

Oracle® Life Sciences InForm

User Guide for Site Users



Release 7.0.1
F56799-02
March 2024



Oracle Life Sciences InForm User Guide for Site Users, Release 7.0.1

F56799-02

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

Contents

Preface

Documentation accessibility	vii
Diversity and Inclusion	vii
Related resources	vii
Access to Oracle Support	vii
Additional copyright information	viii

1 Oracle Life Sciences InForm accounts, training, and study access

Oracle Life Sciences InForm accounts	1-1
Single sign-on (SSO) accounts	1-1
Set up your Oracle Life Sciences IAMS SSO account information	1-2
Federation authentication	1-2
Link your Oracle Life Sciences IAMS and Federated accounts	1-3
Non-SSO accounts	1-3
Oracle Life Sciences InForm training	1-3
Complete your required Oracle Life Sciences InForm training on HS Learn	1-3
Complete your required Oracle Life Sciences InForm training with an alternate training resource	1-4
Oracle Life Sciences InForm study access	1-4
Access your Oracle Life Sciences InForm study	1-5
Log into an SSO study with your Oracle Life Sciences IAMS SSO credentials	1-5
Log into an SSO study with your Federation credentials	1-6
Log in to a non-SSO study	1-6

2 Basics

How is Oracle Life Sciences InForm organized?	2-1
How do I find information about subjects?	2-1
How do I change my password?	2-2
How do I reset a forgotten or expired password?	2-3
How do I log out of a study?	2-4

3 Add a subject to a study

Screen a candidate	3-1
Resubmit a candidate who failed screening	3-1
Enroll a screened candidate	3-2
Complete enrollment after an enrollment failure	3-2

4 Forms and data

Enter data and comments	4-1
Enter data	4-1
Associate two forms	4-2
Associate data on two forms	4-2
Collect related data from multiple forms in a dynamic grid	4-2
Enter and view data in an unscheduled visit	4-3
Enter a comment	4-4
Mark a form or item as incomplete	4-4
Edit or clear data	4-4
Edit data after you submit a form	4-4
Clear a data item	4-5
Clear a form	4-5
Delete or undelete an Add Entry row	4-6
Delete or undelete a repeating form	4-6
View help for a form or item	4-6
Mark a form SV Ready or Not SV Ready	4-7
Review the audit trail	4-7
Sign	4-7
View your signature status	4-8
View the signature status for your site	4-8
Sign a form, visit or case report book	4-8
Re-sign after a signature is invalidated	4-9

5 Queries

View your queries	5-1
Answer a query	5-1

6 FAQs

Screening and enrollment FAQs	6-1
How do I add a subject to a study?	6-1
Why would a screening fail, and what can I do about it?	6-1

Why would an enrollment fail, and what can I do about it?	6-2
Form and data FAQs	6-2
Can I view related data in two forms at the same time?	6-3
Can I view related data in more than two forms at the same time?	6-3
Can I skip an item or form?	6-3
How do I apply a comment to an item, row of repeating data, or a form?	6-3
Can I include clinical data in a comment?	6-4
What are signatures used for?	6-4
What order do repeating visits appear in the user interface?	6-4
Audit trail FAQs	6-4
What information is available in the audit trail?	6-4
Who can see the audit trail?	6-4
How does the audit trail date/time conversion work?	6-4
Query FAQs	6-5
When do I answer queries?	6-5
Study documentation FAQs	6-5
What types of study documentation are there?	6-5
Single sign-on (SSO) account FAQs	6-5
How do I change my SSO account challenge questions?	6-5
I've set up my SSO account, why can't I access the Oracle InForm study?	6-6
HS Learn training FAQs	6-6
Why am I getting an error message when I try to sign in to HS Learn?	6-7
How do I get to HS Learn to take my training?	6-7
How do I create an Oracle Account for signing in to HS Learn?	6-8
Why didn't I receive a training course assignment email?	6-9
Why aren't my training courses loading?	6-9
What if I am assigned to the wrong course?	6-9
How do I enroll myself in a training course?	6-9
How do I view my training status and certificates in HS Learn?	6-9
I completed my training, why can't I see my certificate in HS Learn?	6-10
I completed my training, why did I get assigned to it again?	6-10
Do I have to re-take the HS Learn training every time I am given access to an Oracle Life Sciences InForm study?	6-11
Can the name on my training completion certificate be changed?	6-11
Why there is no date of completion on my certificate?	6-11
How can I get more help with my Oracle Account?	6-12
How can I get more help with HS Learn?	6-12
User Acceptance Testing FAQs	6-12
Can I switch roles during User Acceptance Testing (UAT) environments?	6-13

7 What if...

I can't reset my password	7-1
The link in my reset password email doesn't work	7-1
I didn't receive an email when I reset my password	7-2
I can't enter data	7-2
I can't edit data in a section on a form	7-2
I can't edit a form, visit, or case report book	7-2
I didn't delete an item in a dynamic grid section, but the item's data is crossed out	7-2
I can't see the study documentation	7-3
I accidentally entered the wrong user name or password when I signed a form	7-3
Data changes after I sign	7-3
My answer to a query results in another query	7-3
I can't log in to my SSO account with the temporary password	7-3
I forget my SSO user name	7-3
I forget my SSO password	7-4
I completed my training, but I didn't get an email with the study URL	7-4
I tried to log into my study, but the screen is blank	7-4

Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [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>.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

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 Oracle 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 <https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab> 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

Oracle Life Sciences InForm accounts, training, and study access

In this chapter:

- [Oracle Life Sciences InForm accounts](#)
- [Oracle Life Sciences InForm training](#)
- [Oracle Life Sciences InForm study access](#)

Oracle Life Sciences InForm accounts

You can access Oracle InForm using either a single sign-on (SSO) account, or a non-SSO account. The type of account is determined by your Study Administrator.

- [Single sign-on \(SSO\) accounts](#)
- [Non-SSO accounts](#)

Single sign-on (SSO) accounts

For each Sponsor, you can access all Oracle Life Sciences InForm single sign-on (SSO) studies using a single account with one User Name and Password, which we refer to as a Single sign-on (SSO) or Global User account.

You can authenticate to and access your SSO studies using Oracle Life Sciences IAMS credentials or using Federation credentials.

Oracle Life Sciences IAMS credentials

After your Study Administrator creates your SSO account, you will receive an email from *OracleIdentityManager@oracle.com* that contains your SSO account User Name and a link so that you can set up and manage your SSO account information. For more information, see [Set up your Oracle Life Sciences IAMS SSO account information](#).

Federation credentials

If Federation authentication is set up, you must perform a one-time linking of your Oracle Life Sciences IAMS account with your Federated account. For more information, see [Link your Oracle Life Sciences IAMS and Federated accounts](#).

After you link your accounts you can:

- Log into Oracle InForm with your Federation credentials instead of with your Oracle Life Sciences IAMS single sign-on credentials.
- Sign forms and case report books with your Federation credentials instead of with your Oracle Life Sciences IAMS single sign-on credentials.



Note:

Federation authentication is currently not supported for use with Cognos Reporting.

- [Set up your Oracle Life Sciences IAMS SSO account information](#)
- [Federation authentication](#)
- [Link your Oracle Life Sciences IAMS and Federated accounts](#)

Set up your Oracle Life Sciences IAMS SSO account information

If your Study Administrator set up your account to use Oracle Life Sciences IAMS credentials to log in to your Oracle Life Sciences InForm SSO studies, you will receive an email from *OracleIdentityManager@oracle.com* with the subject line "Oracle Life Sciences Cloud - New Account" that contains your SSO account user name and a link to set up (or reset) your password. The link is valid for 24 hours.

If you didn't use the link within 24 hours, you can begin the process again by going to the expired link and select **Reset Password**.



Note:

This step initiates your SSO account only. At this point, you cannot access the Oracle InForm study because your training and the study authorization process are not complete.

Federation authentication

Federation authentication may be set up for your Oracle Life Sciences InForm 7.0 or above SSO studies.

If Federation authentication is set up you must perform a one-time linking of your Oracle Life Sciences IAMS account with your Federated account. For more information, see [Link your Oracle Life Sciences IAMS and Federated accounts](#).

After you link your accounts you can:

- Log into Oracle InForm with your Federation credentials instead of with your Oracle Life Sciences IAMS single sign-on credentials.
- Sign forms, visits and case report books with your Federation credentials instead of with your Oracle Life Sciences IAMS single sign-on credentials.



Note:

Federation authentication is currently not supported for use with Cognos Reporting.

Link your Oracle Life Sciences IAMS and Federated accounts

Perform these steps if your Study Administrator set up your account to use Federation authentication to log in to your Oracle Life Sciences InForm SSO studies. You must perform a one-time linking of your Oracle Life Sciences IAMS account with your Federated account.

1. Enter the study URL in your browser.
2. Click **Sign In with your Federation account**.
3. Enter your Federation email address, and click **Next**.
4. Enter your Federation password, and click **Next**.

The Link Accounts page appears.

5. Enter your Oracle Life Sciences IAMS SSO user account name and password.
6. Read the legal notice and select **I have read the Legal Notice**.
7. Click **Link Accounts**.

Non-SSO accounts

For non-SSO user accounts, your System Administrator assigns your user name and password.

The first time you log in to Oracle Life Sciences InForm, you must use the temporary password that your study administrator assigned to you.

To access Oracle InForm, you are required to change the temporary password and provide an email address. You can change this information at any time after your initial log in.

Oracle Life Sciences InForm training

You are required to take training for each InForm study you will have access to. Depending on the training resources your Sponsor uses, you'll be assigned to Oracle's Health Sciences Learn (HS Learn) training, or to an alternative training resource.

To access HS Learn, you must have an Oracle Account. For more information, see [How do I create an Oracle Account for signing in to HS Learn?](#)

- [Complete your required Oracle Life Sciences InForm training on HS Learn](#)
- [Complete your required Oracle Life Sciences InForm training with an alternate training resource](#)

Complete your required Oracle Life Sciences InForm training on HS Learn

Your UMT Administrator assigns you to take any Oracle Life Sciences InForm training that is required for your participation in any assigned Oracle InForm studies. Depending on the training resources your Sponsor uses, you'll be assigned to Oracle's Health Sciences Learn (HS Learn) training, or to an alternative training resource.

 **Note:**

The process for completing the required assigned Oracle InForm training is the same for SSO and non-SSO accounts.

If you are assigned to take HS Learn training:

1. You will receive one email from alerts@clinicalone.oraclecloud.com with the subject line "HS Learn Course Assignment" which includes a link to the training:
 - The first time you are assigned to any course by any Sponsor.
 - If you are assigned to the same course by any Sponsor 12 months or more after you most recently completed the course.
2. In the *HS Learn Course Assignment* email, click the **Complete Training Now** button.
 - If you have an Oracle Account, which is used to access the online training in HS Learn, a Sign in page appears and you can sign in to HS Learn to complete your assigned training.
 - If you don't have an Oracle Account, you can create one by clicking **Create Account** on the Sign in page. For more information, see [How do I create an Oracle Account for signing in to HS Learn?](#)

After you complete all assigned HS Learn training, the training status for your account will automatically be updated to **Trained**, which is required for the study access process to continue.

 **Note:**

You can sign in to HS Learn at any time to see your training history, or to view and download your training completion certificates.

Complete your required Oracle Life Sciences InForm training with an alternate training resource

If you are using an alternate training resource other than HS Learn:

- Work with your administrator to make sure you've completed the required training.

After you complete all training, the training status for your account must be manually updated to **Trained** by an administrator, which is required for the study access process to continue.

Oracle Life Sciences InForm study access

After your SSO account is set up (if applicable), and you have completed all the required training, your Study Administrator manually authorizes your access for each Oracle Life Sciences InForm study you are assigned to.

- [Access your Oracle Life Sciences InForm study](#)

- [Log into an SSO study with your Oracle Life Sciences IAMS SSO credentials](#)
- [Log into an SSO study with your Federation credentials](#)
- [Log in to a non-SSO study](#)

Access your Oracle Life Sciences InForm study

After your SSO account is set up (if applicable), and you have completed all the required training, your Study Administrator manually authorizes your access for each Oracle Life Sciences InForm study you are assigned to.



Note:

The process for accessing your Oracle InForm studies is the same for SSO and non-SSO accounts.

1. After a study is live, you will receive one access authorization email for each study you are authorized to access, from *saasadminsUPPORT_ww* with the subject line "Welcome to <sponsor> <studyname>".

An access authorization email is sent for each study you work on for a Sponsor.

- The email contains the study authorization information and the study URL.
- Receiving this email confirms that the SSO account setup (if applicable), and the study authorization process is complete.



Note:

It may take some time before you receive the email with the study URL after you complete your training. The Study Administrator must manually grant you access to the study after you have completed your training and the study URL is available.

2. Enter the study URL in your browser, and log in using the required credentials.

For more information, see:

- [Log into an SSO study with your Oracle Life Sciences IAMS SSO credentials](#)
- [Log into an SSO study with your Federation credentials](#)
- [Log in to a non-SSO study](#)

Log into an SSO study with your Oracle Life Sciences IAMS SSO credentials

To log into an Oracle Life Sciences InForm SSO study with your Oracle Life Sciences IAMS SSO credentials:

1. Enter the study URL in your browser.
2. Click **Sign In with Oracle Life Sciences SSO**.
3. Enter your SSO account user name and password.

After you successfully log in, the Home page for the Oracle InForm study appears.

Log into an SSO study with your Federation credentials

 **Note:**

If this is the first time you are logging in with your Federated account, you must link your account to your Oracle Life Sciences IAMS account. You only need to do this one time. For more information, see [Link your Oracle Life Sciences IAMS and Federated accounts](#).

To log into an Oracle Life Sciences InForm SSO study with your Federation credentials:

1. Enter the study URL in your browser.
2. Click **Sign In with your Federated account**.
3. Enter your Federation email address, and click **Next**.
4. Enter your Federation password, and click **Next**.

After you successfully log in, the Home page for the InForm study appears.

Log in to a non-SSO study

To log in to a non-SSO Oracle Life Sciences InForm study:

1. Enter the study URL in your browser.
2. Enter the user name and password assigned by your System Administrator.

After you successfully log in, the Home page for the Oracle InForm study appears.

2

Basics

In this chapter:


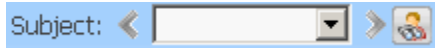
- [How is Oracle Life Sciences InForm organized?](#)
- [How do I find information about subjects?](#)
- [How do I change my password?](#)
- [How do I reset a forgotten or expired password?](#)
- [How do I log out of a study?](#)

How is Oracle Life Sciences InForm organized?

What do you want to know?	Where to go	How to get there
Where am I after I log in?	You're on the Home page, which might have welcome information about your study. Start here to get to the pages where you enter, edit, or review study data.	<ul style="list-style-type: none">• Log in.
How can I see the visits for all of the subjects at my site?	Use the Case Reports Books page to check how the study is progressing and to get to information about individual subjects.	<ul style="list-style-type: none">• Click Subjects.
How can I see the visits and forms for one subject?	Use the Time and Events Schedule to check how a subject is progressing through the study and to get to specific visits and forms.	<ol style="list-style-type: none">1. Click Subjects.2. Click the subject number link for a subject.
Where do I enter clinical data?	Enter data on forms (also called Case Report Forms or CRFs).	<ol style="list-style-type: none">1. Click Subjects.2. On the Case Report Books page, click the status icon for a subject and visit.3. Select a form.
How can I tell the status of what I'm working on?	Visits, forms, queries, and signatures all have icons that indicate status.	<ul style="list-style-type: none">• Point to an icon to display a tooltip that describes the status.

How do I find information about subjects?

What do you want to know?	Where it appears	How to get there
What's the completion status for all of the subjects at my sites?	Case Report Books page	<ul style="list-style-type: none">• Click Subjects.

What do you want to know?	Where it appears	How to get there
What's the completion status for a subject?	Time and Events Schedule - visit view	<ol style="list-style-type: none"> 1. Click Subjects. 2. Click on a subject or Search for a subject by number using the Subject # field and the Search icon in the upper-right corner of the page. 
Which forms in a visit need action?	Time and Events Schedule - form view	<ol style="list-style-type: none"> 1. Click Subjects. 2. Click the link for a subject. 3. On the upper-left side of the page, click Form View.
How do I go straight to a subject record as soon as I log in?	Home page	<ul style="list-style-type: none"> • Select from the Site, Subject, and Visit fields at the bottom of the page, and click Go.
What queries are still open on a form?	Form or Queries page	<ol style="list-style-type: none"> 1. Click Subjects. 2. Click the status icon for a subject and visit. 3. Click a form selector icon. or Click Queries.
I have to enter the same type of data for everybody at my site. Can I go right to that form in each subject's case report book?	Form	<ol style="list-style-type: none"> 1. Click Subjects. 2. Click the status icon for a subject and visit. 3. Click a form selector icon. 4. Use the arrows of the subject navigation control to show the same form for each subject in the site. 
Which forms do I have to sign?	Required Signatures page	<ul style="list-style-type: none"> • Click Signatures.

How do I change my password?

For a non single sign-on (SSO) study:

1. In the upper-right corner of any page, click your picture or user name.
2. Fill in the fields, and click Submit.

For an SSO study with your Oracle Life Sciences IAMS credentials:

1. In the upper-right corner of any page, click your picture or user name.
2. On the left, click **My Profile > My Information**.
3. Fill in the fields in the **Change Password** section, and click **Apply**.

For an SSO study with your Federation credentials:

If you are using use your Federated login to log in to your study, you must follow your Federated account's process for changing your password.

How do I reset a forgotten or expired password?

For a non single sign-on (SSO) study:

1. Click **Forgot Your Password** on the Login page.
2. In the Reset Password page, enter your user name, click **Reset Password**, and then click **Return to Login page**.
An email with instructions for resetting your password is sent to the email address that is associated with your InForm user account. It contains a link that you use to reset your password.

 **Note:**

The application can only send one password reset email every 30 minutes.

3. In the email, click the link to reset your password.
The link is valid for 24 hours.
4. In the **Reset Password** page, enter and confirm your new password, and click **Submit**.
5. Click **Return to Login page**.
6. Use your new password to log in to Oracle Life Sciences InForm.


For an SSO study with your Oracle Life Sciences IAMS credentials:


1. Click **Trouble Signing In** on the Login page.
2. Enter your SSO account user name, and click **Next**.
3. If your account is set up to not require challenge questions, you will receive an email with a link to reset your password.
4. If your account is set up to require challenge questions, answer the challenge questions you selected when you set up your SSO account, and click **Next**.
5. Enter your new password, and click **Save**.

For an SSO study with your Federation credentials:

If you are using use your Federated login to log in to your study, you must follow your Federated account's process for resetting a forgotten or expired password.

How do I log out of a study?

- In the upper-right corner of any page, click the **Logout** button ().

 **Note:**

If you are working in an SSO study and are using a Federation account for authentication, be sure to close your browser to end your Federation account session.

3

Add a subject to a study

In this chapter:

- [Screen a candidate](#)
- [Enroll a screened candidate](#)

Screen a candidate

Adding a subject to a study is a two-step process known as Screening and Enrollment.


1. Click **Enroll**.
2. In the bottom-right corner, click **Add Candidate**.
3. Enter the candidate information required by the study. If your study requires you to enter subject initials, in the **Subject Initials** field, enter three characters.

 **Note:**

You can't change the subject initials or any other data on the Screening form after you enroll a subject. Make sure that you enter it correctly here.

4. Click **Submit**.

The candidate is added to the bottom of the list. Screening is either:

- Successful—The Enrolled column contains an **Enroll** link.
 - Failed—The Enrolled column contains the Enrollment failed icon () , and the Screening Failure column indicates the reason for failure.
- [Resubmit a candidate who failed screening](#)

Resubmit a candidate who failed screening

You can resubmit a candidate who has failed screening if you think the candidate should be eligible for the study.


1. Click **Enroll**.
2. On the Enrollment page, look in the Screening Failure column to see why screening failed.
3. Click the candidate's screening number.
4. On the Screening form, make the changes necessary to resubmit successfully, and click **Submit**.

For more information, see [Why would a screening fail, and what can I do about it?](#)

Enroll a screened candidate

1. Click **Enroll**.
Newly screened candidates appear at the bottom of the list.
 2. Click a candidate's **Enroll** link.
 3. Complete the Enrollment form, and click **Submit**.
The Enrollment Confirmation page appears and indicates whether data is complete and the candidate meets all the study criteria.
 4. Enroll the candidate or refuse enrollment, by clicking **Enroll** or **Do Not Enroll** in the bottom-right corner.
After a successful enrollment, the Visit Calculator appears if your study is configured to use it. The Visit Calculator summarizes the tentative schedule of visits for the subject.
- [Complete enrollment after an enrollment failure](#)

Complete enrollment after an enrollment failure

1. Click **Enroll**.
2. Click the **Enrollment failed** icon () for the candidate.
Enrollment fails if:
 - The candidate doesn't meet study criteria.
 - Data entered on the Enrollment form is incomplete.
 - The candidate is ineligible for the study.
3. Make the changes necessary to complete enrollment.
For more information, see [Why would an enrollment fail, and what can I do about it?](#)

4

Forms and data

In this chapter:

- [Enter data and comments](#)
- [Edit or clear data](#)
- [View help for a form or item](#)
- [Mark a form SV Ready or Not SV Ready](#)
- [Review the audit trail](#)
- [Sign](#)

Enter data and comments

In this section:

- [Enter data](#)
- [Associate two forms](#)
- [Associate data on two forms](#)
- [Collect related data from multiple forms in a dynamic grid](#)
- [Enter and view data in an unscheduled visit](#)
- [Enter a comment](#)
- [Mark a form or item as incomplete](#)

Enter data

Forms for collecting data one time have two columns: questions on the left and data entry fields on the right.

Forms for collecting the same set of data multiple times (for example, multiple vital signs measurements taken at different times during the same visit, or a cumulative list of adverse event reports) have an Add Entry button or a New button in the upper-right corner, and the data appears in rows.

1. Click **Subjects**.
2. On the Case Report Books page, click the status icon for a subject and visit.
3. Select a form.
4. Do one or more of the following to display the form or items you need to enter data in:
 - If the form contains a list of questions, complete each question.
 - If you are entering a set of data such as adverse events that did not occur during the same visit, click the **New** button in the upper-right corner of the form.
 - If you are entering a set of data such as multiple vital signs measurements taken at different times during the same visit:

- Click the **Add Entry** button to display the data-entry items.
or
 - Enter the data in the grid.
5. Click **Submit**.

Associate two forms

If your study has forms with related data (AEs and ConMeds, for example), and you want to make both sets of data visible:

1. Open one of the forms with related data (for example, the Adverse Events form), and at the top-right select **[Summary]** from the drop-down list.
2. From the summary view, select a number in the first column of the form.

The bottom half of the page displays the data that can be linked with the data that you selected (for example, Concomitant Medications).
3. Select the checkbox for the related data to link the data in the two forms, and click **Submit**.

From this view, you can:

- Use the drop-down list on either form to display additional observations and create other links between them.
- Add new data to either form by clicking the **New** button.

Associate data on two forms



Tip:


[Watch a video on how to associate data](#)

If your study has forms with associated data (AEs and ConMeds, for example), you can add data such as a concomitant medication, and link it to existing data such as an adverse event.


1. Open one of the forms with related data (for example, the Concomitant Medications form), and at the top-right select **[Summary]** from the drop-down list.
2. In the top-right of the form, click the **New** button.
3. Fill out the form, and click **Submit**.
4. In the bottom half of the page, select the associated data (for example, an adverse event), and click **Submit**.

Collect related data from multiple forms in a dynamic grid


Forms for collecting a set of related data that already exists on multiple forms (for example, data about a serious adverse event, the concomitant medications taken at the time of the adverse event, and medications taken during a subsequent

hospitalization) have a **Select Subject Data** button (), which allows you to select the entered data that you want to add to the form.

1. Click **Subjects**.
2. On the Case Report Books page, click the status icon for a subject and visit.
3. Select a form.
4. If you see a **New** button in the upper-right corner of the form, click it to create a new instance of the form.
5. If the form contains a list of questions, complete each question.
6. To create a collection of related data, for each form that you can select data from:

- a. In the header row for the form, click the **Select Subject Data** button () on the right of the page.
- b. In the dialog box, select the items that you have determined are related to each other, or to a specific data point.

 **Note:**

Since there are multiple sources, in some cases there may be a large number of records in the dynamic grid dialog box. Click the **Filter** button () to target specific date ranges or specific codelist values.

- c. Click **Submit**.
7. At the bottom of the form, click **Submit**.

Enter and view data in an unscheduled visit

If a subject comes in before the next scheduled visit, you record data in an unscheduled visit.

To enter data in an unscheduled visit:


1. Click **Subjects**.
2. Click the status icon for the unscheduled visit in the subject's row.
3. At the bottom-left corner of the page, click **New**.
4. Select a form.
5. Enter data in the form, and click **Submit**.

To view data in an unscheduled visit:

1. Click **Subjects**.
2. Click the status icon for the unscheduled visit in the subject's row.
3. At the bottom-left corner of the page, select the date of the unscheduled visit from the drop-down list.

Enter a comment

You can enter a comment on an item, a row of repeating data, or a form.

1. Click **Subjects**.
2. Click the status icon for a subject and visit.
3. Select a form.
4. Click a comment icon ()
5. Enter a comment in the **Comment** box, and click **Submit**.

For more information, see [How do I apply a comment to an item, row of repeating data, or a form?](#)

Mark a form or item as incomplete

1. Instead of entering data, create a comment on the item or form.

Note:

If you enter the comment on a form, the comment is also added to each item on the form.

2. In the Reason incomplete section of the Comment page, select the reason that describes why you are leaving the item or form blank.
3. Click **Submit**.

Edit or clear data

In this section:

- [Edit data after you submit a form](#)
- [Clear a data item](#)
- [Clear a form](#)
- [Delete or undelete an Add Entry row](#)
- [Delete or undelete a repeating form](#)

Edit data after you submit a form

Tip:


[Watch a video on how to edit data](#)

1. Open the form.
2. Select the field to edit.


- For an item in a row of repeating data, click any underlined data item.
 - For a form with a **New** button, click the number in the far-left column, and then click the field.
3. In the **Enter New Value** section, enter the new data.
 4. In the **Reason for Change** section, select or enter a reason for changing the data, and click **Submit**.

Clear a data item

Before submitting the form:

Click the **Reset item values** icon () in the far-right column of the data-entry row.

After submitting the form:

1. Click the entered item.
2. On the Data Value(s) page, click the Reset item values icon () and select or enter a reason for the change.
3. Click **Submit**.

Clear a form

Before submitting the form:

Click **Return** without submitting, and in the confirmation dialog box, click **OK**.

After submitting the form:

Tip:

[Watch a video on how to clear a form](#)

1. In the Action menu in the lower-left corner of the form, select **Clear CRF**, and click **Apply**.
2. In the **Reason for clearing the form** field, select or enter a reason for the change.
3. Click **Submit**.

Tip:

If you add data to the form after clearing it, and the data on the form is mapped to a dynamic grid, which is used to collect related data on a single form, you must re-add the data to the dynamic grid. For more information, see [Collect related data from multiple forms in a dynamic grid](#).

Delete or undelete an Add Entry row

To delete a whole Add Entry row:

1. Click the row number in the far-left column of the row.
2. In the **Reason for change** field, select or enter a reason for the deletion.
3. Click **Delete**.
The items in the deleted row are crossed out on the form.

To undelete a whole Add Entry row:

1. Click the row number in the far-left column of a row with crossed-out items.
2. In the **Reason for change** field, select or enter a reason for undeleting.
3. Click **Undelete**.
4. If the data in the Add Entry row is mapped to a dynamic grid, which is used to collect related data on a single form, you must re-add the data to the dynamic grid. For more information, see [Collect related data from multiple forms in a dynamic grid](#).

Delete or undelete a repeating form

1. Click **Subjects**.
2. On the Case Report Books page, click the status icon for a subject and visit.
3. Select a repeating form such as an Adverse Events or Concomitant Medications form.
4. At the bottom-left of the page, in the **Select Action** drop-down list, select **Delete** or **Undelete**.
5. At the top of the page, select the checkbox for the form instance that you want to delete or undelete.
6. Specify a reason for the change, and at the bottom-right of the page, click **Delete** or **Undelete**.
7. If you undelete a repeating form and the data in the Add Entry row is mapped to a dynamic grid, which is used to collect related data on a single form, you must re-add the data to the dynamic grid. For more information, see [Collect related data from multiple forms in a dynamic grid](#).

View help for a form or item

If your study includes form and item help, the descriptions of some forms or items might be underlined. You can click the underlined description to go from the form to the study-specific documentation for the form and items, which is also available if you click **Documents**.



Note:

Your study-specific documentation might also be included on your Home page, which is the first page that appears when you log in.

1. Open the form.
2. Click the underlined form name or item name.


Mark a form SV Ready or Not SV Ready

1. Click **Subjects**.
2. On the Case Report Books page, click the status icon for a subject and visit.
3. Select a form.
4. In the **Select Action** list at the bottom left of the page, select **Mark SV Ready** or **Mark Not SV Ready**, and click **Apply**.

Review the audit trail

You can view the audit trail in different ways, depending on what task you're completing. You can also view audit trail data by running the Audit Trail Report in the Reporting and Analysis module.

If you're entering data on a form:

1. Click the audit trail icon () for an item.

If you're changing or reviewing form data:

1. Click the data entry field for the item.
2. On the Data Value(s) page, select a change date and time from the **Audit Trail** list.
3. Review the details in the Reason for Change section.

or

1. Click the data entry field for the item.
2. On the left side of the Data Value(s) page, click **Audit Trail**.

Sign

In this section:

- [View your signature status](#)
- [View the signature status for your site](#)
- [Sign a form, visit or case report book](#)
- [Re-sign after a signature is invalidated](#)

View your signature status

1. Click **Signatures**.
2. To view details about a specific signature, in the Details column, click **View**.

View the signature status for your site

1. Click **Signatures**.
2. At the bottom-right of the page, click **View All Signatures**.
3. To view details about a specific signature, in the Details column, click **View**.

Sign a form, visit or case report book



Tip:

[Watch a video on how to sign a form or CRB](#)

1. Click **Signatures**.
2. At the bottom right of the page, if the **My Signatures** button is visible, click it to view the list of forms or case report books that you sign.
3. In the Signature column, click **Sign** for a form or a visit, or click **Sign Book** for a case report book.

To sign a visit, you sign the form designated as the signing form for the visit.
To sign a case report book, you sign the form designated as the signing form for the case report book.
4. Read the affidavit.
5. Do one of the following:
 - If you are working in a non-SSO study, enter your InForm username and password, and click **Submit**.
 - If you are working in an SSO study and are using your Oracle Life Sciences IAMS credentials for authentication, enter your SSO account user name and password, and click **Sign**.
 - If you are working in an SSO study and are using a Federation account for authentication:
 - Click **Sign**.
 - Enter your Federation email address, and click **Next**.
 - Enter your Federation password, and click **Next**.

Note:

If you are prompted, do not allow your browser to save your password.

Re-sign after a signature is invalidated

If a user updates a signed form, you have to sign the form, visit and case report book, if applicable, again. The Sign or Sign Book link for the form reappears in the Signature column of the Signatures page

5

Queries

In this chapter:

- [View your queries](#)
- [Answer a query](#)

View your queries

A query icon (🔍) appears next to the icons of visits and forms that contain items with open queries.

To view the list of all queries that you can answer:

- Click **Subjects**, open a form with a query icon and open the query.
- or
- Click **Queries**.

 **Note:**

You can also filter the page to show queries for a single subject or issuer.

To view a query for a single item:

- Click **Queries**, and click a query description.
- or
- Open a form that has a query icon, and click a query description.

Answer a query

 **Tip:**

[Watch a video on how to answer a query](#)

1. Click **Subjects**, open a form with a query icon (🔍) and open the query.
or
Click **Queries**, and in the Description column on the right, click the query description.
2. Answer the query:
 - By changing the data value—Click **Update and Answer**, and then enter a new value.
 - Without changing the data value—Click **Answer**.

3. Select or enter a reason, and click **Submit**.

6

FAQs

In this chapter:

- [Screening and enrollment FAQs](#)
- [Form and data FAQs](#)
- [Audit trail FAQs](#)
- [Query FAQs](#)
- [Study documentation FAQs](#)
- [Single sign-on \(SSO\) account FAQs](#)
- [HS Learn training FAQs](#)
- [User Acceptance Testing FAQs](#)

Screening and enrollment FAQs

In this section:

- [How do I add a subject to a study?](#)
- [Why would a screening fail, and what can I do about it?](#)
- [Why would an enrollment fail, and what can I do about it?](#)

How do I add a subject to a study?

1. Screen a candidate—Capture subject initials, record basic candidate information, and indicate whether the candidate is eligible for the study.
2. Enroll a screened candidate—Capture a subject number, record whether a screened candidate meets the enrollment criteria of the study, and complete the enrollment of the screened candidate. If you don't have all the information, you can submit an incomplete form and complete it at a later time.

Why would a screening fail, and what can I do about it?

The screening form is incomplete.

Complete the form, and then click **Submit**.

The candidate is ineligible for the study.

Check the data and make corrections if necessary. To correct a data value:

1. Click the entered value.
2. On the Data Value(s) page, type the correct value and select or type a reason for change.
3. Click **Submit**.

4. Click **OK**.
5. Click **Return** to go back to the Screening form.

Why would an enrollment fail, and what can I do about it?

The candidate doesn't meet the study criteria because of an error in data entry

1. Review the entries on the form, correct any data entry errors, and select a reason for the change.
2. Click **Submit**.
If the candidate meets all study criteria, a message appears indicating that the subject can be enrolled.
3. In the bottom-right corner, click **Enroll**.

The data entered on the Enrollment form is incomplete

If your protocol does not allow enrollment with incomplete enrollment data:

1. Enter the missing data items. Data items with missing data have a yellow background.
2. Click **Submit**, and then click **Enroll**.

If your protocol allows enrollment with incomplete enrollment data and approval from the sponsor:

1. Click **Submit**.
2. Complete the information on the Enrollment Override page.
3. Document your discussion with the sponsor representative, give the reason for the override, and click **Enroll**.

The candidate is ineligible for the study

If your study protocol allows enrolling candidates who are ineligible with approval from the sponsor:

1. Click **Submit**.
2. Complete the information on the Enrollment Override page.
3. Document your discussion with the sponsor representative, give the reason for the override, and click **Enroll**.

Form and data FAQs

In this section:

- [Can I view related data in two forms at the same time?](#)
- [Can I view related data in more than two forms at the same time?](#)
- [Can I skip an item or form?](#)
- [How do I apply a comment to an item, row of repeating data, or a form?](#)
- [Can I include clinical data in a comment?](#)
- [What are signatures used for?](#)

- [What order do repeating visits appear in the user interface?](#)

Can I view related data in two forms at the same time?

Yes. If your study assumes a relationship between two different sets of observations (for example, adverse events and concomitant medications), the study might have forms that you can link.

When you link two forms, you can see both sets of data at the same time. Both forms are the type that have a New button for entering repeating data. For more information, see [Associate data on two forms](#).

Can I view related data in more than two forms at the same time?

Yes. If your study assumes a relationship between a set of observations (for example, adverse events, concomitant medications, and lab results), the study might have a form where you can collect that related data. For more information, see [Collect related data from multiple forms in a dynamic grid](#).

Can I skip an item or form?

Yes. However, for a form to be complete, you must enter all required items (marked with an asterisk).

- If you don't have all of the data when you fill in a form, skip the missing items. When you submit the form, the missing items have a yellow background, and you can enter the data later.
- If your study protocol allows it, you might need to skip an item or a form permanently if:
 - The item or form does not apply to the subject.
 - The data is not available.
 - The procedure to collect the data was not done, and the data was not collected.

To mark an item or form as skipped, create a comment on the item or form. For more information, see [Mark a form or item as incomplete](#).

How do I apply a comment to an item, row of repeating data, or a form?

To apply a comment to a nonrepeating data item:

Click the icon in the last column for the item.

To apply a comment to an item in a row of repeating data:

Click the number in the first column of the repeating row to display individual items, and then click the icon in the last column for the item.

To apply a comment to a row of repeating data:

Click the icon in the last column of the repeating row.

To apply a comment to a form:

Click the icon in the upper-right corner of the form.

Can I include clinical data in a comment?

Many sponsors prefer that you don't. Check with your sponsor representative before including clinical data in a comment.

What are signatures used for?

Signatures on a form, visit or case report book confirm that required work is done. The significance of a signature is specific to a study, and the signature's meaning appears on an affidavit page that a signer signs.

What order do repeating visits appear in the user interface?

Repeating visits appear in the Time and Events schedule in ascending order based on the date of Date of Visit (DoV).

Audit trail FAQs

In this section:

- [What information is available in the audit trail?](#)
- [Who can see the audit trail?](#)
- [How does the audit trail date/time conversion work?](#)

What information is available in the audit trail?

Each time you change the value of a data item, an audit trail records the date and time of the change, your user name, and the reason for the change.

Who can see the audit trail?

You can see the audit trail information for the data you have access to, based on your rights.

How does the audit trail date/time conversion work?

The time (Date hour:min:sec) at which you enter data into Oracle Life Sciences InForm is stored in the Oracle InForm database in Coordinated Universal Time (UTC). However, the time that displays in the Oracle InForm audit trail depends on the time zone you specify for a site. You specify the time zone for a site through processing of the Site MedML, or by selecting a Time Zone on the Sites detail page when creating a site through the Oracle InForm Admin interface.

Valid time zone values must match those provided by Microsoft in the registry for your operating system. In addition to the list of time zone names, Microsoft stores each time zone's offset from UTC and details on the start and end date/time of daylight saving time where applicable. InForm uses this information to convert the data entry date/time stamp to the time zone for the site.

Oracle InForm:

1. Reads the audit date/time stamp from the database.

2. Retrieves the site's time zone setting specified in the Oracle InForm metadata.
3. Looks up the site time zone in the operating system registry, returns the necessary offset information, and determines whether the date/time in question is within or outside the daylight saving time adjustment.
4. Converts the date/time stamp from the database according to the offset information, and displays the converted information in the audit trail in the user interface.

Query FAQs

In this section:

- [When do I answer queries?](#)

When do I answer queries?

You'll have two types of queries to respond to:

- Automatic queries are generated by InForm. You can see and respond to automatic queries immediately after you submit data.
- Manual queries are created by CRAs or sponsor staff. You can respond to manual queries after source verification or other data review.

Study documentation FAQs

In this section:

- [What types of study documentation are there?](#)

What types of study documentation are there?

- **Study Design**—A set of instructions and other details about forms, data items, and edit checks.
- **Protocol Guide**—A copy of the sponsor's study protocol, formatted for online viewing.
- **Visit calculator**—A list of suggested visit dates based on a start date and the schedule in the study design. You can edit the start date to recalculate suggested visit dates.
- **Sample Book**—A complete set of read-only blank forms that you can use to familiarize yourself with the layout of the forms and visits.

Single sign-on (SSO) account FAQs

In this section:

- [How do I change my SSO account challenge questions?](#)
- [I've set up my SSO account, why can't I access the Oracle InForm study?](#)

How do I change my SSO account challenge questions?

If you didn't set up your challenge questions when you first logged into your SSO account, or if you want to change them:

1. Find the email you received from *OracleIdentityManager@oracle.com* when your SSO account was created with the subject line "Oracle Life Sciences Cloud - Account Password", which contains a link to manage your SSO account.
2. Log in to your SSO account with your account user name and password.
Depending on how your study is configured, either the Oracle Life Sciences Identity and Access Management Service (OLSIAMS) landing page (default) or the My Oracle Bookmarks page appears, and displays the Oracle Life Sciences InForm SSO-enabled studies you are allowed to access.
3. On the left, click **Update Profile**.
4. On the left, click **My Profile > My Information**.
5. Fill in the fields in the **Challenge Questions** section, and click **Apply**.

I've set up my SSO account, why can't I access the Oracle InForm study?

Setting up your account initiates your SSO account only. At this point, you cannot access the Oracle Life Sciences InForm study because your training and the study authorization process are not complete.

HS Learn training FAQs

In this section:

- [Why am I getting an error message when I try to sign in to HS Learn?](#)
- [How do I get to HS Learn to take my training?](#)
- [How do I create an Oracle Account for signing in to HS Learn?](#)
- [Why didn't I receive a training course assignment email?](#)
- [Why aren't my training courses loading?](#)
- [What if I am assigned to the wrong course?](#)
- [How do I enroll myself in a training course?](#)
- [How do I view my training status and certificates in HS Learn?](#)
- [I completed my training, why can't I see my certificate in HS Learn?](#)
- [I completed my training, why did I get assigned to it again?](#)
- [Do I have to re-take the HS Learn training every time I am given access to an Oracle Life Sciences InForm study?](#)
- [Can the name on my training completion certificate be changed?](#)
- [Why there is no date of completion on my certificate?](#)
- [How can I get more help with my Oracle Account?](#)
- [How can I get more help with HS Learn?](#)

Why am I getting an error message when I try to sign in to HS Learn?

Are you using the correct URL?

Make sure you are using the following URL to access HS Learn: <https://oracle.learn.taleo.net/healthsciences>

Note:

Wait until HS Learn loads completely before adding a bookmark.

Are you signing in with the correct account?

You need an Oracle Account to access the training in HS Learn. If you don't have one, see [How do I create an Oracle Account for signing in to HS Learn?](#)

Note:

This Oracle Account is a separate account required to access HS Learn; it does not use the same credentials you use to log in to your study.

IMPORTANT: Have you been assigned to training?

If you have an Oracle Account, but you haven't been assigned any training, you won't be able to sign in.

Was your Oracle Account created with the correct email address?

Your Oracle Account must be created with the email address where you received your HS Learn Course Assignment email.

Is your email address longer than 90 characters?

While you can create an Oracle Account with an email address that is longer than 90 characters, HS Learn has a 90-character limit. If your email address exceeds this limit, you won't be able to log in to HS Learn.

Send a request to your study administrator to be re-assigned to the training with an email address that does not exceed the 90-character limit.

How do I get to HS Learn to take my training?

1. Once you have been assigned to training and you received the training course assignment email from alerts@clinicalone.oraclecloud.com.
2. Go to HS Learn using the following URL: <https://oracle.learn.taleo.net/healthsciences>
3. Sign in to HS Learn using your Oracle Account user name and password.

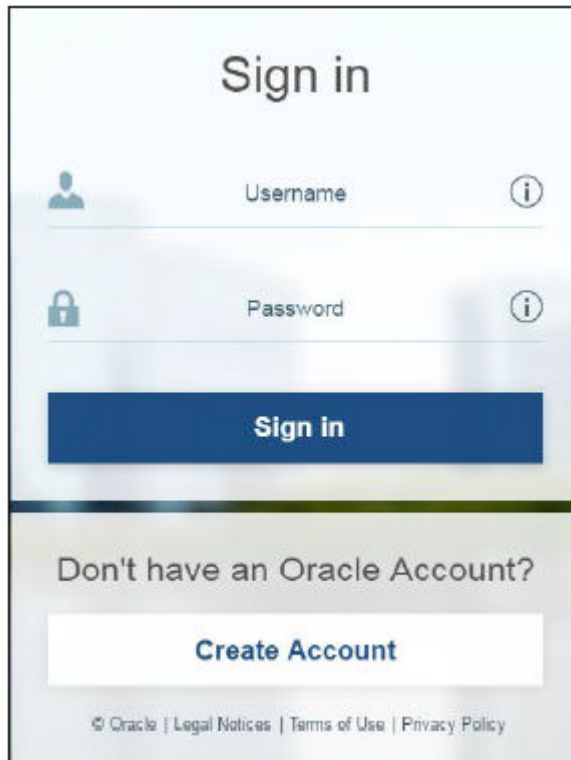
You need an Oracle Account to access the training in HS Learn. If you don't have an Oracle Account, see [How do I create an Oracle Account for signing in to HS Learn?](#)

How do I create an Oracle Account for signing in to HS Learn?

You need an Oracle Account to access the training in HS Learn. This Oracle Account is a separate account required to access HS Learn; it does not use the same credentials you use to log in to your study.

1. Go to HS Learn using the following URL: <https://oracle.learn.taleo.net/healthsciences>

The Sign in page appears.



Note:

Wait until HS Learn loads completely before adding a bookmark. Don't bookmark the HS Learn Sign in page.

2. Under **Don't have an Oracle Account?**, click **Create Account**.
3. Complete all the required fields in the form.
4. Enter the email address where you received your **HS Learn Course Assignment** email.

While you can create an Oracle Account with an email address that is longer than 90 characters, HS Learn has a 90-character limit. If your email address exceeds this limit, you won't be able to log in to HS Learn.

Send a request to your study administrator to be re-assigned to the training with an email address that does not exceed the 90-character limit.

5. Click **Create Account**.

6. Check your email for a confirmation message.
7. Confirm your email by clicking the link received.
8. Go back to <https://oracle.learn.taleo.net/healthsciences> to login.

 **Note:**

If you don't receive a confirmation email, or you have any issues creating your Oracle Account, contact Oracle Account Support using the following URL:
<https://www.oracle.com/corporate/contact/help.html>

Why didn't I receive a training course assignment email?

If you haven't received a training course assignment email or accessed HS Learn before, check to see if the message was sent to your spam folder. The sender's email address is alerts@clinicalone.oraclecloud.com

 **Tip:**

Add the alerts@clinicalone.oraclecloud.com email address to your address book to make sure you receive the assignment emails in the future.

If you still can't find the training course assignment email, contact your study administrator to request that you are assigned to a course.

Why aren't my training courses loading?


Do you have a slow internet connection? Do you have too many applications open that consume internet bandwidth?

If the dialog with the course loading message stops responding, and the course doesn't open, there may be an internet bandwidth problem.

What if I am assigned to the wrong course?



Contact your study administrator who can assign a different course, if appropriate.

How do I enroll myself in a training course?

1. On the HS Learn home page, click **Self Enroll**.
2. Click the Add button () to assign yourself to the course.

How do I view my training status and certificates in HS Learn?

You can log in to HS Learn at any time to see your training history. You can view, print, and download your completion certificates.

1. On the HS Learn home page, in the upper menu, click **Online Training** or **Classroom Training**.
2. On the left, click **View History**.
3. To view, print, or download the certificate, click the **View Certificate** icon () to the right of each completed course.
 - In the upper left of the page, click **Print** to print the certificate.
 - In the upper right of the page, click **PDF** to save and download the certificate in PDF format.
4. To export a list of your completed training courses, click the **Export** icon () , and select **Download Files**.
 - In the Documents Available for Download page, click **Transcript**.

I completed my training, why can't I see my certificate in HS Learn?

Did you look on the View History page?

See [How do I view my training status and certificates in HS Learn?](#) for instructions on how to get to the View History page.

Did you complete all the modules of your course, including the assessment?

For a module to be considered complete, all the modules of the course need to be completed. If the course includes assessments, you must complete all the assessments, to have the course marked as **Completed**.

Did you complete the Course Feedback?

- If you complete the courses as online training, the optional Course Feedback survey is available immediately after you complete all the modules.
- If you complete the courses as classroom training, an email is sent to your email address when the Course Feedback survey is available, which is normally several days after you complete the course. The course feedback is mandatory; you must complete the form in order to download the certificate.

Tip:

The email is sent to the address where you received the HS Learn Course Assignment email. If you don't see the email in your inbox, check your spam folder.

I completed my training, why did I get assigned to it again?

Did you complete the training more than 12 months ago?

Training completion certificates are valid for 12 months.

- If you completed your training more than 12 months ago, you are re-assigned to the training.

Show your previous certificate to your study administrator who can decide whether to accept a certificate that is older than 12 months. Your study administrator may accept the certificate, or decide that you need to re-take the training.

 **Note:**

You may have previously completed a course with a similar name. If the previously completed course contains the correct software name, version, and role you can present its completion certificate to your study administrator as proof of completion.

- If you completed the training within the previous 12 months, your training status will show as Completed/Trained.

Do I have to re-take the HS Learn training every time I am given access to an Oracle Life Sciences InForm study?

No. You are only required to take the training:

- The first time you are assigned to any course by any Sponsor.
- If you are assigned to the same course by any Sponsor 12 months or more after you most recently completed the course.

Can the name on my training completion certificate be changed?

Yes.

The change must be made in two locations, your study platforms and the HS Learn platform.

Contact your study administrator to have your name updated.

Additionally, contact <https://hsgbu.custhelp.com> to have your name changed.

Why there is no date of completion on my certificate?

Please download your certificate as soon as you complete a course; this way the valid date of completion will be added to the certificate.

Most of the courses have a 12-month expiration date, after the expiration of the 12 months you will not be able to download a valid certificate.

If you try to download the certificate after the 12 months have passed, the completion date will not be generated and the certificate is not valid. Contact your study administrator, you might need to be re-assigned to training.



How can I get more help with my Oracle Account?

Contact Oracle Account Support

If you have any issues with your Oracle Account, contact Oracle Account Support using the following URL: <https://www.oracle.com/corporate/contact/help.html>

How can I get more help with HS Learn?

Contact Oracle Life Sciences Support

If you have any additional issues specific to HS Learn, and you need more help, contact Oracle Life Sciences Support using the following URL: <https://hsgbu.custhelp.com>

Create a ticket, if necessary, for help with a specific issue

If you can't find the help you need in Oracle Life Sciences Support, and you decide to create a support ticket, make sure the following fields are populated with the correct values:

- **Product** = HS Learn

Note:

Product = HS Learn

- **Issue Category** = Training Courses

User Acceptance Testing FAQs

In this section:

- [Can I switch roles during User Acceptance Testing \(UAT\) environments?](#)

Can I switch roles during User Acceptance Testing (UAT) environments?

While users can only be associated to a single Rights Group and a single user type in live study environments, a User Acceptance Testing (UAT) environment allows a single user to switch to any user type and any of the Rights Group associated with a UAT study.


Note:

This feature is intended to be used only for test studies that have test data. The intent of this feature is to allow the user to be able to test the roles (rights group) that they are or will be assigned to in the live study. For example, if a user is associated to rights group A, they should test rights group A and not select rights group B.

When switching between user types or Rights Group in a UAT environment, consider that:

- Any Rights Group that includes ODMSUBMIT is excluded from the list of available Rights Groups.
- Any Rights Group that has more admin rights than the current user's Rights Group is excluded from the list of available Rights Groups.
- When comparing which Rights Group has more admin rights, all user admin rights are considered except **View System Configuration**, **View User Information** and **Subject Transfer**.
- Switching from one Rights Group to another does not give users new admin rights, but they may see restrictions if they change to a Rights Group with less admin rights.
- The capabilities of this feature in relation to InForm Reporting are limited to providing or revoking access to the Reporting Module, dependent on if the assigned Rights Group has the right **Reports** selected or un-selected. The functionality and access available to a user within InForm Reporting is controlled by InForm user-specific Reporting Group selection, which will remain unaltered when the Rights Group of a user is changed.
- The only ways to change users to a Rights Group with more admin rights are through MedML, UMT or login with the system admin user.

To change your user type or Rights Group during in a UAT environment:

1. Log into Oracle Life Sciences InForm.
2. Click on the **Modify user** button ()
3. In the **User Type** section, select either **Site User** (default) or **Sponsor User**.



 **Note:**

Oracle recommends that users do not change the user type from **Sponsor User** to **Site User** or viceversa when working with rights related to the Oracle InForm CRF Submit functionality. The request types that these users can create are dependent on their user type. In addition, the requests that were created as a Sponsor user type may have already been shared with Site user types. If the user types are switched after creating the requests, the created or shared requests may not be available for Sponsor or Site users as intended.

4. In the **Rights Group** section, select one of the available Rights Groups from the drop-down menu.
5. Click **Submit** at the bottom right of the page.
6. Click **OK** in the **User information updated** window.

After the Oracle InForm page is reloaded, the new Rights Group associated with the user appears in parenthesis next to the user name.

To view the history of Rights Group and user type changes for a user in the User Audit History record:

1. Log into Oracle InForm.
2. Click on the **Modify user** button (.
3. In the **User Type** section or the **Rights Group** section, click the **User Audit History** button (.

7

What if...

In this chapter:

- [I can't reset my password](#)
- [The link in my reset password email doesn't work](#)
- [I didn't receive an email when I reset my password](#)
- [I can't enter data](#)
- [I can't edit data in a section on a form](#)
- [I can't edit a form, visit, or case report book](#)
- [I didn't delete an item in a dynamic grid section, but the item's data is crossed out](#)
- [I can't see the study documentation](#)
- [I accidentally entered the wrong user name or password when I signed a form](#)
- [Data changes after I sign](#)
- [My answer to a query results in another query](#)
- [I can't log in to my SSO account with the temporary password](#)
- [I forget my SSO user name](#)
- [I forget my SSO password](#)
- [I completed my training, but I didn't get an email with the study URL](#)
- [I tried to log into my study, but the screen is blank](#)

I can't reset my password

For non-SSO studies, the password recovery feature is available only if your study is configured to allow it. If you click **Forgot Your Password** on the Login page and an error message appears stating that the reset password feature is not available, contact your Study Administrator for assistance.

For SSO studies, you can't use the password reset feature if you didn't set up your challenge questions when you first logged into your SSO account.

- If your challenge questions are not set up, ask your Study Administrator to reset your password.
- To set up your challenge questions, see [Single sign-on \(SSO\) account FAQs](#).

The link in my reset password email doesn't work

For non-SSO studies, the link is valid for 24 hours. A message appears on the Reset Password page if the link has expired. You may generate multiple reset password links, however, only the latest one is valid. If you try to use an earlier link, an expired reset password message appears on the Reset Password page.

After your password is successfully reset, the password reset link is no longer valid.

If you do not submit the new password information within 20 minutes of accessing the page, the Password Reset page clears the Password and Confirm Password fields. An error message doesn't appear.

I didn't receive an email when I reset my password


For non-SSO studies, the email with instructions and the link for resetting your password is sent to the email address that is associated with your InForm user account. Ask your Study Administrator to make sure your email address is correct.

I can't enter data

If you receive an error when trying to enter subject data, it might be because your site is getting a new study version and Oracle Life Sciences InForm is updating your study's workflow. Wait a few minutes and try again.

I can't edit data in a section on a form

You can only edit data in a dynamic grid if the item was entered as an editable item. However, if you added non-editable items to a dynamic grid section on a form using

the **Select Subject Data** button (), the item data is mapped to a source form such as the Adverse Events form. As a result, you can't edit the items in the dynamic grid section. However, if you edit the item data on the source form, it is updated in the dynamic grid.

I can't edit a form, visit, or case report book


It might be locked or frozen.

- Freezing prevents data entry and updates, including comment entry, but does not prevent query, source verification, and signing activities.
- Locking prevents all activities except signing.

If the status icon for the form, visit, or case report book includes a frozen (❄️) or locked (🚫) icon, contact a sponsor representative and ask for the object to be unfrozen or unlocked so that you can edit it.

I didn't delete an item in a dynamic grid section, but the item's data is crossed out

The item might have been deleted on the source form. If you added non-editable items

to a dynamic grid section on a form using the **Select Subject Data** button (), the item data is mapped from a source form such as the Adverse Events form. As a result, if you delete the data on the source form, or you delete the entire source form, the item data is subsequently deleted from the dynamic grid section.

I can't see the study documentation

Some sponsors include study documentation on the home page for a study. In addition, study documentation is optional and might not be implemented for your study.

I accidentally entered the wrong user name or password when I signed a form

When signing, you have the same number of tries to enter a correct user name and password as you do when you log in.

If you fail to enter the correct user name and password after the configured number of tries, you are logged out and your account is deactivated.

To reinstate your account, contact your System Administrator.

Data changes after I sign

If a user updates a signed form, you have to sign the form, visit and case report book, if applicable, again. The **Sign** or **Sign Book** link for the form reappears in the Signature column of the Signatures page.

My answer to a query results in another query

If a new query appears when you answer a query by changing the item data, check the data. Answer the new query, entering new data if necessary.

I can't log in to my SSO account with the temporary password

The temporary password is valid for 90 days. If you don't update your password within this time period, contact your Study Administrator to have a new password sent to you.

I forget my SSO user name

If your account is not configured to require security questions:

- Search your email for the one message from *OracleIdentityManager@oracle.com* that you received after your Study Administrator created your SSO account that contained your user name and a link to set up (or reset) your password.
- If you cannot find the email, contact your Study Administrator.

If your account is configured to require challenge security questions:

- Search your email for the two messages from *OracleIdentityManager@oracle.com* that you received after your Study Administrator created your SSO account. You received **two emails** (at the same time) from *OracleIdentityManager@oracle.com*:
 - One email with the subject line "Oracle Life Sciences Cloud - New Account", which contained your SSO account user name.

- A second email with the subject line "Oracle Life Sciences Cloud - Account Password", which contained a temporary password and a link to manage your SSO account.
- If you cannot find the emails, contact your Study Administrator.

I forget my SSO password

1. Click the **Trouble Signing In** link on the Login page.
2. Enter your SSO account user name, and click **Submit**.
 - If your account is set up to not require challenge questions, you will receive an email with a link to reset your password.
 - If your account is set up to require challenge questions, answer the challenge questions you selected when you set up your SSO account, and click **Next**.
 - Enter your new password, and click **Save**.

Note:

If you did not set up the challenge questions, you cannot use the **Trouble Signing In** link to reset your password, and you'll need to ask your Study Administrator to do it for you.

I completed my training, but I didn't get an email with the study URL

It may take some time before you receive the email with the study URL after you complete your training. The Study Administrator must manually grant you access to the study after you have completed your training and the study URL is available.

Or

The study may not be live. You receive an email with the study URL only after you complete the required Oracle Life Sciences InForm training, the study is live, and your UMT Administrator has manually granted you access to the study.

I tried to log into my study, but the screen is blank

This occurs if you try to access the study before your required training is complete, before you are authorized to access the study, or before the study is live.