

Oracle® Life Sciences InForm CRF Submit User Guide for Sponsors



Release 7.0.1.4
F92947-04
June 2024

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

ORACLE®

Copyright © 2019, 2024, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, MySQL, and NetSuite are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

Contents

Preface

Documentation accessibility	vi
Related resources	vi
Access to Oracle Support	vi
Additional copyright information	vi

1 For new users

About Oracle InForm CRF Submit	1-1
Access Oracle InForm CRF Submit to generate an archive or history report	1-1
Archive types and the files and subject data included	1-2
History report details	1-4
Subscribe to release announcements	1-5
What data is migrated across data centers?	1-5

2 Create an archive

Start with a Test Run	2-1
Submission PDF	2-2
Archival PDF	2-5
Blank Forms Only	2-9
Custom PDF	2-11
Custom Blank Forms	2-17
Download the PDF output for an archive	2-20
Create a custom template	2-21
Create a PDF archive from a template	2-21
PDF output options	2-22
How can I handle blank forms?	2-22
About Electronic Trial Master File (eTMF)	2-23
Can I generate archives and history report headers in Japanese?	2-24
How does the Include data as of date and time option affect the output?	2-24
How do I define the Export Selection Criteria?	2-25
How do I enter a large number of subjects?	2-25
Can I save a request?	2-26

What do rights groups do?	2-26
How do I prevent hidden Oracle InForm data from appearing?	2-26
What PDF format is applied to PDF output?	2-27
Why should I create a custom template?	2-27
Can I create a ZIP file even if Oracle InForm CRF Submit encounters errors?	2-27
Transferred subject data	2-28
Are subject data transfers supported?	2-28
Where is subject transfer history included?	2-28

3 Create a history report

Audit Trail Report	3-1
User Assignment History report	3-4
Download a history report	3-7

4 Create other reports

Site Confirmation report	4-1
Download Log report	4-1
Not Yet Downloaded report	4-2

5 Manage archives and history reports

Display the options and settings	5-1
View request processing details	5-1
Resubmit a failed request	5-2
Delete an archive or report	5-2
Monitor request notices	5-3
Check how much storage has been used	5-4
Archives and reports shared by sponsors	5-4
Can I list the archives and reports shared with sites?	5-4
Is there a record of affidavits used to sign off on Oracle InForm data?	5-5

6 For administrators

Manage Trial and Sponsor Settings	6-1
Specify Trial Settings	6-1
Specify Sponsor Settings	6-2
Email notifications	6-2
About email notifications	6-2
Configure email notifications	6-5
Rights management	6-6

Archival rights and descriptions
Where are rights controlled?

6-6
6-8

7 Revision History

Preface

This preface contains the following sections:

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

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Related resources

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

Access to Oracle Support

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

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

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

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

Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

1

For new users

In this chapter

- [About Oracle InForm CRF Submit](#)
- [Access Oracle InForm CRF Submit to generate an archive or history report](#)
- [Subscribe to release announcements](#)
- [What data is migrated across data centers?](#)

About Oracle InForm CRF Submit

Using Oracle InForm CRF Submit, you can initiate PDF archive and history report requests directly from the Oracle InForm user interface for UAT and LIVE studies. You can use the output for:

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

Each PDF archive request includes casebooks or a set of unique forms that include.

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

Oracle allocates 1000 GB of storage server space for each customer, which is shared across all studies. For more information, see [Check how much storage you have used](#).

Access Oracle InForm CRF Submit to generate an archive or history report

Access to Oracle InForm CRF Submit differs based on the version of Oracle InForm you are using.

If you are using Oracle InForm 7.0 or higher:

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

If you are using a version of Oracle InForm lower than 7.0:

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

How do I generate a study archive or history report?

After clicking **Archives** you are taken to the **My Requests - Processing** page.

- Use the links below to generate an archive containing study data or a set of blank forms.
 - Submission PDF
 - Archival PDF
 - Blank Forms Only
 - Custom PDF
 - Custom Blank Forms

For additional information about each, see Archive types and the files and subject data included.

- Use the links below to generate a history report.
 - Audit Trail Report
 - User Assignment History report

For additional information about each, see History report details.

- [Archive types and the files and subject data included](#)
- [History report details](#)

Archive types and the files and subject data included

Here's what's included with the output of each archive request

Each request produces a zip file that includes the following.

Table 1-1 Archive request output details


Request type	Description	Included in the .zip file
Submission PDF	Generate this type for submission to the FDA and other regulatory agencies at the conclusion of a study. The information is automatically compiled and formatted according to the regulators' requirements.	<ul style="list-style-type: none"> • One folder per site, each containing one PDF per subject. • Table of Contents • Request Settings • Blank forms with active controls for each study version. • Protocol Guide • Study Design
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>The zip file includes the protocol guide and study design only if the study administrator made them available on the Documents tab on the study's home page. The Visit Calculator and Sample Book are not included. For more information, see What types of study documentation are there?.</p> </div>		
Archival PDF	Generate this type for mid-study data analysis or to generate a final archive of study data, which can then be made available to auditors, sponsors, sites, and regulatory agencies.	<ul style="list-style-type: none"> • One folder per site, each containing one PDF per subject. • Table of Contents • Request Settings • Blank forms with active controls for each study version.
Blank Forms Only	Generate this type to view blank forms with active controls for a study version.	<ul style="list-style-type: none"> • Request Settings • Blank forms with active controls for each study version.

Table 1-1 (Cont.) Archive request output details

Request type	Description	Included in the .zip file
Custom PDF	This type gives users access to all settings, letting them control what to include in the output.	<ul style="list-style-type: none"> • One folder per site, each containing one PDF per subject. • Table of Contents • Request Settings • Protocol Guide
Custom Blank Forms	Like the Custom PDF, the user can access all available settings, but the output only includes blank forms with active controls.	<ul style="list-style-type: none"> • Request Settings • Blank forms with active controls for each study version.

 **Note:**

The zip file includes the protocol guide only if the study administrator made it available on the Documents tab on the study's home page and the Request Setting, **Protocol Guide**, is set to **Yes**.

What subject data gets included in archive requests and history reports

The PDF layout does not differ between request types; only the data included in the output does.

- For archive requests that include subject data (Submission, Archival, and Custom), Oracle InForm CRF Submit provides a PDF that reflects each subject's casebook and includes item, query, form, and visit details, audit trail information, and details for comments and signatures.
- Oracle InForm CRF Submit relies on the Oracle InForm rights groups to determine what data to include in the archive request and history report output. If a user assigned to a rights group can't see specific information in the study, the output reflects that.
- The data included in the output gets determined by the selection from the **Select the rights group to control content** setting. This setting is only available for sponsor users on the Archival PDF and Custom PDF request types and for the Audit Trail Report.

 **Note:**

The setting defaults to the rights group of the user generating the request.


History report details

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

Table 1-2 History report details

Report name	Description	Included in the .zip file
Audit Trail Report	This report includes traceability details for item-level inserts and edits, query changes, form status changes, SV status changes, and comment and signature history. This report is only available in CSV format.	<ul style="list-style-type: none"> • One folder per site, each containing one CSV per subject. • Table of Contents • Request Settings • A cumulative CSV file containing details for all subjects.
User Assignment History report	<p>This report includes an audit history of changes made to each user account.</p> <ul style="list-style-type: none"> • User status changes, such as created, activated, deactivated, and terminated. • Query group changes • Reporting group changes • Rights group changes • Signature group changes • Site association changes 	<ul style="list-style-type: none"> • One folder per site, each containing one CSV file with details for users at the site. • Table of Contents • Request Settings

Subscribe to release announcements

1. Log in to [Oracle Life Sciences Support Cloud](#).
2. In the upper-right corner, click the My Account icon () , then click **Account Settings**.
3. Enable **Send email notifications when new announcements are posted** at the bottom of the Account Settings page, then click **Save**.

You'll receive an email notification whenever we post an Oracle InForm CRF Submit release announcement on the Oracle Life Sciences Support Cloud.

Note:

You will also receive announcements from other industry-specific applications developed by Oracle Life Sciences.

What data is migrated across data centers?

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

- Requests are migrated.
 - Request Settings are available for migrated requests.
- Migrated requests:

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

Command line utility

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

The utility migrates the following information:

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

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

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

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

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

2

Create an archive

In this chapter

- [Start with a Test Run](#)
A test run is identical to a regular PDF request, except that a test run is limited to one subject or study version, depending on the type of request selected.
- [Submission PDF](#)
At the conclusion of a study, generate this type of request for submission to the FDA and other regulatory agencies. The information is automatically compiled and formatted according to the regulators' requirements. The output contains data visible to the user who creates it based on their assigned rights group.
- [Archival PDF](#)
Generate this type of request for mid-study data analysis or to create a final archive of study data. The archive can be made available to auditors, sponsors, sites, and regulatory agencies.
- [Blank Forms Only](#)
Generate this type of request to view a set of blank forms with active controls for each study version. The output contains no subject data.
- [Custom PDF](#)
This request type gives you access to all settings, letting you control what to include in the output.
- [Custom Blank Forms](#)
Like the Custom PDF, you have access to all available settings, but the output only includes blank forms with active controls and no subject data.
- [Download the PDF output for an archive](#)
- [Create a custom template](#)
- [Create a PDF archive from a template](#)
- [PDF output options](#)
- [Transferred subject data](#)

Start with a Test Run

A test run is identical to a regular PDF request, except that a test run is limited to one subject or study version, depending on the type of request selected.

Create a test run to confirm that your settings produce the desired output.

Follow the steps below to create a Test Run

Start by accessing Oracle InForm CRF Submit.

1. On the **My Requests - Processing** page, click **Create Requests**, then select **Create Test Run**.
2. On the **Study Information** page, update the **PDF Request Name** if applicable, enter an optional **PDF Request Description**, select the appropriate request type, and click **Next**.

 **Note:**

The PDF Request Name defaults to the study name plus the current date and time.

3. Depending on the request type selected, refer to the links below to complete the request.

- Submission PDF
- Archival PDF
- Blank Forms Only
- Custom PDF
- Custom Blank Forms

If you choose the **Submission PDF**, **Archival PDF**, or **Custom PDF** request, the system prompts you to select a single subject.

If you choose the **Blank Forms Only** or **Custom Blank Forms** request, the system prompts you to select a single study version.

Submission PDF

At the conclusion of a study, generate this type of request for submission to the FDA and other regulatory agencies. The information is automatically compiled and formatted according to the regulators' requirements. The output contains data visible to the user who creates it based on their assigned rights group.

 **Tip:**

You can generate a Test Run first to ensure the PDF output contains the correct data.

Here's what a Submission PDF request includes

- One folder per site, each containing one PDF per subject.
- A Table of Contents (TOC).
- A PDF containing the Request Settings.
- A set of blank forms with active controls for each study version.

Follow the steps below to create a Submission PDF

Start by accessing Oracle InForm CRF Submit.


1. On the **My Requests - Processing** page, click **Create Requests**, then select **Create New PDF Request**.
2. On the **Study Information** page, update the **PDF Request Name** (if applicable), enter an optional **PDF Request Description**, select **Submission PDF**, and click **Next**.

 **Note:**

The request name defaults to the study name plus the current date and time.

3. Complete the **Form Options**, then click **Next**.

Table 2-1 Submission PDF Form Options



Option	Details
Header Text	<ul style="list-style-type: none"> Enter text up to 90 characters to appear at the top of each page on the PDF. The study name is the default value.
Page Size	<ul style="list-style-type: none"> Letter: (default) 8-1/2" by 11" A4: European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> Unique Forms: One of each form in your study. Casebook: (default) All forms, even those that are repeated.
<div style="border: 1px solid #0070C0; padding: 5px; background-color: #E6F2FF;">  Note: For more information, see How can I handle blank forms? </div>	
Headings Language	<ul style="list-style-type: none"> Specify the language to use for labeling bookmarks, headers, and footers. English is the default language.
Footer Text	<ul style="list-style-type: none"> Enter text up to 30 characters to appear in the footer of each PDF page. ***Confidential*** along with page numbers is the default.
Include Study Name in the Subject PDF File name	<ul style="list-style-type: none"> Select Yes (default) for the Study Name to appear in the Subject PDF file name. Select No if the study name is not needed.

4. Complete the **Request Settings**, then click **Next**.

Table 2-2 Submission PDF Request Settings

Setting	Details
Audit Location	<ul style="list-style-type: none"> Select After Each Form to place audit trail data at the end of each form. Select End of PDF (default) to place it at the end of the PDF.

Table 2-2 (Cont.) Submission PDF Request Settings

Setting	Details
Include data as of date and time	<ul style="list-style-type: none"> Select Now (default) to include all data available up to the date and time displayed. Select Select date/time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note: The date cannot be before the first subject's study enrollment date.</p> </div> <p>For more information, see How does the Include data as of date and time option affect the output?.</p>
Export Selection Criteria	<p>Select to create PDFs for</p> <ul style="list-style-type: none"> All Subjects (default) By Subject By Site <p>For more information, see How do I define the Export Selection Criteria?, and How do I enter a large number of subjects?</p>
Candidate Queries	<ul style="list-style-type: none"> Select Yes to include Candidate Queries in PDFs. Select No (default) to exclude them.
Generate Linking Blank Forms	<ul style="list-style-type: none"> Select Yes to link a copy of the blank form in another language to this form. Select No (default) to not link a copy of the blank form. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note: For multilingual studies.</p> </div>
Prevent Form Changes	Not editable for this request type, displayed for information purposes only.
Prevent Form Comments Changes	<ul style="list-style-type: none"> Select Yes to prevent comments and annotations from being added to the output PDF. Select No (default) to allow comments or annotations.
Prevent Content Extracts and Copying	<ul style="list-style-type: none"> Select Yes to prevent content being copied from the output PDF. Select No (default) to allow content to be copied.

- Review the request settings displayed on the **Review and Submit** page for accuracy.
 - Click **Save** to save the request to the **Saved** tab under **My Requests**. You can access this request later to make edits and generate it.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the request.

- The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create New PDF Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
- On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

- You can now Download the PDF.

Archival PDF

Generate this type of request for mid-study data analysis or to create a final archive of study data. The archive can be made available to auditors, sponsors, sites, and regulatory agencies.

 **Tip:**

You can generate a Test Run first to ensure the PDF output contains the correct data.

Here's what an Archival PDF request includes

- One folder per site, each containing one PDF per subject.
- A Table of Contents (TOC).
- A PDF containing the Request Settings.
- A set of blank forms with active controls for each study version.

 **Note:**

Blank forms are included only when the Request Setting **Generate Blank Forms** is **Yes**.

Follow the steps below to create an Archival PDF

Start by accessing Oracle InForm CRF Submit.


- On the **My Requests - Processing** page, click **Create Requests**, then select **Create New PDF Request**.
- On the **Study Information** page, update the **PDF Request Name** (if applicable), enter an optional **PDF Request Description**, select **Archival PDF**, and click **Next**.

 **Note:**

The request name defaults to the study name plus the current date and time.

3. Complete the **Form Options**, then click **Next**.

Table 2-3 Archival PDF Form Options

Option	Details
Header Text	<ul style="list-style-type: none"> Enter text up to 90 characters to appear at the top of each page on the PDF. The study name is the default value.
Page Size	<ul style="list-style-type: none"> Letter: (default) 8-1/2" by 11" A4: European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> Unique Forms: One of each form in your study. Casebook: (default) All forms, even those that are repeated.
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>For more information, see How can I handle blank forms?</p> </div>	
Headings Language	<ul style="list-style-type: none"> Specify the language to use for labeling bookmarks, headers, and footers. English is the default language.
Footer Text	<ul style="list-style-type: none"> Enter text up to 30 characters to appear in the footer of each PDF page. ***Confidential*** along with page numbers is the default.
Include Study Name in the Subject PDF File name	<ul style="list-style-type: none"> Select Yes (default) for the Study Name to appear in the Subject PDF file name. Select No if the study name is not needed.

4. Complete the **Request Settings**, then click **Next**.

Table 2-4 Archival PDF Request Settings


Setting	Details
Allow PDF request to be stored in eTMF	For more information about this setting, see About Electronic Trial Master File (eTMF).
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>This setting is only available when the trial setting Enable eTMF Download is enabled.</p> </div>	

Table 2-4 (Cont.) Archival PDF Request Settings








Setting	Details
Share with Sites <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: Appears only if you belong to a rights group with the <i>Share Archives with Sites</i> right.</p> </div>	<ul style="list-style-type: none"> Select Yes (default) if you want to make the PDFs made available for download by site users. Select No if site users do not need to download this request.
Site Confirmation Required <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	<ul style="list-style-type: none"> Select Yes (default) if you want site users to confirm downloading a request shared with them. <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: For more information about the site confirmation process, see Confirm archives and reports.</p> </div> <ul style="list-style-type: none"> Select No if you do not require confirmation from site users.
Select the rights group to control content	<ul style="list-style-type: none"> The rights group selected determines what content gets included in the PDF output. The default is the logged-in user's rights group
Allow any Site User to download this request <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	<ul style="list-style-type: none"> Select Yes to allow any site user with Archives access to download the request. Select No (default) to allow only site users assigned to the rights group selected for Select the Rights Group to Control Content to download the request.
Notify CRFS Site Users <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	<ul style="list-style-type: none"> Select Yes to send site users the, <i>PDF or History Request is available for download (Site user, when share with sites)</i> notification when a request is available for download. <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;"> <p> Note: The notification is only sent if it has been enabled. For more information, see About email notifications. The setting displays even if the notification is not enabled.</p> </div> <ul style="list-style-type: none"> Select No (default) if the notification should not be sent.

Table 2-4 (Cont.) Archival PDF Request Settings

Setting	Details
Audit Location	<ul style="list-style-type: none"> Select After Each Form to place audit trail data at the end of each form. Select End of PDF (default) to place it at the end of the PDF.
Include data as of date and time	<ul style="list-style-type: none"> Select Now (default) to include all data available up to the date and time displayed. Select Select date/time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note: The date cannot be before the first subject's study enrollment date.</p> </div> <p>For more information, see How does the Include data as of date and time option affect the output?.</p>
Export Selection Criteria	<p>Select to create PDFs for</p> <ul style="list-style-type: none"> All Subjects (default) By Site <p>For more information, see How do I define the Export Selection Criteria?, and How do I enter a large number of subjects?</p>
Candidate Queries	<ul style="list-style-type: none"> Select Yes (default) to include Candidate Queries in PDFs. Select No to exclude them.
Generate Blank Forms	<ul style="list-style-type: none"> Select Yes (default) to include blank forms. Select No to exclude them.
Prevent Form Changes	Not editable for this request type, displayed for information purposes only.
Prevent Form Comments Changes	<ul style="list-style-type: none"> Select Yes (default) to prevent comments and annotations from being added to the output PDF. Select No to allow comments or annotations.
Prevent Content Extracts and Copying	<ul style="list-style-type: none"> Select Yes (default) to prevent content being copied from the output PDF. Select No to allow content to be copied.

- Review the request settings displayed on the **Review and Submit** page for accuracy.
 - Click **Save** to save the request to the **Saved** tab under **My Requests**. You can access this request later to make edits and generate it.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the request.
- The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create New PDF Request** page.

- Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
7. On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

8. You can now Download the PDF.

Blank Forms Only

Generate this type of request to view a set of blank forms with active controls for each study version. The output contains no subject data.

 **Tip:**

You can generate a Test Run first to ensure the PDF output contains the correct data.

Here's what a Blank Forms Only request includes

- A PDF containing the Request Settings.
- A set of blank forms with active controls for each study version.

Follow the steps below to create a Blank Forms Only request

Start by accessing Oracle InForm CRF Submit.

1. On the **My Requests - Processing** page, click **Create Requests**, then select **Create New PDF Request**.
2. On the **Study Information** page, update the **PDF Request Name** (if applicable), enter an optional **PDF Request Description**, select **Blank Forms Only**, and click **Next**.

 **Note:**


The request name defaults to the study name plus the current date and time.

3. Complete the **Form Options**, then click **Next**.

Table 2-5 Blank Forms Only Form Options

Option	Details
Header Text	<ul style="list-style-type: none"> • Enter text up to 90 characters to appear at the top of each page on the PDF. • The study name is the default value.
Page Size	<ul style="list-style-type: none"> • Letter: (default) 8-1/2" by 11" • A4: European letter size: 210 x 297 mm

Table 2-5 (Cont.) Blank Forms Only Form Options

Option	Details
Blank Form Format	<ul style="list-style-type: none"> • Unique Forms: One of each form in your study. • Casebook: (default) All forms, even those that are repeated.
	<div style="border-left: 2px solid #0070C0; border-right: 2px solid #0070C0; border-bottom: 2px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>For more information, see How can I handle blank forms?</p> </div>
Headings Language	<ul style="list-style-type: none"> • Specify the language to use for labeling bookmarks, headers, and footers. • English is the default language.
Footer Text	<ul style="list-style-type: none"> • Enter text up to 30 characters to appear in the footer of each PDF page. • ***Confidential*** along with page numbers is the default.

4. Complete the **Request Settings**, then click **Next**.

Table 2-6 Blank Forms Only Request Settings

Setting	Details
Include versions as of date and time	<ul style="list-style-type: none"> • Select Now (default) to include all study versions up to the date and time displayed. • Select Select date/time to enter a specific date.
Study Version	<ul style="list-style-type: none"> • Select All (default) to generate blank forms for all study versions. • Select Select from list to choose one or more study versions.
Prevent Form Changes	Not editable for this request type, displayed for information purposes only.
Prevent Form Comments Changes	<ul style="list-style-type: none"> • Select Yes to prevent comments and annotations from being added to the output PDF. • Select No (default) to allow comments or annotations.
Prevent Content Extracts and Copying	<ul style="list-style-type: none"> • Select Yes to prevent content being copied from the output PDF. • Select No (default) to allow content to be copied.

5. Review the request settings displayed on the **Review and Submit** page for accuracy.
- Click **Save** to save the request to the **Saved** tab under **My Requests**. You can access this request later to make edits and generate it.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the request.

- The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create New PDF Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
- On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

- You can now Download the PDF.

Custom PDF

This request type gives you access to all settings, letting you control what to include in the output.

 **Tip:**

You can generate a Test Run first to ensure the PDF output contains the correct data.

Here's what a Custom PDF request includes

- One folder per site, each containing one PDF per subject.
- A Table of Contents (TOC).
- A PDF containing the Request Settings.
- A set of blank forms with active controls for each study version.

 **Note:**

Blank forms are included only when the Request Setting **Generate Blank Forms** is **Yes**.

Follow the steps below to create a Custom PDF request

Start by accessing Oracle InForm CRF Submit.


- On the **My Requests - Processing** page, click **Create Requests**, then select **Create New PDF Request**.
- On the **Study Information** page, update the **PDF Request Name** (if applicable), enter an optional **PDF Request Description**, select **Custom PDF**, and click **Next**.

 **Note:**

The request name defaults to the study name plus the current date and time.

3. Complete the **Form Options**, then click **Next**.

Table 2-7 Custom PDF Form Options

Option	Details
Header Text	<ul style="list-style-type: none"> Enter text up to 90 characters to appear at the top of each page on the PDF. The study name is the default value.
Page Size	<ul style="list-style-type: none"> Letter: (default) 8-1/2" by 11" A4: European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> Unique Forms: One of each form in your study. Casebook: (default) All forms, even those that are repeated.
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>For more information, see How can I handle blank forms?.</p> </div>	
Headings Language	<ul style="list-style-type: none"> Specify the language to use for labeling bookmarks, headers, and footers. English is the default language.
Footer Text	<ul style="list-style-type: none"> Enter text up to 30 characters to appear in the footer of each PDF page. ***Confidential*** along with page numbers is the default.
Include Study Name in the Subject PDF File name	<ul style="list-style-type: none"> Select Yes (default) for the Study Name to appear in the Subject PDF file name. Select No if the study name is not needed.
Display in the header	<p>By default, the PDF header includes, Header Text, Form Name, Form Status, Subject No., Generated By, and Generated Time. You can also include the following in the header.</p> <ul style="list-style-type: none"> Form Version (default is Yes) Subject Initials (default is Yes) Visit Name and Number (default is Yes) Site Name and Number (default is Yes) Sponsor (default is No) Protocol (default is No)

4. Complete the **Request Settings**, then click **Next**.

Table 2-8 Custom PDF Request Settings






Setting	Details
<p>Allow PDF request to be stored in eTMF</p> <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>This setting is only available when the trial setting Enable eTMF Download is enabled.</p> </div>	<p>For more information about this setting, see About Electronic Trial Master File (eTMF).</p>
<p>Share with Sites</p> <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>Appears only if you belong to a rights group with the <i>Share Archives with Sites</i> right.</p> </div>	<ul style="list-style-type: none"> • Select Yes if you want to make the PDFs made available for download by site users. • Select No (default) if site users do not need to download this request.
<p>Site Confirmation Required</p> <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>Appears only if Share with Sites is Yes.</p> </div>	<ul style="list-style-type: none"> • Select Yes (default) if you want site users to confirm downloading a request shared with them. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>For more information about the site confirmation process, see Confirm archives and reports.</p> </div> <ul style="list-style-type: none"> • Select No if you do not require confirmation from site users.
<p>Select the rights group to control content</p>	<ul style="list-style-type: none"> • The rights group selected determines what content gets included in the PDF output. • The default is the logged-in user's rights group.
<p>Allow any Site User to download this request</p> <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>Appears only if Share with Sites is Yes.</p> </div>	<ul style="list-style-type: none"> • Select Yes to allow any site user with Archives access to download a request. • Select No (default) to allow only site users assigned to the rights group selected for Select the Rights Group to Control Content to download the request.

Table 2-8 (Cont.) Custom PDF Request Settings




Setting	Details
Notify CRFS Site Users	<ul style="list-style-type: none"> Select Yes to send site users the, <i>PDF or History Request is available for download (Site user, when share with sites)</i> notification when a request is available for download.
	<div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div> <div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: The notification is only sent if it has been enabled. For more information, see About email notifications. The setting displays even if the notification is not enabled.</p> </div>
Include Bookmark Prefixes	<ul style="list-style-type: none"> Select Yes to include prefixes (for example CRF, Form, Visit, Study) in PDF bookmarks. Select No (default) if bookmark prefixes are not needed.
Audit Location	<ul style="list-style-type: none"> Select After Each Form to place audit trail data at the end of each form. Select End of PDF (default) to place it at the end of the PDF.
Include data as of date and time	<ul style="list-style-type: none"> Select Now (default) to include all data available up to the date and time displayed. Select Select date/time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: The date cannot be before the first subject's study enrollment date.</p> </div> <p>For more information, see How does the Include data as of date and time option affect the output?.</p>
Export Selection Criteria	<p>Select to create PDFs for</p> <ul style="list-style-type: none"> All Subjects (default) By Site <p>For more information, see How do I define the Export Selection Criteria?, and How do I enter a large number of subjects?.</p>

Table 2-8 (Cont.) Custom PDF Request Settings





Setting	Details
Forms	<ul style="list-style-type: none"> Select All (default) to include all forms. Select Select from list to include selected study forms in the output. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>If you include selected forms, you cannot limit the PDF to selected visits.</p> </div>
Visits	<ul style="list-style-type: none"> Select All (default) Select Select from list to include selected study visits in the output. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>To include common forms across visits you must select the cross visit entry or the forms will be missing from the output.</p> </div> <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>If you include selected visits, you cannot include selected forms.</p> </div>
Transferred Subjects in Current Site Only	<ul style="list-style-type: none"> Select Yes to create a PDF for a transfer subject in just the current site. Select No (default) to create a PDF for both the originating and the current site. <p>For more information, see <i>Where is subject transfer history included?</i>.</p>
Suppress Empty Clinical Forms	<ul style="list-style-type: none"> Select Yes to omit forms for which no data has been entered. Select No (default) to include all forms, even if they are empty.
Suppress Empty Clinical Visits	<ul style="list-style-type: none"> Select Yes to omit visits for which no data has been entered. Select No (default) to include all visits, even if they are empty.
Candidate Queries	<ul style="list-style-type: none"> Select Yes (default) to include Candidate Queries in PDFs. Select No to exclude them.
Generate Blank Forms	<ul style="list-style-type: none"> Select Yes to include blank forms. Select No (default) to exclude them.
Study Version	<ul style="list-style-type: none"> Select All (default) to create blank forms for all study versions. Select Select from list to choose specific study versions. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note:</p> <p>Appears only if Generate Blank Forms is Yes.</p> </div>

Table 2-8 (Cont.) Custom PDF Request Settings






Setting	Details
Generate Linking Blank Forms	<ul style="list-style-type: none"> Select Yes to link a copy of the blank form in another language to this form. Select No (default) to not link a copy of the blank form.
	<div style="border: 1px solid #0070c0; padding: 5px; background-color: #e6f2ff;"> <p> Note: For multilingual studies.</p> </div>
Generate TOC	<ul style="list-style-type: none"> Select Yes (default) to include a table of contents (TOC) with links to all generated subject PDFs in the request. Select No to not include the TOC.
Protocol Guide	<ul style="list-style-type: none"> Select Yes to include the Protocol Guide and the CRF Help in the PDF Request output. Select No (default) to exclude the Protocol Guide and CRF Help.
Prevent Form Changes	<ul style="list-style-type: none"> Select Yes to require a password to make changes to the PDF. <div style="border: 1px solid #0070c0; padding: 5px; background-color: #e6f2ff; margin-top: 10px;"> <p> Note: When set to Yes a field appears allowing you to define a password.</p> </div> <ul style="list-style-type: none"> Select System-created : Hidden to permanently prevent form changes to the PDF. <div style="border: 1px solid #ffc000; padding: 5px; background-color: #fff9c4; margin-top: 10px;"> <p> WARNING: This password cannot be retrieved.</p> </div> <ul style="list-style-type: none"> Select No (default) to allow PDF output to be modified.
Prevent Form Comments Changes	<ul style="list-style-type: none"> Select Yes to prevent comments and annotations from being added to the output PDF. Select No (default) to allow PDF comments or annotations.
Prevent Content Extracts and Copying	<ul style="list-style-type: none"> Select Yes to prevent contents being copied from the output PDF. Select No (default) to allow content to be copied.

Table 2-8 (Cont.) Custom PDF Request Settings

Setting	Details
Password <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p> Note: Appears only when Prevent Form Changes is set to Yes.</p> </div>	Specify a password to be used when Prevent Form Comments Changes and Prevent Content Extracts and Copying are set to Yes . <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p> WARNING: The password entered is not saved in the application and must be retained by the user.</p> </div>
Re-enter Password	Re-enter the password exactly as entered in the Password field.

5. Review the request settings displayed on the **Review and Submit** page for accuracy.
 - Click **Save as New Template** to save the request as a template for future use. Templates are saved under **Templates - Manage Templates**.
 - Click **Save** to save the request to the **Saved** tab under **My Requests**. You can access this request later to make edits and generate it.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the request.
6. The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create New PDF Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
7. On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

8. You can now Download the PDF.

Custom Blank Forms

Like the Custom PDF, you have access to all available settings, but the output only includes blank forms with active controls and no subject data.

 **Tip:**

You can generate a Test Run first to ensure the PDF output contains the correct data.

Here's what a Custom Blank Forms request includes

- Request Settings
- Blanks forms with active controls for each study version.

Follow the steps below to create a Custom Blank Forms request

Start by accessing Oracle InForm CRF Submit.


1. On the **My Requests - Processing** page, click **Create Requests**, then select **Create New PDF Request**.
2. On the **Study Information** page, update the **PDF Request Name** (if applicable), enter an optional **PDF Request Description**, select **Custom Blank Forms**, and click **Next**.

 **Note:**

The request name defaults to the study name plus the current date and time.

3. Complete the **Form Options**, then click **Next**.

Table 2-9 Custom Blank Forms Form Options

Option	Details
Header Text	<ul style="list-style-type: none"> • Enter text up to 90 characters to appear at the top of each page on the PDF. • The study name is the default value.
Page Size	<ul style="list-style-type: none"> • Letter: (default) 8-1/2" by 11" • A4: European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> • Unique Forms: One of each form in your study. • Casebook: (default) All forms, even those that are repeated.
<p> Note:</p> <p>For more information, see How can I handle blank forms?.</p>	
Headings Language	<ul style="list-style-type: none"> • Specify the language to use for labeling bookmarks, headers, and footers. • English is the default language.
Footer Text	<ul style="list-style-type: none"> • Enter text up to 30 characters to appear in the footer of each PDF page. • ***Confidential*** along with page numbers is the default.

4. Complete the **Request Settings**, then click **Next**.

Table 2-10 Custom Blank Forms Request Settings





Setting	Details
Select the rights group to control content	<ul style="list-style-type: none"> The rights group selected determines what content gets included in the PDF output. The default is the logged-in user's rights group.
Include Bookmark Prefixes	<ul style="list-style-type: none"> Select Yes to include prefixes (for example CRF, Form, Visit, Study) in PDF bookmarks. Select No (default) if bookmark prefixes are not needed.
Include versions as of date and time	<ul style="list-style-type: none"> Select Now (default) to include all study versions up to the date and time displayed. Select Select date/time to enter a specific date.
Study Version	<ul style="list-style-type: none"> Select All (default) to create blank forms for all study versions. Select Select from list to select one or more specific study versions.
Prevent Form Changes	<ul style="list-style-type: none"> Select Yes to require a password to make changes to the PDF. <div data-bbox="993 886 1468 1087" style="border: 1px solid #0070C0; background-color: #E6F2FF; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>When set to Yes a field appears allowing you to define a password.</p> </div> <ul style="list-style-type: none"> Select System-created : Hidden to permanently prevent form changes to the PDF. <div data-bbox="993 1213 1468 1390" style="border: 1px solid #FFC000; background-color: #FFF2CC; padding: 10px; margin: 10px 0;"> <p> WARNING:</p> <p>This password cannot be retrieved.</p> </div>
Prevent Form Comments Changes	<ul style="list-style-type: none"> Select Yes to prevent comments and annotations from being added to the output PDF. Select No (default) to allow PDF comments or annotations.
Prevent Content Extracts and Copying	<ul style="list-style-type: none"> Select Yes to prevent contents being copied from the output PDF. Select No (default) to allow content to be copied.

Table 2-10 (Cont.) Custom Blank Forms Request Settings

Setting	Details
Password <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p> Note: Appears only when Prevent Form Changes is set to Yes.</p> </div>	Specify a password to be used when Prevent Form Comments Changes and Prevent Content Extracts and Copying are set to Yes . <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p> WARNING: The password entered is not saved in the application and must be retained by the user.</p> </div>
Re-enter Password	Re-enter the password exactly as entered in the Password field.

5. Review the request settings displayed on the **Review and Submit** page for accuracy.
 - Click **Save** to save the request to the **Saved** tab under **My Requests**. You can access this request later to make edits and generate it.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the request.
6. The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create New PDF Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
7. On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

8. You can now Download the PDF.

Download the PDF output for an archive

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 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 200 MB, Oracle InForm CRF Submit chunks the output into 200 MB files.
- The Firefox browser presents users with an option to Save, while other browsers like Edge and Chrome automatically save the files to the default download folder.

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 6 in Custom Request.
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?](#)
- [About Electronic Trial Master File \(eTMF\)](#)
- [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.

About Electronic Trial Master File (eTMF)

Use this feature to send Archival PDF (sponsor) and Custom PDF archive requests to the Oracle sFTP server, where they can be programmatically retrieved for import into an eTMF system.

About eTMF

The primary purpose of this feature is to allow you to programmatically transfer archives from the Oracle sFTP server to your eTMF system.

Downloading files manually from the sFTP server, while it can be done, is not recommended as no data protections are applied to the content on the Oracle sFTP server, like in Oracle InForm CRF Submit.

Also, archives manually downloaded from the sFTP server are not tracked in the Download Log or the Site Confirmation report.

eTMF setting and archive retention

- To enable this feature, see Specify trial settings
- Once the feature is enabled, the setting, **Allow PDF request to be stored in eTMF**, is available for the following archive types:
 - Archival PDF (sponsor user)
 - Custom PDF
- When the setting **Allow PDF request to be stored in eTMF** is set to **Yes**, archives are delivered to the sFTP server and are available in the Oracle InForm CRF Submit user interface. When set to **No**, archives are only available in the user interface.
- Deleting an archive from one location (sFTP or the user interface) does not delete it from the other.
- Archives are automatically deleted from the sFTP server after 60 days and from the user interface after 120 days.

Named sFTP account details

The username and password of this account are used to access the Oracle sFTP server to retrieve requests programmatically. The email address, first name, and last name of an individual need to be included in the request to create this account.

WARNING:

The data included in a request is based on the rights group selected when the request was generated. The person associated with the named sFTP account can access the sFTP server and manually download requests. This could result in unblinding if the request contains data that the sFTP user should not have access to.

Request a named sFTP account

Follow these steps to create a request for a named sFTP account.

1. Log into [Oracle Life Sciences Support Cloud](#).
2. Click **Create Request** in the upper-right corner, then select **Change Request**.
3. Click the **Maintain an application** tile.
4. Click the **Request user access** tile, then complete the following fields.
 - **Summary:** (Ex.) Requesting the creation of an sFTP named account.
 - **Severity:** Medium
 - **Description:** Grant <enter first name, last name, and email> Read Only access to the sFTP directory defined in this request.
 - **Category:** Change-Cloud Infrastructure > Infrastructure Services > SFTP > User > Add
 - **Customer:** Select your company's name
 - **Product:** CRF Submit
 - **Business Service:** CRF Submit-customer name
 - **Environment:** Prod/Live
 - **Implementation Window:** Make a selection
 - **Action:** Leave set to **No Value**
 - **sFTP:** Reach out to your Oracle Services contact to get the sFTP path.
 - **Date Required:** Enter a date

Error handling

If errors are encountered while copying files to the sFTP server, the request is marked as Failed in the user interface, and the reason captured (in the FailureReport.txt file) is *Request output could not be copied to the sFTP location*.



Note:

An archive can still be downloaded in the user interface even if an error is encountered copying files to the sFTP server.

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 Edge, Google Chrome, or Firefox browsers.

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 a history report

In this chapter

- [Audit Trail Report](#)
- [User Assignment History report](#)
- [Download a history report](#)

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

Follow the steps below to generate the Audit Trail Report

1. On the **My Requests** page, select **Create History Request** from the **Create Requests** drop-down.
2. On the **Study Information** page, accept the default **Request Name** (comprised of the study name plus the current date and time) or enter a different name.
3. Enter an optional **Description**.
4. Select **Audit Trail Report**, and click **Next**.
5. Enter the **Request Settings**, then click **Next**.

Table 3-1 Audit Trail Report - Request Settings

Setting	Description
Headings Language	<ul style="list-style-type: none">• Specify the language to use for labeling headers.• English is the default language.
Include Study Name in the Subject CSV File name	<ul style="list-style-type: none">• Select Yes (default) to include the study name in the output file.• Select No if the study name is not needed.

Table 3-1 (Cont.) Audit Trail Report - Request Settings






Setting	Description
Share with Sites	<ul style="list-style-type: none"> Select Yes if you want to make the report made available for download by site users. Select No (default) if site users do not need to download this report.
Site Confirmation Required	<ul style="list-style-type: none"> Select Yes if you want site users to confirm downloading the report shared with them.
<div style="border: 1px solid #0070C0; padding: 5px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	<div style="border: 1px solid #0070C0; padding: 5px;"> <p> Note: For more information about the site confirmation process, see Confirm archives and reports</p> </div> <ul style="list-style-type: none"> Select No (default) if you do not require confirmation from site users.
Select the rights group to control content	<ul style="list-style-type: none"> The rights group selected determines what content gets included in the PDF output. The default is the logged-in user's rights group.
Allow any Site User to download this request	<ul style="list-style-type: none"> Select Yes to allow any site user with Archives access to download this request. Select No (default) to allow only site users assigned to the rights group selected for Select the Rights Group to Control Content to download the request.
<div style="border: 1px solid #0070C0; padding: 5px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	
Notify CRFS Site Users	<ul style="list-style-type: none"> Select Yes to send site users the, <i>PDF or History Request is available for download (Site user, when share with sites)</i> notification when a request is available for download.
<div style="border: 1px solid #0070C0; padding: 5px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div>	<div style="border: 1px solid #0070C0; padding: 5px;"> <p> Note: The notification is only sent if it has been enabled. For more information, see About email notifications. The setting displays even if the notification is not enabled.</p> </div> <ul style="list-style-type: none"> Select No (default) if the notification should not be sent.
Generate TOC	<ul style="list-style-type: none"> Select Yes (default) to include a table of contents (TOC). Select No to not include the TOC.
Candidate Queries	<ul style="list-style-type: none"> Select Yes (default) to include Candidate Queries. Select No to exclude them.

Table 3-1 (Cont.) Audit Trail Report - Request Settings

Setting	Description
Select Date Range	The date range entered determines the audit trail data included in the report.
Selection Criteria	Use the following filters to generate an Audit Trail Report for an entire trial or site or for a specific subject or form. <ul style="list-style-type: none"> • Sites • Subjects • Visits • Forms • Modification Type • Rights Group • Usernames

- Review the request settings on the **Review and Submit** page for accuracy.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the report.
- The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create History Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
- On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

- You can now Download a history report.

Table 3-2 Audit Trail Report (ATR) Output Details

Output Column	Output Column Description
Study Name	InForm study name
Site ID	InForm site number
Site Name	InForm site name
SubjectID	InForm subject number
Abbreviated Visit Name	InForm visit refname
Abbreviated Form Name	InForm form refname
Form Index	This number uniquely identifies the instance of the repeating form within a subject visit, starting from 1.
Itemset Index	This number uniquely identifies the instance of a repeating section (i.e. itemset) within a subject form.
Item Question	InForm question text

Table 3-2 (Cont.) Audit Trail Report (ATR) Output Details

Output Column	Output Column Description
Modification Type	Indicates the type of modification made to the Item Question. Modification Types: <i>Initial Entry, Association Added, Association Removed, Form Comment, Form Deleted, Form Frozen, Form SDV Complete, Form SDV Partial, Form SDV Ready, Form Started, Form Undeleted, Form Unfrozen, Item Comment, Modification, Query, BOOK Signature, and CRF Signature</i>
Entered Reason	Reason entered in InForm for the modification made to the Item Question. This could be an option from a drop down, i.e., Transcription Error or the text entered by the InForm user.
Current Value	Value currently visible in the Item Question in the InForm study UI
Current Value Date/Time	Date/Time the value was updated to the Current Value
Current Value Date/Time (UTC)	Date/Time in Coordinated Universal Time (UTC) the value was updated to the Current Value
Query Text	The query text associated with the Current Value
Previous Value	The value present in the Item Question prior to the change
Previous Value Date/Time	Date/Time the Previous Value was entered
Previous Value Date/Time (UTC)	Date/Time in Coordinated Universal Time (UTC) the Previous Value entered
Rights Group	InForm Rights Group of the user that made the change
Username	InForm Username of the user that made the change
User Type	InForm user type of the user that made the change

User Assignment History report

This report includes an audit history of changes made to each user account.

- User status changes, such as created, activated, deactivated, and terminated.
- Query group changes
- Reporting group changes
- Rights group changes
- Signature group changes
- Site association changes

Follow the steps below to generate the User Assignment History report

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

3. Enter an optional **Description**.
4. Select **User Assignment History**, and click **Next**.
5. Enter the **Request Settings**, then click **Next**.

Table 3-3 User Assignment History Report - Request Settings







Setting	Description
Headings Language	<ul style="list-style-type: none"> Specify the language to use for labeling headers. English is the default language.
Share with Sites	<ul style="list-style-type: none"> Select Yes (default) if you want to make the report made available for download by site users. Select No if site users do not need to download this report.
Site Confirmation Required	<ul style="list-style-type: none"> Select Yes (default) if you want site users to confirm downloading the report shared with them.
	<div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div> <div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: For more information about the site confirmation process, see Confirm archives and reports</p> </div> <ul style="list-style-type: none"> Select No if you do not require confirmation from site users.
Notify CRFS Site Users	<ul style="list-style-type: none"> Select Yes to send site users the, <i>PDF or History Request is available for download (Site user, when share with sites)</i> notification when a request is available for download.
	<div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: Appears only if Share with Sites is Yes.</p> </div> <div style="border: 1px solid #0070C0; padding: 5px; margin-bottom: 10px;"> <p> Note: The notification is only sent if it has been enabled. For more information, see About email notifications. The setting displays even if the notification is not enabled.</p> </div> <ul style="list-style-type: none"> Select No (default) if the notification should not be sent.
Generate TOC	<ul style="list-style-type: none"> Select Yes (default) to include a table of contents (TOC). Select No to not include the TOC.

Table 3-3 (Cont.) User Assignment History Report - Request Settings

Setting	Description
Include data as of date and time	<ul style="list-style-type: none"> Select Now to include all data up to the date and time displayed. Choose Select date/time to enter a specific date and time. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>The earliest date you can select is the enrollment date of the first subject. For more information, see How does the Include data as of date and time option affect the output?</p> </div>
Export Selection Criteria	<ul style="list-style-type: none"> Select All Sites to include data for all sites. Select By Site to select the sites to include in the report. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>For more information, see How do I define the Export Selection Criteria?</p> </div>

6. Review the request settings on the **Review and Submit** page for accuracy.
 - Click **Print** to print a copy of the request settings. The zip file also includes a copy of the request settings.
 - Click **Submit** to generate the report.
7. The PDF Request Submitted window opens and presents the following options.
 - Click **Yes, Create Another** to return to the **Create History Request** page.
 - Click **No, Go to Processing Page** to be taken to the **My Requests - Processing** page.
8. On the **My Requests - Processing** page, click **Refresh** until the % Complete column displays 100.

 **Note:**

Completed requests are moved to the **My Requests - Completed** page.

9. You can now Download a history report.

Table 3-4 User Assignment History (UAH) Output Details

Output Column	Output Column Description
Study Name	InForm study name

Table 3-4 (Cont.) User Assignment History (UAH) Output Details

Output Column	Output Column Description
Site ID	InForm site number
Site Name	InForm site name
Username	Username of the user to whom changes were applied
Change Type	The type of change made to the user Change Types: Group or Status.
Change Time	Date/Time the change was submitted
Change Time (UTC)	Date/Time in Coordinated Universal Time (UTC) the change was submitted
User Change	The high-level change made to the user User Change Types: User Created, User Activated, User Deactivated, Added to Group & Removed from Group.
Change Rights Group Type	The group change made for the user Change Rights Group Types: Site, Rights Group, Reporting Group, Query Group, and Signature Group
Group Name	The specific group name that was changed
Changing Username	The username of the person who made the change

Example of a Reporting Group change applied to a user.

- **Change Type:** Group
- **User Change:** Added to Group
- **Change Rights Group Type:** Reporting Group
- **Group Name:** Sponsor Users Reporting Group

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

Create other reports

In this chapter

- [Site Confirmation report](#)
- [Download Log report](#)
- [Not Yet Downloaded report](#)

Site Confirmation report

Download this report to view a list of all requests shared with sites where site confirmation was required.



Note:

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

The report includes the confirmation status (Confirmed or Not Confirmed), who confirmed the request, and when it was confirmed.

Archive rights needed to access the report

- Sponsor users with the *View Download Confirmation* right can download this report.

Download the Site Confirmation report

1. From the **Reports** section on the left, click **Site Confirmation**.
2. Use the **Search** filters to locate specific requests or click **Download as CSV** or **Download as PDF** to download a report that includes all requests.
3. When prompted, save the report locally.

Download Log report

Download this report to view a log of downloads performed by sponsor and site users in the Oracle InForm CRF Submit user interface.

This report does not include requests downloaded from the Oracle sFTP server. For more information, see [About Electronic Trial Master File \(eTMF\)](#).

The recommended practice is to download this report as a part of the study decommissioning processes, ensuring you have an audit trail of all downloads.



Note:

After decommissioning the study, you cannot retrieve this report.

Archive rights needed to access the report

- Sponsor users with the *Administer Archives* right can download this report.

Download the Download Log

1. From the **Reports** section on the left, click **Download Log**.
2. Use the **Search** filters to locate specific requests or click **Download as CSV** to download a report that includes all requests.
3. When prompted, save the report locally.

Not Yet Downloaded report

Download this report to track requests created by site users and requests and history reports created by sponsor users and shared with sites that have not yet been downloaded. From the same page, you can also send reminder email notifications.

The report includes the following requests and reports

Requests and history reports generated by a sponsor user and shared with sites include.

- Archival PDF requests
- Custom PDF requests
- Audit Trail Report (ATR)
- User Assignment History (UAH)

Requests generated by site users.

- Site Requests

Requests are added to this report once successfully generated and remain here until the site downloads them.

Once downloaded, it is removed from this report and tracked in the Download Log.

Archive rights needed to access the report

- Sponsor users with the *Administer Archives* right can download this report.

Download the Not Yet Downloaded report

1. From the **Reports** section on the left, click **Not Yet Downloaded**.
2. Use the **Search** filters to locate specific requests.
3. Clicking the checkbox for one or more requests enables the **Send Reminder** button.

 **Note:**

You can select all requests on a page by selecting the check box at the top of the first column.

The *Not yet downloaded PDFs or History Requests (Site user)* email notification is sent when **Send Reminder** is clicked. For more information, see *About email notifications*.

5

Manage archives and history reports

In this chapter

- [Display the options and settings](#)
- [View request processing details](#)
- [Resubmit a failed request](#)
- [Delete an archive or report](#)
- [Monitor request notices](#)
- [Check how much storage has been used](#)
- [Archives and reports shared by sponsors](#)

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.

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 request processing details

Why do this? Follow these steps if you need information about when an archive or history report was processed.

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

If available storage space is exceeded, requests continue to fail with the status of **Failed-out of storage space**. For more information, see Check how much storage you have used.



Tip:

You can manually [delete outdated or downloaded archives and reports](#) to free up space.

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 check box, then click **Download**.
 4. To resubmit a failed file:
 - Try resubmitting the file as is by selecting its check box and clicking **Resubmit**. Sometimes, just resubmitting the request works.
 - Understand why some files failed by reviewing the details in the failure report. Each line of the report describes a single file failure. To view the failure report, select it from the Reports menu in the navigation pane at the left. You cannot download the report.
 - Create a new request based on fixing the errors and submit it.

Delete an archive or report

Requests over 120 days old are automatically deleted to maintain the storage servers.



Note:

The Deleted By column on the My Requests - Deleted page (under My Requests) displays the user name of the person who deleted the request. `System` is displayed for auto-deleted requests.

1. On the My Requests - Completed or My Requests - Saved page, click the check box to the left of a request, then click **Delete**.

The Select Requests page opens.

2. Select the requests you want to delete from the list on the left, then use the arrows to move your selections to the Selected List table on the right. In some cases, the request has already been moved.



Tip:

Click the double arrow to move all requests.

3. Click **Delete**.



WARNING:

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

4. Click **OK** to confirm the deletion.
 - Deleted requests are moved to My Requests - Deleted.
 - Requests shared with sites are also deleted from the Site Archives page.
5. Clicking the check box to the left of the Request Name enables the **Show Settings** button, which when clicked, displays the settings used to generate the request. This page can be printed.
6. Click the request name to open the Request Details page. Here, you can view the files (and associated details) generated for the request. These files can no longer be downloaded.

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 has been used

Oracle allocates 1000 GB of storage server space for each customer, which is shared across all studies. Review the Request Overview report to see server usage details for all your studies.

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

A storage meter in the upper right corner indicates the allocated storage status and shows the total Storage Allocated and Storage Used.

- **Green** indicates that storage is still available.
- **Yellow** indicates that between 75% and 90% of the allocated storage has been used.
- **Red** indicates that >90% of the allocated storage has been used.

Note:

Email notifications are sent when the storage server exceeds 75%. To configure the storage warning email address, see Specify sponsor settings.

2. Use the filters in the **Search** section to locate details based on a date range and study name.
3. Click a column header to sort the requests further.
4. Requests can be manually deleted to free up space. Click the help icon to the right of the storage meter for additional details.

Archives and reports shared by sponsors

In this section

- [Can I list the archives and reports shared with sites?](#)
- [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.

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.

6

For administrators

Here, you can define Trial Settings and Sponsor Settings, enable and customize Email Notifications, view Request Overview details, and view and download the Site Confirmation report, Download Log, and Not Yet Downloaded Report.

- [Manage Trial and Sponsor Settings](#)
- [Email notifications](#)
- [Rights management](#)

Manage Trial and Sponsor Settings

- [Specify Trial Settings](#)
- [Specify Sponsor Settings](#)

Specify Trial Settings

Select **Settings** from the Manage section in the left-side panel, then click **Trial Settings** to change the default configuration for the following trial-level settings.

Table 6-1 Trial Settings and their descriptions


Setting	Description
Maximum Subjects per PDF Request by site user	Enter the maximum number of subjects (between 1 and 50,000) a site user can include in a single PDF request. The setting default is five (5).
	<div data-bbox="1122 1291 1468 1522"> Note: This controls the Export Selection Criteria site request setting.</div>
Default Email Address	Enter an email address to receive email notifications when, <ul style="list-style-type: none">• A request shared with a site has been downloaded.• A a request has been generated by a site. For more information, see About email notifications .
Enable eTMF Download	When enabled, the setting Allow PDF request to be stored in eTMF is made available when creating Archival (sponsor) and Custom requests. For more information, see About Electronic Trial Master File (eTMF)

Table 6-1 (Cont.) Trial Settings and their descriptions

Setting	Description
Give priority to InForm	Limit the concurrent data generation of output for the trial so that InForm activities take priority.

Specify Sponsor Settings

Sponsor users with the *Administer Archives* right can access Settings under the Manage section on the left side panel to enter a valid email address to receive email notifications when allocated storage limits are reached and customize the confirmation text displayed to site users when download confirmation has been requested.

Storage Warning Configuration

When specified, Storage Warning emails are only sent to this address. If an email address is not entered, sponsor users with any of the following permissions receive them: *Generate Archives*, *Delete Archives*, *Administer Archives*, and *View All Completed Archives*.

1. Enter a valid email address or distribution list.

Note:

This is a sponsor-level setting and only needs to be defined in one of your studies. This covers both your LIVE and UAT studies.

2. Click **Save**.

Confirmation Text configuration

During request creation, a sponsor user can require site users to confirm they have downloaded and reviewed a request shared by a sponsor.

The confirmation text is presented to the site user when they confirm the request output. Site confirmation actions are captured in the Site Confirmation report.

1. Remove the check mark next to **Use default text** to unlock the text boxes.
2. Update the text, then click **Save**.

Email notifications

- [About email notifications](#)
- [Configure email notifications](#)

About email notifications

Required permissions

Sponsor users assigned to a Rights Group with the *Administer Archives* right can manage email notifications. For more information, see [Configure email notifications](#).

Who can receive notifications

Sponsor and site users with access to **Archives** can receive email notifications. See the table below for specific details about each notification.



Note:

Notifications are set to **Yes** by default for new studies.

Available languages

Each notification includes default text in both English and Japanese, which you can edit. For more information, see Configure email notifications.

Available Notifications

Table 6-2 Notification Details


Notification	Details	Notes
PDF or History Request is available for download (Sponsor user)	CRF Submit sends a notification to the email address of the requester (Sponsor user) when a PDF or History Report is available for download.	n/a
<div style="border-left: 2px solid #0070C0; border-right: 2px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> No te:</p> <p>History Request here and in the cells below refers to the Audit Trail Report and the User Assignment History report.</p> </div>		
PDF or History Request is available for download (Site user, when shared with sites)	CRF Submit sends a notification to the email address of site users when a PDF or History report, shared with sites, is available for download. It is sent only when Yes is selected for Notify Site Users during request creation.	This notification is sent to site users with Archive rights who are associated with the rights group selected under, Select the Rights Group to Control Content . If the setting Allow any Site User to download this request is set to Yes it is sent to all site users with Archive rights.

Table 6-2 (Cont.) Notification Details

Notification	Details	Notes
PDF or History Request shared with sites has been downloaded (Default Email Address).	CRF Submit sends a notification to the Default Email Address when a request generated by a sponsor user and shared with sites has been downloaded.	See Specify trial settings to see how to define the Default Email Address .
PDF or History Request has been confirmed (Sponsor user).	CRF Submit sends a notification to the email address of the requester (Sponsor user) when a request shared with and downloaded by sites has been confirmed.	This notification is sent to the Default Email Address if there is no email address associated with the sponsors user account. See Specify trial settings to see how to define the Default Email Address .
PDF or History Request submitted by a site user (Default Email Address).	CRF Submit sends a notification to the Default Email Address when a site user has submitted a PDF or History Request.	See Specify trial settings to see how to define the Default Email Address .
PDF or History Request is available for download (Site user).	CRF Submit sends a notification to the email address of the requester (Site user) when a PDF or History Request is available for download.	n/a
Not yet downloaded PDFs or History Requests (Site user).	Sent to remind site users they have not yet downloaded PDF or History Report requests. This notification is sent based on actions taken in the Not Yet Downloaded report .	n/a
PDF or History Request has failed (Site user).	CRF Submit sends a notification to the email address of the requester (Site user) when a PDF or History Request has failed.	n/a
PDF or History Request has failed (Sponsor user).	CRF Submit sends a notification to the email address of the requester (Sponsor user) when a PDF or History Request has failed.	n/a

Configure email notifications

To manage notifications sponsor users need to belong to a Rights Group that includes the *Administer Archives* right.


For more information about email notifications, see [About email notifications](#)

1. Log in to your study and click **Archives** in the top navigation bar.
2. Click **Notifications** under **Manage** in the left navigation panel.

You are presented with nine (9) email notifications set to **Yes** by default.

Note:

To define the **Default Email Address**, see [Specify trial settings](#)

3. Click **No** to disable the notifications you do not want to utilize.
4. Click the expand button () to edit the email text for each notification to be used. You can only expand one notification at a time.
The setting **Use default notification body** if enabled by default.
5. Uncheck the setting **Use default notification body**.
The default English and Japanese email text is now editable. You can enter custom text up to 2000 characters.
6. Update the text and click **Save**.
7. Repeat these steps for each notification.

Rights management

In this section

- [Archival rights and descriptions](#)
- [Where are rights controlled?](#)

Archival rights and descriptions

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

Table 6-3 Description of Archival Rights

Archival Right	For sponsor users	For site users
Generate Archives	<p>Allows sponsor users to generate the following PDF archives and history reports.</p> <p>PDF Archives</p> <ul style="list-style-type: none"> • Submission PDF • Archival PDF • Blank Forms Only • Custom PDF • Custom Blank Forms <p>History Reports</p> <ul style="list-style-type: none"> • Audit Trail Report • User Assignment History <p>For more information, see Access Oracle InForm CRF Submit to generate an archive or history report.</p>	<p>Allows site users to generate the following PDF archives and history reports.</p> <p>PDF Archives</p> <ul style="list-style-type: none"> • Site Request <p>For more information, see Create an archive of study data.</p> <p>History Reports</p> <ul style="list-style-type: none"> • Audit Trail Report • User Assignment History <p>For more information, see What reports are available.</p>

Table 6-3 (Cont.) Description of Archival Rights

Archival Right	For sponsor users	For site users
Administer Archives	<p>Allows sponsor users to specify trial and sponsor settings, configure email notifications, and generate reports.</p> <ul style="list-style-type: none"> Specify trial settings Specify sponsor settings Define email notifications Request Overview report Download Log report Not Yet Downloaded Report <p>If you are using an Oracle InForm version lower than 7.0 and need to manage rights, see <i>Where are rights controlled?</i></p>	<p>This right is for sponsor users only.</p> <p>Adding this right to a site Rights Group does not grant site users administrative access.</p>
Delete Archives	<p>Allows sponsor users to:</p> <ul style="list-style-type: none"> Delete PDF and history report requests generated by them and other sponsor users on the My Requests—Completed page. Delete their saved PDF requests on the My Requests—Saved page. <p>For more information, see <i>Delete an archive or report.</i></p>	<p>Allows site users to delete PDF and history report requests that they generated on the Site Archives page, as well as requests generated by sponsors and site users assigned to the same sites.</p> <p>For more information, see <i>Delete a site archive or report.</i></p>
View All Completed Archives	<p>Allows sponsor users to view all sponsor-generated PDF archive and history report requests on the My Requests—Completed page generated for any site in a study.</p> <p>If you do not include this right, sponsor users can only see requests they generated.</p>	<p>By default, site users can view PDF requests and history reports on the Site Archives page that they generated, ones shared by sponsor users, and requests generated by other site users belonging to the same site.</p> <p>Not including or removing this right does not change what a site user can view.</p>
Manage Templates	<p>Allows sponsor users to create a template based on the Custom PDF archive type.</p> <p>Sponsor users can then select Create from Templates under Create Requests.</p> <p>For more information, see <i>Why should I create a custom template?</i>.</p>	<p>This right is for sponsor users only.</p> <p>Adding this right to a site Rights Group does not allow site users to manage templates.</p>

Table 6-3 (Cont.) Description of Archival Rights

Archival Right	For sponsor users	For site users
Share Archives with Sites	<p>Controls the setting Share with Sites, which is available when generating the following PDF requests and history reports.</p> <ul style="list-style-type: none"> • Archival PDF • Custom PDF • Audit Trail Report • User Assignment History <p>This right also controls the setting Site Confirmation Required, which is linked to Share with Sites. You cannot require a site to confirm a request that was not shared.</p>	<p>This right is for sponsor users only.</p> <p>Site users cannot share requests.</p>
Confirm Archives Download	<p>This right is for site users only, as only site users can confirm an archive or history report shared by a sponsor user.</p>	<p>This right controls access to the Confirm link made available to site users for archive and history report requests shared by sponsors where site confirmation was required.</p> <p>For more information, see Confirm archives and reports.</p>
View Download Confirmation	<p>Allows sponsor users to generate the Site Confirmation report under the Reports section.</p> <p>For more information, see Site Confirmation report.</p>	<p>Site users can also generate the Site Confirmation report for their sites. Adding or removing this right does not change access to this report for site users.</p>
Download for eTMF	<p>Starting with Oracle InForm CRF Submit 7.0.1 this right is no longer relevant but is still present in the Oracle InForm user interface. This will be removed in a future release.</p>	n/a

Where are rights controlled?

For Oracle InForm versions 7.0 and later:

Access is controlled by the Oracle InForm User Management Tool administrator in the Oracle InForm User Management Tool (UMT) interface. For more information, see Archival rights and how to assign them.

Note:

Work with your Oracle point of contact if you have questions about how to best assign rights.

For Oracle InForm versions before 7.0:

1. Log into Oracle InForm as a CRFAdmin.
2. On the InForm Home page, click the **Archives** link below the Oracle InForm icons.
3. From the **Manage** section on the left, click **Rights Group**.
4. Select the radio button of the rights group you want to update.
5. Click **Edit**.
6. Select and deselect the check boxes of the Archival rights as desired.
7. Click **Save**.

7

Revision History

Date	Part number	Description
05 June 2024	F92947-04	A broken link was fixed on Archive types and what files and subject data are included in the Submission PDF row.
04 June 2024	F92947-03	The Submission PDF and Custom PDF, listed on Archive types and what files and subject data are included, were updated with additional details about the Protocol Guide and Study Design.
31 May 2024	F92947-02	The Submission PDF, listed on Archive types and what files and subject data are included, was updated by adding Protocol Guide as one of the output files.
28 May 2024	F92947-01	Original version of this document.