Oracle Life Sciences Site Select
Information for Site Users

ORACLE®

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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.

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About Oracle Site Select LITE

Oracle Site Select LITE is the web-based tool that provides anytime, anywhere access to your site feasibility to-do list and status.

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Getting started

Check your email for an invitation. There are two ways to access Oracle Site Select LITE:

1. **No login required** – No need to remember a password, just click the encrypted link for secure access. This link expires after 60 days.

2. **Log in required** – Provides access to all studies you have been invited to participate in along with a document library with all the documents exchanged with the CRO/sponsor. Click the Log in required link to set a password for your account. If you forget your password, use the reset password link to receive a reset password email.

> ✏ **Note:**
>
> We have documented issues where email servers add tracking links to the Log in button. This may result in you having to re-authenticate after setting your password.

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Home page

On the home page, you'll see completed and future activities/tasks and milestones listed vertically on the left side of the page. Complete a task by taking the **Task action** on the right side of the page. Status for each task is color coded for at-a-glance view:

*   Green – complete
*   Orange – pending review (in progress)
*   Red – discontinued
*   Gray – not started

Your CRO/sponsor can optionally include:

*   additional study information that displays above the tasks
*   additional information for each individual task that displays under the Task name on the right

> ✎ **Note:**
>
> You may be working on more than one study with your CRO/sponsor. Make sure to review the study name in the "Study" drop-down menu, at the upper left, and adjust it as necessary using the down arrow before you begin your work.

The study CRO/Sponsor may include a brief study description on the home page as well. If provided, the descriptive text displays above the task list and may include a document download icon for additional information ( ). Not all studies require this descriptive text or document download, so it is not of concern if it does not display above the task list. To get back to this home page at any time, click the "select LITE" logo at the upper left of any page.

Each task that you need to complete will include a detail panel display to the right of the task. The panel can have information and actions related to the task, and you can view and download files, click the yes/no action buttons, upload files, and click Submit as appropriate
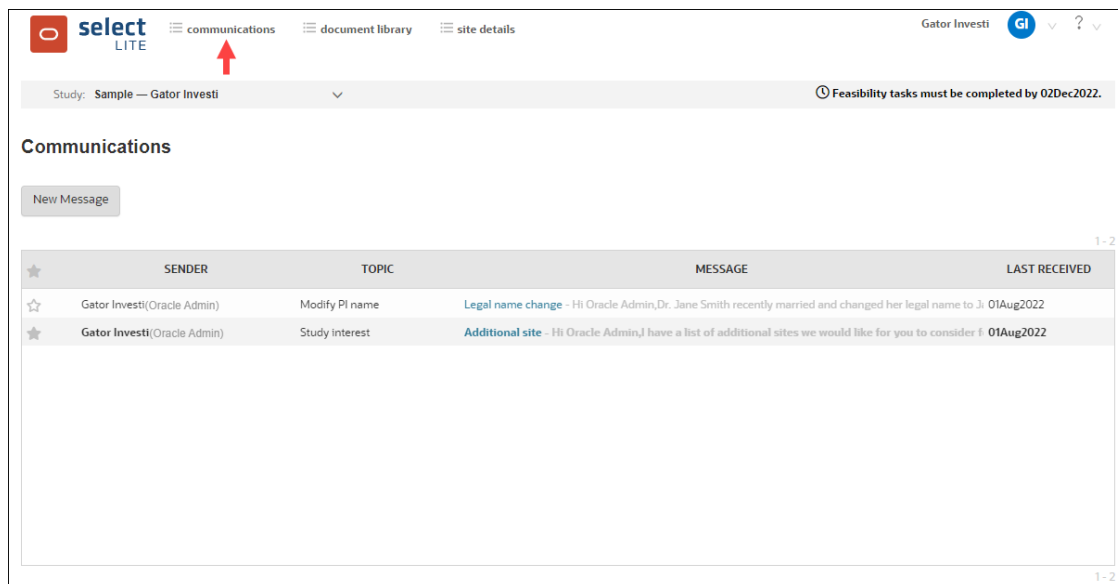
Your CRO/sponsor determines the required tasks, the task materials provided to you, and the order in which each task is available to you for action. Examples of tasks that might be assigned to you include:

- Verify site profile information
- Agree to confidentiality statement
- View protocol
- Verify site interest
- Complete feasibility survey
- Enter estimated patient count
- Sign and return CDA
- Review and/or return a document
- Enter date available for site visit

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Viewing communications with your sponsor or CRO

On the **communications** tab, you can send messages, and you'll see the complete history of communications with your sponsor or CRO.

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Managing documents and updating the site profile

Under the **document library** section, you can manage all the documents that are exchanged within a study in the "Study Documents" subtab (e.g., all CDA versions, protocol and other study documents exchanged with the CRO/sponsor, feasibility survey questionnaire PDF, as well as your completed survey). If your CRO/Sponsor has activated the optional Site document library feature to store investigator- and institution-scoped documents at the account level, you'll also see a "Site document library" subtab in the document library. This tab will include documents that can be re-used across studies (e.g., privacy consents, data use consents, master CDA, etc.).

> ✏️ **Note:**
>
> Remember that you need to create an account to access the document library.

Each CRO/sponsor within Oracle Site Select maintains a profile for the site. To view and manage your site's profile, click the **site details** tab (you'll see a bell icon if someone from your organization or the CRO/sponsor has updated the profile). If you have created an Oracle Site Select LITE account, then the study picker will allow you to switch between CRO/sponsor based on who is managing the study. Make sure to review and update all the tabs that have been made available to you by the CRO/Sponsor managing the study (tabs like Contacts, Study contacts, etc.). If you want someone on your team to work with the CRO/sponsor in Oracle Site Select LITE, add their information and email address in the "Site" sub-tab within profile's Contact tab in the applicable section. The new contact will receive an email with a link to login.

If the site record has been associated with a network, a read-only Network subtab also displays in the site profile. The subtab displays network details like name, ID, Affiliation scope and type, and Network delegate contact information, if available.

> **Note:**
>
> The study sponsor may have disabled your direct access to the site details link for this study. If you have questions about the profile, you can contact your study coordinator using the tool on the communications tab or reply to the email invitation for this study. If you were assigned a task to verify the profile, you can access the profile from the link included in the task on the home page.

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Completing feasibility surveys

Your sponsor or CRO may assign a feasibility survey task to you. This task displays in the home page task list. If you need to change your survey answer(s) and resubmit, just click the **Edit** link next to the survey item in the task list. You can also collaborate with your teammates to complete the survey. The survey link will save your responses automatically, you can exit the survey at any time and re-start the survey from Oracle Site Select LITE.

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Completing CDAs

If your sponsor or CRO assigns you a CDA task, you'll also find this in the task list.

Under the **Task materials** section, you can download the CDA for review and signature. You can also view the full **Document history**, if the CDA has revisions after you review.

To upload your signed CDA or a version with your suggested changes, click the **Task actions** button available under this task, which allows you to attach the document and leave comments for the CRO/sponsor. You will receive email notifications when your sponsor or CRO sends comments or CDAs back to you with changes.

> **Note:**
>
> If your sponsor or CRO opted for digital signatures, you will see additional details and information under the Task actions section on how to sign the document.

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Browsers

With Oracle Site Select LITE, you can use the latest versions of Google Chrome, Microsoft Edge (Chromium), or Mozilla Firefox. Internet Explorer is not a supported browser.

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Getting help

For assistance, reach out to your sponsor or CRO contact. You can also contact Oracle by phone 24/7 at: 1.877.230.4168.