Oracle Life Sciences Site Activate Information for Site Users





Oracle Life Sciences Site Activate Information for Site Users, Release 23.2

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Preface

This preface contains the following sections:

- Documentation accessibility
- · Diversity and Inclusion
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- Access to Oracle Support

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

Product 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.



Accessing Oracle Site Activate

Your study sponsor or CRO has invited you to collaborate in Oracle Site Activate to complete tasks and see status. Once you're added as a collaborating site and complete an online training and assessment, you will receive an email notification that allows you to access the system and set up your account. Then, just click the email link to log in.

If other study team members need to submit documents, contact your sponsor or CRO.





Compatible web browsers

Oracle Site Activate is hosted in the cloud and runs on multiple browsers. We certify or support the latest versions of Google Chrome, Microsoft Edge (Chromium), and Mozilla Firefox. Internet Explorer is not a certified or supported browser.



Logging in to Oracle Site Activate

- 1. Once you receive your Oracle Site Activate invitation, click the link included in the email.
- 2. You'll need to change your password the first time you log in. Create a new password on the **Change your password** page, then confirm it by entering it again.
- 3. Click Change my password.
- 4. Review the Terms of Service and Privacy Policy and click **Accept terms**.



Status indicators used in Oracle Site Activate

Oracle Site Activate uses colors and shapes to indicate status.





Uploading a document

Your pending activities display in a list on the left side of the page, while the document work area (widget) displays on the right. In a widget, you can add a note, upload a file, and view activity context (e.g., file history, lineage, etc.).

1. On the left side of the page, at **Your alerts**, click the activity for which you want to upload a document. The corresponding widget opens on the right side of the page.

Note:

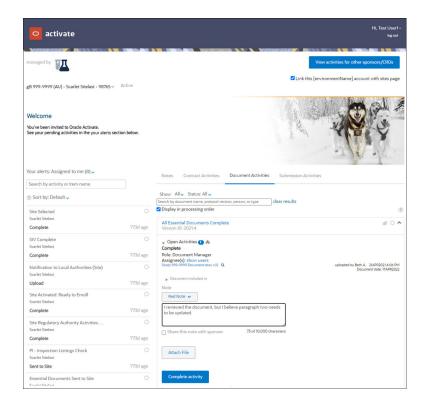
If a document you need to upload does not display in the **Your alerts** list, contact your sponsor or CRO.

- 2. In the widget, click Attach file.
- 3. Choose a file from your computer.
- Click Done.
- 5. As the file uploads, you'll see a progress bar indicating a file virus scan is in progress. Next, you'll see a confirmation message when the file passes the check and saves. Then, under **File history**, you'll see the new document listed.

Note:

If you upload the incorrect file, contact your Oracle Site Activate sponsor or CRO contact.

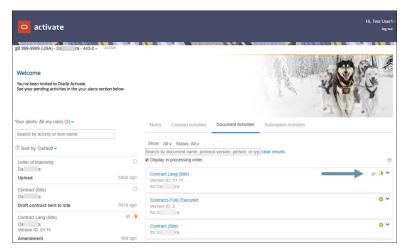






Viewing an uploaded document

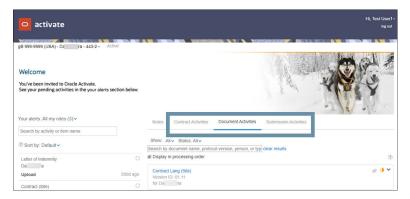
- Click the Document Activities tab.
- 2. Click the name of the document you want to access.
- 3. Scroll down if needed and click the gray arrow next to File history.
- 4. Click the file name download and view it, or if enabled for your account, click the magnifying glass to preview the document.





Viewing contract, document, and submission activities

- 1. Click the Contract Activities, Document Activities, or Submission Activities tab.
- 2. Expand widgets to see activities relevant to contracts, documents, or submissions.
- 3. Complete the necessary activities for the contract, document, or submission.

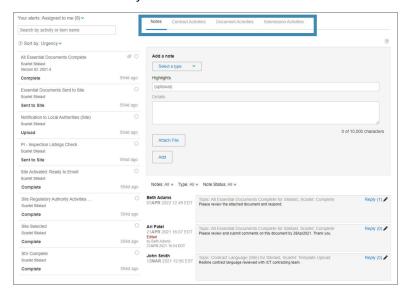


Adding a note for your team

- 1. Click the **Notes** tab to add a note to be shared with your CRO or sponsor.
- 2. Add a highlight and summary of the note.
- 3. If appropriate, you can attach a document to a note. Click **Attach File** and browse to locate the file. Oracle Site Activate will complete a virus scan on the file.
- 4. Click Add to send the note.

You can also add a note for a contract, document, or submission item within the subject area widgets. For example, click the **Document Activities** tab, click the document name, enter your note, then click **Done**.

As you add notes from the Notes tab or from within an activity widget, the note history will also be visible in the Notes tab. Previous notes display below the Note form and you can edit them if necessary.

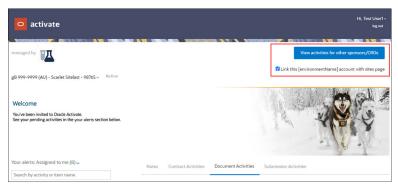


You can view replies for notes that have been shared with you and reply to specific notes. If you reply to a note, you'll see the original shared note and any existing replies in read-only mode. In addition, you can edit any note you create and reply to any note you create.

Linking your accounts under one sign in

Suppose you've been assigned to multiple accounts for multiple studies or sponsors. In that case, you can optionally link your accounts so that you only need to log in to Oracle Site Activate once to see your tasks across accounts.

You'll see the option to configure the connection at the upper right on the Oracle Site Activate home page.

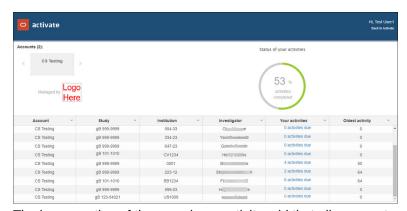


You can add new links or unlink accounts anytime by checking or unchecking the "Link this..." check box on the Oracle Site Activate home page. If you haven't checked the box for any accounts yet and click the "View activities" navigation link, Oracle Site Activate displays brief instructions to help you link your accounts.



After you've clicked the "Link this..." check box to link the account, and you then click the "View activities..." button, a new dashboard page displays. The number of accounts you've linked will display at the upper left just above an account filter. If you have multiple accounts linked, click the left and right buttons to navigate among them.

If the sponsor or CRO has enabled an account-specific logo, that logo displays to the right of "Managed by" text below the account name. You'll also see a graph showing the percentage of your completed assigned activities.



The lower portion of the page is an activity grid that allows you to sort any column to quickly locate activities within the account by study, institution, investigator, number of activities, and activity age. When you click a "<#> activities due" link in the "Your activities" column, the related site page in Oracle Site Activate displays so you can take action on the activity(ies). Return to Oracle Site Activate from the landing page anytime by clicking the "Back to Activate" link at the upper right.



Getting help and support

Here's how to find help if you need it:

- Request help from your sponsor or CRO contact
- Request help from Oracle by phone at 877.230.4168 (24/7)



About Oracle Site Activate LITE

With Oracle Site Activate LITE, you can complete document activities directly from an email link without logging in to Oracle Site Activate. Instead, the link takes you directly to Oracle Site Activate LITE, where you can complete activities and upload or download a file for one or more activities.

- 1. When you receive an email for your incomplete activities, click the Activate LITE logo.
- 2. Complete the activities listed.
- 3. To upload a file, click Attach file.
- 4. To download a file, click the file name. Then, an orange asterisk shows you files that you can download.
- 5. Click Done.



About site email integration

With site email integration, sites can complete activation tasks by viewing and uploading documents and adding comments directly from their email.

- 1. When you receive an email for your outstanding activities, click the option next to **Reply** or click the icon to download a file.
- 2. Upload files to the reply email (do not alter the token text at the bottom of the email).
- 3. Add comments as needed.
- 4. Click Send.



FAQs for Investigative Sites

Oracle Site Activate is a web application that gives you any time, anywhere access to your site activation activities. Upload documents, add notes, and view status of documents assigned to your site.

Here are responses to some frequently asked questions:

Do I need to install software to use Oracle Site Activate or Oracle Site Activate LITE?

No. The applications are hosted in the cloud. You use your web browser to access these applications; no additional software is necessary.

Which web browsers can I use?

You can use the latest versions of Google Chrome, Microsoft Edge (Chromium), or Mozilla Firefox. Internet Explorer is not a supported browser.

Can I access Oracle Site Activate or Oracle Site Activate LITE from anywhere at any time?

You can access the application(s) from anywhere if you have a reliable internet connection. The applications are available 24/7, except on occasional Saturday evenings when we perform system maintenance.

Are Oracle Site Activate and Oracle Site Activate LITE secure?

Yes. A secure Internet connection protects your access to either application, and each document uploaded into Oracle Site Activate or Oracle Site Activate LITE must pass a virus scan before upload.

Who should I contact for questions about:

- The study or study documents? Please contact your assigned study startup associate.
- Oracle Site Activate or logging in to Oracle Site Activate? Ask your assigned study startup associate or call Oracle support at 1.877.230.4168.
- Questions about resetting my password? Follow the instructions on the login page to reset your password. If you have any issues, please call Oracle support at 1.877.230.4168.

Troubleshooting for Investigative Sites

Occasionally, investigative sites need to work with their respective Information Technology associates to resolve issues regarding access to Oracle Site Activate. Below, we identify several common scenarios and guide the next steps.



Tip:

Once you've accessed the Oracle Site Activate application, set a bookmark so you can easily locate it in the future.

Scenario 1: I didn't click on my activation email, and I'm getting a message that the activation token expired.

Follow these steps:

- 1. Click on the link to Oracle Site Activate (where you received the error message).
- 2. Click on the Oracle Site Activate logo to access the Home page.
- 3. Click Forgot Your Password and enter your email address.
- 4. Click **Done**. You will receive a new email to activate your account.

Scenario 2: I received the email to activate my account, but it appears that the link has been blocked/removed by my IT department.

Contact your Sponsor/CRO partner, who will assist with getting this resolved.

Scenario 3: I received the email to activate my account, but when I clicked the link, I received an error message that the site could not be found.

The web application URL address in the link may be blocked by your organization. Please contact your IT department and request that they "allow list" or "safe list" anything associated with <.gobalto.com>. Once this is complete, you will be able to access the application.

Scenario 4: I can log into Oracle Site Activate, but when I do, all I see is a blank screen.

Contact your Sponsor/CRO Partner. You have likely not been assigned to a study at this time.

Scenario 5: I have problems accessing the system with Internet Explorer (IE).

Please use a different browser. Oracle Site Activate is hosted in the cloud and runs on multiple browsers. We certify or support the latest versions of Google Chrome, Microsoft Edge (Chromium), or Mozilla Firefox. Internet Explorer is not a certified or supported browser.

Scenario 6: I received an email alert that I have activities to complete, but the link has been omitted in the email due to e-mail restrictions at my site.

In this case, you will need to treat the alert purely as an email notification and know that when you receive one, you will need to go directly to the Oracle Site Activate application using the bookmark that you created when you activated your account. When you have completed your activity, delete the email.