# Oracle® Health Sciences ClearTrial Cloud Service

Plan and Source User Guide

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Oracle Health Sciences ClearTrial Cloud Service Plan and Source User Guide, Release 5.2

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# Preface

The Oracle Health Sciences ClearTrial Plan and Source Cloud Service User Guide is a reference for users that are creating, editing, and managing studies for their organization.

## Audience

This document is for users that are working with the Oracle Health Sciences ClearTrial Plan and Source Cloud Service application.

## 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`.

### Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit `http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info` or visit `http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs` if you are hearing impaired.

## Finding Oracle Documentation

The Oracle website contains links to all Oracle user and reference documentation. You can view or download a single document or an entire product library.

### Finding Oracle Health Sciences Documentation

To access user documentation for Oracle Health Sciences applications, go to the Oracle Health Sciences documentation page on oracle.com at:

`http://www.oracle.com/technetwork/documentation/hsgbu-154445.html`

or, for the documentation for this product, to:

`http://http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html`

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**Note:** Always check oracle.com to ensure you have the latest updates to the documentation.

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## Related Documents

For more information, see the following documents in the Oracle Health Sciences ClearTrial Cloud Service Release 5.2 documentation set:

- *Oracle Health Sciences ClearTrial Cloud Service 5.2 System Administrator User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.2 Web Services API User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.2 Release Notes*
- *Oracle Health Sciences ClearTrial Cloud Service 5.2 Track User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.2 Third Party Licenses and Notices*

# 1

# Getting Started: Basic Functions and Common Tools

Oracle® Health Sciences ClearTrial Cloud Service integrates clinical operations, resource planning, project management, and finance into a single application that provides your organization with dramatic efficiencies and cost savings from planning through payment in research and development operations.

This chapter covers the basic functions and tools you can use to plan, budget, and forecast clinical studies.

## Products, Studies, and Plans

### You Conduct Studies on Products

A product is a compound, a medical device, or a combination product on which you conduct a study. You can conduct multiple studies on a product.

### Plans Are Based on Studies

A plan is one scenario or design for a study. You can create as many plans for a study as necessary to determine the most cost-effective or time-efficient scenario for a study.

### A Tabbed Interface Guides You through Plan Creation and Modification

You create a plan on the Create Plan screen. You modify plans on the Edit Plan screen. Both screens provide access to a set of data entry screens accessed by clicking tabs on the left side of the screen. The tabs appear in a specific order that provides a logical approach for creating or modifying a plan.

As you complete a tab, you can click **Next** to go to the next related tab. The application highlights the corresponding tab on the left.

#### Your Entries Cascade throughout the Plan

The selections you make on the Overview tab cascade throughout the plan and affect the defaults used on subsequent data entry screens.

### Edit Modes Control the Detail of Your Plan

The four edit modes give you control over how much detail you include in the plan. The tabs and fields included on the tabs vary by edit mode. The more details you enter, the more accurate the representation of costs the application produces. The inactive tabs appear grayed out.

- **Quick mode—**Includes the least amount of detail. Use Quick mode when you have minimal information about the study or want to perform a high-level budget estimate or long-term planning before you have specifics about the study.
- **Basic mode—**Includes a few more assumptions than Quick mode. For example, you enter site information in Basic mode but not in Quick mode.
- **Advanced and Expert modes—**Include all of the tabs and fields. Use these modes when you have detailed specifications about how you plan to conduct the study and are ready to prepare a Request for Proposal, bid on a project, or submit a budget to Management for review and approval.

### Preferred versus Maximum Edit Modes

Your preferred edit mode is the mode to which the application defaults to when you create or edit a plan or template. Your maximum edit mode is the highest edit mode you are authorized to use. You can set your preferred edit mode in your user profile, but the system administrator sets your maximum edit mode.

### Selecting Your Preferred Edit Mode

1. On the menu bar, click your user name.

   The User Profile screen appears.
2. Click **Edit Profile**.

   The Edit User screen appears.
3. From the **Preferred Edit Mode** drop-down list, select the edit mode.
   - For more information about a field, click the field name.
   - For more information about the screen, see topic name-Edit Profile.
4. Click **Save**.

   At any time, you can change your preferred edit mode. Plans configured in a higher or lower edit mode keep all their configured values, but, if you configured a field only accessible in a higher edit mode, for example, you will need to set your preferred edit mode to that edit mode or higher for the fields to be displayed and editable.

### Changing Your Edit Mode Mid-plan

You can change the edit mode for a plan.

1. From the Edit menu, select **Plans**.

   The Plans screen appears.
2. Select the plan checkbox and click **Edit**.

   The Edit Plan screen appears.
3. From the **Current Edit Mode** drop-down list, select a different edit mode.

   The screen refreshes, reflecting the change to the edit mode you selected.

## Managing Your Password

You can change your password at any time.

1. On the menu bar, click your user name.

   The User Profile screen appears.
2. Click **Change Password**.

   The Change Password screen appears.
3. In the **Current Password** field, type your password.
4. In the **New Password** and **Verify New Password** fields, type the new password.
5. Click **Save**.

   The application confirms your password change in an email message.

### If You Forget Your Password

For security, the application does not support the recovery of existing passwords. If you forget your password, you must request a password reset.

1. On the ClearTrial Login screen, click the **Forgot Your Password** link.

   The Reset Password dialog box appears.
2. Enter your **Customer ID**, **Login Name**, and **Email Address**.
3. Click **Reset Password**.

   You will receive an email with instructions on how to reset your password.

> **Note:** If your organization does not allow user account information to be sent by email, your System Administrator needs to communicate the customer code, login name, and temporary password through a secure form of communication.

## Setting Your Preferred Home Page

The preferred home page is the screen that appears when you log into the application. You can change your home page by editing your user profile.

1. On the menu bar, click your user name.

   The User Profile screen appears.
2. Click **Edit Profile**.

   The Edit User screen appears.
3. From the **Preferred Home Page** drop-down list, select the screen to appear when you log in.
4. Click **Save**.

## Setting Your Preferred Locale

The preferred locale determines how dates and numbers appear on screens. You specify your preferred locale on your user profile.

1. On the menu bar, click your user name.

   The User Profile screen appears.
2. Click **Edit Profile**.

   The Edit User screen appears.

3. From the **Preferred Locale** drop-down list, select the location.
4. Click **Save**.

## Filtering Allows You to Show or Hide Items Based on Criteria

Filtering allows you to specify which plans, studies, products, templates, portfolios, service providers, resources, billing rates, departments, GL codes, exchange rates to show on plan-related screens. You always have a choice of showing all items, active items only, or items matching filters you have defined.

On any screen with a Filter section, select which items to show:

- **All <items>—**No filter is applied.
- **Active <items> Only—**Items that have not been deleted or marked as Complete or Archived.
- **<items> matching filter—**Items that match the criteria defined in the filter you select from the drop-down list.

  The screen refreshes to show the selected plans.

### Defining or Modifying a Filter

1. Click the **Modify** link.

   The Define <item> Filter dialog box appears.
2. Complete the Filter Criteria, Save Filter, and Sorting and Paging sections.
   - For more information about a field, click the field name.
   - For more information about the screen, see Define Plan Filter Dialog Box, Define Product Filter Dialog Box Fields, Define Study Filter Dialog Box Fields, Define Template Filter Dialog Box Fields, Define GL Code Filter Dialog Box Fields, Define Portfolio Filter Dialog Box, Define Resource Filter Dialog Box Fields, Define Department Filter Dialog Box Fields, and Define Exchange Rate Table Filter Dialog Box Fields.
3. Click **Ok**.

## Built-in Warnings and Information Provide Guidance

The application provides warnings and guidance as you enter assumptions for a plan. Advice is available when a symbol appears to the right of a value. Double-click the symbol to read the advice.

- **Blue i**—Additional information is available.
- **Yellow !**—A value or piece of data may be outside of standard ranges.
- **Red !**—Entry is invalid.

## The Notes Feature Allows You to Annotate Every Page of Your Plan

You can add notes to your plan to include additional detail, clarify selected options, or coordinate planning with other team members. Notes can be public or private. Private notes can be seen by your internal team. Public notes can be included on reports generated on the Reports tab.

### Adding Notes to a Plan

1. From the Edit menu, select **Plans**.

   The Plans screen appears.

2. Select a plan checkbox.
3. Click **Edit**.

   The Edit Plan screen appears.

4. Click **Notes**.

   The Notes dialog box appears.

5. Enter public notes in the first section and private notes in the second section.

   All notes appear on the Assumptions report, below the table of assumptions for each functional area. You can control whether public and private notes are displayed when you print the Assumptions report. For more information about the Assumptions report, see Generating a Report.

6. Click **Save & Close**.

### Viewing Notes Attached to a Plan

1. From the Edit menu, select **Plans**.

   The Plans screen appears.

2. Select a plan checkbox.
3. Click **Edit**.

   The Edit Plan screen appears. If a screen has an attached note, a notes icon appears to the left of the Notes button.

4. Click **Notes**.

   The Notes dialog box appears and you can view all notes for the plan.

## Working with Plans, Studies, Products, Templates, and Portfolios

You create and edit plans, studies, products, templates, and portfolios from the Edit menu. The main screen for all of these items provides filtering as well as these functions:

- **New—**Define a new item.
- **Edit—**Edit a selected item.
- **Delete—**Delete a selected item.
- **Restore—**Restore a deleted item. To use this option, adjust the filters so that you can see inactive as well as active items.
- **Copy—**Create a copy of a selected item.

In addition, you can lock and unlock plans and templates and compare plans.

## View Currently Defined Products on the Products Screen

1. From the Edit menu, select **Products**.

   The Products screen appears.

2. Filter the products as necessary. For more information, see Define Product Filter Dialog Box Fields.

### Adding or Editing a Product

1. On the Products screen, click **New** or **Edit**.

   The Create Product screen or Edit Product screen appears.

2. Enter or edit the fields as necessary.

   - For more information about the field, click the field name.
   - For more information about the screen, see Create/Edit Product Screen Fields.

3. Click **Save**.

   The application adds the product to the Products screen. You can now create studies for this product.

## View Currently Defined Studies on the Studies Screen

1. From the Edit menu, select **Studies**.

   The Studies screen appears.

2. Filter the studies as necessary. For more information, see Filtering Allows You to Show or Hide Items Based on Criteria.

### The Four Study Phases

The application supports four study phases:

- **Phase I, Screening for safety**—Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase I, For healthy volunteers**—Researchers test healthy subjects, who might have no symptoms, to assess the safety of the product. This is testing the drug for the first time in a human (typically called first in man studies).
- **Phase II, Establishing the efficacy of the drug, usually against a placebo**—Researchers provide experimental treatment to a larger group of people (100–300) to see if it is effective and to further evaluate its safety.
- **Phase III, Final confirmation of safety and efficacy**—The treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.
- **Phase IV with and without IND support**— These post-marketing studies delineate additional information, including the treatment's risks, benefits, and optimal use. You can design studies with and without Investigational New Drug (IND) support.

### Creating or Editing a Study

1. From the Edit menu, select **Studies**.

   The Studies screen appears.

2. Click **New**.

   The Create Study screen appears.

or

Select the study checkbox and click **Edit**.

- Some fields are read only.
- Changes to Phase, Therapeutic Area, Indication, and Sponsor cannot be cascaded to locked plans whose calculated values have been frozen based on the current configuration of this study.

The Edit Study screen appears.

3. Enter general information.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Study Screen Fields.
   - If the product entry has not already been created, from the **Product/Compound** drop-down list, select **New** to display the Create Product dialog box and define a new product.
4. Enter description information.

   Indications are classified into therapeutic areas. The application uses the selected therapeutic area and indication to calculate monitoring time required, time for query resolution, and data entry, and to provide other default values. You can override these calculated values if necessary.

   - By selecting the **Substitute the names below for therapeutic area and indication** checkbox, you can specify an alias for the selected therapeutic area and/or indication. The alias appears on the Studies screen, the plan header, and on all study-related reports.
     - You should use a therapeutic area or indication alias if there are no therapeutic areas or indications included on the predefined list that describe your study.
   - To view a list of all therapeutic areas and their associated indications, from the Reports menu, select **Therapeutic Area/Indications Mapping**.
   - When no therapeutic area or indication seems to fit, choose the most appropriate body system/therapeutic area for the study you are planning.
   - If you cannot find the specific therapeutic area or indication you need:
     - Select a similar therapeutic area or indication from the available list and then use the Alias fields to substitute the name of the actual therapeutic area or indication.
     - Select **Other** from the list of therapeutic areas and choose either a similar indication or Other (Complex), Other (Routine), Other (Simple), or Other (Very Complex).
     - Contact cleartrial-support_ww@oracle.com or your Clinical Services Director and request that the therapeutic area/indication be added.
5. Add a description or note.
6. To save the study, click **Save**.

   or

   To create a plan for the study, click **Create Plan**.

## Use the Plans Screen to Create or Edit a Plan for a Study

1. From the Edit menu, select **Plans**.

   The Plans screen appears.

2. Filter the plans as necessary. For more information, see Filtering Allows You to Show or Hide Items Based on Criteria.

### Creating or Editing a Plan

1. From the Plans screen, click **New**.

   The Choose Study and Plan Template dialog box appears.

   a. Select the radio button of the study for which to create a plan.

   b. Select the radio button corresponding to the template to use.

   c. Click **Ok**.

      The Create Plan screen appears.

      or

      Select the plan checkbox and click **Edit**.

      The Edit Plan screen appears.

2. Enter general information.

   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Plan Screen (Overview Tab).

3. Enter short and long descriptions.

4. Specify currency options. For more information, see Select Currencies and Exchange Rate Options.

5. Define other factors, such as special handling considerations including radioactivity, and study difficulty issues.

6. Add a note. For more information, see The Notes Feature Allows You to Annotate Every Page of Your Plan.

7. To save the plan, click **Save**.

   or

   To continue defining plan assumptions, click **Next**.

## A Template Is a Reusable Plan that Serves as a Starting Point

Using a template to create a plan saves time by storing frequently used values and choices. Templates also enforce standard operating procedures. Unlike a copy of a plan, which remains linked to its original study, you can create a plan based on a template for any study.

### Viewing the Templates You Can Use

1. From the Edit menu, select **Templates**.

   The Templates screen appears.

2. Filter the templates as necessary. For more information, see Filtering Allows You to Show or Hide Items Based on Criteria.

### Creating a New Template

1. On the Templates screen, click **New**.

   The Select Template Defaults dialog box appears.

2. Select the sponsor, phase, therapeutic area, and indication from the drop-down lists.

   These are the defaults the application uses when you create a plan based on this template. You can override these values in your plan, or change the defaults by editing the template.

3. Click **Ok**.

   The Create Template screen appears.

4. Enter or override the information shown on the Overview tab.

   - For more information about a field, click the field name.
   - For more information about the screen, see Template Screen Fields.

5. Click **Next** to display the next tab or click a specific tab. Grayed-out tabs are not available.

6. Work through the tabs until you have completely defined the template.

7. Click **Save**.

### Editing a Template

1. On the Templates screen, select a template checkbox click **Edit**.

   The Edit Template screen appears.

2. On the Overview tab, edit the information.

3. Step through the rest of the tabs by clicking **Next** or a specific tab. Grayed-out tabs are not available.

4. Add a note. For more information, see The Notes Feature Allows You to Annotate Every Page of Your Plan.

5. To save the changes to the template, click **Save**.

## Group Related Plans into a Portfolio

You can use portfolios to group plans by study, product, phase, or indication. Portfolios provide aggregate forecasts, such as monthly budget, monthly resource demand, and time lines across multiple plans. You can also see the effect of adjusting start and end dates.

Portfolios allow you to:

- Obtain visibility into multiple project plans.
- Create what-if scenarios for adding, removing, or delaying studies.
- Assess the financial feasibility of acquiring new compounds.
- Decide which studies to conduct.

After you have created a portfolio, you can:

- Develop a forecast for a full set of studies within a given budget cycle (1-year, 3-years, 5-years, and so on).

- Assess the impact on your budget of including, excluding, or delaying a particular plan or study.
- View the resulting monthly budgets, resource requirements, cycle times, and milestones across a group of studies.
- Account for the likelihood that a plan will come to fruition by discounting the costs associated with the plan.
- Make on-the-fly adjustments and see the immediate impacts on budgets and resource requirements.

You can exclude plans from a portfolio to see how the exclusion affects the overall fees, costs, and hours of a portfolio. When you exclude a plan from the portfolio, it remains listed in the portfolio with a line through it and it can be included again.

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**Note:** Portfolios are designed for rapid scenario planning, not for precise, to-the-penny forecasting.

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### Viewing the Portfolios You Can Use

1. From the Edit menu, select **Portfolios**.

   The Portfolios screen appears.

2. Filter the portfolios as necessary. For more information, see Filtering Allows You to Show or Hide Items Based on Criteria.

### Creating or Editing a Portfolio

1. On the **Portfolios** screen, click **New**.

   The Create Portfolio screen appears.

   or

   Select the portfolio checkbox, and click **Edit**.

   The Edit Portfolio screen appears.

2. On the **Overview** tab, enter a name for the portfolio, short and long descriptions, and the currency to use for portfolio reports.

   - Portfolio reports show all values for all plans in the portfolio rolled up into the single default reporting currency. Each plan in the portfolio uses its own exchange rate rules to convert from the plan values to the reporting currency. When you generate a report, you can override the currency.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Portfolio Screen (Overview Tab).

3. To display the Plans screen, click **Next**.

   or

   Click a specific tab. Grayed-out tabs are not available.

4. On the **Plans** tab, add plans to or remove plans from the portfolio or include or exclude plans from the portfolio.

   - You cannot add more than 200 plans to a portfolio.

- After a plan has been added to a portfolio, it is automatically included, which means that the costs and milestones associated with the plan are added into the portfolio.
- You can see the effect of postponing one or more plans by specifying a **Start Offset**.
  - To adjust the start date forward (earlier), enter a negative number.
  - To postpone a plan, enter a positive number.
  - This feature does not make adjustments for inflation. This is because the billing rate year associated with a plan does not change when you use Start Offset.
- In the **Probability** field, you can specify the probability of a plan being implemented. The application reduces the costs associated with the plan according to the percentage. For example, if you set the probability to 50%, the application adds half of the plan's costs to the portfolio. The plan itself is not affected.

5. On the **Summary** tab, review the portfolio.
   - You can adjust the time frame by constraining the start and end dates, and you can include or exclude particular plans.
   - The Summary tab reflects only costs and hours from included plans. Costs and hours from excluded plans are not added to the costs and hours of the portfolio.
   - If any of the included plans has a probability of less than 100%, the costs and hours are reduced accordingly. For example, if you set probability to 50%, the costs and hours shown reflect only half of the costs and hours.
   - If any of the included plans have an offset start date, the costs and hours associated with the plan begin on the offset date, not on the original start date of the plan.
   - The Cost Distribution graph provides a view of when costs occur over the time range specified. The shaded blue area represents the time frame you selected.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Portfolio Screen (Summary Tab).
6. To print the Portfolio Summary report, click **Print**.
7. On the **Reports** tab, generate additional reports.
   - You can view each report in a separate window, print it, export it to Microsoft Excel, or convert it to PDF.
   - The reports reflect only costs and hours from included plans. Costs and hours from excluded plans are not added to the costs and hours of the portfolio and, therefore, do not appear in reports.
   - If any of the included plans have a probability of less than 100%, the costs and hours are reduced accordingly. For example, if you set probability to 50%, the costs and hours reflect only half of the plan's costs and hours.
   - If any of the included plans has an offset start date, the costs and hours associated with the plan begin on the offset date, not on the original start date.

- For more information about a field, click the field name.
- For more information about the screen, see Create/Edit Portfolio Screen (Reports Tab).

8. Click **Save**.

## Deleting a Product, Study, Plan, Template, or Portfolio

To delete an item, click **Delete**.

You can delete a single, multiple, or all items displayed on a screen. If you want to delete multiple items, use filtering options to group and display them for easier deletion.

Deleted data is not removed immediately. Rather, the application marks the data as deleted and then purges it on a scheduled basis.

Automatic purging, which takes place nightly, permanently removes items that have been deleted more than a specified number of days prior to the current date.

## Restoring a Product, Study, Plan, Template, or Portfolio

1. Clear the **Active <items> Only** filter.

   Either choose to display all items, or use a defined filter that has the **Include deleted items** option selected to display deleted items. If you want to restore multiple items, use filtering options to group and display them.

2. Select the checkbox(es) of the deleted item(s).
3. Click **Restore** to revert the items to their state before deletion.

# 2
# Working with Plans

After you create a plan, you enter assumptions using the tabs on the Edit Plan screen. By working through these tabs, you can specify all the information related to your plan, in the level of detail determined by your edit mode.

## Roadmap: Creating a Plan

***Table 2–1 Roadmap: Creating a Plan***

| Step | Action | Description |
|---|---|---|
| 1 | Create a product. | **1.** From the Edit menu, select **Products**.<br>The Products screen appears.<br>**2.** Click **New**.<br>The Create Product screen appears.<br>**3.** Edit the fields as necessary. For more information about the field, click the field name.<br>**4.** Click **Save**.<br>The application adds the product to the Products screen. You can now use this product to create studies. |
| 2 | Create a study. | **1.** From the Edit menu, select **Studies**.<br>The Studies screen appears.<br>**2.** Click **New**.<br>The Create Study screen appears.<br>**3.** Edit the fields as necessary. For more information about the field, click the field name.<br>**4.** Click **Save**.<br>The application adds the study to the Studies screen. You can now use this study to create plans. |

*Table 2–1 (Cont.) Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 3 | Create a new plan. | 1. From the Edit menu, select **Plans**.<br>The Plans screen appears.<br>2. Click **New**.<br>The Choose Study and Plan Template dialog box appears.<br>3. Select the study for which you are creating a plan.<br>4. Select a template.<br>5. Click **Ok**.<br>The Create Plan page appears.<br>6. On the Overview tab, enter general information about the plan. For more information about a field, click the field name.<br>7. Click **Next**.<br>The data entry screen for the next tab appears. |
| 4 | Enter your assumptions for the plan. | 1. Continue entering your assumptions tab by tab.<br>The number of assumptions you can enter correspond with the edit mode you selected. The higher the edit mode, the more assumptions possible. For more information, see xxtopic. |
| 5 | Save the plan. | 1. Click **Save**. |

*Table 2–2 Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 1 | Create a product. | 1. From the Edit menu, select **Products**.<br>The Products screen appears.<br>2. Click **New**.<br>The Create Product screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the product to the Products screen. You can now use this product to create studies. |
| 2 | Create a study. | 1. From the Edit menu, select **Studies**.<br>The Studies screen appears.<br>2. Click **New**.<br>The Create Study screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the study to the Studies screen. You can now use this study to create plans. |

*Table 2–2 (Cont.) Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 3 | Create a new plan. | 1. From the Edit menu, select **Plans**.<br>The Plans screen appears.<br>2. Click **New**.<br>The Choose Study and Plan Template dialog box appears.<br>3. Select the study for which you are creating a plan.<br>4. Select a template.<br>5. Click **Ok**.<br>The Create Plan page appears.<br>6. On the Overview tab, enter general information about the plan. For more information about a field, click the field name.<br>7. Click **Next**.<br>The data entry screen for the next tab appears. |
| 4 | Enter your assumptions for the plan. | 1. Continue entering your assumptions tab by tab.<br>The number of assumptions you can enter correspond with the edit mode you selected. The higher the edit mode, the more assumptions possible. For more information, see xxtopic. |
| 5 | Save the plan. | 1. Click **Save**. |

*Table 2–3 Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 1 | Create a product. | 1. From the Edit menu, select **Products**.<br>The Products screen appears.<br>2. Click **New**.<br>The Create Product screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the product to the Products screen. You can now use this product to create studies. |
| 2 | Create a study. | 1. From the Edit menu, select **Studies**.<br>The Studies screen appears.<br>2. Click **New**.<br>The Create Study screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the study to the Studies screen. You can now use this study to create plans. |

**Table 2–3 (Cont.) Roadmap: Creating a Plan**

| Step | Action | Description |
|---|---|---|
| 3 | Create a new plan. | 1. From the Edit menu, select **Plans**.<br>The Plans screen appears.<br>2. Click **New**.<br>The Choose Study and Plan Template dialog box appears.<br>3. Select the study for which you are creating a plan.<br>4. Select a template.<br>5. Click **Ok**.<br>The Create Plan page appears.<br>6. On the Overview tab, enter general information about the plan. For more information about a field, click the field name.<br>7. Click **Next**.<br>The data entry screen for the next tab appears. |
| 4 | Enter your assumptions for the plan. | 1. Continue entering your assumptions tab by tab.<br>The number of assumptions you can enter correspond with the edit mode you selected. The higher the edit mode, the more assumptions possible. For more information, see xxtopic. |
| 5 | Save the plan. | 1. Click **Save**. |

**Table 2–4 Roadmap: Creating a Plan**

| Step | Action | Description |
|---|---|---|
| 1 | Create a product. | 1. From the Edit menu, select **Products**.<br>The Products screen appears.<br>2. Click **New**.<br>The Create Product screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the product to the Products screen. You can now use this product to create studies. |
| 2 | Create a study. | 1. From the Edit menu, select **Studies**.<br>The Studies screen appears.<br>2. Click **New**.<br>The Create Study screen appears.<br>3. Edit the fields as necessary. For more information about the field, click the field name.<br>4. Click **Save**.<br>The application adds the study to the Studies screen. You can now use this study to create plans. |

*Table 2–4 (Cont.) Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 3 | Create a new plan. | **1.** From the Edit menu, select **Plans**.<br>The Plans screen appears.<br>**2.** Click **New**.<br>The Choose Study and Plan Template dialog box appears.<br>**3.** Select the study for which you are creating a plan.<br>**4.** Select a template.<br>**5.** Click **Ok**.<br>The Create Plan page appears.<br>**6.** On the Overview tab, enter general information about the plan. For more information about a field, click the field name.<br>**7.** Click **Next**.<br>The data entry screen for the next tab appears. |
| 4 | Enter your assumptions for the plan. | **1.** Continue entering your assumptions tab by tab.<br>The number of assumptions you can enter correspond with the edit mode you selected. The higher the edit mode, the more assumptions possible. For more information, see xxtopic. |
| 5 | Save the plan. | **1.** Click **Save**. |

*Table 2–5 Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 1 | Create a product. | **1.** From the Edit menu, select **Products**.<br>The Products screen appears.<br>**2.** Click **New**.<br>The Create Product screen appears.<br>**3.** Edit the fields as necessary. For more information about the field, click the field name.<br>**4.** Click **Save**.<br>The application adds the product to the Products screen. You can now use this product to create studies. |
| 2 | Create a study. | **1.** From the Edit menu, select **Studies**.<br>The Studies screen appears.<br>**2.** Click **New**.<br>The Create Study screen appears.<br>**3.** Edit the fields as necessary. For more information about the field, click the field name.<br>**4.** Click **Save**.<br>The application adds the study to the Studies screen. You can now use this study to create plans. |

*Table 2–5 (Cont.) Roadmap: Creating a Plan*

| Step | Action | Description |
|---|---|---|
| 3 | Create a new plan. | 1. From the Edit menu, select **Plans**.<br>The Plans screen appears.<br>2. Click **New**.<br>The Choose Study and Plan Template dialog box appears.<br>3. Select the study for which you are creating a plan.<br>4. Select a template.<br>5. Click **Ok**.<br>The Create Plan page appears.<br>6. On the Overview tab, enter general information about the plan. For more information about a field, click the field name.<br>7. Click **Next**.<br>The data entry screen for the next tab appears. |
| 4 | Enter your assumptions for the plan. | 1. Continue entering your assumptions tab by tab.<br>The number of assumptions you can enter is determined by the edit mode you selected. The higher the edit mode, the more assumptions you can enter. |
| 5 | Save the plan. | 1. Click **Save**. |

## Creating or Editing a Plan

1. From the Plans screen, click **New**.

   The Choose Study and Plan Template dialog box appears.

   a. Select the checkbox of the study for which you want to create a plan.

   b. Select the radio button corresponding to the template to use.

   c. Click **Ok**

      The Create Plan screen appears.

   or

   a. Select the plan checkbox and click **Edit**.

      The Edit Plan screen appears.

2. Enter or edit the information on each tab.
3. Add a note.
4. To save the plan, click **Save**.

   or

   To continue defining plan assumptions, click **Next**.

## Enter General Information on the Overview Tab

The Overview tab includes basic information about the plan. Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.

- For more information about the screen, see Create/Edit Plan Screen (Overview Tab).

## Complete the General Information Section

1. In the **Plan Name** field, enter a name for the plan.
   - Oracle recommends that a plan name be a combination of the study name and the version of the plan that you are creating. Your team should establish a standard naming convention for your plans and templates.

     For example, if you create multiple plans for a study named CLARITY, you might name the first version of the study, Clarity version 1. The second version would be Clarity version 2, and so on.
2. To select the **Project Activity Start Date**, click the calendar icon.

   For studies that are outsourced (in whole or in part), the Project Activity Start Date is the date on which any service provider on the study will begin billable work on the project. For studies conducted internally by the sponsor, the Project Activity Start Date is the date on which project initiation activities will begin utilizing sponsor personnel.
   - The value for the **Start pre-study planning** field defaults to three months prior to the Project Activity Start Date. However, you can override this date to any date prior to the Project Activity Start Date.
   - If you change the project activity start date after entering other information, a warning icon appears. Clicking the icon displays a message stating all dates will be adjusted according to the new start date.
3. Select the status of the plan from the **Status** drop-down list.

   The application fills the **Status** field with the status corresponding to the plan currently. Study statuses include:
   - **Incomplete**—Basic assumptions have not been set for the plan.
   - **Draft**—All input questions of the selected edit mode have been answered, but the plan owner or creator might still be working on the plan.
   - **Final**—All input questions have been answered and the plan owner believes the plan will be used to conduct the clinical study. However, the plan has not yet been approved.
   - **Approved**—The plan has been approved and is ready to go out as part of an RFP or proposal or to be used to conduct the trial.
   - **RFP**—The plan has been approved and included as part of an RFP.
   - **Agreement reached; not started—**An agreement has been reached on the plan and it is under contract (if an outsourced study) or ready for study activities to begin (if an internal sponsor-executed study).
   - **In progress**—The study has begun and is operating according to this plan.
   - **Study Complete—**The study has ended.
   - **Archived**—The plan is being preserved for historical purposes only.
4. Select an outsourcing option.
   - **Conducted Internally**—The study will be performed internally by the sponsor, with no outside service providers. This sets all responsibility radio buttons to Sponsor throughout the tabs for the plan.

- **Outsourced**—The entire study will be outsourced to an external service provider (excluding oversight of that service provider). This sets all responsibility radio buttons to Vendor.
- **Combination**—Some of the study tasks (in addition to Oversight) will be performed by the sponsor, while others will be done by one or more external service providers.

## Specify Plan Descriptions

In the **Short Description** and **Long Description** fields, enter meaningful descriptions that might help you recognize a particular scenario or remind you of the purpose of the plan when you view a list of plans.

## Select Currencies and Exchange Rate Options

1. From the **Default Modeling Currency** drop-down list, select the currency to use to enter most costs, determine the default value for monetary assumptions, and display on the Labor, Costs, Payments, and Summary tabs.

   **Note:** You can enter monetary assumptions in the currency of your choice at a later time.

2. From the **Default Reporting Currency** drop-down list, select the default currency for reports.

   **Note:** When you generate a report, you can choose any supported currency.

3. Indicate the option to use for exchanging or converting between currencies:
   - **As of (specified date)**—Select a specific date for calculating exchange rates. If the application does not have rates for the specified date, the date defaults to the first prior date with exchange rates.
   - **Defined in (global exchange rates table)—**Choose a published and named set of rates that can be shared across plans.
   - **As specified here...—**Override one or more exchange rates by clicking the link to launch the Override Currency Exchange Rates dialog box. If you have previously overridden exchange rates, the application removes the overridden values and restores all values to the exchange rates for the newly selected date.
   - **As of plan created date—**This is the recommended option for templates. Indicates that, for each plan created from the template, the exchange rates date defaults to the latest available date.

## Specify Other Factors

1. From the **Drug Storage** drop-down list, define other factors, such as special handling considerations and study difficulty issues.
2. If the product or compound is radioactive, select the **Radio Labeled** checkbox.

### Select the Study Difficulty

Specify study difficulty when there are unusual circumstances about the trial that make aspects other than monitoring and data management more difficult than most clinical studies. This is rare.

The difficulty to which the Drug Storage field refers applies to other aspects of the study (site training, multiple locations, unusual monitoring conventions, sponsor micro management, and so on) not covered by the usual assumptions. For example:

- Several sites might require more than one location to visit or additional interaction with several clinical investigators or their staff (for example, pharmacy or hospital medical unit or record room).
- Sites might be approved and ready to receive a study drug in a very short time, requiring exceptional effort on the part of the vendor. Drug accountability requirements might be atypical.

# Specify Investigation Sites and Languages on the Locations Tab

Use the Locations tab to specify locations for investigation sites and enrolling subjects and to select languages for document translations. The application suggests languages based on the locations specified. You can add or remove languages/dialects as needed. You can translate (and back-translate) all documents, or no documents, or specify which documents are to be translated.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Locations Tab.

## Add a Location to a Plan

1. On the Locations tab, click **Add Location(s)**.

   The Choose Locations dialog box appears.

2. Filter the list by region or country.

   When adding locations in which you will conduct a study, Oracle recommends that you select either regions (if you are not sure of the exact countries) or specific countries (if you know which countries in which the study will be conducted). The application does not prohibit mixing regions and countries, but this practice is not recommended.

3. Select the checkboxes of the locations to add.
4. Click **Ok**.

   The application adds the location to the list of locations.

5. For each location, in the **Number of Sites** text box, enter the number of sites.
6. In the **Subjects to Randomize** text box, enter the number of subjects to be given the study drug/device or an alternative treatment (for example, a placebo).

   This field should contain only the number of subjects that will actually be enrolled in the trial. For example, if the protocol calls for 1000 subjects to be randomized, enter 1000.

7. In the **Avg Grant Amount** text box, enter the amount to be paid to each investigator in this location for each subject enrolled in the study. Select the currency from the drop-down list.

   - Do not include payments made for screen failures, university-related overhead, or other overhead associated with certain sites, or inflation. All of these items are accounted for on the Site tab.
   - The application includes the total for investigator grant payments as a pass-through cost in the budget.
   - If you do not know the grant amount for a location, Oracle recommends that you enter your best estimate or zero. If you enter zero for the grant amount for one location, Oracle recommends that you enter zero for all locations, so that the final budget does not include the grant.
   - The application estimates costs based on completed and partially completed subjects. A completed subject gets 100% of the investigator grant amount. A dropped subject is estimated to require payment to an investigator of 75% of the grant. Oracle expects the average to be closer to 75% of all visits completed since dropped subjects must return for a termination visits (generally a repeat of the last subject visit regardless of where the subject terminates).
   - You can adjust these pass-through costs if specific knowledge of the prorated grant budget is known. For endpoint studies, be sure to include the grant costs for both the standard treatment and the full extended treatment schedules
   - For some rare disease trials, grants might run as high as 500,000 USD per subject. However, this is not typical. Check that you have entered a per-subject amount. This field must contain a value between 0 and 500,000 USD (or the equivalent in another currency).

8. For a MOH / FDA delay, modify the number of days.

   - This field displays the expected Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time frame for each location.
   - This value represents the number of elapsed days required in each location to obtain approval to proceed with the study. The application uses this number with other statistical factors to forecast the number of sites that should be approved by any particular date.
   - The application also uses this forecast to suggest and validate assumptions regarding the first subject enrolled date (FSI / FPI), the enrollment distribution type, and the first quartile enrollment objectives You can override this value if necessary to reflect changes or other knowledge concerning the regulatory delay in any particular location.
   - You can also override the suggested FSI date, enrollment distribution type, and first quartile objectives, which are based on the site approval forecast derived in part from this value.
   - If a large number of sites are in countries with very long MOH / FDA approval times, there may not be enough sites approved at the First Subject Enrolled date to meet enrollment targets. This could require extending the enrollment period, reducing the expectation of enrollment by the first quartile, or moving the First Subject Enrolled date to a later date. Alternatively, this could suggest that the study would benefit from the addition of sites in locations with shorter MOH / FDA delays.

## Remove a Location from a Plan

1. Select the checkboxes of the locations to remove.
2. Click **Remove Location(s)**.

   The application removes the location from the list of locations.

## Add Languages to a Plan

The Locations tab displays the languages into which it is likely that study documents will be translated and allows you to add or remove languages and dialects as needed. The application suggests languages based on the locations specified. You can translate (and back-translate) all documents or no documents or specify which documents to translate.

1. Click A**dd Language(s)**.

   The Choose Additional Languages dialog box appears.
2. Select the checkboxes of the languages to add.
3. Click **Ok**.

   The languages appear in the Languages section.

   If you add a language not suggested by the application, the text, <User specified>, appears in the Locations column. For example, a study being conducted in the USA might require translation into French, for portions of Maine, and Spanish, for parts of the Southwest. Or a study conducted in India, where there are over 27 languages, might require additional translations.
4. In the **Dialects/Variations** column, increase or decrease the number that appears to indicate the number of study document translations required.
5. For each language, specify which documents to translate.

   If you select **Specified Documents**, the Document Translations Required dialog box appears.
6. For each document type:
   - To translate the document, select the **Translate** checkbox.
   - To translate the document back into the original language, select **Back Translate**. Comparison of a back-translation with the original text is sometimes used as a check on the accuracy of the original translation.
   - To prevent the translation cost from being automatically calculated, select **As Pass-Through Cost**. You can then add the translation cost on the Costs tab.
7. Click **Ok**.

   The application calculates the number of translations required.

## Deleting Languages from a Plan

1. Select the checkboxes of the languages to remove.
2. Click **Remove Language(s)**.

   The application deletes the language from the list of selected languages.

# Provide Site Approval and Visit Details on the Site Tab

On the Site tab you specify details regarding how sites are identified, initiated, monitored, and closed out. Your current edit mode determines the choices available.

- For more information about a field, click the field name.
- For more information about the screen, see Site Tab.

## Global Versus By Location Specifications

Because these values can differ from location to location, you can specify values both globally and by location. You first specify the values common to all locations. Then you specify values for the locations whose assumptions differ. It is not necessary to save specific values for each location in the study, only those that differ from those specified for All Locations.

In the **Site Information** section, from the **Values apply to** drop-down list, select **All Locations** or a specific location from the list.

For example, if the site-related values for four out of five locations in the study will be the same, select **All Locations**, specify the values common to the four locations, and click **Save**. Then select the specific location whose values differ, specify the values, and click **Save** or **Next**.

When one or more locations have been overridden, the phrase **Other than <location>, <location>, ..., and <location>** appears to the right of the **Values apply to** drop-down list, listing each location whose values are not represented by those currently displayed. Click this phrase to restore one or more of the listed locations to the values used by All Locations.

> **Note:** All Locations means those locations for which the user has not provided specific values or overridden the values. The application uses these values when calculating effort and costs for any location currently defined or later added to the plan, unless you have defined separate values for that specific location.

## View or Edit the Default Site Approval Schedule for a Location

1. In the **Site Approval** section, click a location's **Clear Trial Default Schedule** link.

   The Edit Site Approval Schedule dialog box appears.

   The Site Approval Schedule section shows the default values on the left. The Sites column in the User Defined section provides the option of specifying the schedule week by week.

2. Accept the default schedule by clicking **Close**.

   or

   Edit the **User Defined** fields to customize the site approval schedule for the location.

   - For more information about a field, click the field name.
   - For more information about the screen, see Edit Site Approval Schedule Dialog Box.

3. Click **Save**.

The Site tab appears. The **Site Approval Schedule** column for the location edited now contains the **User Defined Schedule** link, indicating that you have modified the schedule and allowing you to make additional changes to the schedule.

4. To restore the default schedule, click **Restore Defaults.**

## Enter Site Information for a Location

When adding locations, Oracle recommends that you select regions if you are not sure of the exact countries. For budgeting purposes, you can map reporting locations to regions with the Reporting Regions feature.

1. In the **Site Information** section, from the **Values apply to** drop-down list, select **All Locations** or a specific location from the list.

   This choice determines whether your entries apply to all locations or only the selected location.

2. For each field, enter the percentage of sites to which the information applies.

   The application calculates and displays the number of sites to which the percentage applies.

### Costs Assigned to the Sponsor

The **Percent of sites identified by sponsor** field allows you to specify the percentage of study sites (investigators) that were identified by the sponsor. These may be sites that were used in previous studies or that the sponsor has a special relationship with. The cost of identifying these sites is assigned to the sponsor rather than to the vendor responsible for obtaining all of the regulatory documents and approving the sites.

### Working with Site Visits

Site visits add a significant cost to your plan and can be performed pre-study, at site initiation, and at study closeout. You can specify the percentage of the sites that require in-person visits versus phone-based visits.

- **Pre-study visits**—If a site was used within the last year by either the sponsor or the monitoring vendor, it usually does not need a pre-study site visit. Refer to your own SOPs regarding pre-study visits.
- **Site-initiation visits**— This is normally equal to or less than the number of sites expected to participate in the study. On rare occasions, the study project manager might allow additional sites to be initiated (as back-ups) but, generally, will not approve the drug to be shipped unless the plan is to activate the sites later in the enrollment period.
- **Close-out visits**—Normally, all sites participating in the study need a close out visit when all subjects have completed the study. Therefore, the default for the field is 100%. However, there are some studies where this does not apply. For example, in Phase IV trials not done under an IND, it may not be necessary to close out the sites. In that case, the value for Close-out visits is 0%.

### Specify the Number of Grant Payments per Site

Clinical sites are paid based on certain milestones, subjects enrolled, data collected, and so on. In the **Number of grant payments per site** field, determine the number of payments to be made to investigators (average) over the course of the study. The application derives a default value for this field once the study duration can be calculated. This value assumes quarterly payments. If this value is not appropriate, override this application-suggested value. Otherwise, accept the default. The application updates this value as study assumptions change. Your overriden values are maintained.

### Specify the Percent of Sites Using Local Monitoring

Local monitoring refers to sites assigned to monitors that work in the same city as the investigators. These sites do not require overnight travel or lengthy travel time to and from the site (generally less than 30 minutes each way).

### Specify the Percent of Sites Requiring Overhead

Many sites require an overhead beyond the standard investigator grant. For example, university sites and other independent sites without university affiliations might require overhead. If you have not included this in the investigator grant amount on the Locations tab, specify the percentage of sites that require this additional overhead. For example, if you entered an investigator grant of $10,000 with 50% overhead at 4 of 10 sites requiring overhead and 25% overhead at the remaining 6 sites, the percentage is 35%.

### Assign Outsourcing Responsibilities

Use the radio buttons in the **Responsibilities** section to enter the outsourcing option for each group of assignable tasks.

-
- **Sponsor**— Assigns all tasks in that group to the study sponsor.
- **Vendor**— Initially assigns all tasks in that group to the primary vendor specified on the Provider tab.
- **Mixed**— Allows you to assign some tasks in that group to a vendor and other tasks in that group to the study sponsor on the Assignment tab.
- **N/A**— None of the tasks in that group will be performed, if they are optional.
- To assign a combination of some responsibilities to sponsor and some to vendor, you must change your selection on the Overview tab to **Combination**.

If you selected **Conducted Internally** on the Overview tab, you cannot assign any of the responsibilities to Vendor. If you have selected **Outsourced**, you cannot assign any of the responsibilities to Sponsor.

## Specify the Study Enrollment Details on the Subject Tab

The Subject tab includes information about the expected enrollment period and subject enrollment rate, the treatment schedule, and the First Subject In Date (FSI/FPI).

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Subject Tab.

## Override the Estimated Date of the First Subject First Visit (FSFV)

The First Subject In Date (FSI/FPI) value is the date that the First Subject First Visit (FSFV) is expected to take place. The application estimates this date based on the study sites approval schedule. However, you can override the suggested value with any date later than the Project Activity Start Date.

If you change the Project Activity Start Date after this section has been completed and saved, the following might have to be addressed:

- If you or another user accepted the default First Subject In (FSI) date, the application updates this date according to the changed Project Activity Start Date.
- If you or another user changed the FSI date, any change in the Project Activity Start Date updates the FSI date that was entered. You must revisit and revise any dates that have been overridden.
- If you select a start date that is greater than the user-specified FSI date, a warning appears in the FSI date indicating that the date is before the Project Activity Start Date.

## Define the Treatment Phase Start Date

In this section, you define the relationship between the Project Activity Start Date and the First Subject In (FSI) date.

For studies that are outsourced (in whole or in part), the Project Activity Start Date is the date on which a service provider begins billable work on the project. You selected this date on the Overview tab. For studies conducted internally by the sponsor, the Project Activity Start Date is the date on which project initiation activities begin.

## Manage Location-specific Values

You can specify the expected First Subject In (FSI) date for each location globally. The application applies changes you make to the system-suggested FSI date to each location based on the number of days you shifted the date. If you choose to manage the location-specific dates and enrollment periods per location, a dialog box appears for you to enter a specific date and enrollment period for each location.

## Enter Screening, Failure Rates, Drops, and Payments Options

The **Subjects to randomize** field displays the number of subjects expected in the selected location or for all locations. You can specify a percentage of the total subjects randomized to be screened as alternate subjects and a stipend to pay to alternate subjects.

### Specify the Screen Failure Rate

In the **Screen failure rate** field, enter the percentage of screened subjects expected to fail to become study participants.

For example, if 1 out of every 5 potential subjects is expected to fail the screening, the screen failure rate is 20%. If the number of subjects to randomize is 100, the number of subjects to screen is 125. This value cannot be greater than 99.99%. Oracle recommends entering a value between 0% and 50%. The calculation for this field is as follows:

Number Of Screen Failures Expected = Number of Subjects to be Randomized / (100 - Percent of Subjects that Fail Screen).

For example, if the protocol requires 100 subjects to be randomized, and it is expected that for every four subjects screened, one will fail, the screen failure rate is 25%. You would need to screen at least 133 subjects. 33 screen failures = 100 subjects to randomize / 133 * 0.25.

### Specify the Subject Drop Rate

In the **Subject drop rate** field, indicate the percent of subjects you expect to not complete a full CRF due to early termination. The application uses this percentage as it calculates the data that needs to be monitored and entered into the database.

For example, if you expect only three out of four subjects randomized to complete the study, the drop rate is 25%. If 100 subjects are randomized and you expect a 25% drop-rate, only 75 subjects are expected to complete the study.

Sponsors likely do not have a schedule developed during the bidding or budgeting phase, so the application estimates 75% of the costs will be incurred for dropped subjects. These are pass-through costs and can only be estimated. However, you can easily adjust these costs if more exact amounts are known.

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**Note:** The actual costs per subject are based on a prorated schedule that is given to the investigator prior to the study start.

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# Specify Subject Treatments on the Treatment Tab

On the Treatment tab, you can add, edit, copy, and delete one or more treatments within a plan. You can model single or multiple treatment arm trials, using either parallel or cross-over designs. For late-stage parallel design trials, you can also model endpoint studies. Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Treatment Tab.

## Specify Study Characteristics

In the **Study Characteristics** section, you specify whether this study uses a parallel or cross-over design, the cost per overnight stay, or bednight, and whether to use an electronic subject diary.

### Choosing a Parallel or Cross-over Treatment Plan

Parallel designs are those in which some subjects receive one of the defined treatments while other subjects receive one of the other defined treatments, and all subjects receive treatments during the same period. You can add treatments to Phase II through IV studies and Phase I oncology and vaccines studies with a parallel trial design.

Depending on your selection in the **Trial Design** field, you can also enter baseline and washout assumptions.

### Defining an Endpoint Study

An endpoint study is a study in which all patients conclude their participation in the study on or near the same calendar date. The **Endpoint Study** field is only available for phase II through IV studies and Phase I oncology and vaccine studies.

### Why Include an Electronic Subject Diary?

Many studies require the subject to keep a daily diary. When these diaries are electronic, the data can be uploaded directly into the study database. Data entry and monitoring review of electronic diaries require less time than for paper-based diaries. Third-party vendors provide the electronic diaries.

## Define the Treatment Schedule

You can add, edit, copy, and delete treatments. You can add up to five treatments for a study.

1. In the **Treatment(s)** section, click **Add**.

   A Treatment Parameters section appears. You can specify per-location assumptions for the selected treatment, customize the treatment schedule, and record notes relevant to the treatment.

2. Define the treatment parameters.

   - **Treatment duration**—For each subject, enter the treatment length (time-on-trial). For Phase 1 trials, specify the duration in days. For late-stage trials, use weeks.
   - **Visits per subject**—Specify the number of visits for each subject during the treatment. For Phase 1 trials, a visit is a day for which one or more CRF pages are generate or collected. For late-stage trials, a visit is a week. For example, if you are modeling a trial in which patients are seen twice a week, add the number of pages collected at each of the two visits into a single visit in the treatment schedule.

     For Phase 1 (Healthy Volunteers) trials, in which subjects are confined and procedures are performed throughout the day on most or all days of treatment or washout, each day is a visit for the purposes of the application planning algorithms.
   - **Number of bednights—**Specify the number of nights subjects will be confined to the study center during the treatment. The application uses this value to calculate pass-through costs associated with non-procedural services provided (for example, room, meals, and entertainment). If subjects are also confined during the washout period(s), specify the number of bednights during washout separately.
   - **Number of CRF pages per subject**—Specify the number of Case Report Form (CRF) pages to be collected for each subject during this treatment. This value should include quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.
   - **Number of subject diary pages**—Specify how many of the pages collected during the treatment period are subject diary pages.
   - **Number of pharmacoeconomic pages**—Specify how many of the pages collected during the treatment period are pharmacoeconomic pages. These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.
   - **Number of QOL pages**—Specify how many of the pages collected during the treatment period are Quality of Life (QOL) pages, reviewed to see if they have been filled out by the study subjects. These usually require little or no monitoring.

3. Click **Save**.

4. To add more treatments, click **Add**.

   or

   To continue to the next plan tab, click **Next**.

### Copy a Treatment Schedule

When treatments vary only in a few specific ways, you can save time by defining the first treatment with the most common values, then duplicating that treatment and changing only the values that differ.

1. In the **Treatment(s)** section, select the checkbox of a **Treatment Parameters** section, and click **Copy**.

   A new Treatment Parameters section appears that is a copy of the selected treatment.

2. Change the copied treatment as necessary.
3. Click **Save**.

### Delete a Treatment Schedule

1. In the **Treatment(s)** section, select the checkbox of a **Treatment Parameters** section.
2. Click **Delete**.

   The application deletes the section. Deleting a treatment removes all of its associated assumptions.

## Set Study Data Collection and Management Options on the Data Tab

On the Data tab, you specify information regarding the collection and management of study data. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Data Tab.

### Specify Data Collection Options

1. In the **Data Collection** section, from the **Data Collection Method** drop-down list, select the data collection method to apply to the plan.

   - **Paper (Traditional Monitoring)**—Monitors will visit the sites to collect data. To specify that there will be no monitoring, select this data collection method, but in the **Responsibilities** section, set monitoring responsibilities to **N/A**.
   - **Electronic Data Capture**—A sponsor, CRO, or other service provider added to this plan is responsible for EDC management. The application calculates associated direct labor fees and indirect costs based on the selected EDC maturity level you select from the **EDC Maturity Level** drop-down list.
   - **EDC-3rd Party**—You do not want the application to calculate labor fees related to EDC, but instead want to create or adjust pass-through costs to account for these expenditures. Use this option if none of the service providers added to this plan are responsible for EDC management. You can include and assign individual tasks that are excluded by default for EDC 3rd Party on the Assignment tab.
   - **Investigator Site Data Entry**—Data will be keyed into a data capture system or web-based system by someone at the site. This option is not the same as EDC.
   - **Faxed CRFs**—CRFs will be faxed.

2. In step1, if you selected Electronic Data Capture or EDC-3rd Party, from the **EDC Maturity Level** drop-down list, select the stage to apply to the plan.
   - **Stage 1: Pilot/Single Study**—You are actively conducting experimental EDC implementations within a single study or within a very limited number of clinical trials. The primary goal in conducting pilot or single-study EDC implementations is to identify the possible benefits.
   - **Stage 2: Limited Standardization**—You have moved past piloting EDC and have recognized its potential value. Stage 2 tests EDC abilities to full scale and assesses reliability. EDC deployment is typically expanded to other trial phases or different therapeutic areas during this stage.
   - **Stage 3: Standardization**—You have an established standardization for EDC on all new trials over all phases and therapeutic areas. Most clinical trials using paper are doing so only because they began prior to initial EDC implementation and are grand-fathered until they conclude. There is a high level of integration between EDC and other systems such as CTMS, laboratory systems, project management systems, payment systems, and IVRS. During this stage, companies commit to a preferred EDC solution vendor and entertain discussions about forming long-term partnerships with vendors.
   - **Stage 4: Enterprise Deployment**—You have an established enterprise-wide standardization on a single integrated EDC solution and all clinical management systems are fully integrated with the EDC system. EDC solutions found in Stage 4 provide hybrid paper/electronic features that support a limited number of paper records. All note taking is done directly in the system, and all signatures are recorded electronically. A small number of clinical trials, or certain portions of a trial, might still require the use of paper.
3. In the **Query Rate** field, specify as a percentage the average number of queries expected per every 100 pages of CRF data.
   - If you are planning a single treatment arm trial and have estimated in terms of queries per CRF book instead, enter the value obtained by the following conversion:

     (Number of Queries per CRF Book / Number of Pages in the CRF Book) * 100
4. In the **Percent of database data to audit** field, indicate the percent of the database information that must be audited.

   Typically, the vendor required to manage the data is required to audit some percentage of the database. The default for this value is 10%.
5. In the **Minutes for Data Entry per CRF page** field, the application displays the number of minutes required to enter one CRF page into the database, assuming double data entry. The application calculates this value based on the phase and therapeutic indication of the study. You can override this value.
6. In the **Minutes for Data Coordination per CRF page** field, the application displays the number of minutes required to coordinate CRF data. The application calculates this value based on the phase and therapeutic indication of the study. You can override this value.
7. From time to time the vendor who manages the data must transfer the data in electronic format to the sponsor. This can be done at the end of the study or periodically throughout the study. In the **Total number of data transfers** field, enter the number of data transfers to be performed. If the sponsor is performing data management, enter 0.

8. In the **Number of interim analyses to be performed** field, specify the number of interim analyses to be performed. The default value is 0 and Oracle recommends that the value should not be greater than 3.

   An interim analysis is a preliminary look at the study data to determine if there are large differences between treatment groups. Interim analysis can be planned for specified calendar times (for example, quarterly) or when specific numbers of subjects have enrolled in the study to ensure that a sufficient amount of data is available for review.

   Interim analysis typically requires a dedicated monitoring trip at the end of this period to collect data so that the data can be entered into the database and the interim analysis performed. Oracle recommends that you adjust the monitoring schedule if an interim analysis is required for your study.

9. In the **Number of third-party vendors/data sources** field, specify the number of third-party vendors or data sources used to capture study-related data. These vendors or sources are those, other than the CRO, whose data need to be imported or otherwise collected.

10. In the **Total number of data imports from third-party vendors** field, specify the total number of imports from third-party vendors expected throughout the study. This is the total number of imports, not the number expected per third-party vendor.

## Specify CRF Design Options

1. In the **CRF Design** section, specify the number of Case Report Form (CRF) pages that are not duplicates of another CRF page or screen.

   For example, the same AE page that is required at each visit counts as one unique page. The minimum field value is 1.

2. Define the number of screens per CRF page. This is the number of screens needed to capture one paper CRF page.

## Enter Biostatistical Study Assumptions

1. Estimate the number of unique data tables, data listings, and figures and graphs.

   The application estimates a default setting for these fields based on the number of unique pages.

2. Estimate the number of unique PK/PD data tables, data listings, and figures and graphs.

   The application estimates a default setting for these fields based on the number of unique pages.

## Specify Project Management Options

1. Some studies use newsletters to inform the investigators about overall study progress, compare investigators to each other, and provide updates about issues or protocol/CRF interpretation. In the **Number of newsletters per site** field, indicate how many times you expect to generate newsletters.

   For example, if there are 120 sites in a study and you enter 12 newsletters, all 120 sites are expected to receive 12 newsletters each during the enrollment and treatment period of the study.

2. Specify whether to include an ICF Video/DVD.

3. After a study is concluded, you must archive the data for some period of time. In the **Number of years to archive data** field, enter the number of years. Check with your regulatory department for the most current regulations regarding data archiving. The default value is 5 years.

4. If you selected **Electronic Data Capture (EDC)** or **EDC- 3rd Party** as the data collection method, specify the number of online EDC training sessions required. This is not the training that happens at the Investigator Meeting or the initial CRA training. The default value is 3.

## Enter Medical Writing Choices and Timelines

1. In the **Number of pages in the Investigator Brochure** field, specify the number of pages, which can be a few pages to over 250 pages.

   - The Investigator Brochure provides a description of the drug substance or device and the formulation, a summary of the pharmacological and toxicological effects, a summary of information relating to safety and effectiveness in humans, and a description of possible risks and adverse reactions to be anticipated and precautions or special monitoring required.
   - You provide the brochure to investigators and, ultimately, to ethical committees for review. You can use a vendor to help write, edit, print, translate, or distribute the brochure to clinical investigators.
   - The application uses the approximate size of this brochure to calculate costs for the activities related to the production, translation, and distribution of the brochure.
   - Oracle recommends that you enter the total number of pages of your full Investigator Brochure to calculate the effort required to print and distribute the brochure.
   - The default value for this field assumes that the sponsor requires that the full Investigator Brochure be written and edited for each new study.
   - If the Investigator Brochure:
     - Has been previously written, you can de-select the **Write IB** task on the Assignment tab.
     - If the brochure has been written but needs updating, check **Edit IB** on the Assignment Tab.
     - If no updates are required, de-select **Edit IB**.

2. In the **Number of manuscripts** field, enter the number of manuscripts to be created for journal publication. This field must contain a value between 0 and 99.

   A manuscript is something other than the final Clinical Summary Report (CSR) and is generally a document that appears in a peer industry journal. It may be written by the sponsor, a CRO, or an independent medical writer.

3. Set milestones and due dates related to clinical data.

   - In the **Days from LSO/LPO until Database Lock** field, enter the number of elapsed days from last subject observation (LSO / LPO) until the expected database lock. This typically occurs at least eight days after LSO (due to the possibility of a late reportable SAE) and must occur before the Statistical Report date.

     If you selected Electronic Data Capture (EDC) or EDC- 3rd Party as the data collection method, the application calculates the default value based on the

EDC maturity level. The default values are 30 days for Stage 1; 20 days for Stage 2; 12 days for Stage 3; and 8 days for Stage 4. The minimum value this field can accept is 1.

- In the **Days from Database Lock until Statistical Report is due** field, enter the number of elapsed days from the database lock date until the statistical report is expected to be delivered. This is the time by which the assigned provider is expected to have the statistical report completed, expressed in elapsed days from the database lock date.

  If you selected Electronic Data Capture (EDC) or EDC- 3rd Party as the data collection method, the default value is calculated based on the EDC maturity level. The default values are 45 days for Stage 1; 38 days for Stage 2; 36 days for Stage 3; and 34 days for Stage 4.

- In the **Days from Database Lock until Draft Report is due field**, enter the number of elapsed days from the database lock date until the draft clinical report is expected to be delivered. This is the time by which the assigned service provider is expected to have the draft clinical summary report completed, expressed in elapsed days from the database lock date.

  If you selected Electronic Data Capture (EDC) or EDC- 3rd Party as the data collection method, the default value is calculated based on the EDC maturity level. The default values are 73 days for Stage 1; 70 days for Stage 2; 67 days for Stage 3; and 65 days for Stage 4.

- In the **Days from Database Lock until Final Report is due** field, enter the number of elapsed days from the database lock date until the final clinical summary report (CSR) is expected to be delivered. This is the time by which the assigned service provider is expected to have the clinical summary report (CSR) completed, expressed in elapsed days from the database lock date

  If you selected Electronic Data Capture (EDC) or EDC- 3rd Party as the data collection method, the default value is calculated based on the EDC maturity level. The default values are 98 days for Stage 1; 95 days for Stage 2; 90 days for Stage 3; and 85 days for Stage 4.

## Specify SAE Management Options

1. In the **SAE rate as a percent of randomized subjects** field, estimate the number of anticipated Serious Adverse Events (SAEs) as a percent of the total subject population.

   This value yields the expected number of Serious Adverse Events (SAEs) across all subjects over the entire duration of the study.

2. In the **Hours medical monitor will spend with each SAE** field, specify the number of hours a medical monitor will spend with regard to each Serious Adverse Event (SAE).

3. In the **Expected percent of SAE Reports to be expedited** field, enter the percentage of SAE reports to be expedited to regulatory agencies and ethics committees.

4. From the **Provide data to the DSMB** drop-down list, select the frequency with which to report data to the Data Safety Monitoring Board (DSMB).

## Select Uses for an Interactive Voice Response System

1. In the **IVRS (Interactive Voice Response System)** section, select the **IVRS Usage** checkbox that identifies how the Interactive Voice Response System (IVRS) will be used.
2. Check all choices that apply.

## Add Protocol Amendments

You can add expected protocol amendments to your plan. These are common in clinical trials. Planning for these amendments makes the study budget more accurate.

1. In the **Expected Protocol Amendments** section, click the **Add an amendment** link.

   **An amendment is expected to occur** field appears.
2. Specify the number of days before or after a milestone the amendment is expected to occur.
   a. In the **days** field, enter the number of days.
   b. From the first drop-down list, select **before** or **after**.
   c. From the second drop-down list, select the milestone nearest to the date the amendment will occur.

   The application displays the anticipated amendment date to the right of the milestone drop-down to reflect this offset.
3. To add additional protocol amendments, click the **Add another amendment** link.
4. Click **Save**.

   To delete a protocol amendment, click the **x** button to the right of the expected date.

## Assign Outsourcing Responsibilities for Data Collection

1. In the **Responsibilities** section, assign each group of outsourcing tasks to sponsors and vendors.
   - **Sponsor**—Assigns all of the tasks in that group to the study sponsor.

     If you selected Outsourced on the Overview tab, you cannot assign responsibilities to Sponsor.
   - **Vendor**—Initially assigns all of the tasks in that group to the Primary Vendor specified on the Provider tab.

     If you selected Conducted Internally on the Overview tab, you cannot assign any responsibilities to Vendor.
   - **Mixed**—Allows you to assign some of the tasks in that group to a vendor and other tasks in that group to the study sponsor. You do this on the Assignment tab.

     If you want to assign a combination of responsibilities to the sponsor and a vendor, you must change your selection on the Overview tab to Combination.
   - **N/A**—Indicates that none of the optional tasks in that group will be performed.

# Specify Monitoring Frequency, Approach, and Responsibilities on the Monitoring Tab

On the Monitoring tab, specify information about the monitoring frequency, approach, and which responsibilities are outsourced versus internal. You can also manage monitoring schedules globally or for each location. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Monitoring Tab.

## Select the Monitoring Methods

1. In the **Monitoring Methods** section, specify the types of monitoring to be performed.
   - **On-site**—Monitoring is done in person.
   - **Via phone**—Monitoring is done by phone. Phone-based monitoring is typically done only for Phase IV studies or during long follow-up periods.
2. In the **Manage monitoring schedule values** field, specify whether to manage monitoring schedules globally or per location.
   - If you manage monitoring schedules globally, the application applies all of the assumptions entered on the Monitoring tab to all the plan locations in the study.
   - If you manage monitoring schedules per location, you can modify schedules for each location within the study.
3. To select each location and edit the associated monitoring methods and monitoring schedule, click the **Per Location** link.

   The Edit per Location Monitoring Schedule dialog box appears.

   a. Choose the locations from the navigation tree.

   b. For each location, specify the monitoring methods and the associated on-site and phone-based monitoring schedules
4. Click **Ok**.

## Establish the On-Site Monitoring Schedule

In the **On-Site Monitoring Schedule** section, you control the monitoring schedule, the number of visits, and the travel strategy.

1. In the **Monitor every** field, specify the frequency of monitoring visits to the sites in the study during each period of the monitoring schedule.

   For example, if a monitor will visit each site every 4 weeks, enter 4 in this field.

   If the monitoring will continue at the specified frequency through the end of the treatment period, select the **until LSO/LPO** radio button.

   If you want to use a variable monitoring frequency, for example, monitoring every 4 weeks in the beginning of the study, every 2 weeks in the middle of the study, and every 6 weeks at the end of the study, in the **Monitor every** field, enter the frequency for the first period.

   a. Select the **until week** radio button and enter the week at which this frequency ends and a new monitoring frequency begins.

This value specifies the week at which the specified frequency for monitoring changes. This is the week number corresponding to the start of the next monitoring period and must be greater than or equal to the value for the monitoring frequency for the prior period.

b. In the next **Monitor every** field, enter the frequency to be used for the next period (or until the end of the treatment period).

c. Repeat as necessary to define each change in frequency over the course of the monitoring schedule.

2. Override the total number of monitoring visits in the **Total Visits** field, if necessary (for example, if the value in the RFP is different from the generated value).

   - The application derives the default value shown from the total number of sites, monitoring frequency, and subject enrollment rate. You can increase this number to add more monitoring visits. You can also lower the total number of monitoring visits.
   - If you are working with new sites that have limited research experience or where you know that there is a need to accelerate monitoring for some reason, add monitoring visits. For example, if the application calculates 1068 visits and there are 89 sites in the study o which 35 are inexperienced, you might add one additional monitoring visit for these 35 sites. The new number of monitoring visits is 1103.
   - Oracle recommends that the total number of visits selected be as close to the value calculated by the application as possible.

3. From the **Monitoring Travel Strategy** drop-down list, specify the monitoring visit strategy to use.

   - **Spoke monitoring**— The monitors return to their homes or offices after visiting each site. Selecting **Spoke** roughly doubles the average travel time (in hours) for site monitors.
   - **Loop monitoring**— Monitors travel to site 1, then to site 2, then to site 3, and so on, before returning to their homes or offices.
   - Typically, loop visits are more cost efficient. However, monitors often choose not to spend more than five consecutive days in the field without returning home. Therefore, select **Spoke** if monitoring visits average more than three days per visit.
   - Use the Monitoring Schedule chart or the Monitoring section of the Assumptions report to verify the schedule.

## Set Up the Phone-based Monitoring Schedule

In the **Phone-based Monitoring Schedule** section, you control the call schedule, number of calls, and average hours per visit.

1. In the **Call every** field, specify how frequently a monitor will call the sites during each period of the monitoring schedule.
2. If the phone-based monitoring will continue at the specified frequency through the end of the treatment period, select the **until LSO/LPO** radio button.
3. If you want to use a variable monitoring frequency, for example, calling every four weeks in the beginning of the study, every two weeks in the middle of the study, and every six weeks at the end of the study:

a. In the **Call every** field, enter the frequency for the first period.

b. Select the **until week** radio button and enter the week at which this frequency ends and a new monitoring frequency begins. This is the week number corresponding to the start of the next monitoring period and must be greater than or equal to the value for the monitoring frequency for the prior period.

c. Repeat as necessary to define each change in frequency over the course of the monitoring schedule.

   The application calculates the total number of calls to be made, derived from the phone-based monitoring frequency and the subject enrollment rate, and displays it in the **Total calls** field.

4. In the **Average hours per visit** field, specify the average number of hours required to perform a phone-based monitoring visit, including preparation and follow-up activities.

## Define the Monitoring Approach

1. In the **Monitoring Approach** section, enter the following details.

   - **Percentage of time monitors spend in the field**—The application assumes that monitors spend the remainder of their time on site management activities.
   - **Percentage of monitoring done by CRAs (vs. Senior CRAs)**—In complex studies, you might prefer that a Senior CRA perform a larger percentage of the monitoring. If this is the case, decrease the percentage to indicate that less of the monitoring will be done by CRAs.
   - **Percentage of monitoring done by Regional Monitors**—Even when 100% of monitoring is done by Regional Monitors, some site management activities are performed by CRAs or SCRAs. When using Regional Monitors, time allocated for travel is assigned to monitored CRF and site management tasks.

     **Note:** The values in these fields are not related to travel time or distance. The application uses these values to split the effort of monitoring and site management tasks across resources that have different billing rates.

   - **Avg travel time (in hours) for site monitors**—The average number of hours a monitor needs to travel to sites.
   - **Percent of source documentation verification**—Specify the percent of key safety and efficacy data to be source verified. For most studies, this is 100%. Some Phase III and Phase IV studies might not require this rigorous a level of monitoring the study data.
   - **Time to review queried from previous visit (minutes)**—The application calculates a value representing the number of minutes required to re-review queries and CRF data from a previous monitoring visit, based on the therapeutic area and indication selected for the study. You can override this value.
   - **Manage location-specific value**—Enter monitoring approach assumptions per location by clicking the **Edit location specific overrides** link. In the **Edit Per Location Monitoring Approach** dialog box, enter the monitoring approach assumptions by location, overriding global default values.

## Monitor Data through CRF Pages

To determine the number of total CRFs for a study, shown in the Monitored Data section, including a correction for dropped subjects, the application does the following:

- For the first two weeks of enrollment, the application assumes that no subjects drop (therefore, the retention for weeks 1 and 2 is 100%), and that all scheduled CRFs are completed.
- For each week after week 2 of enrollment (for example, the total enrollment period minus the first two weeks), the application starts correcting the total number of CRFs completed by the drop rate.
- **Total CRF pages generated (without subject drops)—**Displays the total number of predicted CRF pages generated, assuming that no subjects drop. It is the sum of all CRF pages entered for each subject visit across all subjects and sites, as defined on the subject treatment schedule.
- **Total CRF pages monitored (accounting for subject drops)**—Displays the predicted CRF pages that will be monitored, accounting for subjects that drop out of the study. The application derives this value from the subject drop rate, which is applied to each week of the study to calculate the subject retention rate.
- The drop rate is assumed to be linear, and the weekly reduction rate is calculated as the overall drop rate divided by the number of weeks after week 2.
- The application takes the number of CRFs that would have been generated each week if no subjects had dropped out of the study, and multiplies it by the retention rate percentages to calculate the CRFs including drop outs.
- You can increase or decrease this value. The percentage change of your adjustment is applied to the CRF pages generated during each week of treatment to produce the total number of CRF pages, including drop outs you have specified.

## Include Medical Monitoring

1. In the **Estimated number of FTE (full-time equivalent) Medical Monitors** field, accept or change the time for a Medical Monitor (MD) to serve as the team medical lead and provide support to the CRA monitoring staff and investigators for issues beyond safety reporting. Tasks include the following, and others as appropriate:
   - Developing protocol entry criteria.
   - Developing abnormal lab data.
   - Interpreting the protocol and discussing potential deviations.
   - Medical discussion with Investigators.

   The value in this field is the estimated number of full-time equivalent (FTE) Medical Monitors required for all sites for the period from FSI/FPI to LSI/LPO, not the entire study.

   The application supplies a calculated default value based on the study indication, the number of subjects, and the phase of the plan being modeled.
2. You can override the calculated default value. The application calculates the FTEs required based on 1800 hours per FTE per year. This task appears under the Site Management/Monitoring Task Group on the Assignment tab.

## Add Separate Drug Accountability Visits

Use the fields in the **Separate Drug Accountability** section to indicate whether additional drug accountability visits are required, who performs these visits, and how many visits per site to perform.

Separate drug accountability generally applies to oncology and some vaccine studies and is done by someone other than the CRA that monitors the site to assure that all involved in the study are completely blinded to the study drug or test article.

# Add Service Providers on the Provider Tab

On the Provider tab, you can add one or more vendors to the list of possible service providers for this plan. Adding a provider to this list does not automatically assign that provider to any tasks. This tab also displays and allows you to designate the primary service provider, to whom outsourced tasks are automatically assigned. You can change these assignments on the Assignments tab as well as assign tasks to service providers.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Provider Tab.

## View the Service Providers You Can Select for Your Plan

1. From the Edit menu, select **Plans**.

   The Plans screen appears.
2. Select the checkbox of the plan.
3. Click **Edit**.

   The Edit Plan screen appears.
4. Click **Provider**.

   The Provider tab appears, displaying a list of the service providers.

### Types of Service Providers

The application supports two types of service providers: Sponsors and Contract Research Organizations (CROs). There are four types of CROs:

- **Premium—**Provide a global presence in all major regions. You can fully outsource studies to them, but premium CROs are more expensive than other CRO types.
- **Major—**Provide a global presence in all major regions. You can fully outsource studies to them.
- **Medium—**Provide an incomplete global presence. You can fully outsource studies to them, but they may have to sub-contract some of the work.
- **Niche—**Operate in only one country or region and often offers only a subset of services.

## View or Edit the Default Rates and Responsibilities of a Service Provider

1. Click a service provider listed in the **Provider Name** column.

The Specify Provider-Specific Details dialog box appears.

2. In the **Billing Rate Information**, **FTE Utilization Information**, and **Other** sections, accept or override the values shown.
   - For more information about a field, click the field name.
   - For more information about the screen, see Specify Provider-Specific Details Dialog Box.
3. Click **Ok**.

## Add Service Providers to a Plan

1. On the Provider tab, click **Add Provider(s)**.

   The Choose Service Providers dialog box appears.
2. Select one or more service provider checkboxes.
3. Click **Ok**.

   The application adds the service provider(s) to the plan. A service provider does not become part of this plan until you click **Save** or **Next**.

## Remove a Service Provider

1. On the Provider tab, select one or more service provider checkboxes and click **Remove Provider(s)**.

   The application immediately removes the service providers from the list. However, they are not removed from the plan until you click **Save** or **Next**.

   Tasks that have been assigned to a removed service provider are reassigned according to the following rule:
   - If the task assignment is for subject data from a location whose assignments have been overridden, the task is reassigned to the default service provider for that location.
   - Otherwise, the task is reassigned to the service provider specified as the primary provider.

## Designate a Primary Service Provider

The primary service provider is automatically assigned to tasks indicated as outsourced to Vendor. The primary service provider also becomes assigned to tasks assigned to a vendor who is later removed from the plan.

1. On the Provider tab, select a service provider checkbox, and click **Set as Primary Provider**.

   Two asterisks appear to the right of the provider name indicating that this is the primary service provider for the plan.
2. Click **Save**.

## Replace a Service Provider

1. Select a service provider checkbox and click **Replace Provider**.

   The Choose Replacement Provider dialog box appears, listing eligible service providers.

2. Choose the radio button of the service provider to replace the currently selected service provider.
3. Click **Ok**.

   The application saves all of your current service provider-level assumptions and replaces the selected service provider with your new choice.

### Freezing and Unfreezing Billing Rates for a Service Provider

On the Provider tab, if a button says **Unfreeze Billing Rates**, rates have been frozen for this plan. If the button says **Freeze Billing Rates**, no rates have been frozen. The Rate Year in Effect column shows the Rate Year used to look up billing rates for the resources for this service provider for this plan.

When you freeze billing rates for a service provider, changes to the service provider's billing rates no longer impact the plan. The application copies the current rates for the current service providers and stores them with the plan. If you add service providers, the application also copies their current rates to this plan.

If you click **Unfreeze Billing Rates**, the application deletes the copied rates and uses the current rates for the service providers to calculate costs for this plan. The plan reflects the changes to the billing rates of service providers.

**Note:** You cannot freeze billing rates for templates.

## Plan and Track the Cost of Meetings on the Meetings Tab

On the Meetings tab, you can add and edit meetings; specify meeting details, attendees, and notes for each meeting; and track meeting costs.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Meetings Tab.

### Viewing the Planned Meetings

1. From the Edit menu, select **Plans**.

   The Plans screen appears.
2. Select the checkbox of the plan.
3. Click **Edit**.

   The Edit Plan screen appears.
4. Click **Meetings**.

   The Meetings tab appears, displaying a list of the planned meetings. Meetings with a line through them have been excluded from the plan.

### Adding a Meeting

1. To add a meeting, click **Add**.

   The Define New Meeting dialog box appears.
2. In the **Name** field, enter a name for the new meeting.

3. From the **Type** drop-down list, select the meeting type.
4. Click **Continue**.

   The Meeting Details dialog box appears.

### Define the Meeting and Providers Attending

1. On the **Meeting Details** tab, in the **Meeting Definition** section, specify basic information about the meeting.
   - The application uses the code you enter as a prefix for tasks associated with this meeting type.
   - Non-travel costs include audio-visual equipment rental, meeting space, and so on.
2. In the **Schedule** section, enter the frequency, start and stop times, and duration of the meeting.
   - The calculated distribution start date cannot be earlier than the pre-study planning date.
   - To create a recurring meeting, you select the frequency from the **Occurs** drop-down list, the start date, and use the **Until** field to specify the range of time over which the meeting recurs.
3. In the **Providers Attending** section, select the checkbox of each service provider type to participate in the meeting.
4. Click **Save**.

### Add Service Provider Attendees

1. Click the **Attendees** tab.
2. From the **Service Provider** drop-down list, select a service provider type.
3. Click **Add**.

   The Resource Name dialog box appears.
4. Select the checkboxes of the resources to include.
5. Click **Ok**.

   The application adds the service providers to the Provider Attendees list associated with the meeting.
6. For each resource type, specify the number of attendees, the back office billing rate location, how the attendee will attend the meeting, the billable hours expected for meeting attendance, and indirect costs.
7. To divide the billable hours into preparation, travel, attendance, and follow-up costs, click the **Expand All Billable Hours** link and enter a value into each field.
8. Click **Save**.
9. Repeat steps 2 through 8 for each service provider type.

#### Duplicate a Provider Attendee

1. Select the checkbox of an attendee resource type, and click **Duplicate**.

   The application duplicates the settings for the selected attendee and adds it to the bottom of the list.

2. Click **Save**.

#### Delete a Provider Attendee

1. Select the checkbox of an attendee resource type, and click **Delete**.

   The application removes the attendee.

2. Click **Save**.

#### Provide Additional Detail about the Billable Hours

1. Click the **Expand All Billable Hours** link.

   The application unbundles the billable hours so you can enter separate estimates for preparation, travel time, meeting attendance, and follow-up tasks.

2. Click **Save**.

### Manage Attendees from Investigator Sites

1. Click the **Site Attendees** tab.

   If the meeting type involves on-site attendees, meeting details appear and include the number of attendees per site, percentage of sites represented, location, attendance method, and indirect costs associated with the meeting.

   - To change site attendee settings, modify the values in the fields.
   - To delete a site attendee, select the **Attendee/Site** checkbox and click **Delete**.
   - To duplicate a site attendee, select the checkbox of the site attendee to duplicate and click **Duplicate**. The application adds the duplicated site attendee to the bottom of the page. You can modify the duplicated values.
   - To add a site attendee, click **Add**. The application adds another site attendee to the bottom of the page. You can modify the default values used.

2. Click **Save**.

### Add Notes

1. Click the **Notes** tab.

   Any notes associated with the meeting appear.

2. In the text box, type notes associated with this meeting.
3. Click **Save**.

## Editing a Meeting

1. Select a meeting checkbox, and click **Edit**.

   The Meeting Details dialog box appears.

2. Make changes to the meeting on the Meetings Details, Attendees, Site Attendees, and Notes tabs.
3. Click **Save**.

## Copying a Meeting

1. Select a meeting checkbox, and click **Copy.**

The Meeting Details dialog box appears. The application populates the fields on the tabs with the copied meeting values.

2. Accept or change the details from the meeting you copied on the Meetings Details, Attendees, Site Attendees, and Notes tabs.
3. Click **Save**.

### Excluding a Meeting from the Plan Budget

1. To exclude a meeting, select a meeting checkbox, and click **Exclude**.

   The application does not delete the meeting. The excluded meeting appears with a line through it. The application excludes the associated costs from the totals.
2. Click **Save**.

### Including a Meeting from the Plan Budget

1. To include an excluded meeting, select the checkbox of an excluded meeting, and click **Include**.

   The application removes the line crossing out the meeting and includes the associated costs in the totals.
2. Click **Save**.

### Deleting a Meeting

1. Select one or more meeting checkboxes, and click **Delete**. You can delete both application-defined and user-defined meetings.

   The application prompts you to confirm that you want to permanently delete the meeting.
2. To delete the meeting, click **OK**. To retain the meeting, click **Cancel**.

## Assign Tasks to Service Providers on the Assignment Tab

Use this tab to assign the service provider and billing rate location to tasks.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Assignment Tab.

1. From the **Values apply to** drop-down list, select the location.
   - S**elect Centralized Tasks/Location Defaults** if you want assignments to pertain to every location in the study.
   - Select a specific location to assign it to a different service provider.
2. If all outsourced tasks in your plan are performed by a single service provider, from the **Default service provider for outsourced tasks** drop-down list, select that service provider.

   or

If outsourced tasks in your plan are performed by various service providers, from the **Default service provider for outsourced tasks** drop-down list, select the service provider who performs most of the outsourced work.

- Example 1: **Values apply to** is set to **Centralized Tasks/Location Defaults**. To assign all outsourced tasks for all locations to Major CRO, select Major CRO.
- Example 2: **Values apply to** is set to Chile. To assign all outsourced tasks in Chile to Medium CRO, select Medium CRO.
- If a service provider is not available for selection, return to the Provider tab and add the service provider.

3. Click **Save**.
4. Click the **Show Tasks** link.

   For the selected location, the associated assignment groups/tasks appear.
5. To see and assign individual tasks, click the blue triangle to the left of the assignment group.
   - The Included column indicates whether this task is included in the study and, in some cases, allows you to exclude a task from the study. If this checkbox is grayed out, the task must be included (or excluded) from the plan based on other input assumptions you have made or other study characteristics.
   - You can exclude selected tasks from the plan, which eliminates the effort and costs associated with these tasks. Tasks that cannot be excluded or specifically assigned, or whose billing rate location cannot be different from the location of subject data, are presented with the associated option(s) disabled.
   - If, on the Overview tab, you selected **Outsourced**, you can only assign tasks to vendors. If you selected **Conducted Internally**, you can only assign tasks to the sponsor. To assign some tasks to service providers and others to the sponsor, you must select **Combination on the Overview tab**.
6. For each Assignment Group/Task, from the **Assign to** drop-down list, select the service provider.

   The value displayed might indicate additional information when showing the assigned provider(s) for an entire group of tasks, as follows:
   - **Service provider name appears with no additional markers**—All tasks in the group are performed by a single service provider.
   - **Service provider name appears with an asterisk (*)**—The service provider is the default service provider selected to perform tasks in the group.
7. From the **Billing Rate Location** drop-down list, select the billing rate location to use to calculate resource costs for this task or group of tasks.
   - You can specify a different billing rate location for each task group or task. For example, if data management tasks for all European sites are performed in Germany, change this field to Germany for each of the locations in Europe.
   - You can select any location where this activity or activities are conducted. The location does not need to have active sites participating in the study. For example, you might have study sites in France, Germany, and Italy, but perform all data management in the UK or India.
   - To choose a location that does not have sites or subjects, from the drop-down list, choose **Other...**. The Location Selection dialog box appears. Choose the location where the work is performed and click **OK**.

- By default, centralized tasks are calculated using the back office billing rate selected on the Provider tab.

8. To prevent cascading changes, pin the service provider and billing rate location assignments by clicking the **Pushpin icon** in the **Pinned** column to highlight it.
   - If an assigned provider has been deleted from the plan, the task assignment changes to the primary provider in the plan.
   - Any changes to tasks are pinned by default.

     For example, if assignments made for individual tasks included in the group are not pinned, changes made to the Assignment Group or to the Location Defaults override these assignments.
   - Pinned settings are lost if the associated locations or service providers are removed from the plan. However, if you replace a provider, your pinned settings are maintained.
   - Task overrides migrated from plans created in earlier versions of the application are pinned by default.
9. Click **Save**.
10. Repeat as necessary for multiple locations where the service provider is different or the billing rate is different from the local rate for that location.

## Overriding Resources and Rates

You can override the billing rate location and rate for a specific location or all locations and for tasks assigned to a specific service provider. You can save the overrides by clicking the Push Pin icon to ensure that they are not lost due to other cascading changes.

1. Click the **Override Resources or Rates** link.

   The Resource Overrides dialog box appears.
   - For more information about a field, click the field name.
   - For more information about the screen, see Resource Overrides Dialog Box.
2. In the **Scope of Overrides** section, from the **For tasks assigned to** drop-down list, select a service provider.
3. In the **Resources/Overrides** section, specify your override for each default resource specification and pin your changes if desired.
4. Click **Save**.
5. To clear the overrides, click the **Clear Overrides** link.

# Adjust Task Effort and Labor Fees on the Labor Tab

On the Labor tab, view and adjust the calculated labor unit costs and unit hours for each major task for each service provider. You can also edit tasks and resources, assign project tasks to specific service providers and billing rate locations, and override unit hours and the billing rate of a specific resource.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.

- For more information about the screen, see Labor Tab.

## Viewing Major Tasks

1. From the Edit menu, select **Plans**.

   The Plans screen appears.
2. Select the checkbox of the plan.
3. Click **Edit**.

   The Edit Plan screen appears.
4. Click **Labor**.

   The Labor tab appears, displaying a list of the major tasks and their unit hours, unit cost, number of units, extended hours, and extended costs.

### Filtering by Service Provider

- To see the major tasks associated with a specific service provider, in the **Filter** section, from the **Show hours and fees for** drop-down list, select the service provider.
- To view all major tasks, even if the selected service provider is not assigned to any of the tasks, select the **Show major tasks with no planned effort for the selected provider** checkbox.
- To view only those major tasks that are assigned to the selected service provider, clear the **Show major tasks with no planned effort for the selected provider** checkbox.
- Displayed values are rounded to the nearest tenth. Hover over any value to see the actual value.
- Some major tasks have a single unit of work (for example, Study or Database) and others have multiple units of work (for example, Sites, Subjects, or CRF Pages). The unit of measure is displayed when you hover over the number of units displayed.

## Creating a Major Task

A major task is a collection of related tasks that share the same unit of measure, labor scope, and expected distribution of units completed.

The major tasks you add appear below the ClearTrial system-defined major tasks in the order you create them. The application applies inflation to all major tasks, whether user-defined or system-defined, based on inflation settings on the Provider tab.

1. On the Labor tab, click **New Major Task**.

   The Task Manager dialog box appears.
2. On the **Major Task Details** tab, define the basic attributes of the new major task.
   - **Name**—Oracle recommends naming the major task with the explicit deliverable or unit of work expected. Major task names must be unique within a plan.
   - **Description**—Oracle recommends providing a description to help others understand the purpose of the major task.
   - **Labor**—Specify whether associated tasks are location-scoped or study-scoped.

Tasks that are performed locally, such as monitoring or other site visits, are location-scoped and are usually measured in terms of the number of sites or visits in each location. Location-scoped tasks can be assigned to different service providers in different locations. For a location-scoped task, you can create different algorithms to determine the level of effort required to complete the task in that location.

Study-scoped tasks can be assigned to only one service provider. Tasks that are performed as part of project initiation or as part of back-office operations are usually study-scoped and the only relevant unit of measure is the study itself.

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**Note:** Labor scope cannot be changed for major tasks defined in the prior forecast when creating a reforecast.

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- **Unit of Measure**—Select the unit of work this major task represents. The application calculates all effort for associated tasks in terms of hours to complete one such unit.

  For example, a major task whose unit of measure is Sites Approved is composed of tasks whose resources level of effort are calculated as the number of hours required to approve one site. This level of effort (or LOE) represents the unit hours for the resource for the task.

  The application-calculated unit hours are multiplied by the number of units expected (for example, number of sites approved) to produce the Extended Unit Hours.

- When creating a reforecast, you cannot change the unit of measurement, labor scope, and distribution of a custom major task defined in the prior forecast.

3. Click **Save**.

### Add a Custom Task to the New Major Task

1. On the Task Manager dialog box, click **New Task**.

   A dialog box for task details and assignments appears.

2. Specify the name, the assignment group to which the task belongs, and the summary category under which to include the associated hours and fees on the Summary tab.

   - All tasks inherit major characteristics, such as unit of measure, labor scope, and work units distribution, from their major task.
   - The application uses the code as a prefix to the selected task name.
   - The text you enter for the description appears as the help text for this task as it appears on the Assignment tab.
   - The assignment groups are represented by radio-button choices in the Responsibilities section of various tabs throughout the plan and in drop-down lists on the Assignment tab. You can determine whether a task is performed by the sponsor or CRO, or is not performed at all for this trial, by choosing the appropriate radio-button for its assignment group. You can also manage the assignments of each task on the Task Assignments tab on the Task Manager dialog box or on the Assignment tab.
   - The summary category determines how the application summarizes the hours and purposes of display and report fees or the resources on the Summary tab.

3. Click **Save**.
4. Click the **Task Assignments** tab.
5. For each location, select the service provider and billing rate location.
6. To include the service provider, select the **Included** checkbox.
7. To prevent cascading changes, pin the service provider and billing rate location assignments by clicking the **Pushpin icon** in the **Pinned** column to highlight it.
8. Click **Save**.

### Add a Resource

1. Click **Add Resource**.

   The Resource Name dialog box appears.
2. Select the checkbox of one or more resources.
3. Click **Ok**.

   The application adds the resources to the resource list on the Task Assignments tab.

   - The Resource Name column displays the name of the resource normally expected to perform this task.
   - If you or another user has used the resource overrides feature to substitute another resource, you can see those substitutions by clicking the link in the Substitutions column or by editing the resource and navigating to the Billing Rates tab. You can override resources at the plan level, the plan-location level, or for a specific task.
4. Click **Save**.

### Edit a Resource

1. To change details about a resource effort or rates for this task, select the **Resource Name** checkbox, and click **Edit Resource**.

   The Resource Panel appears.
2. Depending on whether you added this resource, you can specify or change the algorithms to calculate this resource's level-of-effort and override billing rate locations, billing rates, and unit hours.
3. If you added the resource to the task, from the **Department** drop-down list, select the department to which this resource belongs when performing this task.
4. From the **GL Code** drop-down list, select the GL code for the fees associated with this resource when performing this task.
5. Click **Save**.
6. Click **Close**.

### Delete a Resource

1. On the **Task Assignments** tab, select the **Resource Name** checkbox, and click **Delete Resource**.
2. Click **Save**.

   The application removes the resources from the task.

Only resources you have added to the task can be removed. To exclude a resource expected by the application, edit the resource and override the unit hours to 0.00%.

## Adjusting Hours and Fees for a Major Task

1. On the Labor tab, select a **Major Task** radio button, and click **Adjust Hours or Fees**.

   The Adjustments tab on the Task Manager dialog box appears.

2. From the **Show hours and fees for** drop-down list, select the service provider whose unit hours or fees are to be adjusted.
3. To make adjustments, click the **Expand All** link.

   The Extended Hours section expands to show the # Units, Unit Hours, and Unit Cost.

4. Edit the **# Units** field and the **Unit Hours** field to align your plan with the study's contract, bid, and internal tasks and costs.

   The application recalculates the unit cost.

5. Click **Save**.

   To restore the values calculated by the application, click the **Clear Overrides** link.

## Distributing Completed Hours and Fees

1. On the Labor tab, select a **Major Task** checkbox, and click **Adjust Hours or Fees**.

   The Adjustments tab on the Task Manager dialog box appears.

2. Click the **Distribution** tab.

   The application shows the date each service provider is expected to begin and complete work related to the major task in the selected location.

   **Note:** This tab lists only service providers assigned to work on the selected major task.

3. In the **Distribute completed units of work according to** field, specify the distribution approach.

   - The distribution of units over time determines how the related fees are incurred, how value is accrued, and what units are expected to be completed as of the reforecast date when reforecasting according to planned values.

     If your company has licensed ClearTrial TRACK®, the distribution determines the planned values against which EVA is calculated. When reforecasting against a tracked plan, you can generate the reforecast based on actual values to determine units remaining.

     Changes to the assumptions in this plan that revise the predicted milestone date automatically revise the distribution of this work.

   - If you select **System Calculated Distribution** or **CRF Data Distribution**, the application calculates the start and end dates and the periods comprising the task. You can spread units according to one of the pre-defined schedules.

- If you select **An Even Distribution**, you can spread units evenly between two dates, based on available milestones and optional off-set in days prior to or past the occurrence of that milestone. When assumptions in the plan change, the application modifies the predicted date of these milestones, and the distribution of the units accordingly.
- If you select **A Custom Distribution**, you can specify the number of days before or after a selected milestone to start the distribution of units of work.
  - You can enter an absolute value per period between available milestones and an optional off-set. You can start the work when this milestone occurs or any number of days before or after this milestone occurs.
  - Example 1: Work is expected to begin 30 days prior to FSI. You enter 30, choose **before** from the first drop-down list, and **First Subject/Patient In (FSI/FPI)** from the next drop-down list.
  - Example 2: Work is expected to complete 15 days after LSI. You enter 15 in this field, choose **after** in the first drop-down list, and **Last Subject/Patient In (LSI/LPI)** in the next drop-down list.
  - You can distribute work from the pre-study planning date up to 10 years after the Final Report Date.

4. Click **Save**.

## Searching for a Major Task

1. On the **Labor** tab, click a **Major Task** radio button, and click **Edit Major Task**.

   The Task Manager appears.
2. In the **Task Search** box above the navigation panel, type one of more characters, and click the **Magnifying Glass** icon.

   The application displays the total number of matches found for the search term and highlights the matches.
3. Click a task or navigate through the list of matches by clicking the **Previous** and **Next** links.

   The selected task appears on the Task Details tab to the right of the navigation tree.

## Editing a Major Task

1. On the **Labor** tab, click a **Major Task** radio button, and click **Edit Major Task**.

   The Task Manager appears.
2. You can edit the description, add tasks to the selected major task, add resources to the tasks associated with this major task, define algorithms to calculate the unit hours for additional resources, and override resources, rates, or unit hours for resources.
3. Click **Save**.

## Deleting a Major Task

1. On the **Labor** tab, click a **Major Task** radio button, and click **Delete Major Task**.
2. To confirm the deletion, click **OK**.

The application permanently deletes the major task and its tasks, resources, algorithms, and overrides. You cannot restore deleted major tasks.

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**Note:** You cannot delete system-defined major tasks.

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## Specify Pass-through and Indirect Cost Categories on the Cost Tab

The Cost tab displays the pass-through and miscellaneous cost categories that have been or can be applied to the plan. Some of these costs are pre-calculated. Other costs appear because many studies require costs of these types, but the application cannot derive these amounts from study characteristics or user-provided assumptions. You can increase or decrease each cost listed by editing the cost details.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Costs Tab.

### Viewing Costs and Adjustments

1. From the Edit menu, select **Plans**.

   The Plans screen appears.
2. Select the checkbox of the plan.
3. Click **Edit**.

   The Edit Plan screen appears.
4. Click **Costs**.

   The Costs tab appears, displaying a list of the calculated costs and adjustments. Items with a line through them have been excluded from the plan.

### Defining a New Cost Category

If none of the predefined cost categories adequately captures the nature of a cost that should be included in the estimate for the plan, you can add a new cost.

1. On the **Costs** tab, click **New**.

   The Define New Category dialog box appears.
2. Enter information about the new category on the **Definition**, **Algorithm**, and **Distribution** tabs.
   - For more information about a field, click the field name.
   - For more information about the screen, see Define New Category Dialog Box (Definition Tab, Algorithm Tab, Distribution Tab).

#### Enter Category Information

1. In the **Name** field, define a name for the cost.
   - For any user-defined cost, specify a name of up to 45 characters that is unique for this plan.
   - You cannot change the name of a system-defined cost.

2. From the **Type** drop-down list, select the cost type.
   - **Pass Through**—The cost is incurred by an outsourced partner and will be passed through to the sponsor for reimbursement.
   - **Miscellaneous**—Costs are incurred by the sponsor as part of the overall study budget.
   - You can associate the cost with a specific department for cost allocation and can specify a GL code for reconciliation against the General Ledger.
3. To make this cost part of the recurring payments plotted on the Cash Flow Chart, select the **Include in Payment Schedule** checkbox. The application assumes the cost is paid out monthly between the specified start and end dates. You can change the frequency of the payment for each cost on the **Payments** tab by clicking **Edit Recurring Payments**.
4. To treat indirect costs as billable items or to allocate one or more resources to manage the costs, select the **Include in Resources by Department/GL Code report** checkbox.
5. To include inflation for this cost in resulting calculations, select the **Include inflation in results** checkbox. This selection clears the **Treat as credit** checkbox, if selected.

   or

   To treat the cost as a credit item, select the **Treat as Credit** checkbox. This selection disables the **Include inflation in results** checkbox. This option is not available to all users.
6. In the **Notes** section, enter details or comments about the new cost category. The application displays these notes as the help content for this cost.
7. Click **Save**.

### Define the Algorithm

1. Click the **Algorithm** tab.

   If you selected the Treat as Credit checkbox on the Definition tab, the Credit Algorithm section and Credits / Adjustments section appear on the Algorithm tab. Otherwise, the Cost Algorithm and Costs / Adjustments sections appear.
2. In the **Cost**s or **Credits** field, choose whether to vary the cost or credit by location or treat as a study-level cost or credit.

   If you choose **vary by location**, you can specify a different per-unit amount for one or more locations, assign the responsibility to a different service provider for each location, override the start and end dates over which to distribute the costs or credits, and express the per-unit cost or credit in a different currency for one or more locations.
3. In the **Calculate as** field, specify the currency in which you have expressed a per unit amount.
   - If you have chosen to vary this cost or credit by location, this value is the default for each location.
   - The application calculates the total value for each location, or the study-level cost, as this value multiplied by the number of units expected for the chosen assumption.

- Editing this field does not convert a previously entered value. The application assumes that the value you entered was expressed in the chosen currency.
- When the currency is edited, the application applies the change to the location-specific costs or credits, unless they have been overridden to vary from the amount and currency entered in this section.

4. From the **per** drop-down list, select a unit-based assumption by which to drive the calculation of this cost or credit.

   The application multiplies the number of units derived for the chosen assumption by the amount entered to produce the total cost or credit. Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption automatically adjust this cost or credit.

5. In the **Costs/Adjustments** section or **Credits/Adjustments** section, show the details for the cost or credit. System-calculated values are either location-scoped or study-scoped and cannot be changed.

   - Assign the responsible provider, if applicable.
   - Map the cost or credit to a specific department.
   - Map the cost or credit to a GL code.
   - Apply costs or credits.

   In the **Total** field, the application displays the total calculated costs or credits, including any adjustments made by you or another user.

### Distribute the Costs

1. Click the **Distribution** tab.
2. In the **Distribute according to** field, select how to distribute the cost for each location in your plan.

   - You can spread costs according to one of the pre-defined schedules. In the **and shift** field, specify an offset for a system-defined distribution curve. You can shift a distribution to occur up to 999 days earlier or later than originally defined.
   - You can spread costs evenly between two dates, based on available milestones and optional off-set in days prior to or past the occurrence of that milestone. When assumptions in the plan change, the predicted date of these milestones and the distribution of the costs, are modified accordingly.
   - You can spread costs according to a custom distribution, where you can enter an absolute value per period between available milestones and an optional off-set timeline period or interval. From the **by** drop-down list, select **Week**, **Month**, or **Quarter**.

3. In the **Default range** field, define a **Start** and **End** milestone for the cost distribution. These are used as the default start and end date for each location.

   - For example, you can indicate that a cost is expected to spread from 30 days prior to FSI to 15 days after LSO.
   - Use the **Start** and **End** offset drop-down lists to specify whether the offset is before or after the selected milestone occurs.
   - From the **Start** and **End** milestone drop-down lists, select a milestone to which to anchor the start and end of the cost distribution. You can start the cost on this milestone or some number of days before or after this milestone. Changes

to the assumptions in this plan that revise the predicted milestone date automatically revise the distribution of this cost. However, the calculated distribution start date cannot be earlier than the pre-study planning date.

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**Note:** You can distribute the cost up to 10 years after the Final Report date. The calculated distribution end date should be less than the Final Report date plus 10 years.

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4. Click **Save**.

## Editing a Cost Category

1. On the **Costs** tab, select a cost checkbox, and click **Edit**.

   The Edit or Adjust dialog box appears.

2. Change the settings on the **Definition**, **Adjustments**, and **Distribution** tabs.
3. Click **Save**.

## Excluding a Cost

1. Exclude a cost by selecting the checkbox to the left of the cost, and clicking **Exclude**.

   The application does not delete the cost, but it no longer includes the amount in the plan and its totals and the cost appear with a line drawn through them.

2. Click **Save**.

## Including a Cost

1. Restore an excluded cost by selecting the checkbox to the left of an excluded cost, and clicking **Include**.
2. Click **Save**.

## Deleting a Cost

1. Select the checkbox to the left of a cost, and click **Delete**.
2. To confirm the deletion and permanently delete the item, click **OK**.

# Specify Service Provider Payment Schedules on the Payments Tab

On the Payments tab, configure the payment schedule for each service provider performing work. You can use the payment schedule with the Cash Flow Chart report to determine the cash flow characteristics of the payment plan.

Enter assumptions in the fields that appear. Your current edit mode determines the fields available.

- For more information about a field, click the field name.
- For more information about the screen, see Payments Tab.

## Setting Payment Terms

Payments are defined as percentage values representing the portion of the total fees paid or received at the completion of each milestone. You can also define the payment terms to specify the number of days from the invoice that payment is expected.

1. On the Payments tab, click **Set Payment Terms**.

   The Payment Terms dialog box appears.

2. From the **Payment Term** drop-down list, select the payment term for a service provider.

3. Click **Ok**.

## Working with Recurring Payments

Fees that will be paid on a repeating schedule (for example, monthly) are recurring payments.

1. On the Payments tab, click **Edit Recurring Payments**.

   The Recurring Payments dialog box appears.

2. For each unit of work or pass-through cost, from the **service provider** drop-down list, select the payment frequency.

   or

   To indicate that the fees associated with that item are included in payments made in response to the occurrence of one or more milestones, select **Milestone**.

3. Click **Ok**.

## Adding a Milestone

If payments are paid in response to events or conditions not currently defined, you can add milestones.

1. On the Payments tab, click **Add Milestone**.

   The Create Milestone dialog box appears.

2. Enter the **Milestone Definition**.

   - You can name the milestone anything appropriate as long as the milestone name is unique for this plan.
   - In the **Occurs** field, enter the number of days before or after the system-defined milestone that this milestone normally occurs.
   - Select **before** or **after** to choose whether to calculate the estimated date for this milestone as a number of days prior to a system-defined milestone or subsequent to a system-defined milestone.
   - From the **milestone** drop-down list, select the system-defined milestone before or after which this milestone is expected to occur. The calculated date for this milestone is the number of days specified prior or subsequent to the system-defined milestone selected.

3. Add a **Description**.

   - In the **Code** field, specify a 3-6 character abbreviation for this milestone. The code appears on reports where the full name does not fit or display properly.

- In the **Description** field, enter additional information to describe this milestone or its purpose for this plan.

4. Click **Ok**.

## Editing a Milestone

You can edit a previously added milestone to change its name and the properties that determine when it is expected to occur.

1. On the Payments tab, select a **Milestone** checkbox, and click **Edit Milestone**.

   The Edit Milestone dialog box appears.

2. Edit the **Milestone Definition**.
3. Edit the **Description**.
4. Click **Ok**.

## Deleting a Milestone

You can delete only user-defined milestones. If you do not intend to make a payment at a system-defined milestone, define the percentage as 0.

1. On the Payments tab, select a **Milestone** checkbox, and click **Delete Milestone**.

   The application deletes the milestone.

# The Summary Tab Provides a Quick Overview of Study Costs

Use the Summary tab to view the study costs and perform what-if scenario testing.

- These values are calculated by converting from each service provider's billing rate currency to the modeling currency, using the exchange rates specified on the Overview tab (or any overrides specified at the service provider level).
- All fees and costs appear in the modeling currency.
- The application calculates the FTE (Full Time Equivalents) values shown based on resource needs. Each FTE is assumed to work 1800 hours over 365.25 days.
- To print a copy of the summary, click **Print**.
- For more information, see Summary Tab.

## Selecting the Included Providers

This section allows you to include (or exclude) fees, hours, and costs from the calculated or displayed summary values for specific providers. Dates and metrics are not affected.

1. Select the **service provider** checkboxes to include.
2. Deselect the **service provider** checkboxes to exclude.

The fees, hours, and FTEs displayed change according to your selections.

## Reviewing Fees, Hours, and FTEs

The Fees, Hours, and FTEs section shows the fees and indirect costs by functional area, as well as the total fees and hours associated with the study and pass-through costs.

- **Startup Fees**—All fees associated with the startup of the study, from Project Activity Start Date to the First subject enrolled (FSFV).
- **Clinical Monitoring Closeout and Site Audit Fees**—All fees associated with site monitoring, site management, telephone monitoring, query resolution, SAE management, site close outs, and clinical compliance audits.
- **Fees, Hours, and FTEs associated with Data Management**—All fees associated with the database design, data entry data coordination, data cleanup, database audits, and annual IND update.
- **Fees, Hours, and FTEs associated with Biostatistics**—All fees associated with table listings and graphs, randomization procedures, statistical and analysis plans, and interim analysis.
- **Project Management / Study Oversight**—All fees associated with the project management of the study from beginning to end.
- **Medical Writing/Final Report—**All fees associated with delivering the statistical report, draft report, and final report (CSR).
- **Other**—All fees associated with other tasks not included in any other line item.

### FTE Calculation

The application calculates the FTE for a functional area based on the total resource hours, total study duration (in days), and number of full-time hours for one year required to complete the work.

- For example, if service providers in a functional area (such as Data Management) work 109,887 hours through a study duration of 2,490 days, the FTE equivalent is 0.9 FTEs or [109,887 / (2,490 days / 365.25)] / 1,800 = 0.9.
- The application also calculates the FTE for resources. For example, if a resource works 6,998 hours over a study duration of 568 days, the FTE equivalent is 2.5 FTEs or [(6,998 total hours) / (568 / 365.25)] / 1,800 = 2.5.
- To obtain an accurate monthly FTE count, use the **Resource Demand Chart report** with the **Show FTEs** option.

### Pass-Through Costs

All pass-through costs are included in the **Total Study Costs** including:

- **CPU Pass-Through Costs**—Total costs associated with the Clinical Pharmacology Unit. This line item appears only for Phase 1 (Healthy Volunteers) trials.
- **Other Pass-Through Costs**—Total indirect costs not associated with the CPU.
- **Total Pass-Through Costs**—All third-party, pass-through, and miscellaneous costs in the study.
- **Inflation (Pass-Through Costs)**—Costs incurred due to inflation as applied to pass-through costs.

## Reviewing Dates and Duration

The **Dates/Duration** section summarizes study-related dates and durations.

- **Pre-Study Activity Start Date**—The date at which the earliest activity on a task or cost is expected to occur.

- **Project Activity Start Date**—The date that the study is expected to begin, defined as the date that vendors or the sponsor start identifying sites and vendors start billable activity on the study.
- **Post-Study Activity End Date**—The date at which the latest activity on a task or cost is expected to occur.
- **Study End Date**—The date the study is expected to be complete, defined as the date that all activity stops. This is usually the date the final report (CSR) is finalized. It does not include any post study follow-up by the sponsor.
- **Total Study Duration**—Represents the total expected study duration in elapsed days defined as the end date minus the start date.
- **Duration of Active Treatment Phase**—Represents the total expected duration of the active treatment phase (in days), defined as the Last Subject observation (LSLV) minus the First Subject observation (FSFV).

## Reviewing Metrics

The **Metrics** section includes the cost per completed subject and the average number of subjects per site per month.

- The application calculates **Cost per Completed Subject** as total study costs divided by the number of subjects expected to complete all scheduled subject visits.
- The **Number of Subjects/Site/Month** value represents the average expected number of subjects monitored at each site per month, defined as the total number of subjects divided by the number of months of enrollment divided by the number of investigator sites.

  For example, 1000 subjects / 12 months / 10 sites = 8.33 subjects per month per site.

# Reports for the Current Plan Appear on the Reports Tab

The Reports tab provides links to reports based on data entered into or calculated from the current plan. You can view each report in a separate window, print it, export it to Microsoft Excel, or convert it to PDF. You can use reports to:

- Check plan assumptions.
- Verify the plan budget.
- Manage resources.
- Monitor the budget.
- Compare fees and prices.

For more information, see Reports Tab.

## Report Types

The application groups the reports into the following categories:

- Clinical Indicators reports
- Costs reports
- FTE / Resources reports

### Generating a Report

1. Click a report name.
2. If the application prompts you to select report-related options, make your selections and click **Ok**.

   The application generates the report and displays it in a separate window.
3. Select report printing and viewing options.
   - Print
   - View as PDF
   - Export to Excel
   - Export to CSV
4. Click **Close**.

## Copying a Plan

1. On the **Plans** screen, select the checkbox of the plan you want to copy.
2. Click **Copy**.

   The Copy Plan dialog box appears.
3. Enter a name for the new plan.
4. Click **Ok**.

## Comparing Plans

1. On the **Plans** screen, select the checkboxes of the plans to compare. Do not include incomplete plans.
2. Click **Compare**.

   The Compare Plans dialog box appears.
3. From the **Available Comparisons** list, select a comparison type.

   Depending on your selection, other options and sections appear.
4. Select the checkboxes of the providers to include. To include all the providers, select the **All Providers** checkbox.
5. Select the currency to be used in the comparison report.
6. Click **Ok**.

   The application generates a Fee and Cost Comparison of the selected plans and the following reports:
   - **Assumptions**—How the plans differ regarding user input and default values.
   - **Fees and Costs**—Differences in fees and pass-through costs for the selected plans.
   - **Fixed Unit Prices**—Comparison of fixed unit prices for two or more plans.
   - **Resources**—Difference in effort and costs per resource for the selected plans.
   - **Milestones**—Differences in milestone dates.

You can print the report, view it as a PDF file, export it to a Microsoft Excel spreadsheet, or export it to CSV.

7. Click **Close**.

# Other Actions You Can Perform on Plans

## Lock and Unlock Plans

When you lock a plan, changes made to the application do not affect that plan.

1. On the **Plans** screen, select one or more plan checkboxes.
2. Click **Other Actions...**, and then click **Lock Plans**.

   A lock icon appears to the right of the checkbox. You cannot edit a locked plan.
3. To unlock a plan, select a plan checkbox with a lock to its right.
4. Click **Other Actions...**, and then click **Unlock Plans**.

## Freeze and Unfreeze Billing Rates

When you freeze the billing rates in a plan, changes made to the billing rates do not affect that plan.

1. On the **Plans** screen, select the plan checkbox.
2. Click **Other Actions...**, and then click **Freeze Billing Rates**.

   Subsequent changes to billing rates no longer affect the plan.
3. To unfreeze the billing rates, select the frozen plan checkbox.
4. Click **Other Actions...**, and then click **Unfreeze Billing Rates**.

   The Unfreeze menu item will be active.

## Copy as Template

1. On the **Plans** screen, select a plan checkbox.
2. Click **Other Actions...**, and then click **Copy as Template.**
3. In the **Copy Plan as Template** dialog box, enter a template name.
4. Click **Ok**.

   The Edit Template screen appears.
5. Work through the tabs to make any changes to the template.
   - For more information about a field, click the field name.
   - For more information about the screen, see Template Screen Fields.
6. Click **Save**.

   If you have made a plan and want to associate your plan with a different study, copy the plan as a template, then create a new plan for the other study based on this template.

## Change Attributes

You can change the name, status, and descriptions of the selected plan.

1. On the **Plans** screen, select a plan checkbox.
2. Click **Other Actions...**, and then click **Change Attributes.**
3. In the **Change Plan Attributes** dialog box, change the attributes shown.
   - If you select multiple plans:
     – The Plan Name field is disabled to prevent you from assigning the same name to multiple plans.
     – The Status field is empty. You can choose any status to apply to the selected plans.
     – The description fields are disabled.
   - You cannot change the status of a deleted plan, a plan that is incomplete, or a plan that has been set as a baseline for tracking.
   - You cannot change the status of plans you did not create unless you are assigned a role that grants you permission to edit other users' plans.
   - Oracle recommends that you select the **Update last modified date and user (plan history)** checkbox. However, if you often filter by the last modified date deselect the checkbox to prevent bulk updates from changing your view.
4. Click **Save & Close**.
   - Changes are made without opening or unlocking the plan.
   - What you can change depends on number of plans selected and status of the plans.

## Add to Portfolio

1. On the **Plans** screen, select one or more plan checkboxes.
2. Click **Other Actions...**, and then click **Add to Portfolio(s).**
3. In the **Add Plans to Portfolio(s)** dialog box, create a portfolio or select one or more portfolios.
4. Enter or modify the portfolio information.
   - For more information about a field, click the field name.
   - For more information about the screen, see Add Plans to Portfolio(s) Dialog Box.
5. Click **Ok**.

## Create Reforecast

1. On the **Plans** screen, select one or more plan checkboxes.
2. Click **Other Actions...**, and then click **Create Reforecast.**
3. In the **Create Reforecast** dialog box, specify a name and date for the reforecast.
4. Enter or modify the portfolio information.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create Reforecast Dialog Box.

- Oracle recommends naming each reforecast after its prior forecast.

5. Click **Ok**.

## Reforecast Exchange Rate

You can create multiple reforecasts in a single operation to apply different sets of exchange rates for different periods of time. The application handles all assumptions that vary over time using the reforecasting feature.

You can specify rates for a period of time beginning with the plan start date and ending with the reforecast date. You can specify a new set of exchange rates to take effect as of the reforecast date until either the end of the study or another reforecast changes these assumptions.

1. On the **Plans** screen, select one or more plan checkboxes.
2. Click **Other Actions...**, and then click **Reforecast Exch Rates.**
3. In the **Create Reforecast** dialog box, specify reforecast details.
   - For more information about a field, click the field name.
   - For more information about the screen, see Reforecast Exch Rates (Create Reforecast) Dialog Box.
   - Oracle recommends naming each reforecast after its prior forecast.
4. Click **Ok**.

   If you are tracking the actual progress of the study against a baseline plan, you can base the reforecast on these actuals (recommended), or you can reforecast based on the planned values, which calculates work remaining as though the study is progressing exactly as was originally forecast.

# 3

# Maintaining Resource Information and Settings

This chapter covers the functions available to manage resource information in the application.

You maintain service providers, resources, billing rates, departments and functional areas, GL codes, exchange rates, and reporting regions from the Maintain menu.

## Maintain Service Providers on the Service Provider Screen

You maintain service providers on the Service Provider screen. The service providers on this screen are available throughout the application and you can assign them work to complete on a study.

To maintain service providers, your system administrator must grant you the Clinical Administrator or System Administrator role.

### Creating a Service Provider

1. On the Service Providers screen, click **New**.

   The Create Provider screen appears.

2. Enter a service provider name, description, and select the type of service provider.

   The application supports two types of service providers: sponsors and Contract Research Organizations (CROs).

3. From the **Billing Rates Currency** drop-down list, select the currency in which you will enter the hourly billing rates for this service provider.

4. From the **Back-Office Billing Rate Location** drop-down list, select the back-office billing rate location.

   - The back-office billing rate location determines the default billing rates for tasks that are typically centralized or conducted at a central location. Choose the country in which these tasks usually occur for this provider.
   - For example, if this provider is headquartered in the USA, but conducts all of its data management, biostatistics, and medical writing tasks in India, choose India for the default Back Office Billing Rate Location.

   **Note:** You can override the Billing Rate Location for any specific task on the Assignment tab or in the Task Manager when you create or edit a plan.

5. Click **Save**.

The **Update Billing Rates** link becomes available for the service provider.

6. Click the **Update Billing Rates** link.

   The Create Billing Rates screen appears and you can enter hourly billing rates for the service provider. For more information on entering billing rates, see Create Billing Rates Screen.

## Editing Service Provider Information

1. On the Service Providers screen, select the checkbox of the service provider to edit.

   > **Note:** You can edit service providers you added to the application, but you cannot edit the default service providers included in the application.

2. Click **Edit**.

   The Edit Provider screen appears.

3. Edit the service provider information as necessary.

   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Service Provider Screen Fields.

4. Click **Save**.

### Update Billing Rates

On the Edit Provider screen, you can select the **Update Billing Rates** link to edit billing rates for the service provider.

## Deleting a Service Provider

1. On the Service Providers screen, select the checkbox of the service provider to delete.
2. Click **Delete**.

## Restoring a Service Provider

1. On the Service Providers screen, select the **Deleted Providers** checkbox.

   Deleted services providers appear with a line through them.

2. Select the checkbox of the deleted service provider to restore.
3. Click **Restore**.

   The application adds the service provider to the application.

## Generating the Billing Rates Report

1. On the Service Providers screen, select the checkbox of a service provider.

   > **Note:** You can only generate a Billing Rates report for service providers you added to the application.

2. Click **Billing Rates Report**.

   The Billing Rates report appears.

# Define Resources to Add to Your Plan on the Resources Screen

You manage resources on the Resources screen. Resources can be assigned to complete work on tasks using the Task Manager. For more information about the Task Manager, see Adjust Task Effort and Labor Fees on the Labor Tab.

To maintain resources, your system administrator must grant you the Resources Administrator additional role/capability.

There are two types of resources in the application:

- **System-defined resources—**Resources the application provides. You can edit these resources. You cannot delete system-defined resources.
- **User-defined resources—**Resources you add to the application. You can edit, delete, and restore these resources. If you delete a user-defined resource that is being used in a plan, that resource remains available in the plan.

## Filtering the Resources Screen

You can filter the Resource screen to search for resources. For information see, Define Resource Filter Dialog Box Fields.

## Creating a User-Defined Resource

1. On the Resources screen, click **New**.

   The Create Resource screen appears.
2. Enter a resource code, name, and description.
3. In the **Default Billing Rates** table, enter the U.S. hourly billing rate for this resource, for each of the application provided service providers.
   - Enter the hourly rates for each of the years chosen as the effective rate year when planning a study. For service providers you added to the application, provide specific rates for each location on the Billing Rates screen. For more information, see Billing Rates Screen Fields.
   - To populate the table automatically, click **Auto Fill**. The Auto-Populate Rates dialog box appears. Apply an hourly rate for a selected service provider or a percentage increase for each year based on the rate specified in the selected starting year. Click **Ok**.
4. Click **Save**.

   The application creates the resource and applies the hourly rates.
5. To return to the Resources screen, click **Close**.

## Editing Resources

You can edit both system-defined and user-defined resources.

1. On the Resources screen, select the resource checkbox.
2. Click **Edit**.

   The Edit Resource screen appears.

3. Edit the code, name, description, and default billing rates for user-defined resources.

   or

   Edit the code and name for system-defined resources.

   - For more information about a field, click the field name.
   - For more information about the screen, see Resources Screen Fields.

4. Click **Save**.

### Deleting User-Defined Resources

1. On the Resources screen, select the resource checkbox.
2. Click **Delete**.

### Restoring User-Defined Resources

1. On the Resources screen, to display deleted resources, select the **All Resources** radio button.

   Deleted resources appear with a line through them.

2. Select the checkbox of the resource to restore.
3. Click **Restore**.

## Draft and Publish Billing Rates on the Billing Rates Screen

You define billing rates for service providers to whom you assign work on the Billing Rates screen. After you publish the billing rates, the application shares the rates between plans.

To work with billing rates, your system administrator must grant you the Clinical or System Administrator role.

- For more information about a field, click the field name.
- For more information about the screen, see Billing Rates Screen Fields.

### Filtering the Billing Rates Screen

1. On the Billing Rates screen, from the **Show rates for** drop-down list, select a service provider. To see rates for all providers, select **Any Provider**.
2. From the **Rate Year** drop-down list, select a rate year. To see rates for all years, select **Any**.

   Billing rates matching your filter criteria appear.

### Draft vs. Published Billing Rates

Draft versions of billing rates are not available for use in plans. You must publish billing rates to use them in plans.

You can edit published billing rates and save them as drafts until you click **Publish**. The application continues to use the previously published billing rates until the new ones are published. You can view past billing rates by clicking **Show Revision History**. For more information, see Viewing the Billing Rate Revision History.

## Defining New Billing Rates for a Service Provider

1. On the Billing Rates screen, click **New**.

   The Create Billing Rates screen appears.

2. From the **When** drop-down list, select a service provider.
3. From the **Performs work for** drop-down list, select the sponsor that is going to be charged these billing rates.
   - If your organization is a sponsor, select your organization or an affiliate from the drop-down list.
   - If your organization is a vendor, select the sponsor for whom these billing rates apply.
4. From the **for Rate Year** drop-down list, select the billing rate year to use.
   - When creating a plan, the effective rate year chosen in the Provider Details dialog determines which rates are used. Rates are inflated per any inflation percentages specified.
5. From the **Base Rate Location** drop-down list, select the country or region the rates you enter in the base rate column represent.
   - By default, the application derives the rates of all other locations using the values in the RATE VARIANCE % row. You can edit any variance or override any specific rate value.
   - The **Currency** field displays the currency in which the billing rates are expressed. The service provider selected from the drop-down list determines the currency.
6. For each **Resource**, for each location column, enter the hourly billing rate.
   - Each resource row represents a job title or type of employee that performs work on a study. For each resource, the application multiples the hourly rate supplied by the number of hours calculated to be necessary for employees of this type to complete the work.
   - The application uses generic job titles. For a description of a resource, click the resource name.
7. Click **Save**.

## Publishing Billing Rates

1. On the Billing Rates screen, select the checkbox of billing rates with a Draft status.
2. Click **Publish**.

   The Confirm Publish Rates dialog box appears.

3. Click **Publish**.

## Editing Billing Rates

You can edit published and draft billing rates.

1. On the Billing Rates screen, select the checkbox of the billing rates to edit.
2. Click **Edit**.

   The Edit Billing Rates screen appears.

3. Edit hourly billing rates as necessary.
4. Click **Save**.

## Deleting Billing Rates

1. On the Billing Rates screen, select the checkbox of the billing rates to delete.
2. Click **Delete**.

## Restoring Billing Rates

1. On the Billing Rates screen, select the **Include Deleted Rates** checkbox.

   Deleted billing rates appear with a line through them.
2. Select the checkbox of a deleted billing rate.
3. Click **Restore**.

## Copying Billing Rates

1. On the Billing Rates screen, select the checkbox of the billing rates to copy.
2. Click **Copy**.

   The Copy Billing Rates dialog box appears.
3. From the **Copy from** drop-down list, select the version of billing rates to copy. If there is only one option, this field is read-only.
4. Apply a percent adjustment to reflect inflation or other negotiated changes to the fees charged by selecting the checkbox and entering a percentage.
5. Click **Ok**.

   The Edit Billing Rates screen appears.
6. Edit the hourly billing rates as necessary.
7. Click **Save**.

## Viewing the Billing Rate Revision History

1. On the Billing Rates screen, select the checkbox of the billing rates.
2. Click **Show Revision History**.

   The Show Revision History dialog box appears.
3. Click the **Show Rates** link to view the billing rates for a previously published set of billing rates.

   The billing rates appear in a separate window.

   or

   Click the **Open as Draft** link to open the Edit Billing Rates screen.

   a. Edit, save, and publish billing rates.
4. Click **Close**.

# Map Departments to Labor and Costs on the Department Screen

You maintain departments and map them to labor and costs on the Department screen. To work with departments, your system administrator must grant you the Departments/GL Codes Administrator additional role/capability.

For more information, see Departments Screen Fields.

## Filtering the Department Screen

You can filter the Departments screen to search for departments. For more information, see Define Department Filter Dialog Box Fields.

## Adding a Department

1. On the Departments screen, click **New**.

   The Create Department screen appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Department Screen Fields.

2. In the **Code** field, enter a department code.

   The code is an alphanumeric code that represents the department and appears throughout the application.

3. In the **Name** field, enter a department name.

   The department name appears throughout the application. Two departments cannot have the same name.

4. In the **Description** field, enter a department description.
5. Click **Save**.
6. To return to the Department screen, click **Close**.

## Editing a Department

1. On the Departments screen, select a department checkbox.
2. Click **Edit**.

   The Edit Department screen appears.

3. Edit the department information as necessary.

   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Department Screen Fields.

4. Click **Save**.
5. To return to the Department screen, click **Close**.

## Deleting Departments

1. On the Departments screen, select the checkbox of a department to delete.
2. Click **Delete**.

## Restoring Departments

1. On the Departments screen, select the **All Departments** radio button.

   Deleted departments appear with a line through them.

2. Select the checkbox of a deleted department.

3. Click **Restore**.

## Mapping Labor and Costs to Departments

1. On the Departments screen, click **Map Labor and Costs**.

   The Edit Department Mapping screen appears. There are four department mapping tabs:

   - **Labor (Late stage)—**Map labor to departments for late stage studies.
   - **Labor (Phase 1)—**Map labor to departments for Phase I studies.
   - **Costs (Late stage)—**Map costs to departments for late stage studies.
   - **Costs (Phase 1)—**Map costs to departments for Phase I studies.

2. For each department mapping tab, click the **Change** link in the upper right corner to select the mapping mode.

   The Change Mode dialog box appears.

3. Select a mapping mode by clicking the radio button. There are four mapping modes:

   - **Resource—**Map labor to departments by resource. You map departments to internal and outsourced providers for each resource. You can provide a default department for internal and outsourced providers for all resources by selecting departments in the default row.
   - **Location—**Map labor to departments by location. You map departments to internal and outsourced providers for each location. You can provide a default department for internal and outsourced providers for all locations by selecting departments in the default row.
   - **Task—**Map labor to departments by task. Departments can be mapped to internal and outsourced providers for each task. You can provide a default department for internal and outsourced providers for all tasks by setting departments in the default row, or for all tasks within a task group by selecting departments in a task group row.
   - **Rule (Advanced Mode)—**Map labor to departments by your own criteria. For more information, see Adding a Department Mapping Rule.

4. Click **Ok**.

   The Edit Department Mapping screen appears.

5. For each tab, do the following:

   - In the **Default** row, select a default department mapping to apply to each resource, location, or task.
   - In the **Internal** column, select a department mapping for each resource, location, or task.
   - In the **Outsourced** column, select a department mapping for each resource, location, or task.

6. Click **Save**.

### Restoring Default Department Mappings

To restore the labor mappings to the default application configuration, click **Restore ClearTrial Defaults**. The application discards any labor mappings you created.

## Editing Department Mappings

1. On the Departments screen, click **Map Labor and Costs**.

   The Edit Department Mapping screen appears.

2. Edit department mappings as necessary.

   - For more information about a field, click the field name.
   - For more information about the screen, see Edit Department Mapping Screen Fields.

3. Click **Save**.

## Adding a Department Mapping Rule

1. On the Departments screen, click **Map Labor and Costs**.

   The Edit Department Mapping screen appears.

2. Select a department mapping tab and click the **Change** link in the upper right corner.

   The Change Mode dialog box appears.

3. Click the **Rule (Advanced Mode)** radio button.
4. Click **Ok**.

   The Edit Department Mapping screen appears.

5. Click **Add Rule**.

   The Create Department Mapping Rule dialog box appears.

6. On the Create Department Mapping Rule dialog box, do the following:

   a. From the **Department** drop-down list, select the department to be assigned when this rule is applied.

   b. On the **Providers** tab, select providers to be matched according to this rule.

      Selecting the **Internal** and **Outsource** checkboxes includes all the service providers in that group.

   c. On the **Locations** tab, select locations to be matched according to this rule.

      Selecting the **Any Location** checkbox includes all locations.

   d. On the **Tasks** tab, select the checkboxes of tasks to be matched according to this rule.

      Selecting the **Any Task** checkbox includes all task groups and tasks.

   e. On the **Resources** tab, select resources to be matched according to this rule.

      Selecting the **Any Resource** checkbox includes all resources.

7. Click **Ok**.

The rule is added to the department mapping tab.

8. Click **Save**.

### Edit and Delete Your Department Mapping Rules

You can edit or delete your department mapping rules by selecting the rule checkbox and clicking **Edit Rule** or **Delete Rule**.

# Map GL Codes to Labor and Costs on the GL Codes Screen

You maintain GL codes and map them to labor and costs on the GL Codes screen. To work with GL codes, your system administrator must grant you the Departments/GL Codes Administrator additional role/capability.

- For more information about a field, click the field name.
- For more information about the screen, see GL Codes Screen Fields.

## Filtering the GL Codes Screen

You can filter the GL Codes screen to search for GL codes. For more information, see Define GL Code Filter Dialog Box Fields.

## Adding a GL Code

1. On the GL Codes screen, click **New**.

   The Create GL Code screen appears.

2. In the **Code** field, enter a code.

   The code is an alphanumeric code that represents the GL code and appears throughout the application.

3. In the **Name** field, enter a name for the GL code.

   The GL code name appears throughout the application. Two GL codes cannot have the same name.

4. In the **Description field**, enter a description about the GL code.
5. Click **Save**.

## Editing a GL Code

1. On the GL Codes screen, select the checkbox of a GL code you want to edit.
2. Click **Edit**.

   The Edit GL Code screen appears.

3. Edit the GL code information as necessary.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit GL Code Screen Fields.
4. Click **Save**.
5. To return to the GL Code screen, click **Close**.

## Deleting GL Codes

1. On the GL Codes screen, select the checkbox of a GL code to delete.
2. Click **Delete**.

## Restoring GL Codes

1. On the GL Codes screen, select the **All GL Codes** radio button.

   Deleted GL codes appear with a line through them.
2. Select the checkbox of a deleted GL code.
3. Click **Restore**.

## Mapping Labor and Costs to GL Codes

1. On the GL Codes screen, click **Map Labor and Costs**.

   The Edit GL Code Mapping screen appears. There are four GL code mapping tabs:

   - **Labor (Late stage)—**Map labor to GL codes for late stage studies.
   - **Labor (Phase 1)—**Map labor to GL codes for Phase I studies.
   - **Costs (Late stage)—**Map costs to GL codes for late stage studies.
   - **Costs (Phase 1)—**Map costs to GL codes for Phase I studies.
2. For each GL code mapping tab, click the **Change** link in the upper right corner to select the mapping mode.

   The Change Mode dialog box appears.
3. Select a mapping mode by clicking the radio button. There are four mapping modes:

   - **Resource—**Map labor to GL codes by resource. You map GL codes to internal and outsourced providers for each resource. You can provide a default GL code for internal and outsourced providers for all resources by selecting GL codes in the default row.
   - **Location—**Map labor to GL codes by location. You map GL codes to internal and outsourced providers for each location. You can provide a default GL code for internal and outsourced providers for all locations by selecting GL codes in the default row.
   - **Task—**Map labor to GL codes by task. GL codes can be mapped to internal and outsourced providers for each task. You can provide a default GL code for internal and outsourced providers for all tasks by selecting GL codes in the default row, or for all tasks within a task group by selecting GL codes in a task group row.
   - **Rule (Advanced Mode)—**Map labor to GL codes by your own criteria. For more information, see Adding a GL Code Mapping Rule.
4. Click **Ok**.

   The Edit GL Code Mapping screen appears.
5. For each tab, do the following:

   - In the **Default** row, select a default GL code mapping to apply to each resource, location, or task.

- In the **Internal** column, select a GL code mapping for each resource, location, or task.
- In the **Outsourced** column, select a GL code mapping for each resource, location, or task.

6. Click **Save**.

## Editing GL Code Mappings

1. On the GL Codes screen, click **Map Labor and Costs**.

   The Edit GL Code Mapping screen appears.

2. Edit GL code mappings as necessary.

   - For more information about a field, click the field name.
   - For more information about the screen, see Edit GL Code Mapping Screen Fields.

3. Click **Save**.

## Adding a GL Code Mapping Rule

1. On the GL Codes screen, click **Map Labor and Costs**.

   The Edit GL Code Mapping screen appears.

2. Select a GL code mapping tab and click the **Change** link in the upper right corner.

   The Change Mode dialog box appears.

3. Click the **Rule (Advanced Mode)** radio button.
4. Click **Ok**.

   The Edit GL Codes Mapping screen appears.

5. Click **Add Rule**.

   The Create GL Code Mapping Rule dialog box appears.

6. On the Create GL Code Mapping Rule dialog box, do the following:

   a. From the **GL Code** drop-down list, select the GL code to be assigned when this rule is applied.

   b. On the **Providers** tab, select providers to be matched according to this rule.

      Selecting the **Internal** and **Outsource** checkboxes includes all the service providers in that group.

   c. On the **Locations** tab, select locations to be matched according to this rule.

      Selecting the **Any Location** checkbox includes all locations.

   d. On the **Tasks** tab, select the checkboxes of tasks to be matched according to this rule.

      Selecting the **Any Task** checkbox includes all task groups and tasks.

   e. On the **Resources** tab, select resources to be matched according to this rule.

      Selecting the **Any Resource** checkbox includes all resources.

7. Click **Ok**.

   The rule is added to the GL code mapping tab.

8. Click **Save**.

### Edit and Delete Your GL Code Mapping Rules

You can edit or delete your GL code mapping rules by selecting the rule checkbox and clicking **Edit Rule** or **Delete Rule**.

# Define Exchange Rates on the Exchange Rate Tables Screen

You maintain exchange rates on the Exchange Rate Tables screen. An exchange rate table allows you to create and define your organization's standardized rates for each currency to be used in your plans.

To work with exchange rate tables, your system administrator must grant you the Exchange Rates Administrator role.

Exchange rate tables you create on this screen can be shared by multiple plans. When you update an exchange rate table, all plans using the table automatically update with the new conversion rates.

- For more information about a field, click the field name.
- For more information about the screen, see Exchange Rate Tables Screen Fields.

## Draft vs. Published Exchange Rate Tables

You apply a published exchange rate table to a plan on the Overview tab. You cannot apply a draft exchange rate table to a plan.

## Filtering the Exchange Rate Tables Screen

You can filter the Exchange Rate Tables screen to search for exchange rate tables. For information on filtering screens, see Define Exchange Rate Table Filter Dialog Box Fields.

## Creating an Exchange Rate Table

1. On the Exchange Rate Tables screen, click **New**.

   The Create Exchange Rate Table screen appears.
2. In the **Details** section, in the **Name** field, enter a name for the exchange rate table.

   This name appears throughout the application.
3. In the **Description** field, enter a description of the exchange rate table.
4. In the **Currency Exchange Rates** section, in the **Use rates as of** field, enter or select a date from the **Calendar** icon and click **Apply** to populate the currency exchange rates from a certain date.
5. In the **Currency Exchange Rate** fields, enter the currency exchange rates for each location.
6. To save the exchange rate table as a draft, click **Save Draft**.

   or

   To make the exchange rate table available for use in plans, click **Publish**.
7. To return to the Exchange Rate Tables screen, click **Close**.

## Editing an Exchange Rate Table

1. On the Exchange Rate Tables screen, select the checkbox of the table to edit.
2. Click **Edit**.

   The Edit Exchange Rate Table screen appears.
3. Edit the exchange rates as necessary.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Exchange Rate Table Screen Fields.
4. To save the exchange rate table as a draft, click **Save Draft**.

   or

   To make the exchange rate table available for use in plans, click **Publish**.
   - Clicking **Publish** replaces values in any plans currently using the exchange rate table. All plans using the exchange rate table automatically update with the new conversion rates.
5. To return to the Exchange Rate Tables screen, click **Close**.

## Deleting an Exchange Rate Table

1. On the Exchange Rate Tables screen, select the checkbox of the table to delete.
2. Click **Delete**.

## Restoring an Exchange Rate Table

1. On the Exchange Rate Tables screen, click the **All Exchange Rate Tables** radio button.

   Deleted exchange rate tables appear with a line through them.
2. Select the checkbox of a deleted exchange rate table.
3. Click **Restore**.

## Publishing Exchange Rate Tables

1. Select the checkbox of the exchange rate table you want to publish.
2. Click **Publish**.

## Setting the Default Exchange Rate Table

The application uses the default exchange rate table when a new plan is created.

1. On the Exchange Rate Tables screen, select the checkbox of the table to make the default.
2. Click **Set Default**.

   On the Exchange Rate Tables screen, the default table appears bold.

# Map Countries to Reporting Regions on the Edit Reporting Regions Screen

Group reporting regions for studies based on your global organizational structure and accounting practices with the Edit Reporting Regions screen.

You map countries to reporting regions. Mapping allows you to view the budget by location with the Monthly Budget by Reporting Region report, available from the Reports tab.

To work with reporting regions, your system administrator must grant you the Reporting Regions Administrator role.

- For more information about a field, click the field name.
- For more information about the screen, see Reporting Regions Screen Fields.

## Adding a Reporting Region

1. On the Edit Reporting Regions screen, click **New Reporting Region**.

   A blank entry appears in the **Reporting Region Name** column.

2. Enter a reporting region name.
3. Click **Save**.

## Editing the Name of a Reporting Region

1. On the Edit Reporting Regions screen, in the **Reporting Region Name** column, click the reporting region name or the **Pencil** icon.

   The reporting region name becomes editable.

2. Edit the reporting region name.
3. Click **Save**.

## Deleting a Reporting Region

To delete a reporting region, click the associated **Trash Can** icon.

When reporting regions are deleted, the application removes the country mappings.

## Mapping Countries to Reporting Regions

1. On the Edit Reporting Regions screen, click **Map Countries to Reporting Regions**.

   The Map Countries to Reporting Regions dialog box appears.

2. For each country, from the **Reporting Region** drop-down list, select a reporting region.
3. To save your changes and keep the dialog box open, click **Save**.

   or

   To save your changes and return to the Edit Reporting Regions screen, click **Save and Close**.

## Viewing the Monthly Budget by Reporting Region report

1. On the Edit Plan screen, **click Reports**.

A list of available study reports appear.

2. Click the **Monthly Budget by Reporting Region** link.

   If you have locations in the plan that are mapped to reporting regions, the Monthly Budget By Reporting Region report appears.

3. Click **Ok**.

# 4

# Plan and Source Field Descriptions

This chapter presents field descriptions for screens, tabs, and dialog boxes in the application. All possible fields are included. If your edit mode is set to Quick or Basic, not every field included will be available to you. For details about the functions and options described here, see Chapter 2, "Working with Plans," and Chapter 3, "Maintaining Resource Information and Settings."

## Home Page Fields

These fields always appear on the screen you have designated as your preferred home page.

***Table 4–1 Home Page Fields***

| Field | Description | Notes |
|---|---|---|
| **Menu Bar** | | |
| Edit | Add or edit plans, studies, products, templates, and portfolios. | |
| Report | Generate standard reports that are not plan-specific. | |
| Maintain | Define, select, and edit:<br>**Service providers**—The service providers to whom you can assign work in a plan.<br>**Resources**—Manage system-defined resources and add, edit, and delete user-defined resources.<br>**Billing rates**—Define billing rates for service providers to whom you assign work. After you publish the billing rates, the application shares the rates between plans.<br>**Departments and functional areas**—Map labor and costs to departments and functional areas. Choose a mapping mode.<br>**GL codes**—Map labor and costs to the general ledger.<br>**Exchange rates**—Create and define your organization's standardized rates for each currency to be used in your plans.<br>**Reporting Regions**—Group reporting regions for studies based on your global organizational structure and accounting practices. | Select **Purge Deleted Items** to permanently remove items. |

*Table 4–1 (Cont.) Home Page Fields*

| Field | Description | Notes |
|---|---|---|
| Admin | **Users** shows all users currently defined and allows the system administrator to add, edit, delete, and restore users; reset a selected user's password; clear a session when a user is locked out; and reset a user account. A reset clears the user's security question and answer, unlocks the account, and forces the user to reset the password. | |
| Help | Display a Help screen associated with the screen currently displayed.<br>View version and product information on the About Oracle Health Sciences ClearTrial Cloud Service dialog box.<br>Contact technical support. | |
| User Name | View your user profile. | You can edit your profile and change your password. |
| Visit Support Center | Displays the application Support Center to access release information, documentation, and reference material or to contact Oracle Support. | |
| Logout | Sign out of the application. | |
| **Filter** | | |
| Show | Show or hide items based on selected criteria.<br>■ **All <items>**—No filter is applied. All items appear.<br>■ **Active <items> Only**—Items that are not deleted or marked as Study Complete or Archived appear.<br>■ **<Items> matching filter**—Only items that match the criteria you selected from the custom filter drop-down list appear. | These choices appear on any screen with a Filter section. |
| Modify link | Define a custom filter on the Define <Item> Filter dialog box. | |

# Plans Screens, Tabs, and Dialog Boxes

## Plans Screen

*Table 4–2 Plans Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| New | Create a new plan. | |
| Edit | Edit the selected plan or open it to view details, the summary, or reports. | You can also a open a plan by double-clicking the plan name. |

*Table 4–2 (Cont.) Plans Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Delete | Delete the selected plan. | Deleted plans are removed at a later time and can be restored. |
| Restore | Restore a deleted plan. | To use this option, adjust the filters so that you can see inactive as well as active items. |
| Copy | Make a copy of the selected plan. | |
| Compare | Compare selected plans. You can specify service provider and location details and change the currency used to generate the costs and comparison reports. | |
| Other Actions... | Access additional features, such as locking and unlocking plans, freezing, and unfreezing billing rates, copying a plan as a template, and so on. | |
| **Columns** | | |
| Plan name | Unique identifier of plans. | |
| Study Name | Name of study. | |
| Description | Short description of the plan. | |
| Status | Status of the plan:<br>■ **Incomplete**—Basic assumptions have not been set for the plan.<br>■ **Draft**—All input questions of the selected edit mode have been answered, but the plan owner or creator might still be working on the plan.<br>■ **Final**—All input questions have been answered and the plan owner believes the plan will be used to conduct the clinical study. However, the plan has not yet been approved.<br>■ **Approved**—The plan has been approved and is ready to go out as part of an RFP or proposal or to be used to conduct the trial.<br>■ **RFP**—The plan has been approved and included as part of an RFP.<br>■ **Agreement reached; not started—**An agreement has been reached on the plan and it is under contract (if an outsourced study) or ready for study activities to begin (if an internal sponsor-executed study).<br>■ **In progress**—The study has begun and is operating according to this plan<br>■ **Study Complete—**The study has ended.<br>■ **Archived**—The plan is being preserved for historical purposes only. | You cannot choose another plan status until you enter information on all tabs through the Provider tab. |
| Last Modified | Date a user last modified this plan. | |

# Plans Screen Dialog Boxes

## Define Plan Filter Dialog Box

*Table 4–3 Define Plan Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Plan Filter Criteria** | | |
| Created or modified in the last n days | Includes plans last edited and saved the specified number of days. | |
| Include deleted plans | Includes plans that have been previously deleted. | |
| Plan name starts with | Includes plans whose names start with the specified text. | |
| Created by | Includes only plans created by one of the selected users. | To include all plans, select **Any User**. |
| Last Modified by | Includes only plans last edited and saved by the selected user. | To include all plans, select **Any User**. |
| Status | Includes only plans with the selected status. | To include all plans, select **Any Status.** |
| Phases | Includes only plans pertaining to the selected Phase(s). | To include all plans, select the **Any Phase**. |
| Therapeutic Areas | Includes only plans pertaining to the selected Therapeutic Area(s). | To include all plans, select **Any Therapeutic Area**. |
| Indications | Includes only plans for the selected indication(s). | To include all plans, select **Any Sponsor**. |
| **Save Filter** | | |
| Save filter as | Name assigned to the filter. | |
| **Sorting and Paging** | | |
| Sort By | Orders the plans based on your selections. | Change the order by clicking a column heading. |
| Show n plans per page | Number of plans displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## Choose Study and Plan Template Dialog Box

*Table 4–4 Choose Study and Plan Template Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Study Columns** | | |
| Study Name | Unique name given to study by its creator. | Read-only. |
| Product/Compound | The product or compound being studied. | Read-only. |

*Table 4–4 (Cont.) Choose Study and Plan Template Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Phase | The study phase being planned. The application supports study phases I, II, IIa, IIb, III, IIIb, Phase IV with an IND, and Phase IV without an IND.<br>The application supports Phase I for oncology and vaccine studies, as well as Phase I studies for healthy volunteers.<br>Phase I Oncology or Phase I Vaccine studies more closely resemble Phase IIa trials. | Read-only. |
| Therapeutic Area | The therapeutic area or body system for which this study will be conducted.<br>The application uses this selection to calculate monitoring time required, time for query resolution, data entry, and to provide other default values. | Read-only. Determines the choices available for the indication. |
| Indication | The reason selected to perform this study. Indications are classified into therapeutic areas.<br>The application uses this selection to calculate monitoring time required, time for query resolution, data entry, and to provide other default values. | Read-only. |
| **Template Columns** | | |
| Template Name | Name of a plan or partial plan that can be used as a starting point for new plans for a study. | Read-only. |
| Description | Information describing the template to help you recognize a particular scenario or purpose for the plan. | Read-only. |
| Applicable For | Study phase(s) for which the template has been defined. | Read-only. |

## Copy Plan Dialog Box

*Table 4–5 Copy Plan Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Plan Name | Name of the new copy plan. | |

## Compare Plan Dialog Box

*Table 4–6 Compare Plan Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Available Comparisons | Comparisons to be made and details to include. | |
| Providers To Include | Service providers to include in the comparison. | |
| Reporting Currency | Currency to use for the comparison report. | |

## Copy Plan as Template Dialog Box Fields

*Table 4–7 Copy Plan as Template Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Template Name | Name of the new template based on the plan. | |

## Change Plan Attributes Dialog Box

The attributes you can change vary depending on the number of plans you select and the status of the selected plans.

*Table 4–8 Change Plan Attributes Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Plan Name | Unique name that identifies the plan. | If you select multiple plans, the name field is disabled to prevent you from changing the name of more than one plan to the same name. |
| Status | Status of the plan:<br>■ **Incomplete**—Basic assumptions have not been set for the plan.<br>■ **Draft**—All input questions of the selected edit mode have been answered, but the plan owner or creator might still be working on the plan.<br>■ **Final**—All input questions have been answered and the plan owner believes the plan will be used to conduct the clinical study. However, the plan has not yet been approved.<br>■ **Approved**—The plan has been approved and is ready to go out as part of an RFP or proposal or to be used to conduct the trial.<br>■ **RFP**—The plan has been approved and included as part of an RFP.<br>■ **Agreement reached; not started—**An agreement has been reached on the plan and it is under contract (if an outsourced study) or ready for study activities to begin (if an internal sponsor-executed study).<br>■ **In progress**—The study has begun and is operating according to this plan<br>■ **Study Complete—**The study has ended.<br>■ **Archived**—The plan is being preserved for historical purposes only. | |
| Short Description | Short description of the plan that appears on the Plans screen. | |
| Long Description | Detailed plan description. | |
| Update last modified date and user (plan history) | Updates the selected plans' Last Modified Date and Last Modified fields when changes are applied to the name, status, and/or description. | |

## Add Plans to Portfolio(s) Dialog Box

***Table 4–9 Add Plans to Portfolio(s) Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Name | Portfolios to which you can add the selected plan(s). | |
| Description | Short description of the portfolio. | |
| # Plans Now | Number of plans in the portfolio before adding the selected plan(s). | |
| # Plans After | Number of plans in the portfolio after adding the selected plan(s). | |
| Also create a new portfolio and add the selected plans to it | Create a new portfolio. | |
| **Create New Portfolio** | | |
| Portfolio Name | Name for the new portfolio. | |
| Short Description | Short description of the portfolio. This description appears on the Portfolios screen. | |
| Default Reporting Currency | Default reporting currency for generating portfolio reports. | Determines the currency used to display monetary values on the Portfolios Summary tab. |

## Create Reforecast Dialog Box

***Table 4–10 Create Reforecast Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| Reforecast Name | Name of the new forecast. | |
| Reforecast Date | Reforecast date for all listed plans. | Changes to assumptions take effect on this date. |
| Prior Forecast Date | Date of the prior forecast plan. | |
| Study End Date | Date by which study is expected to be complete, defined as the date that all activity stops (usually the date the final report <CSR> is finalized). | |
| Create reforecast based on | Actuals for reforecast based on actual tracked data or Plan for reforecast based on planned data. | Only available to users licensed to the Track module. |

## Reforecast Exch Rates (Create Reforecast) Dialog Box

***Table 4–11 Create Reforecast Dialog Box Fields (Reforecast Exchange Rates)***

| Field | Description | Notes |
|---|---|---|
| **Reforecast Details** | | |

*Table 4–11 (Cont.) Create Reforecast Dialog Box Fields (Reforecast Exchange Rates)*

| Field | Description | Notes |
|---|---|---|
| Reforecast Date | Reforecast date for all listed plans. | You can edit the date for each plan individually. |
| Use Exchange Rates | Exchange rates reforecast method.<br>▪ To reforecast based on exchange rates as of a particular date, choose the first radio button and then specify that date.<br>▪ To reforecast based on exchange rates specified in a predefined published exchange rate table, choose the second option and choose the table by name from the list. | |
| Use Exchange Rates: as of (date) | Date from which to obtain exchange rates as they were at the close of market on that day. | |
| Use Exchange Rates: defined in (published exchange rates table) | Published set of exchange rates to apply | |
| **Columns** | | |
| Reforecast Name | Suggested name for each reforecast. You can either accept this name or type a new name. | |
| Prior Forecast Date | Date of the last forecast per plan. | The new reforecast date must be later than this date. |
| Study End Date | Date by which study is expected to be complete, defined as the date that all activity stops (usually the date the final report <CSR> is finalized). | |
| Reforecast Date | Date from which to apply the newly chosen exchange rates for each plan. | Recommended option if progress was tracked and actuals are up to date. |
| Based on | Base the reforecast on the actual progress, rather than on the predicted progress. | Only available to users licensed to the Track module and for plans whose studies are being tracked. |

## Create/Edit Plan Screen (Overview Tab)

*Table 4–12 Overview Tab fields*

| Field | Description | Notes |
|---|---|---|
| **General Information** | | |
| Plan Name | Unique name that identifies the plan. | |
| Project Activity Start Date | Date the study begins, defined as the date that vendors and the sponsor start identifying sites and vendors start billable activity. | |
| Status | Plan status. | |

*Table 4–12 (Cont.) Overview Tab fields*

| Field | Description | Notes |
|---|---|---|
| Start pre-study planning | Date a sponsor begins pre-planning activities. The default date is three months prior to the Project Activity Start Date. | Not used to calculate effort or costs for the study. |
| Study will be | Outsourcing option for the plan:<br>■ **Conducted Internally**—Study is performed internally. Sets all responsibility radio buttons to Sponsor throughout the plan.<br>■ **Outsourced—**Entire study is outsourced to an external service provider (excluding oversight of that service provider). Sets all responsibility radio buttons to Vendor throughout the plan.<br>■ **Combination—**Study tasks are divided between an external service provider and the sponsor. | |
| **Description** | | |
| Short Description | Short description of the plan that appears on the Plans screen. | |
| Long Description | Detailed plan description. | |
| **Currency Options** | | |
| Default Modeling Currency | Currency used to enter plan costs. | |
| Default Reporting Currency | Currency the application uses to generate reports. | |
| Use Exchange Rates | Exchange rates to use when converting between currencies.<br>■ **As if (specified date)—**Exchange rates from a specific date.<br>■ **Defined in**—User-defined exchange rate table. For more information on creating exchange rate tables, see Creating an Exchange Rate Table.<br>■ As specified here—Override of one or more exchange rates with values you supply.<br>■ **As of plan created date:** When creating templates, use exchange rates from the date the plan was created. | If you select a date the application does not support, it defaults to the most recent date for which exchange rates are available. |
| **Other Factors** | | |
| Drug Storage | Special handling considerations. | |
| Radio Labeled | Compound is radioactive. | Optional. |

*Table 4–12 (Cont.) Overview Tab fields*

| Field | Description | Notes |
|---|---|---|
| Study Difficulty | Unusual circumstances about a trial make aspects other than monitoring and data management more or less difficult than most clinical studies. | For example, multiple monitoring sites, complex ICF or other study regulatory documents, complex interaction with multiple groups at the study sites, additional interaction with the sponsor and or a DSMB. |
| **History** | | |
| Created By | Displays the name of the user who created the plan. | |
| Last Modified By | Displays the name of the user who last modified the plan. | |
| Created Date | Displays the date the plan was created. | |
| Last Modified | Displays the date the plan was last modified. | |
| Created as a copy of | Displays the plan that was copied. | |
| Original Template | Displays the template from which the plan was created. | |

### Override Currency Exchange Rates Dialog Box

*Table 4–13 Override Currency Exchange Rates Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Currency Exchange Rates | | |
| 1 US Dollar (USD) equals... | Default exchange rates for 1 US dollar as of the current date. | |

## Locations Tab

*Table 4–14 Locations Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| Add Location(s) | Add one or more locations on the Choose Locations dialog box. | |
| Remove Location(s) | Remove selected location(s). | Removing a location from a plan does not delete that location from the application. |
| Add Language(s) | Add one or more languages not suggested for the plan by the application. | |
| Remove Language(s) | Remove a selected user-specified language. | |

*Table 4–14 (Cont.) Locations Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Name of a location (either the country or the region) where sites will be located and subjects enrolled. | |
| Number of Sites | Number of sites for the location. | |
| Subjects to Randomize | Number of subjects to randomize in this location.<br>Should contain only the number of subjects that will actually be enrolled in the trial. | Must be a value between 1 and 999,999. |
| Avg Grant Amount | Average grant amount is paid to each investigator for each subject the investigator enrolls in the study at the location. | Payment for a dropped subject is approximately 75% of the grant.<br>Must be a value between 0 and 500,000 USD (or the equivalent in another currency). |
| MOH / FDA Delay | Ministry of Health (MOH) or Federal Drug Administration (FDA) approval timeframe for each location. | Must be a value between 0 and 999. |
| Total / Avg | Averages of the total sites, subjects to randomize, grant amount and MOH / FDA time delay. | |
| **Language** | | |
| Language | Language into which study materials might need to be translated. | |
| Dialects / Variations | Number of dialects or variants of this language into which to translate study documents. | |
| Document Translations | Which documents are to be translated into the languages specified. | |
| Number of Translations / Dialects | Total number of translations required. | |

## Choose Locations Dialog Box

*Table 4–15 Choose Locations Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Filter | | |
| Regions | Include locations by region. | |
| Counties | Include locations by country. | |
| Remove Language(s) | Removes the selected language. | |
| **Columns** | | |
| Region | Regions available for selection. | |
| Country | Countries available for selection. | |

*Table 4–15 (Cont.) Choose Locations Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Primary Language | Primary language of the selected region or country. | |
| Primary Currency | Primary currency of the selected region or country. | |
| MOH / FDA Delay | Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time for each location. | |

### Choose Additional Languages Dialog Box

*Table 4–16 Choose Additional Languages Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Columns | | |
| Language | Languages available for selection. | |
| ISO Code | Internationally recognized country code associated with the language. | |

### Document Translations Required Dialog Box

*Table 4–17 Document Translations Required Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Document Type | Type of document. | |
| Translate | Translates the document type to the languages indicated. | |
| Back Translate | Translates the document back into the language of the original text, from the translated version. | |
| As Pass-Through Cost | Translation costs are to be considered pass-through costs, not calculated costs. | |
| Apply these choices for: | Applies selected translation choices to other languages. | |

## Site Tab

*Table 4–18 Site Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Site Approval (Columns)** | | |
| Location | Name of a location where sites will be located and subjects enrolled. | |
| Number of Sites | Number of sites within the selected location. | |
| Site Approval Schedule | Type of site approval schedule for the location.<br>**User Defined Schedule**—Site approval schedule has been modified.<br>**ClearTrial Default Schedule**—Site approval follows the application-defined schedule. | |

*Table 4–18 (Cont.) Site Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Site Information** | | |
| Values apply to | Location for which the values apply.<br>Select a single location or **All Location**s to enter information for all locations in the plan. | If you select a single location, click **Save** before selecting another location. |
| Number of sites | Number of sites in the location. | |
| Percent of sites identified by sponsor | Percentage of study sites that the study sponsor identifies. The application calculates the number of sites. | |
| Percent of sites requiring a pre-study site visit (in-person) | Percentage of sites that require an in-person pre-study site visit. The application calculates the number of sites. | |
| Percent of sites requiring a phone-based pre-study site visit | Percentage of sites that require a phone-based pre-study visit. The application calculates the number o f sites. | |
| Percent of sites requiring site initiation visits (in-person) | Percentage of sites that require an in-person site initiation visit. The application calculates the number o f sites. | |
| Percent of sites requiring only phone-based site initiation | Percentage of sites that require a phone-based site initiation visit. The application calculates the number o f sites. | |
| Percent of on-site close-out visits | Percentage of sites that require an on-site close-out visit. The application calculates the number o f sites. | |
| Percent of sites requiring only phone-based close-outs | Percentage of sites that require only phone-based close-outs. The application calculates the number o f sites. | |
| Number of grant payments per site | Estimated number of grant payments per site. | The application derives a default value after the study duration is calculated. Assumes quarterly payments. |
| Percent of sites using local monitoring | Percentage of sites using a local monitor. The application calculates the number o f sites. | |
| Percent of sites requiring overhead | Percentage of sites requiring overhead above the standard investigator grant. The application calculates the number o f sites. | |
| Average percent overhead | Average overhead percentage for sites requiring overhead. | |
| Number of drug shipments per site | Estimated number of drug shipments for each site. | |
| Percent of sites requiring a QA audit | Percentage of sites requiring a quality assurance audit. The application calculates the number o f sites. | |

*Table 4–18 (Cont.) Site Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Percent of regulatory documents collected | Enter the percentage of regulatory documents to collect during the investigator approval process. | |
| Percent of sites using BOTH a central and local IRB/EC | Percentage of sites using both a central and local review board or ethics committee. The application calculates the number of sites and applies the percentage separately to each site. | IRB is applicable to US sites only. Other countries use either central or local ethics committees. |
| Percent of sites using ONLY a central IRB/EC | Percentage of sites using only a central review board or ethics committee. The application calculates the number of sites and applies the percentage separately to each site. | Exclude all university centers and sites that are affiliated with hospitals that require that their own ethics committees are used. |
| Percent of sites using ONLY a local IRB/EC | Percentage of sites using a local review board or ethics committee based on the percentage entered. The application calculates the number of sites. | Percentages are applied to the number of sites in each location and partial values are rounded up for central IRBs/ECs and rounded down for local IRBs/ECs. |
| **Responsibilities** | | |
| Columns | | |
| Task Group | Assignment group to which outsourcing responsibilities are applied. | For a list of tasks, see the online Help for the Sites tab. |
| Sponsor | Assign all of the tasks in that group to the study sponsor. | |
| Vendor | Assign all of the tasks in that group to the primary vendor assigned on the Provider tab. | |
| Mixed | Assign some of the tasks to the sponsor and some to the vendor. | Make these assignments on the Assignment tab. |
| N/A | None of the tasks in the group will be performed. | |

## Edit Site Approval Schedule Dialog Box

*Table 4–19 Edit Site Approval Schedule Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Site Approval Schedule for the Selected Location** | | |

*Table 4–19 (Cont.) Edit Site Approval Schedule Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Site Approval Schedule | Type of site approval schedule for the location.<br>**User Defined Schedule**—Site approval schedule has been modified.<br>**ClearTrial Default Schedule**—Site approval follows the application-defined schedule. | |
| Default Site Approval Period | Default length of the site approval period. | |
| Additional Site Approval Weeks | Number of weeks added to the application-defined approval period. | |
| Total Number of Weeks of Site Approval | Total length of the site approval period for this location, accounting for the default site approval period plus any additional weeks applied. | |
| **Site Approval Schedule (Columns)** | | |
| Week # | Week number. within the site approval schedule. | |
| Week Of | Start date of each week of the site approval period. | |
| Sites (Default) | Number of sites expected to be approved (according to the ClearTrial Default Site Approval Schedule) each week. | Cumulative totals appear inside parentheses. |
| % (Default) | Percentage of sites expected to be approved (according to the ClearTrial Default Site Approval Schedule) each week. | |
| Sites (User Defined) | Number of sites expected to be approved (according to the user-defined Site Approval Schedule) each week. | |
| % (User Defined) | Percentage of sites expected to be approved (according to the user-defined Site Approval Schedule) each week. | |
| Total | Total for each column. | |
| **Buttons** | | |
| Restore Defaults | Restore the default site approval schedule for this location. | |
| Apply | Add the specified number of weeks to the site approval schedule. | |
| Copy Default Value | Populate the user-defined site approval schedule with the application defaults. | Use to revise part of the schedule rather than entering a new set of assumptions. |

## Subject Tab

*Table 4–20 Subject Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Define Treatment Phase Start Date** | | |

*Table 4–20 (Cont.) Subject Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Project Activity Start Date | Date the study begins, defined as the date that vendors and the sponsor start identifying sites and vendors start billable activity. | Appears here for easy reference. |
| First Subject In Date (FSI/FPI) | Date for the first subject visit (FSFV) to occur. | |
| Manage location-specific values | Manage location-specific values for the First Subject In (FSI) date.<br>**Globally**—Changes you make to the application-calculated FSI date apply to each location based on the number of days you shift the date.<br>**Per Location**—Enter the dates and enrollment periods for each location in the study on the Edit Subject Arrival Dates dialog box. | |
| **Screening and Drops** | | |
| Subjects to randomize | Number of subjects in the selected location or all locations. | |
| Additional percent of randomized subject as alternates | Percentage of the total subjects randomized to be screened as alternate subjects. | |
| Stipend per alternate subjects | Stipend provided each alternate subject. | |
| Screen failure rate | Percentage of subjects expected to fail to become study participants. | Value cannot be greater than 99.99%. Oracle recommends a value between 0 and 50%. |
| Number of subjects to screen | Calculated number of subjects to screen based on the percentage of subjects expected to fail. | |
| Investigator payment per screen failure | Amount paid to the investigator for a subject that fails study screening. | |
| Percent of screen failures paid for | Percentage of the expected screen failures for which investigators are paid. | |
| Screen failures allowed | Maximum number of screen failures for which investigators in this location will be paid. | Represents the cap on amounts paid for subjects that do not become subject participants. |
| Stipend per screen failure | Stipend amount provided for each screen failure. | |
| Number of CRF pages per screen failure | Number of CRF pages collected for each screen failure. | |
| Subject drop rate | Percent of subjects expected to not complete a full CRF due to early termination. | Must be a value between 0 and 99. |
| Subjects expected to complete all study visits | Number of subjects expected to complete all study visits/data, based on the percentage entered for subject drop rate. | |

*Table 4–20 (Cont.) Subject Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Manage location-specific values | Link to Edit Location-specific Screening and Drop Rate and Assumption dialog box to manage subject screen and drops by location. | |

## Edit Subject Enrollment Dialog Box

*Table 4–21 Edit Subject Enrollment Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Study Level Adjustments** | | |
| Update study level enrollment period to | Study-level enrollment period. | |
| **Enrollment per Location** | | |
| Adjust first subject date for the selected locations by | Shifts the First Subject In date for the selected locations by the number of days (positive or negative). | |
| **Columns** | | |
| FSI | First Subject In. Date that the First Subject First Visit (FSFV) is expected to take place. | |
| Enrollment Period | Number of weeks during which subjects will be enrolled in the trial. | If the enrollment period is less than four weeks, contact cleartrial-support_ww@oracle.com. |
| Last Subject In Date | Location -specific First Subject In date plus the enrollment period. | |
| Enrollment Rate | Number of subjects expected to be enrolled per site per month. | |

## Edit Subjects Arrival Dates Dialog Box Fields

*Table 4–22 Edit Subjects Arrival Dates Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Enrollment per Location | Defines subjects arrival dates per location. | |
| Adjust first subject date for the selected locations by | Shifts the First Subject In date for the selected locations by the number of days (positive or negative) entered. | |
| **Buttons** | | |
| Apply | Applies the FSI date shift value to the selected locations. | |
| **Columns** | | |
| Location | Subject arrival region. | |

*Table 4–22 (Cont.) Edit Subjects Arrival Dates Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| FSI | First Subject In date. | If a start date that is greater than the user-specified FSI date is selected, a warning appears in the FSI date indicating that the date is before the Project Activity Start Date. |
| Study Level | Location-specific First Subject In date plus the enrollment period. | |

## Edit Enrollment Distribution Dialog Box

*Table 4–23 Edit Enrollment Distribution Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Options** | | |
| Location | Location for which the subject enrollment distribution is managed. | |
| Type of enrollment distribution | Expected enrollment distribution.<br>■ **Acute**—For indications where the subjects must present with the condition and will not be found by searching the medical records. Example: Anti-infective trials might experience an Acute or Acute Short Startup enrollment distribution.<br>■ **Acute Short Startup**—For Acute indications AND when you expect that less than 75% of the sites will be approved at the time when the first subject enrolls.<br>■ **Bell Curve**—Used only when the enrollment type is unclear to get an estimate of the study using an approach other than an even distribution of subjects across the enrollment period. | |

***Table 4–23 (Cont.) Edit Enrollment Distribution Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| | ■ **Block Enroll—**For situations such as allergy studies where it is expected that patients will be enrolled quickly over the first two quartiles of the enrollment period and stragglers over the last two quartiles.<br>■ **Chronic—**For studies where the subjects that meet the criteria are generally known and can be readily found by reviewing the patient charts and you expect all or most of the sites will be approved before the first subject visit takes place.<br>Example: Chronic illness like diabetes, Alzheimer's, AIDs.<br>■ **Chronic Short Startup—**For chronic indications when you expect that less than 75% of the sites will be approved at the time when the first subject enrolls.<br>■ **Even Distribution—**Rarely used, and then only for general estimations.<br>■ **Custom...—**To enter the percentage of the total subject population expected to be enrolled during each quartile of the enrollment period. | |
| Distribution resolution | Resolution at which to manage the subject enrollment distribution. | |
| **Columns** | | |
| Period | Period, quartile, or study week, during which subjects are planned to enroll. | |
| Subjects | Number of subjects expected to enroll during a particular period or quartile. | |
| Percentage | Percentage of subjects expected to enroll during a particular period or quartile. | |

## Edit Location-specific Screening and Drop Rate Assumptions Dialog Box

***Table 4–24 Edit Location-specific Screening and Drop Rate Assumptions Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| **Subject Screening and Drops** | | |
| Location | Screening and drops region. | |
| Subjects to randomize | Number of subjects expected in the selected location or for All Locations. | |
| Additional percent of randomized subjects as alternates | Percentage of the total subjects randomized to be screened as alternate subjects. | |
| Stipend per Alternate subject | Stipend provided each alternate subject. | |

*Table 4–24 (Cont.) Edit Location-specific Screening and Drop Rate Assumptions Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Screen failure rate | Percentage of screened subjects expected to fail to become study participants. | Must contain a value between 0 and 99.99.<br>Cannot be greater than 99.99%.<br>Recommended values are between 0% and 50%. |
| Number of subjects to screen | Calculated number of subjects to screen based on the percentage of subjects that are expected to fail and the number of subjects that are expected to be screened. | Calculation:<br>Number of Screen Failures Expected = Number of Subjects to be Randomized / (100 - Percent of Subjects that Fail Screen. |
| Investigator payment per screen failure | Amount that will be paid to the investigator for each subject that fails screening. | |
| Stipend per screen failure | Stipend to be paid to each potential subject that fails to pass the screening. | |
| Percent of screen failures paid for | Percentage of the expected screen failures investigators will still be paid. | |
| Number of screen failures allowed | Maximum number of screen failures for which investigators will compensated in this location. | |
| Subject drop rate | Percent of subjects that will not complete a full CRF due to early termination. | |

## Treatment Tab

*Table 4–25 Treatment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Study Characteristics** | | |
| Trial Design | Parallel or Cross-over study design.<br>**Parallel** —Different subjects receive different treatments during the same period.<br>**Cross-over**—Each subject receives all of the defined treatments, but in a different sequence. | |
| Will there be an electronic subject diary? | Whether there is an electronic subject diary. | |
| Cost per bednight | Cost per night that a subject is confined to a study center during the treatment period. | |
| **Baseline and Washout (Cross-over Trials)** | | |

*Table 4–25 (Cont.) Treatment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Number of CRF pages collected in the baseline visit | Number of CRF pages collected in baseline visits. | Must be a value between 0 and 99. |
| Baseline visit monitoring time required (in minutes) | Monitoring time required for baseline visits. | Must be a value between 0 and 9,999.99. |
| Washout period duration | Length of the washout period. | Time between treatments in a cross-over trial in which subjects are not treated. Done to reduce or avoid residual effects of the prior treatment from skewing the data or compromising the validity of the subsequent treatment(s). |
| Number of bednights during the washout period | Number of nights that a subject is confined to a study center during the washout period. | |
| **Treatment(s)** | | |
| **Buttons** | | |
| Add | Add a new treatment. | You can add up to five treatments to the study. |
| Edit | Edit a treatment on the Treatment Details dialog box. | |
| Copy | Duplicate an existing treatment. | |
| Delete | Remove a treatment. | Deleting a treatment removes all of its associated assumptions. |
| **Treatment Parameters** | | |
| ID | Alphabetic identifier for the treatment entry. | |
| Number of subjects | Number of subjects that will receive the treatment. | Included for parallel studies.<br>Not included for cross-over studies because all subjects receive all treatments (in a different sequence).<br>Must be a value between 1 and 999,999. |

*Table 4–25 (Cont.) Treatment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Treatment duration | Treatment length for each subject.<br>For late-stage trials, specified as weeks.<br>For Phase I trials, specified as days. | Must be a value between 2 and 999. |
| Visits per subject | Number of visits for each subject during the treatment. | Must be a value between 2 and 999. |
| Number of bednights | Number of nights subjects are confined to a study center during the treatment period. | Must be a value between 0 and 999. |
| Number of CRF pages per subject | Number of Case Report Form (CRF) pages collected for each subject during this treatment. | Must be a value between 0 and 9,999. |
| Number of QOL pages | Number of Quality of Life (QOL) pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| Number of subject diary pages | Number of subject diary pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| Number of pharmacoeconomic pages | Number of pharmacoeconomic pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| **Cross-over Design** | | |
| Name | Cross-over design that determines the sequences of treatments to which subjects are randomized.<br>The application supports Latin Square and Balaam's Design. Balaam's design is only applicable to trials with exactly two treatments. | |
| Treatment Sequence | Order in which treatments are administered. | |

## Edit Washout Period Dialog Box

*Table 4–26 Edit Washout Period Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Washout Period** | | |
| Day | Integer representing day within washout period. | |
| Number of CRF pages | Number of Case Report Form (CRF) pages that will be collected for each subject during this period. | Must contain a value between 0 and 99. |
| Monitoring Time (minutes) | Calculated amount of time (in minutes) required to monitor the pages collected during this period. | Must contain a value between 0 and 9,999.99. |
| Total number of CRF pages | Number of CRF pages to be collected for a single subject during each washout period. | |

## Edit Treatment Dialog Box (Details Tab, Schedule Tab)

*Table 4–27 Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Details Tab** | | |

*Table 4–27 (Cont.) Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Treatment Details** | | |
| Treatment duration | Treatment length for each subject.<br>For late-stage trials, specified as weeks.<br>For Phase I trials, specified as days. | Must be a value between 2 and 999. |
| Visits per subject | Number of visits for each subject during the treatment. | Must be a value between 2 and 999. |
| Number of bednights | Number of nights subjects are confined to a study center during the treatment period. | Must be a value between 0 and 999. |
| Number of CRF pages per subject | Number of Case Report Form (CRF) pages collected for each subject during this treatment. | Must be a value between 0 and 9,999. |
| Number of QOL pages | Number of Quality of Life (QOL) pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| Number of subject diary pages | Number of subject diary pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| Number of pharmacoeconomic pages | Number of pharmacoeconomic pages collected during the treatment period. | Must be a value between 0 and 9,999. |
| **Columns** | | |
| Location | Location to which each treatment cost is applied. | |
| # Subjects | Number of subjects expected to be randomized to this treatment in each location. | |
| Procedure Cost | Amount paid to the CPU for each subject to perform the standard / common procedures required by the trial. | Must be a value between 0 and 500,000 USD (or the equivalent in another currency). |
| Special Procedure Cost | Amount paid to the CPU for each subject to perform special or uncommon procedures required by this treatment. | Must be a value between 0 and 500,000 USD (or the equivalent in another currency). |
| Stipend Per Enrolled Subject | Amount paid to the subjects in this location. | Must be a value between 0 and 500,000 USD (or the equivalent in another currency). |

*Table 4–28 Schedule Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Schedule Tab** | | |
| **Subject Treatment Schedule** | | |
| Day | Day within the treatment period, represented by an integer. | |

*Table 4–28 (Cont.) Schedule Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Number of CRF Pages | Number of CRF pages expected to be collected during this period. | The total number of CRF pages should equal the Number of CRF Pages Per Completed Subject. |
| Monitoring Time (minutes) | Number of minutes required for this visit. | |
| Percent of Grant | Percentage of the grant amount allocated to each visit. | |
| Total Number of CRF Pages | Total number of CRF pages to be collected for a single subject during the course of this treatment. | |
| Total visits per subject. | Total number of visits for each subject for this treatment. | Must be a value between 2 and 999. |
| Total Grant Allocation | Total percentage of the grant allocated to the subject treatment schedule. | Must equal 100% for the schedule to be valid. |
| **Links** | | |
| Clear CRF Defaults | Overrides the calculated schedule. | |
| Restore CRF Defaults | Restores default values for CRF pages and monitoring time. | |
| Clear Grant Overrides | Restores default values for grant allocations. | |

## Data Tab

*Table 4–29 Data Tab fields*

| Field | Description | Notes |
|---|---|---|
| **Data Collection** | | |
| Data Collection Method | Data collection method for the study.<br>■ **Paper (Traditional Monitoring)—** Monitors visit the sites to collect data.<br>■ **Electronic Data Capture (EDC)—**Study data is collected electronically. The application calculates associated direct labor fees and indirect costs based on the level of EDC proficiency.<br>■ **EDC-3rd Party—**The application does not calculate labor fees related to EDC. Instead, you can create or adjust pass-through costs to account for these expenditures.<br>■ **Faxed CRFs—**Case Report Forms (CRFs) are completed at the investigator site and faxed to the data management location.<br>■ **Investigator Site Data Entry—**Data is entered into a data capture system or web-based system by someone at the site. | If there is no data monitoring for the study, select Paper (Traditional Monitoring) and set monitoring responsibilities to N/A. |

*Table 4–29 (Cont.) Data Tab fields*

| Field | Description | Notes |
|---|---|---|
| EDC Maturity Level | Level of EDC proficiency for the study. Enter if you selected **Electronic Data Capture (EDC)** or **EDC-3rd Party** data collection method.<br>■ **Stage 1: Pilot/Single Study—**Actively conduct experimental EDC implementations within a single study or within a limited number of trials.<br>■ **Stage 2: Limited Standardization:**—Use EDC in a limited number of studies.<br>■ **Stage 3: Standardization—** Use EDC for all new trials.<br>■ **Stage 4: Enterprise Deployment—**EDC is fully integrated for all of your trials. | |
| Query Rate | Average percentage of queries expected for every 100 pages of Case Report Form (CRF) data. | Must be a value between 0 and 999.99. |
| Percent of database data to audit | Percent of database information that is audited. | Default value is 10%. |
| Minutes for Data Entry per CRF page | Number of minutes required to enter one Case Report Form (CRF) into the database. | |
| Minutes for Data Coordination per CRF page | Number of minutes required to coordinate Case Report Form (CRF) data, calculated by the application based on the phase and therapeutic indication of the study. | Assumes double data entry. |
| Total number of data transfers | Number of expected data transfers. | If the sponsor is performing data management, enter 0. |
| Number of interim analyses to be performed | Number of interim analyses to be performed. | The default value is 0.<br>Must be a value between 0 and 9, but Oracle recommends a value between 0 and 3. |
| Number of third-party vendors / data sources | Number of third-party vendors or data sources used to capture study-related data. | Must be a value between 0 and 99. |
| Total number of data imports from third-party vendors | Total number of imports from third-party vendors expected throughout the study. | This is the total number of imports, not the number expected per vendor. |
| **CRF Design** | | |
| Number of Unique Pages | Number of unique pages in the Case Report Form (CRF) that are not duplicates of another CRF page or screen. | Minimum value is 1. |
| Number of screens per CRF page | Number of screens needed to capture one paper Case Report Form (CRF) page. | Must be a value between 1 and 10. |
| CRF page NCR ply | Type of paper on which the Case Report Form (CRF) prints. | 2, 3, or 4 ply NCR paper. |

*Table 4–29 (Cont.) Data Tab fields*

| Field | Description | Notes |
|---|---|---|
| Cost per page to print CRF | Cost per page for printing the Case Report Form (CRF). | Between 1.00 and 1.60 USD per page, depending on ply. Must be a value between 0.00 and 10.00 USD (or the equivalent in another currency). |
| **Biostatistics** | | |
| Number of Unique Data Tables | Number of unique data tables. | The application calculates a default number based on the Number of Unique Pages field. |
| Number of Unique PK/PD Data Tables | Number of unique PK/PD related tables. | |
| Number of Unique Data Listings | Number of unique data listings. | The application calculates a default number based on the Number of Unique Pages field. |
| Number of Unique PK/PD Data Listings | Number of unique PK/PD related listings. | |
| Number of Unique Figures and Graphs | Number of unique figures and graphs. | The application calculates a default number based on the Number of Unique Pages field. |
| Number of Unique PK/PD Figures and Graphs | Number of unique PK/PD related figures or graphs. | |
| **Project Management** | | |
| Number of newsletters per site | Number of newsletters to provide per site. | |
| Will there be an ICF Video/DVD? | Whether there will be an ICF Video/DVD. | |
| Number of years to archive data | Number of years study data must be kept after the study completes. | Default value is 5 years. Must be a value between 0 and 30. |
| Number of online EDC training sessions | Number of online EDC training sessions. | Default value is 3. |
| **Medical Writing / Timelines** | | |
| Number of pages in the Investigator Brochure | Number of pages in the Investigator Brochure. | |
| Number of manuscripts | Number of manuscripts. | Must be a value between 0 and 99. |

*Table 4–29 (Cont.) Data Tab fields*

| Field | Description | Notes |
|---|---|---|
| Days from LSO / LPO until Database Lock | Number of days from last subject observation (LSP / LPO) until the database lock. | Default values are 30 days for Stage 1, 20 days for Stage 2, 12 days for Stage 3, and 8 days for Stage 4.<br>The minimum value is 1. |
| Days from Database until Statistical Report is due | Number of days from the database lock date until the statistical report is delivered. | Default values are 45 days for Stage 1, 38 days for Stage 2, 36 days for Stage 3, and 34 days for Stage 4.<br>Minimum value is 1. |
| Days from Database Lock until Draft Report is due | Number of days from the database lock date until the draft clinical report is delivered. | Default values are 73 days for Stage 1, 70 days for Stage 2, 67 days for Stage 3, and 65 days for Stage 4.<br>Minimum value is 1. |
| Days from Database Lock until Final Report is due | Number of days from the database lock until the final clinical summary report (CSR) is delivered. | Default values are 98 days for Stage 1, 95 days for Stage 2, 90 days for Stage 3, and 85 days for Stage 4.<br>Minimum value is 1. |
| **SAE Management** | | |
| SAE rate as a percent of randomized subjects | Percentage of anticipated serious adverse events (SAEs) in terms of a percent of the total subject population. | Must be a value between 0 and 9,999.99. |
| SAEs | Number of serious adverse events (SAEs) calculated by the application. | |
| Hours medical monitor will spend with each SAE | Number of hours a medical monitor spends with each serious adverse event (SAE). | |
| Expected percent of SAE Reports to be expedited | Percentage of serious adverse event (SAE) reports to be expedited to regulatory agencies and ethics committees. | |
| Expedited SAEs | Number of expedited serious adverse events (SAEs) calculated by the application. | |
| Provide data to the DSMB | How often data is reported to the Data Safety Monitoring Board (DSMB). | |
| **IVRS (Interactive Voice Response System)** | | |
| IVRS Usage | Tasks for which an Interactive Voice Response System (IVRS) is used. | |
| **Amendments** | | |
| Expected Protocol Amendments | Add one or more protocol amendments. | |

*Table 4–29 (Cont.) Data Tab fields*

| Field | Description | Notes |
|---|---|---|
| An amendment is expected to occur | The number of days before or after a specific milestone this amendment is expected to occur | |
| Milestone nearest to the protocol amendment | The selected milestone from which the application calculates the approximate date of the amendment. | |
| Add another amendment | Add additional protocol amendments to the study. | |
| **Responsibilities** | | |
| **Columns** | | |
| Task Group | Assignment groups to which outsourcing responsibilities are applied. | For a list of tasks, see the online Help for the Sites tab. |
| Sponsor | Assign all of the tasks in that group to the study sponsor. | |
| Vendor | Assign all of the tasks in that group to the primary vendor assigned on the Provider tab. | |
| Mixed | Assign some of the tasks to the sponsor and some to the vendor on the Assignment tab. | |
| N/A | None of the tasks in the group will be performed. | |

## Monitoring Tab

*Table 4–30 Monitoring Tab fields*

| Field | Description | Notes |
|---|---|---|
| **Monitoring Methods** | | |
| Monitoring will be performed | Whether monitoring will be done in-person, by phone, or by a combination of these methods. | |
| Manage monitoring schedule values | Management of monitoring schedules.<br>**Globally**—Assumptions entered on the Monitoring tab apply to all the locations in the study.<br>**Per Location**—Modify schedules for each location within the study by clicking the **Per Location** link. | |
| **On-Site Monitoring Schedule** | | |
| Monitor every | Frequency, in weeks that a monitor visits the study sites during each period of the monitoring schedule. | |
| Until LSO/LPO | Site monitoring continues at the entered frequency until the end of the treatment period. | |
| Until Week | The week during the study the monitoring frequency changes. | |

*Table 4–30 (Cont.) Monitoring Tab fields*

| Field | Description | Notes |
|---|---|---|
| Total visits | Total number of monitoring visits during the study.<br>The application calculates the total visits based on the number of sites, monitoring frequency, and subject enrollment rate. | Must be a value between 0 and 999,999. |
| Monitoring Travel Strategy | Travel strategy for monitoring trips.<br>**Spoke**—Monitors returns to their home or office between each site visit.<br>**Loop**—Monitor travels to each site before returning to their home or office. | |
| **Monitoring Approach** | | |
| Percentage of time monitors spend in the field | Percentage of time monitors spend in the field. | The application assumes the remainder of the time is used for management activities. |
| Percentage of monitoring done by CRAs (vs. Senior CRAs) | Percentage of monitoring and site management conducted by Clinical Research Assistants (CRAs) versus Senior CRAs. | |
| Percentage of monitoring done by Regional Monitors | Percentage of monitoring regional monitors complete. | |
| Avg travel time (in hours) for site monitors | Average travel time, in hours, for site monitors. | |
| Percent of source document verification | Percentage of safety and efficacy data to be source verified while monitoring the data. | |
| Time to review queries from previous visit (minutes) | Number of minutes required to review queries and Case Report Form (CRF) data from a previous monitoring visit. | The application calculates this value based on the therapeutic area and indication. |
| Manage location-specific values | Include monitoring approach assumptions for each location by selecting the **Edit Location Specific Overrides** link. This opens the Edit Per Location Monitoring Approach dialog box. | |
| **Monitored Data** | | |
| Total CRF pages generated (without subject drops) | Number of predicted Case Report Form (CRF) pages generated, assuming no subjects drop out of the study. | |
| Total CRF pages monitored (accounting for subject drops) | Number of predicted Case Report Form (CRF) pages that are monitored, accounting for any subjects that drop out of the study. | |
| **Medical Monitoring** | | |

*Table 4–30 (Cont.) Monitoring Tab fields*

| Field | Description | Notes |
|---|---|---|
| Estimated number of FTE (full-time equivalent) Medical Monitors | Estimated time medical monitors serve as the team leaders. Medical monitors support the Clinical Research Assistant (CRA) staff and the study investigators. | |
| **Separate Drug Accountability** | | |
| Will there be additional drug accountability visits? | Whether additional drug accountability visits are required. | |
| Additional drug accountability visits performed by | Who will perform additional drug accountability visits, if applicable. | |
| Additional drug accountability visits per site | Number of additional drug accountability visits to be made per site. | |

## Edit Per Location Monitoring Schedule Dialog Box

*Table 4–31 Edit Per Location Monitoring Schedule Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Monitoring Methods** | | |
| Monitoring will be performed | Whether monitoring will be done in-person or by phone or by a combination of these methods. | |
| **On-Site Monitoring Schedule** | | |
| Monitor every | Frequency, in weeks that a monitor visits the study sites during each period of the monitoring schedule. | |
| until LSO/LPO | Indicates that site monitoring will continue at the specified frequency throughout the end of the treatment period. | |
| until period | Week at which the specified frequency for monitoring will change | This is the week number of the START of the next monitoring period and must be greater than or equal to the value for the monitoring frequency for the prior period. |
| Total visits | Value derived from the total number of sites, monitoring frequency, and subject enrollment rate. | |
| Monitoring Travel Strategy | Travel strategy to be used for most of the monitoring trips. | |
| **Phone-Based Monitoring Schedule** | | |

*Table 4–31 (Cont.) Edit Per Location Monitoring Schedule Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Call every | Week at which the specified frequency for monitoring changes. | Must be greater than or equal to the value for the monitoring frequency for the prior period |
| Total calls | Total number of calls. This value is derived from the phone-based monitoring frequency and the subject enrollment rate. | Must be a value between 0 and 999,999. |
| Average hours per visit | Average number of hours required to perform a phone-based monitoring visit, including preparation and follow-up activities. | |
| Total Visits | Total number of visits across all locations. | |
| Total Calls | Total number of calls across all locations. | |
| Manage location-specific values | Monitoring approach assumptions for each location. | |

## Edit Per Location Monitoring Approach Dialog Box

*Table 4–32 Edit Per Location Monitoring Approach Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Monitoring Approach (Location)** | | |
| Restore Defaults | Click to restore the monitoring assumptions to the global values for a specific location. | |
| Restore All Defaults | Click to restore the monitoring assumptions to the global values for all locations. | |
| Percentage of time monitors spend in the field | Indicates the percentage of time monitors spend in the field. It is assumed that the remainder of their time is then spent on site management activities. | |
| Percent of source document verification | Specify the percent of key safety and efficacy data to be source verified while monitoring the data. | |
| Percentage of monitoring done by CRAs (vs. Senior CRAs) | Indicates the percentage of monitoring and site management that will be done by normal Clinical Research Assistants (CRAs) versus Senior Clinical Research Assistants (SCRAs). | |
| Percentage of monitoring done by Regional Monitors | Indicates the percentage of monitoring that will be done by Regional Monitors. | |
| Avg travel time (in hours) for site monitors | The average number of hours a monitor will need to travel to sites | |

## Provider Tab

*Table 4–33 Provider Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| Add Provider(s) | Add providers. | |
| Remove Provider(s) | Remove providers. | |
| Set as Primary Provider | The primary, or default, provider for tasks. | |
| Replace Provider | Replace the selected provider with another provider. | |
| Freeze Billing Rates / Unfreeze Billing Rates | Freeze or unfreeze the rates for the plan. | The application copies the current rates for the current providers and stores them with this plan. |
| **Columns** | | |
| Provider Name | Provider name. | |
| Provider Type | Provider type. | |
| Rate Year in Effect | Rate Year used to look up billing rates for the resources for this service provider for this plan. | |
| Back-Office Billing Rate Location | Location used to determine the default billing rates for centralized tasks or tasks conducted at a central location. | To change this or other provider-specific values, click the provider name to open the Provider Details dialog. |

### Choose Service Providers Dialog Box

*Table 4–34 Choose Service Providers Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Name | Name of the service provider. | |
| Type | Provider type. | |
| Last Updated | Date and time when service provider was last updated. | |
| Updated By | User who last updated the service provider. | |

### Specify Provider-Specific Details Dialog Box

*Table 4–35 Specify Provider-Specific Details Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Billing Rate Information** | | |
| Rate Year in effect | Rate year, associated with the billing rate, selected from the drop-down list. | |

*Table 4–35 (Cont.) Specify Provider-Specific Details Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Discount rate to apply to this study | Discount rate negotiated for the study, as a percentage. | |
| Inflation rate to apply to year 2 of study | Percentage to be added to billing rates in year 2 to offset inflation. | |
| Inflation rate to apply to subsequent years of study | Percentage to be added to billing rates after year 2 to offset inflation. | |
| Compound inflation annually | Whether or not to calculate inflation by compounding it annually. | |
| Back-Office Billing Rate Location | Location used to determine the default billing rates for centralized tasks or tasks conducted at a central location. | |
| Billing Rate Currency | Currency type for billing rate. | |
| Currency Exchange Rates | When converting between currencies, whether to select rates from the Overview tab or to define the rates for each country on this dialog box. | |
| 1 US Dollar (USD) equals... | Exchange rate for the dollar in other currencies. | Appears if you select Use Rates as defined below... for the Currency Exchange Rates field. |
| **FTE Utilization Information** | | |
| Project Manager utilization prior to FSI/FPI | Percentage of project manager resources required before the first patient has enrolled. | |
| Project Manager utilization after FSI/FPI | Percentage of project manager resources required after the first patient has enrolled. | |
| Resource Allocation Factor | Percentage of each full workday that the service provider's team works on the project. | |
| **Other** | | |
| Number of sponsor affiliates | The number of affiliates that the provider is to work with. | |
| Type of reporting to affiliates | The types of reporting to sponsor affiliates by the provider. | |
| Additional type of vendor with which this service provider will work | Relationship this service provider has with another provider. | |
| Will this provider manage the CTMS | Whether or not this service provider will enter data into the sponsor's Clinical Trial Management System. | |

### Choose Replacement Provider Dialog Box

*Table 4–36 Choose Replacement Provider Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Name | Name of the service provider. | |
| Type | Provider type. | |
| Last Updated | Date and time when service provider was last updated. | |
| Updated By | User who last updated the service provider. | |

## Meetings Tab

*Table 4–37 Meetings Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| Add | New meeting. | |
| Edit | Edit a meeting. | |
| Copy | Copy a meeting. | |
| Include | Include a meeting. | |
| Exclude | Exclude a meeting. | |
| Delete | Delete a meeting. | |
| **Columns** | | |
| Name | Meeting name. | |
| Type | Meeting type. | |
| Location | Meeting location. | |
| Occurs | Meeting frequency. | |
| Planner | Meeting organizer. | |

### Define New Meeting Dialog Box

*Table 4–38 Define New Meeting Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Name | Meeting name. | |
| Type | Meeting type. | |

### Meeting Details Dialog Box: Meeting Details Tab, Attendees Tab, Site Attendees Tab

*Table 4–39 Meeting Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Meeting Definition** | | |
| Name | Meeting name. | |

*Table 4–39 (Cont.) Meeting Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Type | Meeting type. | |
| Code | Meeting code. | The application uses the code as a prefix for the task associated with the meeting type. |
| Organizer/Planner | Meeting planner. | |
| Location | Meeting location. | |
| City | Name of the city where the meeting takes place. | |
| Non-travel event costs | Non-travel meeting costs. | |
| **Schedule** | | |
| Occurs | Meeting frequency. | |
| Starts | Meeting start date. | |
| Until | Meeting end date. | |
| # Meetings | Displays the number of meetings. | |
| Meeting Duration | Enter the number of hours each meeting lasts. | |
| **Providers Attending** | | |
| Provider | Service providers attending the meeting. | |
| **Locations Attending** | | |
| Location | Personnel from sites in the chosen location attending the meeting. | |
| % Sites Attending | Percentage of sites in this location sending participants to the meeting. | |
| # Sites Attending | Number of sites attending the meeting from this location. | |

*Table 4–40 Attendees Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Service Provider | Service provider for which you are editing or viewing meeting attendees. | |
| **Provider Attendees (Buttons)** | | |
| Add | Add additional meeting attendees. | |
| Delete | Delete meeting attendees. | You can only delete user-defined attendees. |
| Duplicate | Copy a meeting attendee. | |
| Expand All Billable Hours link | View details about billable hours for each meeting attendee. | |
| **Provider Attendees (Columns)** | | |

*Table 4–40 (Cont.) Attendees Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Attendees | Number of meeting attendees for the associated resource type. | |
| Resource Type | The resource type attending the meeting. | |
| Billing Rate Location | The billing rate location for the meeting attendee. | |
| Attendance Method | Attendee travel method. | |
| Billable Hours | Number of billable hours for the meeting attendee. | |
| Preparation | Number of hours of preparation expected by this resource. | Appears if the Expand All Billable Hours or Edit links are selected.<br>Must contain a value between 0 and 999.99. |
| Travel | Number of hours of travel expected by this resource. | Appears if the Expand All Billable Hours or Edit links are selected.<br>Must contain a value between 0 and 999.99. |
| Attendance | Number of hours that this resource is expected to attend the meeting. | Appears if the Expand All Billable Hours or Edit links are selected.<br>Must contain a value between 0 and 999.99. |
| Follow Up | Number of follow up hours expected by this resource. | Appears if the Expand All Billable Hours or Edit links are selected.<br>Must contain a value between 0 and 999.99. |
| Indirect Costs | Indirect costs for the meeting attendee. | |
| Travel | Total travel indirect costs for each meeting attendee. | |
| Other | Other indirect costs for each meeting attendee. | |

*Table 4–41 Add Provider Attendees Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Resource Name | Resource you can add to the task. | |
| Code | Code for a resource you can add to the meeting. | |

*Table 4–42 Site Attendees Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Attendees/Site | Number of attendees attending from each site for the selected location. | |
| % Sites | Percentage of sites attending that send this number of attendees by this attendance method. | |
| # Sites | Number of sites attending that send this number of attendees by this attendance method. | |
| Source Location | Location from which each meeting attendee is coming. | |
| Attendance Method | How attendees attend the meeting, such as Travel Domestic, Travel International, Teleconference, and No Travel. | Modifying this field populates the default travel cost and hours for these attendees. |
| Travel Cost | Travel cost expected by the site attendees for this location. | |
| Other Cost | Miscellaneous other costs expected by the site attendees for this location. | |
| Total Costs | Total indirect costs for each meeting attendee. | |

*Table 4–43 Notes Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Notes | Description and notes about the meeting. | Any user who has permission to edit the plan can view and edit these notes. |

## Assignment Tab

*Table 4–44 Assignment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Task Assignments** | | |
| Values apply to | Assign responsibility for a specific country or region to a specific service provider. | If you select Centralized Tasks/Locations Defaults, your task assignments apply to all locations in the study.<br>If you select the country or region, the task assignments you make only apply to that country or region. |
| Default service provider for outsourced tasks | Default service provider for outsourced tasks. | |
| Show Tasks link | List of assignment groups and tasks. | |
| Hide Tasks link | List of assignment groups and tasks. | |

*Table 4–44 (Cont.) Assignment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Override Resources or Rates | Override Resources or rates. | |
| **Columns** | | |
| Assignment Group / Task | Available assignment groups and tasks. | |
| Assign to | Service provider to which the task is assigned. | |
| Billing Rate Location | Billing rate location. | The application uses this location to calculate resource costs for the task. |
| Pinned | Save your assignments for a specific task or assignment group. | Pinning a task or assignment group ensures your selections are not lost due to other changes in the work breakdown structure.<br>Pinned settings are lost if the associated locations or service providers are removed from the plan.<br>If you replace a service provider, your pinned settings are saved. |

## Resource Overrides Dialog Box

*Table 4–45 Resource Overrides Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Scope of Overrides** | | |
| Values apply to | Locations affected by the overrides. | |
| Default service provider for outsourced tasks | Service provider whose resources or rates are to be overridden. | |
| **Resources/ Overrides** | | |
| Resource Name | Resource name. | |
| Billing Rate Location | Billing Rate Location. | |
| Rate | Billing rate. | This field must contain a value between 0.00 and 9,999 USD or the equivalent in another currency. |

*Table 4–45 (Cont.) Resource Overrides Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| % Adjust | Percentage adjustment applied to the billing rate. | This field must contain a value between 0 and 999.99. |
| Pinned | Save overridden values. | |
| Clear Overrides link | Restore the default resources and rates for the associated service provider. | |

## Labor Tab

*Table 4–46 Labor Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Filter** | | |
| Show hours and fees for | Service provider for which hours and fees appear. | |
| Show major tasks with no planned effort for the selected provider | **Select**—All major tasks appear, even if the selected service provider is not assigned to any of these tasks.<br>**Deselect**—Only major tasks assigned to the selected service provider appear. | |
| **Buttons** | | |
| New Major Task | Create a major task. Opens the Task Manager dialog box. | |
| Edit Major Task | Edit the selected major task. Opens the Task Manager dialog box. | |
| Delete Major Task | Delete the selected user-defined major tasks. | Permanently deletes the major task and its tasks, resources, algorithms, and overrides. You cannot restore deleted major tasks. |
| Adjust Hours of Fees | Adjust the labor unit hours and fees for the selected major task and service provider on the Task Manager dialog box. | |
| Pin Labor | Pin all labor units, costs, hours and distributions. | |
| Unpin Labor | Unpin all labor units, costs, hours and distributions. | |
| **Columns** | | |
| Major Task | Major task type. | For a description of each major task, see the online Help for the Labor tab. |
| Unit Hours | Level of effort (in hours) for the selected service provider to complete one unit of work for the major task. | Displayed values are rounded to the nearest 10th. Hover over the value to see the actual value. |

*Table 4–46 (Cont.) Labor Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Unit Cost | Total cost for the selected service provider to complete one unit of work for the major task. | Displayed values are rounded according to the conventions of the currency. |
| # Units | Total number of units of work expected (or, in the case of a re-forecast, remaining). | Some major tasks have a single unit of work; for example, Study or Database. Hover over the value to see the number of units. |
| Ext Hours | Total level of effort (in hours) for the selected service provider to complete the major task. | The application multiplies the Unit Hours by the # Units.<br>Displayed values are rounded to the nearest 10th. Hover over the value to see the actual value. |
| Ext Cost | Total cost for the selected service provider to complete the major task. | Displayed values are rounded to the nearest whole number. Hover over any value to see the value rounded according to the conventions of the currency. |
| Total Ext Hours | Total level of effort in hours for the selected service provider to complete the major task. | Determined by multiplying the Unit Hours by # Units. |
| Total Ext Cost | Total cost for the selected service provider to complete the major task. | Determined by multiplying Unit Cost by # Units. |

## Task Manager Dialog Box (Major Task Details Tab, Adjustments Tab, Distribution Tab)

*Table 4–47 Task Manager: Major Task Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Name | Name of the major task. | Must be unique within a plan. |
| Description | Detailed description of the major task. | |
| Labor | Whether associated tasks vary by location or centralized.<br>If you select **varies by location**, the associated tasks are completed at the study sites. | |
| Unit of Measure | Unit of work this major task represents. | |
| **Buttons** | | |
| New Task | Create a new task for the selected major task. | |

*Table 4–47 (Cont.) Task Manager: Major Task Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Edit Task | Edit the selected task. | |
| Delete Task | Delete the selected task. | |
| Edit Assignments | Edit service provider assignments for the selected task. | |

*Table 4–48 Task Manager: Adjustments Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Show hours and fees for | Service provider, whose unit hours or fees are to be adjusted. | |
| Expand All | View all hours and fees in each location for the selected service provider. | |
| Collapse All | Close the expanded view of hours and fees and display only planned and adjusted extended hours and extended cost. | |
| Clear Overrides | Restore all fields to the application default values. | |
| **Columns** | | |
| Location | Location (countries / regions or centralized) where the service provider is conducting work on the major task. | |
| Planned | Planned number of units, unit hours, and unit cost for the major task. | |
| Adjusted | Adjusted number of units, unit hours, and unit cost for the major task. | You can override these fields. Enter the number of unit hours and unit cost or a percentage. |
| Pinned | Saves the number of units, unit hours, and unit costs preventing changes from cascading through the plan. | |
| Extended Hours | Total plan hours for each location. | The application calculates this number based on plan assumptions. |
| Extended Cost | Total cost for each location. | The application calculates this number based on plan assumptions. |

*Table 4–49 Distribution Tab fields*

| Field | Description | Notes |
|---|---|---|
| Distribute completed units of work according to | How to distribute completed units of work across time. | |
| Default range | Start and end date for the labor distribution, based on the number of days before or after the selected milestone. | This field is only available when you select an Even or Custom Distribution. |

*Table 4–49 (Cont.) Distribution Tab fields*

| Field | Description | Notes |
|---|---|---|
| Start | Number of days before or after a selected milestone to start the distribution. | |
| End | Number of days before or after a selected milestone to end the distribution. | |
| Service Provider | Service provider to which these assumptions apply. | |
| Location | Location to which to apply these distribution assumptions. | |
| Start | Date on which the service provider begins work in the selected location. | If using an Even Distribution or Custom Distribution, you can select the number of days before or after a selected milestone to start the distribution of this work unit. |
| End | Date on which the service provider completes work in the selected location. | If using an Even Distribution or Custom Distribution, you can select the number of days before or after a selected milestone to end the distribution of this work unit. |
| **Columns** | | |
| Period | Period during which the number or percentage of units are expected to be completed. | |
| Percentage | Percentage of units expected to be completed during the associated period. | |
| Total | Total percentage of work completed during the work periods. | |

## Task Manager: New Task Dialog Box (Task Details Tab, Task Assignments Tab)

*Table 4–50 Task Manager: New Task, Task Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Name | Name for the task. | |
| Code | Code for the task that the application will use as a prefix to the selected task name. | |
| Description | Detailed description of the task. | Appears as Help text and as the task description on the Assignment tab. |
| Assignment Group | Assignment group to which the task belongs. | Determine which group the task appears in the Responsibilities section. |

*Table 4–50 (Cont.) Task Manager: New Task, Task Details Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Summary Category | Summary category to which the task belongs. | Determines how the hours and fees are summarized on the Summary tab and Summary report. |
| **Buttons** | | |
| Add Resource | Add a resource to this task. | |
| Edit Resource | Change details about the resource effort or rates for this task. resource | |
| Delete Resource | Remove a resource from this task. | |
| **Columns** | | |
| Resource Name | Resource typically assigned to this task. | |
| Substitutions | Resource overrides for a resource. | |

*Table 4–51 Task Manager: New Task, Task Assignments Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Location in which task is performed. | For centralized tasks, All Locations appears. |
| Included | If selected, the task is included in the study, for the location. | Deselect to exclude a task for a specific location. |
| Service Provider | Service provider who performs the task for this location. | |
| Billing Rate Location | Billing rate location for each location.<br>If you select Local, the application uses the location from where the subject data are collected for the billing rate calculations.<br>If you select a country, the application uses the billing rate data for that country.<br>If you select Back Office, the application uses the location specified as the back office billing rate location for the assigned service provider. | You can choose a different billing rate location for each resource for each location. |
| Pinned | Saves your task settings so that changes made at general levels do not affect the task. | |
| **Buttons** | | |
| Add Resource | Add a resource to this task. | |
| Edit Resource | Change details about the resource effort or rates for this task. resource | |
| Delete Resource | Remove a resource from this task. | |
| **Columns** | | |
| Resource Name | Resource typically assigned to this task. | |
| Substitutions | Resource overrides for a resource. | |

## Task Manager: Add Resource Dialog Box

***Table 4–52 Task Manager: Add Resource Details Tab Fields***

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Resource Name | Resource you can add to the task. | |
| Code | Code for a resource you can add to the task. | |

### Task Manager: Edit Resource Dialog Box (Resource Details Tab, Algorithm Tab, Billing Rate Location Tab, Rates & Substitutions Tab, Unit Hours Tab)

***Table 4–53 Task Manager: Edit Resource, Resource Details Tab Fields***

| Field | Description | Notes |
|---|---|---|
| Name | Resource name. | You may have overridden the named resource with another resource on the Billing Rates tab or at the plan level or plan-location level. This field displays the name of the originally expected resource. |
| Description | Detailed description of the resource. | |
| **Columns** | | |
| Location | Location in which the resource performs the work. | |
| Service Provider | Service provider to which the resource belongs. | |
| Department | Department to which this resource belongs when performing the task. | |
| GL Code | General Ledger code for fees associated with this resource when performing the task. | |

***Table 4–54 Task Manager: Edit Resource, Algorithm Tab Fields***

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Location to which the algorithm applies. | |
| Calculate unit hours as | Default number of hours the selected resource must spend performing this task to complete one unit-of-measure for this location. | Must be a value between 0 and 10,000. |
| Unit Hours | Number of unit hours (per cost driver) the selected resource must spend performing this task to complete one unit-of-measure for this location. | |
| Cost Driver | Work unit to use for this Level of Effort (LOE) algorithm. | |
| # Units | Number of units per the unit of measure defined by the major task. | |

*Table 4–54 (Cont.) Task Manager: Edit Resource, Algorithm Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Ext. Hours | Total hours for the selected resource to complete the task for this location. | |

*Table 4–55 Task Manager: Edit Resource, Billing Rate Location Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Name of the location where sites and subjects are located. | |
| Service Provider | Service provider assigned to handle this task for sites and subjects in the listed location. | |
| Pinned | When pinned, changes made at more general levels will not affect your settings for this resource. | Your pinned settings are lost if the associated locations or service providers are removed from the plan. |

*Table 4–56 Task Manager: Edit Resource, Rates & Substitutions Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Location where sites and subjects are located. | |
| Service Provider | Name of the service provider assigned to this task for the listed location. | |
| Substitute | A different resource to perform this task in the location. | By default, the application uses the billing rate of the selected resource. |
| Rate | Hourly billing rate for the selected resource to perform the task. | Override standard billing rates on a case-by-case basis. |
| % Adjust | Percentage adjustment applied to the rate of the selected resource performing the task, you can enter a | Must contain a value between 0 and 999.99. |
| Pinned | When pinned, changes made at more general levels will not affect your settings for this task. | Your pinned settings are lost if the associated locations or service providers are removed from the plan. |

*Table 4–57 Task Manager: Edit Resource, Unit Hours Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Location | Location where sites and subjects are located. | |
| Service Provider | Service provider assigned to this task for the listed location. | |

*Table 4–57 (Cont.) Task Manager: Edit Resource, Unit Hours Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Unit Hours | Specific number of hours for the selected resource to perform the task in the location. | Must be a value between 0 and 10,000. |
| % Adjust | Specific percentage adjustment to apply to the calculated hours for the selected resource to perform the task in the location. | Must be a value between 0 and 1,000,000. |
| # Units | Number of units as per the unit of measure defined by the major task. | |
| Ext. Hours | Extended hours for this location. | The application calculates this number by multiplying the unit hours by the number of units expected. |

## Costs Tab

*Table 4–58 Costs Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Filter** | | |
| Show: Excluded Cost(s) | Displays costs that have been previously excluded. | Excluded costs are not included in the plan budget. |
| Show: Categories where costs total 0.00 | Displays cost categories where the total cost equals 0.00.<br>Deselect to hide cost categories where the total cost equals 0.00. | |
| **Buttons** | | |
| New | Opens the Define New Category dialog box to create a user-defined cost. | |
| Edit | Opens the Edit or Adjust Cost dialog box to display the breakdown of costs by location and adjust the cost category type, department, and GL code. | If the Edit button is disabled, you have selected more than one cost. Deselect the additional costs. |
| Exclude | Excluded the selected costs from the plan budget totals. | Excluded costs are not deleted. They appear with a line through them. |
| Include | Restores the selected excluded costs. | Set the filter to show excluded costs. |
| Delete | Permanently delete the selected user-defined costs. | You cannot delete default application costs. You cannot restore deleted user-defined costs. |
| **Columns** | | |

*Table 4–58 (Cont.) Costs Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Name | Name referring to a specific cost or cost type. | For a description of each cost, see the online Help for this tab. |
| Type | Whether the cost type is a pass-through or another type of indirect cost. | |
| Calculated | Application-calculated cost based on the assumptions entered on other tabs. | |
| Adjustment | Total amount of adjustments entered on the Adjustments tab of the Edit or Adjust Dialog box. | |
| Total | Total calculated cost, including any adjustments. | Must be zero or greater. |

## Define New Category Dialog Box (Definition Tab, Algorithm Tab, Distribution Tab)

*Table 4–59 Define New Category Dialog Box, Definition Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Category Information** | | |
| Name | Name for the user-defined cost, containing up to 45 characters. | The name must be unique to the plan. |
| Type | Whether the cost is a pass-through or miscellaneous cost, or associated with a specific department. | |
| Include in Payment Schedule | Includes this cost in the recurring payments plotted on the Cash Flow Chart. | Edit the recurring payments schedule on the Payments tab. |
| Include in Resources by Department/GL Code Report | Includes this cost in the Resources by Department and treat indirect costs as billable items or allocated to one or more resources. | |
| Include inflation in results | Includes inflation for this cost in resulting calculations. | Selection of this checkbox deselects the Treat as Credit checkbox. |
| Treat as Credit | Treats this cost as a credit. | Selection of this checkbox deselects the Include inflation in results checkbox. |
| **Notes** | | |
| Notes | Additional notes or comments about the cost. | Displayed as help content for user-defined costs. |
| **History** | | |
| Created By | Name of the user who created the cost. | |
| Created Date | Date the cost was created. | |
| Last Modified By | Name of the user who last modified the cost. | |
| Last Modified | Date the cost was last modified. | |

*Table 4–60 Define New Category Dialog Box, Algorithm Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Cost/Credit Algorithm** | | |
| Costs / Credits | Whether the cost or credit varies by location or is calculated at study-level. | Application-calculated costs and credits are either location-scoped or study-scoped and cannot be changed. |
| Calculate as: | Per unit cost. | Becomes the default for each location. The application calculates the study-level cost as this value multiplied by the number of units. |
| Currency | Currency of the per unit cost. | Must contain a value between 0 and 99,999,999 USD (or the equivalent in another currency). |
| per | Unit-based assumptions that drive this cost calculation. | The application multiplies the number of units derived for the chosen assumption is the amount entered to produce the total cost. |
| **Study-Wide or Location-specific Costs/Credits and Adjustments** | | |
| Location | Location with which a cost is associated. | Applies only to costs that are defined to vary by location. |
| Provider | Service provider associated with a cost. | |
| Department | Department associated with the cost. | |
| GL Code | Association of a cost or set of costs with a particular entry in the General Ledger. | |
| Costs | Amount and currency override the per unit cost for a specific location. | Must contain a value between 0 and 99,999,999 USD (or the equivalent in another currency). |
| Credits | Amount and currency override the per unit cost for a specific location. | |
| Total | Total calculated cost, including any adjustments. | Must be zero or greater. |

*Table 4–61 Define New Category Dialog Box, Distribution Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Distribute according to | How a cost will be distributed for each location in your plan.<br>You can allocate costs based on an application schedule, evenly between two dates, or create a custom distribution. | Frequency includes week, month, and quarter. |
| and shift | Number of days earlier or later to offset the distribution from an application-defined distribution curve. | Applies to custom distribution. Must contain a value between 0 and 999. |
| Default range | Start and end date for the cost distribution, based on the number of days before or after the selected milestone. | If you select an application-defined distribution, you cannot edit this field. |
| Start | Number of days before or after a selected milestone to start the distribution of this cost. | The calculated distribution start date cannot be less than the pre-study planning date. |
| End | Number of days before or after a selected milestone to end the distribution of this cost. | You can distribute the cost up to 10 years after the Final Report date. The calculated distribution end date should be less than the Final Report date plus 10 years. |
| Location | Location for which you are defining a custom distribution or custom Start and End dates. | |
| Start | Date to start the distribution of this cost. | Click **Apply** to recalculate the distribution according to the date. |
| End | Date to end the distribution of this cost. | Click **Apply** to recalculate the distribution according to the date. |
| Period | Each week, month, or quarter that the cost incurs. | |
| Percentage | Percentage of the total cost paid during the associated period. | |
| Total | Displays the total of the cost distribution. | |

## Payments Tab

*Table 4–62 Payment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| Set Payment Terms | Open the Payment Terms dialog box to specify the number of days from invoice to payment is expected for each service provider. | |

*Table 4–62 (Cont.) Payment Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Edit Recurring Payments | Open the Recurring Payments dialog box to define the frequency of payments for any listed unit of work or pass-through cost. | Defining the frequency as <milestone> indicates that the fees associated with that item are included in payments made in response to the occurrence of one or more milestones. |
| Add Milestone | Opens the Create Milestone dialog box to add a user-defined milestone to this plan. | Adding milestones allows you to add payments in response to events not currently defined in the application. |
| Edit Milestone | Opens the Edit Milestone dialog box to edit a user-defined milestone. | You can edit a previously added milestone to change its name and properties, which determine when it occurs. |
| Delete Milestone | Delete a user-defined milestone. | To not make a payment at a system-defined milestone, define the percentage as 0. |
| **Columns** | | |
| Milestone | The milestone at which payments can be made or received. | |
| Inv. Date | Displays the date on which the milestone is expected to occur and trigger an invoice. | |
| Service Provider (Payment Percentage and Amount) | The payment percentages and amounts to be received by the service provider. | For example, Major CRO, Medium CRO, Premium CRO. |
| Total | Total amount paid to all service providers at this milestone. | |
| Budget Total | Total payment percentage and amount for all plan milestones. | |

## Payment Terms Dialog Box

*Table 4–63 Payment Terms Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Payment Terms (Columns)** | | |
| Provider | Service provider. | |
| Payment Term | Number of days between the invoice date and the date of payment. | |

### Recurring Payments Dialog Box

*Table 4–64 Recurring Payments Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Item Name | Major task or pass-through cost that can be set as a milestone triggering a recurring payment. | |
| Specific Service Provider | For each service provider, the milestone when the recurring payment is to be made. | |

### Create/Edit Milestone Dialog Box

*Table 4–65 Create/Edit Milestone Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Milestone Definition** | | |
| Name | Name of user-defined milestone. | The name must be unique to the plan. |
| Occurs | The number of days before or after the application-defined milestone that this milestone occurs. | The application calculates user-defined milestones in relation to application-defined milestones. |
| Before or After | Whether to calculate the estimated date for this milestone as a number of days prior to an application-defined milestone or following an application-defined milestone. | |
| Milestone | The application-defined milestone before or after which this user-defined milestone occurs. | |
| **Description** | | |
| Code | A 3-6 character abbreviation for the milestone. | The application displays the code on reports where the full name does not fit. |
| Description | Additional information to describe the milestone. | |

## Summary Tab

*Table 4–66 Summary Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Included Providers | Selected service provider checkboxes identify which service providers' fees. hours, and costs appear on the Summary Tab. | Dates and metrics are not affected. |
| **Fees, Hours, and FTEs** | | |
| Startup Fees | All fees, hours, and FTEs associated with the start up of the study from Project Activity Start Date to the First subject enrolled date (FSFV). | |

*Table 4–66 (Cont.) Summary Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Clinical Monitoring Closeout and Site Audit Fees | All fees, hours, and FTEs associated with site monitoring, site management, telephone monitoring, query resolution, SAE management, site closeouts, and clinical compliance audits. | |
| Data Management | All fees, hours, and FTEs associated with database design, data entry data coordination, cleaning the data, database audits, and the annual IND update. | |
| Biostatistics | All fees, hours, and FTEs associated with table listings and graphs, randomization procedures, statistical and analysis plans, and interim analysis. | |
| Project Management / Study Oversight | All fees, hours, and FTEs associated with project management of the study from beginning to end. | |
| Medical Writing / Final Report | All fees, hours, and FTEs associated with delivering the statistical report, draft report, and final report (CSR). | |
| Other | All fees, hours, and FTEs associated with other tasks not included in any other line item. | |
| Total Fees | All fees associated with the study. | |
| Total Hours | Total hourly effort associated with the study. | |
| Total FTEs | Total of all FTEs associated with this study, by functional area. | |
| CPU Pass-Through Costs | All costs associated with the Clinical Pharmacology Unit. | Applicable for Phase I (Healthy Volunteers) trials. |
| Other Pass-Through Costs | All indirect costs not associated with the CPU Total Pass-Through Costs. | |
| Total Pass-Through Costs | All third-party, pass-through, and miscellaneous costs in the study. | |
| Inflation (Pass-Through Costs) | Costs incurred due to inflation applied to pass-through costs. | |
| Total Study Costs | Total study costs, including vendor fees, pass-through costs, and sponsor internal costs. | |
| **Dates / Duration** | | |
| Pre-Study Activity Start Date | Date on which the earliest activity or cost occurs. | |
| Project Activity Start Date | Date the study begins, defined as the date that vendors and the sponsor start identifying sites and vendors start billable activity. | |
| Study End Date | Date the study is complete, defined as the date that all activity stops (usually the date the final report (CSR) is finalized). | |
| Total Study Duration | The total study duration (in elapsed days), defined as the end date minus the start date. | |

*Table 4–66 (Cont.) Summary Tab Fields*

| Field | Description | Notes |
|---|---|---|
| Duration of Active Treatment Phase | The total duration of the active treatment phase (in days), defined as the last subject observation (LSLV) minus the First Subject Observation (FSFV). | |
| **Metrics** | | |
| Cost per Completed Subject | The expected cost per each completed subject. | Calculated as the total study costs divided by the number of subjects expected to complete all scheduled subject visits. |
| Number of Subjects / Site / Month | The average expected number of subjects monitored at each site each month. | |

## Reports Tab

There are three types of reports in the application: Clinical Indicator, Costs, and FTE / Resources Reports.

### Clinical Indicators Reports

*Table 4–67 Clinical Indicator Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Assumptions | Assumptions based on data entry. | |
| Currency Exchange Rates | Currency exchange rates based on data entry. | |
| Responsibilities | Responsibilities based on data entry. | |
| Site Approval Schedule - Cumulative | Cumulative site approval curve for the entire study by week. | |
| Site Approval Schedule By Location | Site approval curve by week for each location in the study. | |
| On-Site Monitoring Schedule - Total Hours | Total hours for all on-site monitoring visits for the entire study. | |
| On-Site Monitoring Schedule By Location | Average hours per on-site monitoring visit for each location in the study. | |
| CRF Pages - Cumulative | Cumulative CRF pages generated per week. | |
| CRF Pages By Location | CRF pages generated per week for each location in the study. | |
| Subject Enrollment - Cumulative | Cumulative subject enrollment per week. | |
| Subject Enrollment by Location | Subject enrollment per week by location. | |
| Metrics | Various performance and cost metrics. | |

*Table 4–67 (Cont.) Clinical Indicator Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Milestone Dates | Critical dates in the study. | |
| Milestones Timeline Chart | Graphical view of key milestones. | |

## Costs Reports

*Table 4–68 Costs Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Plan Summary | Printable view of the Plans Summary Tab. | |
| Fees by Major Task | Fees by major task. | |
| Fixed Unit Prices | Fixed unit prices. | |
| Pass-Through and 3rd Party Costs | Pass-through and 3rd party costs. | |
| Monthly Budget | Monthly budget. | |
| Monthly Budget By Reporting Region | Monthly budget by reporting region. | |
| Labor Adjustments | Breakdown of unit level adjustments by major task. | |
| Cash Flow | Planned value (PV) versus payments. | |
| Milestone Payment Schedule | Schedule of payments at each milestone. | |
| Meetings Report | Meeting costs and assumptions. | |
| Bid Grid | Bid grid for the plan. | |

## FTE/Resources Reports

*Table 4–69 FTE/Resources Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Resource / FTE Demand Summary | Summary of the plan resources and FTE demands. | |
| Resources By Major Task | Resources by major task. | |
| Resources By Department | Resources by department. | |
| Resources By GL Code | Resources by GL code. | |
| Resource Demand by Date | Resources by demand date. | |
| Resource Demand Chart | Graphical view of resource demand by date. | |
| Billing Rates by Resource Name | Billing rates by resource name. | |

# Studies Screen Fields

## Studies Screen Fields

*Table 4–70 Studies Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| New | New study. | |
| Edit | Edit a study. | |
| Delete | Delete a study. | |
| Restore | Restore a deleted study. | |
| Create Plan | Create a plan based on a study. | |
| **Columns** | | |
| Study Name | Studies in the application. | |
| Product/Compound | Product or compound the associated study is based on. | |
| Phase | Study phase of the associated study. | |
| Therapeutic Area | Therapeutic area the associated study is based on. | |
| Indication | Indication the associated study is based on. | |
| Status | Study status. | |

## Create/Edit Study Screen Fields

*Table 4–71 Create/Edit Study Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **General Information** | | |
| Study Name | Study name. | |
| Protocol | Protocol ID. | The protocol ID number identifies the protocol for this study. |
| Product/Compound | Product or compound the associated study is based on. | |
| Phase | Study phase. | |
| Sponsor | Study sponsor. | |
| Status | Study status. | |
| Billing Code | Study billing code. | |
| **Therapeutic Area & Indication** | | |
| Therapeutic Area | Therapeutic area the study is based on. | |

*Table 4–71 (Cont.) Create/Edit Study Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Indication | Indication the study is based on. | |
| Substitute the names below for therapeutic area and indication | Substitute names for the chosen therapeutic area and / or indication. | The substitute names are available on the Studies screen and displayed on all reports related to the study. |
| Therapeutic Area (Alias) | Substitute name for the chosen therapeutic area. | Use a therapeutic area alias if there are no therapeutic areas included on the pre-defined list that describe your study. |
| Indication (Alias) | Substitute name for the chosen indication. | Use an indication alias if there are no indications included on the pre-defined list that describe your study. |
| **Description/Notes** | | |
| Description | Study description | |

## Define Study Filter Dialog Box Fields

*Table 4–72 Define Study Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Study Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the study was last edited and saved. | |
| Include deleted studies | Selecting this option includes studies that have been previously deleted. | |
| Study name starts with | When this option is selected, the criteria applied include the text entered in the **Study name starts with <text>** field. | |
| Created by | Only studies created by one of the selected users are listed. | If you want to display all studies regardless of who created them, select the **Any User** option.<br>To display more users to choose from, click the **Expand list...** link. |

*Table 4–72 (Cont.) Define Study Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Last Modified by | Only studies last edited and saved by one of the selected users are listed. | If you want to display studies regardless of who last updated them, choose the **Any User** option. To display more users to choose from, click the **Expand list...** link. |
| Status | Only studies with that status are listed. | If you want to see studies regardless of their status, select the **Any Status** option. |
| Phases | Only studies pertaining to the selected Phase(s) are listed. | If you want to see studies regardless of the Phase, select the **Any Phase** option. |
| Therapeutic Areas | Only studies pertaining to the selected Therapeutic Area(s) are listed. | If you want to display studies regardless of the Therapeutic Area, select the **Any Therapeutic Area** option. |
| Sponsors | Only studies for the selected sponsor(s) will be listed. | If you want to display studies regardless of the sponsor, select the **Any Sponsor** option. |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of studies can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking a column heading. |
| Show n studies per page | Number of studies to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## Create Product Dialog Box Fields

*Table 4–73 Create Product Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Product ID | Unique product identifier, typically and alphanumeric code used to identify the product/compound. | |
| Name | Name used to refer to the product. | |

*Table 4–73 (Cont.) Create Product Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Description | Description of the product. | |

# Products Screen Fields

## Product Screen Fields

*Table 4–74 Product Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| New | Add a product. | |
| Edit | Edit a product. | |
| Delete | Delete a product. | |
| Restore | Restore a deleted product. | |
| **Columns** | | |
| Product Name | Products in the application. | |
| Description | Product description. | |
| Last Updated | Date and time the product was lasted modified. | |
| Updated By | User who modified the product. | |

## Create/Edit Product Screen Fields

*Table 4–75 Create/Edit Product Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Product ID | Product ID. | |
| Name | Product name. | |
| Description | Product description. | |

## Define Product Filter Dialog Box Fields

*Table 4–76 Define Product Table Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Exchange Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the product was last edited and saved. | |
| Include deleted products | Selecting this option includes products that have been previously deleted. | |
| Product name starts with | When this option is selected, the criteria applied include the text entered in the **Product name starts with <text>** field. | |

*Table 4–76 (Cont.) Define Product Table Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Created by | Only exchange rate table by one of the selected users are listed. | If you want to display all products regardless of who created them, select the **Any User** option.<br>To display more users to choose from, click the **Expand list...** link. |
| Last Modified by | Only products last edited and saved by one of the selected users are listed. | If you want to display products regardless of who last updated them, choose the **Any User** option.<br>To display more users to choose from, click the **Expand list...** link. |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of products can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking a column heading. |
| Show n products per page | Number of products to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

# Templates Screen Fields

## Template Screen Fields

*Table 4–77 Template Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| New | Add template. | |
| Edit | Edit a template. | |
| Delete | Delete a template. | |
| Restore | Restore a deleted template. | |
| Copy | Copy a template. | |
| Lock Templates | Lock templates. | |
| Unlock Templates | Unlock templates. | |

*Table 4–77 (Cont.) Template Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Template Name | Template name. | |
| Phase | Study phase. | |
| Therapeutic Area | Therapeutic area of the associated template. | |
| Indication | Indication of the associated template. | |

## Define Template Filter Dialog Box Fields

*Table 4–78 Define Template Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Template Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the template was last edited and saved. | |
| Include deleted templates | Selecting this option includes templates that have been previously deleted. | |
| Template name starts with | When this option is selected, the criteria applied include the text entered in the **Template name starts with <text>** field. | |
| Created by | Only templates created by one of the selected users are listed. | To display all templates regardless of who created them, select the **Any User** option.<br><br>To display more users to choose from, click the **Expand list...** link. |
| Last Modified by | Only templates last edited and saved by one of the selected users are listed. | If you want to display templates regardless of who last updated them, choose the **Any User** option.<br><br>To display more users to choose from, click the **Expand list...** link. |
| Status | Only templates with that status are listed. | If you want to see templates regardless of their status, select the **Any Status** option. |
| Phases | Only templates pertaining to the selected Phase(s) are listed. | If you want to see templates regardless of the Phase, select the **Any Phase** option. |

*Table 4–78 (Cont.) Define Template Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Therapeutic Areas | Only templates pertaining to the selected Therapeutic Area(s) are listed. | If you want to display templates regardless of the Therapeutic Area, select the **Any Therapeutic Area** option. |
| Sponsors | Only templates for the selected sponsor(s) will be listed. | If you want to display templates regardless of the sponsor, select the **Any Sponsor** option. |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | Orders the plans based on your selections. | Change the order by clicking a column heading. |
| Show n templates per page | Number of plans displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## Select Template Defaults Dialog Box Fields

*Table 4–79 Select Template Defaults Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Sponsor | Default sponsor for the template. | |
| Phase | Phase from which to derive values when creating the Plan Template. | The plan you create uses the values and assignments stored in the template, but calculates according to the study phase. |
| Therapeutic Area | Therapeutic Area from which to derive values when creating the plan template. | The plan you create uses the values and assignments stored in the template, but calculates according to the study therapeutic area and indication. |
| Indication | Indication from which to derive values when creating the plan template. | |

## Copy Template Defaults Dialog Box Fields

*Table 4–80 Copy Template Defaults Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Template Name | Name of the new copy template. | |

# Portfolios Screens, Tabs, and Dialog Boxes

## Portfolio Screen

*Table 4–81 Portfolio Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Filter Section** | | |
| Show | Show or hide portfolios based on selected criteria:<br>**All Portfolios**—No filter is applied. All portfolios appear.<br>**Active Portfolios Only**—Portfolios that are not deleted or marked as Study Complete or Archived appear.<br>**Portfolios matching filter**—Only portfolios that match the criteria you selected from the custom filter drop-down list appear. | |
| Modify link | Define a custom filter on the Define Portfolio Filter dialog box. | |
| **Buttons** | | |
| New | Create a new portfolio on the Create Portfolio screen (Overview tab). | |
| Edit | Edit the selected portfolio or open it to view details, the summary, or reports. | |
| Delete | Delete the selected portfolio. | Deleted portfolios are permanently removed at a later time. |
| Restore | Restore a deleted portfolio. | To use this option, adjust the filters so that you can see inactive as well as active items. |
| Copy | Make a copy of the selected portfolio. | |
| **Columns** | | |
| Portfolio Name | Name of the portfolio. | |
| Description | Description of the portfolio. | |
| Number of plans | Number of plans included in the portfolio. | |
| Last Modified | Date a user last modified this portfolio. | |

## Portfolio Screen Dialog Boxes

### Define Portfolio Filter Dialog Box

***Table 4–82 Define Portfolio Filter Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| **Portfolio Filter Criteria** | | |
| Created or modified in the last n days | Includes in the criteria applied the number of days since the portfolio was last edited and saved. | |
| Include deleted portfolios | Includes portfolios that have been previously deleted. | You can recover, or restore, portfolios that have been deleted.<br>Deleted portfolios are, however, permanently deleted and purged, after 30 days. |
| Portfolio name starts with | Includes only portfolios whose name begins with the specified text. | |
| Created by | Includes only portfolios created by one of the selected users. | To include portfolios regardless of their creator select **Any User**. |
| Last Modified by | Includes only portfolios last edited and saved by one of the selected users. | To include portfolios regardless of their creator select **Any User.** |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | Sort order for the Portfolios screen. Sort according to this selection, rather than by the first displayed column. Up to three levels of sorting are permitted. | Change the order by clicking a column heading. |
| Show n portfolios per page | Number of portfolios to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## Create/Edit Portfolio Screen (Overview Tab)

***Table 4–83 Create/Edit Portfolio Screen (Overview Tab) Fields***

| Field | Description | Notes |
|---|---|---|
| **Portfolio Overview** | | |
| Portfolio Name | Unique name for the portfolio. | |
| **Description** | | |

*Table 4–83 (Cont.) Create/Edit Portfolio Screen (Overview Tab) Fields*

| Field | Description | Notes |
|---|---|---|
| Short Description | Details that appear on the Portfolios screen to help you recognize the portfolio. | |
| Long Description | Detailed description of the portfolio. | |
| **Currency Options** | | |
| Default Reporting Currency | Default reporting currency that is used to generate portfolio reports. | Each plan in the portfolio uses its own exchange rate rules to convert from the plan values to the reporting currency. |
| **History (Edit Portfolio Screen only)** | | |
| Created By | Name of the user who created the portfolio. | |
| Created Date | Date the portfolio was created. | |
| Last Modified By | Name of the user who last modified the portfolio. | |
| Last Modified | Date the portfolio was last modified. | |

## Create/Edit Portfolio Screen (Plans Tab) Fields

*Table 4–84 Create/Edit Portfolio Screen (Plans Tab) Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| Add Plans | Add plans to the Portfolio on the Choose Plans dialog box. | You cannot add more than 200 plans. |
| Remove Plans | Remove plans from a portfolio. | |
| Include Plans | Restores an excluded plan to a portfolio. | |
| Exclude Plans | Excludes a plan from the portfolio. | Excluded plans have a line through them on the Plans tab. |
| **Columns** | | |
| Plan Information | Plan name and description. | |
| Start Date | Plan project activity start date. | |
| Start Offset | Effects of beginning a plan, or plans, earlier or later than originally scheduled.<br>To move the start date earlier, enter a negative number of days. To postpone the start date, enter a positive number of days. | No adjustments are made for inflation. Must contain a value between -999 and 9,999. |
| Probability | Likelihood that the plan is going to occur on schedule, expressed as a percentage. | |

## Create/Edit Portfolio Screen (Summary Tab)

***Table 4–85 Create/Edit Portfolio Screen (Summary Tab) Fields***

| Field | Description | Notes |
|---|---|---|
| **Portfolio Plan Summary** | | |
| Start | By default, start date of the earliest plan in the portfolio, including any offset dates. | |
| End | By default, end date of the final plan in the portfolio. | |
| **Cost Distribution** | | |
| Cost Distribution Graph | Graphical view of when costs occur over the time range specified. | The blue shaded area represents the time frame selected in the Summary Portfolio dialog box. |
| **Buttons** | | |
| Reset | Resets Start and End values to portfolio defaults. | |
| **Columns** | | |
| Plan Name | Displays the plan name. | |
| Study Name | Displays the study for the plan. | |
| Plan Cost | Displays the total plan cost. | |
| **Fees, Hours, and Pass Through Costs** | | |
| Start-up Fees | All fees, hours, and FTEs associated with the start up of the study from Project Activity Start Date to the First subject enrolled date (FSFV). | |
| Clinical Monitoring Closeout and Site Audit Fees | All fees, hours, and FTEs associated with site monitoring, site management, telephone monitoring, query resolution, SAE management, site closeouts, and clinical compliance audits. | |
| Data Management | All fees, hours, and FTEs associated with database design, data entry data coordination, cleaning the data, database audits, and the annual IND update. | |
| Biostatistics | All fees, hours, and FTEs associated with table listings and graphs, randomization procedures, statistical and analysis plans, and interim analysis. | |
| Project Management / Study Oversight | All fees, hours, and FTEs associated with project management of the study from beginning to end. | |
| Medical Writing / Final Report | All fees, hours, and FTEs associated with delivering the statistical report, draft report, and final report (CSR). | |
| Other | All fees, hours, and FTEs associated with other tasks not included in any other line item. | |
| Total Fees | All fees associated with the study. | |

*Table 4–85 (Cont.) Create/Edit Portfolio Screen (Summary Tab) Fields*

| Field | Description | Notes |
|---|---|---|
| Total Hours | Total hourly effort associated with the study. | |
| Total Pass-Through Costs | All third-party, pass-through, and miscellaneous costs in the study. | |
| Total Portfolio Costs | Total portfolio costs, including vendor fees, pass-through costs, and sponsor internal costs. | |

## Create/Edit Portfolio Screen (Reports Tab)

There are three types of portfolio reports in the application: Clinical Indicator, Costs, and FTE / Resources Reports.

### Clinical Indicator Reports Descriptions

*Table 4–86 Clinical Indicator Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Portfolio Milestones Timeline Chart | Displays a graphical view of key milestones in the portfolio. | |

### Costs Reports Descriptions

*Table 4–87 Costs Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Portfolio Summary | Displays a printable view of the Portfolio Summary Tab. | |
| Fees by Major Task | Displays fees by major task. | |
| Monthly Budget | Displays monthly budget. | |

### FTE/Resources Reports Descriptions

*Table 4–88 FTE/Resources Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Resource Demand Summary | Displays a summary of the portfolio resources demands. | |
| Resource Demand by Date | Displays a summary of the portfolio date demands. | |
| Resource Demand Chart | Displays resources demand chart. | |

## Portfolio Reports Descriptions

There are three types of portfolio reports in the application: Clinical Indicator, Costs, and FTE / Resources Reports.

### Portfolio Clinical Indicator Reports Descriptions

*Table 4–89 Clinical Indicator Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Portfolio Milestones Timeline Chart | Graphical view of key milestones in the portfolio. | |

### Portfolio Costs Reports Descriptions

*Table 4–90 Costs Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Portfolio Summary | Printable view of the Portfolio Summary Tab. | |
| Fees by Major Task | Fees by major task. | |
| Monthly Budget | Monthly budget. | |

### Portfolio FTE/Resources Reports Descriptions

*Table 4–91 FTE/Resources Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Resource Demand Summary | Summary of the portfolio resources demands. | |
| Resource Demand by Date | Summary of the portfolio date demands. | |
| Resource Demand Chart | Resources demand chart. | |

# Report Menu

The reports listed in this section apply to all data in the application.

- For plans-specific reports, see Report Types.
- For portfolios-specific reports, see Portfolio Costs Reports Descriptions.

## Reports Descriptions

*Table 4–92 Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Bid Grid (Late Stage) | Global bid grid report. | |
| Bid Grid (Phase 1 - Healthy Volunteers) | Bid grid report for Phase I studies with healthy volunteers. | |
| Therapeutic Area / Indications Mapping | Indication mapping for all therapeutic areas. | |
| Study Performance Summary | Overall schedule and budget performance per study. | |
| User Report | Details for all users in the application. | |
| Inactive Users Report | Users who have not logged within a number of specified days. | |

*Table 4–92 (Cont.) Reports Descriptions*

| Field | Description | Notes |
|---|---|---|
| Plan Inventory Report | Complete list of plans, and their study and product attributes. | |
| Planned Trials | Planned trials. | |
| Tracked Trials | Tracked trials. | |

## Reports Options

*Table 4–93 Study Performance Summary Report Options*

| Field | Description | Notes |
|---|---|---|
| **Date Range Options** | | |
| Tracked in the last | Filters the report by studies' last tracked date. | |
| **Study Attributes** | | |
| Status | Filters the report by study status. Studies with one or more statuses can be included in the report. | By default, all study statuses are included. |
| Phases | Filters the report by study phase. One or more study phases can be included in the report. | By default, all study phases are included. |
| Therapeutic Areas | Filters the report by therapeutic area. One or more therapeutic areas can be included in the report. | By default, all therapeutic areas are included. |
| Budget Performance Threshold | Filters the report by the Budget Performance Threshold of tracked studies. One or more of the following can be selected: Ok, Warning, Error, and Extreme. | By default, all Budget Performance Thresholds are included. |
| Schedule Performance Threshold | Filters the report by the Schedule Performance Threshold of tracked studies. One or more of the following can be selected: Ok, Warning, Error, and Extreme. | By default, all Schedule Performance Thresholds are included. |
| Overall Performance Threshold | Filters the report by the Overall Performance Threshold of tracked studies. One or more of the following can be selected: Ok, Warning, Error, and Extreme. | By default, all Overall Performance Thresholds are included. |

*Table 4–94 User Report Options*

| Field | Description | Notes |
|---|---|---|
| **Options** | | |
| Include user roles | Includes the user’s primary and additional Roles. | |

*Table 4–95 Inactive Users Report Options*

| Field | Description | Notes |
|---|---|---|
| **Options** | | |
| Days Since Last Login | Includes users who have not logged in the number of days specified. | |

# Maintain Menu

## Service Providers Screen Fields

### Service Providers Screen Fields

*Table 4–96 Service Providers Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Show | Service providers that appear on the Service Providers screen. | You can select sponsors, vendors, and deleted service providers to be included. |
| New | Add a service provider. | |
| Edit | Edit a service provider. | |
| Delete | Delete a service provider. | |
| Restore | Restore a service provider. | |
| Billing Rates Report | Billing rates report for a service provider. | |
| **Columns** | | |
| Name | Service provider name. | |
| Type | Service provider type. | |
| Last Updated | Date and time the service provider was last edited. | |
| Updated By | User who last edited the service provider. | |

### Create/Edit Service Provider Screen Fields

*Table 4–97 Create Service Provider Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Provider Name | Service provider name. | |
| Provider Type | Type of service provider. | |
| Description | Service provider description. | |
| Billing Rates Currency | Currency of the hourly billing rates associated with the service provider. | All billing rates defined for this service provider must be expressed in this currency. |
| Back-Office Billing Rate Location. | Determines the default billing rates for tasks that are typically centralized or conducted at a central location. | |
| Created By | User who created the service provider. | |
| Created Date | Date and time this service provider was created. | |
| Last Modified By | User who last edited the service provider. | |

*Table 4–97 (Cont.) Create Service Provider Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Last Modified | Date the service provider was last modified. | |
| Update Billing Rates | Billing rates for this service provider. | |

# Resources Screen Fields

## Define Resource Filter Dialog Box Fields

*Table 4–98 Define Resource Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Resource Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the resource was last edited and saved. | |
| Include deleted resources | Selecting this option includes resources that have been previously deleted. | |
| Resource name starts with | When this option is selected, the criteria applied include the text entered in the **Resource name starts with <text>** field. | |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of resources can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking a column heading. |
| Show n resources per page | Number of resources to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## Resources Screen Fields

*Table 4–99 Resources Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Show | Resources that appear on the Resources screen. | You can include All Resources, Active Resources Only, or resources matching a filter. |
| New | Add a resource. | |
| Edit | Edit a resource. | |
| Delete | Delete a resource. | |
| Restore | Restore a resource. | |

*Table 4–99 (Cont.) Resources Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Name | Resources in the application. | |
| **Columns** | | |
| Name | Resource name. | |
| Last Updated | Date and time the resource was last updated. | |
| Updated By | User who last modified the resource. | |

### Create Resource Screen

*Table 4–100 Create Resource Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Code | Resource code. | |
| Name | Resource name. | |
| Description | Resource description. | |
| **Default Billing Rates** | | |
| Rate Year | Rate year for each service provider. | |
| Auto Fill | Billing rates for each service provider. | |

## Billing Rates Screen Fields

### Billing Rates Screen Fields

*Table 4–101 Billing Rates Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Show rates for | Service provider for which billing rates appear on the Billing Rates screen. | |
| For Rate Year | Year for which billing rates appear on the Billing Rates screen. | |
| Include Deleted Rates | Include deleted rates. | |
| **Buttons** | | |
| New | Add billing rates. | |
| Edit | Edit billing rates. | |
| Delete | Delete billing rates. | |
| Restore | Restore deleted billing rates. | |
| Copy | Copy billing rates. | |
| Publish | Publish billing rates. | |
| Show Revision History | Revision history of the selected billing rates. | |
| **Columns** | | |

*Table 4–101 (Cont.) Billing Rates Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Rates for | Service provider who charges the billing rates. | Service providers can charge different rates to different sponsors. |
| When performing work for | Organization for whom the service provider is performing the work when these rates apply. | |
| Rate Year | Billing rate year. | |
| Status | Billing rate status. | Billing rates can be published or drafts. |
| Last Modified | Date and time the billing rates were last edited. | |
| Last Modified By | User who edited the billing rates. | |

## Create Billing Rates Screen

*Table 4–102 Create Billing Rates Screen Fields*

| Field | Description | Notes |
|---|---|---|
| When | Service provider who charges these billing rates. | |
| Performs work for | Organization the service provider is charging these billing rates. | |
| For Rate Year | Billing rate year. | |
| Base Rate Location | The country or region for the rates in the base rate column. | |
| Currency | Billing rates currency. | |

## Copy Billing Rates Dialog Box Fields

*Table 4–103 Copy Billing Rates Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Copy from | The version of billing rates to copy. | If there is only one version, this field is ready-only. |
| Apply percentage adjustment | Percentage adjustment to apply to the copied billing rates. | |

## Show Revision History Dialog Box Fields

*Table 4–104 Show Revision History Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Status | Status of the billing rates. | Billing rates are drafts or published. |
| Last Modified | Date and time the billing rates were last edited. | |
| Last Modified By | User who last edited the billing rates. | |
| Show Rates | Billing rates of the prior versions. | |

## Departments Screen Fields

### Define Department Filter Dialog Box Fields

***Table 4–105 Define Department Filter Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| **Department Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the department was last edited and saved. | |
| Include deleted departments | Selecting this option includes departments that have been previously deleted. | |
| Department name starts with | When this option is selected, the criteria applied include the text entered in the **Department name starts with <text>** field. | |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of departments can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking a column heading. |
| Show n departments per page | Number of departments to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

### Departments Screen Fields

***Table 4–106 Departments Screen Fields***

| Field | Description | Notes |
|---|---|---|
| Show | Departments that appear on the Departments screen. | You can show all departments, active departments only, or select a department filter. |
| New | Add a department. | |
| Edit | Edit a department. | |
| Delete | Delete a department. | |
| Restore | Restore a deleted department. | |
| Map Labor and Costs | Edit department mappings. | |
| **Columns** | | |
| Name | Department name. | |
| Code | Department code. | |

*Table 4–106 (Cont.) Departments Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Description | Department description. | |
| Last Updated | Date and time the department was last edited. | |
| Updated By | User who last edited the department. | |

## Create/Edit Department Screen Fields

*Table 4–107 Create Department Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Code | Department code. | |
| Name | Department name. | |
| Description | Department description. | |

## Edit Department Mapping Screen Fields

*Table 4–108 Edit Department Mapping Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Change | Method of mapping departments. | You can map by resource, location, task, or Rule (Advanced Mode). |
| Restore ClearTrial Defaults | Restore department mappings to the application default mappings. | Any mappings you created are discarded. |
| **Mapping by Resource** | | |
| Resource | Resources to which departments can be mapped. | |
| Internal | Department to apply when the resource performs work for an internal provider. | |
| Outsourced | Department to apply when the resource performs work for an outsourced provider. | |
| **Mapping by Location** | | |
| Location | Locations to which departments can be mapped. | |
| Internal | Department to apply when an internal provider is assigned to the location. | |
| Outsourced | Department to apply when an outsourced provider is assigned to the location. | |
| **Mapping by Task** | | |
| Task Group | Task groups to which departments can be mapped. | |
| Internal | Department to apply when an internal provider is assigned to the task or task group. | |

*Table 4–108 (Cont.) Edit Department Mapping Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Outsourced | Department to apply when an outsourced provider is assigned to the task or task group. | |
| **Map by Rule (Advanced Mode)** | | |
| Add Rule | Add a rule for mapping labor to departments. | |
| Edit Rule | Edit a rule for mapping labor to departments. | |
| Delete Rule | Delete a rule for mapping labor to departments. | |
| Criteria | Rule criteria, which applies when the rule is used to map labor to departments. | |
| Department | The department associated with the rule. | |
| Drag to Order | Prioritize mapping rules. | Rules at the top of the list take priority over the bottom. |

## GL Codes Screen Fields

### Define GL Code Filter Dialog Box Fields

*Table 4–109 Define GL Code Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **GL Code Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the GL Code was last edited and saved. | |
| Include deleted GL Codes | Selecting this option includes GL Codes that have been previously deleted. | |
| GL Code name starts with | When this option is selected, the criteria applied include the text entered in the **GL Code name starts with <text>** field. | |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of GL Codes can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking a column heading. |
| Show n GL Codes per page | Number of GL Codes to be displayed on each page. | Use the paging tool to move to the next or previous page or directly to a page number. |

## GL Codes Screen Fields

***Table 4–110 GL Codes Screen Fields***

| Field | Description | Notes |
|---|---|---|
| Show | GL codes that appear on the GL Codes screen. | You can show all GL codes, active GL codes only, or select a GL code filter. |
| New | Add a GL code. | |
| Edit | Edit a GL code. | |
| Delete | Delete a GL code. | |
| Restore | Restore a deleted GL code. | |
| Map Labor and Costs | Edit GL code mappings. | |
| **Columns** | | |
| Name | GL code name. | |
| Code | Code for the GL code. | |
| Description | GL code description. | |
| Last Updated | Date and time the GL code was last edited. | |
| Updated By | User who last edited the GL code. | |

## Create/Edit GL Code Screen Fields

***Table 4–111 Create GL Code Screen Fields***

| Field | Description | Notes |
|---|---|---|
| Code | General Ledger code. | |
| Name | GL code name. | |
| Description | GL code description. | |

## Edit GL Code Mapping Screen Fields

***Table 4–112 GL Code Mapping Screen Fields***

| Field | Description | Notes |
|---|---|---|
| Change | Method of mapping GL codes. | You can map by resource, location, task, or Rule. |
| Restore ClearTrial Defaults | Restore GL code mappings to the application default mappings. | Any mappings you created are discarded. |
| **Mapping by Resource** | | |
| Resource | Resources to which GL codes can be mapped. | |
| Internal | GL code to apply when the resource performs work for an internal provider. | |
| Outsourced | GL code to apply when the resource performs work for an outsourced provider. | |

*Table 4–112 (Cont.) GL Code Mapping Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Mapping by Location** | | |
| Location | Locations to which GL codes can be mapped. | |
| Internal | GL code to apply when an internal provider is assigned to the location. | |
| Outsourced | GL code to apply when an outsourced provider is assigned to the location. | |
| **Mapping by Task** | | |
| Task Group | Task groups to which GL codes can be mapped. | |
| Internal | GL code to apply when an internal provider is assigned to the task or task group. | |
| Outsourced | GL code to apply when an outsourced provider is assigned to the task or task group. | |
| **Map by Rule (Advanced Mode)** | | |
| Add Rule | Add a rule for mapping labor to GL codes. | |
| Edit Rule | Edit a rule for mapping labor to GL codes. | |
| Delete Rule | Delete a rule for mapping labor to GL codes. | |
| Criteria | Rule criteria, which applies when the rule is used to map labor to GL codes. | |
| GL Code | The GL code associated with the rule. | |
| Drag to Order | Prioritize mapping rules. | Rules at the top of the list take priority over the bottom. |

## Exchange Rate Tables Screen Fields

### Define Exchange Rate Table Filter Dialog Box Fields

*Table 4–113 Define Exchange Rate Table Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| **Exchange Filter Criteria** | | |
| Created or modified in the last n days | When this option is selected, the criteria applied include the number of days since the exchange rate table was last edited and saved. | |
| Include deleted exchange rate tables | Selecting this option includes exchange rate tables that have been previously deleted. | |
| Exchange Rate Table name starts with | When this option is selected, the criteria applied include the text entered in the **Exchange rate table name starts with <text>** field. | |

*Table 4–113 (Cont.) Define Exchange Rate Table Filter Dialog Box Fields*

| Field | Description | Notes |
|---|---|---|
| Created by | Only exchange rate tables by one of the selected users are listed. | If you want to display all exchange rate tables regardless of who created them, select the **Any User** option.<br><br>To display more users to choose from, click the **Expand list...** link. |
| Last Modified by | Only exchange rate tables last edited and saved by one of the selected users are listed. | If you want to display exchange rate tables regardless of who last updated them, choose the **Any User** option.<br><br>To display more users to choose from, click the **Expand list...** link. |
| **Save Filter** | | |
| Save filter as | Name to assign to the filter. | |
| **Sorting and Paging** | | |
| Sort By | The list of exchange rate tables can be ordered according to your selection, rather than by the first displayed column. | Change the order by clicking the column heading on which to sort the list. |
| Show n exchange rate tables per page | Number of exchange rate tables to be displayed on each page. | A paging tool appears at the lower right, allowing you to move to the next page. |

## Exchange Rate Tables Screen Fields

*Table 4–114 Exchange Rate Table Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Show | Exchange rate tables that appear on the Exchange Rate Tables screen. | You can show all exchange rate tables, only active ones, or tables matching a filter. |
| New | Add an exchange rate table. | |
| Edit | Edit an exchange rate table. | |
| Delete | Delete an exchange rate table. | |
| Restore | Restore a deleted exchange rate table. | |
| Publish | Publish an exchange rate table. | |
| Set Default | Set the default exchange rate table. | |

*Table 4–114 (Cont.) Exchange Rate Table Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Columns** | | |
| Name | Exchange rate table name. | |
| Description | Exchange rate table description. | |
| Status | Exchange rate table status. | Exchange rate tables can be published or drafts. |
| Last Updated | Date and time the exchange rate table was last edited. | |
| Updated By | User who last edited the exchange rate table. | |

### Create/Edit Exchange Rate Table Screen Fields

*Table 4–115 Create Exchange Rate Table Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Details** | | |
| Name | Exchange rate table name. | |
| Status | Status of the exchange rate table. | Exchange rate tables can be drafts, published, or published with a draft. |
| Description | Exchange rate table description. | |
| **Currency Exchange Rates** | | |
| Use rates as of | Date from which to populate the exchange rates. | |
| Apply | Populate the exchange rate fields with the values from the **Use rates as of** field. | |

## Reporting Regions Screen Fields

*Table 4–116 Reporting Regions Screen Fields*

| Field | Description | Notes |
|---|---|---|
| **Buttons** | | |
| New Reporting Region | Add a reporting region. | |
| Map Countries to Reporting Regions | Select a reporting region for a country. | |
| **Columns** | | |
| Reporting Region Name | Reporting regions. | |
| # of Countries Mapped | Number of countries that are mapped to the associated reporting regions. | |

*Table 4–116 (Cont.) Reporting Regions Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Total Number of Countries Mapped to Reporting Regions | Total number of countries mapped to reporting regions. | |

# Admin Menu

## User Profile Screen Fields

### User Profile Screen Fields

*Table 4–117 User Profile Screen Fields*

| Field | Description | Notes |
|---|---|---|
| Login Name | Name or phrase you use to log in. | |
| First Name | Your first name. | |
| Last Name | Your last name. | |
| Email Address | Your email address. | This email address allows users to use the Forgot Your Password? feature.<br>If users forget their password, they need to supply this email address to reset their password. |
| Security Question | Security question used for authentication purposes. | |
| Security Answer | Security answer used for authentication purposes. | |
| Preferred Edit Mode | Your preferred edit mode, used for creating or editing plans. | Plans automatically open in this mode. |
| Preferred Home Page | The page that appears when you log in. | If a user requests a specific screen or follows a previously bookmarked URL, that page appears after a successful login, not the Preferred Home Page. |
| Preferred Locale | Your preferred geographical location. | Determines how dates and numbers are displayed and interpreted. |

## Reset Password Page Fields

***Table 4–118 Create Product Dialog Box Fields***

| Field | Description | Notes |
|---|---|---|
| New Password | Your new password. | Passwords must be at least eight characters, contain at least one letter, one number, and one of the following special characters: !$*+-.=?@^_\|~.<br><br>Passwords must not contain your login name or any of the following words: password, oracle, guest, admin, administrator, or cleartrial.<br><br>Do not use easily guessed passwords such as a pet's name; your own name, address, or phone number; or any easily identifiable personal information. |
| Verify New Password | Your new password. | |