

Oracle Life Sciences Site Activate

Information for Site Users



Release 23.3

F93382-01

February 2024



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	v
Diversity and Inclusion	v
Related resources	v
Access to Oracle Support	v

1 Accessing Oracle Site Activate

2 Compatible web browsers

3 Logging in to Oracle Site Activate

4 Status indicators used in Oracle Site Activate

5 Uploading a document

6 Viewing an uploaded document

7 Viewing contract, document, and submission activities

8 Adding a note for your team

9 Linking your accounts under one sign in

10 Getting help and support

11 About Oracle Site Activate LITE

12 About site email integration

13 FAQs for Investigative Sites

14 Troubleshooting for Investigative Sites

Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [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/>)

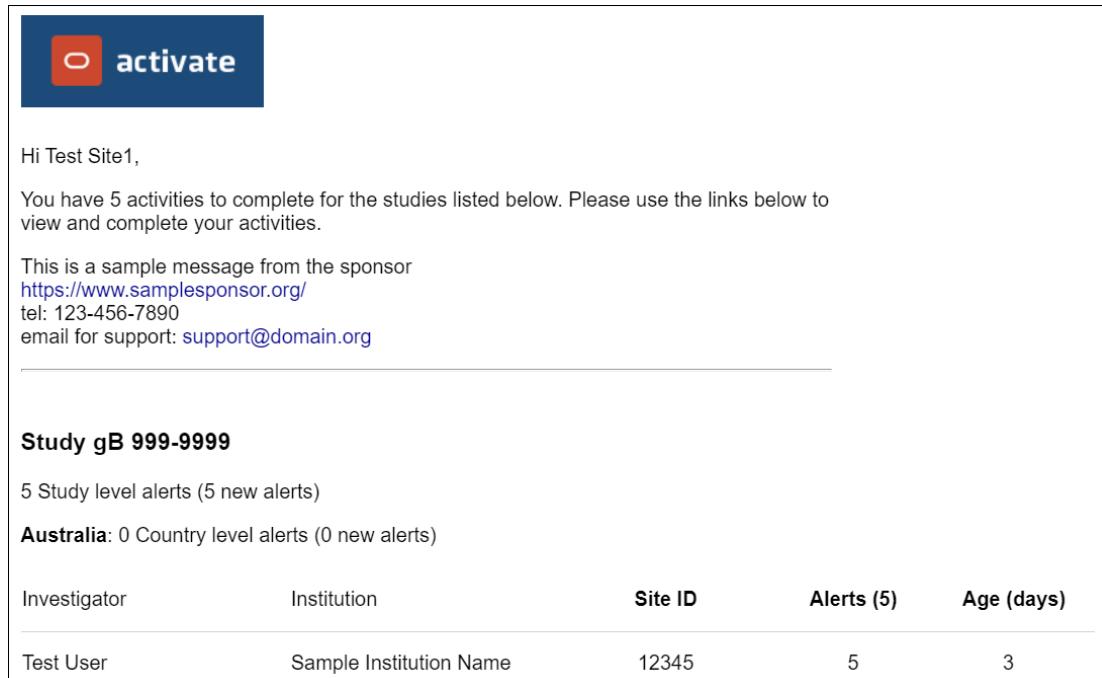
You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

1

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.



The image shows an email invitation from Oracle Site Activate. The subject line is "Hi Test Site1, You have 5 activities to complete for the studies listed below. Please use the links below to view and complete your activities." The message body includes a sample message from the sponsor with a URL, telephone number, and email address. It then lists study alerts and a table of user information.

Hi Test Site1,

You have 5 activities to complete for the studies listed below. Please use the links below to view and complete your activities.

This is a sample message from the sponsor
<https://www.samplesponsor.org/>
tel: 123-456-7890
email for support: support@domain.org

Study gB 999-9999

5 Study level alerts (5 new alerts)

Australia: 0 Country level alerts (0 new alerts)

Investigator	Institution	Site ID	Alerts (5)	Age (days)
Test User	Sample Institution Name	12345	5	3

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.

 Not started

 In progress

 Completed

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.
4. 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.

Hi, Test User! [log out](#)

View activities for other sponsors/CROs [Link this \[environmentName\] account with sites page](#)

managed by

gB 999-9999 (AU) - Scarlet Sitelast - 98765 Active

Welcome

You've been invited to Oracle Activate.
See your pending activities in the your alerts section below.

Your alerts: Assigned to me (8) [View details](#)

Search by activity or item name

Sort by: Default [Change](#)

Display in processing order

Notes Contract Activities Document Activities [Submission Activities](#)

Show: All [Status: All](#) [Search by document name, protocol version, person, or type](#) [clear results](#)

All Essential Documents Complete Version ID: 2021.4 [Edit](#) [Delete](#)

uploaded by Beth A. 21APR2021 4:06 PM Document date: 17APR2022

Open Activities [View](#) [Edit](#)

Complete Role: Document Manager Assigned to: Scarlet Sitelast (1) [View users](#)

Study 999-9999 Document.docx(v1) [Download](#)

Document included in Note [Edit Note](#)

I reviewed the document, but I believe paragraph two needs to be updated.

Share this note with sponsor 78 of 10,000 characters

Attach File [Upload](#)

Complete activity [View details](#)

Site Selected Scarlet Sitelast Complete 773d ago

SIV Complete Scarlet Sitelast Complete 773d ago

Notification to Local Authorities (Site) Scarlet Sitelast Upload 773d ago

Site Activated: Ready to Enroll Scarlet Sitelast Complete 773d ago

Site Regulatory Authority Activities ... Scarlet Sitelast Complete 773d ago

PI - Inspection Listings Check Scarlet Sitelast Sent to Site 773d ago

Essential Documents Sent to Site Scarlet Sitelast Complete 773d ago

6

Viewing an uploaded document

1. 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.

The screenshot shows the Oracle Activate interface. At the top, there is a navigation bar with a logo, the text 'activate', and a user dropdown 'Hi, Test User1 - log out'. Below the navigation bar, the page title is 'gB 999-9999 (USA) - D...ra - 443-2 - Active'. The main content area has a 'Welcome' message: 'You've been invited to Oracle Activate. See your pending activities in the your alerts section below.' There is a large image of dogsled dogs.

The 'Document Activities' tab is selected. Below it, there is a table of alerts:

Alert Type	Details	Timestamp
Letter of Indemnity	Da...ra	580d ago
Upload	Da...ra	580d ago
Contract (Site)	Da...ra	581d ago
Draft contract sent to site	Da...ra	581d ago
Contract Lang (Site)	Da...ra	581d ago
Amendment	Da...ra	48d ago

Below the table, there is a 'Contracts Fully Executed' section with a single entry:

Contract Lang (Site)	Version ID: 01.11	for Da...ra
----------------------	-------------------	-------------

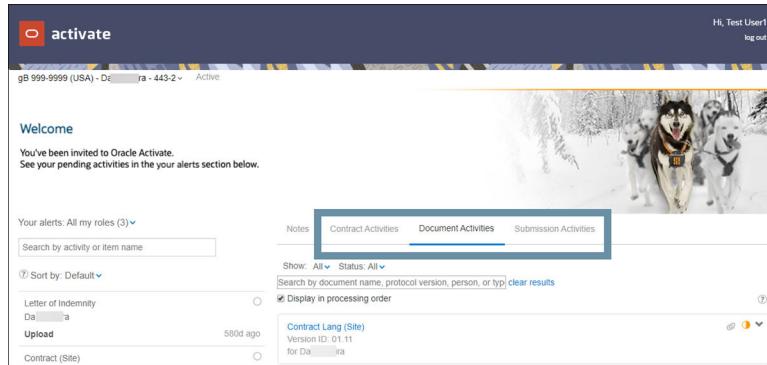
On the right side of the interface, there are three large blue arrows pointing downwards, indicating the flow from the main activities list to the detailed view of a specific document's history.

The detailed view for the 'Contracts Fully Executed' document (Version ID: 01.11) includes:

- Complete Activity** button
- Notes: 'View all notes for this document'
- Lineage information: 'None'
- Document information: 'Version ID: 01.11', 'Item ID: 71823'
- Related Activities** section:
 - Draft contract sent to site: 'Completed by Br...er' (27.JUN.2018)
 - Negotiations started: 'Completed by Br...er' (14.JUN.2019)
 - Finalized: 'Completed by Br...er' (14.JUN.2019)
 - Signature required: 'Sponsor signs first by Br...er via Activity Widget'
 - Signed by sponsor: 'Completed by Br...er via Activity Widget'
 - Signed by site: 'Completed by Br...er'
- File history** section:
 - Study 999-9999 Site...contract P123.docx v11
 - Add electronic signature request
- Download links: 'uploaded by Br...er 14.Jun.2019 12:24 PM' and 'Shared with site 19.Nov.2019 3:21 PM'
- Links: 'previous files' and 'Contracts Fully Executed'

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.

The screenshot shows the Oracle Site Activate interface with the Notes tab selected. On the left, a list of activities is displayed, including 'All Essential Documents Complete', 'Sent to Site', 'Upload', 'PI - Inspection Listings Check', 'Site Activated: Ready to Enroll', and 'Site Regulatory Authority Activities ...'. Each activity has a timestamp and a 'Details' link. On the right, a 'Notes' tab is open, showing a form to 'Add a note'. The form includes fields for 'Selected a type' (dropdown), 'Highlights' (text area), 'Details' (text area with a character count of 0 of 10,000 characters), 'Attach File' (button), and 'Add' (button). Below the form, there are three previous notes listed with their details and reply buttons. The notes are:

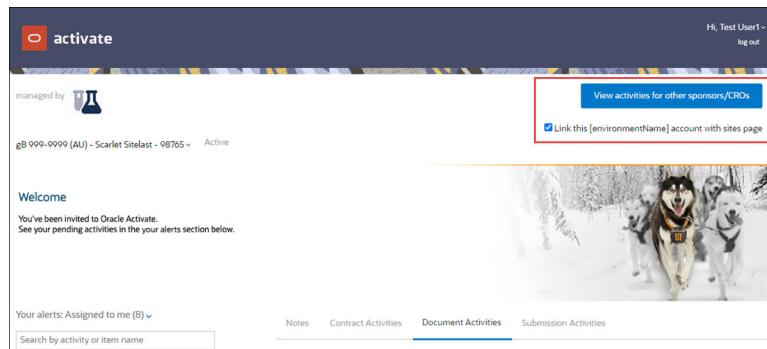
- Beth Adams** (07APR 2021 12:49 EDT): Topic: All Essential Documents Complete for Sitelast, Scarlet: Complete. Please review the attached document and respond. **Reply (1)**
- Ari Patel** (21APR 2021 16:07 EDT): Topic: All Essential Documents Complete for Sitelast, Scarlet: Complete. Edited by Beth Adams. Please review and submit comments on this document by 28Apr2021. Thank you. **Reply (0)**
- John Smith** (12MAR 2021 12:56 EST): Topic: Contract Language (Site) for Sitelast, Scarlet: Template Upload. Redline contract language reviewed with ICT contracting team. **Reply (0)**

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.

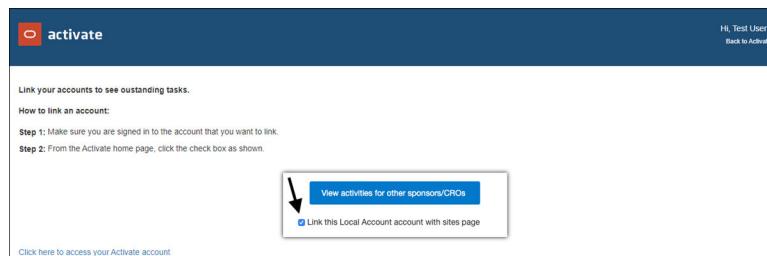
Linking your accounts under one sign in

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.

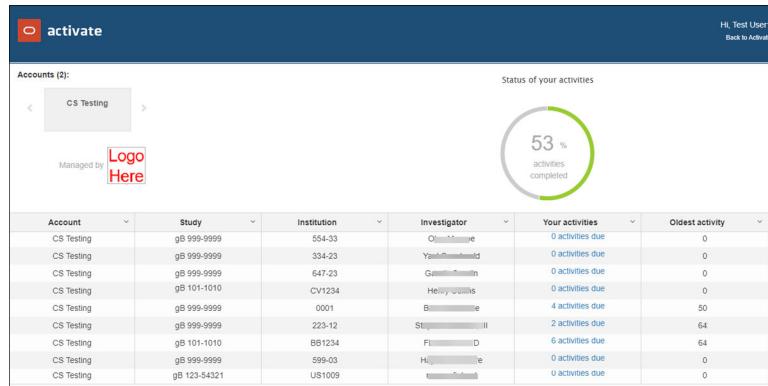


You can add new links or unlink accounts anytime by checking or unchecking the "Link this..." check box on the Oracle Site Activate home page. If you haven't checked the box for any accounts yet and click the "View activities" navigation link, Oracle Site Activate displays brief instructions to help 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 screenshot shows the Oracle Site Activate dashboard. At the top, there is a navigation bar with the Oracle logo, the word "activate", and a "Hi, Test User!" greeting with a "Back to Activate" link. Below the navigation bar, there is a section titled "Accounts (2):" showing two accounts: "CS Testing" and "CS Testing". Each account entry includes a "Logo" link, a "Managed by" link, and a "Here" link. To the right of the account list is a circular progress bar with the text "53 % activities completed". Below this, there is a table titled "Your activities" with columns: Account, Study, Institution, Investigator, Your activities, and Oldest activity. The table contains 10 rows of data, each representing an activity entry. The "Your activities" column shows values such as "0 activities due" and "4 activities due".

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 <.globalto.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.