

Oracle® Life Sciences InForm CRF Submit

User Guide for Site Users



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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

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>.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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1

For new users:

In this chapter

- [What do I use Oracle InForm CRF Submit for?](#)
- [Where do I go in Oracle InForm to create archives?](#)
- [What is included in a PDF archive request?](#)
- [What reports are available?](#)
Site users can generate the following reports for sites they are associated to.
- [What data is migrated across data centers?](#)
- [How do I get help?](#)

What do I use Oracle InForm CRF Submit for?

Using Oracle InForm CRF Submit, you can initiate site-specific archival and history report requests directly from the Oracle InForm user interface for both UAT and LIVE studies. The output generated can be used for:

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

Where do I go in Oracle InForm to create archives?

If you are using Oracle InForm 6.2 or higher:

1. Log into Oracle InForm.
2. On the navigation toolbar, click **Archives**.

If you are using a prior version of Oracle InForm:

1. Log into Oracle InForm.
2. Below the navigation toolbar, click the **Archives** link.

What is included in a PDF archive request?

The ZIP file Oracle InForm CRF Submit creates for an archival request includes:

- A site folder for any site included in the request.
- Each site folder contains PDFs for any subject included in the request.

 **Note:**

The site folder also includes a prth.pdf (Subject Record Transfer History) file for transferred subjects. For more information on transferred subjects, see [Transferred subject data](#).

- Table of Contents (TOC).
- RequestSettings.pdf.
- Blank forms.

What reports are available?

Site users can generate the following reports for sites they are associated to.

Audit Trail Report (ATR)

- Generate this report to view site specific details for traceability of item-level inserts and edits, query changes, form status changes, Source Verification (SV) changes, and comment and signature history. To learn how, see [Create an Audit Trail Report \(ATR\)](#).
- The report also includes audit trail information for the following Oracle InForm form and SV statuses:
 - Date form started
 - Date form frozen / unfrozen
 - Date form locked / unlocked
 - Date form signed / unsigned
 - Date form deleted / undeleted
 - Date form is marked SDVReady, SDVPartial, and SDVComplete
 - Date SDVReady, SDVPartial, and SDVComplete are deleted
- Sponsor users can also generate this report and share it with site users.

User Assignment History

- Generate this report to view a history of changes made to users at a site. The report output includes details about changes made to the following. To learn now, see [Create the User Assignment History Report](#).
 - User status changes, for example, created, activated, deactivated, and terminated.
 - Query Groups
 - Reporting Groups
 - Rights Groups
 - Signature Groups
 - Site associations
- Sponsor users can also generate this report and share it with site users.

Site Confirmation Report

- Download this report (in PDF or CSV format) to view details for PDF and history report requests generated by a sponsor and shared with sites where site confirmation was required. To learn how, see [Download a Site Confirmation Report](#).

 **Note:**

Site users only see requests generated for their site(s) and rights group.

- For more information on the confirmation process, see [Confirm archives and reports](#).

What data is migrated across data centers?

Oracle InForm CRF Submit includes the following features and a command line utility to support migration across data centers (from GBUCS 1.0 to GBUCS 3.0) without impacting regulatory data.

- Requests are migrated.
 - Request Settings are available for migrated requests.
- Migrated requests:
 - Are displayed as part of the Completed Requests, and their status shows as Migrated. Users cannot click on the Migrated request name, and therefore they cannot navigate to the Request Details page.
 - Always stay in the Completed Requests section regardless of their status, and do not auto-purge.
 - Cannot be downloaded.
- There is a new Migrated status for Requests and Audit Reports. The Request name must be unique per study.

Command line utility

Oracle InForm CRF Submit supports a command line utility for migrating Regulatory and Administration data for a study from the GBUCS 1.0 to GBUCS 3.0 data center. Prior to migration, the PDFs and History Reports must be downloaded by the user.

The utility migrates the following information:

- Study settings (Sponsor settings are not migrated because they are not specific to a study)
- Regulatory data
 - Download log
 - Site Confirmation log
- Administration data
 - CRFS Settings—Study Settings
 - Admin Tool—Study Data
 - CRF Submit rights for the study and the rights history

For Oracle InForm pre-6.2 studies, CRF Submit rights are migrated.



For Oracle InForm 6.2 and later studies, CRF Submit rights are not migrated.

All migration requests have a status of Migrated (instead of, for example, Completed or Deleted).

Previously generated files (for example, PDFs or CSVs) in GBUCS 1.0 are not migrated and there are no links to them in the Downloaded requests.

How do I get help?

A number of user assistance devices are built into Oracle InForm CRF Submit.

- **Progress indicator**—As you complete each page, the corresponding circle 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 this message by clicking anywhere. Select the **Click here to see example** link to view the effects of selecting the option.
- **User documentation and videos**—Click the Help icon () to the far right of the page title to open the Oracle Help Center and access the Oracle InForm CRF Submit documentation set and videos. Videos are also accessible from topics within the user guide. Click the **Show me how!** link.

2

Create an archive or report

In this chapter

- [Create an archive of study data](#)
Site users with the *Generate Archives* right can generate a PDF archive of study data.
- [Create an Audit Trail Report \(ATR\)](#)
Generate this report to view a history of changes made to study data.
- [Create the User Assignment History report](#)
Generate this report to view a history of changes made to users at a site.
- [Download the Site Confirmation report](#)
Site users with the *Generate Archives* right can download the **Site Confirmation** report.
- [PDF output options](#)
- [Transferred subject data](#)

Create an archive of study data

Site users with the *Generate Archives* right can generate a PDF archive of study data.

1. Click **Archives** in the top navigation bar.
The **Site Archives** page opens, your site is displayed by default. You are presented with a drop-down if you are associated with multiple sites.
2. On the **Requests** tab click **Create Requests** then select **Site Request**.
The **Create New PDF Request - Study Information** page opens.
3. Complete **PDF Request Name**, **PDF Request Description**, and confirm the correct site is selected for **Select the site for the request**.

Details about each field can be found in the following table.

Table 2-1 Study Information field details

Field	Details
PDF Request Name	The default value is the study name plus the current date/time. Rename if applicable.
PDF Request Description	Optional
Select the site for the request	The default is your site if you belong to only one. If you belong to more than one it displays the site selected on the Site Archives page.

4. Click **Next**.
The **Create New PDF Request - Form Options** page opens.
5. Complete the **Form Options** fields.
Details about each field can be found in the following table.

Table 2-2 Form Options field details

Field	Details
Header Text	The default value is the study name. You can enter up to 90 characters to appear at the top of each PDF page.
Page Size	Select Letter (default) or A4 for the page size of your PDF archive.
Blank Form Format	Select Unique Forms to show one of each blank form in every visit. Select Casebook (default) to show all forms in every visit. For more details, see How can I handle blank forms?
Headings Language	To display bookmarks, headers, and labels in Japanese, select Japanese from the Headings Language drop-down. The default is English .
Include Study Name in the Subject PDF File Name	Select Yes (default) for the Study Name to appear in the Subject PDF file name.

6. Click **Next**.

The **Create New PDF Request - Request Settings** page opens.

7. Define your **Request Settings** filters.

Details about each filter can be found in the following table.

Table 2-3 Request Settings filter details



Filter	Details
Include data as of date and time	Select Now (default) or Select date/time . The output includes all available information up to now or the date and time entered. For more details, see How does the Include data as of date and time option affect the output?
Export Selection Criteria (Up to 50000 subjects can be selected)	Select All Subjects or By Subject . If By Subject is selected a window opens allowing you to choose specific subjects. Hold Ctrl to select multiple subjects, then use the arrows to move them. If you need to edit the list click By Subject again to reopen the window.
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%; border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>The sponsor-controlled trial setting, <i>Maximum Subjects per PDF Request by site user</i>, controls the number of subjects that can be selected. For more information, see Specify trial settings.</p> </div> <div style="width: 45%; border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>Only subjects enrolled prior to the as-of date appear in the By Subject list.</p> </div> </div>	
Generate Blank Forms	Select Yes (default) to include blank forms (without clinical data) in the output.
Prevent Form Comments Changes	Select Yes to prevent comments from being added to the output PDF, select No (default) to allow comments or annotations to be added to the PDF.

Table 2-3 (Cont.) Request Settings filter details

Filter	Details
Prevent Content Extracts and Copying	Select Yes to prevent contents being copied from the output PDF, select No (default) to allow text to be copied.

- Click **Next**.

The **Create New PDF Request - Review and Submit** page opens.

- Review your request settings and click **View Selected Subjects** to confirm the request includes the correct details.

- Click **Submit**.

- Click **Yes, Create another** or **No, Go to Site Archives**.

If **Yes, Create another** is selected you are taken to the Create New PDF Request page. If **No, Go to Site Archives** is selected you are taken to the Site Archives page.

- On the Site Archives page click **Refresh** until the **Download** link is made available.

For more information, see Download archives and reports .

Create an Audit Trail Report (ATR)

Generate this report to view a history of changes made to study data.

For more information about this report, see What reports are available?

- Click **Archives** in the top navigation bar.

The **Site Archives** page opens, your site is displayed by default. You are presented with a drop-down if you are associated with multiple sites.

- On the **Requests** tab click **Create Requests**, then select **Audit Trail Report**.

The **Create History Request - Study Information** page opens.

- Complete the following fields, then click **Next**.

The **Create History Request - Request Settings** page opens.

Table 2-4 Study Information field details

Field	Details
Request Name	The default value is the study name plus the date/time. Rename if applicable.
Request Description	Optional
Select Request Type	Select Audit Trail Report

- Define your filters.

Details about each filter can be found in the following table.

Table 2-5 Request Settings field details

Filter	Details
Headings Language	Select Japanese to display bookmarks, headers, and labels in Japanese. The default is English.
Include Study Name in the Subject CSV File name	Select Yes (default) for the study name to appear in the subject CSV file name.
Generate TOC	Select Yes to create a table of contents (TOC) with links to all generated files in a request.
Select Date Range	Select a From and To date range to include all or some data in the output.
Selection Criteria	<p>Use the Sites, Subjects, Visits, Forms, and Modification Type filters to generate the report for an entire trial or site, or for a specific subject, visit, form or modification type.</p> <p>The Sites filter defaults to your site and cannot be changed. If you belong to multiple sites, it displays the site selected on the Site Archives page.</p> <p>The Rights Group and Usernames filters are disabled and set to ALL by default.</p> <ol style="list-style-type: none"> Click the arrow to the left of the filter to expand the section. Use the arrows to move your selections from Available to the Selected List. Hold Ctrl to select multiple options.

5. Click **Next**

The **Create History Request - Review and Submit** page opens.

6. Confirm the report settings and click the **View Selection** link to confirm the report includes the correct information. Click **Print** to print the report settings.

7. Click **Submit**.

The **Request Submitted** page opens.

8. Click **Yes, Create another** or **No, Go to Processing Page**.

If **Yes, Create another** is selected you are taken to the Create History Request - Study Information page. If **No, Go to Processing Page** is selected you are taken to the Site Archives page.

9. On the Site Archives page click **Refresh** until the **Download** link is made available.

For more information, see Download archives and reports.

Create the User Assignment History report

Generate this report to view a history of changes made to users at a site.

For more information about this report, see What reports are available?

1. Click **Archives** in the top navigation bar.

The **Site Archives** page opens, your site is displayed by default. You are presented with a drop-down if you are associated with multiple sites.

2. On the **Requests** tab click **Create Requests**, then select **User Assignment History**.

- The **Create History Request - Study Information** page opens.
- Complete the following fields, then click **Next**.
The **Create History Request - Request Settings** page opens.

Table 2-6 Study Information field details

Field	Details
Request Name	The default value is the study name plus the date/time. Rename if applicable.
Request Description	Optional
Select Request Type	Select User Assignment History

- Complete the following fields, then click **Next**.
The **Create History Request - Review and Submit** page opens.

Table 2-7 Request Settings field details

Field	Details
Headings Language	Select Japanese to display bookmarks, headers, and labels in Japanese. The default is English.
Generate TOC	Select Yes to create a table of contents (TOC).
Include data as of date and time	Select Now (default) or Select date/time . The output includes all available information up to now or the date and time entered.
Selection Criteria	The Sites filter defaults to your site and cannot be changed. If you belong to multiple sites, it displays the site you selected on the Site Archives page. Click the arrow to the left of the filter to expand the section.

- Confirm the report settings and click the **View Selected Sites** link to confirm the report includes the correct information. Click **Print** to print the report settings.
- Click **Submit**.
The **Request Submitted** page opens.
- Click **Yes, Create another** or **No, Go to Processing Page**.
If **Yes, Create another** is selected you are taken to the Create History Request - Study Information page. If **No, Go to Processing Page** is selected you are taken to the Site Archives page.
- On the Site Archives page click **Refresh** until the **Download** link is made available.
For more information, see Download archives and reports.

Download the Site Confirmation report

Site users with the *Generate Archives* right can download the **Site Confirmation** report.

For more information about this report, see What reports are available?

- Click **Archives** in the top navigation bar.

The Site Archives page opens.

2. Click the **Site Confirmation** tab under the site and, if applicable, use the Search filters to locate specific requests.
3. Click **Download as CSV** or **Download as PDF** and save the file locally.

PDF output options

In this section

- [How can I handle blank forms?](#)
- [Can I generate archive headers in Japanese?](#)
- [How does the Include data as of date and time option affect the output?](#)
- [What PDF format is applied to PDF output?](#)

How can I handle blank forms?

You specify how to handle blank forms on the Form Options page.

- To include one of each form in alphabetic order, select **Unique Forms**. This option 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 separately defined forms with the same form name.

Can I generate archive headers in Japanese?

Oracle InForm CRF Submit is Unicode-based and supports PDF report generation for multilingual studies.

You can specify a submission language in the **Headings Language** field on the Form Options page. The chosen language is applied to the structure of the PDF file, including headers, headings, and labels. The study content remains in the language it was entered into the Oracle 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.

How does the Include data as of date and time option affect the output?

You specify an as-of date on the Request Settings page.

The default is **Now**. The data export includes all eCRF data available at the current date and time (displayed in the browser time zone). Use the **Include data as of date and time** option to include data up to (as of) the date and time you enter. The earliest date you can select is the enrollment date of the first subject.

When you select subjects using the **Export Selection Criteria** option, only subjects enrolled prior to the as-of date appear in the selection list.

What PDF format is applied to PDF output?

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

Page orientation—By default, output is printed in portrait orientation. Oracle InForm CRF Submit 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 and top margins are at least 0.98 inches. Bottom is at least 1.26 inches. The right margin is at least 0.59 inches.

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.

Compression—Oracle InForm CRF Submit compresses individual PDF files to fit within regulatory standards.

Transferred subject data

In this section

- [Are subject data transfers supported?](#)
- [Where is subject transfer history included?](#)

Are subject data transfers supported?

Oracle InForm allows you to transfer a subject's information from one site to another; that is, the subject data associated with the originating site is transferred 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.

Where is subject transfer history included?

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`.

Links to the Subject Record Transfer History are in the `crftoc.pdf` file.

 **Tip:**

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.

3

Work with archives and reports

In this chapter

- [View archives and reports](#)
- [Download archives and reports](#)
- [Confirm archives and reports](#)
- [View the history of an archive or report](#)
- [View site request and report processing details](#)
- [View the form options and PDF settings](#)
- [Resubmit a failed site request](#)
- [Delete a site archive or report](#)
- [Archives and reports shared by sponsors](#)

View archives and reports

The Requests tab on the Site Archives page provides a list of requests created by a site user and those created and shared by a sponsor. These include:

- Archival PDF (generated and shared by a sponsor user)
- Site Request (Archival PDF generated by a site user)
- Custom PDF (generated and shared by a sponsor user)
- Audit Trail Report (can be generated by a site or sponsor user)
- User Assignment History report (can be generated by a site or sponsor user)

After 120 days, requests are automatically deleted. For more information about deleted requests, see [Delete a site archive or report](#).

Follow these steps to locate and view requests.

1. Start by confirming your site.
 - If you are associated with one site it is displayed by default.
 - If you are associated with multiple sites you are presented with a drop-down.
2. Click **Refresh** to update the list of requests and their statuses.
3. To include deleted requests in the list, click **Include Deleted Requests**.
4. (Optional) Use the Search filters to locate specific requests.
5. (Optional) Click the arrow at the top of each column to sort the list.

The following information is presented for each archive and report.

Table 3-1 Site Archives page column descriptions

Column	Description
Check box	Selecting a row displays the Request History and limits actions to the selected request.
Request Name	Displays the default or custom request name. Clicking the name (Site Request) opens the Request Details page, and clicking the name (Sponsor request) opens the Request History.
File Type	Lists the type of request generated.
Created By	Provides the user name of the person who generated the request.
Status	Indicates each request's status, including Created, Processing, and Available. Click Refresh to get the latest status for a request.
Status Date	Indicates the date and time when processing started. The time reflects the browser's time zone used to generate the request.
File Size (MB)	The size of the output.
Download	You can download an entire request or specific files. For more information, see Download archives and reports.
Confirmation	A Confirm link appears after downloading a request if the sponsor who generated it requires confirmation. For more information, see Confirm archives and reports.

Download archives and reports

The Requests tab on the Site Archives page provides a list of requests created by a site user and those created and shared by a sponsor.



Note:

For additional details about requests, see view archives and reports.

Download an entire request generated by a site or sponsor user

Follow these steps to download an entire request generated by a site or sponsor user.

1. Click **Download** under the Download column. Each download is tracked in the Download Log report, which is available to sponsor users.



Note:

The download link is replaced with a date indicating the last download. This is an active link that allows users to download a request multiple times.

2. A Confirmation Required message appears if the sponsor user who generates a request requires confirmation after download; click **OK** to close the window.

 **Note:**

A **Confirm** link appears under the Confirmation column when confirmation is required. For more information about the confirmation process, see Confirm archives and reports.

Download a specific file from a site request

Follow these steps to download a specific file from a site request.

1. Click the **Request Name** to open the Request Details page.
2. Check the box to the left of the file you'd like to download.

 **Note:**

Only one file can be downloaded at a time.

3. Click **Download** and save the file locally.
4. Click **Return** to be brought back to the Site Archives page.

Confirm archives and reports

A sponsor user may require confirmation that a site has downloaded and reviewed a request that they have generated.

Confirmation can be requested for Archival and Custom PDF requests, the Audit Trail Report, and the User Assignment History report.

 **Note:**

To request confirmation, the sponsor user must select **Yes** for **Site Confirmation Required** when creating the request.

If confirmation is required, a **Confirm** link appears under the Confirmation column on the Site Archives page after download.

 **Note:**

To confirm the request, the site user must belong to a rights group that includes the *Confirm Archives Download* right.

Follow these steps to confirm a request

1. Click the **Confirm** link under the Confirmation column.
The Confirm Archival window opens.
2. Read the confirmation text, click the check box, then click **Submit**.
An information window opens indicating the action was successful.

3. Click **OK** to complete the process.
 - The Confirm link is replaced with the date and time of the action.
 - Unlike download, the confirm action can only be performed once per request.
 - Click the request name to view confirmation details in the Request History.
 - Confirmation actions are captured in the Site Confirmation report.

View the history of an archive or report

Why do this? If you need a detailed history of processing, downloading, and confirmation of the archive or report, follow this procedure.

1. On the Site Archives page, select an archive or history request checkbox or click anywhere on the row and the Request History appears below the request table. The information includes:
 - **Request Name**—The default or custom request name.
 - **Available**—Date and time when processing of the archive or report was complete, along with the user name of the site or sponsor user who created the request.
 - **Confirmed**—Date and time the site user shown confirmed the download of the archive or report the sponsor shared with the site. This information does not appear for site requests.
 - **Deleted**—Date and time the archive or report was deleted and the user who deleted it.
 - **Download Log**—The most recent three downloads. Click **More** to display the full list of downloads.
2. To close the history section, click **Request History**.

View site request and report processing details

Why do this? Follow these steps if you need information about the individual files included in a site request or report generated by a site user.

1. On the Site Archives page, click the **Request Name** for any site request or report generated by a site user. If needed, you can use the search feature to filter requests by file type.

The **Request Details** page opens and lists the following information about each file included in the site request or report. All times are in the time zone of the current browser.

 - **Start Time**—Date and time processing started.
 - **Complete Time**—Date and time processing completed.
 - **File Type**—Type of information included in the output.
 - **File Name**—Name of the file generated.
 - **State**—Status of the request. The **Ready for Download** state is most likely the status that you will see.
2. To download a file within the site request or report, select the checkbox and click **Download**.

 **Tip:**

To download the entire site request or report, click **Return** to get back to the Site Archives page, then click the **Download** or the date link under the Download column.

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

View the form options and PDF settings

Why do this? Use this option to see the form options and request settings used to create a site archive.

1. On the Site Archives page, select the checkbox for any archive with the **Site Request** file type and click **Show Settings**.
2. View the request settings.
3. To print the request settings, click **Print**.
4. To return to the Site Archives page, click **Close**.

Resubmit a failed site request

When a request fails, its status shows Failed on the Site Archives page. A ZIP folder is still created and contains files for any subjects for which the request was successful. The ZIP folder also includes a failure report. You can correct the errors and resubmit the request.

 **Tip:**

If available storage space is exceeded, archive requests will continue to fail with the status **Failed-out of storage space**. You can manually [delete outdated or downloaded archives](#) you created.

1. On the Site Archives page, locate a site request with a **Failed** status.
2. Click the **Request Name**.

On the Request Details page, you can see which files failed and why, files that succeeded and are ready for download, and a failure report.

- The reason for failure appears in red in the **State** column. You can click the reason to see more information.
 - Files that were successfully created are labeled **Ready for Download** in green.
3. To download a successful file, click its check box, then click **Download**.
 4. To resubmit a failed file:
 - Try resubmitting the file as is by selecting its check box and clicking **Resubmit**. Sometimes, just resubmitting the request works.
 - Understand why some files failed by reviewing the details in the failure report. Each line of the report describes a single file failure. To view the failure report, select it from the Reports menu in the navigation pane at the left. You cannot download the report.
 - Create a new request based on fixing the errors and submit it.

Delete a site archive or report

Overview

- Requests over 120 days old are automatically deleted to maintain the storage servers.
- Site users can manually delete site-generated requests but cannot delete sponsor-generated ones.
- Requests shared by a sponsor and later deleted by the sponsor no longer appear on the Site Archives page even when **Include Deleted Requests** is clicked.

Note:

Deleted requests that required confirmation appear on the Site Confirmation tab with a status of Not Confirmed.

Follow these steps to manually delete a site-generated request.

1. Click **Include Deleted Requests** on the Site Archives page.
2. Set the **File Type** filter to Site Request, then click **Search** to retrieve a list of site-generated requests.

Tip:

If File Type is set to Audit Trail Report or User Assignment History, the search results include site and sponsor-generated reports. Use the Created By filter to narrow the results to those requests created by the site.

3. Click the check box to the left of a request, then click **Delete**.
The Select Requests page opens.
4. Select the requests you want to delete from the list on the left, then use the arrows to move your selections to the Selected List table on the right. In some cases, the request has already been moved.

Tip:

Click the double arrow to move all requests.

5. Click **Delete**.

WARNING:

Deleting a request permanently removes all data files associated with the request. These cannot be retrieved after deletion. This is also true for requests automatically deleted after 120 days.

6. Click **OK** to confirm the deletion.
7. Click **Include Deleted Requests** to view deleted requests in the table.

- Click the check box to the left of the Request Name to view the Request History, which includes the date and time of the deletion and the user name of the person who deleted the request.
- Clicking the check box also enables the **Show Settings** button. This provides the settings used to generate the request.
- Click the request name to open the Request Details page. Here, you can view the files (and associated details) generated for the request. These files can no longer be downloaded.

Archives and reports shared by sponsors

In this section

- [Is there a record of affidavits used to sign off on Oracle InForm data?](#)

Is there a record of affidavits used to sign off on Oracle InForm data?

Why is this important? After a trial has been decommissioned, you might need to see the affidavit used during a particular Oracle InForm casebook or form signing.

Affidavit text can be changed at any time. The Submission, Archival, and Custom PDF output shows the affidavit text that was in effect at the time the casebook or form was signed. This may be different than the affidavit text currently being used.

The affidavit text appears in the language that was in use when the affidavit was signed.

4

Email notifications

In this chapter

- [Email notifications](#)
Sponsor users with appropriate access can configure study level email notifications in the Oracle InForm CRF Submit user interface.

Email notifications

Sponsor users with appropriate access can configure study level email notifications in the Oracle InForm CRF Submit user interface.

Notifications are sent to site users based on the configuration set by a sponsor user.

Table 4-1 Email notifications for site users

Notification Name	Details
PDF or History Request is available for download (Site user, when shared with sites).	This notification is sent when a PDF request or History report, shared with sites (by a sponsor user), is available for download.
PDF or ATR Request is available for download (Site User).	This notification is sent to the requester (site user) when a PDF or ATR Report is available for download.
Not yet downloaded PDFs or History Requests (Site Users).	This notification is sent to remind site users they have not yet downloaded PDF or History Report requests.
PDF or ATR Request has failed (Site User).	This notification is sent to the requester (site user) when a PDF or History Request has failed.

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Revision History

Date	Part number	Description
28 May 2024	F92946-01	Original version of this document.