Oracle® Health Sciences InForm CRF Submit

User Guide for Sponsors

Release 6.3

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Oracle Health Sciences InForm CRF Submit User Guide for Sponsors, Release 6.3

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Contents

Preface

This preface contains the following sections:

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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.

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1 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 and history reports?

If you are using Oracle InForm 6.2 or higher:

1. Log into Oracle InForm 6.2.
2. On the toolbar, click **Archives**.

If you are using a prior version of Oracle InForm:

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

What is included in a PDF archive request?

For each PDF archive request, Oracle InForm CRF Submit creates subject casebooks or a set of unique forms that include:

- CRFs
- Visits
- Audit trails (including queries)

- Comments
- Signatures

What are the differences between the PDF request types?

- **Submission PDF**—The Submission PDF type is most suitable for PDF files to be included in submissions to a regulatory authority. Blank forms are also generated.
- **Archival PDF**—The Archival PDF request type is most suitable for PDFs that will represent study contents for archival purposes. Blank forms are also generated by default. Use this request type to create a mid-trial archive or final archive and share the archive with one or more sites. The sites can download their PDFs, examine them, and confirm that they have downloaded and reviewed the PDFs.
- **Blank Forms Only**—This option produces blank forms only (no completed subject forms).
- **Custom PDF**—This option gives you complete control over all settings as well as the ability to share the archive with sites and require confirmation.
- **Custom Blank Forms**—This option produces blank forms only, but allows you complete control over all settings that relate to blank forms.

What types of history reports are available?

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

- **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**—This report 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.

What data is included in archives and history reports?

Oracle InForm CRF Submit relies on the Oracle InForm rights groups to manage the data included in the archive and history report output. Depending on the rights group involved, particular data items might be hidden from users in that rights group.

The selection you make from the **Select the rights group to control content** drop-down list on the Archival, Custom, and Custom Blank Forms PDF Request Settings pages and for the Audit Trail Report determines the data included in the output. The default is the rights group of the user generating the request.

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 a PDF containing study data

In this chapter

Start with a test run

Why should I do this? Create a test run to confirm that your settings result in the desired archive. A test run is identical to a regular PDF request, except that the test run is limited to one subject and one study version.

Show me how!

> **Tip:**
>
> After you have downloaded and reviewed the output, you can select a test run from the Completed page proceed with the PDF request.

1. On any My Requests page, from the **Create Requests** drop-down menu, click **Create Test Run**.
2. On the **Study Information** page, specify a PDF request name and description.

   Click the **Help icon** (?) for details and sample output.
3. Select the PDF request type and click **Next**.
4. Complete the Forms Options page and click **Next**.
5. Select one subject or one study version.
   a. For Submission, Archival, and Custom PDFs, select a subject and click **Save**.
   b. For Blank Forms Only and Custom Blank Forms, select a study version and click **Save**.

6. Specify the Request Settings for the request type you specified. For details, see:
   - Create a submission archive for regulatory agencies
   - Create an archival PDF for a milestone or completed study
   - Create an archive with only blank forms
   - Create a custom archive
   - Create a custom archive with blank forms
7. Click **Next**.
8. Review your settings and click **Submit Test Run**.
9. Click **No, Go to Processing Page**.

   When complete, the test run PDF request moves to the My Requests - Completed page. **Yes** in the **Test Run** column identifies the request as a test run.
10. On the My Requests - Complete page, select the checkbox of the test run and click **Download**.

    (Optional) To edit this test run before downloading it, select the checkbox of the test run, click **Edit Test Run**, make changes, and submit the test run.
11. **Save** the file. We recommend that you save the file(s) to a local machine and then extract the output from the downloaded ZIP file.

    > **Tip:**
    >
    > If you view files without extracting them in the ZIP tool, the hyperlinks in the files might not work correctly.
12. Review the output.
13. Continue creating test runs or on the My Requests - Completed page, select a test run (has a **Yes** in the Test Run column) and click:
    - **Proceed with PDF Request** to edit the request options and settings and submit the request.
    - **Clone Test Run** to copy these settings to another test request.

    In either case, the Study Information, Form Options, and PDF Request Settings pages are populated with the values in the test run request. You can edit the settings before submitting the request.

What's next? Select the type of request you want to create and follow the directions in this chapter.

Create a submission archive for regulatory agencies

The Submission PDF type is most suitable for submissions to a regulatory authority. Blank forms are also generated.

Show me how!

> **Tip:**
>
> Create this archive as a test run to make sure that the PDF output contains the data that you need.

1. From the **Create Requests** drop-down menu, click **Create New PDF 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.
3. Enter a **Description** (optional), select **Submission PDF**, and click **Next**.
4. 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**—either one of each form or as a casebook containing all forms, even those that are repeated. See How can I handle blank forms?
   d. To display bookmarks, headers, and labels in Japanese, from the **Headings Language** drop-down list, select **Japanese**.
   e. In the **Footer Text** field, enter up to 30 characters to alternate left and right on all pages of the PDF output. If no footer is specified, the footer on each page of the PDF is ***Confidential***, along with page numbers; e.g., Page 1 of 115.
5. Click **Save**.
6. Enter the **Submission PDF request settings:**
   a. If the **Enable eTMF download** setting appears, select it to make the PDF output available where someone with the eTMF right can access it. See Can I make the PDF output available to an eTMF system?
   b. For **Audit Location**, identify the location of the audit trail history information in the PDF output: either after each form or at the end of the PDF.
   c. 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?
   d. For the **Export Selection Criteria** setting, select **All Subjects**, **By Subject**, or **By Site** and click **Save**. See How do I define the Export Selection Criteria? To select a large number of subjects, import them from a CSV (comma-separated value) file.
   e. Include or exclude **Candidate Queries**, preliminary queries issued by a sponsor user and visible only to other sponsor users.
   f. If you have a multilingual study, select the **Generate Linking Blank Forms** setting to link a blank form in another language to a study form. This enables a reviewer who is unfamiliar with the language on the original form to view the form structure in another language.
   g. Click **Save**.

7. Review your settings and click **Submit**.
8. To create another request, click **Yes, Create Another**, or to process this request, click **No, Go to Processing Page**.
9. You can monitor the progress on the My Requests - Processing page.
   - To update the processing statistics shown, click **Refresh**.
   - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
   - To cancel the request, select a request checkbox and click **Cancel**.

   When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
10. Select the checkbox and click **Download**.
11. Review the output.

> **Tip:**
>
> The PDF Request Name appears on lists of Processing, Completed, Saved, and Deleted PDF requests. The name can contain blank spaces, but no special characters. For example, Mass General Blank Forms.

Create an archival PDF for a milestone or completed study

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

Show me how!

> **Tip:**
>
> Create this archive as a test run to make sure that the PDF output contains the data that you need.

1. From the **Create Requests** drop-down menu, click **Create New PDF 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.
3. Enter a **Description** (optional), select **Archival PDF**, and click **Next**.
4. 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**—either one of each form or as a casebook containing all forms, even those that are repeated. See How can I handle blank forms?

d. To display bookmarks, headers, and labels in Japanese, from the **Headings Language** drop-down list, select **Japanese**.

e. In the **Footer Text** field, enter up to 30 characters to alternate left and right on all pages of the PDF output. If no footer is specified, the footer on each page of the PDF is ***Confidential***, along with page numbers; e.g., Page 1 of 115.

5. Click **Next**.

6. Enter the **Archival PDF request settings**:

   - If the **Enable eTMF download** setting appears, select it to make the PDF output available where someone with the eTMF right can access it. See Can I make the PDF output available to an eTMF system?

     > **Tip:**
     >
     > This option only can be set to Yes when **Share with Sites** is set to No.

7. Select the **Share with Sites** option to provide sites with archival PDFs to download. This field appears only if you have the Share with Sites right.

8. If you choose **Share with Sites**, select **Site Confirmation Required** if these PDFs are meant for final archiving, or an MHRA site audit, to require sites to confirm download and review of this request.

   a. Select the rights group with control over the content of the request type. The default is the logged-in user's rights group. See What do rights groups do?

   b. Select **Yes** for **Allow Any Site User to Download the Request Output** to allow any site user with Archives access to download request output. Select **No** to allow only site users assigned to the rights group selected for **Select the Rights Group to Control Content** to download the request output.

   c. For **Audit Location**, identify the location of the audit trail history information in the PDF output: either after each form or at the end of the PDF.

   d. 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?

   e. For the **Export Selection Criteria** setting, select **All Subjects**, **By Subject**, or **By Site** and click **Save**. See How do I define the Export Selection Criteria? To select a large number of subjects, import them from a CSV (comma-separated value) file.

   f. Include or exclude **Candidate Queries**, preliminary queries issued by a sponsor user and visible only to other sponsor users.

   g. To include blank forms (without clinical data), select the **Generate Blank Forms** setting.

   h. To prevent comments and annotations from being added to the output PDF, select the **Prevent Form Comments Changes** setting.

   i. To prevent contents from being copied from the output PDF, select the **Prevent Content Extracts and Copying** setting.

9. Click **Save**.

10. Review your settings and click **Submit**.
11. To create another request, click **Yes, Create Another** , or to process this request, click **No, Go to Processing Page**.
12. You can monitor the progress on the My Requests - Processing page.
    - To update the processing statistics shown, click **Refresh**.
    - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
    - To cancel the request, select a request checkbox and click **Cancel**.

    When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
13. Select the checkbox and click **Download**.
14. Review the output.

Create an archive with only blank forms

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

Show me how!

> **Tip:**
>
> Create this archive as a test run to make sure that the PDF output contains the data that you need.

1. From the **Create Requests** drop-down menu, click **Create New PDF 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.
3. Enter a **Description** (optional), select **Blank Forms Only**, and click **Next**.
4. 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**—either one of each form or as a casebook containing all forms, even those that are repeated. See How can I handle blank forms?
    d. To display bookmarks, headers, and labels in Japanese, from the **Headings Language** drop-down list, select **Japanese**.
    e. In the **Footer Text** field, enter up to 30 characters to alternate left and right on all pages of the PDF output. If no footer is specified, the footer on each page of the PDF is ***Confidential***, along with page numbers; e.g., Page 1 of 115.
5. Click **Next**.
6. Enter the **Blank Forms Only request settings**:

a. If the **Enable eTMF download** setting appears, select it to make the PDF output available where someone with the eTMF right can access it. See Can I make the PDF output available to an eTMF system?

b. 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?

c. To include all study versions, select **All** or select **Select from list** and choose one or more study versions and click **Save**.

7. Click **Save**.
8. Review your settings and click **Submit**.
9. To create another request, click **Yes, Create Another**, or to process this request, click **No, Go to Processing Page**.
10. You can monitor the progress on the My Requests - Processing page.
    - To update the processing statistics shown, click **Refresh**.
    - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
    - To cancel the request, select a request checkbox and click **Cancel**.

    When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
11. Select the checkbox and click **Download**.
12. Review the output.

Create a custom archive

This request type gives you complete control over all settings.

Show me how!

> **Tip:**
>
> Create this archive as a test run to make sure that the PDF output contains the data that you need.

1. From the **Create Requests** drop-down menu, click **Create New PDF 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.
3. Enter a **Description** (optional), select **Custom PDF**, and click **Next**.
4. 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**—either one of each form or as a casebook containing all forms, even those that are repeated. See How can I handle blank forms?

d. To display bookmarks, headers, and labels in Japanese, from the **Headings Language** drop-down list, select **Japanese**.

e. In the **Footer Text** field, enter up to 30 characters to alternate left and right on all pages of the PDF output. If no footer is specified, the footer on each page of the PDF is ***Confidential***, along with page numbers; e.g., Page 1 of 115.

f. In the **Display in the header** section, specify the additional information to include in the PDF header. The PDF header, by default includes:
   - Header Text
   - Form Name
   - Form Status
   - Subject No:
   - Generated By
   - Generated Time

g. Click **Next** to advance to the Custom PDF request settings page.

5. If the **Enable eTMF download** setting appears, select it to make the PDF output available where someone with the eTMF right can access it. See Can I make the PDF output available to an eTMF system?
6. Select the **Share with Sites** setting to provide sites with archival PDFs to download. This field appears only if you have the Share with Sites right.
7. If you choose **Share with Sites**, select **Site Confirmation Required** if these PDFs are meant for final archiving, or an MHRA site audit, to require sites to confirm download and review of this request.
8. Select the rights group with control over the content of the request type. The default is the logged-in user's rights group. See What do rights groups do?
9. Select **Yes** for **Allow Any Site User to Download the Request Output** to allow any site user with Archives access to download request output. Select **No** to allow only site users assigned to the rights group selected for **Select the Rights Group to Control Content** to download the request output.
10. Enter the **Data Format** options:
    a. Select **Include Bookmark Prefixes** to add a prefix (for example, CRF, Form, Visit, Study) to PDF bookmarks.
    b. For **Audit Location**, identify the location of the audit trail history information in the PDF output: either after each form or at the end of the PDF.
11. Specify **Subject and Site Selection** options:
    a. 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?
    b. For the **Export Selection Criteria** setting, select **All Subjects**, **By Subject**, or **By Site** and click **Save**. See How do I define the Export Selection Criteria? To select a large number of subjects, import them from a CSV (comma-separated value) file.

12. Enter the **Form and Visit** selection options:
    a. Include all study forms or selected forms in a clinical study. If you include selected forms, you cannot limit the PDF to selected visits.
    b. Include all study visits or selected study visits in a clinical PDF. If you include selected visits, you cannot include selected forms.

       To include common forms across visits you must select the cross visit entry or the forms will be missing from the output.
       i. Select the **Select from list** radio button.
       ii. From the **Select visits from list below** list, select the cross-trial visit. It might be labeled something similar to **Common (Cross Trial)**.
       iii. Use the right-arrow to move it to the **Selected List**.
       iv. Click **Save**.
13. Specify **Study Content** options:
    a. For the **Transferred Subjects in Current Site Only** option, select **Yes** to create a PDF for a transfer patient in just the current site. Select **No** to create a PDF for both the originating and the current site. A Subject Record Transfer History document is generated along with the PDF output.
    b. To omit forms without data, select **Suppress Empty Clinical Forms**. Select **No** to include all forms, even if they contain no data.
    c. To omit visits without data, select **Suppress Empty Clinical Visits**. Select **No** to include all visits, even if they contain no data.
    d. Include or exclude **Candidate Queries**, preliminary queries issued by a sponsor user and visible only to other sponsor users.
14. To further refine your request, specify these **Additional Content** options:
    a. To include blank forms (without clinical data), select the **Generate Blank Forms** setting.
    b. If you have a multilingual study, select the **Generate Linking Blank Forms** setting to link a blank form in another language to a study form. This enables a reviewer who is unfamiliar with the language on the original form to view the form structure in another language.
    c. To create a table of contents as a separate file with links to all generated patient PDFs in the request, select **Generate TOC**, which is the default choice. The table of contents is sorted by site and then by subject.
    d. To include the Protocol Guide and the CRF Help in the output, select **Protocol Guide**. Each of these items is a separate PDF.
15. Specify **Security** options:
    a. To require a password to make changes to the PDF, select **Prevent Form Changes**. Select **System-created: Hidden** to permanently prevent form changes to the PDF. Select **No** to allow PDF output to be modified.
       - This selection disables the **Prevent Form Comments Changes** and **Prevent Content Extracts and Copying** options.
       - Passwords are not saved in the application and must be retained.
       - This option cannot be selected if you select **Share with Sites**.
    b. To prevent comments from being added to the output PDF, select **Prevent Form Comments Changes**. Select **No** to allow comments and annotations.

   c. To prevent contents from being copied from the output PDF, select the **Prevent Content Extracts and Copying** setting.

16. Click **Next**.
17. Review your settings and click **Submit**.
18. To create another request, click **Yes, Create Another**, or to process this request, click **No, Go to Processing Page**.
19. You can monitor the progress on the My Requests - Processing page.
    - To update the processing statistics shown, click **Refresh**.
    - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
    - To cancel the request, select a request checkbox and click **Cancel**.

    When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
20. Select the checkbox and click **Download**.
21. Review the output.

> **Tip:**
>
> Save time and increase consistency when you need to create multiple custom archives by saving these settings as a template. To do this:
>
> 1. On the **Review and Submit** page, click **Save as New Template**.
> 2. Enter a unique name for the template and a description.
> 3. Click **Save**.

Create a custom archive with blank forms

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

Show me how!

> **Tip:**
>
> Create this archive as a test run to make sure that the PDF output contains the data that you need.

1. From the **Create Requests** drop-down menu, click **Create New PDF 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.
3. Enter a **Description** (optional), select **Custom Blank Forms PDF**, and click **Next**.
4. 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**—either one of each form or as a casebook containing all forms, even those that are repeated. See How can I handle blank forms?

d. To display bookmarks, headers, and labels in Japanese, from the **Headings Language** drop-down list, select **Japanese**.

e. In the **Footer Text** field, enter up to 30 characters to alternate left and right on all pages of the PDF output. If no footer is specified, the footer on each page of the PDF is ***Confidential***, along with page numbers; e.g., Page 1 of 115.

5. Click **Next** to advance to the **Request Settings** page.

6. If the **Enable eTMF download** setting appears, select it to make the PDF output available where someone with the eTMF right can access it. See Can I make the PDF output available to an eTMF system?

7. In the **Data Format** section, select **Include Bookmark Prefixes** to add a prefix (for example, CRF, Form, Visit, Study) to PDF bookmarks.

8. Specify **Additional Content** options:

   a. 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?

   b. To include all study versions, select **All** or select **Select from list** and choose one or more study versions and click **Save**.

9. Enter **Security Options**:

   a. To require a password to make changes to the PDF, select **Prevent Form Change**. Select **System-created: Hidden** to permanently prevent form changes to the PDF. Select **No** to allow PDF output to be modified.

      - This selection disables the **Prevent Form Comments Changes** and **Prevent Content Extracts and Copying** options.
      - Passwords are not saved in the application and must be retained.

   b. To prevent comments from being added to the output PDF, select **Prevent Form Comments Changes**. Select **No** to allow comments and annotations.

   c. To prevent contents from being copied from the output PDF, select the **Prevent Content Extracts and Copying** setting.

10. Click **Next**.

11. Review your settings and click **Submit**.

12. To create another request, click **Yes, Create Another**, or to process this request, click **No, Go to Processing Page**.

13. You can monitor the progress on the My Requests - Processing page.

    - To update the processing statistics shown, click **Refresh**.
    - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.

- To cancel the request, select a request checkbox and click **Cancel**.

When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.

14. Select the checkbox and click **Download**.
15. Review the output.

Download the PDF output for an archive

Show me how!

1. Perform one of the following:
   - To download an entire request, on the My Requests - Completed page, select the checkbox on the archive or history request you want and click **Download**.
   - To download individual subjects or files, click the **Request Name** to go to the Request Details page, then select the checkbox and click **Download**. You must download these files one at a time.

   > **Note:**
   >
   > When a request fails, Oracle InForm CRF Submit creates a .zip file containing those PDFs generated successfully. You can download all successfully generated PDFs from the Completed page as well as a a failure report that lists the failures (`FailureReport.txt`).

2. **Open** or **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. If you view files without extracting them in the ZIP tool, the hyperlinks in the files might not work correctly.

> **Tip:**
>
> Archives are kept for 120 days after they are generated and then purged automatically. You can manually delete archives if you wish.

Create a custom template

You can create a template from a custom archive request.

1. Follow steps 1 through 16 in Create a custom archive.

2. On the Review and Submit page, click **Save as New Template**.
3. Enter a unique name for the template and a description.

> **Tip:**
>
> The description tells other users what's in the template.

4. Click **Save**.

Create a PDF archive from a template

1. From the **Create Requests** drop-down menu on any My Requests page, select **Create from Templates**.
2. Enter the PDF request name and description.
3. From the **Select Custom Template** drop-down list, select a template.
4. Click **Next**.
5. Step through the Forms Options and PDF Request Settings pages.

   These have been prepopulated with the values from the template you selected. Note that you cannot change the security options associated with adding comments to PDF output and copying content.
6. Click **Next**.
7. On the Review and Submit page, click **Submit**.

> **Tip:**
>
> Manage templates from the **Templates** menu on the left. To save the changes to a new template, on the **Review and Submit** page, click **Save as New Template**, specify a new name and description, and click **Save**.

PDF output options

In this section

- How can I handle blank forms?
- Can I make the PDF output available to an eTMF system?
- Can I generate archives and history report headers in Japanese?
- How does the Include data as of date and time option affect the output?
- How do I define the Export Selection Criteria?
- How do I enter a large number of subjects?
- Can I save a request?
- What do rights groups do?
- How do I prevent hidden Oracle InForm data from appearing?
- What PDF format is applied to PDF output?

- Why should I create a custom template?
- Can I create a ZIP file even if Oracle InForm CRF Submit encounters errors?

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 make the PDF output available to an eTMF system?

An eTMF download allows an Oracle InForm user with the eTMF right to retrieve it and load it into an electronic trial master file (eTMF) system.

eTMF users can't perform any other archive or history report activities and do not have access to the study data.

> **Note:**
>
> The option appears only if eTMF download has been enabled on the Settings page. See Specify trial settings.

Can I generate archives and history report headers in Japanese?

Oracle InForm CRF Submit is Unicode-based and supports PDF and history 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 or history report, 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 site:

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**.

How do I enter a large number of subjects?

> **Tip:**
>
> - This option is available for Submission, Archival, and Custom PDF requests.
> - To use the import feature, you must use Microsoft Internet Explorer 11 or higher, or another browser supported by Oracle InForm.

To use the import feature:

1. On the PDF Request Settings page, in the **Export Selection Criteria** field, select **By Subject**.
2. In the **Select Subjects** dialog box, click the **Import Subjects** tab.
3. Select the **CSV** (comma-separated value) file to import from your directory by clicking **Browse** and locating the file. The CSV file cannot be greater than 1MB.
4. Click **Import**.
5. Click **Save**.
6. Complete the PDF request.

To create the CSV file:

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

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

- 100012,LLL

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

- 11510,2333
- 2333,012-001
- 22486,012-003

Can I save a request?

A saved-but-not-submitted PDF request is visible only to the user who created it and persists across sessions.

- On the Review and Submit page, instead of Submit, click **Save**.

What do rights groups do?

The rights group controls what data will and will not appear on the PDF. Items hidden from sites will not be added to the PDF if a site user rights group is selected.

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

How do I prevent hidden Oracle InForm data from appearing?

When you create Archival, Custom, and Custom Blank Forms archives or an Audit Trail report and share the output with sites, the PDF Request Settings page includes the option of choosing a different rights group than the one to which you belong.

This creates a subset of the items your rights group and the selected rights group are able to see in the PDF output.

> **Note:**
>
> Only site users that belong to the rights group selected will be able to download the PDFs once generated. The PDFs will not be visible to users belonging to other rights groups.

To include all data items, you must be logged in with a rights group that has been set up to see all items present in the study design. The rights group needs Read-Only or Editable display overrides to any item that is hidden by design default.

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

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

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.

Why should I create a custom template?

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

Can I create a ZIP file even if Oracle InForm CRF Submit encounters errors?

If a request results in a Failed status, Oracle InForm CRF Submit still generates a ZIP file containing all successfully generated PDFs. You can download this ZIP file from the My Requests - Completed page. The ZIP file contains a report, *FailureReport.txt*, which contains details for any file that failed. You can use the details in this report to generate a new request. If the failure continues, provide the report to Oracle Support.

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 Create reports on data changes and users' access

In this chapter

When would I create a history report?

Some regulatory agencies require the following reports:

- **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**—This report 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.

Sponsors can generate these reports by going to the My Requests - Processing page and selecting **Create History Request** from the **Create Request** drop-down menu.

By selecting the **Share with Sites** option and **Site Confirmation Required** option, you can request the sites to acknowledge the receipt of the file.

The file is in CSV format for import into Microsoft Excel.

- For the Audit Trail 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 or by subject.
- For the User Assignment History report, one CSV file is generated per site and the entire request can be downloaded as one zipped file.

Create an Audit Trail Report

The 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.

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, & SDVComplete
- Date SDVReady, SDVPartial, & SDVComplete are deleted

1. On any My Requests page, from the **Create Requests** drop-down, select **Create History Request**.
2. On the Study Information page, accept the default **Request Name** (composed of the study name and the current date-time) or enter a different name.

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

3. Enter a **Description** (optional).
4. Select **Audit Trail Report**, and click **Next**.
5. Enter the **Request Settings**:
   - **Headings Language**—The language to use for bookmarks, headers, and labels.
   - **Share with Sites**—Select **Yes** to provide sites with the Audit Trail Rreport. This field appears only if you have the Share with Sites right.
   - **Site Confirmation Required**—If the report is meant for final archiving, or an MHRA site audit, select **Yes** to require sites to confirm download and review of this report.
   - **Select the rights group to control content**—Select the rights group with control over the content of the request type. The default is the logged-in user's rights group. See What do rights groups do?
   - **Allow Any Site User to Download the Request**—Select **Yes** to allow any site user with Archives access to download request output. Select **No** to allow only site users assigned to the rights group selected for **Select the Rights Group to Control Content** to download the request output.
   - **Generate TOC**—Create a table of contents as a separate file with links to all generated records in the report. The default is **Yes**.
   - Include or exclude **Candidate Queries**, preliminary queries issued by a sponsor user and visible only to other sponsor users.
   - **Select Date Range**—Enter the date range the report should cover in the **From** and **To** fields.

- **Selection Criteria**—Customize the report by selecting the history to include for each item. Click the right-arrow and move items from the **Available List** to the **Selected List**.

6. Click **Next**.
7. Review your settings. You can view your selection criteria. You can also print the settings or go back and change settings.
8. Click **Submit**.
9. To create another request, click **Yes, Create Another** , or to process this request, click **No, Go to Processing Page**.
10. You can monitor the progress on the My Requests - Processing page.
    - To update the processing statistics shown, click **Refresh**.
    - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
    - To cancel the request, select a request checkbox and click **Cancel**.

    When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
11. Select the checkbox and click **Download**.
12. Review the output.

    The file is in CSV format for import into MS Excel. One folder per site with one .CSV file per subject within each site is generated.

Create a User Assignment History report

1. On any My Requests page, from the **Create Requests** drop-down, select **Create History Request**.
2. On the Study Information page, accept the default **Request Name** (composed of the study name and the current date-time) or enter a different name.

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

3. Enter a **Description** (optional), select **User Assignment History**, and click **Next.**
4. Enter the **Request Settings**:
    - **Headings Language**—The language to use for bookmarks, headers, and labels.
    - **Share with Sites**—Select **Yes** to provide sites with this history report to download. This field appears only if you have the Share with Sites right.
    - **Site Confirmation Required**—Select **Yes** to require sites to confirm download and review of this report.

- **Generate TOC**—Create a table of contents as a separate file with links to all generated records in the report. The default is **Yes**.
- 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 Sites** or **By Site** and click **Save**. See How do I define the Export Selection Criteria?

5. Click **Next**.
6. Review your settings and click **Submit**.
7. To create another request, click **Yes, Create Another**, or to process this request, click **No, Go to Processing Page**.
8. You can monitor the progress on the My Requests - Processing page.
   - To update the processing statistics shown, click **Refresh**.
   - To pause processing, select a request checkbox and click **Pause**. To resume processing, click **Resume**.
   - To cancel the request, select a request checkbox and click **Cancel**.

   When the request disappears from the My Requests - Processing page and moves to the My Requests - Completed page, processing is complete.
9. Select the checkbox and click **Download**.
10. Review the output.

    The file is in CSV format for import into MS Excel. One CSV file is generated per site and the entire request can be downloaded as one zipped file.

Download a history report

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

   The browser prompts you to **Open** or **Save** the file. We recommend that you save the file(s) to a local machine and then extract the output from the downloaded ZIP file.
2. Click **Save** to save the output to your local machine at the designated location.
3. Extract the output from the ZIP file.
   - The name of the ZIP file matches the request name.
   - The file is in CSV format for import into MS Excel. One ZIP file is created and includes all sites.

> **Tip:**
>
> If you view files without extracting them in the ZIP tool, the hyperlinks in the files might not work correctly.

4 Manage archives and history reports

In this chapter

Display the options and settings

Why do this? When reviewing a test run or archive or report, it is useful to see the request details.

Show me how!

1. On the My Requests - Processing, My Requests - Completed, My Requests - Saved, or My Requests - Deleted page, select the request checkbox and click **Show Settings**.
2. Review the request details:
   - If you selected specific subjects, sites, or visits, you can click a link to see your selections.
   - To print the settings, click **Print**.
3. To return to the My Requests page, click **Close**.

View the processing details

Why do this? If you need information about when an archive or history report was processed, follow this procedure.

Show me how!

1. On the My Requests - Completed or My Requests - Deleted page, click the **Request Name** to get to the Request Details page.

   The following information about the archive and report requests appears. 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 archive or report request.

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

Resubmit a failed request

When do I do this? When a request fails, the status on the My Requests - Completed 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, requests will continue to fail. The status will be **Failed-out of storage space**. You can delete outdated or downloaded archives and reports.

1. On the My Requests - Completed page, locate a 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 an archive or report

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

> **Tip:**
>
> You can see who deleted a request on the Processing - Deleted page in the Deleted By column. For auto-deleted requests, you will see `"System."`

1. On the My Requests - Completed or My Requests - Saved page, click **Delete**.
2. On the Select Requests page, from the list on the left, select the archive and report requests to delete and click the right arrow to move them to the Selected List.

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

3. Click **Delete**.
4. Click **OK** to confirm the deletion.
   - Oracle InForm CRF Submit removes all stored output from the request and moves the request to the My Requests - Deleted page. The information used to generate the output is not removed from the database.
   - If this was a shared-with-sites request, the request is also deleted from the Site Archives page.

Verify the site has downloaded, reviewed, and confirmed the archive or report

View the Site Confirmation report to see which site user(s) have clicked **Confirm** after they have downloaded and reviewed the PDFs.

Show me how!

1. From the **Reports** section on the left, select **Site Confirmation**.

   > **Tip:**
   >
   > If you don't see the archive or report, it might not have been shared with sites.

2. Download the Site Confirmation report as a **CVS** file or a **PDF**.

   Both the PDF and CSV output include:
   - Sponsor name (if selected).
   - Report title: CRF Submit Site Confirmation Report and the date of the report.
   - Study name.
   - Username of the person who downloaded the report and when (date and time).

- Report Filter Criteria and whether or not the value was applied to the report:
  - Request Name
  - Request Type
  - Published Time (GMT)
  - Site Name
  - Confirmed By
  - Confirmation Time (GMT)

  If the filter has not been applied, the word, `None`, appears.

Additionally:

- The file name includes the date or range of dates covered in the report .
- Submission, Archive, and Custom Archive PDFs include the signature affidavit text.

3. The browser prompts you to **Open** or **Save** the file. We recommend that you save the report to a local machine.
4. Click **OK**.
5. Review the information.

Monitor request notices

Why should I do this? View notifications to see when archive and report requests have completed, failed, or been downloaded.

> **Tip:**
>
> You must activate this feature on the Settings page.

1. In the **Notifications** section on the left, click **Request Notices**.
2. (Optional) Filter the information within each column heading:
   - **Request Name**—Default or user-defined name for the request. Click the **Request Name** to display the request on the My Requests-Completed page.
   - **Notification Type**—Status or action with which the email notification is associated (for example, Completed or Failed).
   - **Email Sent**—The date and time when the email notification was sent (in GMT).
   - **Email Status**—Message status. For example: Sent means the email notification was sent successfully.
3. To view the notification details, click the **Details** link in the Details column to see:
   - **Subject**—Subject line of the email message.
   - **Body**—Content of the message.
   - **Email Sent**—Date and time the notification was sent.
   - **Sender**—The email address of the sender.

- **Recipient**—The email address of the person who received the message.
- **Sent**—Status of the notification. For example, Sent or Failed.

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

Check how much storage you have used

The Request Overview report shows the storage used, a progress meter comparing allocated storage with total storage used, and suggestions on how to reduce storage.

How often should I do this? Use this procedure when you are concerned that your archive is so large that the allocated space will be exhausted.

Show me how!

1. From the **Reports** section on the left, select **Request Overview**.

   A progress meter in the upper right corner shows how much storage has been allocated and used.

   - If the total used versus allocated is 75% or less, the progress bar is green.
   - If the total used versus allocated is between 75% and 90%, the progress bar is yellow.
   - If the total used versus allocated is >90%, the progress bar is red.

   > **Note:**
   >
   > The warning threshold defaults to 75%.

2. (Optional) From the **Date Range** drop-down list, select a reporting interval.
3. (Optional) Filter the list by typing a specific study in the **Study Name** text box, or click a column header to sort the requests by that statistic.
4. To see how to clear storage or request space, click the Help icon to the right of the progress bar.

> **Tip:**
>
> - When you log into Oracle InForm and select **Archives**, users with rights to generate, administer, delete, or view requests see an alert at the top of the screen when storage space is running low.
> - While entering requests, when 75 percent of the storage has been reached or exceeded, Oracle InForm CRF Submit sends an email alert to sponsor users with Generate, Delete, Administer, and View Other Requests rights.
> - To delete requests that have been downloaded or are outdated, see Delete an archive or report.

Review usage statistics across studies

Show me how!

1. From the **Reports** section on the left, select **Request Overview**.
2. Review the processing and storage statistics shown.

> **Tip:**
>
> Based on the data in this report, you can delete files that are no longer needed from the trials.

View the Download Log

When should I do this? Create a Download Log for a trial after the Oracle InForm trial is decommissioned. During decommissioning, all references to the decommissioned trial are deleted from the Oracle InForm CRF Submit database. By creating a Download Log, you can preserve the trial information for future use or reference.

Show me how!

1. From the **Reports** section on the left, select **Download Log**.

   > **Tip:**
   >
   > The report contains all the downloads, but you can filter the content, as shown in Step 2, and then generate the filtered log.

2. (Optional) Filter the list by typing a specific value in the text boxes associated with the column headers or selecting a date or file type. For example, type a specific request name in the **Request Name** text box.

   > **Tip:**
   >
   > Your filter selections appear in a header section at the top of the spreadsheet.

3. Review the information about the output file as well as the date and time of the download in GMT.
4. To download the report, click **Download as CSV** (Excel spreadsheet).
5. **Open** or **Save** the file. We recommend that you save the report to a local machine.

Archives and reports shared by sponsors

In this section

- Can I list the archives and reports shared with sites?

- How do I see which sites have confirmed they downloaded and reviewed an archive or report?
- Is there a download log to meet HIPAA requirements?
- Is there a record of affidavits used to sign off on Oracle InForm data?

Can I list the archives and reports shared with sites?

The Site Notices page lists requests created by sponsors and downloaded by sites.

1. From the **Notifications** section on the left, click **Site Notices**.
2. (Optional) Filter the information within each column heading:
   - **Request Name**—Default or user-defined name for the archive or report request.
   - **Notification Type**—Action the notification is about (for example, Create or Download).
   - **Site Name**—Site that initiated the request or performed the download.
   - **Site User**—User name of the person who generated the request.
   - **Email Sent**—Date and time the notification was sent.
   - **Email Status**—Notification status (for example, Sent or Failed).
   - **Source**—Whether this was a Site or Sponsor request.
   - **Details**—A link to display the email message.
3. To view the notification details, click the **Details** link in the Details column to see:
   - **Subject**—Subject line of the email message.
   - **Body**—Content of the message.
   - **Email Sent**—Date and time the notification was sent.
   - **Sender**—The email address of the sender.
   - **Recipient**—The email address of the person who received the message.
   - **Sent**—Status of the notification (for example, Sent).
4. To close the Details window, click the **X** in the upper right corner.

How do I see which sites have confirmed they downloaded and reviewed an archive or report?

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

The Site Confirmation report is only viewable by Sponsor users belonging to a rights group with the View Download Confirmation right enabled.

Is there a download log to meet HIPAA requirements?

According to HIPAA, a log of electronic downloads is required for data containing electronic protected health information (ePHI).

The **Download Log**, available from the Reports menu at the left, contains all sites for the study. The log is saved in CSV format and is available until the trial is decommissioned. You can download the log as a spreadsheet.

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.

5 For administrators: Set up and manage a trial and users

In this chapter

- What can administrators do?
- Add Oracle InForm CRF Submit Archival Rights to an Oracle InForm rights group
- Specify trial settings
- Specify sponsor settings
- Rights management

What can administrators do?

If you have administrative rights, in addition to archive/report creation rights, the Manage and Reports administrative sections appear on the left. If you only have administrative rights, the Admin page appears when you log into Oracle InForm. You cannot generate archives and reports.

Administrative activities include:

- Managing rights groups.
- Specifying trial settings.
- Setting up email notifications.
- Running reports, including the Request Overview report, Site Confirmation report, and Download Log.

Add Oracle InForm CRF Submit Archival Rights to an Oracle InForm rights group

> **Note:**
>
> This procedure is for use with Oracle InForm 6.2 and earlier. If you are using Oracle InForm 6.1 or later, you perform this task with the Oracle InForm User Management Tool (UMT). See Managing users in the *User Management Tool User Guide*. You must have the InForm Manage Rights Group right to perform this task.

Show me how!

1. Log into Oracle InForm as an administrator.
2. On the InForm Home page, click the **Archives** link below the Oracle InForm icons.

3. From the **Manage** section on the left, select **Rights Group**.
4. Select the radio button of the rights group to add Archival rights to.
5. Click **Edit**.
6. Select and deselect the checkboxes of the Archival rights as desired.

> **Note:**
>
> You can assign a site user the Confirm Archives right without the Generate Archives right.

7. Click **Save**.

> **Note:**
>
> If you assign additional Oracle InForm CRF Submit archival rights to a user, that user must log out and back in for the rights to be applied.

Specify trial settings

Why is this important?

- To reduce storage space by keeping the maximum number of subjects per request low.
- To send email notifications upon request completion or failure.
- To enable the eTMF download option.

Show me how!

1. From the **Manage** section on the left, select **Settings**.
2. Click the **Trial Settings** tab.
3. Accept or change the trial settings and click **Save**.
   - **Maximum Subjects per PDF Request by site user**—Enter the maximum number of subject PDF files (between 1 and 25) that a site user can include in a single PDF request.
   - **Send email on request completion**—Activate email notifications to the email address associated with the user. For a sponsor user with no email address, the default email address is used. For a site user with no email address, no notification is sent.
   - **Default Email Address**—Enter the default email address for notifications.
   - **Enable eTMF download**—Enable a rights group with the eTMF right to retrieve output for loading into an eTMF application.
   - **Give priority to InForm**—Limit the concurrent data generation of output for the trial so that InForm activities take priority.

   Changes to settings are audited and logged in the Oracle InForm CRF Submit database.

Specify sponsor settings

Why is this important? To customize PDF and reports confirmation text.

1. From the **Manage** section on the left, select **Settings**.
2. Click the **Sponsor Settings** tab.
3. To accept the default confirmation text or reset the confirmation to the default text, select the **Use default text** checkbox.
4. To customize the confirmation text:
   a. Make sure that **Use default text** isn't selected.
   b. Enter both the PDF and history request confirmations in both English and Japanese. You must include English and Japanese confirmation text for both PDF request confirmations and report confirmations.
      - You can enter up to 1000 characters.
      - You don't have to include the request/report identification information. Oracle InForm CRF Submit appends the request name, trial name, site name, and mnemonic at the beginning of the confirmation.
      - If you are not translating the trial forms into Japanese, you can leave the default Japanese translations in place instead of translating your custom text.
5. Click **Save**.

Rights management

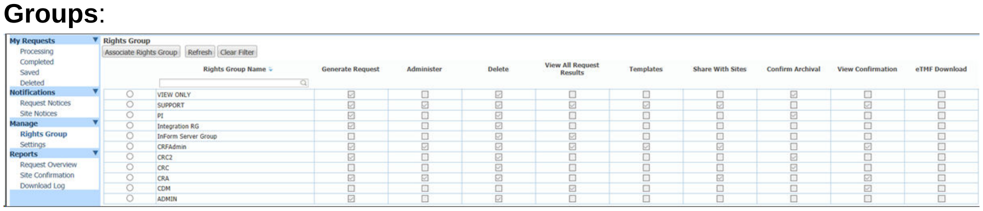
In this section

- Where are rights controlled?
- What are the nine archival rights and how should I assign them?
- How do the archival rights interact for sponsor users?
- How do the archival rights interact for site users?

Where are rights controlled?

For Oracle InForm versions before 6.2

- Access is controlled by the CRFAdmin via the Oracle InForm CRF Submit interface in Oracle InForm by going to the **Manage** menu and selecting **Rights Groups**:

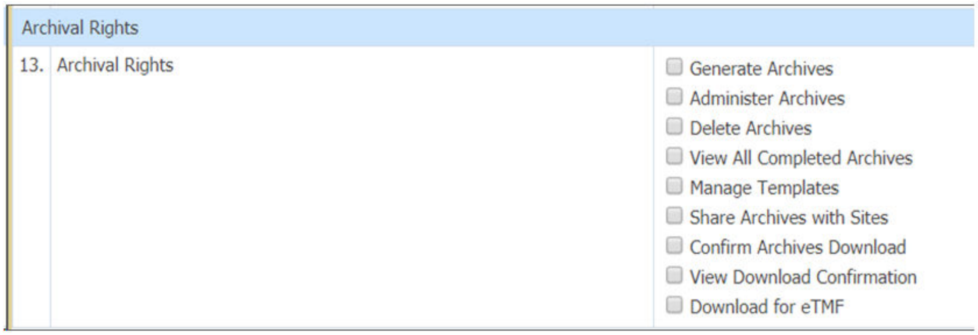


- The CRFAdmin can:
  – Enable/disable rights for already associated rights groups.

  – Grant other rights groups access by using **Associate Rights Group**.

For Oracle InForm versions after 6.2:

- Access is controlled by the Oracle InForm User Management Tool Admin via the Oracle InForm User Management Tool interface.
- The Oracle InForm User Management Tool Admin can assign any of the following rights to any rights group:



- The Services team can provide details for best practice setup for each rights group.

What are the nine archival rights and how should I assign them?

The following Oracle InForm CRF Submit archival rights can be added to Oracle InForm rights groups in Oracle InForm User Management Tool:

- **Generate Archives—**Generate archival PDFs based on the user's Oracle InForm account configuration.
- **Administer Archives—**Configure Oracle InForm CRF Submit. The CRFAdmin is the only rights group that can do this.
- **Delete Archives—**Delete a request. Users can only delete their own requests.
- **View All Completed Archives—**(For sponsor users) See all completed requests, including those generated by other users.
- **Manage Templates—**Create, edit, and use Oracle InForm CRF Submit request templates.
- **Share Archive with Sites—**Sponsor users with this right can share PDFs with Site users. Site users with Archives access will be able to log into Oracle InForm and download the PDFs.
- **Confirm Archives Download—**Although it is typical for those who can sign CRFs and casebooks are the same people that can accept/confirm they have received the PDFs, this right allows site users to download requests without the right to generate requests.
- **View Download Confirmation—**View a report showing which sites have accepted their PDF archives.
- **Download for eTMF—**Make the PDF output available where someone with the eTMF right can access it. An eTMF download allows an InForm user with the eTMF right to retrieve it and load it into an electronic trial master file (eTMF) system. If you choose this right, you cannot select any other archival rights.

How these rights interact

If you choose the Download for eTMF right, you cannot select any other archival rights.

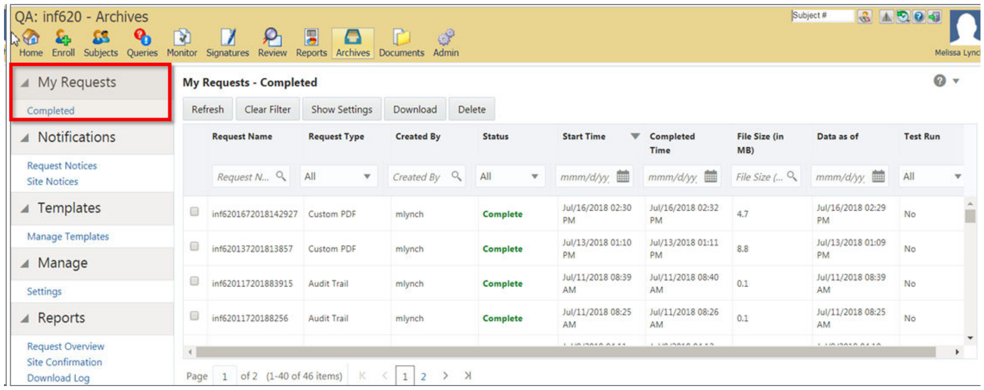
Typical rights assignments

The table below shows the nine rights and the rights groups to which they are typically assigned.

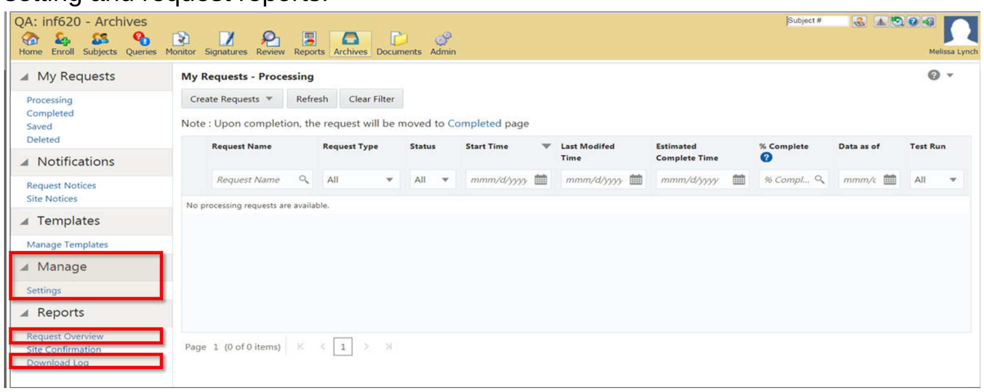
Oracle InForm CRF Submit Right	CRC	PI	Sub-I	CRA	CDM	Project Manager	Medical Monitor	View Only	CRF Admin	CRF Unblinded
Generate Archives	X	X	X	X	X	X	--	--	X	X
Administer Archives	--	--	--	--	--	--	--	--	X	--
Delete Archives	X	X	X	X	X	X	--	--	X	X
View All Completed Archives	--	--	--	--	--	--	--	--	--	X
Manage Templates	--	--	--	--	--	--	--	--	X	--
Share Archives with Sites	--	--	--	--	X	--	--	--	X	X
Confirm Archives Download	--	X	X	--	--	--	--	--	--	--
View Download Confirmation	--	--	--	--	X	X	--	--	X	X

How do the archival rights interact for sponsor users?

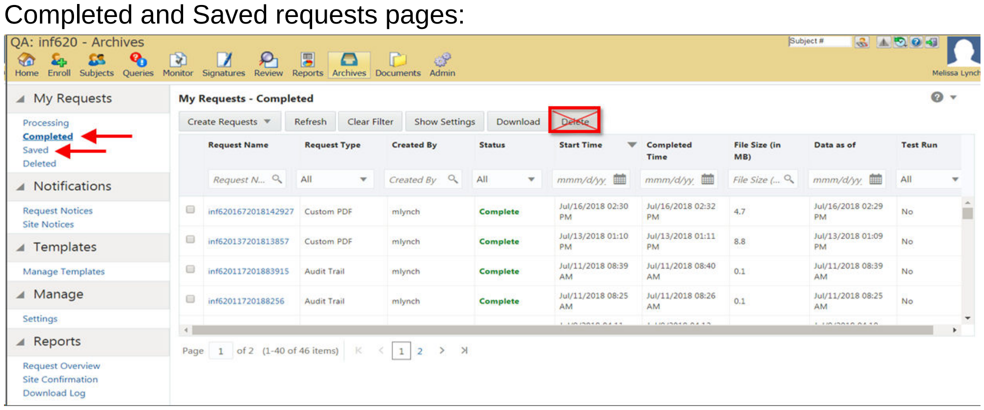
- **If you remove the Generate Archives right**, only Completed requests are available:



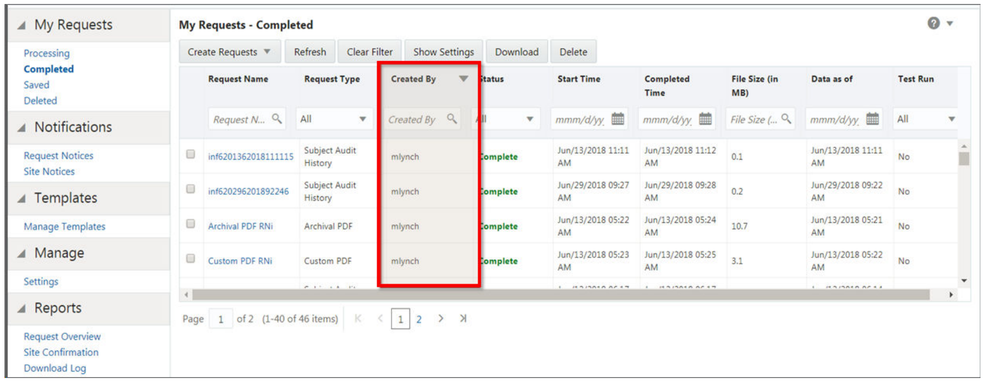
- **If you remove the Administer Archives right**, the user can no longer manage setting and request reports:



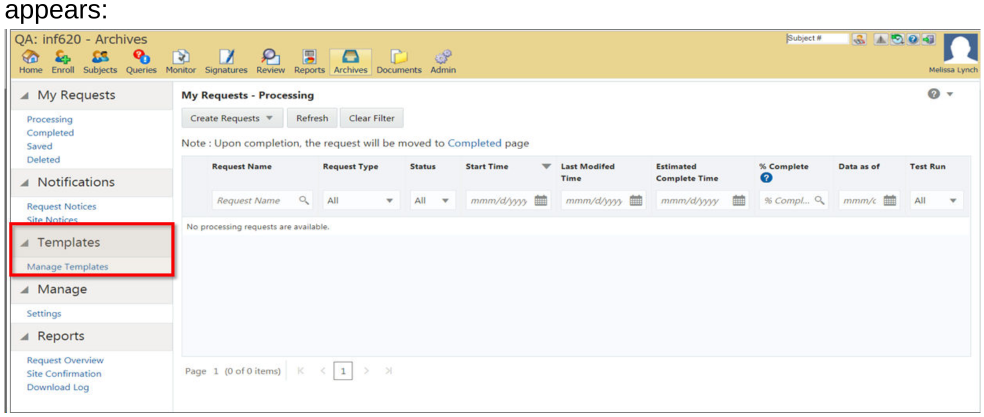
- **If you remove the Delete Archives right**, the Delete option is removed from the Completed and Saved requests pages:



- **If you remove the View All Completed Archives right**, users can see only their requests:



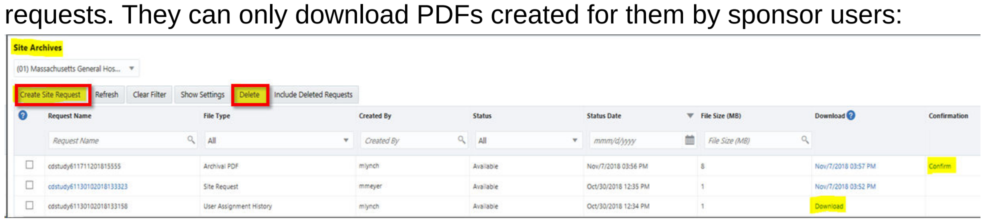
- **If you remove the Manage Templates right**, the Templates menu no longer appears:



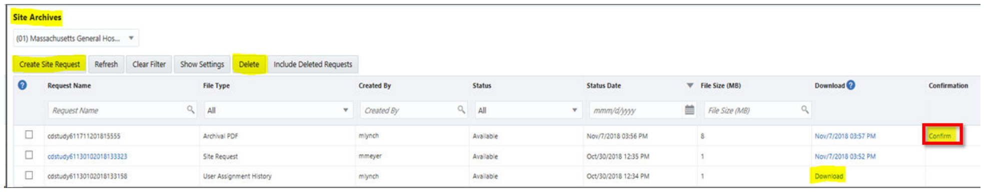
- **If you remove the Share Archives with Sites right**, the **Share with Sites** option no longer is available for Archival and Custom requests:

How do the archival rights interact for site users?

- **If you remove the Generate Archives right**, site users cannot create site requests. They can only download PDFs created for them by sponsor users:



- **If you remove the Confirm Archives Download right**, site users cannot confirm PDF downloads:


Site Archives
(01) Massachusetts General Hos...
Create Site Request
Refresh
Clear Filter
Show Settings
Delete
Include Deleted Requests
Request Name
File Type
Created By
Status
Status Date
File Size (MB)
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Download