Oracle® Life Sciences AI Agents

User Guide

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Oracle Life Sciences AI Agents User Guide,

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Introduction to Oracle Life Sciences AI Agents

Oracle Life Sciences AI Agents (Life Sciences AI Agents) is a web-based, unified workspace for designing, planning, conducting, and monitoring clinical trials across their lifecycle.

The *Life Sciences AI Agents User Guide* is for all users who design, plan, conduct, and monitor clinical trials. This guide provides an overview of Life Sciences AI Agents, information on how trial data is integrated into the application, and descriptions of the interface, user roles, trial access, and navigation and search features. It also provides detailed instructions for getting started, managing user accounts and trial access, and managing your trial data after it is integrated into Oracle Life Sciences AI Agents.

- Overview of Life Sciences AI Agents
  Life Sciences AI Agents provides centralized trial planning in a single, intelligent platform that eliminates redundant manual tasks, connects operational and clinical data, and provides AI-driven insights, risk scoring, and real-time monitoring to help you make faster, more confident decisions across the entire clinical trial lifecycle.
- Trial categories and data integration
  There are two categories of trials in Life Sciences AI Agents: Ongoing Trials and Trials in Planning. How you integrate your trial data into Life Sciences AI Agents determines how the trials are categorized.
- Life Sciences AI Agents interface
  The Life Sciences AI Agents interface is a centralized platform for managing your trial data and administrative tasks. There are two parts of the Life Sciences AI Agents interface: Trials (for managing trial data) and User Management (for managing user accounts and trial access).
- User roles
  There are two user roles in Life Sciences AI Agents that determine your feature access: Administrator and Trials.
- Trial access
  Depending on your responsibilities, and regardless of your role or roles, you may have access to all trials or to a subset of the trials in Life Sciences AI Agents.
- Navigation and search
  Life Sciences AI Agents provides multiple options for navigating through the interface.
- Sign in to Life Sciences AI Agents
  An administrator creates an Oracle Cloud account for you that you must activate and associate with Life Sciences AI Agents.
- Get started
  Before you start working in Life Sciences AI Agents, review the summary of steps available for managing users and assigning trial access, managing trial data for active ongoing trials and for trials that are in the planning phase, managing the AI-generated alerts, and for navigating to source Oracle Life Sciences applications.

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Overview of Life Sciences AI Agents

Life Sciences AI Agents provides centralized trial planning in a single, intelligent platform that eliminates redundant manual tasks, connects operational and clinical data, and provides AI-driven insights, risk scoring, and real-time monitoring to help you make faster, more confident decisions across the entire clinical trial lifecycle.

Life Sciences AI Agents unifies the processes from separate source Oracle Life Sciences applications, which enable you to complete most of your trial oversight and decision-making workflows within the application.

The source Oracle Life Sciences applications can include:

- Oracle Life Sciences Clinical One Cloud Service
- Clinical Trial Management System (CTMS)
- Oracle Life Sciences Site Activate
- Oracle Life Sciences Site Select
- Electronic Trial Master File (eTMF)

Use Life Sciences AI Agents for:

- **Portfolio and trial health monitoring**—Clinical operation leads and executives can view real-time portfolio health across studies, sites, and countries with AI agents highlighting emerging risks in enrollment, timelines, or quality metrics. AI-generated alerts and suggested actions enable proactive intervention and resource optimization across programs.
- **Trial planning and startup**—Study managers and clinical operations leads can generate trial plans from protocol inputs leveraging AI to extract key parameters, model timelines and budgets, rank countries and sites, and initiate activation workflows. This eliminates manual feasibility and planning work, accelerating study startup while ensuring plans remain aligned with enrollment and budget targets.

> **Note**
>
> Life Sciences AI Agents does not perform calculations on clinical data using any proprietary algorithm. It aggregates data from connected source systems and applies standard, transparent analytics and rule-based logic to surface operational insights. Any AI-driven suggestions are based on non-proprietary reasoning patterns and do not alter or calculate clinical measurements.

Trial categories and data integration

There are two categories of trials in Life Sciences AI Agents: Ongoing Trials and Trials in Planning. How you integrate your trial data into Life Sciences AI Agents determines how the trials are categorized.

There are two methods for integrating trial data into Life Sciences AI Agents. You can collaborate with Oracle to import existing trial data from an Oracle Life Sciences source application, such as Clinical One Cloud Service or CTMS. Or, you can manually upload protocols for new trials that are not yet active.

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- **Ongoing trials**—Active trials that have had their data onboarded into Life Sciences AI Agents by Oracle from a source application.

  Ongoing Trials are active clinical trials with ongoing or completed patient enrollment and data collection. They can be at any stage of the clinical trial lifecycle and are supported in Life Sciences AI Agents through the provision of AI-driven insights and summaries.

- **Trials in Planning**—Inactive trials whose protocols you manually uploaded into Life Sciences AI Agents.

  Trials in Planning are not yet active, with all or some features (such as protocols, operational plans, and site identification) that are still being developed or refined. The trial data is in the process of being reviewed and validated.

Depending on your permissions, you may have access to only Ongoing Trials or to Ongoing Trials and Trials in Planning. You cannot have access to just Trials in Planning.

Life Sciences AI Agents interface

The Life Sciences AI Agents interface is a centralized platform for managing your trial data and administrative tasks. There are two parts of the Life Sciences AI Agents interface: Trials (for managing trial data) and User Management (for managing user accounts and trial access).

Depending on your role or roles, you can access the Trials interface, the User Management interface, or both. If you have access to both, you can switch between the Trials interface and User Management interface as often as you like.

> **Note**
>
> Life Sciences AI Agents supports the latest versions of the Google Chrome, Mozilla Firefox, Microsoft Edge, and Apple Safari browsers.

Trials interface

You use the Trials interface to manage trial data. The tabs and pages you see depend on whether you have access to all trials or a subset of trials, and to Ongoing Trials or Trials in Planning. The Trials interface provides access to the pages you use to view and manage all or individual trial data, add trials, and manage alerts (AI-generated notifications that provide important information or identify potential issues). For more information, see Trials interface.

User Management interface

You use the User Management interface to manage user accounts, permissions, and trial access. The User Management interface is only available to you if you are a Life Sciences AI Agents administrator. For more information, see User Management interface.

- Trials interface
  The Trials interface allows you to manage trial data and includes three sections: Home, Trials, and Alerts. The sections and pages you see depend on your trial access and permissions.
- User Management interface
  The User Management interface allows you to manage user accounts, permissions, and trial access. This interface is only available to you if you are a Life Sciences AI Agents administrator.

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Trials interface

The Trials interface allows you to manage trial data and includes three sections: Home, Trials, and Alerts. The sections and pages you see depend on your trial access and permissions.

Home

The Home tab opens the Portfolio Health overview, which serves as the single-entry hub for all the active, ongoing trials in a customer's portfolio.

The Portfolio Health overview is your Home page when you sign in. You can select the Home tab at any time to return to the Portfolio Health overview. For more information, see Portfolio Health overview.

Trials

The Trials tab opens the Trial list, which serves as the central navigation hub for all the trials you have access to, and provides easy navigation between the Trials list and trial details.

You can select the Trials tab at any time to view the complete list of trials you can access. For more information, see Trials list.

> **Note**
>
> The Trials list provides information for Ongoing Trials and if you have access, to Trials in Planning.

Alerts

The Alerts tab opens the Alerts list that serves as a central repository for all the alerts for the Ongoing Trials you have access to, and provides easy navigation between the Alerts list and alert details. Alerts are AI-generated notifications that provide important information or identify potential issues for the Ongoing Trials you can access.

You can select the Alerts tab at any time to view the complete list of alerts in the Ongoing Trials you can access. For more information, see Alerts list.

- Portfolio Health overview
  The Portfolio Health overview serves as the single-entry hub for all the active, ongoing trials in a customer's portfolio.
- Trials list
  The Trials list serves as the central navigation hub for all the trials you have access to, and provides easy navigation between the Trials list and trial details. You can use the Trials list as a convenient and organized way to access and navigate through the trials you can access.
- Alerts list
  The Alerts list serves as a central repository for all the alerts in the Ongoing Trials you have access to, and provides easy navigation between the Alerts list and alert details. Alerts are AI-generated notifications that provide important information or identify potential issues for the Ongoing Trials you can access.

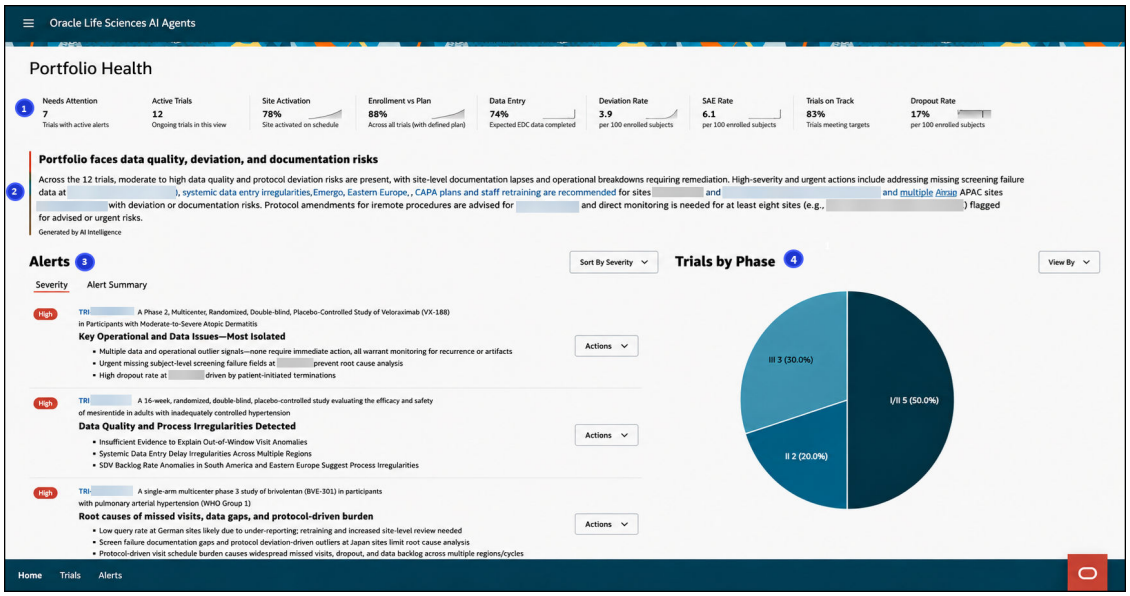
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Portfolio Health overview

The Portfolio Health overview serves as the single-entry hub for all the active, ongoing trials in a customer's portfolio.

The Portfolio Health overview provides key performance indicators, an AI-generated text summary of the portfolio health, a list of the highest priority AI-generated alerts, and data in selectable graph formats. Data in the Portfolio Health overview is from active trials that have been onboarded by Oracle from a source Oracle Life Sciences application.

The Portfolio Health overview serves as your Home page, which opens by default when you sign in to Life Sciences AI Agents. You can select the Home tab at any time to return to the Portfolio Health overview. For example:



The Portfolio Health overview provides the following information:

- **1 - Portfolio Key Performance Indicators (KPIs)**—Standardized KPIs that provide unified metrics that measure study performance consistency across all trials in the portfolio for the past 90 days to identify areas of operational risk.

  The portfolio health KPIs appear across the top of the page below the title. They are refreshed every 24 hours at 2 am UTC and are only calculated and shown if there is enough data for each. The KPIs can include Needs Attention, Active Trials, Site Activation, Enrollment vs Plan, Data Entry, Deviation Rate, SAE Rate, TMF Completeness, Trials on Track, Dropout Rate, and Data Entry Timeliness.

  For more information and descriptions of the portfolio health KPIs, see View the portfolio key performance indicators.

- **2 - Portfolio Health Summary**—An AI-generated text summary of the portfolio health for all Ongoing Trials in the portfolio. The health summary highlights top risks, study-level callouts with direct (deep) links, and cross-portfolio trends impacting efficiency and quality.

  The portfolio health summary appears below the KPIs and provides executives, study managers, and clinical operations leads with access to all trials a consolidated view of the portfolio health by surfacing the most critical risks, trends, and study-level callouts.

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> **Note**
>
> The portfolio health summary appears on the Portfolio Health Overview page only if you have access to all trials.

For more information, see View the portfolio health summary.

- **3 - Portfolio Alerts**—An AI-generated list of the highest priority alerts (for example, insights and recommendations) for all Ongoing Trials in the portfolio. The portfolio alerts provide a concise and regularly updated view of the most critical issues in a customer's clinical trial portfolio, enabling you to quickly respond to emerging issues or trends.

  The portfolio alerts:

  – Show one row per trial and up to three top ranked issues for each trial (each alert provides a link to the Alert details).
  – Prioritize trials based on risk severity (Critical, High, Moderate, or Low). The default sort of the trials in the list is by risk severity.
  – Provide sorting of the alerts by Severity (default), Trial Name, or Alert Title.
  – Refresh every 24 hours at 2 am UTC. If no trials need attention, a "No trials currently require attention." message appears in the Alerts section.

  The portfolio alerts appear at the bottom left of the page. For more information and descriptions of each alert severity, see View the portfolio alerts.

- **4 - Portfolio Data Graphs**—Data for all the ongoing trials in the portfolio in any of the following selectable formats: Trials by Status (bar graph), Trials by Phase (pie graph), Trials by Therapeutic Area (bar graph), and Enrollment by Region (bar graph). Each graph format includes a timestamp. Hovering over the graphs displays statistic details.

  The portfolio data graphs enable you to tailor the visualization of your trial data to suit your analytical requirements, potentially enhancing your ability to understand and act upon the insights provided by the data.

  The portfolio data graphs appear at the bottom right of the page. For more information and descriptions of the data in the portfolio graphs, see View the portfolio data graphs.

Trials list

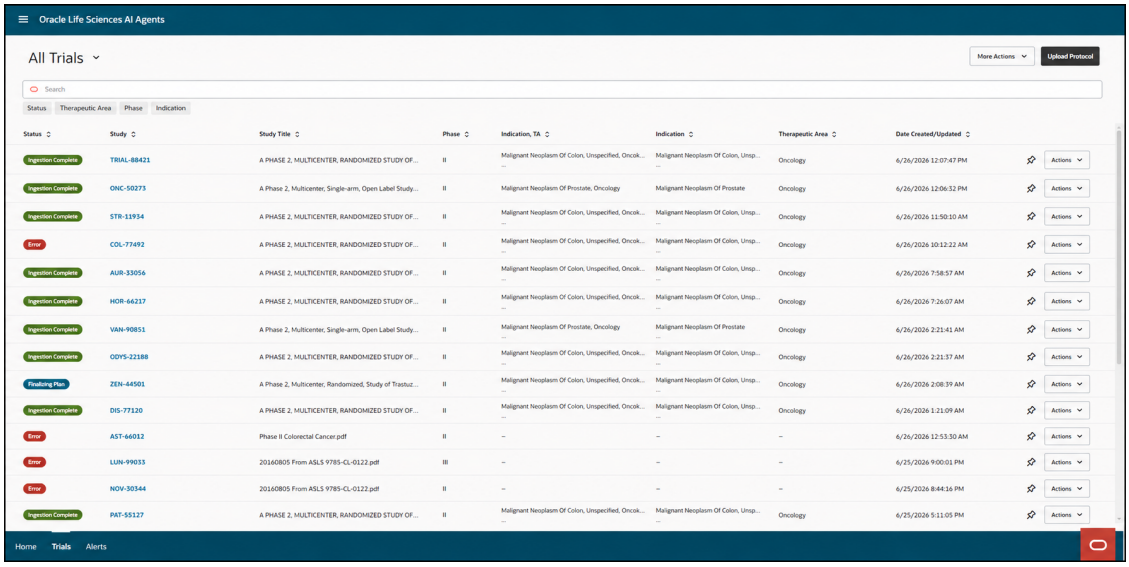
The Trials list serves as the central navigation hub for all the trials you have access to, and provides easy navigation between the Trials list and trial details. You can use the Trials list as a convenient and organized way to access and navigate through the trials you can access.

If you have access to a single trial or a subset of trials, the Trials list serves as your Home page, which opens by default when you sign in to Life Sciences AI Agents. However, you can select the Trials tab at any time to view the complete list of trials you can access.

You can filter the list by the operational lifecycle stage: All Trials, Ongoing Trials, Other Trials (trials that are completed, suspended, or terminated), and if you have access, to Trials in Planning. You can switch between the list views as often as you like. Each Trial list view provides the same filters and columns.

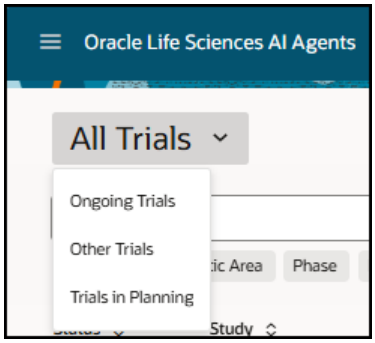
The first time you open the Trials list it defaults to the All Trials view. For example:

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> **Note**
>
> - To resize a column, move your pointer to the border between two column headers.
>
> When the pointer changes to the resize cursor , select and drag the border left or right to decrease or increase the column width.
> - You can also customize the columns that appear on the page and rearrange their order to optimize your view. For more information, see Customize the columns in the Trials list.

You use the drop-down menu at the top of the page to filter the list by the operational lifecycle stage (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). For example:



> **Note**
>
> If you do not have access to Trials in Planning, it does not appear as an option in the drop-down menu. The next time you sign in or select the Trials tab, the last view you selected will open (All Trials, Ongoing Trials, Other Trials, or Trials in Planning).

Use the Trials list to:

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- View the status, study name, study title, phase, indication and therapeutic area, and the dates the trials were created or last updated.
- Search for and sort the trials in the list.
- Filter the list based on Status, Therapeutic Area, Phase, and Indication to easily locate the list of relevant trials for your role.
  - **Status**—Filters the alerts by status. Enter text or select one or more options from the drop-down menu. The status options vary by the type of trials you are viewing (ongoing or in planning).
  - **Therapeutic Area**—Select an option from the drop-down menu to show only the trials for one or more therapeutic areas.
  - **Phase**—Select an option from the drop-down menu to show only the trials for one or more clinical trial phase.
  - **Indication**—Select an option from the drop-down menu to show only the trials for one or more indication.
- Navigate to a trial details page to view details of a specific trial and then return to the Trials list while keeping the Trials list filters in place. For more information, see View the details of an Ongoing Trial or View the details of a Trial in Planning.
- Export all trial data (filtered for All Trials, Ongoing Trials, Other Trials, or Trials in Planning) to a CSV file. For more information, see Export trial data.
- Add a new trial. For more information, see Add a trial for planning and monitoring.
- Use the Actions drop-down menus to initiate the following tasks:

  For Ongoing Trials:

  - Navigate to the study details. When you open the study details, a new tab with the study name appears at the bottom of the Trials interface page. For more information, see View the details of an Ongoing Trial.

  For Trials in Planning:

  - Upload another version of the same study protocol and regenerate the trial plan. For more information, see Upload a different version of a trial protocol.
  - Navigate to the study details. When you open the study details, a new tab with the study name appears at the bottom of the Trials interface page. For more information, see View the details of a Trial in Planning.

> **Note**
>
> For more information, see Manage all trials.

Alerts list

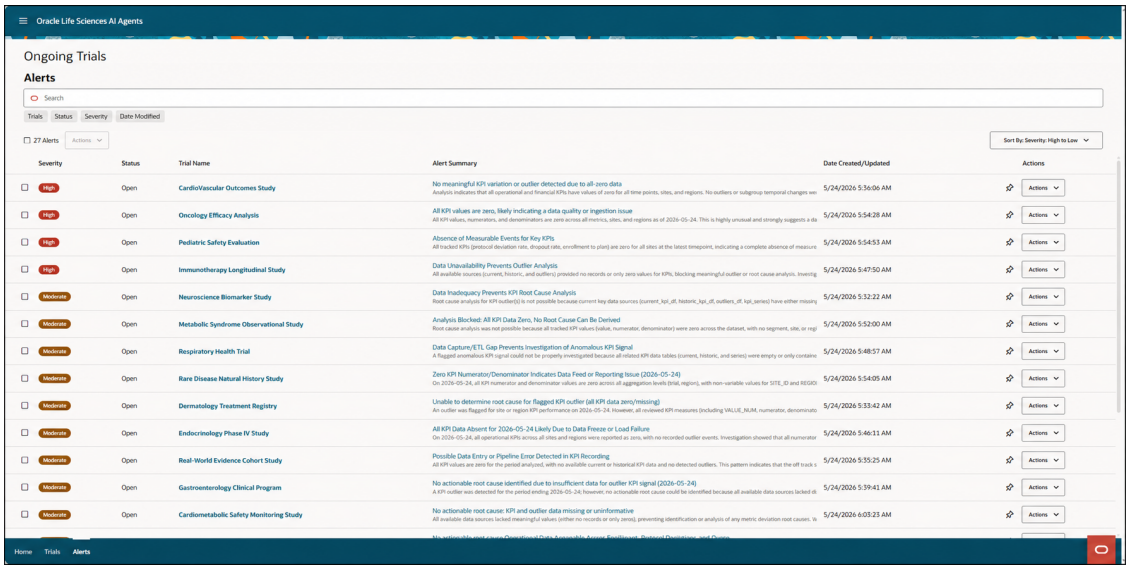
The Alerts list serves as a central repository for all the alerts in the Ongoing Trials you have access to, and provides easy navigation between the Alerts list and alert details. Alerts are AI-generated notifications that provide important information or identify potential issues for the Ongoing Trials you can access.

You can use the Alerts list to efficiently manage and respond to alerts across multiple trials, streamlining your workflow and improving your ability to address potential issues or opportunities. By default, the alerts are prioritized based on risk severity (Critical, High, Moderate, or Low).

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You can view alerts details and provide feedback on every alert. You can also view the AI reasoning steps for an alert, view the history of the alert, snooze or dismiss alerts, and view details for the study where the alert originated.

When you select the Alerts tab at the bottom of the Trials interface window, the Alerts list opens. For example:



> **Note**
>
> The Alerts list and associated pages provide information for Ongoing Trials only.

Use the Alerts list to:

- View the risk severity (Critical, High, Moderate, or Low), study name, alert name, alert summary, and the dates the alerts were created or last updated.
- Search for an alert.
- Sort the alerts in the list. Use the Sort By drop-down menu on the right to sort the alerts by:
  - Severity: High to Low
  - Severity: Low to High
  - Date: Most Recent Updated
  - Trial Name: A-Z
  - Trial Name: Z-A
- Filter the list based on:
  - **Trials**—Filters the alerts by trial name(s).
  - **Status**—Filters the alerts by status. Enter text or select an option from the drop-down menu:
    - **Snoozed**—Shows only the alerts that you snoozed.
    - **Dismissed**—Shows only the alerts that you dismissed.

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    - **Completed**—Shows only the alerts that you acted on that resolved the issue.
    - **Open**—Shows all your active alerts (this filtered list shows the alerts that do not have any other status).
  - **Severity**—Filters the alerts by severity risk. Enter text or select an option from the drop-down menu:
    - **Critical**—Imminent or ongoing serious risk to patient safety or trial integrity that may warrant immediate trial halt, enrollment hold, or urgent regulatory notification.
    - **High**—Credible and significant risk to patient safety, primary endpoint integrity, or critical milestones if not addressed promptly.
    - **Moderate**—No immediate safety risk, but material risk to timelines or quality; major (non-critical) protocol deviations; secondary or operational data degradation; sustained under-enrollment likely to delay non-critical milestones.
    - **Low**—Minor, localized, or transient issue with limited impact; generally reversible with routine follow-up and unlikely to affect safety or milestones.
  - **Date Modified**—Filters the alerts by the date modified. Use the Calendar icon to select a Start Date and End Date, or enter a date for each in MM/DD/YYYY format.
- Navigate to an Alert details page to view details of a specific alert and then return to the Alerts list while keeping the Alerts list filters in place. For more information, see View the details of an alert and provide feedback.
- Navigate to the study details. When you open the study details, a new tab with the study name appears at the bottom of the Trials interface page. For more information, see View the details of an Ongoing Trial.
- Use the Actions drop-down menu to initiate the following tasks:
  - View the details of an alert and provide feedback.
  - View the study details associated with an alert.
  - Snooze an alert.
  - View the history of an alert.
  - View the AI reasoning steps for an alert.
  - Dismiss an alert.

> **Note**
>
> For more information, see Manage the alerts for all Ongoing Trials.

User Management interface

The User Management interface allows you to manage user accounts, permissions, and trial access. This interface is only available to you if you are a Life Sciences AI Agents administrator.

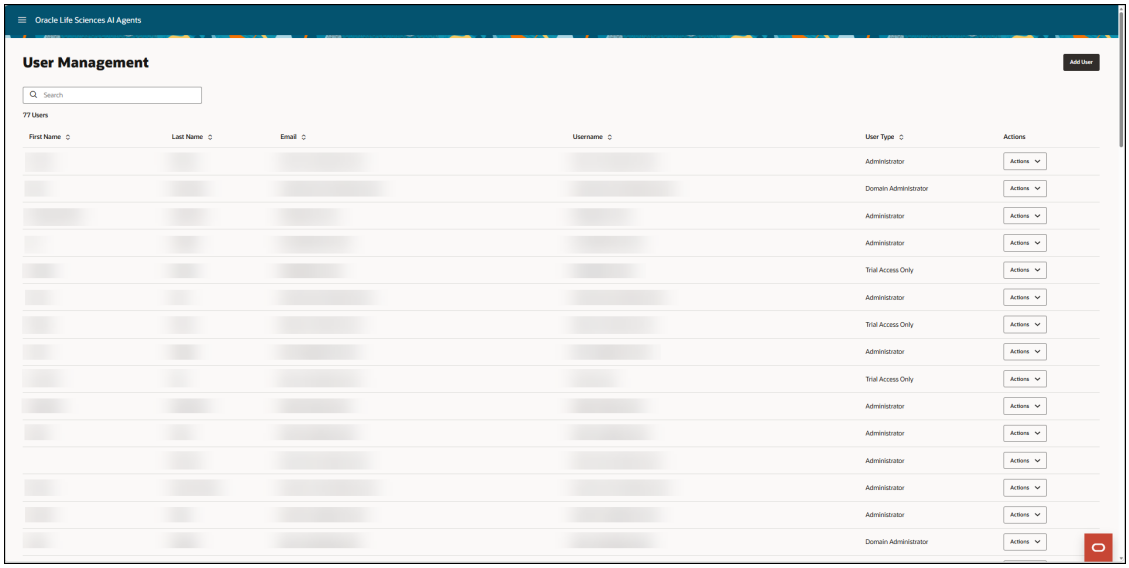
There are two ways to open the User Management interface.

- If you are an administrator without access to trial data, the User Management interface opens after you sign in to Life Sciences AI Agents.

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- If you are an administrator with trial access, select the **Oracle** icon at the bottom of any page in the Trials interface and then select the User Management option from the Roles drop-down menu.

Depending on your permissions, you can switch between the Trials interface and User Management interface as often as you like.



User roles

There are two user roles in Life Sciences AI Agents that determine your feature access: Administrator and Trials.

- **Administrator**—Gives you access to the User Management interface so that you can manage all Life Sciences AI Agents users and assign their access to trials. As an administrator, you can:
  - Add, remove, and update users.
  - View existing users and user details.
  - Assign, remove, and update user roles and trial access.
  - Assign the Trials in Planning Access permission that controls access to Trials In Planning in the Trials list and allows users to add trial protocols into Life Sciences AI Agents.

  If you have only the Administrator role, you cannot access trial data. If you, as an Administrator, need trial access you must also have the Trials role.

> **Note**
>
> As an administrator, you cannot change your own role and trial access or revoke your Administrator role. However, another administrator can revoke your Administrator role at any time.

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- **Trials**—Gives you access to the Trials interface so that you can access all trials or a subset of trials. Optionally, this role gives you access to Trials In Planning, which allows you to view Trials in Planning in the Trials list and to add trial protocols into Life Sciences AI Agents. As a user with the Trials role, depending on your trial access and permissions, you can:
  - View the portfolio data for all Ongoing Trials.
  - Manage all trial data (for Ongoing Trials or Trials in Planning).
  - Manage the alerts for all Ongoing Trials.

  If you have only the Trials role, you cannot manage users or assign trial access.

You can have the Administrator role, Trials role, or both. If you only have the Administrator role, you cannot access trial data.

Trial access

Depending on your responsibilities, and regardless of your role or roles, you may have access to all trials or to a subset of the trials in Life Sciences AI Agents.

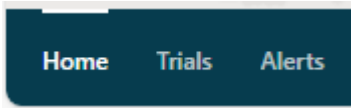
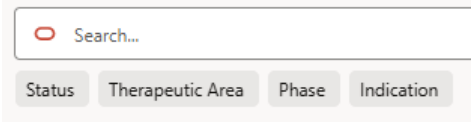
- **Portfolio-level access**—Portfolio-level access allows you to view and manage the summary data for all the trials in a customer's portfolio and to view and manage individual trial data. Users with portfolio-level access typically include study managers, portfolio managers, clinical operation leads, and executives.

  Portfolio-wide users with access to all trials can use the Portfolio Health overview to see a consolidated view of the portfolio health, which surfaces the most critical risks, trends, and study-level callouts.
- **Study-level access**—Study-level access allows you to view and manage the data only for the individual trials you have access to (you cannot access the portfolio data). Users with study-level access typically include study teams, medical directors, clinical research associates, and data managers.

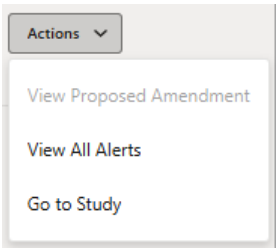
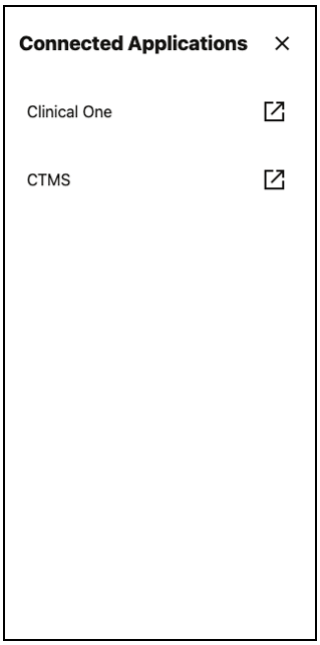
Navigation and search

Life Sciences AI Agents provides multiple options for navigating through the interface.

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Item	Description	Details
Oracle icon	Appears at the bottom of every page. For example:  Opens the Profile dialog box from which you can access product documentation on Oracle Help Center and to sign out. If you are an administrator you can also use the Profile dialog box to open the User Management interface to manage user accounts and set trial access. For example: 	• Select the **Oracle** icon at the bottom of any page to open the Profile dialog box and select the **X** to close it.
Tabs	Provide access to features in Life Sciences AI Agents based on your permissions. The tabs appear at the bottom of the Trials interface window. The active tab is highlighted. For example: 	• **Home** tab—The Home tab is selected and the Portfolio Health overview opens when you sign in. This overview serves as the single-entry hub for all the active, ongoing trials in a portfolio. You can select the Home tab at any time to return to the Portfolio Health overview. • **Trials** tab—The Trials tab opens the Trials list, which serves as the central navigation hub for all Ongoing Trials, and if you have access, to Trials in Planning. The Trials list provides easy navigation between the Trials list and trial details. • **Alerts tab**—The Alerts tab opens the Alerts list, which serves as a central repository for all the alerts in the Ongoing Trials you have access to and provides easy navigation between the Alerts list and alert details.
Search field	A search feature appears on most list pages. To search for a specific item or to filter a list, you can enter text or select one or more of the filter options that appear (on some pages) below the Search field and are specific to the page. For example: 	In the **Search** field, do one or both of the following, and then select **Enter**: • Enter at least three characters in the **Search** field. • If available, select one or more of the filter options that appear below the **Search** field and provide any required details. The filters are specific to the page you are working in.

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Item	Description	Details
Actions drop-down menu	Actions drop-down menu options initiate an action. The Actions drop-down menu options show only the options you have rights to access or are relevant to the stage of the item you want to perform the action on (options not available appear inactive). For example: 	• Select the **Actions** drop-down menu to access options available to you.
Navigation Menu icon	Appears at the top left of the banner. For example:  Opens the Connected Applications panel that you use to access the source Oracle Life Sciences applications you have access to. For example: 	• Select the **Navigation Menu** icon to open the Connected Applications panel and select the **X** to close it.

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Sign in to Life Sciences AI Agents

An administrator creates an Oracle Cloud account for you that you must activate and associate with Life Sciences AI Agents.

You only need to activate your user account one time. Signing in to Life Sciences AI Agents requires that you provide your user name, password, and secure identity verification.

You can sign out of Life Sciences AI Agents at any time. However, you are automatically signed out of the system after a set amount of continuous use or inactivity (both values are defined in your Oracle Cloud account).

> **Note**
>
> Contact your administrator for details on activating your account and the required secure verification method with multi-factor authentication (MFA) that you need to verify your identity every time you sign in.

Get started

Before you start working in Life Sciences AI Agents, review the summary of steps available for managing users and assigning trial access, managing trial data for active ongoing trials and for trials that are in the planning phase, managing the AI-generated alerts, and for navigating to source Oracle Life Sciences applications.

To get started:

1. Access Life Sciences AI Agents using the URL provided by your Life Sciences AI Agents administrator.
2. **Manage users and trial access**.

   For Life Sciences AI Agents administrators only, use to add, modify, and delete users and assign their trial access. You can modify the user details, roles, and trial access at any time.

   The User Management interface provides comprehensive control over user management and trial access. Administrators ensure that the system is used securely and efficiently, with users having appropriate access to perform their roles.
3. **Review the Portfolio Health overview**.

   If you collaborated with Oracle to have your active trial data integrated into Life Sciences AI Agents from a source Oracle Life Sciences application you can use the Portfolio Health overview to view the summary of the data for all Ongoing Trials.

   > **Note**
   >
   > The Portfolio Health overview provides information for Ongoing Trials only.
4. **Manage all trials**.

   As a user with access to a single trial or a subset of trials in Life Sciences AI Agents, you use the Trials list to view a list of all the trials you can access. You can filter the list by the operational lifecycle stage: All Trials, Ongoing Trials, or Trials in Planning (if you have

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access). You can view details of the trials, easily navigate between the Trials list and trial details, and export the trial data to a CSV file. For more information, see:

- View the list of trials you can access.
- View the details of an Ongoing Trial.
- View the details of a Trial in Planning.
- Export trial data.

5. **Add a trial for planning and monitoring**.

   If you have access to Trials in Planning, you can add and edit trial protocols, initiate the AI-generation of trial plans based on the protocol, and select the best plan for your trial.

   To add a trial, you upload a draft or final version of a protocol or synopsis, Life Sciences AI Agents validates the data and then uses AI to generate three trial plans with different objectives: cost efficient, fastest, and balanced. You can review the trial plans, make adjustments and regenerate the trial plans if necessary, and then select the best plan for your trial.

   You can replace the version of the draft or final protocol or protocol synopsis after the initial upload, if necessary. You can upload multiple versions of the same protocol or synopsis.

6. **Manage the alerts for all Ongoing Trials**.

   Use the Alerts list to efficiently manage and respond to alerts across all the Ongoing Trials you have access to, streamlining your workflow and improving your ability to address potential issues or opportunities. Alerts are AI-generated notifications that provide important information or identify potential issues for the Ongoing Trials you can access.

   The alerts are prioritized based on risk severity (Critical, High, Moderate, or Low). You can view alerts details and provide feedback on every alert. You can also view the AI reasoning steps for an alert, view the history of the alert, snooze or dismiss alerts, and view details for the study where the alert originated.

   > **Note**
   >
   > The Alerts pages provide information for Ongoing Trials only.

7. **Access source Oracle Life Sciences applications**.

   You can navigate to the source Oracle Life Sciences applications that are onboarded to Life Sciences AI Agents for you to quickly investigate or take action on a record without manually searching for the record in multiple systems.

   When navigating to or from Life Sciences AI Agents to a source application, you are not required to re-authenticate as long as you have access to the source application and both applications have active sessions.

8. **Troubleshoot issues**.

   At any time after you sign in, you can:

   - Reset your password.
   - Request removal of subject data.
   - Access product documentation.

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2

Manage users and trial access

As a Life Sciences AI Agents administrator, you can add, modify, and delete users and assign their trial access.

For each user, you must provide a first and last name, email address, and a username. Then, you select the role(s) for the user and select whether to give the user access to trials in planning, access to all trials, or access to a subset of trials. You can modify the user details and trial access at any time.

- View the list of users
  As a Life Sciences AI Agents administrator, you can view the list of users in the system.
- View the list of trials a user can access
  As a Life Sciences AI Agents administrator, you can view the list of trials that a user can access.
- Add a user and assign trial access
  As a Life Sciences AI Agents administrator, you can add new users and assign their trial access.
- Modify a user and their trial access
  As a Life Sciences AI Agents administrator, you can modify the details for any user and modify the trials the user can access.
- Delete a user
  As a Life Sciences AI Agents administrator, you can delete a user with the Administrator role, Trials role, or both roles if necessary.

View the list of users

As a Life Sciences AI Agents administrator, you can view the list of users in the system.

For each user, you can view their First Name, Last Name, Email, Username, and User Type (Domain Administrator, Administrator, or Trial Access Only).

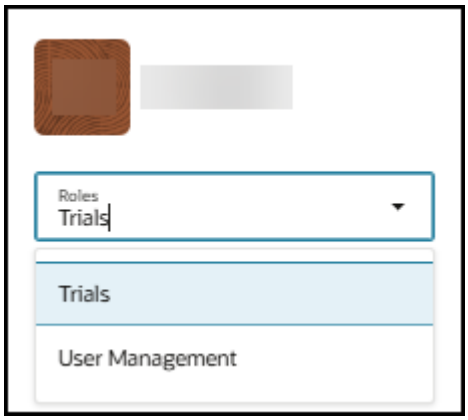
To open the User Management interface to view the list of the users in the system:

1. Select the **Oracle** icon  at the bottom of any page in the Trials interface. The Profile dialog box opens. For example:

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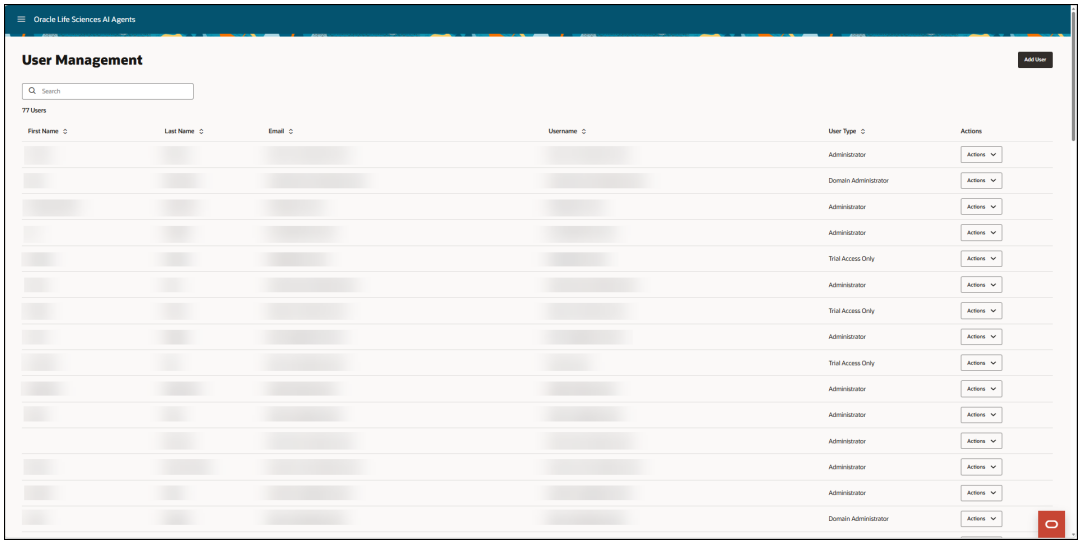
2. In the **Roles** drop-down menu, select **User Management**. For example:



> **Note**
>
> The User Management role option is only available if you are a Life Sciences AI Agents administrator.

As soon as you select **User Management**, the interface refreshes and the User Management page opens. For example:

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> **Note**
>
> - To search for a specific user, enter at least three characters in the **Search** field above the list.
> - You may see the Domain Administrator role in the User Type column on the User Management page. This role is assigned automatically based on your system configuration and cannot be assigned or removed manually.

3. From the **User Management** page, you can:
   - View the list of trials a user can access.
   - Add a user and assign trial access.
   - Modify a user and their trial access.
   - Delete a user.
4. To exit the User Management interface:
   a. Select the **Oracle** icon at the bottom of the page to open the **Profile** dialog box.
   b. In the **Roles** drop-down menu, select **Trials** to return to the Trials interface.
   c. If you do not have any trial access, select **Sign Out**.

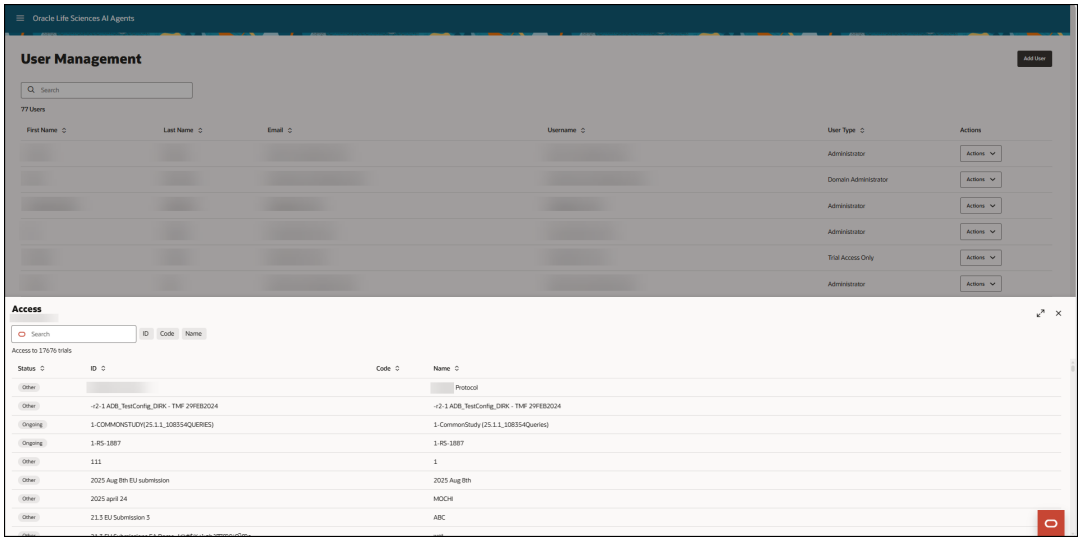
View the list of trials a user can access

As a Life Sciences AI Agents administrator, you can view the list of trials that a user can access.

To view the list of trials a user can access:

1. Open the list of users.
2. In the **User Management** page, find the user whose trial access you want to view, and in the **Actions** column, select **View Trials with Access** from the **Actions** drop-down menu. The Access panel opens. For example:

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3. In the **Access** panel you can:
   - Search for a trial in the list. The search starts after you enter three characters in the **Search** field.
   - Expand the list to full size by selecting the arrows at the top right.
4. To close the **Access** panel, select the **X** at the top right.
5. To exit the User Management interface:
   a. Select the **Oracle** icon at the bottom of the page to open the **Profile** dialog box.
   b. In the **Roles** drop-down menu, select **Trials** to return to the Trials interface.
   c. If you do not have any trial access, select **Sign Out**.

Add a user and assign trial access

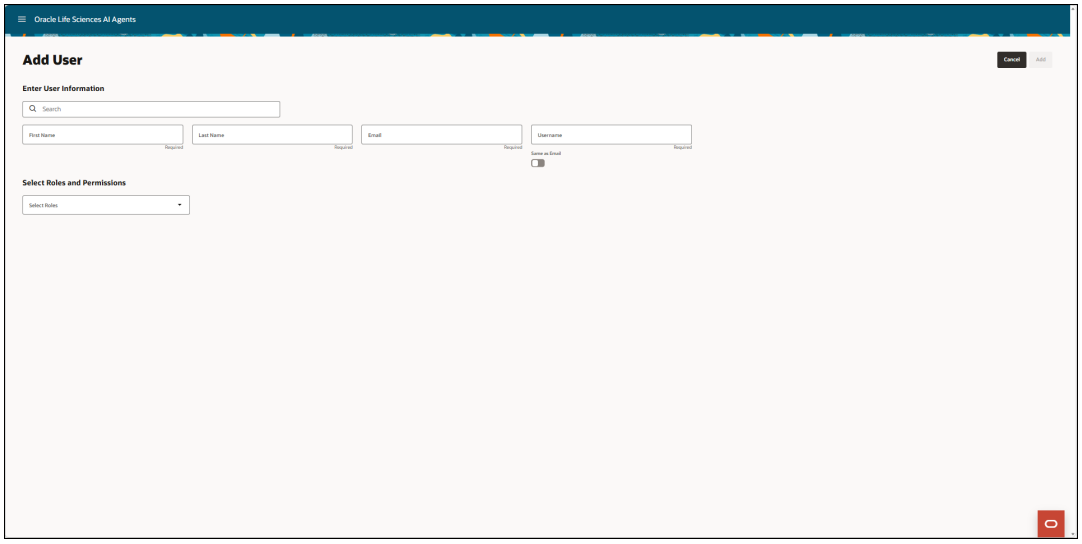
As a Life Sciences AI Agents administrator, you can add new users and assign their trial access.

> **Note**
>
> All users who need access to Life Sciences AI Agents must have an Oracle Cloud account.

To add a user and assign their trial access:

1. Open the list of users.
2. In the **User Management** page, at the top right, select **Add User**. The Add User page opens. For example:

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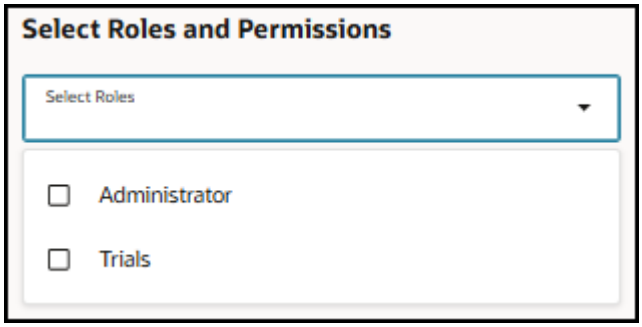
> **Note**
>
> The Add button at the top right of the page is disabled by default until you enter all of the required information.

3. In the **Enter User Information** section, provide the following information:
   - **Search**—Enter the name of the user you want to add to make sure that they have an Oracle Cloud account. The search starts after you enter three characters.
   - **First Name**—Required. Enter the user's first name.
   - **Last Name**—Required. Enter the user's last name.
   - **Email**—Required. Enter the user's email address.
   - **Username**— Required. Enter a name for the user. If you want to use the email address as the user name, select the **Same as Email** toggle button until it turns green and the white button moves to the right .

     > **Note**
     >
     > When you set the toggle button to the on position, the Username field is automatically populated with the email address and it becomes read-only. To make the Username field editable again, turn the toggle button off by selecting the button so that the white button appears on the left ().

4. In the **Select Roles and Permissions** section, select the role or roles you want to assign to the user. The available roles are Administrator and Trials. For example:

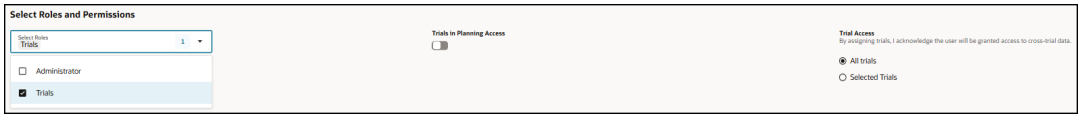
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- **Administrator**—Select to give the user permission to manage all the Life Sciences AI Agents users and to assign their access to trials.

> **Note**
>
> If you want a user with the Administrator role to also have access to any trials, you must also select the Trials role for the user.

- **Trials**—Select to display the options you use to allow the user access to Trials in Planning and to identify the trials the user can access. When you select this role, the Trials in Planning Access toggle button and Trial Access section appear on the page. For example:



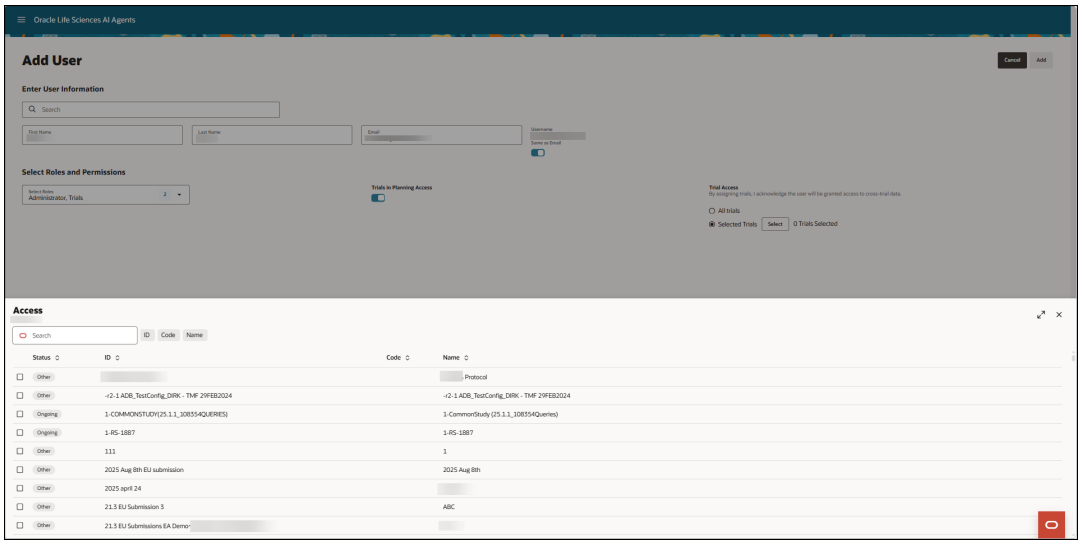
> **Note**
>
> Users with only the Trials role cannot manage users or assign trial access.

5. To give the user access to Trials in Planning, and allow them to view uploaded protocols and to add new protocols, select the **Trials in Planning Access** toggle button until it turns green and the white button moves to the right ( ).
6. In the **Trial Access** section, select one of the following options:
   - **All Trials**—Select to give the user access to all trials. Proceed to step 10.
   - **Selected Trials**—Select to give the user access to only selected trials. The Select button appears next to the Selected Trials option. Proceed to step 7.

> **Note**
>
> - You can grant access to Ongoing Trials or to Ongoing Trials and Trials in Planning. But, you cannot grant access to just Trials in Planning.
> - When you assign trials, you acknowledge that the user will be allowed access to cross-trial data.

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7. Select **Select** to open the Access panel. For example:



8. In the **Access** panel, select the checkbox in the first column for each trial you want to give the user access to.

   You can expand the panel to full size by selecting the arrows ( ) at the top right.

> **Note**
>
> Your trial selections are saved when you add the new user (step 10).

9. When you are done assigning trial access, select the **X** at the top right to close the **Access** panel.
10. At the top right of the **Add User** page, select **Add**. The Add User page closes and the User Management page opens again.
11. To exit the User Management interface:
    a. Select the **Oracle** icon at the bottom of the page to open the **Profile** dialog box.
    b. In the **Roles** drop-down menu, select **Trials** to return to the Trials interface.
    c. If you do not have any trial access, select **Sign Out**.

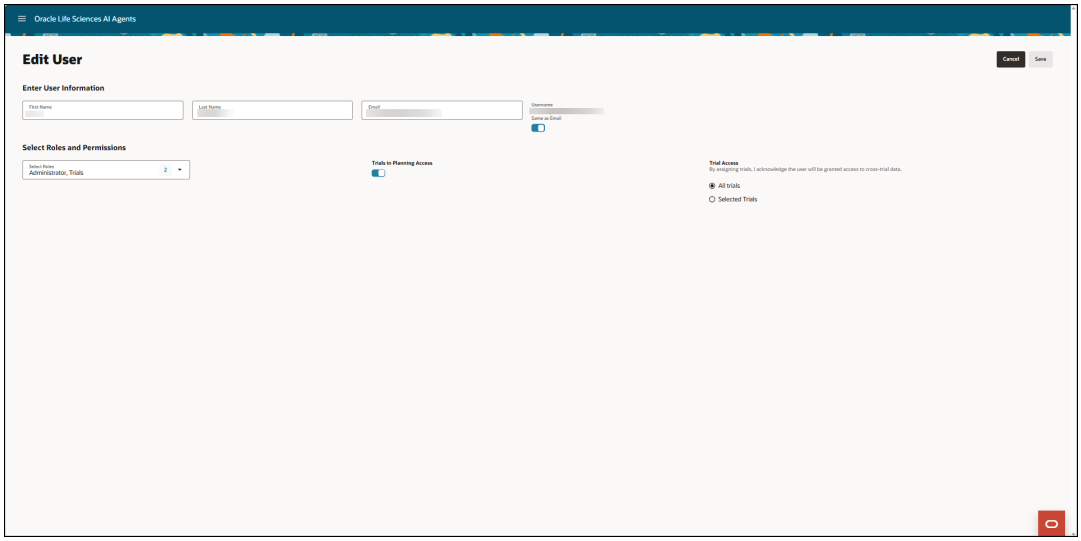
Modify a user and their trial access

As a Life Sciences AI Agents administrator, you can modify the details for any user and modify the trials the user can access.

To modify a user and their trial access:

1. Open the list of users.
2. In the **User Management** page, find the user you want to modify, and in the **Actions** column, select **Edit** from the **Actions** drop-down menu. The Edit User page opens. For example:

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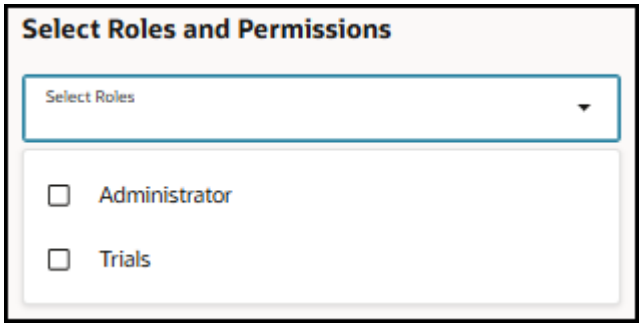
> **Note**
>
> The Save button at the top right of the page is disabled by default until you make changes.

3. In the **Enter User Information** section, update the following information as needed:
   - **First Name**—Required. Enter the user's first name.
   - **Last Name**—Required. Enter the user's last name.
   - **Email**—Required. Enter the user's email address.
   - **Username**— Required. Enter a name for the user. If you want to use the email address as the user name, select the **Same as Email** toggle button until it turns green and the white button moves to the right ( ).

     > **Note**
     >
     > When you set the toggle button to the on position, the Username field is automatically populated with the email address and it becomes read-only. To make the Username field editable again, turn the toggle button off by selecting the button so that the white button appears on the left ( ).

4. In the **Select Roles and Permissions** section, update the role or roles you want to assign to the user. The available roles are Administrator and Trials. For example:

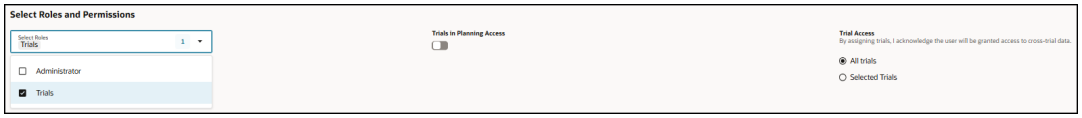
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- **Administrator**—Select to give the user permission to manage all of the Life Sciences AI Agents users and to assign user access to trials.

> **Note**
>
> If you want a user with the Administrator role to also have access to any trials, you must also select the Trials role for the user.

- **Trials**—Select to display the options that you use to allow the user access to Trials in Planning and to identify the trials the user can access. When you select this role, the Trials in Planning Access toggle button and Trial Access section appear on the page. For example:



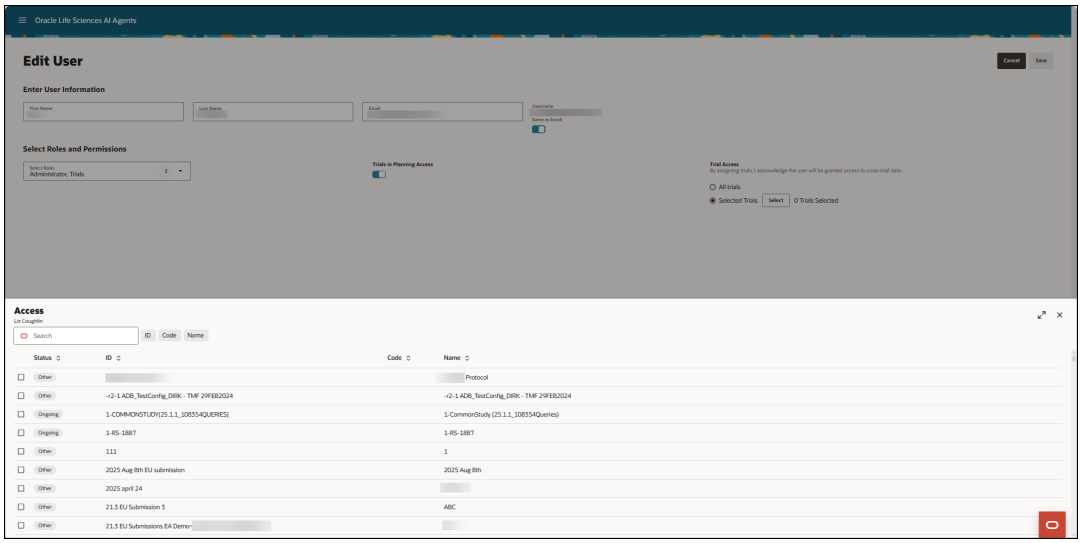
> **Note**
>
> Users with only the Trials role cannot manage users or assign trial access.

5. To give the user access to Trials in Planning, and allow them to view uploaded protocols and to add new protocols, select the **Trials in Planning Access** toggle button until it turns green and the white button moves to the right ( ).
6. In the **Trial Access** section, select one of the following options:
   - **All Trials**—Select to give the user access to all trials. Proceed to step 10.
   - **Selected Trials**—Select to give the user access to only selected trials. The Select button appears next to the Selected Trials option. Proceed to step 7.

> **Note**
>
> - You can grant access to Ongoing Trials or to Ongoing Trials and Trials in Planning. But, you cannot grant access to just Trials in Planning.
> - When you assign trials, you acknowledge that the user will be allowed access to cross-trial data.

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7. Select **Select** to open the Access panel. For example:



8. In the **Access** panel, do the following as needed:
   - Select the checkbox in the first column for each trial you want to give the user access to.
   - Deselect the checkbox in the first column to remove the user's access to the associated trial.

   You can expand the panel to full size by selecting the arrows at the top right.

   > **Note**
   >
   > Your trial selections are updated when you save the modified user information (step 10).

9. When you are done updating trial access, select the **X** at the top right to close the **Access** panel.
10. At the top right of the **Edit User** page, select **Save**. The Edit User page closes and the User Management page opens again.
11. To exit the User Management interface:
    a. Select the **Oracle** icon at the bottom of the page to open the **Profile** dialog box.
    b. In the **Roles** drop-down menu, select **Trials** to return to the Trials interface.
    c. If you do not have any trial access, select **Sign Out**.

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Delete a user

As a Life Sciences AI Agents administrator, you can delete a user with the Administrator role, Trials role, or both roles if necessary.

> **Caution**
>
> Deleting a user revokes their access to Life Sciences AI Agents. It does not delete their Oracle Cloud user account.

To delete a user:

1. Open the list of users.
2. In the **User Management** page, find the user you want to delete, and in the **Actions** column, select **Delete** from the **Actions** drop-down menu. A confirmation dialog box opens.

   > **Note**
   >
   > - You may see the Domain Administrator role in the User Type column on the User Management page. This role is assigned automatically based on your system configuration and cannot be assigned or removed manually.
   > - You cannot delete a Domain Administrator. If you select a user who is a Domain Administrator the Delete option does not appear in the Actions drop-down menu.

3. Select **Delete**.
4. To exit the User Management interface:
   a. Select the **Oracle** icon  at the bottom of the page to open the **Profile** dialog box.
   b. In the **Roles** drop-down menu, select **Trials** to return to the Trials interface.
   c. If you do not have any trial access, select **Sign Out**.

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3

Review the Portfolio Health overview

As a user with access to all trials, you use the Portfolio Health overview to review the data for all active ongoing trials. The overview shows a consolidated view of the portfolio health, which surfaces the most critical risks, trends, and study-level callouts.

The Portfolio Health overview provides key performance indicators, an AI-generated text summary of the portfolio health for all Ongoing Trials in the portfolio, a list of the highest priority AI-generated alerts, and data in selectable graph formats.

Data in the Portfolio Health overview is from active trials that have been onboarded by Oracle from a source Oracle Life Sciences application.

Ongoing Trials are active clinical trials with ongoing or completed patient enrollment and data collection. They can be at any stage of the clinical trial lifecycle and are supported by Life Sciences AI Agents through the provision of AI-driven insights and summaries.

> **Note**
>
> The Portfolio Health overview provides information for Ongoing Trials only.

- Open the Portfolio Health overview
  As a user with access to all trials, you use the Portfolio Health overview to view summary data of the overall health of all active, ongoing trials in a customer's portfolio.
- View the portfolio key performance indicators
  As a user with access to all trials, you can view the key performance indicators (KPIs) that measure study performance consistency across all active ongoing trials in the portfolio for the past 90 days to identify areas of operational risk.
- View the portfolio health summary
  As a user with access to all trials, you can view the AI-generated health summary of all active ongoing trials in a customer's portfolio. The health summary highlights top risks, study-level callouts with direct (deep) links, and cross-portfolio trends impacting efficiency and quality.
- View the portfolio alerts
  As a user with access to all trials, you can view the AI-generated alerts for all ongoing trials in the portfolio. The highest priority alerts for each trial appear in the Portfolio Health overview.
- View the portfolio data graphs
  As a user with access to all trials, you can view the portfolio trial data for all ongoing trials in four graph formats: Trials by Status (bar graph), Trials by Phase (pie graph), Trials by Therapeutic Area (bar graph), or Enrollment by Region (bar graph).

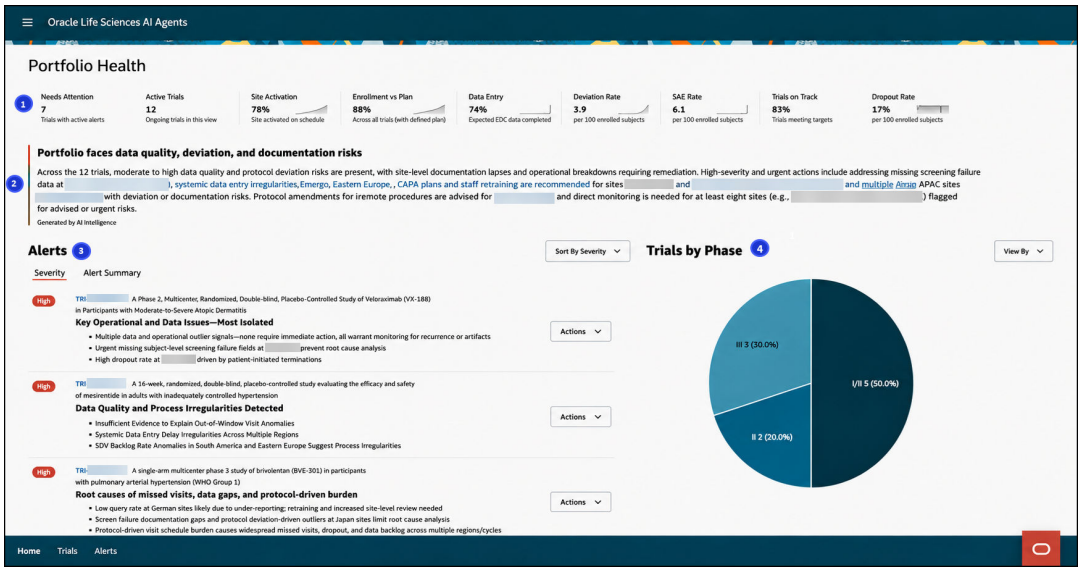
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Open the Portfolio Health overview

As a user with access to all trials, you use the Portfolio Health overview to view summary data of the overall health of all active, ongoing trials in a customer's portfolio.

To open the Portfolio Health overview:

1. Select the **Home** tab at the bottom of the page. The Portfolio Health overview opens. For example:



> **Note**
>
> The Portfolio Health overview provides information for Ongoing Trials only.

2. The Portfolio Health overview provides the following information:

   - **1 - Portfolio Key Performance Indicators (KPIs)**—Standardized measurements of performance consistency across all trials in the portfolio for the past 90 days to identify areas of operational risk.

     The portfolio health KPIs appear across the top of the page below the title. They are refreshed every 24 hours at 2 am UTC and are only calculated and shown if there is enough data for each. The KPIs can include Needs Attention, Active Trials, Site Activation, Enrollment vs Plan, Data Entry, Deviation Rate, SAE Rate, TMF Completeness, Trials on Track, Dropout Rate, and Data Entry Timeliness.

     For more information and descriptions of the portfolio health KPIs, see View the portfolio key performance indicators.

   - **2 - Portfolio Health Summary**—An AI-generated text summary of the portfolio health for all Ongoing Trials in the portfolio. The health summary highlights top risks, study-level callouts with direct (deep) links, and cross-portfolio trends impacting efficiency and quality.

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The portfolio health summary appears below the KPIs and provides executives, study managers, and clinical operations leads with access to all trials a consolidated view of the portfolio health by surfacing the most critical risks, trends, and study-level callouts.

> **Note**
>
> The portfolio health summary appears on the Portfolio Health Overview page only if you have access to all trials.

For more information, see View the portfolio health summary.

- **3 - Portfolio Alerts**—An AI-generated list of the highest priority alerts (for example, insights and recommendations) for all Ongoing Trials in the portfolio. The portfolio alerts provide a concise and regularly updated view of the most critical issues in a customer's clinical trial portfolio, enabling you to quickly respond to emerging issues or trends.

  The portfolio alerts:

  – Show one row per trial and up to three top ranked issues for each trial (each alert provides a link to the Alert details page).
  – Prioritize trials based on risk severity (Critical, High, Moderate, or Low). The default sort of the trials in the list is by risk severity.
  – Provide sorting of the alerts by Severity (default), Trial Name, or Alert Title.
  – Refresh every 24 hours at 2 am UTC. If no trials need attention, a "No trials currently require attention." message appears in the Alerts section.

  The portfolio alerts appear at the bottom left of the page and are prioritized based on risk severity (Critical, High, Moderate, or Low). For each alert you can view its severity, associated trial name, alert title, and alert summary. For more information and descriptions of each alert severity, see View the portfolio alerts.

  From the portfolio alerts list you can:

  – View all the alerts you can access by selecting **View All** at the bottom left of the section.

    The View All link appears only if there are six or more portfolio alerts.

    For more information, see View all alerts from the Portfolio Health overview.
  – View details for an alert by selecting **View All Alerts** from the associated **Actions** drop-down menu on the right. The Alerts list opens and is filtered to display the trial associated with the alert. For more information, see View the details for an alert from the Portfolio Health overview.
  – Open the study details by selecting **Go to Study** from the associated **Actions** drop-down menu on the right. The [Study Name] details page opens, which provides a summary health overview page for the study. A tab with the study name appears at the bottom of the window. For more information, see View the study details associated with an alert from the Portfolio Health overview.

- **4 - Portfolio Data Graphs**—Data for all the ongoing trials in the portfolio in any of the following selectable formats: Trials by Status (bar graph), Trials by Phase (pie graph), Trials by Therapeutic Area (bar graph), and Enrollment by Region (bar graph). Each graph format includes a timestamp. Hovering over the graphs displays statistic details.

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The portfolio data graphs enable you to tailor the visualization of your trial data to suit your analytical requirements, potentially enhancing your ability to understand and act upon the insights provided by the data.

The portfolio data graphs appear at the bottom right of the page. For more information and descriptions of the data in the portfolio graphs, see View the portfolio data graphs.

View the portfolio key performance indicators

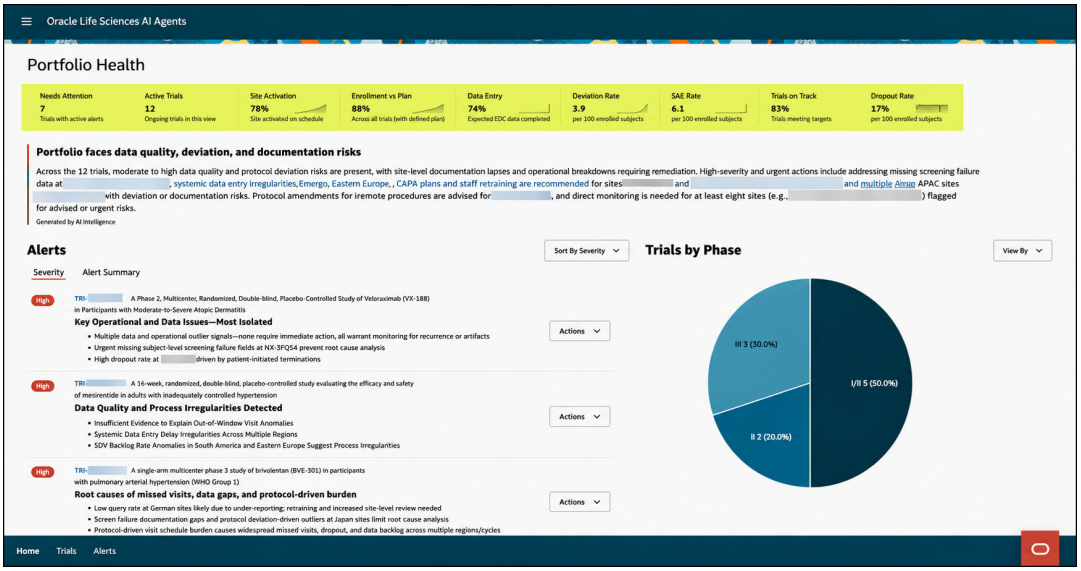
As a user with access to all trials, you can view the key performance indicators (KPIs) that measure study performance consistency across all active ongoing trials in the portfolio for the past 90 days to identify areas of operational risk.

The portfolio KPIs appear across the top of the page below the title and can include Needs Attention, Active Trials, Site Activation, Enrollment vs Plan, Data Entry, Deviation Rate, SAE Rate, TMF Completeness, and Trials on Track. The KPIs are refreshed every 24 hours at 2 am UTC and are only calculated and shown in the Portfolio Health overview if there is enough data for each.

> **Note**
>
> You can hover over any KPI to see details about how its value was calculated, including the minimum and maximum values, the number of trials used, and the calculation date.

To view the portfolio KPIs for all ongoing trials:

- Open the Portfolio Health overview. The portfolio KPIs appear at the top of the overview below the page title and are highlighted in the following example:



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Ongoing Trials Portfolio - Key Performance Indicator (KPI)	Description
Needs Attention	Count of trials with active alerts (insights). The count depends on the number of active alerts.
Active Trials	Number of active trials users have access to in Life Sciences AI Agents.
Site Activation	Percent of activated sites that have met their activation target dates. This metric is a measure of start-up efficiency. A high variance signals bottlenecks.
Enrollment vs Plan	Actual enrollment divided by the planned enrollment (uses the enrollment forecast). This metric shows if the portfolio is meeting recruitment goals.
Data Entry	Percentage of expected CRFs completed (regardless of query status). This metric serves as an early warning of operational lag. Low data entry completeness correlates to monitoring backlog and slow data entry timeliness.
Deviation Rate	Number of protocol deviations reported per 100 subjects across the portfolio or a subset of trials. This metric represents the universal compliance indicator.
SAE Rate	Serious adverse event rate per 100 subjects enrolled. This is a key portfolio safety metric that normalizes by exposure (compares safety risks across different studies).
TMF Completeness	Percentage of expected documents collected. This metric provides leadership a sense of inspection readiness across the portfolio.
Trials on Track	Percentage of trials hitting enrollment targets within ±10% of plan. This executive indicator shows the percentage of studies that are progressing as planned.
Dropout Rate	Percentage of enrolled subjects that have dropped out or were terminated early. Appears only if you are not using a supported source application.
Data Entry Timeliness	Average number of days from subject visit dates to when the data is entered into eCRFs in EDC systems. This metric provides an early warning signal for downstream delays in cleaning, reporting, and analysis. Appears only if you are not using a supported source application.

View the portfolio health summary

As a user with access to all trials, you can view the AI-generated health summary of all active ongoing trials in a customer's portfolio. The health summary highlights top risks, study-level callouts with direct (deep) links, and cross-portfolio trends impacting efficiency and quality.

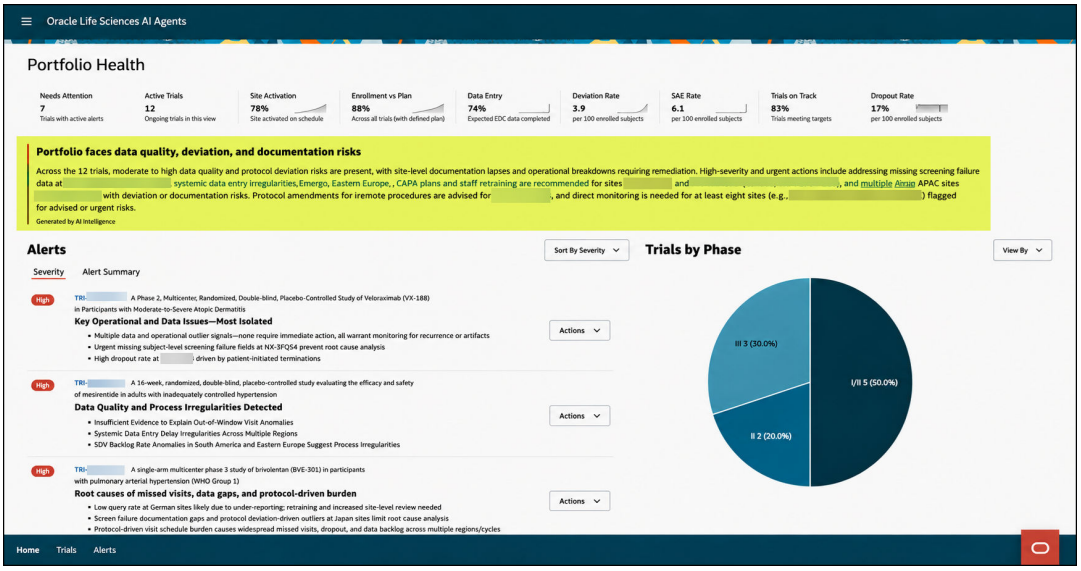
The health summary provides executives, study managers, and clinical operations leads with access to all trials a consolidated view of the portfolio health by surfacing the most critical risks, trends, and study-level callouts.

> **Note**
>
> The portfolio health summary appears on the Portfolio Health Overview page only if you have access to all trials.

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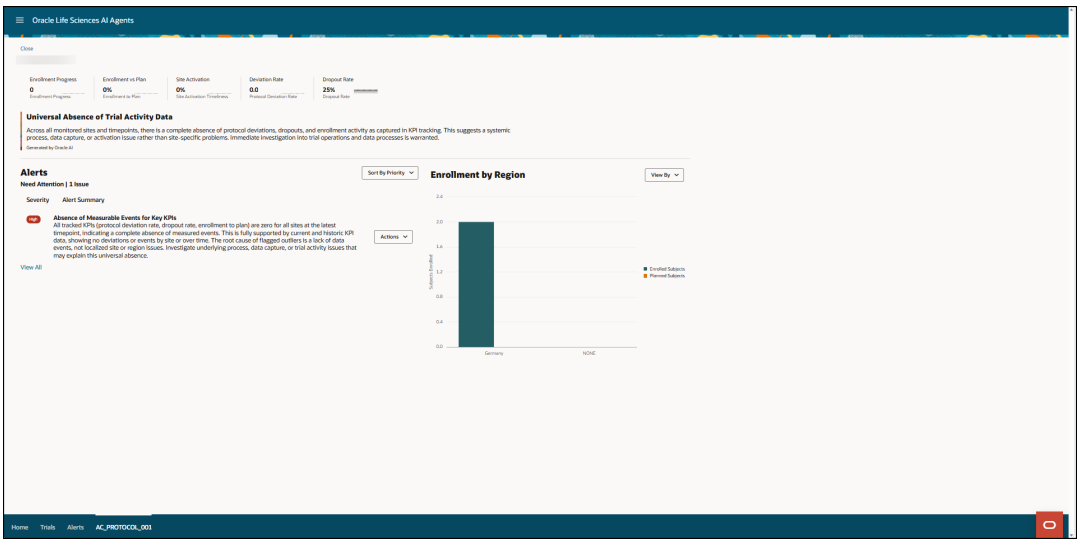
To view the portfolio health summary for all ongoing trials:

1. Open the Portfolio Health overview. The AI-generated health summary appears at the top of the overview below the KPIs and is highlighted in the following example:



> **Note**
>
> A Generated by AI Intelligence disclaimer appears below the health summary text.

2. In the health summary, select any **Study** name link (highlighted in blue) to open the details page for the study. For example:



For more information, see View the details of an Ongoing Trial.

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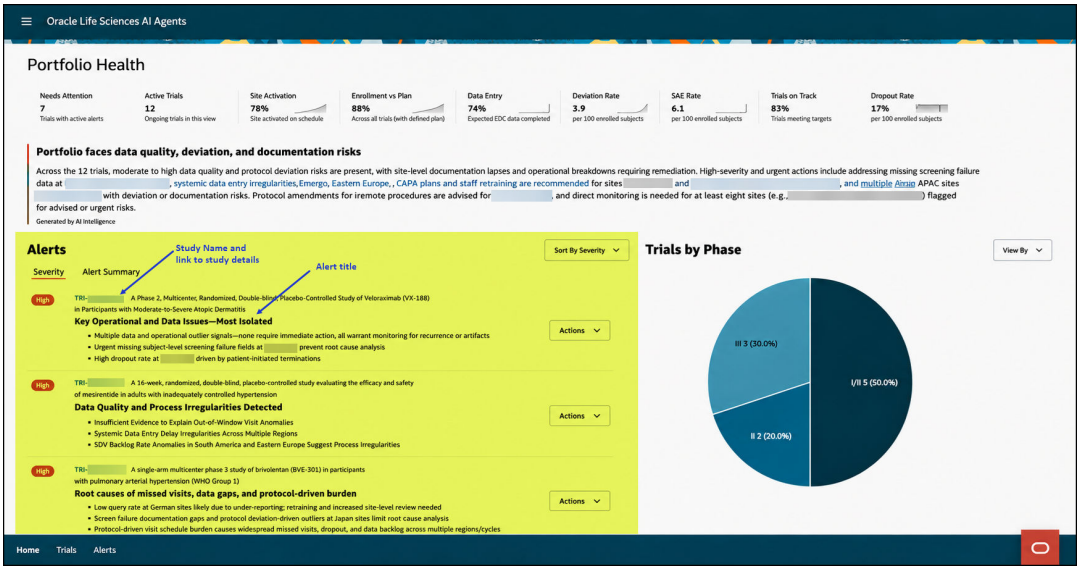
View the portfolio alerts

As a user with access to all trials, you can view the AI-generated alerts for all ongoing trials in the portfolio. The highest priority alerts for each trial appear in the Portfolio Health overview.

The alerts are prioritized based on risk severity (Critical, High, Moderate, or Low). For each alert you can view its risk severity, associated trial name, alert title, and alert summary.

To view the portfolio alerts for all ongoing trials:

1. Open the Portfolio Health overview. The portfolio alerts appear at the bottom left of the overview and are highlighted in the following example:



Alert risk severity	Description
Critical	Imminent or ongoing serious risk to patient safety or trial integrity that may warrant immediate trial halt, enrollment hold, or urgent regulatory notification.
High	Credible and significant risk to patient safety, primary endpoint integrity, or critical milestones if not addressed promptly.
Moderate	No immediate safety risk, but material risk to timelines or quality; major (non-critical) protocol deviations; secondary or operational data degradation; sustained under-enrollment likely to delay non-critical milestones.
Low	Minor, localized, or transient issue with limited impact; generally reversible with routine follow-up and unlikely to affect safety or milestones.

The portfolio alerts:

- Show one row per trial and up to three top ranked issues for each trial (each alert provides a link to the Alert details page).
- Prioritize trials based on risk severity (Critical, High, Moderate, or Low). The default sort of the trials in the list is by risk severity.

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- Provide sorting of the alerts by Severity (default), Trial Name, or Alert Title.
- Refresh every 24 hours at 2 am UTC. If no trials need attention, a "No trials currently require attention." message appears in the portfolio alerts section.

The View All link appears only if there are six or more portfolio alerts.

For more information, see View all alerts from the Portfolio Health overview.

2. To view all the alerts you can access, select **View All** at the bottom left of the section. The Alerts list opens and displays all the alerts for the Ongoing Trials you can access. For more information, see View all alerts from the Portfolio Health overview.
3. From the **Actions** drop-down menu for each alert, you can select any of the following options:
   - **View All Alerts**—Opens the Alerts list filtered to display the trial associated with the alert. For more information, see View the details for an alert from the Portfolio Health overview.
   - **Go To Study**—Opens the study level page. Use to navigate to a details page for the study associated with the alert. Use the alert details to help you understand the alert summary and the AI reasoning for the alert. For more information, see View the study details associated with an alert from the Portfolio Health overview.

- View all alerts from the Portfolio Health overview
  If there are six or more portfolio alerts, you can open the Alerts list directly from the Portfolio Health overview so that you can view all the alerts for the trials you can access.
- View the details for an alert from the Portfolio Health overview
  You can view the details for an alert from the Portfolio Health overview.
- View the study details associated with an alert from the Portfolio Health overview
  You can view the study details associated with an alert from the Portfolio Health overview.

View all alerts from the Portfolio Health overview

If there are six or more portfolio alerts, you can open the Alerts list directly from the Portfolio Health overview so that you can view all the alerts for the trials you can access.

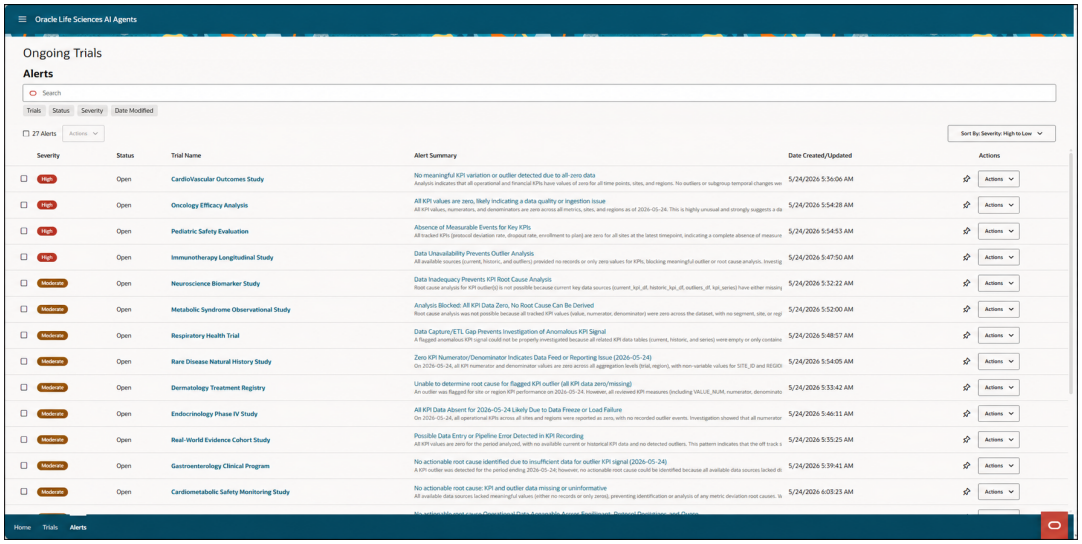
To view all the alerts for the trials you can access from the Portfolio Health overview:

1. Open the Portfolio Health overview to view the portfolio alerts as described in View the portfolio alerts.
2. At the bottom left of the **Alerts** section, select **View All**.

> **Note**
>
> The View All link appears only if there are six or more portfolio alerts.

The Alerts list opens. For example:

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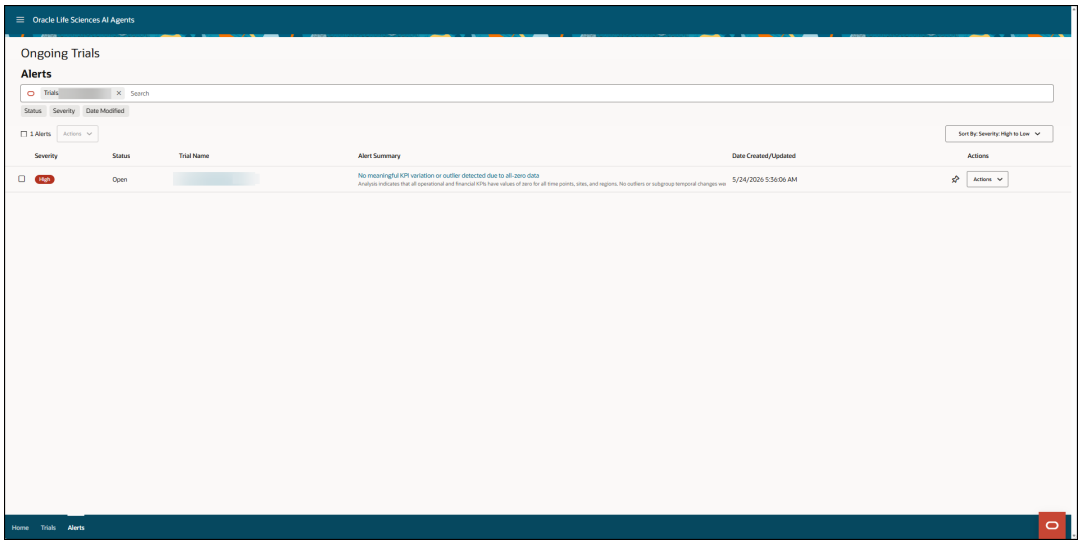


View the details for an alert from the Portfolio Health overview

You can view the details for an alert from the Portfolio Health overview.

To view the details for an alert from the Portfolio Health dashboard:

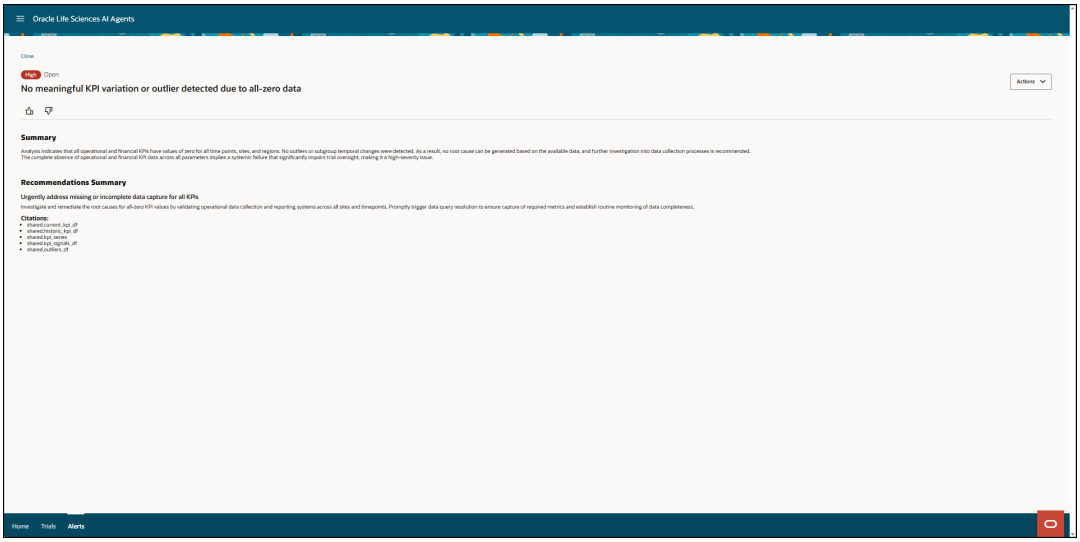
1. Open the Portfolio Health dashboard to view the portfolio alerts as described in View the portfolio alerts.
2. In the portfolio **Alerts** section, find the alert you want to view the details for, and in the **Actions** drop-down menu on the right, select **View All Alerts**. The Alerts list opens and is filtered to display the trial associated with the alert. For example:



3. Do one of the following to open the [Alert Name] details page.
   - In the **Alert Summary** column, select the [Alert Name] link (highlighted in blue).
   - In the **Actions** column on the right, select **View Alert Details** from the **Actions** drop-down menu.

   The [Alert Name] details page opens. For example:

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4. Select **Close** at the top left to return to the Alerts list filtered for the study associated with the alert (as shown in Step 2).

View the study details associated with an alert from the Portfolio Health overview

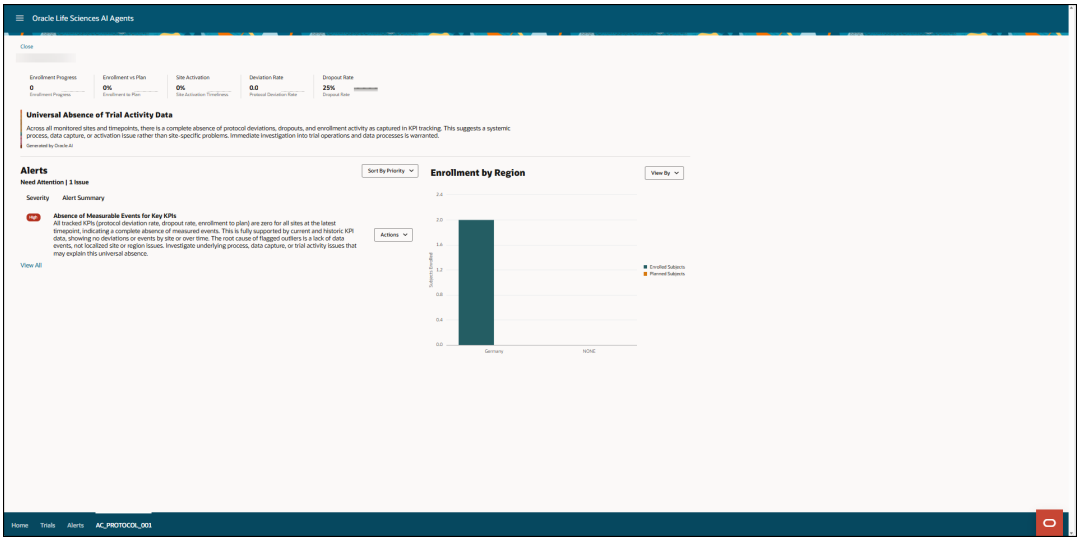
You can view the study details associated with an alert from the Portfolio Health overview.

To view the study details associated with an alert from the Portfolio Health overview:

1. Open the Portfolio Health overview to view the portfolio alerts as described in View the portfolio alerts.
2. In the portfolio **Alerts** section, find the alert you want to view the study details for, and do one of the following:
   - In the **Alert Summary** column, select the **Study Name** link (highlighted in blue).
   - In the **Actions** column on the right, select **Go to Study** from the **Actions** drop-down menu.

   The [Study Name] details page opens, which provides a summary health dashboard page for the study. A tab with the study name appears at the bottom of the page. For example:

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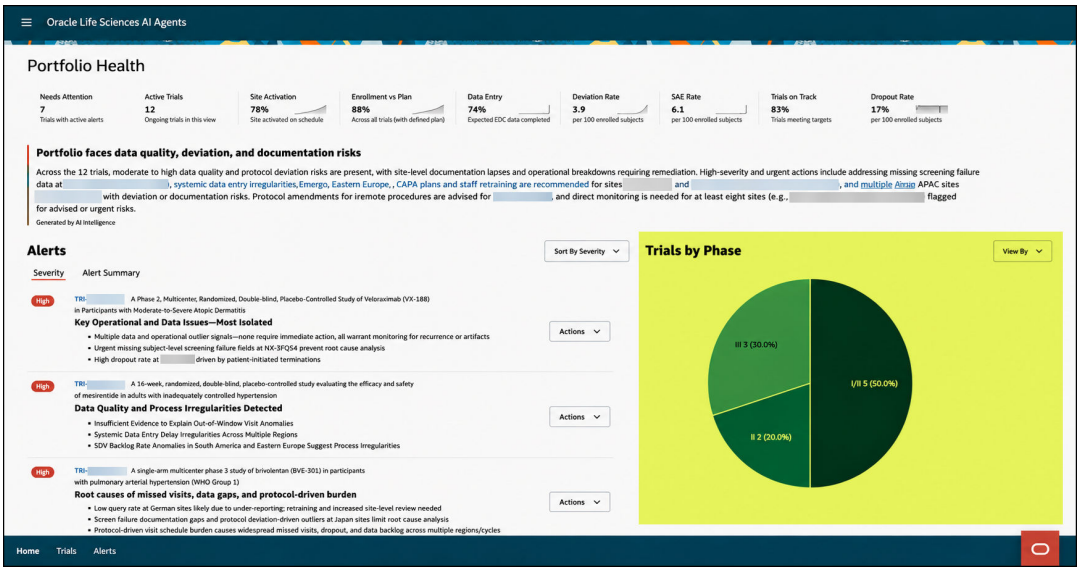
3. Select **Close** at the top left to return to the Portfolio Health overview. The study name tab at the bottom of the page is removed.

View the portfolio data graphs

As a user with access to all trials, you can view the portfolio trial data for all ongoing trials in four graph formats: Trials by Status (bar graph), Trials by Phase (pie graph), Trials by Therapeutic Area (bar graph), or Enrollment by Region (bar graph).

To view the portfolio data for all ongoing trials in graph format:

1. Open the Portfolio Health overview. The data graphs appear at the bottom right of the overview and are highlighted in the following example:



2. In the **View By** drop-down menu, select the format of the data you want to view:
   - **Status**—Opens the **Trials by Status** bar graph that shows the number of Active and In Progress trials.
   - **Phase**—Opens the **Trials by Phase** pie graph that shows the percentage of trials in each clinical trial phase (I to IV and unknown).

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- **Therapeutic Area**—Opens the **Trials by Therapeutic Area** bar graph that shows the number of trials by therapeutic area (for example, Cardiology/Vascular Diseases, Dermatology, and Endocrinology).
- **Region**—Opens the **Enrollment by Region** bar graph that shows the number of enrollments by country.

Each graph format includes a timestamp.

3. Hover over the graph to display statistic details.

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4

Manage all trials

Use the Trials list as a convenient and organized way for you to view all the Ongoing Trials and Trials in Planning you can access, easily navigate between the Trials list and trial details, and export the trial data to a CSV file.

You can filter the Trials list by the operational lifecycle stage (All Trials, Ongoing Trials, Other Trials (trials that are completed, suspended, or terminated), and if you have access, to Trials in Planning). You can switch between the list views as often as you like.

If you have access to Trials in Planning, you can also add and edit trial protocols, initiate the AI-generation of the trial plans based on the protocol, and then select the best plan for your trial.

- View the list of trials you can access
  You can use the Trials list to view lists of all the trials you can access and to easily navigate between the Trials list and trial details.
- View the details of an Ongoing Trial
  You can view the details for any Ongoing Trial that you have access to.
- Add a trial for planning and monitoring
  If you have access to planning trials, you can add new trials to be digitized and operationally planned. You can start planning a trial as early as when the protocol's synopsis has been drafted.
- View the details of a Trial in Planning
  You can view the details of any Trial in Planning that you have access to.
- Export trial data
  You can export trial data in CSV format for All Trials, all Ongoing Trials, all Other Trials, or all Trials in Planning that you have access to. The exported file includes data from the columns visible on the Trials list page.

View the list of trials you can access

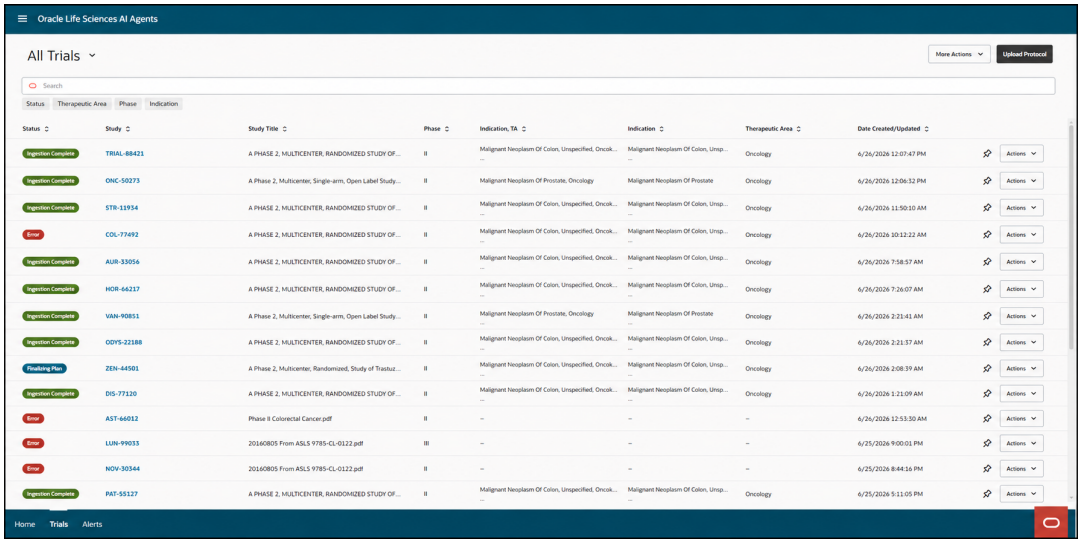
You can use the Trials list to view lists of all the trials you can access and to easily navigate between the Trials list and trial details.

You can filter the list by the operational lifecycle stage: All Trials (default), Ongoing Trials, Other Trials (trials that are completed, suspended, or terminated), or Trials in Planning (if you have access). You can switch between the list views as often as you like.

To view the list of trials you can access:

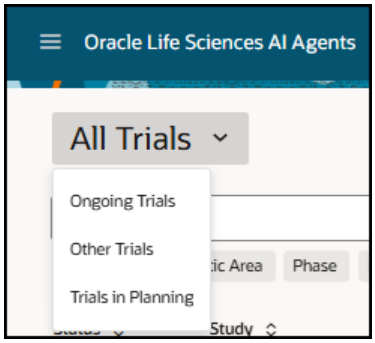
1. Select the **Trials** tab at the bottom of the Life Sciences AI Agents Trials interface window. The Trials list opens. The first time you open the Trials list it defaults to the All Trials view. For example:

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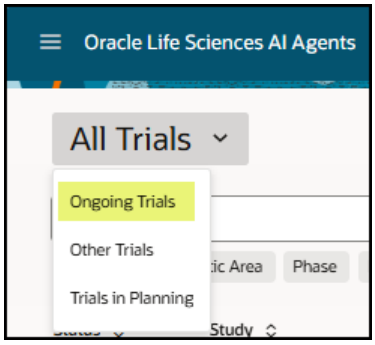
> **Note**
>
> - To resize a column, move your pointer to the border between two column headers. When the pointer changes to the resize cursor , select and drag the border left or right to decrease or increase the column width.
> - You can also customize the columns that appear on the page and rearrange their order to optimize your view. For more information, see Customize the columns in the Trials list.

You use the drop-down menu at the top of the page to filter the list by the operational lifecycle stage (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). For example:

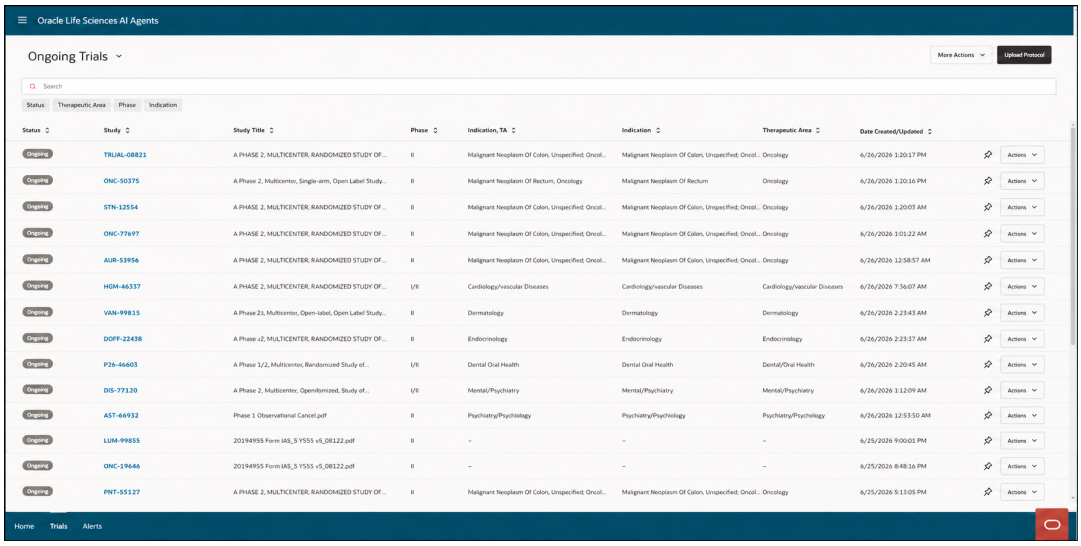


2. To filter the list to show only Ongoing Trials, use the drop-down menu next to the page title to select **Ongoing Trials** as highlighted in the following example:

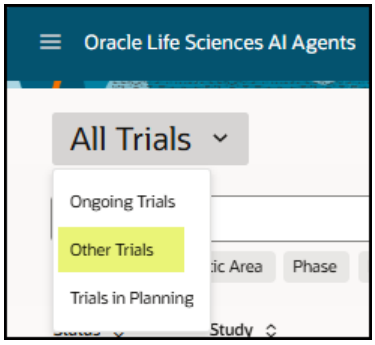
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After you select the Ongoing Trials drop-down menu option, the Ongoing Trials list view opens. For example:

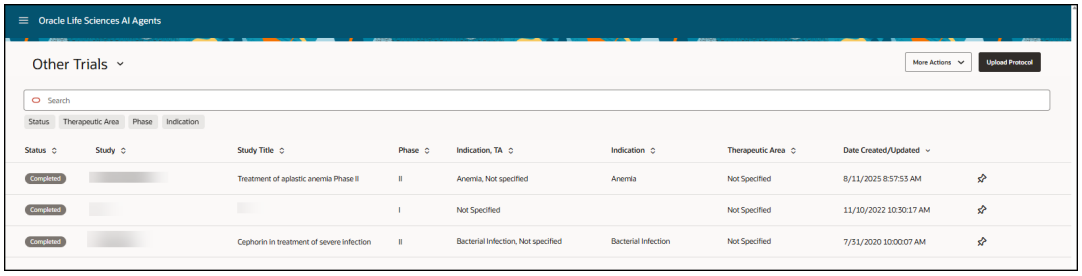


3. To filter the list to show only Other Trials, use the drop-down menu next to the page title to select **Other Trials** as highlighted in the following example:



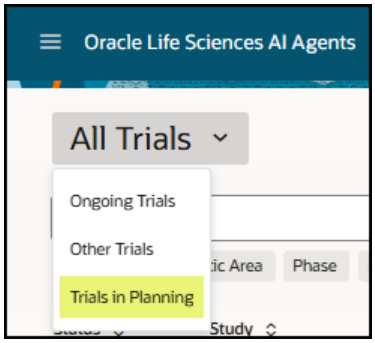
After you select the Other Trials drop-down menu option, the Other Trials list view opens. For example:

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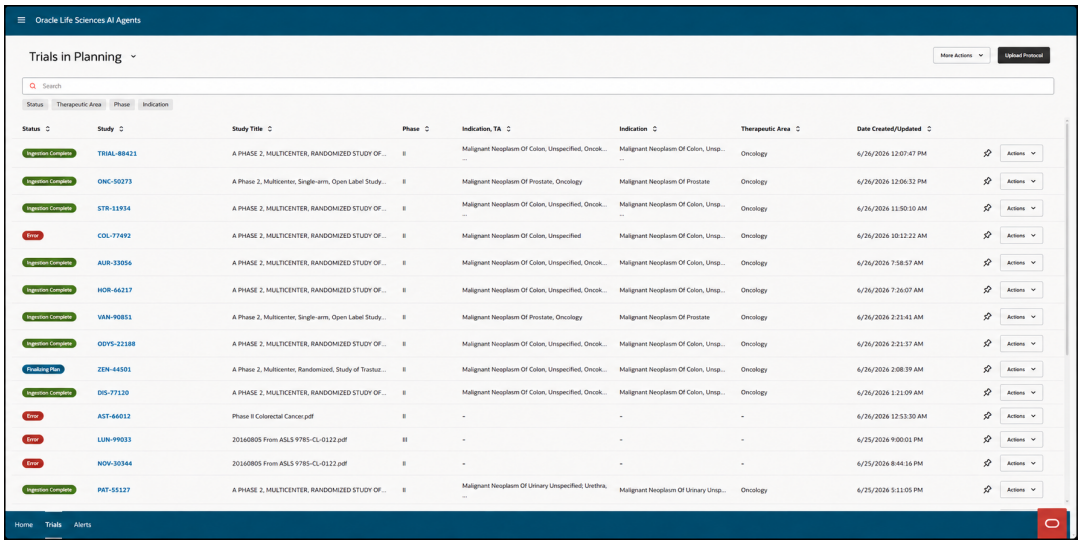


> **Note**
>
> Actions are not available in the Other Trials list view.

4. To filter the list to show only Trials in Planning, use the drop-down menu next to the page title to select **Trials in Planning** as highlighted in the following example:



If you do not have access to Trials in Planning, the option does not appear in the drop-down menu. After you select the Trials in Planning drop-down menu option, the Trials in Planning list view opens. For example:



5. To filter any view of the Trials list or to search for a specific trial, do one or more of the following:

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- Enter at least three characters in the **Search** field.
- Select a filter that appears below the **Search** field and provide any required details. You can select multiple details for each filter.
  - **Status**—Filters the trials by status. The status options vary depending on whether the trial is ongoing or in planning.
  - **Therapeutic Area**—Filters the trials by a specific field of medicine or disease (for example, oncology, cardiology, dermatology, or endocrinology).
  - **Phase**—Filters the trials by clinical trial phase (for example, I, II, III, or IV).
  - **Indication**—Filters the trials by a specific disease or medical condition (for example, chronic pain or diabetes).

6. Select the **Pin** ( ) icon if you want the trial name to remain at the top of the list. Pinned items adjust based on the filter selections, but they remain at the top of the filtered list.

> **Note**
>
> The next time you select the Trials tab, the last view you selected will open (All Trials, Ongoing Trials, or Trials in Planning).

- Customize the columns in the Trials list
  In all of the Trials list views (All Trials, Ongoing Trials, Other Trials (trials that are completed, suspended, or terminated), and if you have access, Trials in Planning) you can customize the columns that appear on the page and rearrange their order to optimize your view.

Customize the columns in the Trials list

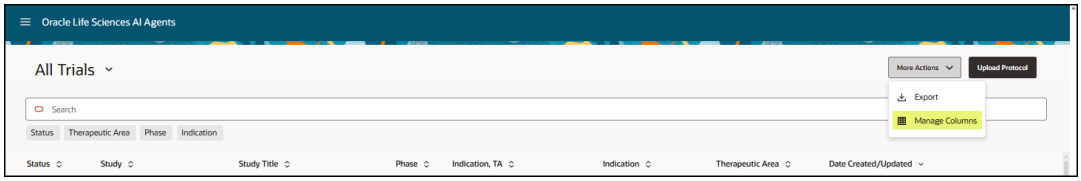
In all of the Trials list views (All Trials, Ongoing Trials, Other Trials (trials that are completed, suspended, or terminated), and if you have access, Trials in Planning) you can customize the columns that appear on the page and rearrange their order to optimize your view.

> **Note**
>
> Any customizations you make apply to all of the Trial list views (All Trials, Ongoing Trials, and if you have access, Trials in Planning).

To customize the columns in a Trials list view:

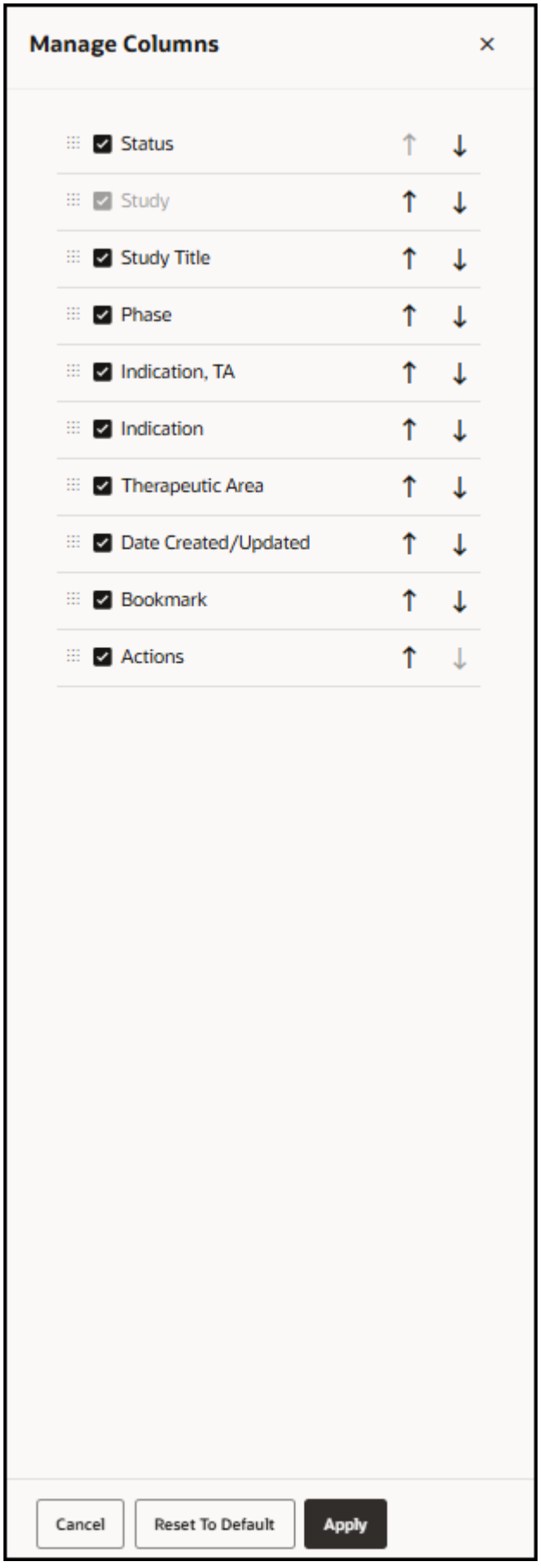
1. Open the list of trials you can access, and filter the list by operational lifecycle (All Trials, Ongoing Trials, Other Trials, or Trials in Planning) as needed as described in View the list of trials you can access.
2. In the **Trials** list (filtered to All Trials, Ongoing Trials, Other Trials, or Trials in Planning), select **Manage Columns** from the **More Actions** drop-down menu at the top right of the page as highlighted in the following example:

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The Manage Columns panel opens. For example:

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3. Select the checkbox next to the columns you want to appear on the Trials list page.
4. Deselect the checkbox next to the columns you do not want to appear on the Trials list page.
5. Optionally, for each column you select in step 3, use the up or down arrows to set the order you want the columns to appear on the Trials list page.
6. Do one of the following:
   - To save your changes and close the panel, select **Apply**.
   - To close the panel without saving your changes, **Cancel**.
   - To clear any previous customizations you made to the page columns, select **Reset to default** and then select **Apply**.

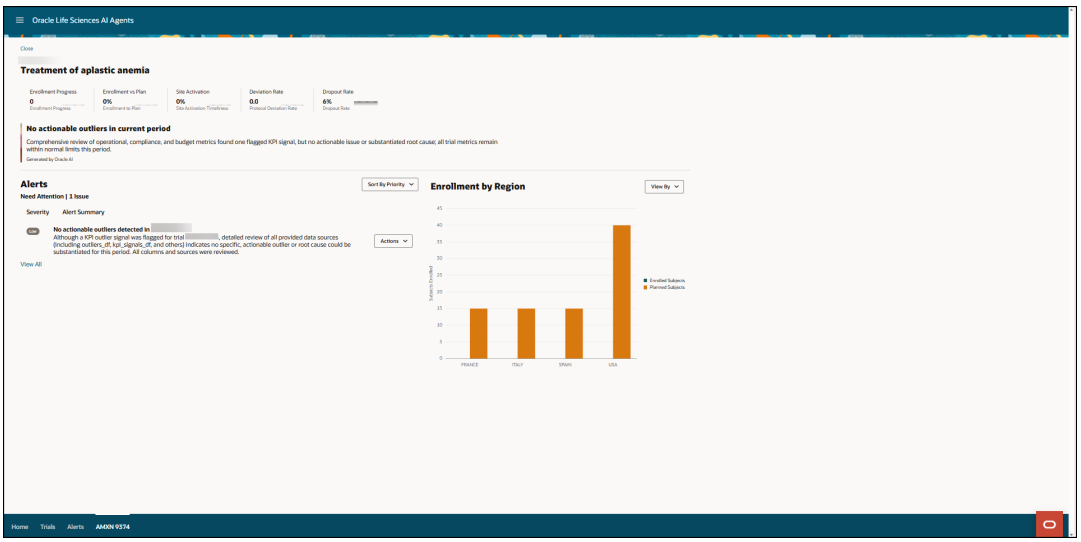
View the details of an Ongoing Trial

You can view the details for any Ongoing Trial that you have access to.

To view the details of an Ongoing Trial:

1. Open the list of trials you can access, and filter the list for Ongoing Trials, as described in View the list of trials you can access.
2. In the **Ongoing Trials** list view, do one of the following:
   - In the **Study** column, select the identifier of the trial you want to view the details for.
   - Find the trial you want to view the details for, and select **Go to study** from the **Actions** drop-down menu on the right.

   The [Trial Name] details page opens. A tab with the trial name appears at the bottom of the page. For example:



3. At the top of the page below the page title, you can view the trial health key performance indicators (KPIs) that provide standardized metrics that measure trial performance consistency for the past 90 days to identify areas of operational risk.

   The trial KPIs can include Enrollment Progress, Enrollment vs Plan, Site Activation, Data Entry, Deviation Rate, SAE Rate, Query Rate, Requery Rate, Dropout Rate, and Data

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Entry Timeliness. The trial KPIs are refreshed every 24 hours at 2 am UTC and are only calculated and shown if there is enough data for each.

> **Note**
>
> You can hover over any KPI to see details about how its value was calculated, including the minimum and maximum values and the calculation date.

Ongoing Trials Portfolio - Key Performance Indicator (KPI)	Description
Enrollment Progress	Actual enrollment accrued in CTMS at the protocol level. This metric shows the total number of subjects enrolled for the trial at any time.
Enrollment vs Plan	Actual enrollment divided by the planned enrollment (uses the enrollment forecast). This metric shows if the trial is meeting its recruitment goals.
Site Activation	Percentage of activated sites that have met their activation target dates. This metric is a measure of start-up efficiency. A high variance signals bottlenecks.
Data Entry	Percentage of expected CRFs completed (regardless of query status). This metric serves as an early warning of operational lag. Low data entry completeness correlates to monitoring backlog and slow data entry timeliness.
Deviation Rate	Number of protocol deviations reported per 100 subjects across the trial. This metric represents a universal compliance indicator.
SAE Rate	Serious adverse event rate per 100 subjects enrolled. This is a key portfolio safety metric that normalizes by exposure (compares safety risks across different studies).
Query Rate	Number of queries raised at the site divided by the number of items on any started eCRF (for example, for data that has been collected so far).
Requery Rate	Number of re-opened queries divided by the total number of queries. This metric shows when the site's initial response was insufficient, incorrect, or generated a new query. This can occur if: • The initial site response did not close a query, resulting in a "re-query" to the site (the query state changed from Answered to Opened). • The initial site action (data change) did not close a query, resulting in a "re-query" to the site (the query state changed from Opened to Answered to Opened).
Dropout Rate	Percentage of enrolled subjects that have dropped out or were terminated early. Appears only if you are not using a supported source application.
Data Entry Timeliness	Average number of days from the date of a subject visit to the date the data is entered into an eCRF in EDC. This metric provides an early warning signal for downstream delays in cleaning, reporting, and analysis. Appears only if you are not using a supported source application.

4. Below the KPIs, you can view a summary health overview for the trial.
5. In the **Alerts** section, you can:

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> **Note**
>
> The alerts are refreshed every 24 hours at 2 am UTC.

- Sort the alerts by Severity or Alert Title.
- Select the following Actions for each alert:
  - **View Alert**—Select to view the details for an alert. For more information, see View the details of an alert and provide feedback.
  - **Snooze**—Use to pause the alert notifications to you. For more information, see Snooze an alert.
  - **Dismiss**—Use to stop the alert notifications to you. For more information, see Dismiss an alert.
- Select **View All**—Use to open the Alerts list filtered for the study associated with the alert. For more information, see View the study details associated with an alert.

6. In the **Enrollment by Region** section, use the **View By** drop-down menu to select a different view of the data graph. The options are: Enrollment by Region, Site initiated by Region, and Subjects Screened and Enrollment by Region.
7. Select **Close** at the top left to return to the Trials list. The study name tab at the bottom of the page is removed.

Add a trial for planning and monitoring

If you have access to planning trials, you can add new trials to be digitized and operationally planned. You can start planning a trial as early as when the protocol's synopsis has been drafted.

To add a trial you upload a trial protocol or synopsis including the Schedule of Assessments into Life Sciences AI Agents. AI extracts the planning-specific protocol elements. During the upload or during review of the extracted elements, you can define specific targets such as the expected project start date, maximum budget threshold, study and enrollment duration thresholds, milestone date targets, and specific sites and countries. Then, Life Sciences AI Agents generates three operational plans with different objectives: cost efficient, fastest, and a balance of both. You can review the trial plans, make any necessary adjustments, and then select the best plan for your trial.

- Trial protocols
  You can begin operational planning as soon as a protocol synopsis is drafted by uploading the synopsis including the Schedule of Assessments into Life Sciences AI Agents.
- Trial plans
  After the protocol processing is complete, Life Sciences AI Agents provides three trial plans by default with different objectives: cost efficient, fastest, and a balance of both. You can review the trial plans, make any necessary adjustments, and then select the best plan for your trial.
- Workflow to add a trial
  The workflow for adding a trial into Life Sciences AI Agents includes a series of steps starting with uploading a protocol or synopsis, reviewing and updating certain data parameters as needed, generating the three trial plans, and then selecting and finalizing an operational plan for the trial.

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- Upload a trial protocol
  As a user with access to Trials in Planning, you can view all uploaded protocols and add new protocols into Life Sciences AI Agents. You can upload a draft or final protocol or protocol synopsis including the Schedule of Assessments.
- Review the uploaded trial protocol and generate the trial plans
  After you upload a trial protocol, you can review it and, if needed, add or modify some of the trial parameters.
- Review the AI-generated trial plans
  After Life Sciences AI Agents generates the three trial plans, you can review the plans and make adjustments and comparisons before you select a plan for your trial.
- Select a trial plan
  After you review and make any necessary adjustments to the AI-generated trial plans, you can select the best plan for your trial from the available options.

Trial protocols

You can begin operational planning as soon as a protocol synopsis is drafted by uploading the synopsis including the Schedule of Assessments into Life Sciences AI Agents.

Depending on the stage of your protocol development workflow, you can upload the latest draft, final version, or amended version of the protocol so that Life Sciences AI Agents can generate the top recommended operational plans for your review.

Before you upload a trial protocol or synopsis:

- Ensure that the protocol or synopsis is in PDF or DOCX format. The maximum file size is 50 MB.
- If you are uploading a synopsis, include the Schedule of Assessments because it is required to forecast study plan costs.
- Review the planning-specific protocol elements per section and correct them as needed.
  - Study Overview
  - Objectives and Endpoints
  - Population Characteristics
  - Study Design
  - Assessment Plan
  - Optional planning parameters

Trial plans

After the protocol processing is complete, Life Sciences AI Agents provides three trial plans by default with different objectives: cost efficient, fastest, and a balance of both. You can review the trial plans, make any necessary adjustments, and then select the best plan for your trial.

The following three operational trial plans are provided by default:

- **Cost efficient**—The goal of this option is to conclude the trial with the lowest cost possible. Choosing this plan may increase the duration of the trial.
- **Fastest**—The goal of this option is to conclude the trial as fast as possible. Choosing this plan may increase the cost of the trial.

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- **Balanced**—The goal of this option is to provide a middle point between cost and speed, where both variables are balanced.

Workflow to add a trial

The workflow for adding a trial into Life Sciences AI Agents includes a series of steps starting with uploading a protocol or synopsis, reviewing and updating certain data parameters as needed, generating the three trial plans, and then selecting and finalizing an operational plan for the trial.

The workflow steps are:

1. Upload a PDF or DOCX file with the trial protocol or synopsis. The maximum file size is 50 MB.

   Life Sciences AI Agents confirms that the file type is supported. If yes, the process automatically advances to step 2. If no, the process stops and does not continue.
2. Life Sciences AI Agents extracts (also called *ingests*) data in the protocol or synopsis.
3. Life Sciences AI Agents validates required elements in the protocol. If any required elements are missing, you must provide the missing information.
4. Confirm or correct any parameters in the protocol or synopsis, as needed, and then generate the trial plans.

   You can review the trial objectives, study design, population characteristics, assessment plan, and optional planning parameters. When you review the extracted protocol elements, you can define specific operational assumptions such as:

   - Which sites to leverage in which countries.
   - Expected milestone dates aside from the expected Project Start date.
   - Maximum budget.
   - Maximum study duration (where the study duration is defined from the Project Start date, enrollment duration, and so on).

   For more information on the protocol parameters and generating the trial plans, see Upload a trial protocol and Review the uploaded trial protocol and generate the trial plans.
5. After Life Sciences AI Agents generates the three trial plans, you can review the plans, make adjustments as needed, and view plan comparisons before you select a plan for your trial.

   You can review, adjust, and compare the trial plans as often as you like. Then, you can regenerate the plans as needed before selecting the best plan for your trial.

   For more information, see Review the AI-generated trial plans.
6. Adjust any of the trial plans as needed. You can edit the details and sites for a trial plan, download a trial plan, and rename a trial plan.

   For more information, see Adjust a single trial plan.
7. Compare and download the trial plans as needed.

   You can view one or compare two trial plans at a time to help you identify which objective is the best option for your trial. You can download any combination of trial plan comparison charts as you like to a CSV file.

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You can also view the enrollment duration, expected enrollment, or average grant per subject by country for one trial plan, or you can compare the enrollment duration, expected enrollment, or average grant per subject by country for two trial plans. You can download the details for each to a CSV file.

For more information, see Compare and download trial plans.

8. After you review and make any necessary adjustments to the trial plans, you can select the best plan for your trial from the available options.

   For more information, see Select a trial plan.

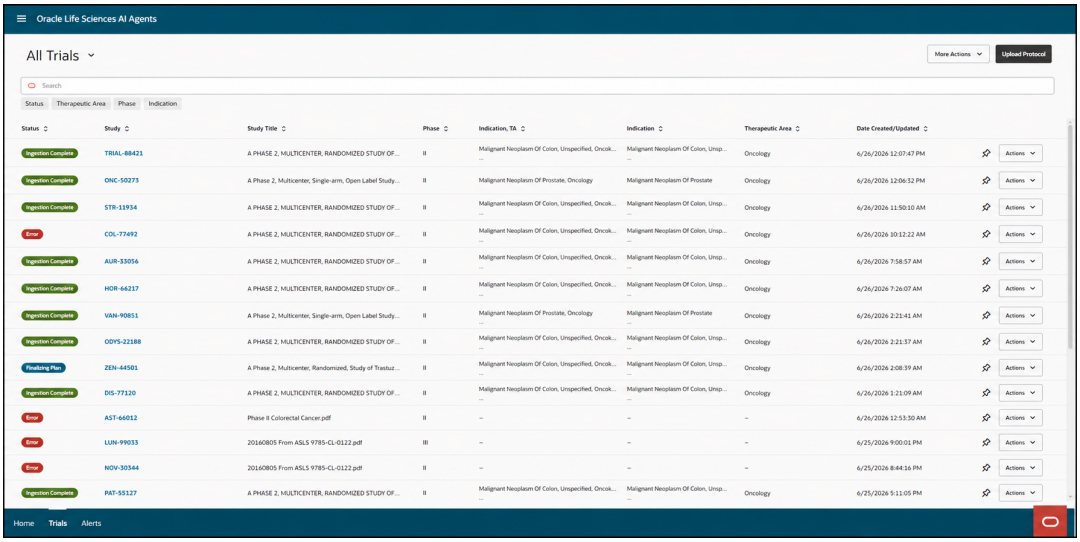
Upload a trial protocol

As a user with access to Trials in Planning, you can view all uploaded protocols and add new protocols into Life Sciences AI Agents. You can upload a draft or final protocol or protocol synopsis including the Schedule of Assessments.

> **Note**
>
> You can upload a different version of the same draft or final protocol or protocol synopsis after the initial upload, if necessary. For more information, see Upload a different version of a trial protocol.

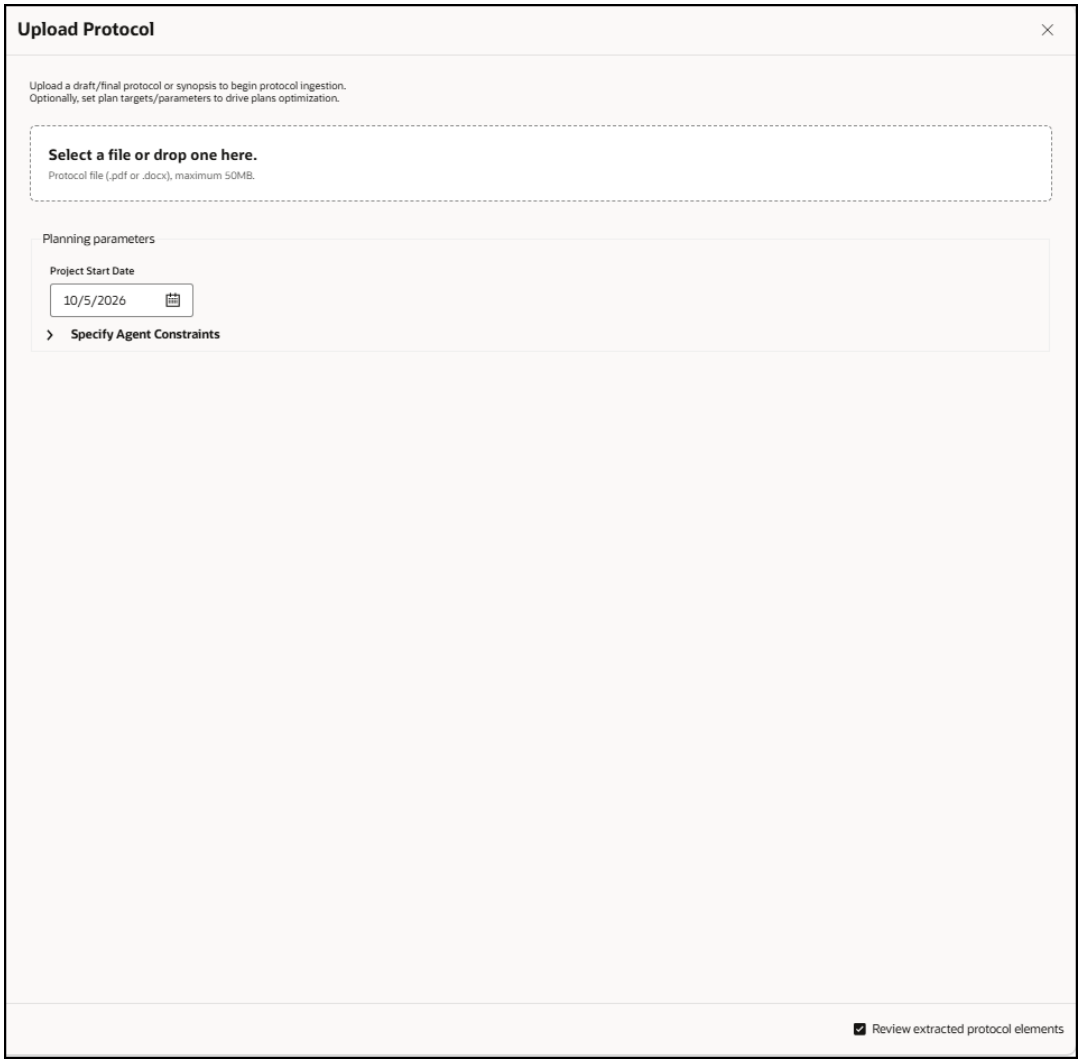
To upload a trial protocol or synopsis:

1. Select the **Trials** tab at the bottom of the Life Sciences AI Agents Trials interface window. The Trials list opens. The last view you selected opens (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). For example:



2. At the top right, select **Upload Protocol**. The Upload Protocol option is available from any Trials list view (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). The Upload Protocol panel opens. For example:

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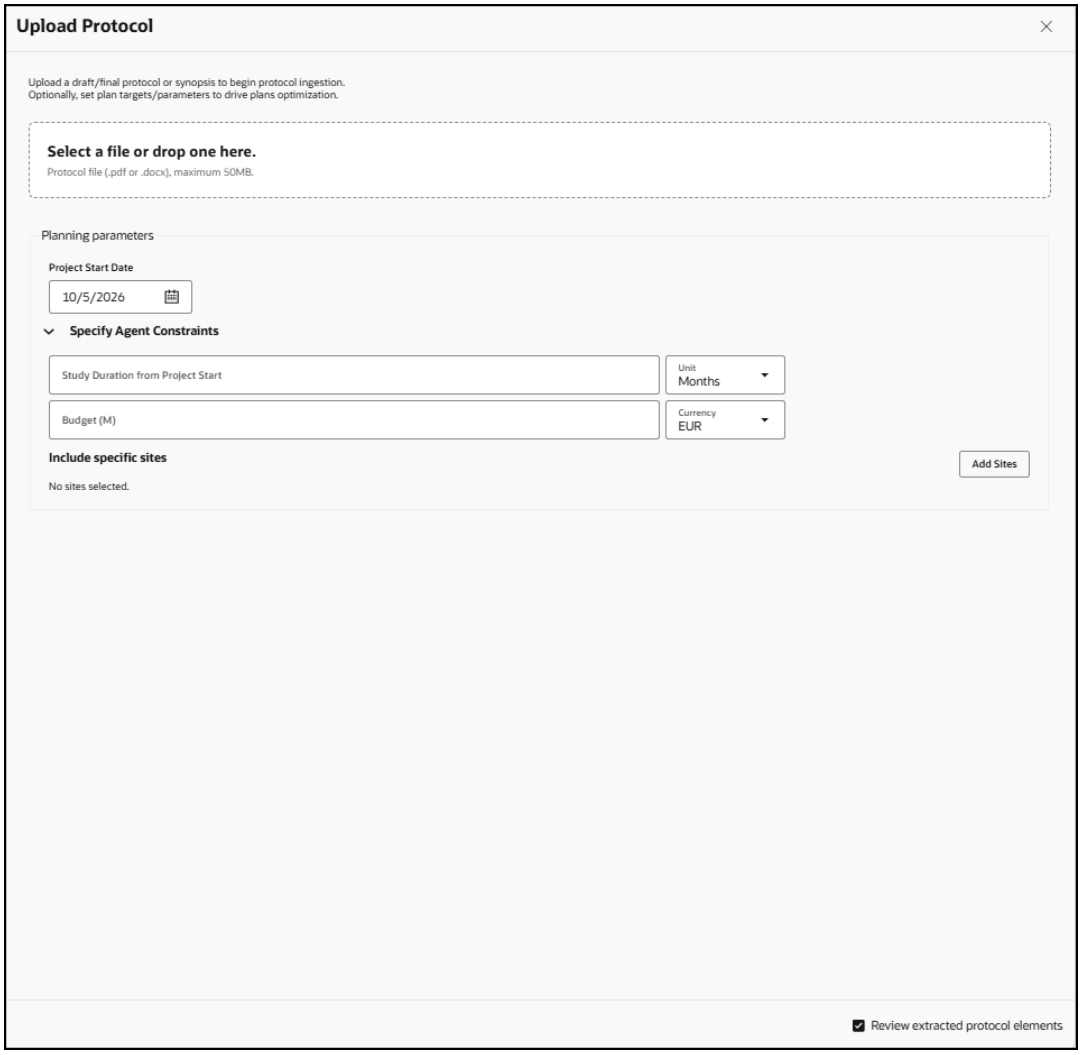
3. In the **Upload Protocol** panel, add the protocol or synopsis file you want to upload.

   You can navigate to the file or drag and drop the file into the block at the top of the panel. The protocol must be in PDF or DOCX format and be 50 MB or less.

> **Note**
>
> A progress bar opens and shows the status of the protocol extraction (also called ingesting) process. This step may take some time.

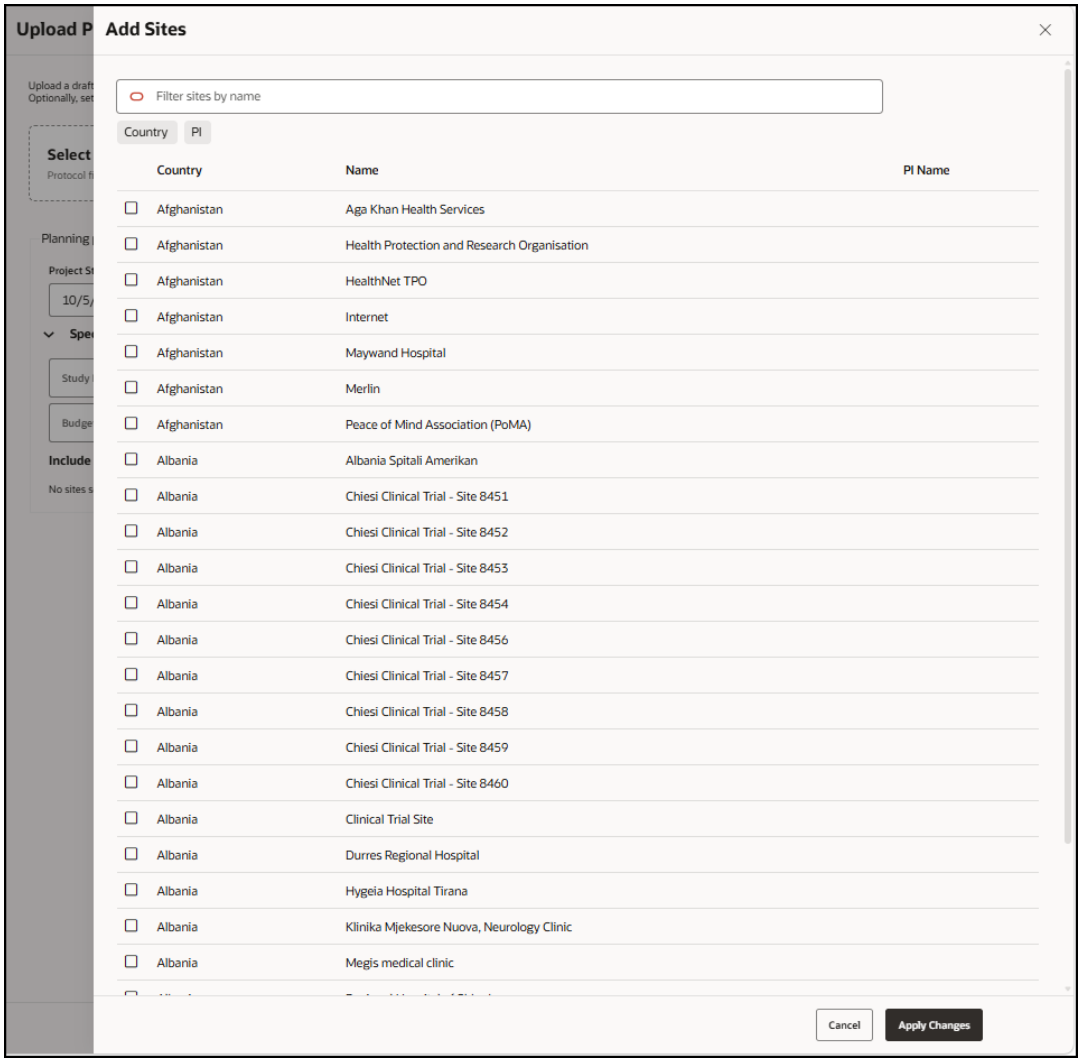
4. In the **Project Start Date** field, use the Calendar icon to select a date, or enter a date in MM/DD/YYYY format for the date you want costing to begin. If you do not enter a date, the field defaults to the current date.
5. After the protocol extraction completes, select the right arrow next to the **Specify Agent Constraints** heading to expand the section so that you can view and edit the parameters as needed. For example:

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6. In the **Specify Agent Constraints** section, provide or update the following information as needed:
   - **Study Duration from Project Start**—Enter a value for the expected study duration, and in the adjacent **Units** drop-down menu select **Days**, **Weeks**, **Months**, or **Years**.
   - **Budget ($M)**—Enter a value and in the adjacent **Currency** drop-down menu select **EUR** or **USD**. The currency value you select is used for all monetary amounts that appear in the interface.
7. In the **Include specific sites** section, select **Add Sites** on the right. The Add Sites panel, which shows the countries and sites defined in the protocol, opens. For example:

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8. Select the check box next to each country and site you want to add, and select **Apply Changes**. The Add Sites panel closes and the Upload Protocol panel becomes active again.

   The sites you added appear in the **Include specific sites** section in the Upload Protocol panel. Select the **X** on the right to remove a site, as needed.

9. In the **Upload Protocol** panel, update the choice for the **Review extracted protocol elements** checkbox at the bottom right, as needed.

   - Select **Review extracted protocol elements** (default) if you want to review the protocol extraction after it completes and before the trial plans are generated. You are presented with protocol elements to confirm or to correct misinterpretations, and then you can proceed to the generating plan step. For more information, see Review the uploaded trial protocol and generate the trial plans.
   - Deselect **Review extracted protocol elements** if you want to skip reviewing the protocol extraction before the trial plans are generated. For more information, see Review the AI-generated trial plans.

10. In the **Upload Protocol** panel, select **Save Changes**.

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- Upload a different version of a trial protocol
  You can upload a different version of the same draft or final protocol or protocol synopsis after the initial upload, if necessary. You can upload multiple versions of the same protocol or synopsis.

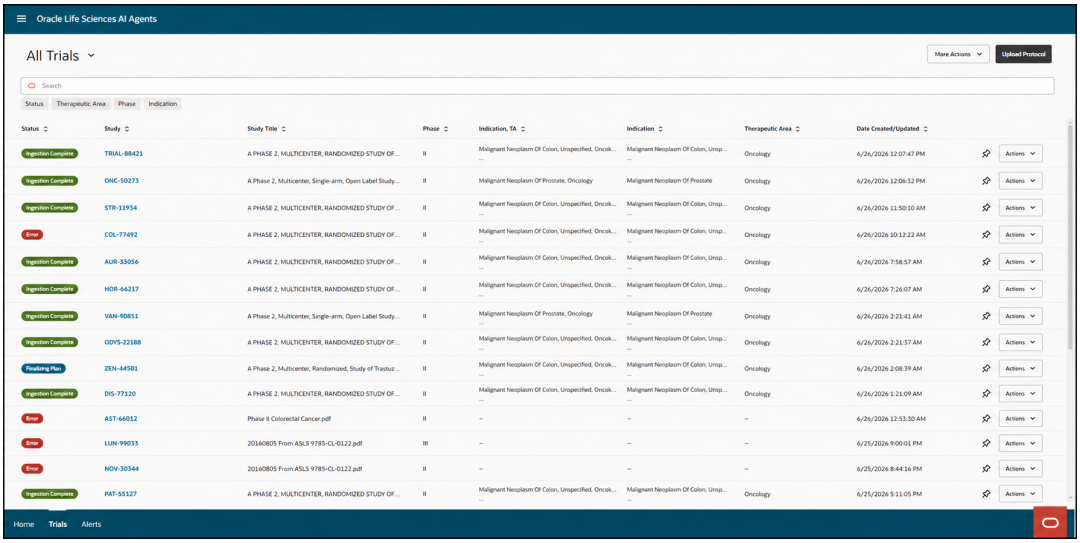
Upload a different version of a trial protocol

You can upload a different version of the same draft or final protocol or protocol synopsis after the initial upload, if necessary. You can upload multiple versions of the same protocol or synopsis.

> **Note**
>
> For more information on uploading the original version of a trial protocol or synopsis, see Upload a trial protocol.

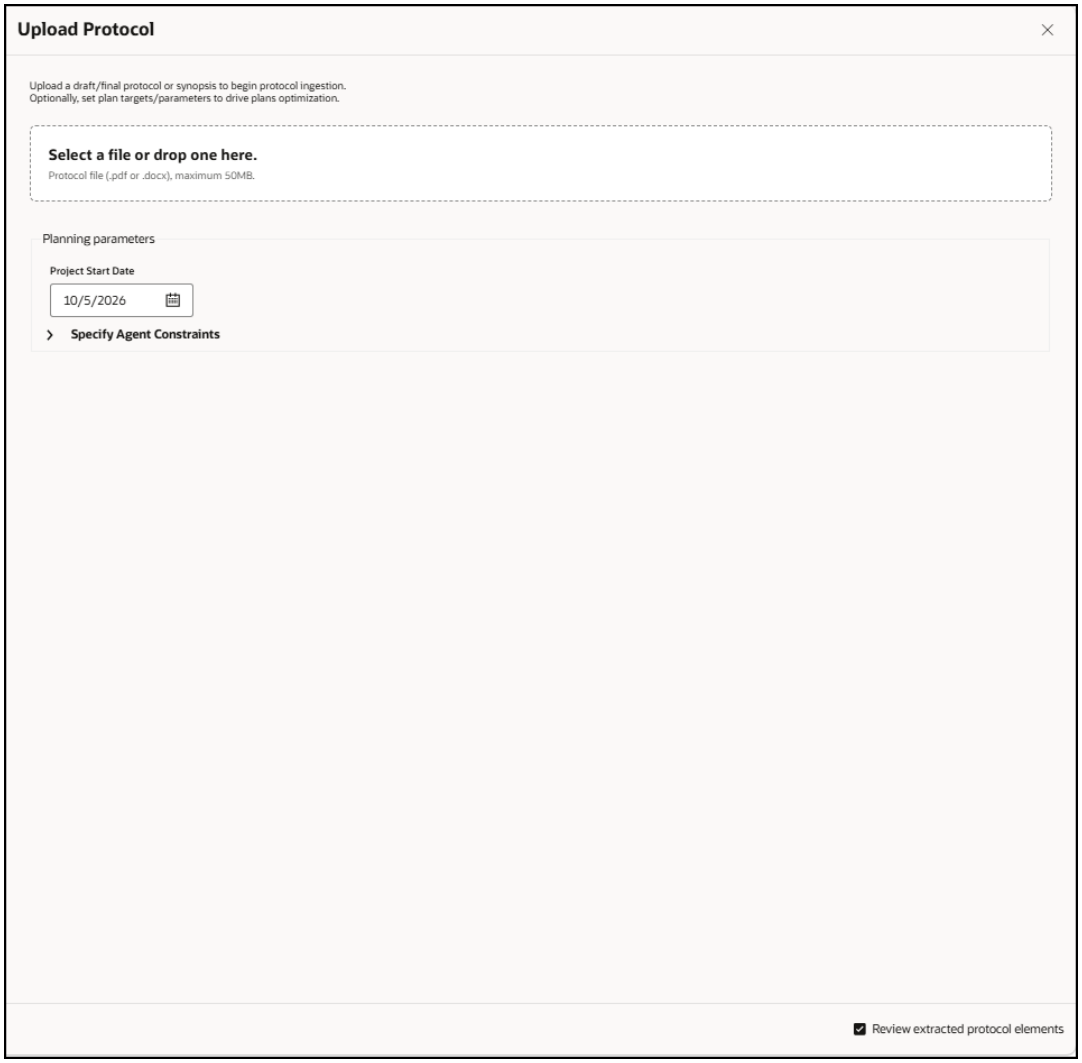
To upload a new version of the same trial protocol or synopsis:

1. Select the **Trials** tab at the bottom of the Life Sciences AI Agents Trials interface window. The Trials list opens. The last view you selected opens (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). For example:



2. In the **Status** column, find the trial with a status of **Ingestion Complete** that you want to upload a new protocol version for, and at the top right, select **Upload Protocol**. The Upload Protocol option is available from any Trials list view (All Trials, Ongoing Trials, Other Trials, or Trials in Planning). The Upload Protocol panel opens.

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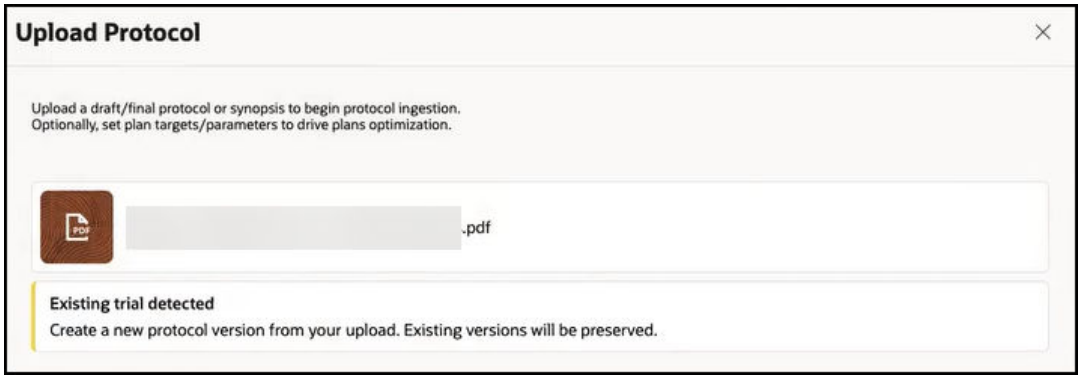
3. In the **Upload Protocol** panel, add the updated protocol or synopsis file you want to upload.

   You can navigate to the file or drag and drop the file into the block at the top of the panel. The protocol must be in PDF or DOCX format and be 50 MB or less.

> **Note**
>
> A progress bar opens and shows the status of the protocol extraction (also called ingesting) process. This step may take some time.

4. In the **Project Start Date** field, use the Calendar icon to select a date, or enter a date in MM/DD/YYYY format for the date you want costing to begin. If you do not enter a date, the field defaults to the current date.
5. When the ingestion process completes, if the new upload contains the same planning-specific elements and key study information, such as Study Type, Protocol ID, Phase, Therapeutic Area(s), Indication(s), and Product(s), an **Existing trial detected** message appears in the Upload Protocol panel. For example:

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6. Scroll down and select the right arrow next to each heading in the panel to expand the section so that you can view and update any of the editable parameters as needed.

> **Note**
>
> The parameters are populated with information from the previous version of the protocol or synopsis that you uploaded.

- **Study Overview**—Shows the following details:
  - **Protocol ID**
  - **Study Type**—Select **Interventional** or **Observational**.
  - **Study Title**
  - **Study Acronym**
  - **Phase**
  - **Product(s)**
  - **Indications and Therapeutic Areas**—Add or remove the indications and therapeutic areas as needed.
- **Objectives & Endpoints**—Shows the following details for each objective:
  - **Type**
  - **Objective**
  - **Endpoint(s)**
- **Population Characteristics**—Shows the following details:
  - **Target sample size**
  - **Target locations**—Required.
  - **Inclusion Criteria**—Required.
  - **Exclusion Criteria**—Required.
- **Study Design**—Shows the following details:
  - **Interventional Model**
  - **Number of treatment arms**
  - **Number of planned subjects per treatment arm**

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- **Assessment Plan**—Shows the following details:
  - **Screening**—Provide the Duration, Unit (Days, Weeks, or Months), and the Number of visits per subject/patient.
  - **Treatment**—Provide the:
    - Duration, Unit (Days, Weeks, or Months), and the Number of visits per subject/patient
    - Cycle Duration, Unit (Days, Weeks, or Months), and Number of cycles.
  - **Follow-up**—Provide the Duration, Unit (Days, Weeks, or Months), and Number of visits per subject/patient.
- **Specify Agent Constraints**—Shows the following details:
  - **Study Duration from Project Start**—Enter a value for the expected study duration, and in the adjacent **Units** drop-down menu select **Days**, **Weeks**, **Months**, or **Years**.
  - **Budget ($M)**—Enter a value and in the adjacent **Currency** drop-down menu select **EUR** or **USD**. The currency value you select is used for all monetary amounts that appear in the interface.
  - **Include specific sites**—Select **Add Sites** to open the **Add Sites** panel. Select the check box next to each site you want to add, and select **Apply Changes**. The Add Sites panel closes and the [Trial Name] panel becomes active again.

7. Select **Save Changes**.
8. Select **Create Version [Number]** to create a new version of the protocol.

   From the drop-down menu at the top of the [Trial Name] panel, you can view all versions of the protocol.

Review the uploaded trial protocol and generate the trial plans

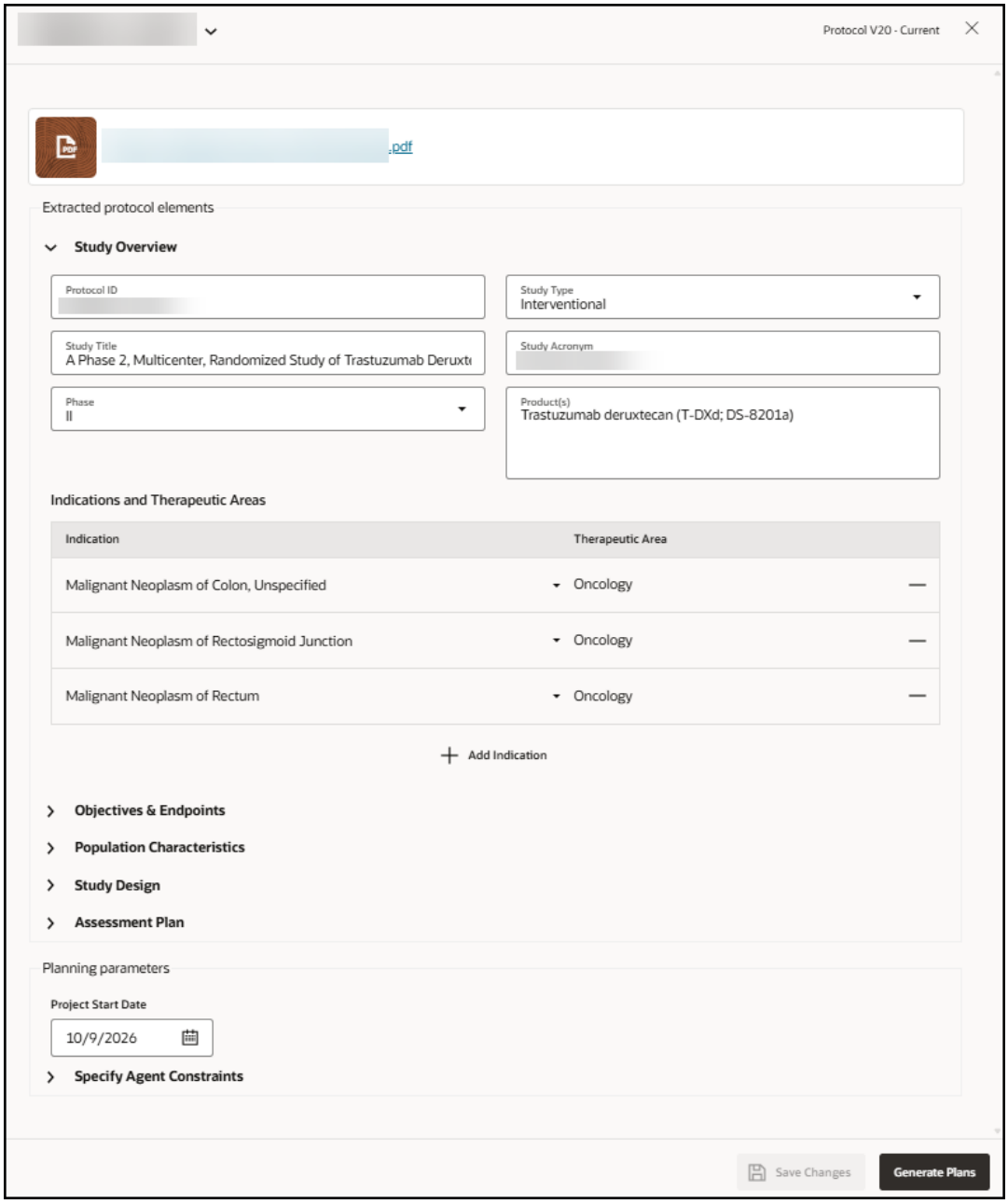
After you upload a trial protocol, you can review it and, if needed, add or modify some of the trial parameters.

You can review and edit protocols with a status of Ingestion Complete. You can review the trial objectives, study design, population characteristics, assessment plan, and optional planning parameters.

To review an uploaded trial protocol and generate the trial plans:

1. Ensure that you have uploaded a trial protocol.
2. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
3. In the **Trials** list, in the **Status** column, find a trial with a status of **Ingestion Complete**, and in the **Study** column, select the identifier of the trial you want to see the protocol details for. The **[Protocol Name]** panel opens. For example:

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4. Expand each section and provide updates as needed.
   - **Study Overview**—Shows the following details:
     - **Protocol ID**
     - **Study Type**—Select **Interventional** or **Observational**.
     - **Study Title**
     - **Study Acronym**
     - **Phase**
     - **Product(s)**
     - **Indications and Therapeutic Areas**—Add or remove the indications and therapeutic areas as needed.
   - **Objectives & Endpoints**—Shows the following details for each objective:

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  - **Type**
  - **Objective**
  - **Endpoint(s)**
- **Population Characteristics**—Add and remove inclusion and exclusion criteria as needed.
  - **Target sample size**—Update as needed.
  - **Target locations**
  - **Inclusion Criteria**
  - **Exclusion Criteria**
- **Study Design**—Shows the following details:
  - **Interventional Model**
  - **Number of treatment arms**
  - **Number of planned subjects per treatment**
- **Assessment Plan**—Shows the following details:
  - **Screening**—Provide the Duration, Unit (Days, Weeks, or Months), and the Number of visits per subject/patient.
  - **Treatment**—Provide the:
    * Duration, Unit (Days, Weeks, or Months), and the Number of visits per subject/patient
    * Cycle Duration, Unit (Days, Weeks, or Months), and Number of cycles.
  - **Follow-up**—Provide the Duration, Unit (Days, Weeks, or Months), and Number of visits per subject/patient.
- **Specify Agent Constraints**—Shows the following details:
  - **Study Duration from Project Start**—Enter a value for the expected study duration, and in the adjacent **Units** drop-down menu select **Days**, **Weeks**, **Months**, or **Years**.
  - **Budget ($M)**—Enter a value and in the adjacent **Currency** drop-down menu select **EUR** or **USD**. The currency value you select is used for all monetary amounts that appear in the interface.
  - **Include specific sites**—Select **Add Sites** to open the **Add Sites** panel. Select the check box next to each site you want to add, and select **Apply Changes**. The Add Sites panel closes and the [Trial Name] panel becomes active again.

5. Select **Save changes**. The Save changes button is disabled by default until you make changes.
6. To generate the trial plans, select **Generate Plans** . The **Generating plans for [Trial Name]** panel opens. A progress bar shows the status as Life Sciences AI Agents generates the trial plan recommendations.

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> **Note**
>
> After Life Sciences AI Agents generates the trial plans, you can review and compare the three plan recommendations. If necessary, you can adjust some of the trial plan details. For more information, see Review the AI-generated trial plans.

Review the AI-generated trial plans

After Life Sciences AI Agents generates the three trial plans, you can review the plans and make adjustments and comparisons before you select a plan for your trial.

You can review, adjust, and compare the trial plans as often as you like. Then, you can regenerate the plans as needed before selecting the best plan for your trial.

- Open the AI-generated trial plans
  After Life Sciences AI Agents generates the trial plans, you can open, view, adjust, and compare the details for each plan as needed.
- Adjust a single trial plan
  For each trial plan, you can edit some of the plan details, add or remove sites, download the plan to a CSV file, and rename the plan.
- Compare and download trial plans
  You can compare the details in the AI-generated trial plans to help you identify the best option for your trial. You can download each plan and any plan comparison charts to save as CSV files.

Open the AI-generated trial plans

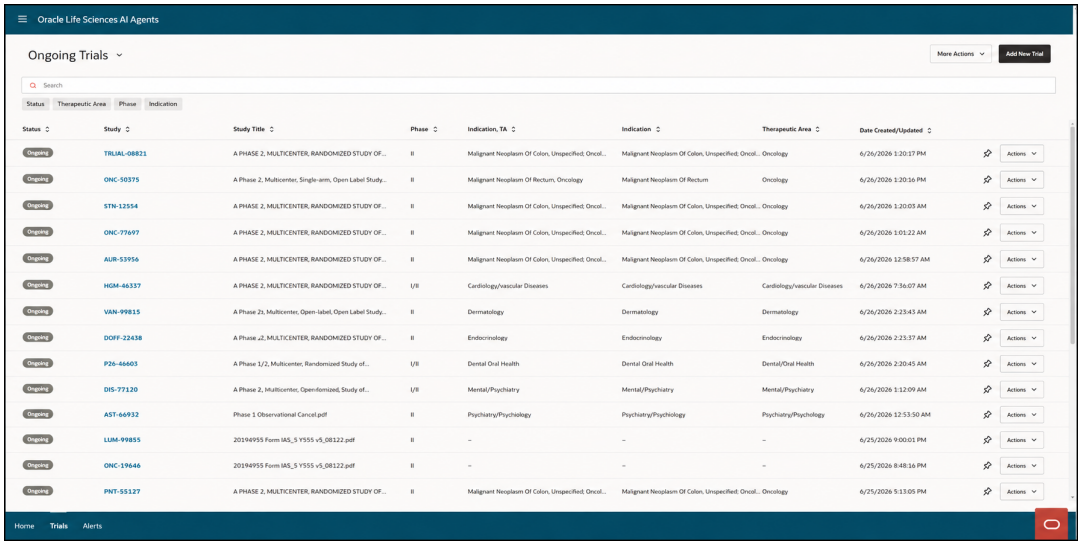
After Life Sciences AI Agents generates the trial plans, you can open, view, adjust, and compare the details for each plan as needed.

Each trial plan provides details including the total budget, study duration, enrollment duration and rates, total countries, number of sites, per patient cost, number of participants and patients per site.

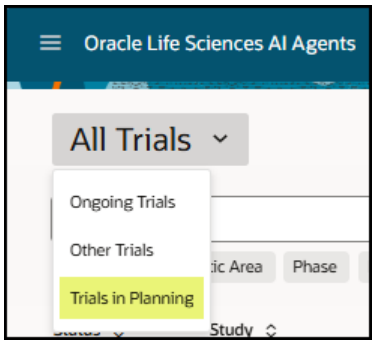
To open the AI-generated trial plans:

1. Select the **Trials** tab at the bottom of the Life Sciences AI Agents Trials interface window. The Trials list opens. The last view you selected opens (All Trials, Ongoing Trials, or Trials in Planning). For example:

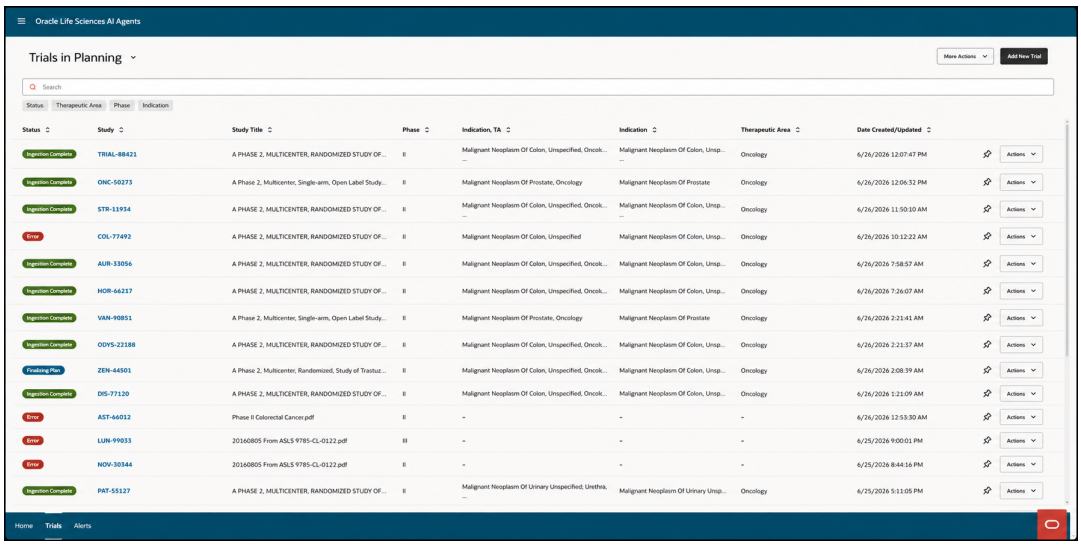
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2. If necessary, use the drop-down menu next to the page title to select **Trials in Planning** as highlighted in the following example:



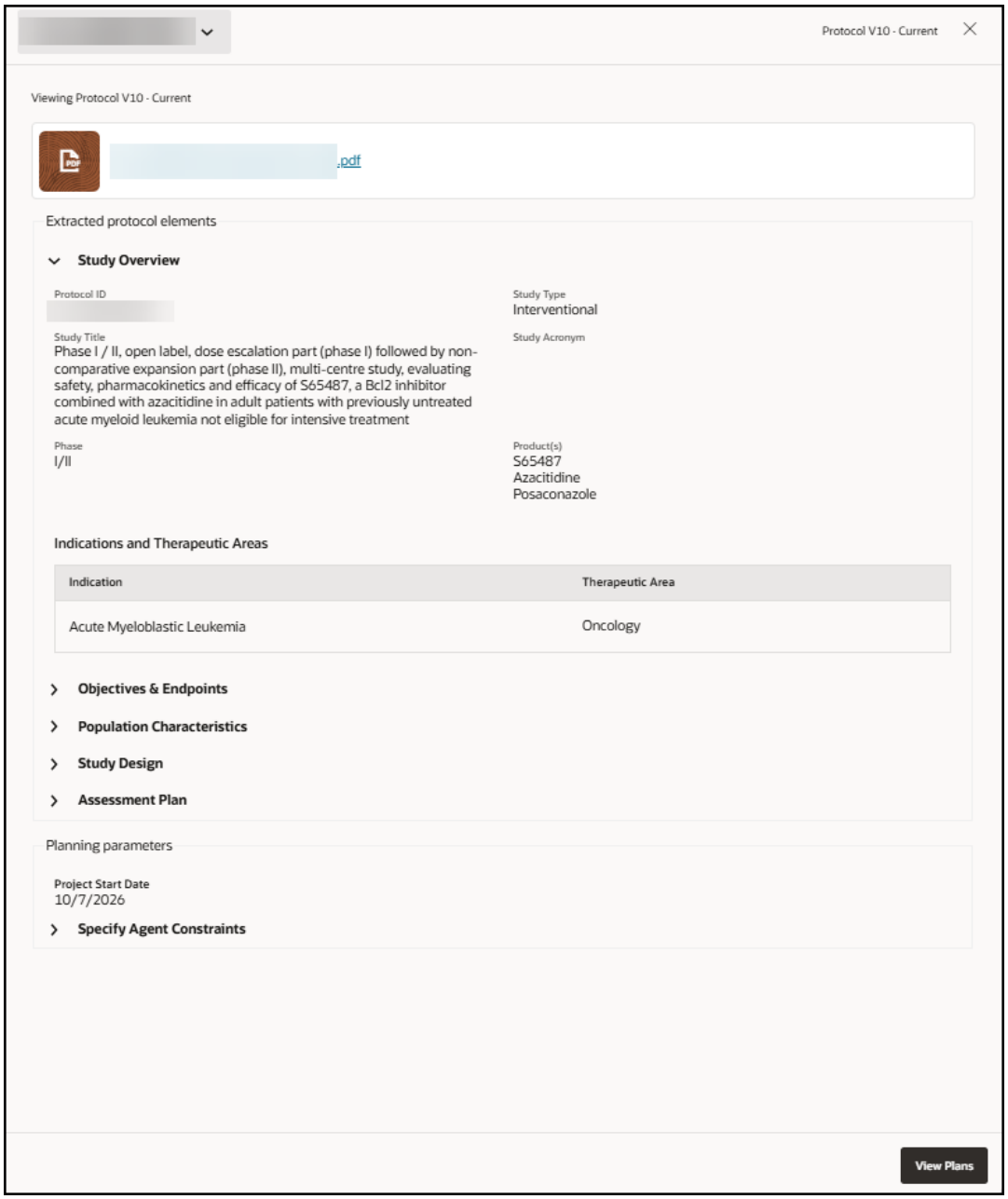
If you do not have access to Trials in Planning, the option does not appear in the drop-down menu. After you select the Trials in Planning drop-down menu option, the Trials in Planning list view opens. For example:



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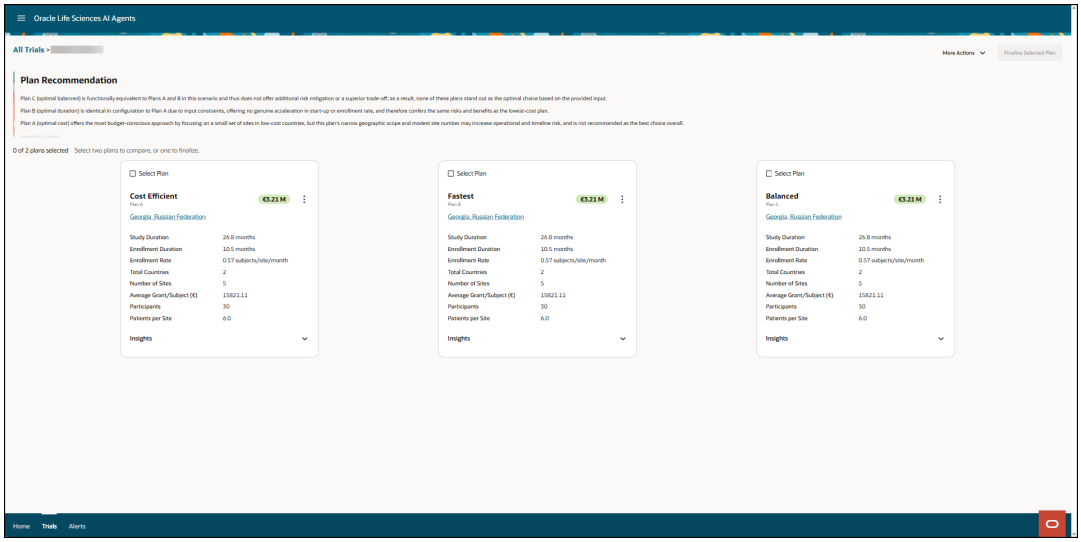
3. In the **Trials** list, in the **Status** column, find a study with a status of **Finalizing Plan**, and in the **Study** column, select the name of the trial you want to review the plans for. The **[Protocol Name]** panel opens. For example:

> **Note**
>
> The version of the protocol appears at the top right of the panel and above the [Protocol Name].pdf link. Select the link to download the protocol, if needed.



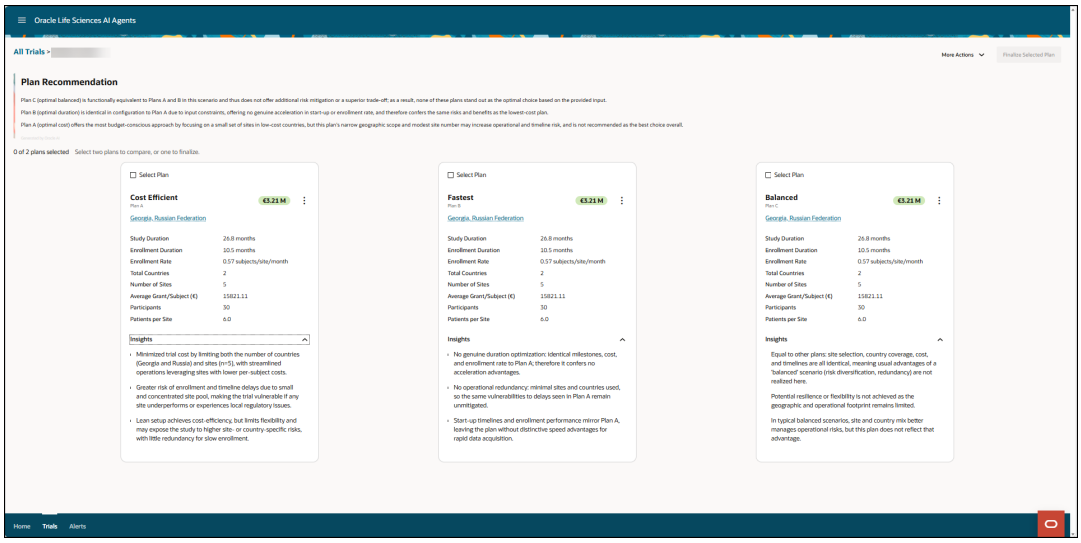
4. Select **View Plans**. The Plan Recommendation page opens. For example:

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> **Note**
>
> Alternatively, you can open the Plan Recommendation page directly by selecting **Go To Study** from the **Actions** drop-down menu on the right.

5. To view the insights used to generate each plan, select the down arrow at the bottom right in each tile. The tile expands to show the insight details. For example:



6. To review and adjust the details in any of the trial plans, see Edit plan details and sites.

   For each plan, you can adjust some of the parameters (for example, the study duration, approval timelines, per patient cost, and enrollment rates), add or remove sites, download the plan to a CSV file, and rename the plan.

7. To view side-by-side comparisons of the trial plans, see Compare one or more trial plans.

8. To view an earlier version of any of the plans, select **Toggle Versions** from **More Actions** drop-down menu at the top right of the page, and select a date and time for the plan you want to view.

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Adjust a single trial plan

For each trial plan, you can edit some of the plan details, add or remove sites, download the plan to a CSV file, and rename the plan.

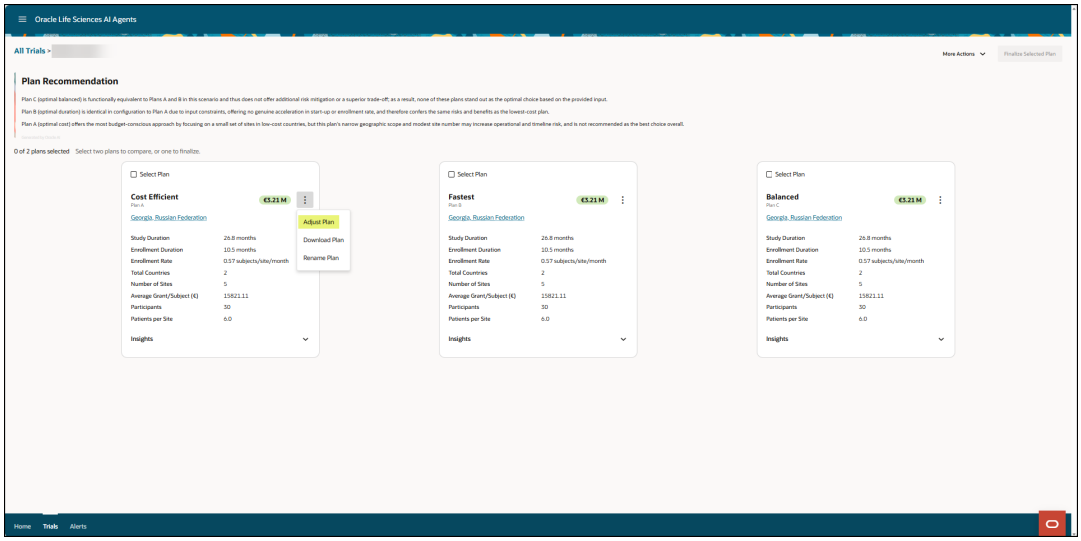
- Edit the details and sites for a trial plan
  For each AI-generated trial plan, you can review and adjust the plan details and add or remove sites.
- Download a trial plan
  You can download any of the Life Sciences AI Agents AI-generated trial plans to a CSV file.
- Rename a trial plan
  You can rename any of the Life Sciences AI Agents AI-generated trial plans.

Edit the details and sites for a trial plan

For each AI-generated trial plan, you can review and adjust the plan details and add or remove sites.

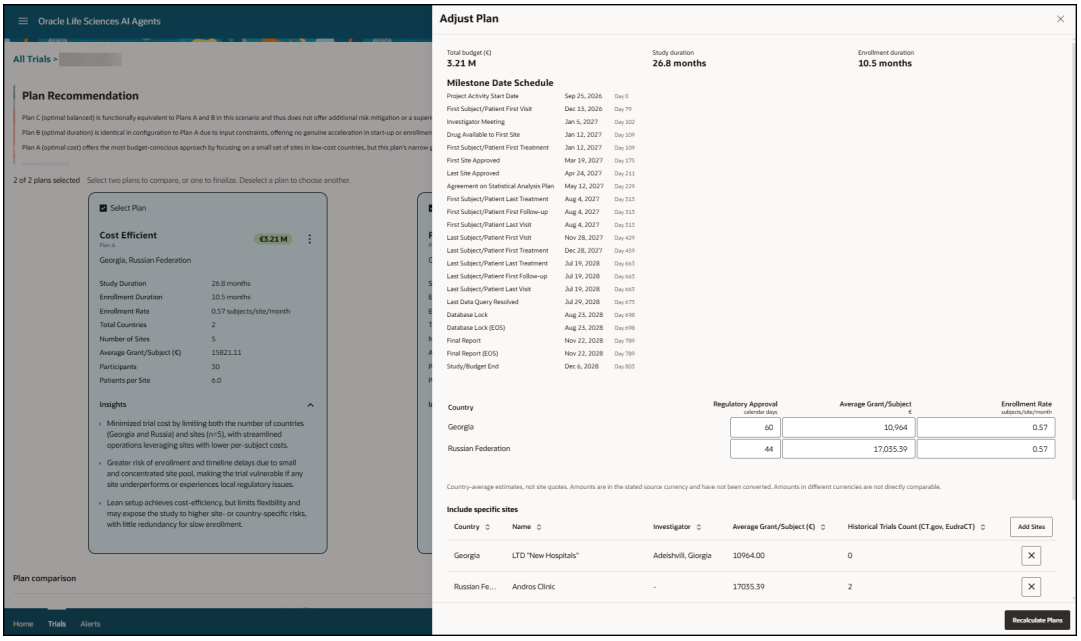
To edit the details and sites in a trial plan:

1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, at the top right of the tile for the plan you want to adjust, select **Adjust Plan** from the vertical ellipsis menu as highlighted in the following example:

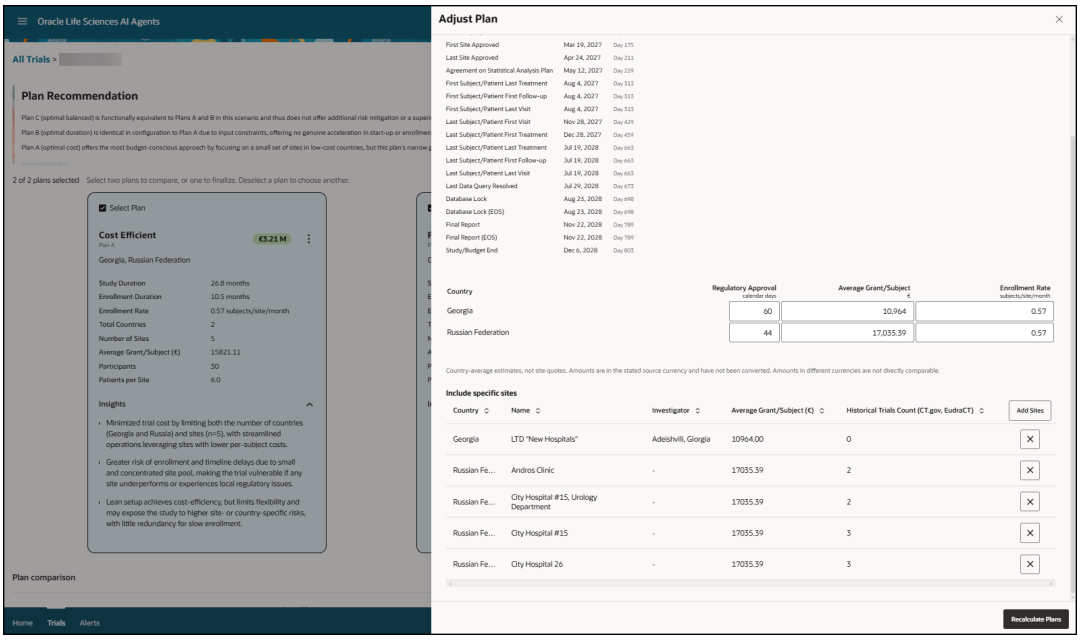


The Adjust [Plan Name] panel opens. For example:

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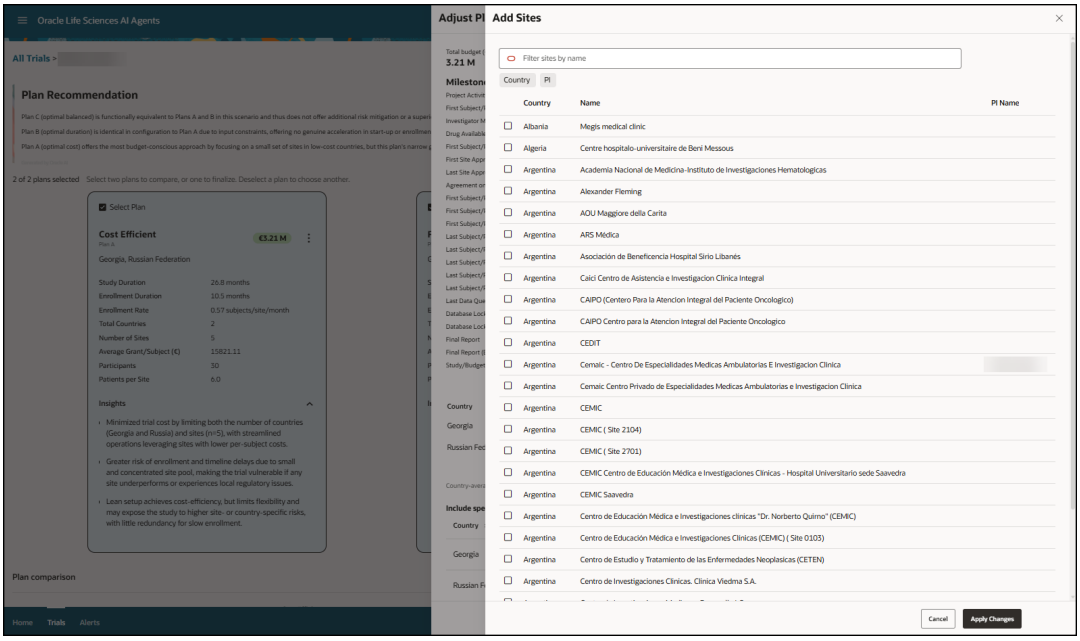


3. In the **Adjust Plan** panel, adjust any parameters as needed. Scroll down to see all the details and the Sites list. For example:



4. To add or update sites, select **Add Sites** on the right. The Add Sites panel opens. The available sites appear by country. For example:

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5. In the **Add Sites** panel:
   - Search for a site by entering the site name in the **Search** field. Scroll down the list to see all the available sites, and select **Load More** at the bottom of the panel as needed.
   - In the **Country** column, select or deselect sites as needed.
   - Select **Apply Changes** to save your changes and close the Add Sites panel. Or, select **Cancel** to close the Add Sites panel without saving your changes. The **Adjust Plan** panel becomes active again.
6. At the bottom right of the **Adjust Plan** panel, select **Recalculate plans**.

   This option is only available if you made adjustments to the trial plan.
7. Select the **X** at the top right to close the **Adjust Plan** panel.

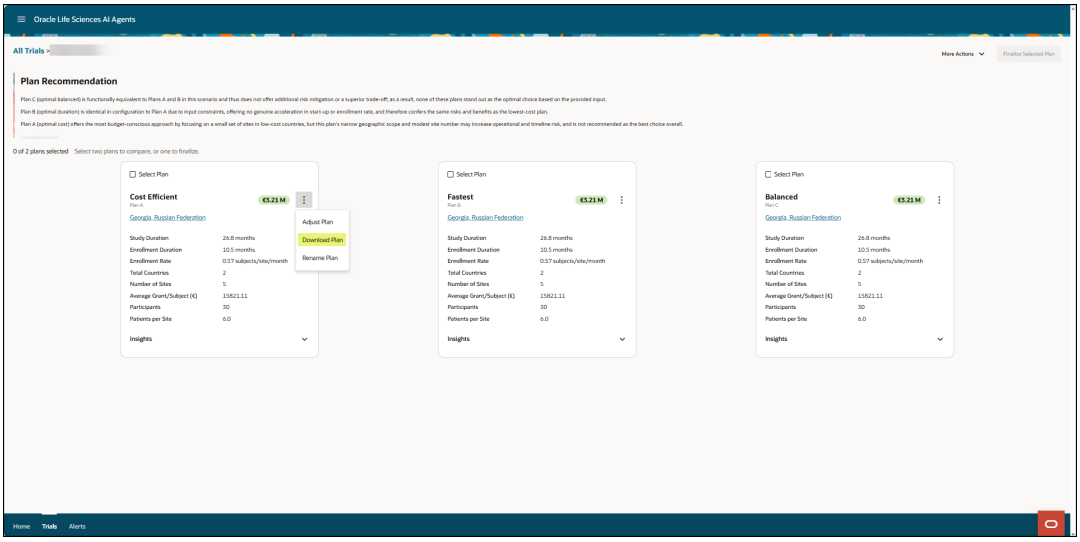
Download a trial plan

You can download any of the Life Sciences AI Agents AI-generated trial plans to a CSV file.

To download a trial plan to a CSV file:

1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, at the top right of the tile for the plan you want to download, select **Download Plan** from the vertical ellipsis menu as highlighted in the following example:

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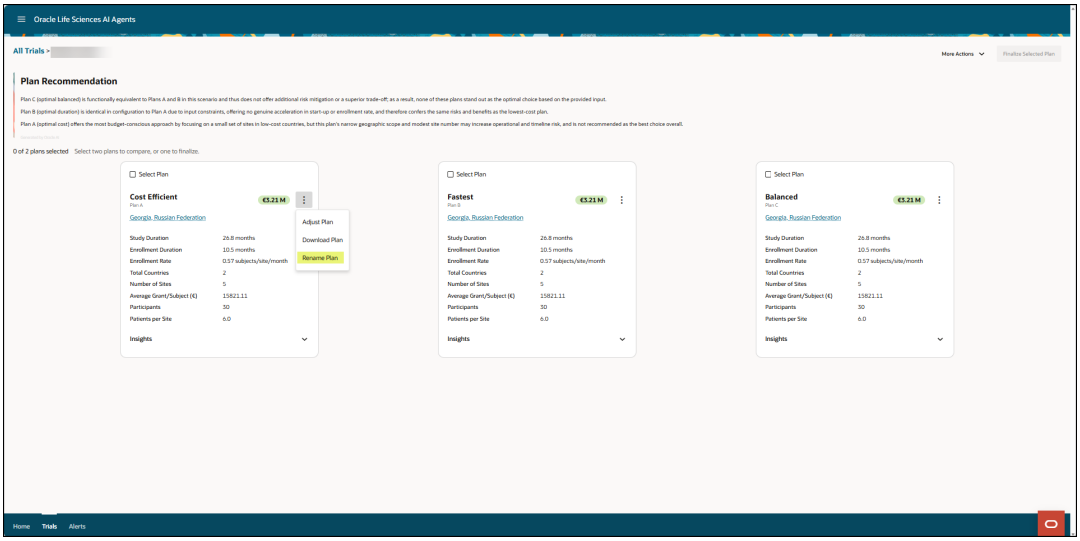
The trial plan is downloaded to your Downloads folder as **[Plan Name].csv**.

Rename a trial plan

You can rename any of the Life Sciences AI Agents AI-generated trial plans.

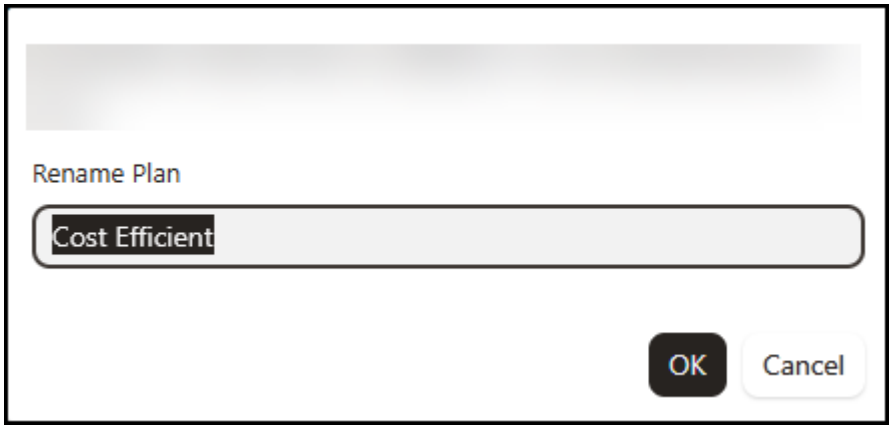
To rename a trial plan:

1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, at the top right of the tile for the plan you want to rename, select **Rename Plan** from the vertical ellipsis menu as highlighted in the following example:



The Rename Plan dialog box opens at the top of the page. For example:

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3. In the **Rename Plan** field, enter the new name for the plan and select **OK**.

Compare and download trial plans

You can compare the details in the AI-generated trial plans to help you identify the best option for your trial. You can download each plan and any plan comparison charts to save as CSV files.

- Compare two trial plans
  You can compare the details in two of the AI-generated trial plans at a time to help you identify which objective is the best option for your trial (cost efficient, fastest, or balanced). You can compare different combinations of the trial plans as often as you like.
- Download a trial plan comparison chart
  You can download as many trial plan comparison charts as you like to a CSV file.
- Compare the enrollment duration by country
  You can view the enrollment duration by country for one trial plan, or you can compare the enrollment duration by country for two trial plans.
- Compare the expected enrollment rate by country
  You can view the expected enrollment rate by country for one trial plan, or you can compare the expected enrollment rate by country for two trial plans.
- Compare the average grant per subject by country
  You can view the average grant per subject by country for one trial plan, or you can compare the average grant or subject by country for two trial plans.

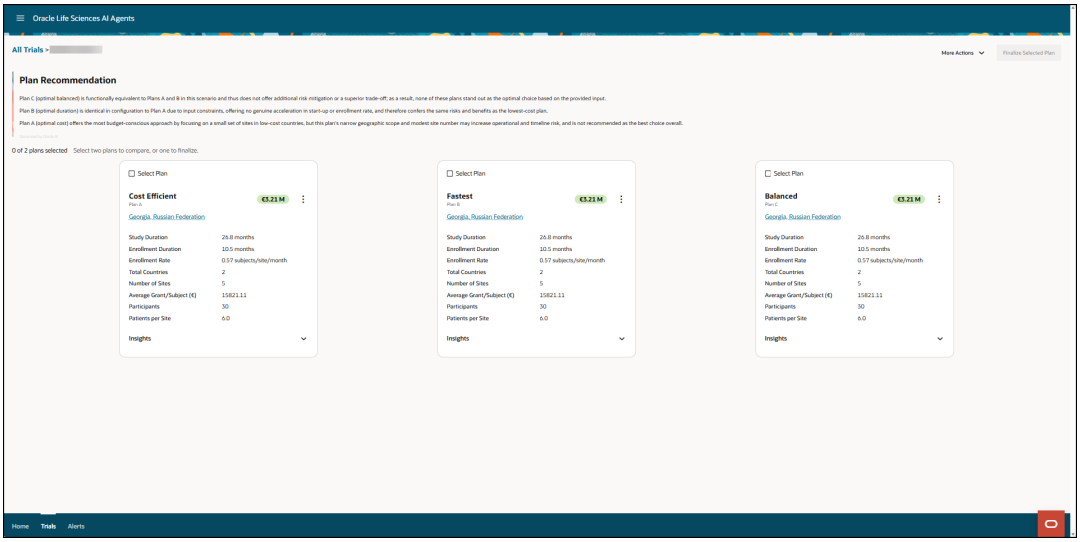
Compare two trial plans

You can compare the details in two of the AI-generated trial plans at a time to help you identify which objective is the best option for your trial (cost efficient, fastest, or balanced). You can compare different combinations of the trial plans as often as you like.

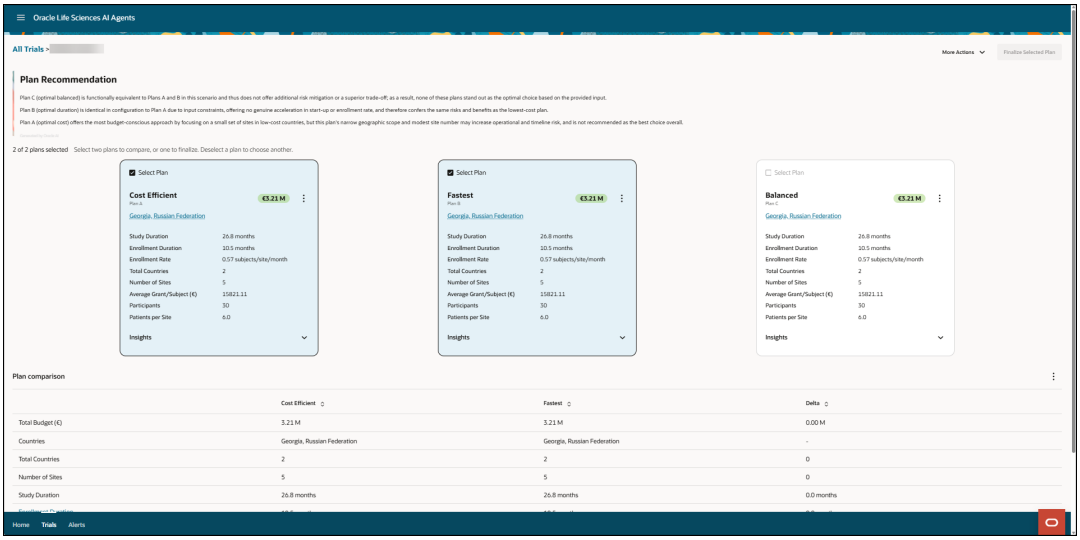
To compare two trial plans:

1. Open the AI-generated trial plans to open the Plan Recommendation page. For example:

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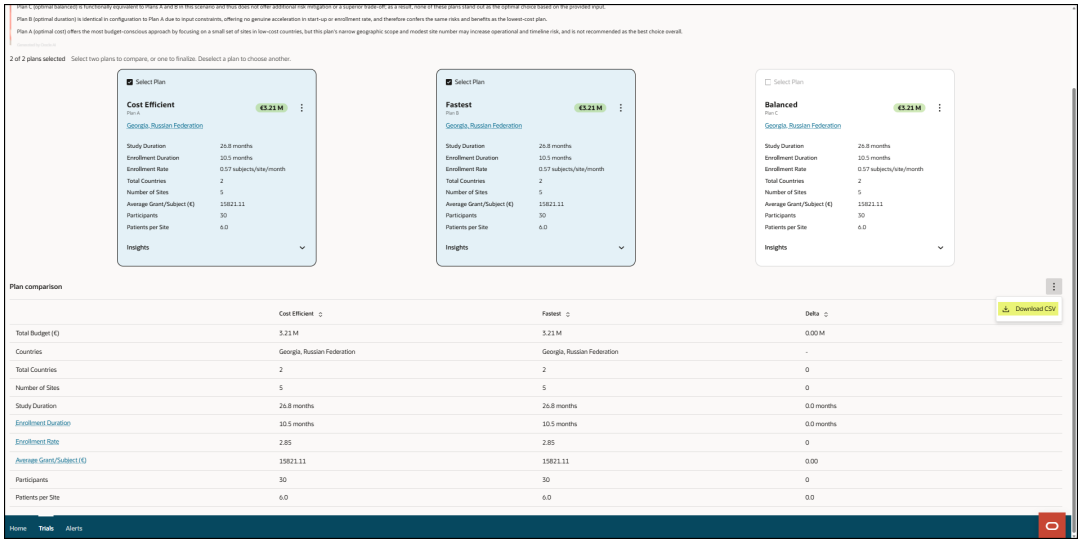
2. In the **Plan Recommendation** page, select **Select Plan** in the tiles for the plans you want to compare. The tiles you select are highlighted in blue and the comparison chart appears below the tiles. For example:



- The columns in the comparison chart appear in the order you select the tiles. To deselect a tile, select it again (the blue highlight is removed) and its data is removed from the comparison chart. You can select and deselect the trial plan tiles as often as you like.
- The comparison chart includes a column with the delta for each parameter in the list.

3. To download the comparison chart, select **Download CSV** from the vertical ellipsis menu (⋮) menu a the top right of the comparison chart as highlighted in the following example:

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The comparison chart is downloaded to your Downloads folder as **plans_comparison.csv**.

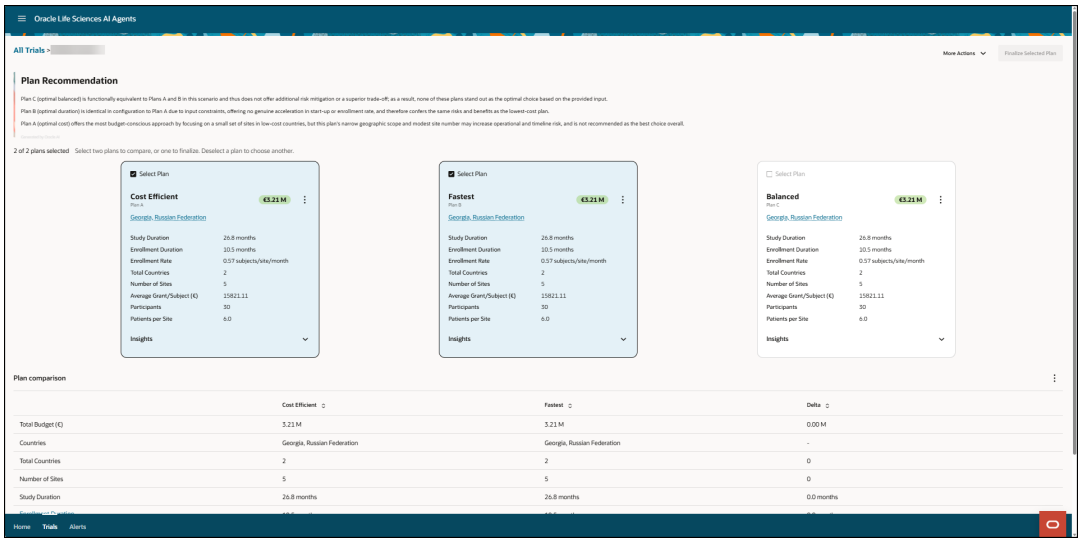
4. Repeat steps 2 and 3 as often as needed.

Download a trial plan comparison chart

You can download as many trial plan comparison charts as you like to a CSV file.

To download a trial plan comparison chart:

1. Compare two trial plans.
2. In the **Plan Recommendation** page, select the tiles for the plans you want to compare the details for. The tiles you select are highlighted in blue and the comparison chart appears below the tiles. For example:



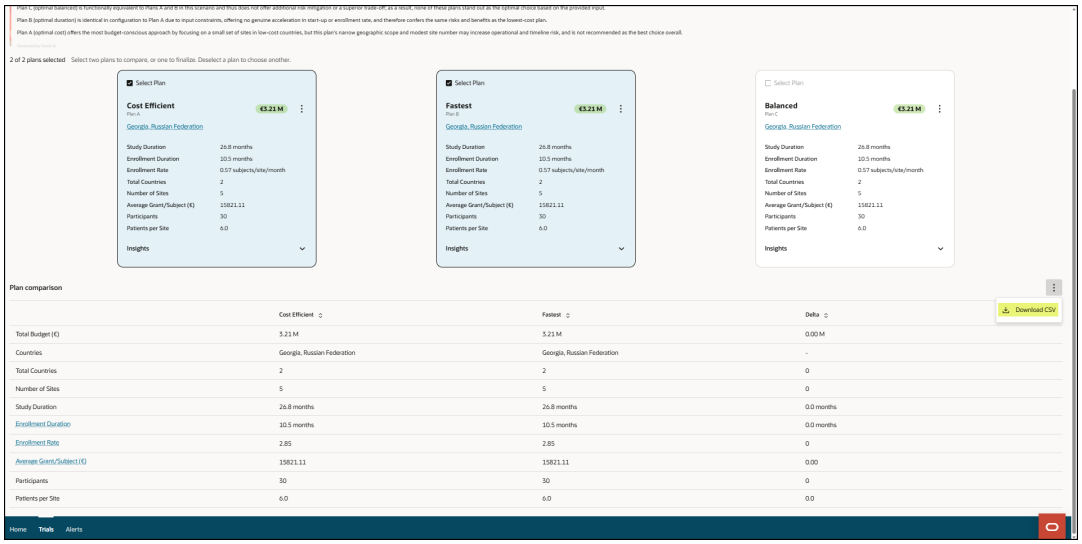
- The columns in the comparison chart appear in the order you select the tiles. To deselect a tile, select it again (the blue highlight is removed) and its data is removed

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from the comparison chart. You can select and deselect the trial plan tiles as often as you like.

- The comparison chart includes a column with the delta for each parameter in the list.

3. To download the comparison chart, select **Download CSV** from the vertical ellipsis menu ( ) menu a the top right of the comparison chart as highlighted in the following example:



The trial comparison chart is downloaded to your Downloads folder as **plans_comparison.csv**.

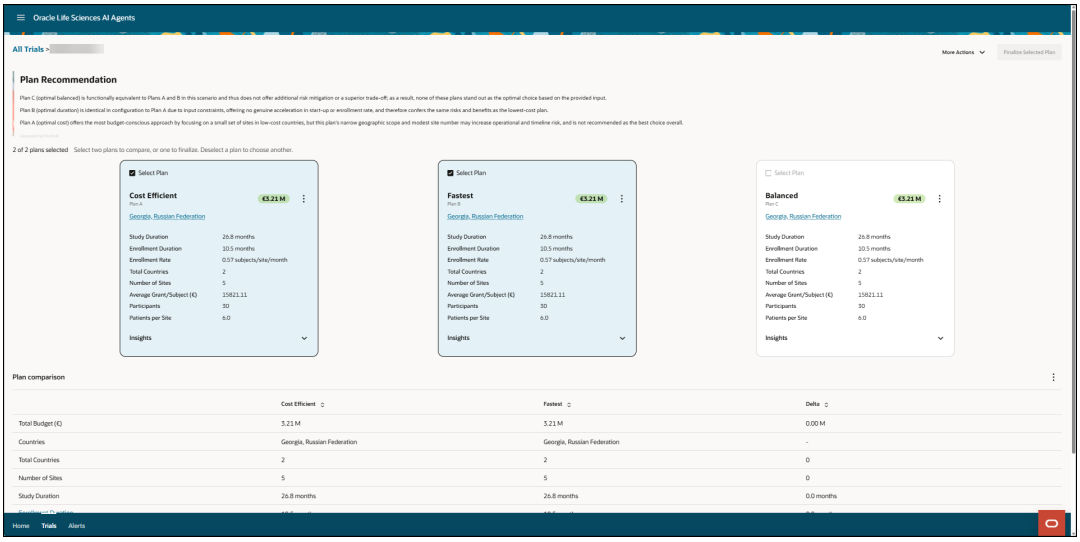
Compare the enrollment duration by country

You can view the enrollment duration by country for one trial plan, or you can compare the enrollment duration by country for two trial plans.

To view or compare the enrollment duration by country for one or two trial plans:

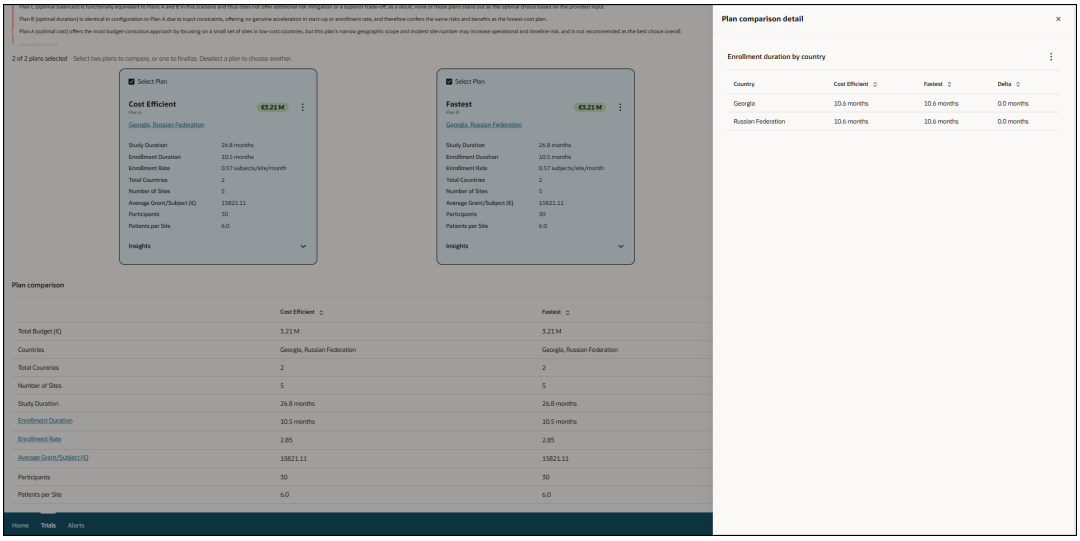
1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, select the tile for the plan or plans you want to view or compare the enrollment duration by country for. The tile or tiles you select are highlighted in blue and the comparison chart appears below the tiles. For example:

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- The columns in the comparison chart appear in the order you select the tiles. To deselect a tile, select it again (the blue highlight is removed) and its data is removed from the comparison chart. You can select and deselect the trial plan tiles as often as you like.
- If you select two plans, the comparison chart includes a column with the delta for each parameter in the list.

3. Scroll down as needed until you see the **Enrollment Duration** link in the first column in the comparison chart, and then select the link. The Plan comparison detail - Enrollment duration by country panel opens. For example:



4. To download the **Enrollment duration by country** plan comparison, select **Download CSV** from the vertical ellipsis menu (⋮) at the top right of the panel. The comparison plan is downloaded to your Downloads folder as **plans_comparison_Enrollment_duration_by_country.csv**.
5. Select the **X** at the top right to close the panel.

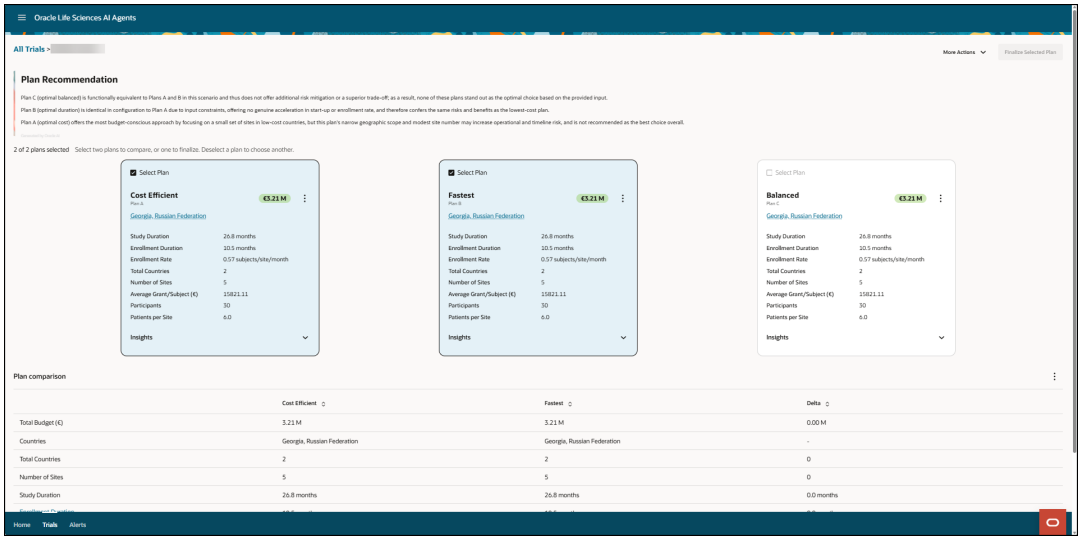
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Compare the expected enrollment rate by country

You can view the expected enrollment rate by country for one trial plan, or you can compare the expected enrollment rate by country for two trial plans.

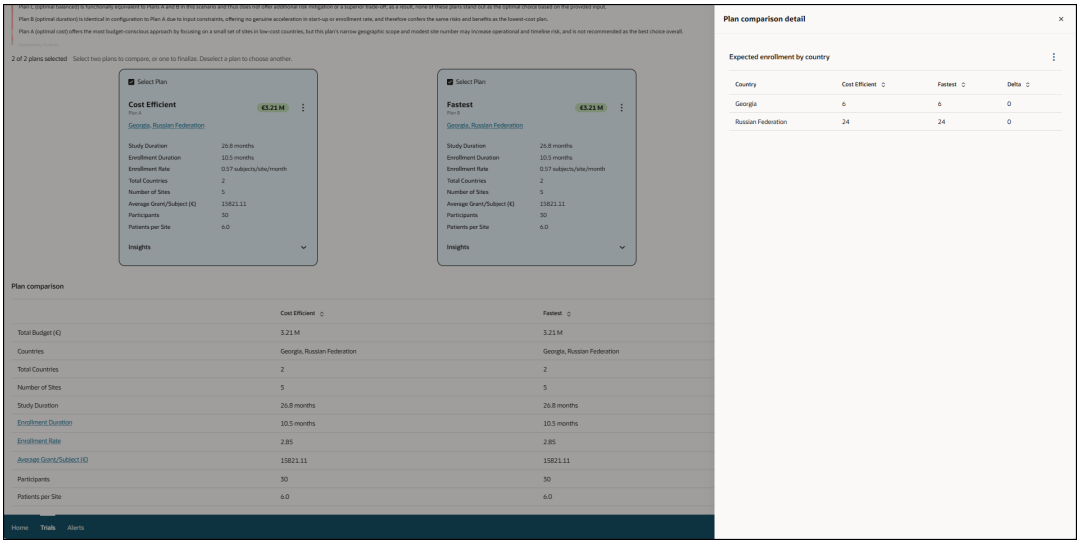
To view or compare the expected enrollment rate by country for one or two trial plans:

1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, select the tiles for the plan or plans you want to view or compare the expected enrollment by country for. The tiles you select are highlighted in blue and the comparison chart appears below the tiles. For example:



   - The columns in the comparison chart appear in the order you select the tiles. To deselect a tile, select it again (the blue highlight is removed) and its data is removed from the comparison chart. You can select and deselect the trial plan tiles as often as you like.
   - If you select two plans, the comparison chart includes a column with the delta for each parameter in the list.
3. Scroll down as needed until you see the **Enrollment Rate** link in the first column in the comparison chart, and then select the link. The Plan comparison detail - Expected enrollment by country panel opens. For example:

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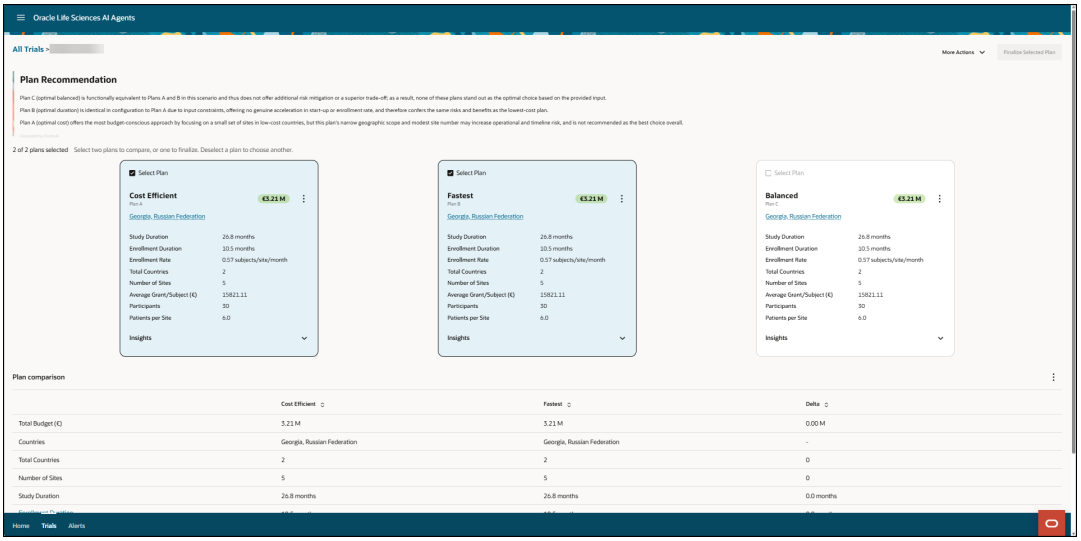
4. To download the **Expected enrollment by country** plan comparison, select **Download CSV** from the vertical ellipsis menu (⋮) at the top right of the panel. The comparison plan is downloaded to your Downloads folder as **plans_comparison_Expected_enrollment_by_country.csv**.
5. Select the **X** at the top right to close the panel.

Compare the average grant per subject by country

You can view the average grant per subject by country for one trial plan, or you can compare the average grant or subject by country for two trial plans.

To view or compare the average grant per subject by country for one or two trial plans:

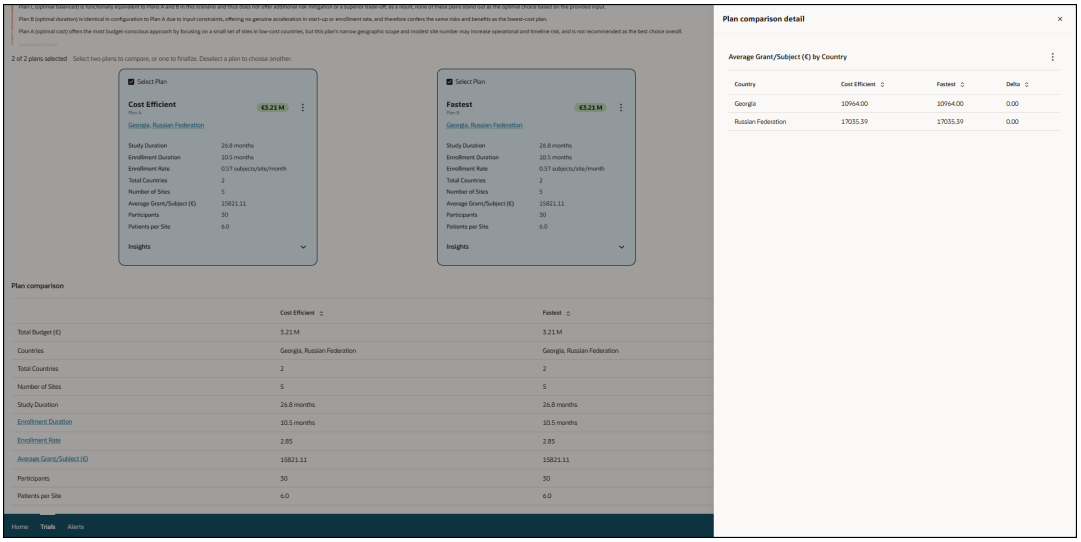
1. Open the AI-generated trial plans.
2. In the **Plan Recommendation** page, select the tile for the plan or plans you want to view or compare the average grant or subject by country for. The tile or tiles you select are highlighted in blue and the comparison chart appears below the tiles. For example:



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- The columns in the comparison chart appear in the order you select the tiles. To deselect a tile, select it again (the blue highlight is removed) and its data is removed from the comparison chart. You can select and deselect the trial plan tiles as often as you like.
- If you select two plans, the comparison chart includes a column with the delta for each parameter in the list.

3. Scroll down as needed until you see the **Average Grant/Subject** link in the first column in the comparison chart, and then select the link. The Plan comparison detail - Average Grant/Subject by Country panel opens. For example:



4. To download the **Average Grant/Subject by Country** plan comparison, select **Download CSV** from the vertical ellipsis menu (⋮) at the top right of the panel. The comparison plan is downloaded to your Downloads folder as **plans_comparison_Average_Grant_Subject_by_Country.csv**.
5. Select the **X** at the top right to close the panel.

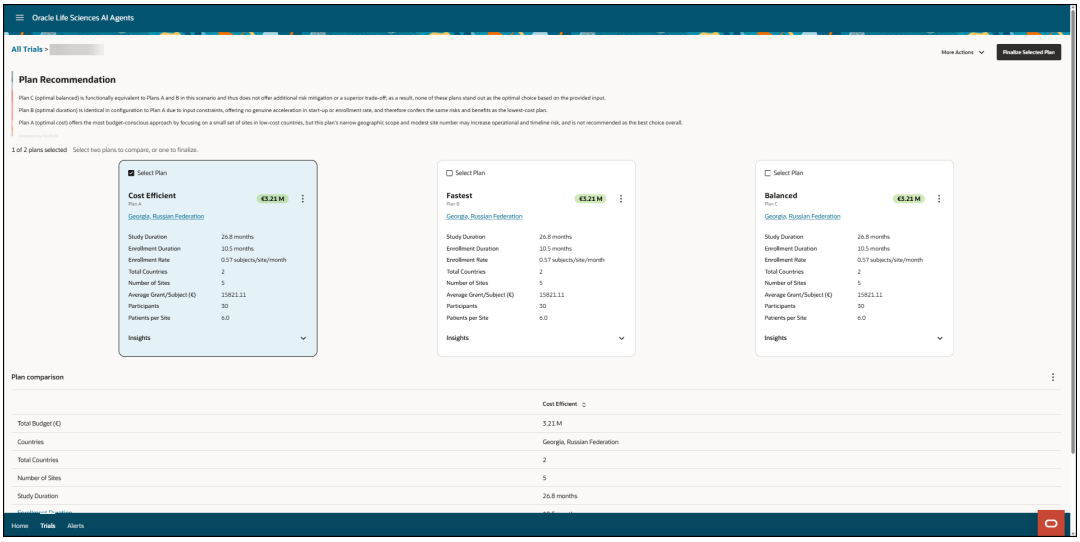
Select a trial plan

After you review and make any necessary adjustments to the AI-generated trial plans, you can select the best plan for your trial from the available options.

To select a trial plan:

1. Open the AI-generated trial plans.
2. To make sure you select the best plan for your trial, review the following information:
   - Adjust the details for a plan as needed.
   - Compare the AI-generated plans.
3. In the **Plan Recommendation** page, select **Select Plan** in the tile for the plan you want to use (the tile you select is highlighted in blue). For example:

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4. At the top right select **Finalize Selected Plan**.

View the details of a Trial in Planning

You can view the details of any Trial in Planning that you have access to.

To view the details of a Trial in Planning:

1. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
2. In the **Trials in Planning** list view, in the **Study** column, select the identifier of the trial you want to view the details for.

   The Study column displays study identifier(s) such as the Protocol ID, NCT ID, and EudraCT Number (EUCT Number).

> **Note**
>
> - The page that opens and the information you see depends on the status of the trial you select. The status options include: Ingestion Complete, Generating Plans, Finalizing Plan, and Start-Up.
> - If, for example, the protocol ingestion failed or the plan generation failed, an Error status may appear for a trial. You can select the Error status to open an information panel on the right side of the Trials list page. Follow the instructions in the panel or contact Oracle for assistance. Select the **X** at the top right to close the panel.

- View the details of a trial - Ingestion Complete status
  You can view the details of a Trial in Planning that has a status of Ingestion Complete.
- View the details of a trial - Generating Plans status
  You can view the details of a Trial in Planning that has a status of Generating Plans.
- View the details of a trial - Finalizing Plan status
  You can view the details of a Trial in Planning that has a status of Finalizing Plan. This status means that the trial plans have been generated, but one has not been selected.

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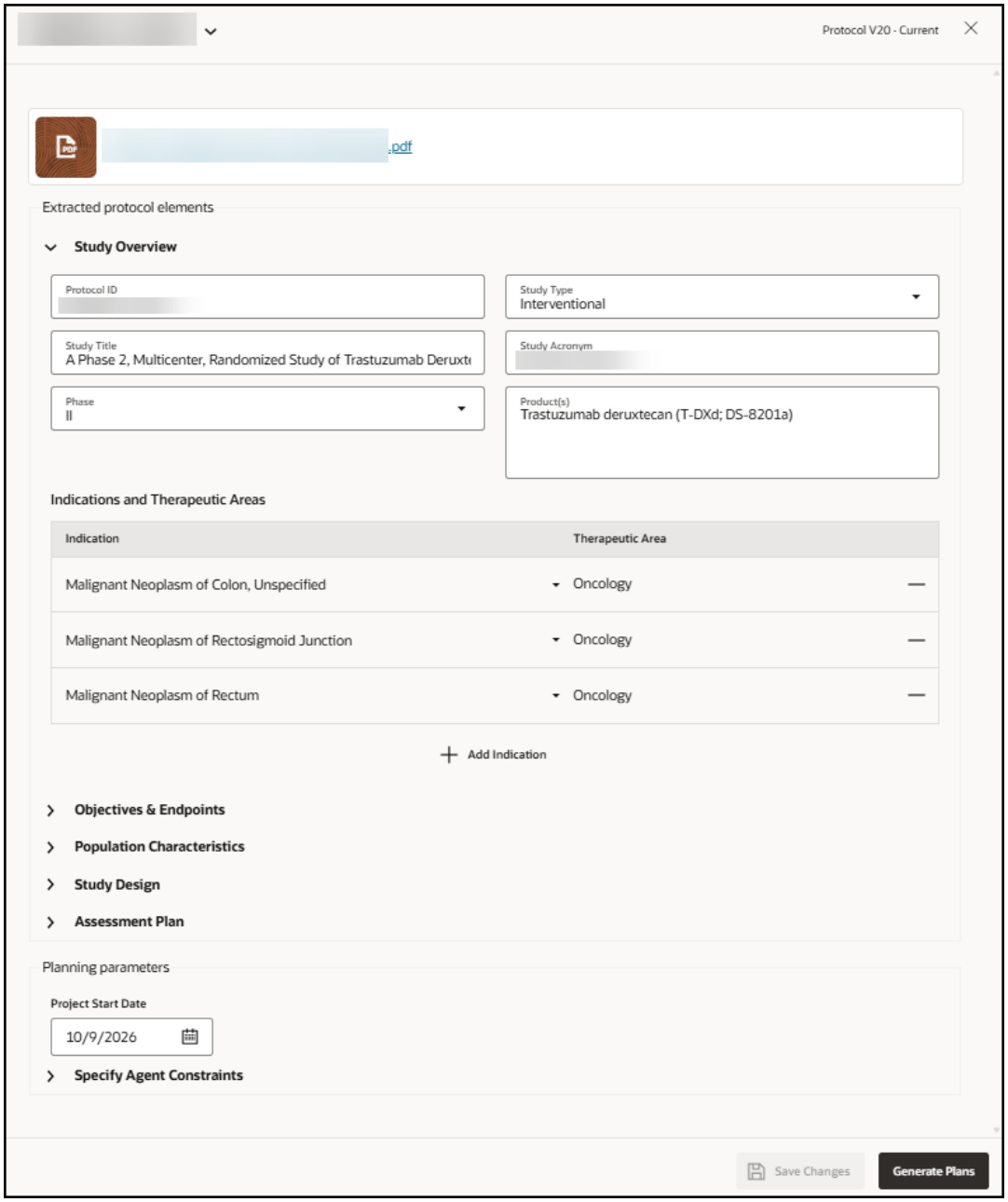
- View the details of a trial - Start-Up status
  You can view the details of a Trial in Planning that has a status of Start-Up.

View the details of a trial - Ingestion Complete status

You can view the details of a Trial in Planning that has a status of Ingestion Complete.

To view the details of a Trial in Planning with a status of Ingestion Complete:

1. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
2. In the **Trials in Planning** list view, in the **Status** column, find a study with a status of **Ingestion Complete**, and in the **Study** column, select the identifier of the trial you want to view the details for. The **[Trial Name]** panel opens that shows the operational parameters from the ingested protocol. For example:



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> **Note**
>
> If any required information is missing from the uploaded protocol, a detailed message appears at the top of the panel.

3. Expand each section and provide updates as needed.
   - **Study Overview**—Shows the following details:
     - **Protocol ID**
     - **Study Type**—Select **Interventional** or **Observational**.
     - **Study Title**
     - **Study Acronym**
     - **Phase**
     - **Product(s)**
     - **Indications and Therapeutic Areas**
   - **Objectives & Endpoints**—Shows the following details for each objective:
     - **Type**
     - **Objective**
     - **Endpoint(s)**
   - **Population Characteristics**—Shows the following details:
     - **Target sample size**
     - **Target locations**—Required.
     - **Inclusion Criteria**—Required.
     - **Exclusion Criteria**—Required.
   - **Study Design**—Shows the following details:
     - **Interventional Model**
     - **Number of treatment arms**
     - **Number of planned subjects per treatment arm**
   - **Assessment Plan**—Shows the following details:
     - **Screening**—Provide the Duration, Unit, and Number of visits per subject/patient.
     - **Treatment**—Provide the Duration, Unit, Number of visits per subject/patient, Cycle Duration, Unit, and Number of cycles.
     - **Follow-up**—Provide the Duration, Unit, and Number of visits per subject/patient.
   - **Specify Agent Constraints**—Shows the following details:
     - **Study Duration from Project Start**—Enter a value for the expected study duration, and in the adjacent **Units** drop-down menu select **Days**, **Weeks**, **Months**, or **Years**.
     - **Budget ($M)**—Enter a value and in the adjacent **Currency** drop-down menu select **EUR** or **USD**. The currency value you select is used for all monetary amounts that appear in the interface.

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- **Include specific sites**—Select **Add Sites** to open the **Add Sites** panel. Select the check box next to each site you want to add, and select **Apply Changes**. The Add Sites panel closes and the [Trial Name] panel becomes active again.

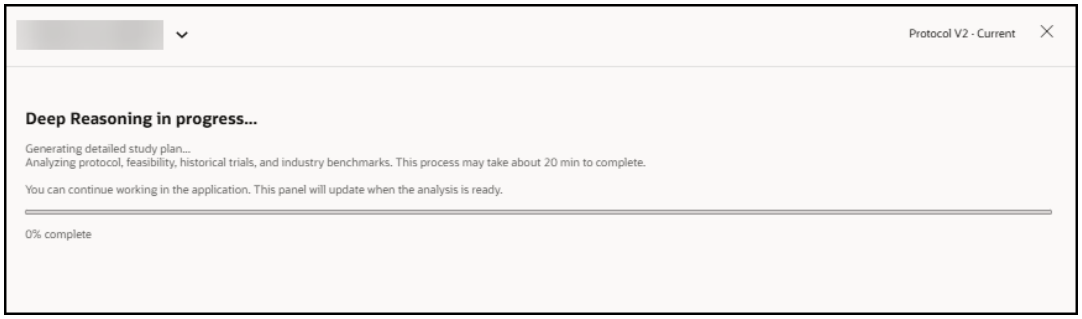
4. Do one of the following:
   - Select the **X** at the top right to close the panel without saving any changes.
   - Select **Save changes** to save any updates you made to the parameters.
   - Select **Generate plans** to generate the trial plans.

View the details of a trial - Generating Plans status

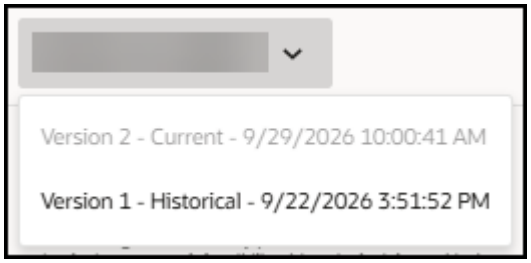
You can view the details of a Trial in Planning that has a status of Generating Plans.

To view the details of a Trial in Planning with a status of Generating Plans:

1. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
2. In the **Trials in Planning** list view, in the **Status** column, find a study with a status of **Generating Plans**, and in the **Study** column, select the identifier of the trial you want to view the details for. The **[Trial Name]** panel opens that shows the status of the protocol ingestion. For example:



Select the down arrow next to the trial name to view a list of all versions of the protocol. For example:



3. Select the **X** at the top right to close the panel.

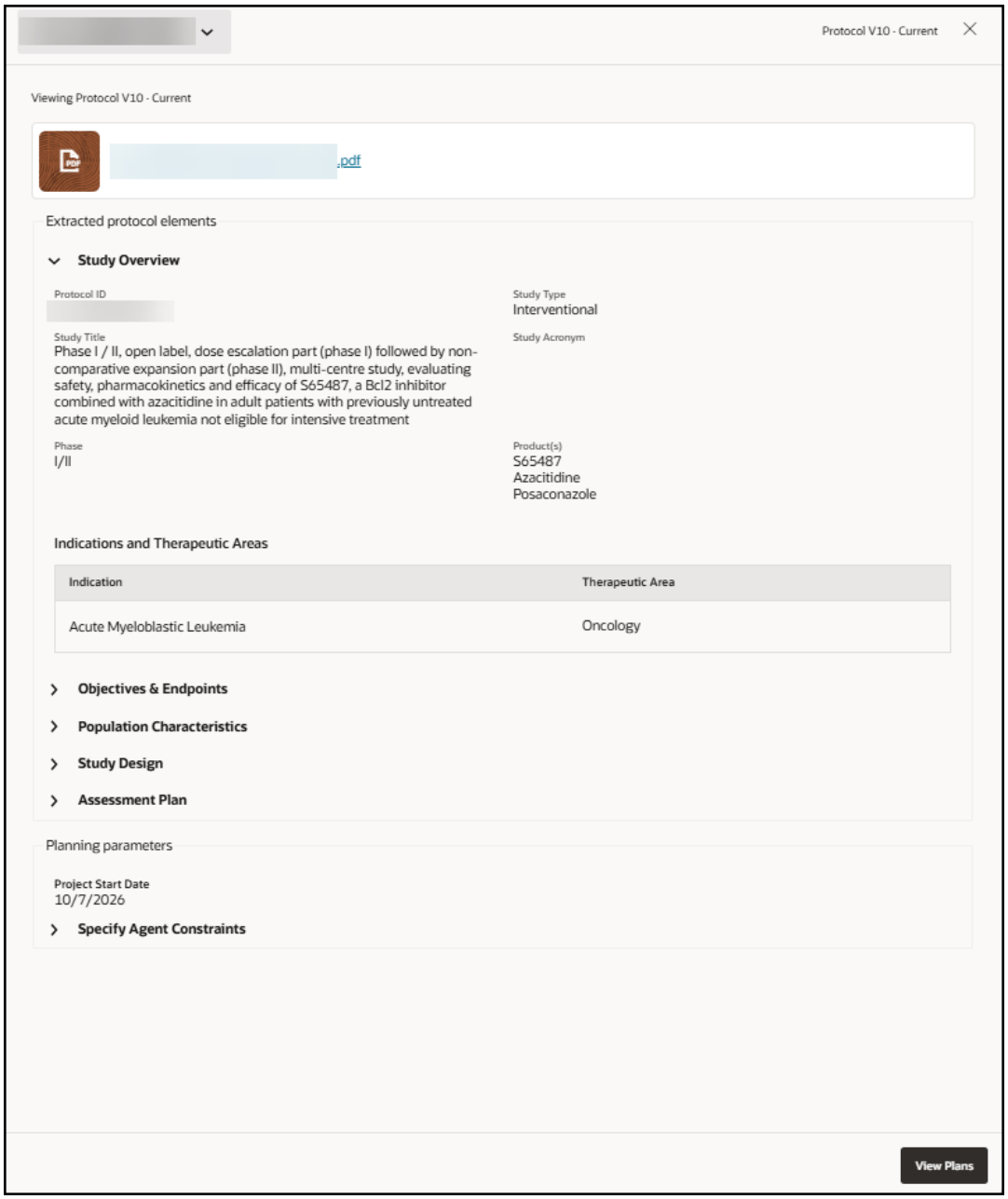
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View the details of a trial - Finalizing Plan status

You can view the details of a Trial in Planning that has a status of Finalizing Plan. This status means that the trial plans have been generated, but one has not been selected.

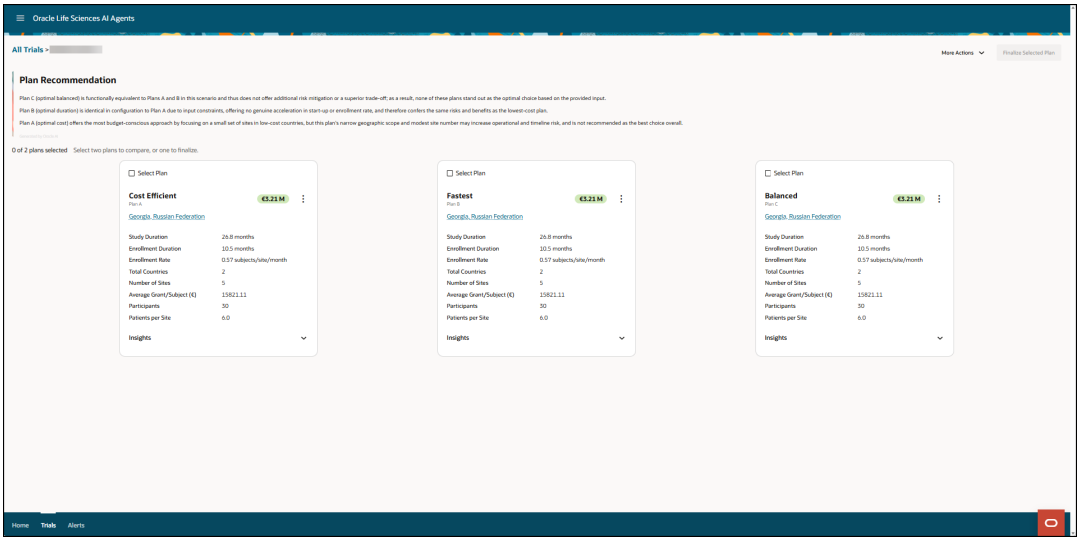
To view the details of a Trial in Planning with a status of Finalizing Plan:

1. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
2. In the **Trials in Planning** list view, in the **Status** column, find a study with a status of **Finalizing Plan** and in the **Study** column, select the identifier of the trial you want to view the details for. The **Protocol Name** panel opens. For example:

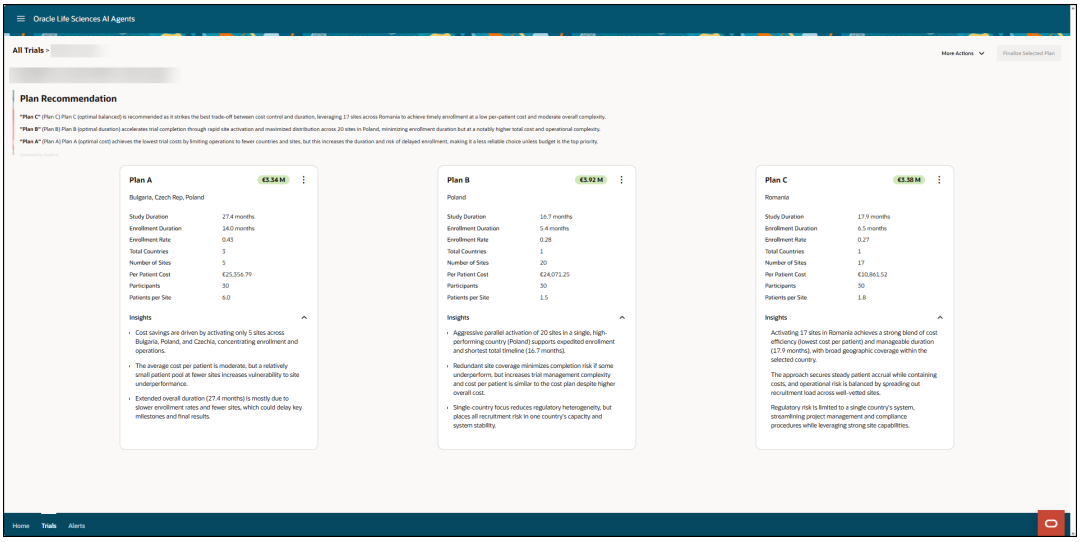


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3. Select **View Plans**. The Plan Recommendation page opens. For example:



4. In the **Plan Recommendation** section, view the descriptions of each plan.
5. To view the insights used to generate each plan, select the down arrow at the bottom right in each tile. The tile expands to show the insight details. For example:



6. To review and adjust the details in any of the trial plans, see Edit plan details and sites.

   For each plan, you can adjust some of the parameters (for example, the study duration, approval timelines, per patient cost, and enrollment rates), add or remove sites, download the plan to a CSV file, and rename the plan.
7. To view side-by-side comparisons of the trial plans, see Compare one or more trial plans.
8. If ready, select **Finalize Selected Plan** at the top right. For more information, see Select a trial plan.

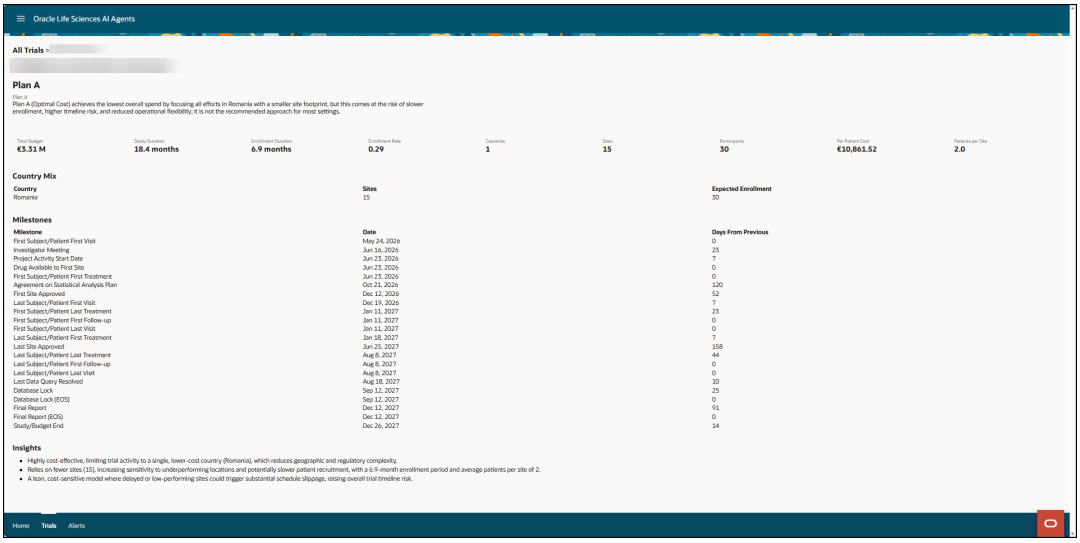
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View the details of a trial - Start-Up status

You can view the details of a Trial in Planning that has a status of Start-Up.

To view the details of a Trial in Planning with a status of Start-Up:

1. Open the list of trials you can access, and filter the list for Trials in Planning, as described in View the list of trials you can access.
2. In the **Trials in Planning** list view, in the **Status** column, find a study with a status of **Start-Up**, and in the **Study** column, select the identifier of the trial you want to view the details for. An information page for the **[Trial Name]** opens. For example:



3. Select **All Trials** at the top left or the browser **Back** button to close the information page and return to the Trials list.

Export trial data

You can export trial data in CSV format for All Trials, all Ongoing Trials, all Other Trials, or all Trials in Planning that you have access to. The exported file includes data from the columns visible on the Trials list page.

For information on customizing the columns that appear on the Trials list page, see Customize the columns in the Trials list.

To export trial data:

1. Open the list of trials you can access, and filter the list by operational lifecycle (All Trials, Ongoing Trials, Other Trials, or Trials in Planning) as needed as described in View the list of trials you can access.
2. Select **Export** from the **More Actions** drop-down menu at the top right of the page.

   Life Sciences AI Agents downloads the trial data for all the trials in the list (filtered for All Trials, Ongoing Trials, Other Trials, or Trials in Planning) as **All_Trials.csv**, **Ongoing_Trials.csv**, **Other_Trials.csv**, or **Trials_In_Planning.csv** to your Downloads folder.

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5

Manage the alerts for all Ongoing Trials

Use the Alerts list to efficiently manage and respond to alerts across multiple ongoing trials, streamlining your workflow and improving your ability to address potential issues or opportunities.

The alerts are prioritized based on risk severity (Critical, High, Moderate, or Low). You can view alerts details and provide feedback on every alert. You can also view the AI reasoning steps for an alert, view the history of the alert, snooze or dismiss alerts, and view details for the study where the alert originated.

> **Note**
>
> The Alerts list and associated pages provide information for Ongoing Trials only.

- View the list of alerts for all trials you can access
  Life Sciences AI Agents stores the AI-generated alerts for all the trials you have access to in the Alerts list. The alerts are prioritized based on risk severity.
- View the details of an alert and provide feedback
  You can view the details of an AI-generated alert for any trial you have access to. You can also provide feedback on each alert to help improve the quality, accuracy, and relevance of the AI-generated insights.
- View the study details associated with an alert
  From the Alerts list you can view the study details associated with an alert.
- View the history of an alert
  You can view the history of an alert to see its chronological history including the date the alert was first detected, and the actions taken on the alert including any severity or status changes. You can view the alert history from the Alerts list or from an Alert details page.
- View the AI reasoning steps for an alert
  You can view the AI reasoning steps for an alert to understand how the insights and recommendations were rationalized. You can view the AI reasoning for an alert from the Alerts list or from an Alert details page.
- Snooze an alert
  You can snooze an alert to pause the alert notifications to you. When you snooze an alert it is immediately removed from the Alerts list. The notifications appear to you again if the criticality of the alert increases at a later time or if you undo the snooze action.
- Dismiss an alert
  You can dismiss an alert to stop the alert notifications to you. When you dismiss an alert it is immediately removed from the Alerts list. The notifications do not appear to you again unless you undo the dismiss action.

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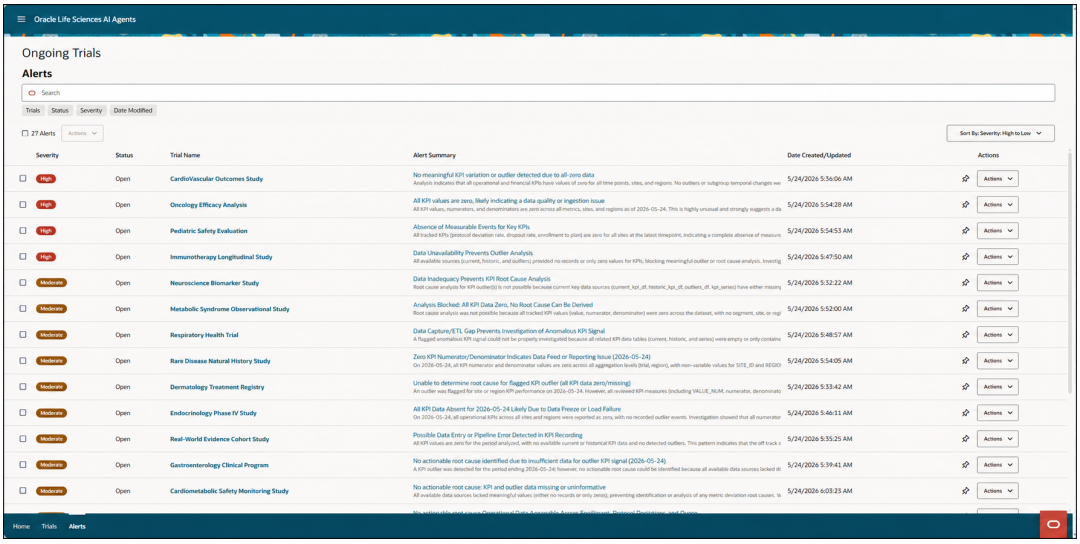
View the list of alerts for all trials you can access

Life Sciences AI Agents stores the AI-generated alerts for all the trials you have access to in the Alerts list. The alerts are prioritized based on risk severity.

For all alerts, the Alerts list shows the risk severity (Critical, High, Moderate, or Low), study name, alert name, the alert summary, and the dates the alerts were created or last updated.

To view the list of alerts for all the Ongoing Trials you have access to:

1. Select the **Alerts** tab at the bottom of the page. The Alerts list opens. For example:



2. To search for a specific alert, enter at least three text characters in the **Search** field.
3. To sort the list, select one of the following options from the **Sort By** drop-down menu on the right (above the Actions column):
   - Severity High to Low
   - Severity: Low to High
   - Date: Most Recent Updated
   - Trial Name: A-Z
   - Trial Name: Z-A
4. To filter the list, select one or more of the filter options that appear below the **Search** field and then provide any required details. You can select multiple details for each filter.
   - **Trials**—Filters the alerts by trial name. Enter a trial name in the **Search** field or select the **Trials** filter and select a trial name from the drop-down menu.
   - **Status**—Filters the alerts by status. Enter a status in the **Search** field or select the **Status** filter and select any of the following options:
     - **Open**—Shows all the alerts that do not have any other status.
     - **Completed**—Shows only the alerts that were resolved by the AI agent.
     - **Snoozed**—Shows only the alerts that you snoozed.
     - **Dismissed**—Shows only the alerts that you dismissed.

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- **Severity**—Filters the alerts by risk severity. Enter a severity in the **Search** field or select the **Severity** filter and select any of the following options:
  - **Low**—Minor, localized, or transient issue with limited impact; generally reversible with routine follow-up and unlikely to affect safety or milestones.
  - **Moderate**—No immediate safety risk, but material risk to timelines or quality; major (non-critical) protocol deviations; secondary or operational data degradation; sustained under-enrollment likely to delay non-critical milestones.
  - **High**—Credible and significant risk to patient safety, primary endpoint integrity, or critical milestones if not addressed promptly.
  - **Critical**—Imminent or ongoing serious risk to patient safety or trial integrity that may warrant immediate trial halt, enrollment hold, or urgent regulatory notification.

  > **Note**
  >
  > The Severity filter automatically hides options that are not present in the current Alerts list.

- **Date Modified**—Filters the alerts by the last updated dates. Select the **Date Modified** filter and then use the Calendar icon to select a **Start Date** (the date the alert was created) and **End Date** (the date the alert was last updated). Alternatively, you can enter a date in either field in MM/DD/YYYY format. Both dates are required.

5. Select the **Pin** ( ) icon if you want the alert to remain at the top of the list. Pinned items adjust based on the filter selections, but they remain at the top of the filtered list.

View the details of an alert and provide feedback

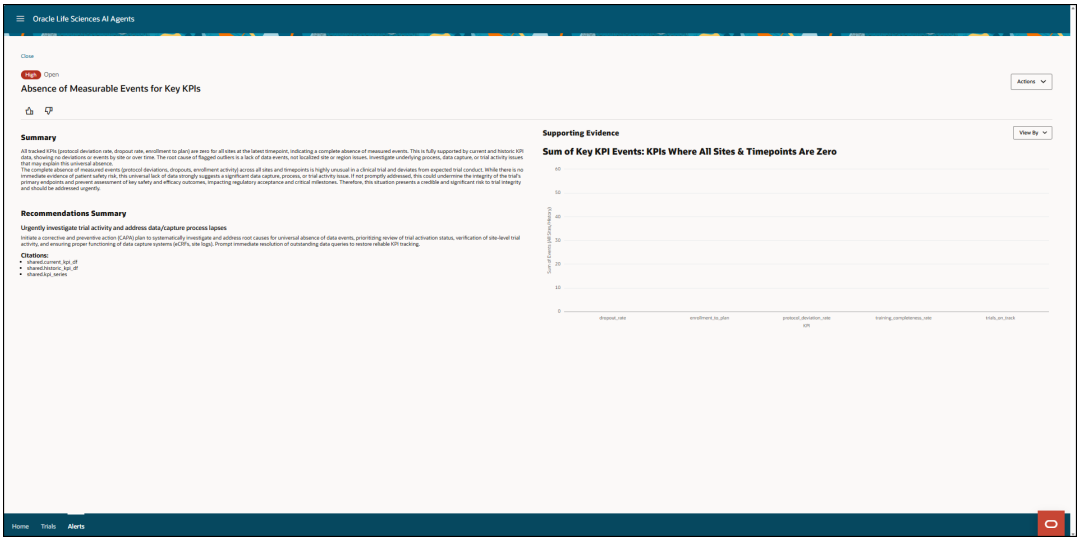
You can view the details of an AI-generated alert for any trial you have access to. You can also provide feedback on each alert to help improve the quality, accuracy, and relevance of the AI-generated insights.

To view the details of an alert and provide feedback:

1. Open the list of alerts for all the trials you can access.
2. In the Alerts list, find the alert you want to view the details for, and do one of the following to open the [Alert Name] details page.
   - In the **Alert Summary** column, select the [Alert Name] link (highlighted in blue).
   - In the **Actions** column on the right, select **View Alert Details** from the **Actions** drop-down menu.

   The [Alert Name] details page opens. For example:

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> **Note**
>
> The details in the Supporting Evidence section and the View By options vary with each alert and are dependent on the AI-generated insights.

3. To view the standard actions Life Sciences AI Agents provides for all alerts, select the **Actions** drop-down menu at the top right of the page, and then select any of the following options.

   - **View History**—Select to open the History panel. The name of the alert appears at the top of the panel below the title. You can view the history of an alert to see its chronological history including the date the alert was first detected, and the actions taken on the alert including any severity or status changes. You can also view the history of an alert from the Alerts list.

     For more information, see View the history of an alert.

   - **View AI Reasoning Steps**—Select to open the AI Reasoning panel to view how the insights and recommendations for the alert were rationalized.

     For more information, see View the AI reasoning steps for an alert.

   - **Snooze** or **Unsnooze**—Only one of these options appears in the drop-down menu. Do one of the following:

     – Select **Snooze** to pause the alert notifications to you. The notifications appear to you again if the criticality of the alert increases at a later time or if you undo the snooze action. When you snooze an alert, it is immediately removed from the Alerts list. In the Actions drop-down menu the Snooze option is replaced with the Unsnooze option.

     – Select **Unsnooze** to undo the snooze action. The alert appears again in the Alerts list. In the Actions drop-down menu the Unsnooze option is replaced with the Snooze option.

     You can also snooze an alert from the Alerts list. For more information, see Snooze an alert.

     To view a list of all of your snoozed alerts, navigate to the Alerts list, select the Status filter, and then select the Snoozed option. For more information, see View the list of alerts for all trials you can access.

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- **Dismiss** or **Undismiss**—Only one of these options appears in the drop-down menu. Do one of the following:
  - Select **Dismiss** to stop the alert notifications to you. The notifications will not appear to you again unless you undo the dismiss action. When you dismiss an alert, it is immediately removed from the Alerts list. In the Actions drop-down menu the Dismiss option is replaced with the Undismiss option.
  - Select **Undismiss** to undo the dismiss action. The alert appears again in the Alerts list. In the Actions drop-down menu the Undismiss option is replaced with the Dismiss option.

  You can also dismiss an alert from the Alerts list. For more information, see Dismiss an alert.

  To view a list of all of your dismissed alerts, navigate to the Alerts list, select the Status filter, and then select the Dismissed option. For more information, see View the list of alerts for all trials you can access.

4. To view the AI-generated actions that Life Sciences AI Agents provides for the alert, select the **Actions** drop-down menu at the top right of the page, and then select any of the options that appear below the divider.

   Examples of AI-generated actions may include:

   - **Increase Monitoring Frequency**
   - **Retrain Site Staff**
   - **Address Data Quality Issues**
   - **Adjust Country/Site Mix**
   - **Remove Site**

5. To provide feedback on the alert, select either the **Thumbs Up** or **Thumbs Down** icon that appears at the top of the page below the [Alert Name] details page title.

   - Select the **Thumbs Up** icon  if you have a positive response to the content of the alert.
   - Select the **Thumbs Down** icon  if you have a negative response to the content of the alert.

   When you provide feedback, Life Sciences AI Agents logs your username, timestamp, Alert ID, and Trial ID. You can change your feedback on an alert at any time.

6. Select **Close** at the top left of the page to close the **[Alert Name]** details page. The page that opens depends on how you navigated to the [Alert Name] details page (from the [Trial Name] details page or the Alerts list).

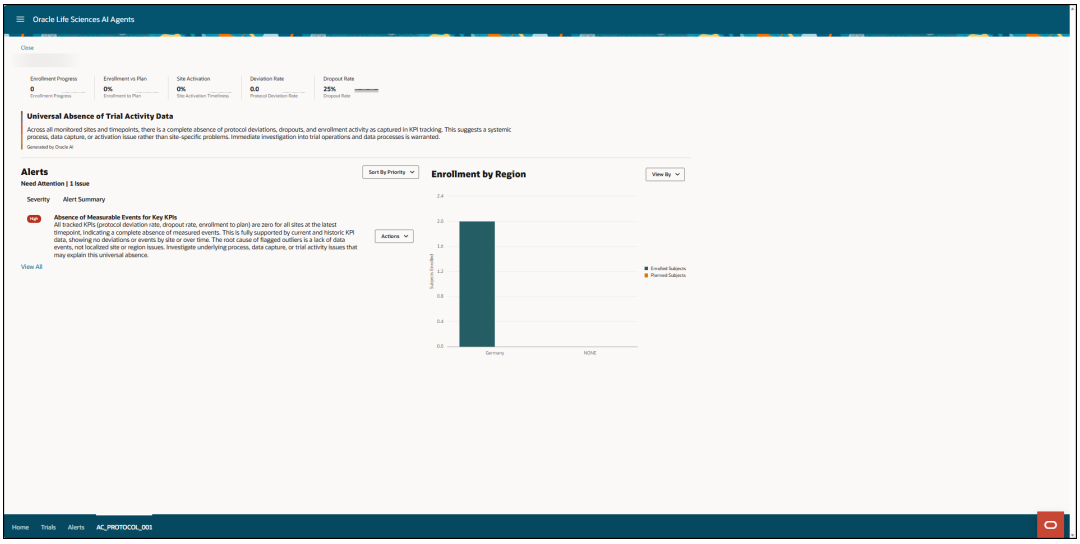
View the study details associated with an alert

From the Alerts list you can view the study details associated with an alert.

To view the study details associated with an alert:

1. Open the list of alerts for all the trials you have access to.
2. In the **Alerts** list, find the alert you want to view the study details for, and in the **Actions** column on the right select **Go to Study** from the **Actions** drop-down menu. The [Study Name] details page opens, which provides a summary health dashboard page for the study. A tab with the study name appears at the bottom of the window. For example:

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3. Select **Close** at the top left to return to the Alerts list. The study name tab at the bottom of the window is removed.

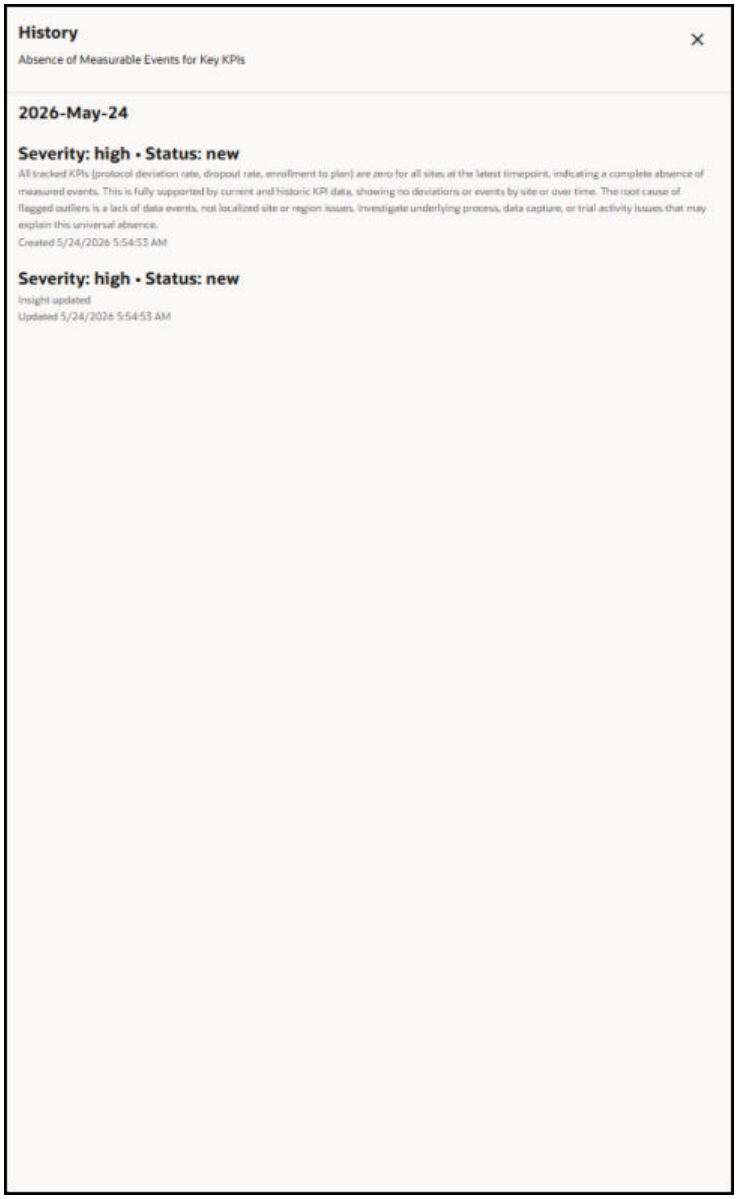
View the history of an alert

You can view the history of an alert to see its chronological history including the date the alert was first detected, and the actions taken on the alert including any severity or status changes. You can view the alert history from the Alerts list or from an Alert details page.

To view the history of an alert:

1. To view the history of an alert from the **Alerts** list, open the Alerts list as described in View the list of alerts for all trials you can access.
    - In the **Alerts** list, find the alert you want to view the history of, and in the **Actions** column on the right select **View History** from the **Actions** drop-down menu. The History panel opens. The name of the alert appears at the top of the panel below the title. For example:

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- Select the **X** at the top right to close the History panel.

2. To view the history of an alert from an **[Alert Name]** details page, open the details of an alert as described in View the details of an alert and provide feedback.
   - In the **[Alert Name]** details page, select **View History** from the **Actions** drop-down menu at the top right. The History panel opens. The name of the alert appears at the top of the panel below the title as shown in Step 1.
   - Select the **X** at the top right to close the History panel.

View the AI reasoning steps for an alert

You can view the AI reasoning steps for an alert to understand how the insights and recommendations were rationalized. You can view the AI reasoning for an alert from the Alerts list or from an Alert details page.

To view the AI reasoning steps for an alert:

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1. To view the AI reasoning steps for an alert from the **Alerts** list, open the Alerts list as described in View the list of alerts for all trials you can access.
   - In the **Alerts** list, find the alert you want to view the AI reasoning steps for, and in the **Actions** column on the right select **View AI Reasoning Steps** from the **Actions** drop-down menu. The AI Reasoning panel opens. For example:

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- Select the **X** at the top right to close the AI Reasoning panel.

2. To view the AI reasoning steps for an alert from an **[Alert Name]** details page, open the details of an alert as described in View the details of an alert and provide feedback.

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- In the **[Alert Name]** details page, select **View AI Reasoning Steps** from the **Actions** drop-down menu at the top right. The AI Reasoning panel opens as shown in Step 1.
- Select the **X** at the top right to close the AI Reasoning panel.

Snooze an alert

You can snooze an alert to pause the alert notifications to you. When you snooze an alert it is immediately removed from the Alerts list. The notifications appear to you again if the criticality of the alert increases at a later time or if you undo the snooze action.

You snooze your own alerts, and you can view a list of the alerts you snoozed.

To snooze an alert:

1. Open the list of alerts for all the trials you have access to.
2. In the Alerts list, do one of the following:
   - To snooze all of the alerts, select the checkbox below the **Search** field and above the list of alerts, and then select **Snooze** from the adjacent **Actions** drop-down menu. The Actions menu is disabled until you select one or more alerts in the list.
   - To snooze an individual alert, select the checkbox in the first column for the alert you want to snooze, and in the **Actions** column on the right select **Snooze** from the **Actions** drop-down menu.

   > **Note**
   >
   > - After you snooze an alert, the Snooze option in both Actions drop-down menus is replaced with the Unsnooze option.
   > - To view a list of all of your snoozed alerts, navigate to the Alerts list, select the Status filter, and then select the Snoozed option. For more information, see View the list of alerts for all trials you can access.

3. To undo the snooze action on one or more alerts, do one of the following:
   - To unsnooze all of the alerts, select the checkbox below the **Search** field and above the list of alerts, and then select **Unsnooze** from the adjacent **Actions** drop-down menu. The Actions menu is disabled until you select one or more alerts in the list.
   - To unsnooze an individual alert, select the checkbox in the first column for the alert you want to unsnooze, and in the **Actions** column on the right select **Unsnooze** from the **Actions** drop-down menu.

   > **Note**
   >
   > - After you unsnooze an alert, the Unsnooze option in both Actions drop-down menus is replaced with the Snooze option.
   > - To view a list of all of your unsnoozed alerts, navigate to the Alerts list, select the Status filter, and then select the Unsnoozed option. For more information, see View the list of alerts for all trials you can access.

Alternatively, you can snooze and unsnooze an alert on the [Alert Name] details page. For more information, see View the details of an alert and provide feedback.

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Dismiss an alert

You can dismiss an alert to stop the alert notifications to you. When you dismiss an alert it is immediately removed from the Alerts list. The notifications do not appear to you again unless you undo the dismiss action.

You dismiss your own alerts, and you can view a list of the alerts you dismissed.

To dismiss an alert:

1. Open the list of alerts for all the trials you have access to.
2. In the Alerts list, do one of the following:
   - To dismiss all of the alerts, select the checkbox below the **Search** field and above the list of alerts, and then select **Dismiss** from the adjacent **Actions** drop-down menu. The Actions menu is disabled until you select one or more alerts in the list.
   - To dismiss an individual alert, select the checkbox in the first column for the alert you want to dismiss, and in the **Actions** column on the right select **Dismiss** from the **Actions** drop-down menu.

   > **Note**
   > - After you dismiss an alert, the Dismiss option in both Actions drop-down menus is replaced with the Undismiss option.
   > - To view a list of all your dismissed alerts, navigate to the Alerts list, select the Status filter, and then select the Dismissed option. For more information, see View the list of alerts for all trials you can access.

3. To undo the dismiss action on one or more alerts, do one of the following:
   - To undismiss all of the alerts, select the checkbox below the **Search** field and above the list of alerts, and then select **Undismiss** from the adjacent **Actions** drop-down menu. The Actions menu is disabled until you select one or more alerts in the list.
   - To undismiss an individual alert, select the checkbox in the first column for the alert you want to undismiss, and in the **Actions** column on the right select **Undismiss** from the **Actions** drop-down menu.

   > **Note**
   > - After you undismiss an alert, the Undismiss option in both Actions drop-down menus is replaced with the Dismiss option.
   > - To view a list of all of your undismissed alerts, navigate to the Alerts list, select the Status filter, and then select the Undismissed option. For more information, see View the list of alerts for all trials you can access.

Alternatively, you can dismiss and undismiss an alert on the [Alert Name] details page. For more information, see View the details of an alert and provide feedback.

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6

Access source Oracle Life Sciences applications

A navigation menu and deep linking in the user interface provide seamless access to the source Oracle Life Sciences applications that are onboarded to Life Sciences AI Agents.

For more information on the source Oracle Life Sciences applications, see Overview of Life Sciences AI Agents.

- The navigation menu provides access to the Home page for a source application.
- Deep links provide access from an insight, recommendation, or metric in Life Sciences AI Agents directly to the relevant page, form, or record in the source application with the context pre-filtered (for example, the subject, site, or query ID). You can only access the pages you have the rights to in the source application.

When navigating to or from Life Sciences AI Agents to a source application, you are not required to re-authenticate as long as you have access to the source application and both applications have active sessions.

- View the list of source Oracle Life Sciences applications
  You can view the list of source Oracle Life Sciences applications whose trials are onboarded to Life Sciences AI Agents and that you have access to.
- Open a source Oracle Life Sciences application
  If you have a valid account for an application that has trials onboarded to Life Sciences AI Agents, you can use the navigation menu to open the Home page in the source application.

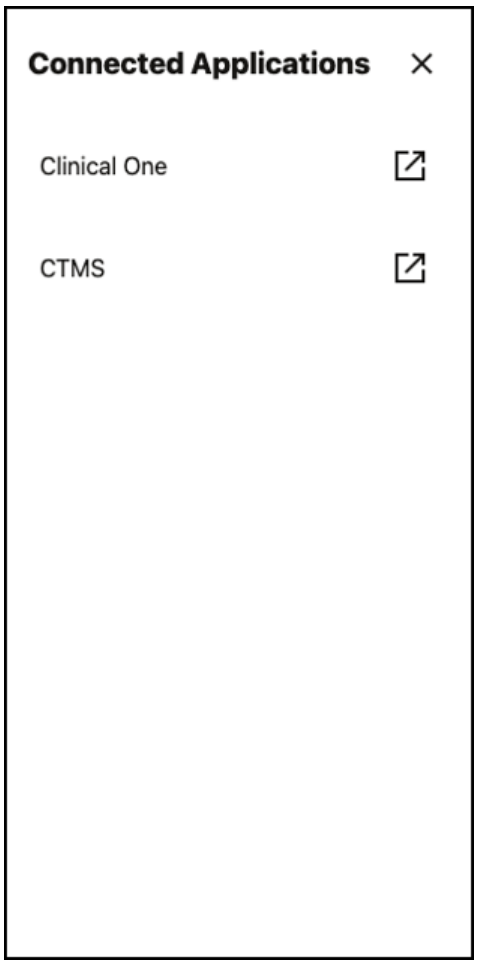
View the list of source Oracle Life Sciences applications

You can view the list of source Oracle Life Sciences applications whose trials are onboarded to Life Sciences AI Agents and that you have access to.

To view the list of source Oracle Life Sciences applications:

- Select the **Navigation Menu** icon  at the top left of the banner. The Connected Applications panel opens. For example:

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Note

Only the source applications you have the rights to access appear in the Connected Applications panel.

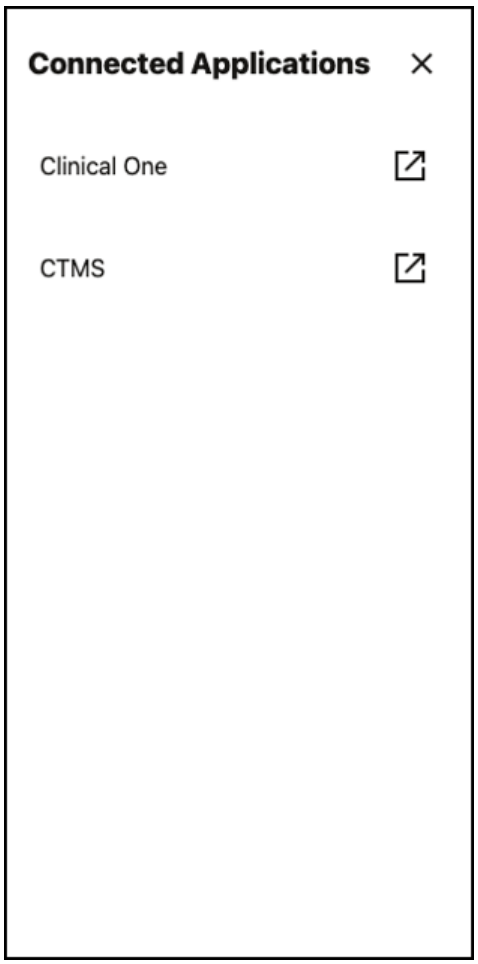
Open a source Oracle Life Sciences application

If you have a valid account for an application that has trials onboarded to Life Sciences AI Agents, you can use the navigation menu to open the Home page in the source application.

To open the Home page in a source Oracle Life Sciences application:

1. Select the **Navigation Menu** icon at the top left of the banner. The Connected Applications panel opens. For example:

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> **Note**
>
> Only the source applications you have the rights to access appear in the Connected Applications panel.

2. Select the link to the source application you want to access.
   - If you have access to the source application and you are already signed in, you are not required to sign in again when the source application opens. If you are not signed in to the source application, you are prompted to sign in using your source application credentials.
   - The source application opens in a new browser tab.

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7

Troubleshoot issues

You can reset your password and access the online product documentation on Oracle Help Center.

If necessary, you can submit a ticket to Oracle Support if any subject data needs to be removed from Life Sciences AI Agents.

- Reset your password
  You can reset your password if necessary (for example, if you forgot your password or if you were locked out of your account after five attempts to enter your password when signing in to Life Sciences AI Agents). You can also ask an administrator to reset your password.
- Request removal of subject data
  If you need to request the removal of any subject data from Life Sciences AI Agents, submit a ticket to Oracle support. Contact your administrator for assistance.
- Access product documentation
  Life Sciences AI Agents provides direct access to the product documentation on Oracle Help Center.

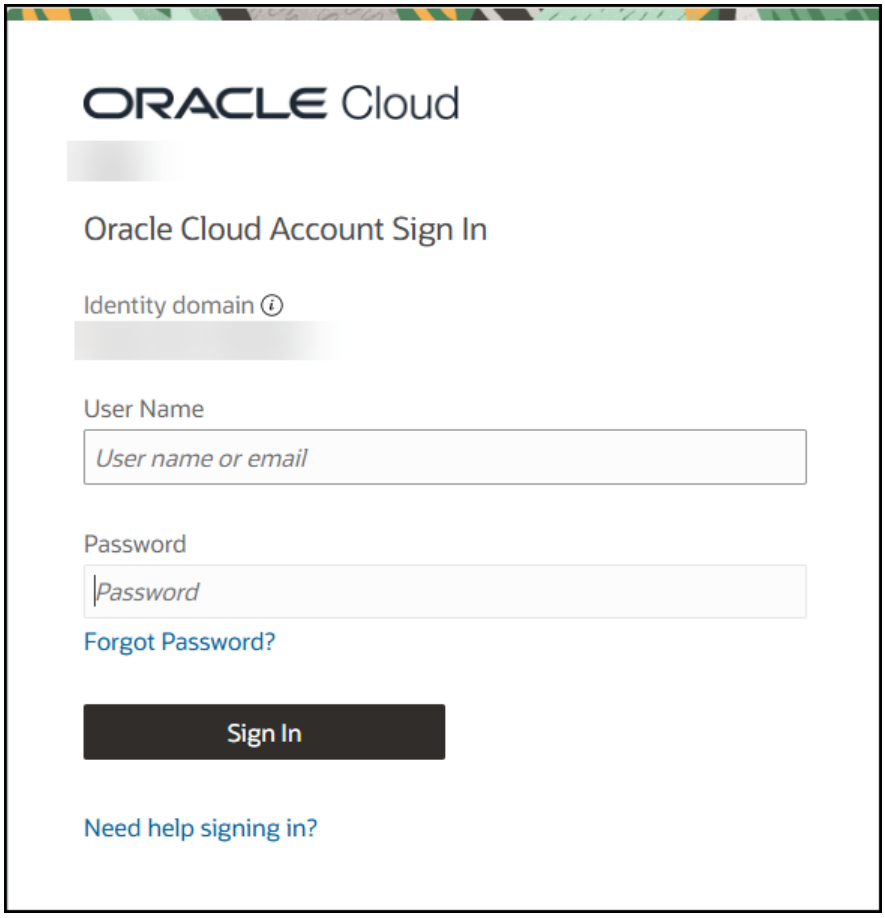
Reset your password

You can reset your password if necessary (for example, if you forgot your password or if you were locked out of your account after five attempts to enter your password when signing in to Life Sciences AI Agents). You can also ask an administrator to reset your password.

To reset your password:

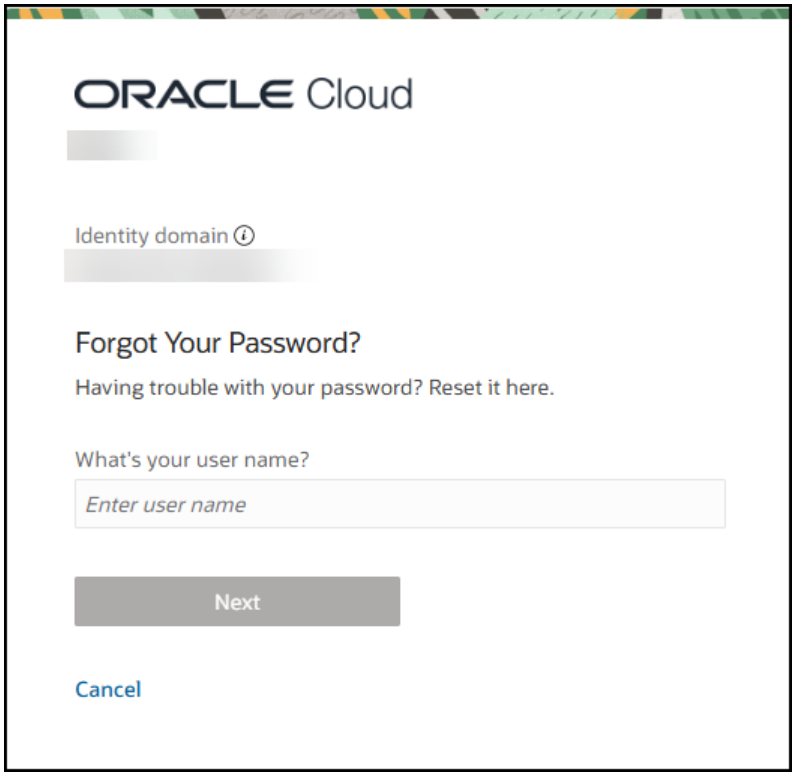
1. Open Life Sciences AI Agents in a browser to access the **Sign In** page. For example:

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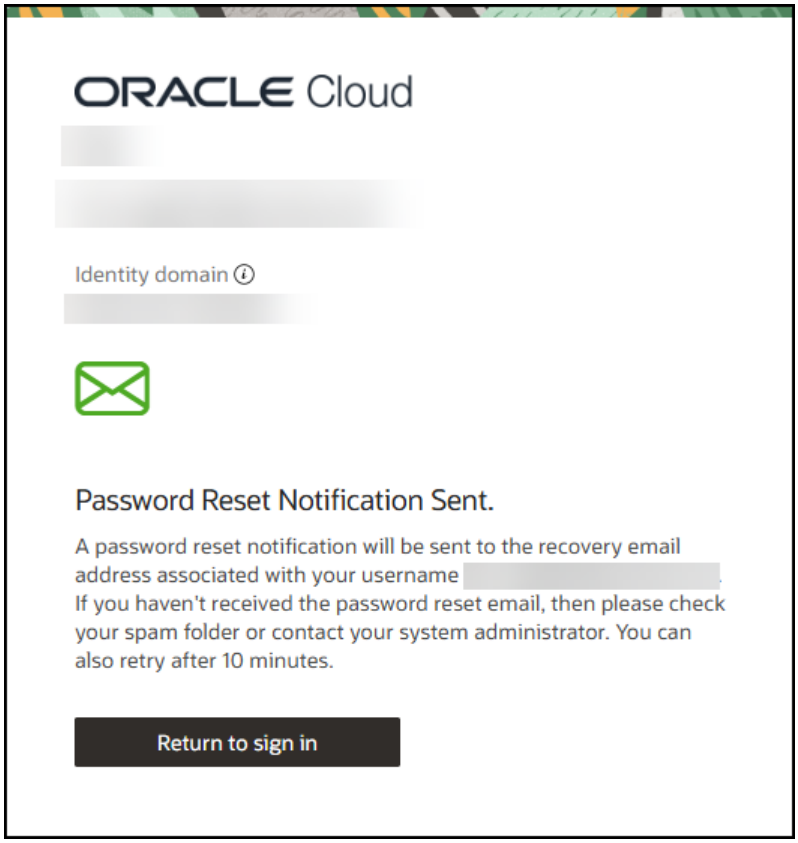


2. Select **Forgot Password?**. The Forgot Your Password? page opens. For example:

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3. Enter or confirm your user name and select **Next**. The Password Reset Notification Sent page opens. For example:



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4. Locate the password reset notification email sent to you from Oracle, and select the **Reset Password** link in the email. The Reset your password page opens.
5. Enter your new password in the **New Password** and **Confirm New Password** fields. You cannot re-use any of your four previous passwords. The password:
   - Must have at least 12 characters.
   - Cannot exceed 40 characters.
   - Cannot contain the First Name of the user.
   - Cannot contain the Last Name of the user.
   - Cannot contain the user name.
   - Must have at least 1 lowercase character.
   - Must have at least 1 uppercase character.
   - Must have at least 1 numeric character.
6. Select **Reset Password**. A confirmation message is sent to your email account and the Congratulations page opens in your browser.
7. In the **Congratulations** page, select **Continue to Sign In**. The Sign In page opens.
8. In the **Sign In** page, enter your user name or email address, and select **Sign In**. The Password page opens.
9. In the **Password** page, enter your password, and select **Verify**. The page that opens depends on the secure verification method you last used.

> **Note**
>
> You are locked out of your account after five attempts to enter your password.

Request removal of subject data

If you need to request the removal of any subject data from Life Sciences AI Agents, submit a ticket to Oracle support. Contact your administrator for assistance.

Access product documentation

Life Sciences AI Agents provides direct access to the product documentation on Oracle Help Center.

To access the product documentation on Oracle Help Center:

1. Select the **Oracle** icon  at the bottom of any page to open the Profile dialog box. For example:

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2. Select **Help**. The Oracle Help Center opens.

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