

Oracle Life Sciences Site Activate

Information for Study Planners



Release 23.2

F84101-01

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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

ORACLE®

Oracle Life Sciences Site Activate Information for Study Planners, Release 23.2

F84101-01

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Diversity and Inclusion

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

Related resources

Product documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

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

1

About the Study Planning tool

The Study Planning tool creates a forecast that shows how long it will take to complete the study startup selection and activation processes (e.g., from Final Protocol Approval through completion of SIVs) for all sites in every country in a study. Based on provided and predicted milestones and defined cycle times, this forecast data enables your organization to plan a study faster and more accurately than ever before.

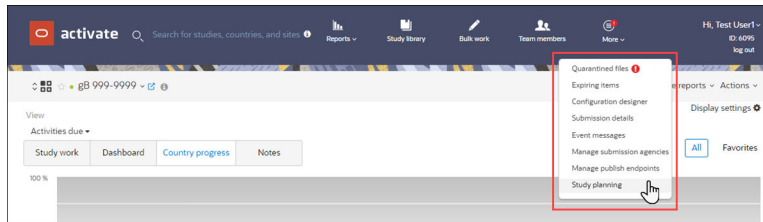
Key questions the planning tool can answer are:

- How long will it take to complete the entire study?
- How long will it take to have all sites contracted in a specific country?
- How long will it take to have sites reach IP Release in specific countries?

2

Access and user permissions

Study Planning is not functionally tied to Oracle Site Activate studies – meaning the tool itself does not allow users to create or modify studies, and users do not access Study Planning based on assigned study access. Instead, users who have a business role with one or more of the permissions described below log in or single sign in to Oracle Site Activate and navigate to Study Planning from the option in the global navigation "More" menu.



Oracle Site Activate permissions related to Study Planning are:

- **Enable access to Study Planning** – Users with this permission may view, create, and modify study plans.
- **Enable edit of other's plans in Study Planning** – Users with this permission may access a different user's plan and modify that plan's dates, probabilities, countries, and/or site characteristics.
- **Enable access to Study Planning set up area** – Users with this permission may configure and modify provided milestones, cycle times, and dependency maps.
- **Enable tying of Study Planning global milestones to milestones** – This is a powerful permission appropriate only for administrators or super users. Global milestone settings directly affect milestone predictions for the account as well as a plan's outcome. Users with this permission can configure global milestones within the Study Planning Set Up area.
- **Enable read only access to Study Planning** – Users with this permission may view study plans but may not modify them.

3

Creating study plans

Create plans in five steps

When creating a study plan, Saved plans display in the account-level Studies Planned list, which users access from the "studies" item in the left navigation panel. By design, only the individual who created a plan may delete that plan. The plan creator will find the Delete option in the plan's Actions menu (ⓘ) on the studies list.

Study planners can create new plans in two ways:

1. Click "plan study" in the left navigation. This method allows the user to specify all plan attributes. Users give the plan a name, and complete all required fields that enforce plan uniqueness. Planners also specify one or more countries to include in the plan, define site characteristics for the sites in each country, and specify relevant dates.
2. Copy and modify an existing plan. Study planners who have permission to edit other's plans may copy and modify any plan listed on the "studies" page to create a new plan. The "Copy Plan" option in plan's Actions menu (ⓘ) provides a quick way for users to create new plans by changing just the relevant attributes (e.g., Planning version, plan description, countries, number of sites, prediction calculation start event, etc.).

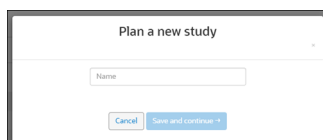
The five step process to plan creation is:

1. **Name:** Enter a unique study plan name
2. **General specs:** Specify attributes like Study number, Sponsor, Sponsor protocol number, Therapeutic area, Phase, Planning version, and more
3. **Countries & Sites:** Identify study countries in the study and the number of sites per country
4. **Dates:** Enter starting dates
5. **Manage milestone probabilities:** Understand the likelihood that a predicted date will be met

At the upper left of planning pages, a "go back" link allows users to return to the previous page in the study planning process. For example, when a user opens a study plan from the Studies page and clicks go back, the final planning page (manage milestone probabilities) displays. The user can optionally navigate backward through to the previous planning steps (Countries & Sites and General Specs) to modify the plan as preferred. When the user saves changes to the plan, the studies list displays that user's name in the "Planned by" column to reflect that user as the individual who most recently made plan changes.

1. Plan name

Users specify a unique plan name in the modal below.



The screenshot shows a modal window titled "Plan a new study". It contains a text input field labeled "Name". Below the input field are two buttons: "Cancel" and "Save and continue".

2. General specifications

The General specifications step includes multiple fields where planners can enter unique tracking attributes for the plan. Required fields are:

- Version Reason (Proposal, Bid defense, Kick off, Study baseline, or Revised plan)
- Therapeutic Area (searchable list)
- Planning Version (free text up to 50 characters)
- Phase (I, II, III, IV, Other)

The General specifications steps provides other common fields to help users distinguish plans as well. For instance, users can enter the Sponsor name and or Sponsor Protocol Number, as well as a free text plan description of up to 500 characters.

3. Countries & Sites

On the Countries & Sites step, users specify the country(ies) included in the plan as well as the number of planned sites per country. Study planners can either manually specify countries and site characteristics or planners can may upload a CSV format file that contains the country and site information instead.

When a planner edits an existing study plan and navigates back to the countries & sites page, Study Planning disables the "Import countries and sites" button until the user deletes the countries currently included in the plan. To help study planners understand this CSV upload behavior, tooltip text states: "Use CSV import to populate the country, site, and site characteristic information. Once you add a country or site, you can no longer use CSV import. Delete all countries to re-enable import button."

To manually complete the Countries & Sites step, study planners specify the number of planned countries, country name, and number of sites planned for each country. Only countries with a saved dependency map may be selected when planning a study. Dependency mapping is available to users who have permission to access the Set Up area of Study Planning. Then users click "Site Characteristics" for each country in the plan to record planned IRB Type and PI Study Experience for sites in each country.

The Site Characteristics modal includes a dynamic countdown based on the number of sites specified in the Countries & Sites planning step. In the example shown below, the country is configured for 6 sites, and the modal displays the number of Sites Remaining (0 sites of 6 total) that still need to be distributed. Study Planning enables the Save button on the modal only when the count of sites remaining for distribution reaches 0. The Site Characteristics fields accept only whole, positive integers of 1-3 digits (i.e., 0-999). If the user enters a total distribution that is greater than the total planned (e.g., user enters values adding up to 30 when the plan is 20 sites), the dynamic count displays a negative number (-10/20 Sites Remaining).

As we mentioned above, planners can complete the Countries & Sites step by uploading a CSV format file, which then automatically fills the following fields:

- Study country(ies)
- Number of sites in each country
- IRB Type/PI Study Experience distribution for each site in a country

The CSV file must include the following columns:

- Two letter country code
- Central IRB sites low PI experience
- Central IRB sites medium PI experience
- Central IRB sites high PI experience
- Local IRB sites low PI experience
- Local IRB sites medium PI experience
- Local IRB sites high PI experience

By design, if the study planner manually interacts with the Countries & Sites page (e.g., to select one or more countries), the “Import countries and sites” button is inactive. If the user later removes any selected countries, the button is available and the study planner can then upload a CSV file, if preferred.

When necessary, study planners can update study and site characteristics by importing the same CSV file with updated information (e.g., add/remove countries, redistribute PI study

experience values, etc.). The subsequent import updates existing data and will not create duplicate data.

4. Enter dates

In the final planning step, users specify a prediction starting point and indicate dates for all provided milestones. The "Prediction start date" field allows study planners to specify the starting event when predictions are enabled in the "set up" area. When multiple global milestones have predictions enabled, the Prediction start date field defaults to Final Approved Protocol, and study planners can optionally choose IP release or Essential docs sent to site as the starting event, if preferred.

5. Manage milestone probabilities

Study planners access the country milestone probabilities dashboard from the planning flow using the "manage milestone probabilities" page. The page follows the planning "dates" page and displays for the first time when the study planner clicks Save and Continue on the "dates" page.

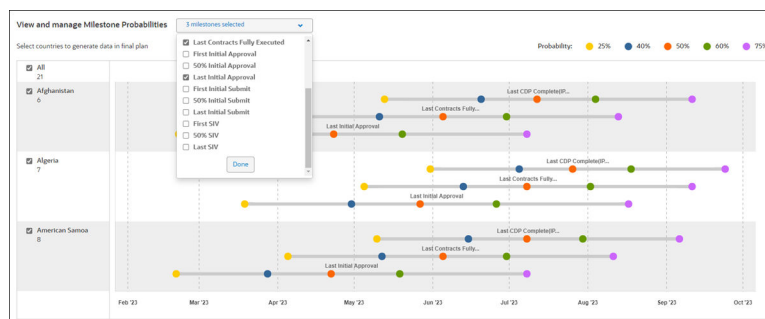
The dashboard allows study planners to evaluate how aggressive or conservative a plan is and helps them quickly evaluate which countries are expected to have the fastest timelines. For example, the IP Release ready prediction returns 25%, 40%, 50%, 60%, and 75% percentiles, and the dashboard can plot these percentages along a country-specific timeline so study planners can evaluate predictions by percentage chance that milestone will be met or delivered faster than the suggested completion date.

Planners can adjust the dashboard's display to any milestone that has a prediction (i.e., all country milestones associated with Contracts Executed and IP Release ready, including the first site contracted, 25% sites contracted, etc.). Dots plotted along each country row represent the 25%, 40%, 50%, 60%, and 75% percentile milestone prediction dates. When users hover over a dot on a row, tool tip text displays the following information:

- Milestone name
- Country name
- Planned sites (e.g., if there are 20 in a country, and the milestone is 25% sites contracted, then the tool tip displays 5/20)

- Probability %: predicted completion date

The View and manage Milestone Probabilities drop-down list provides multiselect control, which allows planners to view the timelines grouped at the country level. When the planner chooses multiple milestones, the label on the drop-down list updates to reflect the total selected.



By default, the dashboard includes a row for all countries included on the planning "countries & sites" page. If a study planner prefers to see a subset of the countries in the final plan outcome (i.e., tabular view, cumulative bar chart, and Gantt chart), a "Select Countries" button on the plan outcome page returns the planner to this probabilities dashboard where the planner can then select/deselect countries as preferred.

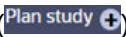
- [Create a study plan](#)
Create a new, unique study plan when you want to specify all plan attributes.
- [Copy a study plan](#)
Study Planning includes copy plan functionality that allows you to create new plans by changing just a few attributes (e.g., Planning version, countries, sites, etc.) of an existing plan.

Create a study plan

Create a new, unique study plan when you want to specify all plan attributes.

Note:

To complete this task, you must have a business role permission that allows you to access Study Planning

1. In the left navigation panel, click **Plan study** (.
2. In the **Plan a new study** modal, enter a study plan name and click **Save and Continue**.
3. On the **General specs** (Plan study) page, add entries for the required **Version Reason**, **Therapeutic Area**, **Planning Version**, and **Phase** fields. All other fields are optional.
4. Click **Save and Continue**.
5. On the Countries & Sites page, choose the number of countries from the drop-down list. For each country row:
 - a. Use the **Select Country** drop-down list to select the country name
 - b. Enter the number of Sites.

- c. Click **Site Characteristics**. On the Site Characteristics modal, enter the country's site Central or Local IRB/EC distributions, and click **Save**.
6. Click **Save and Continue**.
7. On the **Dates** page, select the preferred event for **Prediction start date** event (i.e., Final approved Protocol, Essential docs sent to sites) and enter the preferred start date.
8. Select dates for each milestone in the **Projection start date** section and click **Save and Continue**.
9. On the **View and Manage Milestone Probabilities** page, adjust the summary milestones as preferred using the drop-down list.
10. Click **Save and Continue**.
11. The plan output page displays. Click **Save and Exit** to save the plan.

Copy a study plan

Study Planning includes copy plan functionality that allows you to create new plans by changing just a few attributes (e.g., Planning version, countries, sites, etc.) of an existing plan.



Note:

To complete this task, you must have a business role permission that allows you to modify another user's plan in Study Planning

1. On the **Studies Planned** page, click the Study Identifier of the study plan you want to copy.
2. The **Planned** page displays all versions of the plan. On the row for the plan you want to copy, click Actions (⋮) and select **Copy Plan**. You will see this option only if you have the appropriate user permissions to copy and edit another user's plan.
3. On the **Plan Study** page, you can optionally click edit (✎) next to the plan name and enter a unique plan name.
4. Edit or add entries for the required **Version Reason**, **Therapeutic Area**, **Planning Version**, and **Phase** fields.
5. Optionally adjust or add entries to all non-required fields (e.g., add a plan **Description** for this copy).
6. Click **Save and Continue**.
7. On the **Countries & Sites** page, optionally adjust the entries for selected **Countries**, **Number of Sites**, and **Site Characteristics** if the values needed for the copy are different from the original plan version.
8. Click **Save and Continue**.
9. On the Dates page, optionally adjust the **Prediction start date** event and date and all **Projection start date** fields if the values needed for the copy are different from the original plan version.
10. Click **Save and Continue**.

11. On the **View and Manage Milestone Probabilities** page, optionally adjust the summary milestones using the drop-down list if the values needed for the copy are different from the original plan version.
12. Click **Save and Continue**.
13. The plan output page displays. Adjust the view as preferred (e.g., adjust the displayed **Probability Range** filter).
14. Click **Save and Exit** to save the copied plan.

4

Plans and visualizations

Studies Planned list

All users within an account who have been granted permission to access the Study Planning tool can view all study plans created for the account. The Studies Planned page provides a search field as well as pagination controls that simplify finding a plan. When you access the studies list, unique study identifiers display on a single row and a Versions column provides access to distinct plan versions tied to that study identifier. The Versions column shows the number of available versions in parentheses (e.g., (2)). Clicking on the version column displays the list of one or more plan versions, and you can access a plan's outcome by clicking on the version in the drop-down list.

Study Identifier	Versions	Last Update	Study Number	Sponsor	Protocol Number	Planned By
999-9999.d	1.0(1) v	18NOV2022	12345	GlobalPharma	98765	2user@example.org
999-9999.c	22.4.0(1)(2) v	09.JUL.2021	1232	GlobalPharma	98765	2user@example.org
999-9999.b	1.0(1) v	08DEC2020	999-9999	GlobalPharmaCorp	12345	101user@example.org
999-9999.a	2.Sep2020(2) v	18NOV2022	12345.09876	Sponsor 1	ST_P12345	3user@example.org

If you click the Study Identifier instead, a "Planned" subpage displays all saved plan versions and provides access to Actions (⋮). You can access a unique version's plan outcome by clicking on a value in the Versions column. You can also navigate back to the Studies Planned page by clicking the "Planned" link at the upper left of the page.

Version	Version Reason	Description	Last Update	Date Planned	Planned By	Actions
2.Sep2020	Proposal	RFP 12345 for Sponsor 1	25NOV2020	25NOV2020	user1@example.org	1
5.Sep2020	Bid defense	Bid defense for Proposal 12345 for Sponsor 1, Study protocol ST_P12345	18NOV2022	20SEP2020	user101@example.org	1

Plan outcome in Tabular view

After a user selects a study from the "Studies Planned" list, the Study Planning tool displays plan outcome in Tabular (table) and Dashboard (bar chart and Gantt chart visualizations) format. By default, Tabular view displays, and users can switch the view to Dashboard using the tabs displayed above the plan outcome data. All countries specified in the plan's "Countries and Sites" setup display in the table and visualizations, and users can optionally adjust the filter control to view preferred countries.

The summary milestone columns automatically order by date, from left (earliest) to right (latest). By design, dates displayed for summary milestones are not editable by study planners, as these dates are calculated automatically by the Study Planning tool.

Tabular view, shown below, shows study summary milestones that have been enabled for the account in the milestones set up area. When a study planner selects "Final Approved Protocol" or "Essential Docs Sent to Site" as the Prediction start date, the country summary

milestone table's "Provided milestones" column shows only that milestone the planner selected. For example, when the planner selects Final Approved Protocol, Essential Docs Sent to Site will not display under Provided milestones. Instead, only the predictions of the selected (provided) milestone will be calculated and displayed to the user.

Tabular results also includes a projection table below the country summary milestone table. The table has two columns:

- Provided Milestones - start milestone used as the beginning of projection
- Projected Milestones - target milestone to be forecasted/projected. This is the provided milestone + user set interval (set specifically for the projected milestone, country and therapeutic area)

On the "country summary milestone" table, provided milestones are editable for each country. On the "projected milestone" table, both provided and projected milestones are editable for each country.

The screenshot displays the Oracle Study Planning tool interface for a study with ID 999-9999.a, dated 3.Sep2020. The interface includes a navigation bar with 'go back' and 'Close' buttons, and a 'Probability Range' dropdown menu set to 50%. Below the navigation bar, there are tabs for 'Tabular' and 'Dashboard', and a 'Select Countries' button. A note indicates that changing a date or probability will automatically update and save the plan. The main content area is divided into three sections: 'Study summary milestones', 'Country summary milestones', and 'Projection'. The 'Study summary milestones' table shows dates for 'First CDP Executed', 'First CDP Complete', 'First SVV', '50% Contracts Fully Executed', '50% CDP Complete', '50% SVV', 'Last Contracts Fully Executed', 'Last CDP Complete', and 'Last SVV'. The 'Country summary milestones' table lists countries (Australia 10, Germany 10, Netherlands 20) and provides dates for 'Essential Docs sent to Site', 'First CDP Fully Executed', 'First CDP Complete', 'First SVV', '50% Contracts Fully Executed', '50% CDP Complete', '50% SVV', 'Last Contracts Fully Executed', 'Last CDP Complete', and 'Last SVV'. The 'Projection' table shows dates for 'Essential Docs sent to Site', 'All core documents', 'Contract and Budget Templates', 'Final Approved Protocol', 'ICF Final', 'Site list final', 'MY Projected', and 'CDP Complete'.

Using the Probability drop-down menu above the table, study planners can adjust the plan output to display a preferred percentage for prediction probability (25%, 50%, 75%, etc.). The default probability value is 50%, and when a planner selects a different value, the plan output page (tabular view, cumulative bar chart, and Gantt chart) automatically recalculates. When the user saves the plan, the newly-selected probability value will be saved as well.

Probability ranges

Study planners can create more realistic plans by specifying the probability range for plan results. On the study plan results page, above the tabular results, planners can select from the following Probability Range values:

- 25%
- 40%
- 50% (default minimum and maximum)
- 60%
- 75%

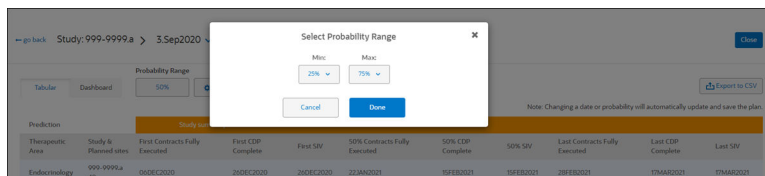
The Study Planning tool enforces realistic minimum/maximum selections and automatically modifies values and notifies users. For instance, if the user selects a minimum value of 75 and a maximum value of 25, Study Planning automatically

updates the minimum value to 25, and the following message displays in the value selection modal, "Min value has been changed to match the lesser max value."

When a planner specifies probability range values, the following calculation logic applies to each plan country in succession:


- Study Planning tags the first site in a country with the lowest probability and subsequent sites with the next lowest probability, in succession, until it tags a site with each probability option from the specified range. Then tagging begins again from the lowest of the range. Sites that are historically the slowest receive the lowest probability.
- Example distributions for a selected range of 25%-50%:
 - For a country with three sites, Study Planning tags one site as 25%, one as 40%, and one as 50%.
 - For a country with five sites, Study Planning tags two sites as 25%, two sites as 40%, and one site as 50%.
 - For a country with two sites, Study Planning tags one site as 25% and one site as 40%.
- Study Planning also follows a defined IRB/PI experience order when tagging sites for probability range distribution. The order is:
 1. Local/1 year
 2. Central/1 year
 3. Local/2-5 year
 4. Central/2-5 year
 5. Local/5 year
 6. Central/5 year

For example, when the specified range is 25%-75%, and the country includes three sites in Local/1 year and three sites in Central/1 year, Study Planning will tag Local/1 year as 25%, 40%, and 50% and Central/1 year as 60%, 75%, and 25%.



Milestone predictions

The prediction engine uses study plan attributes and site characteristics to create accurate predictions. Country, Therapeutic Area, number of sites, IRB/EC type, and more – each of these data points affect milestone predictions. For instance, the prediction engine uses the plan's data points to calculate Contract Fully Executed and IP Release dates for each site, and the calculated dates are then used to predict the study summary and country milestone dates. Depending upon the number of sites planned in a country and the characteristics of those sites, some predicted summary milestones may specify the same date. This is expected behavior.

If a study planner manually edits a provided or projected milestone date (using  in the date field), and that milestone is tied to a global milestone with prediction enabled, the predictions engine recalculates the date. When that recalculated date affects other downstream milestones, Study Planning dynamically adjusts the plan output view to reorder milestones

from earliest to latest, as necessary. For example, if a study planner moves Essential Documents Sent to Site to an earlier or later date, predictions for the summary milestones for IP Release and Contract Fully Executed are automatically recalculated and ordered based on that new starting date. When a user manually updates a date, Study Planning automatically updates and saves the plan.

When prediction is enabled for a projected global milestone, and the milestone that is mapped to the global milestone no longer obtains its projected date (cycle time) from the milestone's projection settings, it does not display on the plan outcome page. This is by design, as only summary milestones enabled for the global milestone display on the plan output page.

CSV export

Study planners can optionally export a plan to a .csv format file. The study plan Tabular view includes an “Export to CSV” button at the upper right, and Study Planning enables the button only for a saved plan. The first time the user views study plan page, before saving, the export button is inactive. The export button is also inactive when a user makes any change to a previously-saved plan.

The export includes significant plan detail, including:

- All completed fields from Planning “general specs” step, including:
 - Study number
 - Sponsor
 - Sponsor protocol number
 - Version reason
 - Therapeutic Area
 - Phase
 - Indication
 - Planning version
 - Description
- Selected probability percentage
- Study summary milestones
- Country summary milestones
- Prediction results for the study, prediction results for each country, and projection results for each country
- Under the country area, the export includes individual site results, with sites organized by country name and:
 - Country/Site description/Probability %
 - Contracts Fully Executed (displays the customer-configured name for this global milestone)
 - IP Release (displays the customer-configured name for this global milestone)
 - Site description with Study experience and IRB/EC Type and probability percentage (e.g., “>5 Studies and Central IRB/EC 25%”)

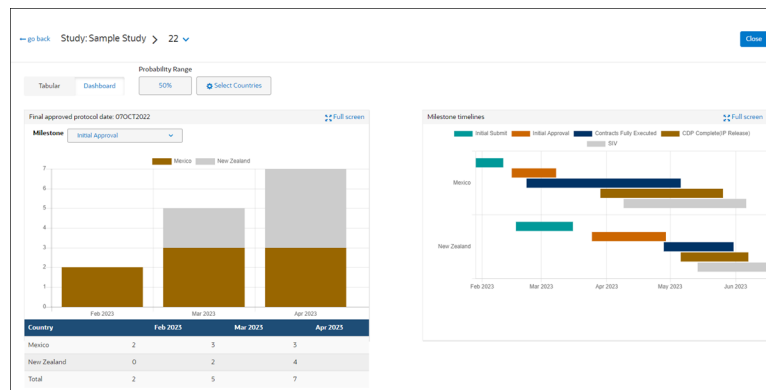
When exported, the file name follows the format: study plan name_study number_plan version number.csv (e.g., samplestudyplannname_12345_2.csv).

Plan outcome in Dashboard view

Study planners also have the ability to view plan visualizations in the Dashboard view. This view displays plan data in bar and Gantt charts. By default, all countries display in the charts, and users can optionally adjust the filter above the charts to specify preferred countries. The bar chart visualization's Milestone drop-down list also allows study planners to adjust the selected value without expanding the view to full-screen format.

The Dashboard view provides optional export to PDF format, if desired. These exports provide an easy way for study planners to share plan visualizations with others. When viewing a visualization in full-screen mode, an Export to PDF action button displays at the upper right of the screen. When clicked, the file exports with the following naming conventions based on the visualization type:

- Bar chart: Plan name_Version Reason_Planning Version_Bar
- Gantt chart: Plan name_Version Reason_Planning Version_GANTT



Note:

The Gantt chart displays a vertical line when the site characteristics of a country dictate that all sites are scheduled to start and complete a milestone on the same day.


- [View plan outcome in tabular format](#)
Tabular view shows study summary milestones enabled for the account in the milestones set up area. The summary milestone columns automatically order by date, from the left (earliest) to the right (latest).
- [View plan outcome in chart format](#)
Use the Study Planning dashboard mode to evaluate plan outcome in bar chart and Gantt chart visualizations.
- [Export plan outcome table to CSV](#)
Export tabular plan outcome to a CSV file to share the plan's milestone data with others.
- [Export plan outcome chart to PDF](#)
Optionally export bar chart and Gantt chart plan outcome to a PDF format file to share the visualizations with others.
- [Delete a study plan](#)
You can delete a plan you created to remove it from the Studies Planned page.

View plan outcome in tabular format

Tabular view shows study summary milestones enabled for the account in the milestones set up area. The summary milestone columns automatically order by date, from the left (earliest) to the right (latest).

Note:

To complete this task, you must have a business role permission that allows you to access Study Planning. If you want to change the data shown in the tabular view and another user created the plan you are viewing, you must have a business role permission that allows you to modify the other user's study plan.



1. On the **Studies Planned** page, click the name of the study plan you want to see in the tabular view.
2. Optionally adjust the **Select Countries** filter to view preferred plan countries.
3. Optionally adjust the **Probability Range** filter to select a different range, as preferred.
4. Optionally adjust milestone dates where edit () displays on hover over. By design, summary milestone dates are not editable; the Study Planning tool automatically calculates dates for summary milestones.

View plan outcome in chart format

Use the Study Planning dashboard mode to evaluate plan outcome in bar chart and Gantt chart visualizations.

Note:

To complete this task, you must have a business role permission that allows you to access Study Planning.

1. On the **Studies Planned** page, click the **Study Identifier** for study plan you want to see in a chart view.
2. On the studies subpage, click the appropriate study plan version.
3. Click the **Dashboard** tab.
4. Optionally adjust the filter panel to view preferred plan countries
5. Optionally expand the bar chart or Gantt chart to full-screen view ( **Full screen**). Click exit ( **Exit full view**) to return to the default Dashboard view.


Export plan outcome table to CSV

Export tabular plan outcome to a CSV file to share the plan's milestone data with others.



Note:

To complete this task, you must have a business role permission that allows you to access Study Planning.

1. On the plan outcome page, click the **Tabular** tab, if necessary
2. At the upper right of the table, click **Export to CSV** ( [Export to PDF](#)).

The file exports with the following naming convention: Study identifier_Version Reason_Planning Version.csv

Export plan outcome chart to PDF

Optionally export bar chart and Gantt chart plan outcome to a PDF format file to share the visualizations with others.



Note:

To complete this task, you must have a business role permission that allows you to access Study Planning

1. On the plan outcome page, click the **Dashboard** tab
2. Expand the bar chart or the Gantt chart to full-screen view ( [Full screen](#)).
3. Click **Export to PDF** ( [Export to PDF](#)).

The file exports with the following naming conventions based on the visualization type you viewed in full-screen mode:

- Bar chart: Study Identifier_Version Reason_Planning Version_Bar.pdf
- Gantt chart: Study Identifier_Version Reason_Planning Version_GANTT.pdf

Delete a study plan

You can delete a plan you created to remove it from the Studies Planned page.



Note:

To complete this task, you must have a business role permission that allows you to access Study Planning and you must be the user who created the plan.

1. On the **Studies Planned** page, click the Study Identifier of the study plan you want to delete.
2. The **Planned** page displays all versions of the plan. On the row for the plan you want to delete, click Actions (⋮) and select **Delete Plan**. The option to delete is available to you only if you are the study planner who created the plan.
3. Click **Confirm**.

5

Milestone set up

Create milestones

In the "Create milestones" section, users add new milestones and specify the milestone's Type (Provided or Projected). After saving a milestone, users can drag-and-drop (+) to order milestones as preferred and edit the milestone name/type as necessary. However, to prevent users from invalidating dependency maps, Study Planning prevents deletion of a milestone after it has been added to a dependency map. In this case, the Create milestones page allows users only to edit the milestone name, and the "Remove" option is disabled. Removing the milestone or modifying the milestone Type is not possible on the Create milestones page until the user deletes the milestone from the dependency map.

The screenshot shows the 'Set up milestones' page with the following structure:

- Navigation tabs: Create milestones (active), Manage global settings, Projected dates, Map dependencies.
- Instruction: Order milestones by dragging and dropping. Milestone dates will be automatically saved and display in the defined order.
- Milestone 1: Name 'Essential Docs sent to Site', Type 'Provided milestone', Date '25/0'. Buttons: Save, Remove (+).
- Milestone 2: Name 'Final Approved Protocol', Type 'Provided milestone', Date '25/0'. Buttons: Save, Remove (+).
- Milestone 3: Name 'Projected 1', Type 'Projected milestone', Date '15/0'. Buttons: Save, Remove (+).
- Milestone 4: Name 'Contracts Fully Executed', Type 'Projected milestone', Date '26/0'. Buttons: Save, Remove (+).

Manage global milestones

Study Planning uses milestone prediction functionality for certain global milestones. Users who have an explicit permission to manage global milestones in the set up area can configure projected and provided milestones for the account.

For projected milestones, a user can enable or disable prediction functionality milestones mapped to the IP Release, Contracts Fully Executed, Site Initiation Visit (SIV), Initial Submit, and Initial Approval global milestones. Users can also enable the SIV cycle time milestone, if preferred. When prediction or cycle time calculation has been enabled for any of these milestones, the user can also configure use of Summary milestones that predict first, last, and specific percentages (e.g., 25, 50, 90) for milestone completion. Note that summary milestones are not calculated when prediction functionality is not enabled for the projected milestone(s).

Provided milestones also include prediction functionality. Users can enable predictions for milestones mapped to the Essential Documents Sent to Site and/or Final Approved Protocol global milestones.

The screenshot shows the 'Set up milestones' configuration page. At the top, there are tabs for 'Create milestones', 'Manage global settings', 'Projected dates', and 'Map dependencies'. The 'Manage global settings' tab is active. Below this, there are three main sections:

- Account type:** Radio buttons for 'CRO' (selected) and 'Sponsor'. A 'Save' button is in the top right.
- Projected milestones:** A table with columns for 'Milestones', 'IP Release', 'Contracts Fully Executed', 'SIV', 'Initial Submit', and 'Initial Approval'. Rows include 'Prediction milestone', 'Cycle time milestone', and 'Summary milestones' (First, Last, 25%, 50%, 75%, 80%, 90% complete).
- Provided milestones:** A table with columns for 'Milestones', 'Essential Documents Sent to Site', and 'Final Approved Protocol'. A row includes 'Prediction milestone'.

At the bottom, there is a 'Customize fields for the account' section with a text input field for 'Version reason (values separated by comma?)' containing 'revised plan, unapproved, timing, site'. A '4 of 10 values' indicator is at the bottom right.

- [Set up milestones](#)
The milestones set up area allows you to create and specify the display order for your organization's milestones.
- [Specify CRO or sponsor account type](#)
Certain fields in study planning include CRO or Sponsor labels. You can affect the displayed label text by setting the account type in the Set Up area.
- [Set up global milestone predictions](#)
Certain global milestones, like IP release or Contracts Fully Executed, use prediction functionality. Other global milestones use cycle time calculation. Use these instructions to configure settings for predicted and provided global milestones.

Set up milestones

The milestones set up area allows you to create and specify the display order for your organization's milestones.



Note:

To complete this task, you must have permission to access the Study Planning Set Up area.

1. In the left navigation, click **set up**.
2. At the top of the page, click the **Create milestones** tab.
3. At **Milestone name**, enter a milestone name (50 character maximum).
4. At **Type**, select either **Provided milestone** or **Projected milestone**.
5. For Projected milestones, select a predefined global milestone from the drop-down list.
6. If necessary, you can **Remove** a milestone from the list.

The study planning tool automatically saves your entries. When you have two or more milestones saved, you can reorder the list using order control (+) to drag and drop the item to your preferred order.

Specify CRO or sponsor account type

Certain fields in study planning include CRO or Sponsor labels. You can affect the displayed label text by setting the account type in the Set Up area.



Note:

To complete this task, you must have permission to access the Study Planning Set Up area.

1. In the left navigation, click **set up**.
2. At the top of the page, click the **Manage global settings** tab.
3. In the **Account type** section, click either the **CRO** or **Sponsor** radio button.
4. Click **Save**.

Set up global milestone predictions

Certain global milestones, like IP release or Contracts Fully Executed, use prediction functionality. Other global milestones use cycle time calculation. Use these instructions to configure settings for predicted and provided global milestones.



Note:

To complete this task, you must have permission to access the Study Planning Set Up area. You must also have explicit permission to manage global milestones. If you do not have both permissions, please contact your Oracle services representative.

1. In the left navigation, click **set up**.
2. At the top of the page, click the **Manage global settings** tab.
3. In the **Projected milestones** section, click the check boxes to enable milestones as preferred for Prediction, Cycle time, and Summary milestones. Uncheck a box to disable that milestone.
4. In the **Provided milestones** section, click the check boxes to enable prediction milestones as preferred.
5. Click **Save**.

6

Projected dates set up

In the "Projected dates" area, users identify cycle times, in days, for specific therapeutic area and country combination milestones. For easy navigation, the Therapeutic Area column at the far left and all milestone column headers freeze and are visible to users as they scroll horizontally and vertically.

Therapeutic Area	CDP Complete (IP Release)	Contracts Fully Executed	First Patient In	FPI	Initial Approval	Initial Subject	Last Patient In
Cardiology/Vascular Disease	1	2				1	
CNS	5	4	5	6	10	12	
Dental and Oral Health							
Dermatology							
Endocrinology							

- **Set up projected dates**
Specify cycle times for specific therapeutic area and country combination milestones.

Set up projected dates

Specify cycle times for specific therapeutic area and country combination milestones.



Note:

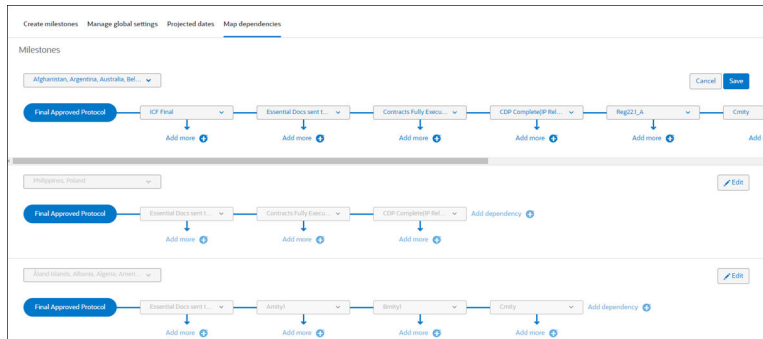
To complete this task, you must have permission to access the Study Planning Set Up area.

1. In the left navigation, click **set up**.
2. At the top of the page, click the **Projected dates** tab.
3. Above the table, at the upper left, use the drop-down list control to select the appropriate country.
4. For each applicable Therapeutic Area row, enter cycle times in each milestone field. Cycle time measurement is in days.
5. Click **Save**.

7

Dependency map set up

In the "Map dependencies" area, users create maps that identify the order in which milestones will be completed for one or more countries. Currently, the starting point for all maps is the "Final Approved Protocol" milestone. When appropriate, "Add more" and "Add dependency" links display to allow users to customize the map to a preferred flow.



- **Set up dependency maps**
Dependency mapping allows you to specify milestone completion order for one or more countries in a study plan.

Set up dependency maps

Dependency mapping allows you to specify milestone completion order for one or more countries in a study plan.



Note:

To complete this task, you must have permission to access the Study Planning Set Up area.

1. In the left navigation, click **set up**.
2. At the top of the page, click the **Map dependencies** tab.
3. Click **Add new map** ([Add new map](#)).
4. Select a country from the country drop-down.
5. Select a milestone from the milestone drop-down.
6. Click **Add dependency** ([Add dependency](#)) and select a milestone from the milestone selection drop-down.
7. Click **Add more** ([Add more](#)) to include additional milestones
8. Click **Add dependency** and **Add more** as necessary to include additional dependencies and select additional milestones as appropriate for the countries in the map.

9. Click **Save**.