays request details and history below the request table.
- **File Type**—The request type, including sponsor and site requests, and History report request. File types include Archival PDF, Custom PDF, Subject Audit History, User Assignment History, and Site Request.
- **Created By**—The user name of the person who created the request.
- **Status**—From the drop-down list, select **All** statuses, or:
  - Processing
  - Created
  - Available (for download)
  - Failed
  - Deleted

To update the statuses shown, click **Refresh**.

- **Status Date**—Enter the date and time on which the request was started. The time reflects the time zone of the browser used to create the request.
- **File Size (in MB)**—Include requests that generate files of the specified size.
- **Download**—Select the request checkbox and click the link in the Download column—either **Download** or a specific date and time.

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.

- **Confirmation**—Select the request checkbox and click the **Confirm** link in the Confirmation column.
  - a On the Confirm Archival dialog box, select the checkbox and click **Submit**.
  - b Click **OK**.

**Note:** Unless you select a different site from the Site drop-down list, only the requests associated with the site shown are included.



## Displaying request history

At the bottom of the Site Archives page is a Request History section. All times are in the time zone of the current browser.

- 1 Select a request checkbox or click anywhere on a request line and the Request History appears below the request table. The information includes:
  - **Request Name**—The system-generated or custom request name.
  - **Available**—Date\Time when the request was created, along with the user name of the site or sponsor user who created the request.
  - **Confirmed**—Date/Time the site user confirmed the download of the sponsor request shared with the site. Does not appear for site requests.
  - **Deleted**—Date/Time the request was deleted, and the user who deleted the request.
  - **Download Log**—The most recent three downloads of the request, filtered by users that belong to the selected site. Click **More** to display the full list of download logs.
- 2 To expand and collapse the history section, click the **Request Name** or click any column value that is not a hyperlink.

## Filtering the requests to be displayed

You can filter the requests by site and the information displayed in various columns on the Site Archives page. Only those requests that match your filtering criteria appear. All times are in the time zone of the current browser.

- **By site**—When you have access to more than one site, you can select the site from the **Site** drop-down list. Only requests from the specified site are included.  
If you have access to a single site, the site name is displayed in the By site field.
- **By entering or selecting values for the columns shown.**—The columns include:
  - **Request Name**—Type all or three-characters, or more, of the request name.
  - **File Type**—From the drop-down list, select the PDF request type, including Archival PDF, Submission, Custom PDF, Subject Audit History, User Assignment History, and Site request.
  - **Created By**—Type all or three-characters, or more, of the user name of the user who created the request.
  - **Status**—From the drop-down list, select **All** statuses, or:
    - Processing
    - Created
    - Available (for download)
    - Failed
    - Deleted
  - **Status Date**—Enter the date and time on which the request was started. If no requests match the status date, the application displays the message, No requests match the search criteria.
  - **File Size (in MB)**—Include requests that generate files of the specified size, rounded up to the nearest whole number.

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.

## Viewing the details of a request

- 1 On the Site Archives page, click the underlined **Request Name** for any rows where file type is **Site Request**.

The Request Details page appears and lists the following information about the request. All times are in the time zone of the current browser.

- **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.
- **State**—Status of the request. The **Ready for Download** state is most likely the status that you will see. The full list of states include:
  - Ready for Download
  - Connector Started
  - Connector Submitted
  - Connector Complete
  - Connector Failed
  - DocGen Started
  - DocGen Complete
  - DocGen Failed
  - Storage Started
  - Storage Failed

- 2 To return to the Site Archives page, click **Return**.

## Displaying the settings

- 1 On the Site Archives page, select the request checkbox for any row with a Site Request and click **Show Settings**.

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

- 2 To print the request settings, click **Print**.
- 3 To return to the Site Archives page, click **Close Window**.

## Downloading the output from a request

You can download the complete output from a request from the Site Archives page.

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 will receive the request output in csv format for use with a spreadsheet application.

- 1 On the **Site Archives** page, select the request checkbox and click the link in the Download column—either **Download** or a specific date and time.

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.

Depending on the PDF Request Settings selected, you may be prevented from adding comments to the PDF output or copying text appearing in the output.

## 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.

## Canceling a request

At any time during the request process, you can cancel the request by clicking the **Cancel Request** button. The application returns you to the Site Archives page.

## Resubmitting a failed request

When a request fails, the status of the request on the Site Archives 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 Site Archives page, locate a request with a **Failed** status.
- 2 Select the checkbox of the failed request.
- 3 Click **Resubmit**.
- 4 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 files that were not generated in the previous run**.
  - To regenerate the entire request, select **Yes, generate a completely new set of files**.
  - To cancel the resubmitted request and return to the Site Archives page, select **No, go back to the previous page**.
- 5 Click **OK**.

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

- 6 Click **OK**.

## Deleting a request

**Note:** Site users can delete site-generated requests only.

- 1 On the Site Archives page, click **Delete**. To delete a single request, select its checkbox and click **Delete**.
- 2 On the **Select Requests** dialog box, select the request(s) to delete.
  - a (Optional) To search for a request, in the **Select requests from list below** text box, start typing the request name to display matching requests.
  - b Select one or more requests from the left-hand list and click the right single right arrow to move them to the **Selected List**. I
    - If you selected a request checkbox, that request appears in the Selected List.
    - To delete all requests, don't make a selection, click the double right arrow.
- 3 Click **Delete**.
- 4 Confirm that you want the request(s) 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.
- 5 To include deleted requests on the Site Archives page, click **Include Deleted Requests**. To exclude deleted requests, click **Exclude Deleted Requests**.



## CHAPTER 4

# Working with archival requests and History reports

### **In this chapter**

Downloading and confirming sponsor-created requests.....	30
The Subject Audit History and User Assignment History reports .....	31

## Downloading and confirming sponsor-created requests

Archival and Custom PDF requests and history reports that a sponsor has chosen to share with sites appear on the Site Archives page. The Created By column identifies sponsor-shared requests with the sponsor user name. You can download the request output and confirm that you have downloaded the request.

- 1 On the **Site Archives** page, identify an archival or custom PDF or History report. The value in the Request type column will be one of the following:

- Archival PDF
- Custom PDF
- Subject Audit History
- User Assignment History

The value in the Source column will be the user name of a sponsor user.

- 2 To download the request output, click the **Download** link in the Download column.

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.

The Download column and the **Request History** section of the Site Archives page shows the date and time you downloaded the output under **Download Log**.

- 3 To confirm to the sponsor that you have downloaded the request output, click the **Confirm** link in the Confirmation column.
- 4 On the Confirm Archival dialog box, select the checkbox and click **Submit**.

The Confirm column and the **Request History** section of the Site Archives page shows the date and time you confirmed the download.

## 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.



# About the documentation

## Where to find the product documentation

The product documentation is available from the following locations:

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

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

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

## Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc> ([http://www.oracle.com/docaccessibility.us.oracle.com/accessibility\\_statements.html](http://www.oracle.com/docaccessibility.us.oracle.com/accessibility_statements.html)).

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Oracle customers that have purchased support have access to electronic support.

For phone support visit: <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> (<http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html>).

To send an email use one of the following addresses:

For Japanese support: [saasclinicalsupportjp\\_ww@oracle.com](mailto:saasclinicalsupportjp_ww@oracle.com)

For all other countries: [saasclinicalsupport\\_ww@oracle.com](mailto:saasclinicalsupport_ww@oracle.com)

## Documentation

Document	Description	Part number	Last Updated
<i>Release Notes</i>	The <i>Release Notes</i> document provides hardware and software requirements and describes the new features, enhancements, and fixed issues in this release.	E79082-01	4.0.2
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.	E79083-01	4.0.2
<i>Sponsor User Guide and online Help</i>	The <i>User Guide</i> 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 of study data, and a detailed description of the user interface.	E79079-01	4.0.2
<i>Site User Guide and online Help</i>	The <i>User Guide</i> 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 of study data, and a detailed description of the user interface.	E79080-01	4.0.2
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes licenses and notices for third party technology that may be included with the InForm software.	E79081-01	4.0.2