Oracle® Health Sciences InForm CRF Submit

User Guide for Site Users

Release 6.3
F30576-01

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Contents

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 of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

Additional copyright information

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For new users:

In this chapter

What do I use Oracle InForm CRF Submit for?

Using Oracle InForm CRF Submit, you can initiate PDF archive and history report requests directly from the live Oracle InForm study database and retrieve the requested data from the cloud. You can use the output created with Oracle InForm CRF Submit 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:

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.
- Within each site folder, PDFs for each subject included in the request.
- Table of Contents (TOC).
- RequestSettings.pdf.
- Blank forms.

What history reports are available?

Sponsor users with appropriate access can generate the following reports, which can be shared with site users:

- **Audit Trail Report**—Includes traceability for item-level inserts/edits, query changes, form status changes, SV status changes, and comment and signature history. This report is only available in CSV format.
- **User Assignment History**—Includes the following for each user:
  - User status changes; e.g., created, activated, deactivated, terminated.
  - Query group changes.
  - Reporting group changes.
  - Rights group changes.
  - Signature group changes.
  - Site association changes.

Sponsor users can generate these reports and share them with sites.

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.

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Create an archive of study data

In this chapter

Step 1: Enter the study information

Show me how!

1. On the Site Archives page, click **Create Site Request**.
2. On the Study Information page, accept the default **PDF Request Name** (composed of the study name and the current date-time) or enter a different name.

   > **Tip:**
   >
   > The name can contain blank spaces, but no special characters. For example, Mass General Blank Forms 2.

3. Enter a **PDF Request Description** (optional).
4. From the **Select the site for the request** drop-down list, select a site.
5. Click **Next**.

   The Form Options page appears.

> **Tip:**
>
> To the right of most data entry fields is a Help icon (?). Click it to see data entry requirements. Dismiss this tooltip by clicking anywhere. Select the **Click here to see example** link to view the effects of selecting the option.

Step 2: Enter the form options

Show me how!

1. Complete the **Forms Options** page.

a. Enter **Header Text** to appear at the top of each form in the PDF output. The default is the study name.
b. Select a **Page Size**, either **Letter** (8-1/2 " by 11") or **A4** (European letter size: 210 x 297 mm).
c. Specify the **Blank Form Format**. See How can I handle blank forms?
d. To display bookmarks, headers, and labels in Japanese, select it from the **Headings Language** drop-down list.

2. Click **Next**.

   The PDF Request Settings page appears.

Step 3: Enter the PDF request settings

Show me how!

1. Enter the PDF Request Settings.
   - Use the **Include data as of date and time** setting to include all data available at the current date and time or up to (as of) the date and time you enter. The earliest date you can select is the enrollment date of the first subject. See How does the Include data as of date and time option affect the output?
   - **Export Selection Criteria**—Select **All Subjects** or click **By Subject** to select individual subjects. See How do I define the Export Selection Criteria?
   - To include blank forms (without clinical data), select the **Generate Blank Forms** setting.
   - To prevent comments from being added to the output PDF, select **Prevent Form Comments Changes**. Select **No** to allow comments and annotations.
   - To prevent contents from being copied from the output PDF, select the **Prevent Content Extracts and Copying** setting.
2. Click **Next**.

   The Review and Submit page appears.

> **Tip:**
>
> 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 archive. Oracle InForm CRF Submit generates a separate PDF for each subject.

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

1. Review your settings and click **Submit**.
2. To create another archive, click **Yes, Create Another** or, to process this archive request, click **No, Go to Site Archives**.

   The archive request appears on the Site Archives page. Its status is **Processing**.

3. To update the processing statistics shown, click **Refresh**.

When processing is complete, the status changes to **Available** and a **Download** link appears in the Download column.

PDF output options

In this section

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.

How do I define the Export Selection Criteria?

You define the Export Selection Criteria on the Request Settings page. The default for PDF requests is **All Subjects**. That choice includes everything in the study. The default for history reports is **All Sites**.

If you select **By Subject** or **By Site**, a page opens for you to make your selections.

To select subjects:
You can select subjects from multiple sites or import subject identifiers from a file.

1. (Optional) From the **Select a site to filter** drop-down list, limit the subjects shown to the selected site.
2. (Optional) In the **Select subjects from list below** text box, search for subjects by typing at least three characters of the subject ID.

   Only subjects enrolled prior to the as-of date appear in the list.
3. Using the **Shift** and **CTRL** keys, highlight the subjects you want to include, and click the right arrow to move the selected subjects to the **Selected List**.
4. To select subjects from another site, from the **Select a site to filter** drop-down list, select the site.
5. Follow the instructions in steps 2 through 4.
6. Click **Save**.

To select sites:

1. (Optional) In the **Select sites from list below** text box, search for a site by typing at least three characters of the site name.

   Only sites enrolled prior to the as-of date appear in the list.
2. Using the **Shift** and **CTRL** keys, highlight the sites you want to include, and click the right arrow to move the sites to the **Selected List**.
3. Continue selecting sites.
4. Click **Save**.

Can I cancel an archive request?

To cancel a PDF request, click the **Cancel Request** button.

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?

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 available archives and reports

Archives created by site users as well as archives and reports shared with sites by sponsors appear on the Site Archives page.

Show me how!

1. Click **Refresh** to update the page with the latest status of archives and reports.
2. To choose a site, on the Site Archives page select it from the drop-down list. If you have access to a single site, the site name appears at the top of the page.
3. (Optional) Filter the list by the information displayed in the various columns. Only those requests that match your filtering criteria appear.
4. (Optional) To include deleted requests, click **Include deleted requests**. To exclude deleted requests, click **Exclude deleted requests**.

   For each archive or report, the following columns of information appear.

   - **Checkbox**—Select to show the Request History and to limit the action to the selected request.
   - **Request Name**—The default or custom request name. Click to display request details.
   - **File Type**—The request type, including site archives and sponsor archives and history reports.
   - **Created By**—The user name of the person who created the request.
   - **Status**—Include **All** statuses or select a specific status from the drop-down list.

> **Tip:**
>
> To update the status, click **Refresh**.

- **Status Date**—The date and time on which processing was started. The time reflects the time zone of the browser used to create the request.
- **File Size (in MB)**—The size of the output.
- **Download**—To initiate a download, click **Download**. After the download, the date and time of the download appears in the Download column. The download date and time is an active link allowing you to download PDFs more than one time, if needed.
- **Confirmation**—The **Confirm** link appears dynamically If the archive or report requires confirmation. Confirm actions are tracked in the Site Confirmation report, which is only viewable by Sponsor users. See Confirm you have downloaded and reviewed an archive or report generated and shared by the sponsor.

Download archives and reports

Show me how!

1. Perform one of the following:
   - To download the entire archive, on the Site Archives page, click the **Download** link or the date of a previous download in the **Download** column.
   - To download an individual file from a site request, click **Request Name** to go to the Request Details page.
     a. Select the checkbox of a file with the **Ready for Download** state.
     b. Click **Download**.
2. **Save** the file(s). We recommend that you save the file(s) to a local machine and then extract the output from the downloaded ZIP file.

   > **Tip:**
   >
   > - The name of the ZIP file matches the request name.
   > - If the output exceeds 500 MB, Oracle InForm CRF Submit chunks the output into 500 MB files.

3. Extract the output from the ZIP file.

Tip:

- If you view files without extracting them in the ZIP tool, the hyperlinks in the files might not work correctly.
- For history requests, you will receive the request output in CSV format for use with a spreadsheet application.
- Requests are kept for 120 days after they are generated and then purged automatically. You can manually delete archives if you wish.

4. To return to the Site Archives page after the download, click **Return**.

Confirm you have downloaded and reviewed an archive or report generated and shared by the sponsor

When do I do this? A **Confirm** link appears dynamically in the Confirmation column if the Sponsor user who generated the archive or report requires confirmation that you have downloaded and reviewed it. Confirm actions are tracked in the Site Confirmation report, which is only viewable by Sponsor users.

Show me how!

1. Make sure that you have downloaded and reviewed the archive or report. The **Confirm** link does not appear on the Site Archives page until you have downloaded the shared-by-sponsor archive or report.
2. Click **Confirm**.

   Tip:

   If no **Confirm** link appears, the sponsor does not require you to confirm that you have downloaded the request or you do not have the right to confirm a download.

3. On the **Confirm Archival** dialog, select the checkbox and click **Submit**.
4. Click **OK**.

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

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.

Show me how!

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 the processing details

Why do this? If you need information about when an archive requested by a site user was processed, follow this procedure.

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

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

   - **Start Time**—Date and time processing of the archive started.
   - **Complete Time**—Date and time processing of the archive completed.
   - **File Type**—Type of information included in the output.
   - **File Name**—Name of the file generated.
   - **State**—Status of the archive request. The **Ready for Download** state is most likely the status that you will see.

2. To download a file within the archive, select the checkbox and click **Download**.

   > **Tip:**
   >
   > To download the entire archive, return to the Site Archives page, select the archive request and click **Download**.

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 do I do this? When a request fails, the status on the Site Archives page becomes **Failed**. Oracle InForm CRF Submit still creates a .ZIP file from which you can download any subjects for which the request succeeded, as well as a failure report. You can correct the request and resubmit the request.

> **Tip:**
>
> If available storage space is exceeded, archive requests will continue to fail. The status will be **Failed-out of storage space**. You can 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 checkbox, then click **Download**.
4. To resubmit a failed file:
   - Try resubmitting the file as is by selecting its checkbox 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

Why might I delete an archive? Although site archives over 120 days old are automatically deleted, you can quickly exhaust the space allocated to your site.

> **Tip:**
>
> You can only delete archives created by sites, not archives and reports shared by sponsors.

1. On the Site Archives page, locate the site request you want to delete. You can select Site Request from the **File Type** drop-down to list all site requests.
2. Click **Delete**.

3. From the list of site requests shown, select the request(s) to delete and click the right arrow.

> **Tip:**
>
> To delete all requests, don't make a selection. Click the double right arrow.

4. Click **Delete**.
5. Click **OK** to confirm the deletion and remove the archive(s) from the Site Archives page. The status of the request changed to **Deleted**.

> **Tip:**
>
> - The Request History includes the date and time of the deletion and who deleted the request. Click anywhere in the deleted request to display the Request History.
> - Shared archives and history reports with a **Deleted** status were deleted by the sponsor.

6. To keep deleted requests on the Site Archives page, click **Include Deleted Requests**.

Archives and reports shared by sponsors

In this section

- What information is shown on the Site Archives page?
- Is there a record of affidavits used to sign off on Oracle InForm data?

What information is shown on the Site Archives page?

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

- **Checkbox**—Select to show the Request History and to limit the action to the selected archive or history report.
- **Request Name**—The default or custom request name. For site requests, click to display request details.
- **File Type**—The request type, including site archive requests and sponsor archives and history report requests.
- **Created By**—The user name of the person who created the request.
- **Status**—Include **All** statuses or select a specific status from the drop-down list.

> **Tip:**
>
> To update the status, click **Refresh**.

- **Status Date**—The date and time on which the archive or history request was started. The time reflects the time zone of the creator's browser.
- **File Size (in MB)**—The size in MB of the archive or report.
- **Download**—To initiate a download, click **Download**. After the download, the date and time of the download appears in the Download column.
- **Confirmation**—The **Confirm** link appears dynamically If the archive or report requires confirmation. Confirm actions are tracked in the Site Confirmation report, which is only viewable by Sponsor users. See Confirm you have downloaded and reviewed an archive or report generated and shared by the sponsor.

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.