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 5.5

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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.

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

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Related Documents

For more information, see the following documents in the Oracle Health Sciences ClearTrial Cloud Service Release 5.5 documentation set:

- *Oracle Health Sciences ClearTrial Cloud Service 5.5 System Administrator User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.5 Web Services API User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.5 Release Notes*
- *Oracle Health Sciences ClearTrial Cloud Service 5.5 TRACK User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.5 Third Party Licenses and Notices*

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Getting Started: Basic Functions and Common Tools

Oracle® Health Sciences ClearTrial Cloud Service is license-based software as a service (SaaS) for clinical trial planning, sourcing, and tracking. ClearTrial Cloud Service offers embedded intelligence to help life science companies manage the costs and plan their clinical trials and projects on time and within budget.

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.

ClearTrial Plan and Source Cloud Service products leverage embedded industry intelligence and clinical knowledge to optimize your clinical study planning and sourcing and rationalize the deployment of your R&D spending. The cloud-based software enables you to compress study timelines while reducing costs; accelerate the delivery of accurate, defensible, and achievable budgets; and reduce outsourcing cycle times while increasing negotiation leverage.

The activity-based planning methodology in ClearTrial Plan and Source encompasses the detailed tasks and costs required to plan a clinical study—enabling you to build study plans and Request for Proposal (RFP) documents from the bottom up by entering your clinical assumptions. Delivered as cloud-based, software as a service (SaaS) applications, ClearTrial Plan and Source products offer industry-proven algorithms for more than 200 therapeutic indications, specific clinical development data and clinical research organization (CRO) labor rates for 90 countries, and detailed clinical, cost, and resource reports.

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.

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 select a product checkbox and click **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**.

4. Click **Close**.

   The application adds the product to the Products screen or changes the values as requested.

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.

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 therapeutic area and indication 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).

5. Add a description or note.

6. To save the study, click **Save**.

or

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

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.

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 or Template 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**.

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 or role.

   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 **User Profile Screen Fields**.

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. However, if you configured a field only accessible in a higher edit mode, you must 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 or role.

   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 or role.

   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 or role.

   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 items.

Defining or Modifying a Filter

1. Click the **Modify** link.

   The Define <item> Filter dialog box appears.

2. Complete the Filter Criteria and Save Filter 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**.

List Configuration Options Allow You to Customize Columns

The Configure List Options link appears along with the Filter section and allows you to select which columns you want to display on the Plans, Studies, Products, Portfolios, RFPs, Bids, Templates, Resources, Departments, GL Codes, and Exchange Rate screens. You can also select the order of the columns from left to right.

Configuring or Modifying Columns

1. On any screen with a Filter section, click the **Configure List Options** link.

The Configure List Options dialog box appears. Each dialog box is tailored to the list screen with which it is associated.

2. From the Configure Columns section, select the checkboxes of the columns to include in listings.
3. In the Sorting and Paging section, specify up to three sort levels.
   a. From the **Sort By** drop-down list, select a field or category by which to group the items in the listing. Available choices appear in boldface type.
   b. From the first **and then** drop-down list, select a sort order within the first sorting criterion selected.
   c. From the second **and then** drop-down list, select a sorting order for the second sorting criterion.
4. 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 an information (i) symbol appears to the right of a value. Double-click the symbol to read the advice.

Color coding provides additional information.

- **Yellow !**—A value or piece of data might be outside of standard ranges.
- **Red !**—The 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.

5. Click **Close**.

Accessing Basic Functions

The List screens include a row of buttons that provide access to basic and advanced functions, Basic functions include:

- **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, context-specific buttons appear. For example, on the RFPs screen, there are three additional buttons: Import Bid, Compare Bids, and Download Bid Grid.

For a description of each button, see the associated screen in Chapter 5, "Plan and Source Field Descriptions".

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.

The portfolio costs include any inflation and line-item discount that exist on a plan within the portfolio.

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

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.
   - In the Portfolio Fees, Hours, and Pass-Through Costs section, if inflation and/or line-item discount exist in the plans included in the portfolio, inflation and line-item discounts appear as separate line items.
   - 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 ca n 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**.

Cost Model Versions

The ClearTrial application calculates the level of effort, costs, distributions, and timelines for plans using the logic and work breakdown of the current release. This set of calculations is referred to as a "cost model" and each cost model is identified by the ClearTrial release with which it is associated. For example, ClearTrial release 5.3 has a cost model of "5.3." Each ClearTrial release, beginning with release 5.3, will have its own cost model available. ClearTrial releases earlier than 5.3 do not have a cost model available.

When a new ClearTrial release is made available, the cost model for the new release is updated to reflect changes in the industry standards. Any unlocked plan or template will continue to use the same cost model calculations that were in effect at the time the plan or template was created, allowing the budgets, forecasts, and dates to remain consistent from release to release. You do not need to lock your existing plan if you do not want the plan's cost model to be upgraded to the new released cost model; however, you might want to lock your plans if you do not want users to change assumption values.

If you want the billing rates to remain the same from release to release, ClearTrial recommends that you freeze rates prior to a new ClearTrial release as billing rates are not preserved as part of the cost model. For more information, see Freeze and Unfreeze Rates.

Note: When you change the cost model on a plan, you should expect to see changes to the plan fees and costs as the plan will be recalculated according to the new cost model.

Viewing the Cost Model of a Plan

You can add the cost model as a column on the Plans screen. For more information, see Configuring or Modifying Columns.

When a plan is open, a message stating which cost model is being used appears in the upper right-hand corner of the screen.

Custom Assumptions

If you have purchased the Plan Enterprise feature of the ClearTrial application, you can create your own custom assumptions. You might want to create a custom assumption when ClearTrial does not have a defined assumption that meets your need for calculating a custom task or for use as a unit of measure for billing.

There are two concepts related to custom assumptions. They are:

1. **Custom field—**The data field that allows a user to enter a custom assumption value.

- Custom fields can only be created by users who have been assigned the additional role/capability of Custom Fields Designer. This additional capability is available only to users who already have Clinical or System Administrator as their assigned role.
- Custom fields, which are developed and published for use in plans, are grouped and versioned as a custom field model. You can assign a custom field model to a plan to display and use the custom fields of that model in your plan.
- Custom fields have a default of 0. It is recommended that you click the field label to display the Help text for the custom field and review any guidance for default values that may have been provided by your custom field designer

2. **Custom assumption—**The value of the assumption.
   - Custom assumptions behave like ClearTrial-defined assumptions. They appear on the Assumptions report, vary by location, if appropriate, and have associated Help text.
   - Any user who has permission to edit the value of a ClearTrial default assumption can edit the value of a custom assumption.

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. Only deleted products, studies, plans, and portfolios will be purged.

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

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

Step	Action	Description
3	Create a new plan.	**1.** From the Edit menu, select **Plans**. The Plans screen appears. **2.** Click **New**. The Choose Study and Plan Template dialog box appears. **3.** Select the study for which you are creating a plan. **4.** Select a template. **5.** Click **Ok**. The Create Plan page appears. **6.** On the Overview tab, complete the sections shown. For more information about a field, click the field name. **7.** Click **Next**. The data entry screen for the next tab appears.
4	Enter your assumptions for the plan.	**1.** Continue entering your assumptions tab by tab. 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 Edit Modes Control the Detail of Your Plan.
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**.

> **Note:** If you have created a request for proposal for a plan, you can no longer edit it. The Edit button is replaced with a View button.

Applying a Different Cost Model or Custom Field Model to a Plan

When you create a new plan, the cost model and custom field model applied depends on the template selected. If you use the ClearTrial template, the new plan inherits the cost model for the current release and the most recently published custom field model. If you use a custom template, the new plan inherits the cost model and custom field model from the custom template.

If you determine that your plan should use a different cost model or custom field model, you can select new models through the Change Attributes option. The cost model and custom field model can only be updated for unlocked plans. For more information, see Change Attributes.

Working with Custom Fields in a Plan

If you assigned a custom field model to a plan, the custom fields that are available in the custom field model can be used in the plan. A custom field can be set by your custom field designer to display on one of the following assumption tabs:

- Overview
- Site
- Subject
- Treatment
- Data
- Monitoring

If custom fields exist for a tab, they appear in a separate section, labeled Custom Fields, that appears below the ClearTrial default assumptions. If you do not see an expected assumption, change your edit mode to the highest level of detail available to you. For information about changing your edit mode, see Changing Your Edit Mode Mid-plan. Your custom field designer determines the edit mode in which a custom field appears.

Custom assumptions can be centralized or location-scoped. A location-scoped custom field has a Blue Globe indicator to the right of the field. When you enter a value in the field, that value cascades to each plan location. You can click the Blue Globe to see a list of locations and edit the value for each location separately. If a location-specific value has been entered for any location, the Blue Globe indicator changes from light blue to dark blue.

A centralized custom field will not have a Blue Globe indicator and accepts a single value.

Copying a Plan

1. On the **Plans** screen, select the checkbox of the plan you want to copy. You cannot copy a plan in an Incomplete status.
2. Click **Copy**.

   The Copy Plan dialog box appears.
3. In the **Plan Name** field, enter a name for the new plan.
4. From the **Use Cost Model from** drop-down list, select a cost model. The default selection is the cost model of the plan being copied.

5. From the **Custom Field Model** drop-down list, select a custom field.

   The new plan inherits the custom field model from the source plan. You can change the custom field model, or choose not to attach a custom field model, using Change Attributes. For more information, see Change Attributes.

6. Click **Ok**.

   The new plan inherits the cost model and custom field model from the source plan. You can change the cost model and the custom field model through the Change Attributes option. For more information, see Change Attributes.

Enter Overall 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 shown.

- For more information about a field, click the field name.
- For more information about the screen, see Create/Edit Plan or Template 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 for plans include the following. There are additional statuses associated with the RFPs and Bids features.

   - **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 that you specify on the Assignments tab.

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, or show both regions and countries.

   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 allows 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)**.

   If there is more than one location in the plan, you can quickly select all locations with a single click by using the checkbox that appears to the left of the Location column label.

   The application removes the location from the list of locations.

Add Languages to a Plan

The Locations tab also includes 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, 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)**.

   If there is more than one user-specified language in the plan, you can quickly select all user-specific languages with a single click by using the checkbox that appears to the left of the Language column label.

   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 the **Clear Trial Default Schedule** link of the selected location.

   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 week-by-week schedule in the Sites column in the **User Defined** section 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**, and then **Close**.

   The Site tab refreshes. 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, display the Edit Site Approval Schedule dialog box, and click **Restore Defaults.**

5. Click **Save**, and then **Close**.

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.

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

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 onsite 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 overridden 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 and Average Percent 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.

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.

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 site 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.

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.

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

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.

Cross-over designs are those in which each subject receives all defined treatments, but in a different order or sequence.

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 Treatments

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

Specify the Details

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.
- **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. The application considers the Number of CRF Pages Per Subject, the treatment period, the enrollment period, subject visits, and other factors to estimate the treatment schedule. Baseline visits and final visits are estimated differently than interim visits. The application calculates interim visits based on the average number of pages remaining and spread evenly throughout the first to last subject visit.
- **Subject diary pages—**Specify how many of the pages collected during the treatment period are subject diary pages.
- **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 /z./; or no monitoring.
- **Lab and diagnostic tests per subject—**Specify the number of expected lab and diagnostic tests per subject per treatment arm. This field is only available in cost models 5.5 above.
- **Cohort escalation reviews—**Specify the number of dose escalation reviews per treatment arm. This field is only available in cost models 5.5 above.
- **Monitoring minutes per CRF page—**Specify the number of minutes to monitor one regular CRF page. If a study is complex, or you want the monitors to spend extra time onsite performing additional activities, increase the monitoring time. This field does not apply to monitoring pages generated during the baseline visit. The application calculates the default value based on the chosen phase and therapeutic indication of the study. You can override this value for each treatment arm. Overridden values do not affect minute-per-page values for the baseline visit or washout period for a crossover study.
- The default or custom monitoring minutes per CRF page applies to both the treatment and extended treatment period for the treatment arm.
- **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.

Define the Schedule

1. In the **Subject Treatment Schedule** section, optionally specify how many CRF pages are to be collected each week, the monitoring time in minutes, and how to distribute investigator costs.
2. You can override the calculated collection of CRF pages created for each week (or day for Phase 1 trials). However, the total number of CRF pages should equal the

Number of CRF Pages Per Completed Subject. If the calculations are accurate, and you still want to adjust the monitoring time associated with a specific week, update the Monitoring Time value for any of the visits.

3. If you know the specific weeks/periods when visits will occur during the treatment period and the number of CRF pages that will be collected at each of those visits, you can enter that information. If you do not know that information, accept the default values.

4. If there are two or more patient visits that occur in the same week, combine those visits and the respective CRFs into a single visit for calculation purposes.

   The application considers the Number of CRF Pages Per Subject, the treatment period, the enrollment period, subject visits and other factors to estimate the treatment schedule. It estimates the Baseline visit and the final visit differently than interim visits. All interim visits are then calculated based on the average number of pages remaining and spread evenly throughout the first to last subject visit.

Add Notes

1. Click the **Notes** tab.
2. Enter any additional information about the treatment.
3. Click **Ok**.

   The application refreshes the Treatment tab.
4. Click **Save**.
5. To add more treatments, click **Add**.
6. To continue to the next plan tab, click **Next**.

Copy a Treatment

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

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. This is the default data collection method.
   - **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. Enter the number of unique and repeat tables, listings, and figures and graphs for the study.

2. If your study is a Phase 1, Healthy Volunteers trial, complete the Unique and Repeat PK/PD sections.

   The application displays a default setting for these fields based on the number of CRF unique pages specified. You can override the estimates.

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 Safety and Medical 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

Changes are common in clinical trials. You can add expected changes in the form of protocol amendments to your plan. Planning for these amendments makes the study budget more accurate. Protocol amendments cannot be added to Phase 1, Healthy Volunteer plans.

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.
   - **Combination**—Select both the on-site and via phone checkboxes.
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 Monitoring Schedule for Each Location

1. 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.
2. Choose the locations from the navigation tree.
3. For each location, specify the monitoring methods and the associated on-site and phone-based monitoring schedules
4. Click **Ok**.

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 requires 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 a level of monitoring the study data this rigorous.
   - **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

The cost model applied to your plan determines the options that appear in the Medical Monitoring section.

Cost Models Prior to 5.5

Estimated number of FTE (full-time equivalent) Medical Monitors is only available in cost models prior to 5.5.

1. In the **Estimated number of FTE (full-time equivalent) Medical Monitors** field, you can 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.

Cost Models 5.5 and Above

- In the 24/7 coverage field, specify whether monitoring will be provided 24 hours per day, 7 days per week.

- In the Number of medical data listing reviews field, enter the number of times the medical monitor will perform medical data listing reviews during the course of the trial.

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 offer 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**

Specify Provider-specific Information on the Details Tab

1. Click a provider name.

   The Specify Provider-Specific Detail dialog box appears.

2. In the **Billing Rate Information** section, override the default billing rate settings for the provider:

   - **Rate Year in effect—**Specify which set of billing rats to use to calculate the provider's fees. The application uses the hourly rates published for this provider for the rate chosen as the base rate, plus or minus any discount indicated here, then applies the specified inflation percentages over the course of the study.
   - **Discount rate to apply to this study—**Specify any negotiated percentage discount established with this provider.
   - **Back-Office Billing Rate Location—**Specify the location where centralized or regionalized tasks or functions are performed. The application uses this location to calculate fees based on the billing rates associated with resources in this location. When you edit the detailed assignments on the Assignment tab, you can choose another location for one or more centralized tasks if necessary.
   - **Line-item Discount—**Specify any negotiated monetary discount established with this provider for the plan. This discount is only applied to the provider's labor fees. Select the currency in which to calculate the discount from the drop-down list. If there is more than one provider for a plan, each could offer a different discount.
   - **Currency Exchange Rate**s—Choose an option to indicate which exchange rates the application uses to convert between currencies:
     - **Use rates defined on the Plan Overview tab—**Do not override any exchange rates specified on the Overview tab.

   - **Use rates defined below**—Open a new section on the screen to override exchange rates for this provider. If you have overridden exchange rates on the Overview tab, those values appear. To override these rates, type the exchange rate that is equal to one unit of the provider’s billing rate currency. Overridden values appear with a shaded background. To restore the default value, delete the value in the field.

3. In the **FTE Utilization Information** section, override the percentages in the Project Manager utilization before/after FSI/FPI.

   - The application suggests percentages of project manager resources prior to and after a first-subject-in date. These values are not calculated until after all study tasks have been assigned on the Assignment tab.

     These values change whenever certain assumptions are modified, including the number of sites or locations.

     Oracle recommends that you review the values if the number of sites or locations change or if tasks are reassigned.

   - For example, if you know that one full-time project manager will be allocated to the project before the date the first subject is enrolled, then you should enter 100% in the utilization prior field. If two full-time project managers are needed during this period, enter 200%. If a project manager will spend only half time on this study during the period, enter 50%.

4. Enter a **Resource Allocation Factor percentage,** if desired.

   Note: Do not modify this factor without a full understanding of how it will affect the plan

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   - Use this field only to allow comparison of the cost and time for a sponsor to conduct a study (or subset of study tasks) versus a CRO to conduct a study or perform certain tasks.
   - This field indicates the percentage of time, on average, that this service provider or sponsor team is working on the project, as a percentage of their overall workday.
     - For CROs, the recommended value is 80%.
     - For sponsors, the recommended values are between 50 and 70%.
     - If you decrease this percentage, you are indicating that this service provider requires more hours to complete a task than a service provider with a higher allocation. For example, if a sponsor's employees are dedicated to the project 70% of the time and spend only 30% of their time on other company activities, including meetings, conferences, vacation, sick, time, or other duties, then enter 70% in this field for the sponsor.
     - Generally, the larger the organization, the more time is spent on non-project-related activities.

5. Enter values in the fields in the **Other** section.

   - **Number of sponsor affiliate**s—Enter the number of your affiliates with which this vendor will be working.
   - **Type of reporting to affiliates**—Select those items you want the vendor to do.

- **Additional type of vendor with which this service provider will work**—From the drop-down list, select the type of provider with which this provider will work. This indicates the relationship that this vendor has with these other third parties. Do not include relationships where there is little or no daily interaction. For example, if the vendor only collects data from the central lab and does not interact with the central laboratory on a daily basis, do not include this interaction. If the vendor is managing the activities of another vendor, however, include this relationship.
- **Will this provider manage the CTM**S—Indicate whether or not this provider will enter data into the sponsor's Clinical Trial Management System (CTMS).

Editing or Creating an Inflation Profile for a Provider on the Inflation Tab

Built-in service providers have default inflation profiles associated with them. You can also set default inflation profiles per custom provider from the Maintain menu. When using a ClearTrial built-in provider, or a custom provider with an established profile, you can use the default inflation rates, plan-specific inflation rates, or no inflation at all. Access the inflation table in the plan and make your updates as needed.

Note: To use your plan-specific inflation rates only for specific locations, overwrite the default ClearTrial values with your values for those specific locations. Leave the ClearTrial defaults in the remaining locations in the event one of those remaining locations is later included in a plan.

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1. Click a provider name.

   The Specify Provider-Specific Details dialog box appears.
2. Click the **Inflation** tab.

   The application renders the Inflation Rates table for the selected provider.
3. In the **Compound inflation annually** field, select **Yes** or **No**.
4. To change inflation rates for the provider, enter the new rate for each location for each year.
5. To remove your overrides, click **Clear Overrides**.
6. To reset the inflation rate to zero, click **Set Inflation to 0%**.
7. Click **Ok**.

Note: To quickly update the inflation table to your desired rates, overwrite only the default inflation values for the locations you have included in your plan. Oracle recommends that you leave the ClearTrial default values in the unused locations in the event a user adds new locations later and does not revisit the inflation table. If you prefer to model your plan without inflation, click **Set Inflation to 0%**.

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**.

If there is more than one service provider in the plan, you can quickly select all service providers with a single click by using the checkbox that appears to the left of the Provider Name column label.

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.

   If you replace a provider who has a line-item discount, the new provider inherits the same line-item discount value and currency.

Freezing and Unfreezing Rates for a Service Provider

If there is an **Unfreeze Rates**, button, billing and inflation rates have been frozen for this plan. If there is a **Freeze Rates button**, no rates have been frozen. The Rate Year in Effect column shows the Rate Year used to look up billing and inflation rates for the resources for this service provider for this plan. If no billing or inflation rates have been published for a provider, an information icon appears to the right of the rate year. When you click the icon, a message appears stating that neither billing rates nor inflation rates have been published for the provider for the year the study is expected to start.

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 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. On the Attendees tab, 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. On the Attendees tab, 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.

   If there is more than one meeting in the plan, you can quickly select all meetings with a single click by using the checkbox that appears to the left of the Name column label.

   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.

   - **Select 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 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 Choose Location 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 you remove the associated locations or service providers 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. Save the entries you have already made.
2. 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.
3. In the **Scope of Overrides** section, from the **For tasks assigned to** drop-down list, select a service provider.
4. In the **Resources/Overrides** section, specify your override for each default resource specification and pin your changes if desired.
5. Click **Save**.
6. 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 for hours are in the thousandths. Displayed values for costs are in the hundredths.
- 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.

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

- **Unit of Measure—**From the drop-down list, select the unit of work this major task represents. Both ClearTrial default and custom units of work are available to be selected. 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.

  Custom Units of work appear in the drop-down list in italicized type followed by an asterisk.

- 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 with Task Details and Task Assignments tabs appears.

2. On the Task Details tab, specify the name of the task, a code to use as a prefix to the task 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**.

   The application assigns the new task a mapping key. Mapping keys are included in the Bid Grid export to allow vendors to programmatically map their costs to the Bid Grid format.

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 Select Resources 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 value in the Substitutions column or by editing the resource and navigating to the Rates & Substitutions 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 application displays information about the resource on five tabs, including Resource Details, Algorithm, Billing Rate Location, Rates & Substitutions, and Unit Hours.

   - For more information about a field, click the field name.
   - For more information about the screen, see Task Manager: Select Resources Dialog Box.

   You can specify or change the algorithms to calculate this resource's level-of-effort only for resources that are not part of the ClearTrial default model. You can adjust billing rate locations, billing rates, and unit hours for any resource.
2. On the **Resource Details** tab, specify the department to which this resource belongs and the GL Code for the fees associated with this resource when performing this task.

   - If you overwrote the resource with another resource on the Billing Rates tab, or at the plan- or plan-location-level, the name of the original resource appears.
   - Different providers can use different names for the resources that perform tasks. Review and change the description to make sure it identifies the appropriate resource.

3. On the **Algorithm** tab, use expressions to specify the cost driver, a percentage to apply to the cost driver, and the level of effort in hours for the selected resource to produce one unit of the particular work product.

   - You can only define algorithms for resources that are not part of the ClearTrial default model.
   - You can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different cost driver percentage to apply to the cost driver and level of effort in hours.
   - If you have specified the Major Task as location-scoped, then you can define an algorithm for each location.
   - For more information on multi-expression resource algorithms, see Working with Multi-Expression Resource Algorithms.

   a. In the **Calculate as** field, specify the number of hours (per a percentage of the cost driver) the resource must spend to complete one unit-of-measure for the expression.

   b. In the **per** field, specify the percentage value to apply to the selected cost driver for the expression.

      This percentage will increase/decrease the number derived from the underlying assumption for the driver.

   c. In the **of** field, select the unit-based assumption by which to drive the calculation for the expression.

      Custom units of work appear in the **of** drop-down list in italicized type followed by an asterisk.

      The application evaluates each expression by multiplying the number of units derived for the chosen assumption by the percentage and hours entered. The value of each expression within the algorithm is totaled to calculate the level of effort in hours for the selected resource to produce one unit of the particular work product. 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.

Note: While defining an algorithm, review the extended hours column to ensure that you have chosen the correct cost driver. An incorrect cost driver can greatly skew the effort estimated to complete a task

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4. On the **Billing Rate Location** tab, assign the billing rate location for the selected resource when working on this task.

   - Select any location where this activity to activities will be conducted. It is not necessary for the location 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.
   - By default, the application calculates centralized tasks using the back office billing rate of the assigned provider.
   - To prevent cascading changes, pin the billing rate location assignment by clicking the Pushpin icon in the Pinned column to highlight it. Changes made to the billing rate location for the task or task group assignments will not

override pinned billing rate locations for this resource for this task. However, pinned settings will be lost if the associated location and/or service provider are removed from the plan.

5. On the **Rates & Substitutions** tab, override the billing rates for the selected resource when performing a specified task.
   - If the task is location scoped, you can override the rate for each location.
   - Each row displays the hourly billing rate for the selected resource based on the applicable billing rate location, which may differ from the location listed.
   - If you have overridden the billing rate location, the rate displayed reflects that choice rather than the local rate.
   - When selecting a resource to substitute, by default the bill rate used is the effective billing rate, which can be overridden at the plan level or plan-location level, of the selected resource.
   - If resource substitutions have also been made at the plan level or plan-location level for the assigned service provider, the default effective billing rate is defined as the rate for the selected resource when performing the work of the original resource.
   - You can override the standard billing rate on a case-by-case basis. For example, a Medical Director might have a billing rate of $300.00 per hour. For a specific task, he or she bills at $500.00 per hour. If you enter $500.00 in the rate field for this task, the application uses the $500.00 per hour rate. All other tasks are calculated at $300.00 per hour.
   - You can also apply a percentage adjustment to the rate for a selected resource on a case-by-case basis.
   - To prevent cascading changes, pin the substitute resource and billing rate by clicking the Pushpin icon in the Pinned column to highlight it. Changes made to the billing rate or resource at the plan level or plan-location level will not override pinned billing rates or substitutions for this resource for this task. However, pinned settings will be lost if the associated location and/or service provider are removed from the plan.
6. Click **Save**.
7. On the **Unit Hours** tab, override system-calculated unit hours for the selected resource. For location-scoped tasks, you can override the unit hours expected for each location.
   - You can override the default unit hours and the unit hours percentage adjustment for the selected resource for all unpinned locations.
   - Use the **Unit Hou**rs field to specify a specific number of hours. Oracle recommends using this option if you want the hours to remain the same even if the study assumptions change.
   - If you want hours to change as study assumptions change, use the **% Adjus**t field for the selected resource to specify a percentage adjustment to be applied to calculated hours.
8. Click **Save**.
9. Click **Close**.

Delete a Resource

1. On the **Task Details** or **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%.

Working with Multi-Expression Resource Algorithms

You use algorithms to calculate the level of effort required for a resource to complete a task. You can only define algorithms for resources that are not part of the ClearTrial default model. When dealing with algorithms, there are two concepts to understand:

- **Expression—**Elements of an algorithm. For resources, the element includes input parameters for hours, cost driver, and percentage to apply to the cost driver.

  Example: 1.5 hours per 50% of sites = one expression. If the number of sites is 10, then the value of the expression is 7.5 hours (1.5 hours * 0.50 * 10 sites).

- **Algorithm—**One or more expressions whose total value evaluate to the level of effort in hours required for the resource to complete the task.

  Example: If an algorithm has 3 individual expressions and the value of each expression is 7.5 hours, 2 hours and 3.25 hours, respectively, then the total value of the algorithm is 12.75 hours (7.5 + 2 + 3.25).

If you have the Advanced Algorithm Editor role, you can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different cost driver. If you do not have that role, you can cannot add new or remove existing expressions. However, you can update the input parameters on any existing expression that was created by another user.

Adding or Removing Expressions

To add a new expression to an algorithm, click the **Add another expression…** link.

To remove an expression from an algorithm, click the **X** icon that appears next to the expression. There must always be at least one expression listed.

Default Algorithm

For tasks that vary by location, you can create a default algorithm made up of multiple expressions that can be applied to all locations. If you modify the default algorithm, those changes will cascade down to each location-specific algorithm, unless a location is overridden.

You can override the algorithm for any location to be different from the default algorithm. This includes changing any input parameter for a location-specific expression, or adding or removing expressions at the location level.

If you have manually overridden a location-specific algorithm to be different from the default algorithm, there are two links that can be used to restore the overridden location algorithm back to the default algorithm.

- The **Restore Defaults** link will appear at the default algorithm level if any location-specific algorithm has been overridden. Use the link to restore the algorithms for all locations back to the default algorithm.

- The **Use Default Algorithm** link will appear for a location-specific algorithm if it has been overridden. Use the link to restore a single location-specific algorithm back to the default algorithm.

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 by selecting it from the drop-down list.

   - 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, adjust hours or fees on the Adjustments tab, change the distribution of work units on the Distribution tab, 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.

Note: You cannot delete system-defined major tasks.

Specify Pass-through and Indirect Cost Categories on the Costs 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.

Filtering by Costs

- To show costs that have been previously excluded, in the **Show** field in the **Filter** section, select the **excluded cost(s)** checkbox.
- To display only cost categories with a value, de-select the **categories where costs total 0.00** checkbox.

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**, **Assignments**, **Algorithm**, and **Distribution** tabs.

   - For more information about a field, click the field name.
   - For more information about the screen, see Define New/Edit Category Dialog Box (Definition Tab, Assignments, Algorithm/Adjustments Tab, Distribution Tab).

Enter Category Information

1. On the Definition tab, in the **Name** field, define a name for the cost.
   - For any user-defined cost, specify a name of up to 60 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.
3. In the **Costs 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 **Costs vary by location**, you can specify a different per-unit amount for one or more locations, assign the responsibility for the cost to a different provider for each location (on the Assignments tab), override the start and end dates over which to distribute the costs or credit (on the Distribution tab), and express the per-unit cost or credit in a different currency for one or more locations (Algorithm tab).
4. 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**.
5. 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. To include inflation for this cost in resulting calculations, select the **Apply inflation over time** 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 **Apply inflation over time** 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**.

   The application assigns the new cost a mapping key. Mapping keys are included in the Bid Grid export to allow vendors to programmatically map their costs to the Bid Grid format.

Define Assignments

You can associate the cost with a specific provider, with a department for cost allocation, and with a GL code for reconciliation against the General Ledger.

1. Click the **Assignments** tab.
2. For each location, select the service provider, department, and GL Code.
   a. Assign the responsible provider, if applicable.

b. Map the cost or credit to a specific department.

c. Map the cost or credit to a GL Code.

Define the Algorithm

1. Click the **Algorithm** tab.
2. Use expressions to specify the cost driver, percentage to apply to the cost driver, monetary value and currency.
   - You can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different cost driver, percentage to apply to the cost driver and monetary value.
   - If you have specified the cost as location-scoped, then you can define an algorithm for each location.
   - For more information on multi-expression cost algorithms, see Working with Multi-Expression Cost Algorithms.
3. In the **Calculate as** field, specify the per unit cost value.
4. From the **currency** drop-down list, select the currency for the cost.
   - 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.
5. In the **per** field, specify a percentage value to apply to the selected cost driver for the expression.

   This percentage will increase/decrease the number derived from the underlying assumption for the driver.
6. From the **of** drop-down list, select a unit-based assumption by which to drive the calculation of this 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.
   - Custom cost drivers appear in the drop-down list in italicized type followed by an asterisk.
7. Click **Save**.

   The application calculates the total value for each location- or study-level expression as the monetary value multiplied by the specified percentage of the number of units expected for the chosen assumption.
   - The total calculated value for each expression displays to the right of the expression.
   - System-calculated cost values are displayed next to the **Calculated** field and cannot be changed.
   - In the **Total** field, the application displays the total calculated costs or credits, including any adjustments made by you or another user.

Working with Multi-Expression Cost Algorithms

You use algorithms to calculate the cost value. When dealing with algorithms, there are two concepts to understand:

- **Expression—**Elements of an algorithm. For costs, the element includes input parameters for monetary value, currency, cost driver, and percentage to apply to the cost driver.

  Example: 250 EUR per 50% of sites = one expression. If the number of sites is 10, then the value of the expression is 1,250 EUR (250 EUR * 0.50 * 10 sites).

- **Algorithm—**One or more expressions whose total value evaluate to the monetary value in a specific currency.

  Example: If an algorithm has 3 individual expressions and the value of each expression is 1,250 EUR, 500 EUR and 2,000 EUR respectively, then the total value of the algorithm is 3,750 EUR (1,250 + 500 + 2,000).

If you have the Advanced Algorithm Editor role, you can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different cost driver. If you do not have that role, you can cannot add new or remove existing expressions. However, you can update the input parameters on any existing expression that was created by another user.

Adding or Removing Expressions

To add a new expression to an algorithm, click the **Add another expression…** link.

To remove an expression from an algorithm, click the **X** icon that appears next to the expression. There must always be at least one expression listed.

Default Algorithm

For costs or credits that vary by location, you can create a default algorithm made up of multiple expressions that can be applied to all locations. If you modify the default algorithm, those changes will cascade down to each location-specific algorithm, unless a location is overridden.

You can override the algorithm for any location to be different from the default algorithm. This includes changing any input parameter for a location-specific expression, or adding or removing expressions at the location level.

If you have manually overridden a location-specific algorithm to be different from the default algorithm, there are two links that can be used to restore the overridden location algorithm back to the default algorithm.

- The **Restore Defaults** link will appear at the default algorithm level if any location-specific algorithm has been overridden. Use the link to restore the algorithms for all locations back to the default algorithm.
- The **Use Default Algorithm** link will appear for a location-specific algorithm if it has been overridden. Use the link to restore a single location-specific algorithm back to the default algorithm.

Distribute the Costs

1. Click the **Distribution** tab.
2. From the **Distribute according to** drop-down list, select how to distribute the cost for each location in your plan.

- You can spread costs according to one of the pre-defined schedules, including site approval distribution, subject enrollment distribution, or CRF data distribution. 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.

   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.

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**, **Assignments**, **Adjustments**, and **Distribution** tabs.
3. Click **Save**.

Excluding a Cost

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

   Any line-item discount will be allocated to the payment amounts based on the percentage values specified for each milestone payment.

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, including any applicable inflation and line-item discounts, 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, the total fees and hours associated with the study and pass-through costs, as well as any application inflation and line-item discounts.

- **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, safety and medical management (included here for cost models prior to 5.5), site close outs, and clinical compliance audits
- **Safety and Medical Management** (applicable to cost models 5.5 or above)—All fees associated with medical monitoring, SAE processing, and safety oversight.
- **Data Management**—All fees associated with the database design, data entry data coordination, data cleanup, database audits, and annual IND update.
- **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.

Inflation and Line-Item Discount

The total applicable inflation and line-item discount aggregated for all providers are included as separate line-items. Inflation adds to the overall fees, while any line-item discount reduces the overall fees.

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. When you are finished working with the report, click **Close**.

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.
   - **Assumptions**—Comparison of assumptions for two or more plans.
   - **Fees and Costs**—Differences in fees, line-item discounts, 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 (including line-item discounts) per resource for the selected plans.
   - **Milestone Dates**—Differences in milestone dates.

   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.

   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

On the Plans screen, the Other Actions... button provides access to a number of additional features. Features that you can perform on the selected plan(s) or based on your edit mode or permissions are highlighted in the list. You cannot select grayed-out features.

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**.

> **Note:** If the plan being unlocked has a cost model version earlier than the 5.3 cost model, the plan will be automatically upgraded to use the 5.3 cost model when the application unlocks it. Even though you are able to change the cost model used by an unlocked plan (see Change Attributes), you will not be able to reassign the plan back to a cost model that is older than 5.3.

Freeze and Unfreeze Rates

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

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

   Subsequent changes to billing and inflation rates no longer affect the plan.
3. To unfreeze the rates, select the frozen plan checkbox.
4. Click **Other Actions...**, and then click **Unfreeze 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. From the **Use Cost Model from** field, select the cost model version.
5. From the **Custom Field Model** field, select a custom field.
6. Click **Ok**.

   The Edit Template screen appears.
7. 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.
8. 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, cost model, custom field model, 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.
     - The **Cost Model** and **Custom Field Model** 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.

- You can only change the cost model and custom field model for an unlocked 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 plans.
    - What you can change depends on the number of plans selected and the 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. For more information, see Creating or Editing a Portfolio.
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

Use reforecasting to update your plan once your study has started, or to model scenarios in which study assumptions change over the course of the trial.

For example, the study has been in progress for six months and you have been tracking actuals since the Study Start Date. Today, you receive a change order to estimate the impact of adding 15 new sites and 150 new subjects. You can use reforecasting to update the plan to reflect these new assumptions. The reforecasted plan knows the history of the study, based both on the actuals you have entered and the previous and new assumptions. The reforecast provides new estimates for unit hours, labor fees, and costs by combining the actual progress, captured using the ClearTrial Track application, with the changes to the assumptions you provide.

You can also reforecast without tracking or considering actuals. In these cases, the ClearTrial application generates new estimates as if the study is continuing exactly as previously planned.

A plan with a cost model earlier than 5.3 cannot be reforecasted with the same cost model. When creating the reforecast, you will choose a new cost model to use for your reforecast that is a supported cost model.

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.
    - 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.

4. In the **Use Cost Model from** field, select a cost model version.
5. In the **Custom Field Model** field, select a custom field model.
6. In the **Create reforecast based on** field, select **Actual Values** to base the reforecast on actual tracked data. Select **Planned Values** to reforecast based on planned date.

   You must be licensed to use the ClearTrial Track application to use actual values.
7. 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. You can also select an exchange rate date or a user-defined Exchange Rate table to apply to the reforecasted plans.

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.
   - If you base the reforecast on the planned values, the application calculates the work remaining as though the study is progressing exactly as was originally forecast.
   - When you reforecast exchange rates on a plan with a cost model that is earlier than 5.3, the application applies the 5.3 cost model to the reforecast. If the cost model of the plan being reforecast is 5.3 or above, the reforecast inherits the cost model from the source plan.
   - You do not have the ability to manually apply a different cost model or custom field model when using this feature.
   - If you have licensed ClearTrial Track and are tracking the actual progress of this study against a baseline plan, you can base the reforecast on the actual progress (recommended) rather than on the predicted progress.
4. Click **Ok**.

3

Creating Requests for Proposals and Reviewing Bids

If you have purchased the Plan Enterprise feature of the ClearTrial application, you have the ability to create a request for proposal (RFP) from a plan, generate a bid spreadsheet for vendors, known as the Bid Grid, to use to respond to your RFP, import the bid into the ClearTrial application, and use a set of powerful features to analyze, evaluate, and compare bids.

Working with RFPs

If you have licensed the ClearTrial Plan and Source Enterprise edition, you are granted the required permissions to work with requests for proposal and bids as outlined in this chapter. If you are not a licensed user, you will see these features on menus; however, they are disabled.

Viewing the RFPs

The RFPs screen shows the requests for proposal that have been generated from plans. You can send each RFP to any number of vendors by downloading the bid grid and providing the file to the vendor(s). You can import the populated bid grids you receive into the ClearTrial application and compare them to each other or to the associated RFP.

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

   The RFPs screen appears.

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

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

   RFPs that match your filtering criteria appear.

3. Perform any of the following activities with RFPs:

   - Create a new RFP.
   - Edit a selected RFP.
   - Delete one or more RFPs.
   - Restore a deleted RFP.
   - Import a populated bid grid from a vendor.

- Compare bids associated with a selected RFP.
- Download the blank bid grid associated with an RFP.

Note: If you want to see the full set of assumptions that are the basis for the RFP, run the Assumptions report for the plan associated with the RFP.

Creating an RFP

You can create one or more RFPs per plan. However, the RFP is for one provider only.

1. On the **Plans** screen, select a plan checkbox, click **Other Actions...**, and choose **Create RFP**.

   The Create RFP dialog box appears.

   or

   On the **RFPs** list, click **New**.

   The Choose Plan for RFP Dialog Box appears.

   a. Select the radio button of the plan.

   b. Click **Ok**.

      The Create RFP Dialog Box appears.

2. In the **Scope of Work/Assigned to Provider** section, select the provider representing the scope of work on which the RFP is based.

   - The provider does not have to correlate in any way with the vendors to which you plan to send the RFP.
   - The selected provider is used to model the trial and scope the tasks and costs that vendors bid on.
   - When you import the bids at a later time, each bid is associated with an actual vendor.

3. In the **RFP Info** section, enter a short description of the RFP, a title for the bid grid the application will generate for the RFP, and any comments.

   - The short description does not appear on the bid grid. Use it to recognize the RFP in the RFP list.
   - The application includes the bid grid title in the header on the bid grid. You can customize this value for each vendor by editing the RFP and regenerating the bid grid.
   - The Comments field is a space in which to record any notes relevant to the RFP. For example, you might record who you send the bid grid to and on what date.

4. Click **Ok**.

   The application generates the RFP, downloads the Bid Grid, a Microsoft Excel spreadsheet for responding to the RFP, and displays a lock icon next to the plan name to indicate that the plan is now locked and cannot be changed.

   The application-generated fees and costs for the plan can be used as a benchmark for your vendor bids.

Note: You cannot change a plan after you have generated an RFP for it. You can, however, copy it and make changes if you do not want to start from scratch.

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5. View the bid grid.
   - If you created the RFP from the Plans screen, download the bid grid spreadsheet from your browser and save it locally on your computer.
   - On the RFPs screen, select the RFP and click **Download Bid Grid**. Open or save the bid grid from your browser.
   - The bid grid is populated with the number of expected units per task, based on the assumptions in the plan. The specific assumptions that led to those numbers of units are in the Plan Assumptions report.

Editing an RFP

Use the edit function to view the RFP or to edit its details. Editing an RFP allows you to change basic header information for your RFP (for example, Bid Grid Title, Comments, RFP Description) and to work with bids associated with the RFP.

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

   The RFPs screen appears.
2. Select the checkbox of the RFP you want to edit, and click **Edit**.

   The Edit RFP screen appears. You now have access to four tabs: Details, Labor, Costs, and Bids.
   - For more information about a field, click the field name.
   - For more information about the screen, see Edit RFP Screen (Details Tab).
3. Edit and save the information on each tab. Click **Next** to save your changes and advance to the next tab.
   a. On the **Details** tab, edit basic information about the RFP including the description, title of the bid grid, and comments. You can also download the bid grid.

      To view the bid grid, click the **Download Bid Grid** link.

   b. On the **Labor** tab, you can view the hours and number of units assigned for major tasks.

      To include the impact of inflation in the values displayed, select the Include Inflation checkbox.

   c. On the **Costs** tab, you can view expected pass-through costs.

   d. On the **Bids** tab, you can view a single bid or compare bids to one another and to the RFP.
4. To view the plan on which the RFP is based, click the plan name link at the top of the Edit RFP screen.

Deleting an RFP

1. On the **RFPs** screen, select the checkbox of the RFP to delete.
2. Click **Delete**.

3. To confirm the deletion, and any bids for the selected RFP, click **Ok**.

   The application marks the RFP and associated bids for deletion and draws a line through the plan name on the RFPs list.

> **Note:** The application does not permanently delete the RFP. You can restore the deleted RFP.

Restoring an RFP

1. On the **RFPs** screen, in the **Filter** section, select **All RFPs**.

   Deleted RFPs appear with a line through them. Purged RFPs do not appear.

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

   The application adds the RFP to the application.

Working with Bids

Working with bids involves uploading bids submitted by vendors and using the ClearTrial Compare feature to analyze hours and costs of a vendor bid against another vendor bid or against the RFP.

Importing a Bid

The bid grid is designed to be associated with only one RFP. If you try to import a bid grid into an RFP other than the RFP from which it was generated, you will receive an error message and the import process will fail. You can also import one bid associated with a provider at a time. If a bid already exists for the provider, you have the option of overwriting the existing bid.

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

   The RFPs screen appears.

2. Select the checkbox of the RFP plan name.
3. Click **Import Bid**.

   The Import Bid dialog box appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Import Bid Dialog Box.

4. In the **Vendor Name** section, select the radio button of the vendor whose bid you want to import.
5. In the **Bid Information** section, choose the bid grid file to upload by clicking Choose File and browsing the files on your computer. The application assumes that you have saved the submitted bid grid to your computer.
6. Add a short description to identify the bid, the bid number supplied by the vendor, and any comments about the bid.
7. Click **Ok**.

   If a bid for this RFP for this provider already exists, the application asks you whether to overwrite the existing bid or create a new version of the bid.

The application displays the issues encountered on the Import Bid dialog box.

8. To see or save the list of issues encountered, click the **Download Issues** link.
9. Save the issues list to your computer and share it with the vendor.

   You or the vendor must correct the bid grid prior to import if you encounter fatal errors. All non-fatal errors are listed for your review. You can decide if they require a correction from the vendor.
10. Click **Continue**.

    The application completes the import action.
11. Click **Close**.

    The imported bid is added to the Bids screen.

Warnings and Fatal Exceptions

Although warnings appear on the issues list, the application will import the bid even if warnings are present. Vendors must, however, correct fatal exceptions. These include, but are not limited to:

- The uploaded bid file is greater than the allowed size of 25MB.
- The uploaded bid file is not of supported Excel type (.xls).
- The uploaded bid file is empty or bid file was not uploaded.
- The uploaded bid file appears to have removed or added rows.
- The uploaded bid file appears to be missing one of the sheets.
- The uploaded bid file appears to have encountered an unknown error.
- The uploaded bid file appears to be of a different RFP.
- The RFP Bid was not found in cache.
- The uploaded bid file appears to have a duplicate labor entry.
- The uploaded bid file appears to have a duplicate cost entry.
- Bid file name contain illegal characters.
- Line-Item Discount has to be a negative number or 0.

Displaying the Bids

1. From the **Edit** menu, click **Bids**.

   The Bids screen appears.
2. Filter the bids as necessary. For more information, see Filtering Allows You to Show or Hide Items Based on Criteria.

   For each bid, the application shows the plan name, scope, vendor, version of the bid, short description, status, and date created.

Creating a New Bid

There can be multiple bids in response to the RFP.

To create a new bid, import a completed bid grid from a vendor. Make sure you provide a descriptive name so that you can tell the bids apart. To import the new bid:

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

The RFPs screen appears.

2. Select the checkbox of the RFP plan name.
3. Click **Import Bid**.

   The Import Bid dialog box appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Import Bid Dialog Box.
4. In the **Vendor Name** section, select the radio button of the vendor whose bid you want to import.

   If a bid already has been imported for this vendor, an Existing Bids section appears and the application prompts you to choose whether to replace that bid or create a new version of the bid.
5. To replace an existing bid, select **Replace Existing Bid**, then select the bid to replace from the list displayed.

   or

   To create a new bid, select **Create a New Version**.
6. In the **Bid Information** section, choose the bid grid file to upload by clicking Choose File and browsing the files on your computer. The application assumes that you have saved the submitted bid grid to your computer.
7. Add a short description to identify the bid, the bid number supplied by the vendor, and any comments about the bid.
8. Click **Ok**.
9. Click **Continue**.

   The application completes the import action.
10. Click **Close**.

    The imported bid is added to the Bids screen.

Editing a Bid

1. Select the checkbox of the bid, and click **Edit**.

   The **Edit Bid** screen appears. You now have access to four tabs: Details, Labor, Costs, and Issues.
2. On the **Details** tab, edit basic information about the bid including the short description, CRO bid number, status, and comments. You can also view the history of the bid and download the bid grid. For more information, see Edit Bid Screen (Details Tab).
3. On the **Labor** tab, you can view the hours and number of units assigned for major tasks.

   To include the impact of inflation on the values, select the **Include Inflation** checkbox.
4. On the **Costs** tab, you can view pass-through and miscellaneous costs supplied by this vendor.
5. On the **Issues** tab, you can review the warnings and issues the application found when importing the bid. These issues have not been corrected.

6. To view the bid grid, click the **Download** link.
7. To view the plan on which the bid is based, click the plan name link at the top of the Edit RFP screen.
8. Click **Save**.
9. Click **Close**.

Deleting a Bid

1. On the **Bids** screen, select the checkbox of the bid to delete.
2. Click **Delete**.
3. To confirm the deletion, a click **Ok**.

Note: The application does not permanently delete the bid. You can restore the deleted bid. For more information, see Purge Deleted... Screen.

Restoring a Bid

1. On the **Bids** screen, in the Filter section, select **All Bids**.

   Deleted bids appear with a line through them. Purged bids do not appear.
2. Select the checkbox of the deleted bid to restore.
3. Click **Restore**.

   The application adds the bid to the application.

Updating the Status of a Bid

You can manually update the status of a bid.

1. On the **Bids** screen, select the checkbox of the bid, and click **Update Status**.

   The Change Bid Status dialog box appears.
2. From the **Status** drop-down list, select the status to assign to the selected bid.
3. To add this action to the bid history, select the U**pdate Bid History** checkbox.
4. Click **Save & Close**.

   The status of the bid on the Bids screen changes.

Comparing Bids

You can compare bids for a single RFP or bids across RFPs. The information in the comparison report generated depends on the comparison scenario:

- When comparing a bid to the RFP, the report shows the variance between the bid and the RFP.
- When comparing two or more bids, the application generates the variances between one chosen baseline bid and the remaining bids.
- When comparing two or more bids and the RFP, the application generates the variances between one chosen baseline and the remaining bids or the RFP.
- Rules governing the comparisons include:

- The baseline plan appears first.
- All variances greater than the options specified are shaded yellow.
- Hours, dollars, and variances with negative values appear in parentheses; for example, (4.5).
- Variance percentages with negative values are denoted by a minus (-) sign.

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

   The RFPs screen appears.
2. Select the checkbox of the RFP plan name.
3. Click **Compare Bids**.

   The Vendor Bid Comparison Options dialog box appears. The application assumes that you want to compare all bids for this RFP. If you want to limit your comparison to specific bids for this RFP, access the comparison from the Bids screen.

or

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

   The Bids screen appears.
2. Select the checkboxes of the bids to compare.
3. Click **Compare Bids**.

   The Vendor Bid Comparison Options dialog box appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Vendor Bid Comparison Options Dialog Box
4. In the **Available Comparisons** section, select the level of detail for the comparison:
   - **Major Task and Cost Summary**—Compare values aggregated by major task and cost.
   - **Detailed Fees and Costs by Location, Task, Resource**—Compare values by resource per task per location. This report is only available when comparing bids for a single RFP.
5. In the **Compare Options** section, specify whether or not to include the RFP itself in the comparison and whether to show the variances to the RFP or to a selected bid.
6. In the **Variance Analysis** section, specify whether or not to include variance analysis and the percentage of total costs and total hours above which to highlight variances.
7. In the **Reporting Currency** section, select the currency to use to render the report to ensure that all monetary values displayed are in the same currency.
8. Click **Ok**.

   The application generates the Bid Comparison report reflecting the options specified.

   Line-item discounts are also compared across providers.

   You can print the report, view it as a PDF file, export it to an Excel worksheet, or export it to a comma-separated file.

9. Click **Close**.

Working with the Bid Grid

The bid grid is a Microsoft Excel workbook based on RFP data. Bidders use the bid grid to respond to the associated RFP. Instructions for completing the bid grid appear as the first page of the workbook. After filling in the bid grid, the bidder submits it to the provider, who then imports it into the ClearTrial application and uses features and tools in the ClearTrial application to evaluate and compare bids.

The steps that vendors follow to complete the bid grid are, as follows:

1. Opens the downloaded bid grid in Microsoft Excel.
2. Reads and understands the rules governing use of the bid grid.
   - The bidder must not alter the workbook structure or format.
   - The workbook is password protected.
3. Completes each sheet of the workbook.
   - Only cells that are shaded light blue can be edited.
   - The currency that must be used for the bid appears on each worksheet.

   The bid grid format and metadata are preserved even if bid grid changes occur in the next ClearTrial release. This allows you to continue to produce bid grids for negotiations that span multiple releases with the same format and metadata.

Elements of the Bid Grid

A summary worksheet exists that provides subtotals by location and an overall total of fees and costs. You enter the vendor name on this worksheet and it is automatically populated on all other worksheets of the bid grid. You can also enter any applicable line-item discount to be applied against the total fees on this worksheet.

There is a separate worksheet for every location (country or region) included in the clinical trial. Activities that occur in locations where sites and patients are not involved, such as biostatistics, appear in the worksheet named BidGrid_Centralized.

Header Section

Each worksheet contains a header section, comprised of:

- Bid Grid Title
- RFP Name
- Phase
- Indication
- Location corresponding to the worksheet: Centralized or a specific location.

Column Headers and Input Fields

These password-protected headers describe the data in each column.

- **Cost Type—**Either Labor or Cost, depending on the row. This column is populated based on the RFP and is not editable.

- **Location—**Centralized or the plan's location. This column indicates the location of the sites/patients related to this task. This column is populated based on the RFP and is not editable.
- **Major Task/Cost—**Name. This column is populated based on the RFP and is not editable.
- **Task—**Name. This column is populated based on the RFP and is not editable.
- **Resource—**Resource Name. This column is populated based on the RFP and is not editable.
- **Mapping Key—**Prepopulated with a ClearTrial-defined key for mapping tasks and costs between the RFP, bids, and plans.
- **Unit of Measure—**Definition of the unit of activity for this task. This column is populated based on the RFP and is not editable.
- **# Units—**Number of units of activity. This column is populated based on the RFP and is not editable.
- **Resource Location—**Defaults to a blank, blue input field. The bidder can select from a defined location.
- **Base Billing Rate—** The base billing rate is the non-inflated billing rate based on the agreed-upon rate card or, if no agreed-upon rate card exists, the vendor's standard or discounted rates. Defaults to a blank, blue input field. Entered in the RFP currency format with two-decimal point precision.
- **Inflated Billing Rate—**Inflated billing rate for the applicable resource. If no inflation is included, the base billing rate and inflated billing rate are the same value. Defaults to a blank, blue input field. Entered in the RFP currency format with two-decimal point precision.
- **Unit Hours—**Unit hours for the applicable task and resource. Unit hours reflect the effort for the resource to complete one unit of activity for the task. Defaults to a blank, blue input field. Three-decimal point precision.
- **Total Hours—**Three-decimal point precision. This column is calculated based on the vendor's input and the number of units.
- **Unit Cost—**In the RFP currency format with two-decimal point precision. This column is calculated based on the vendor's input.
- **Total Cost—**In the RFP currency format with two-decimal point precision. This column is calculated based on the vendor's input and the number of units.
- **Comments—**Column for vendors to add an explanation or clarification for each activity in the bid grid. Comments are only available to be viewed in exported bid grids. Comments are not available for viewing within the application.

Mapping Bids to RFPs Using Mapping Keys

By using mapping keys, you can ensure that you are comparing apples to apples when evaluating bids.

A mapping key is a value assigned by the ClearTrial application to uniquely identify an activity by location, task, and resource. The mapping keys are in the format [location code]-[task code]-[resource code]. The three elements for the mapping key are determined as follows:

- Location Codes—Location codes represent either a country or a ClearTrial-defined region. The values that reflect the ClearTrial-defined regions are:

- USA, Canada, Australia/New Zealand NA01
- Western Europe & Japan WE02
- Eastern Europe EE03
- Nordic Countries NC04
- Latin America LA05
- Asia AP06
- Other ZZ07
- Middle East ME08

The values assigned for countries are based on the standard two-digit ISO codes.

- **Task Codes—**Task codes are uniquely assigned by the ClearTrial application and can be found on the Task Details screen in the Task Manager.
- **Resource Codes—**Resource codes are uniquely defined by the user when a resource is added using the Add Resource feature, which is accessed by choosing Resources from the Maintain menu. The values for the resource codes can be seen on the Resources list screen or as a prefix to a resource name in the Task Details screen in the Task Manager.

4

Maintaining Resource Information and Settings

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

You maintain templates, service providers, resources, billing rates, inflation rates, departments and functional areas, GL codes, exchange rates, and reporting regions from the Maintain menu. You can also purge deleted items.

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 Maintain menu, select **Templates**.

   The Templates screen appears.

2. Filter the templates as necessary. For more information, see Define Template Filter Dialog Box Fields.

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 to calculate suggested values 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.

   - Choose values that correspond to most of the plans to which this template will apply. You can then modify the plan as necessary.
   - You can select this template to plan studies even if the study to be planned is for a different phase, therapeutic area, or indication.
   - For more information about a field, click the field name.
   - For more information about the screen, see Select Template Defaults Dialog Box Fields.

3. Click **Ok**.

   The Create Template screen appears and is identical to the Plans screen. Enter values as you would for any plan.

   Note: The new template will be created using the cost model for the current release. If the cost model used by the template needs to change, you can make that change through the Change Attributes option. For more information, see Changing Template Attributes.

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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 Create/Edit Plan or Template Screen (Overview Tab).
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

Revise the values as you would for any plan.

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

   The Edit Template screen appears and is identical to the Edit Plan screen. The application displays the cost model version associated with the template in the upper right-hand corner.
2. On the Overview tab, edit the information.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Plan or Template Screen (Overview Tab).
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**.

Deleting a Template

The application does not remove deleted templates permanently until a later time. You can restore a deleted template prior to that time.

1. On the Templates screen, select the checkbox of the template to delete.
2. Click **Delete**.

Restoring a Template

1. On the Templates screen, in the Filter section, select **All Templates**.

   Deleted templates appear with a line through them.

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

   The application removes the line and makes the template active..

Copying a Template

1. On the Templates screen, select the checkbox of the template to copy.
2. Click **Copy**.

   The Copy Template dialog box appears.
3. Provide a name for the copy.
4. Click **Ok**.

Note: The new template inherits the cost model from the source template.

Locking a Template

Locking a template freezes the template. It can no longer be edited.

1. On the Templates screen, select the checkbox of the template to lock or multiple checkboxes.
2. From the Other Actions menu, click **Lock Templates**.

   A lock icon appears to the right of the checkbox. You cannot edit a locked template.

Unlocking a Template

Unlocking a template allows the selected template to be edited.

1. On the Templates screen, select the checkbox of a locked template.
2. From the Other Actions menu, click **Unlock Templates**.

   The application unlocks the template and deletes the lock icon.

Note: If the template being unlocked has a cost model version earlier than the 5.3 cost model, the template will be automatically upgraded to use the 5.3 cost model when it is unlocked by the application. Even though you are able to change the cost model used by an unlocked template (see Changing Template Attributes), you will not be able to reassign the template back to a cost model that is older than 5.3.

Changing Template Attributes

You can change the name, status, cost model, custom field model, and descriptions of a selected template.

1. On the Templates screen, select a template checkbox.
2. Click **Other Actions...**, and then click **Change Attributes**.

   The Change Template Attributes dialog box appears.
3. Change the attributes shown.

- If you select multiple templates:
  - The **Template Name** field is disabled to prevent you from assigning the same name to multiple templates.
  - The **Status** field is empty. You can choose any status to apply to the selected templates.
  - The description fields are disabled.
  - The **Cost Model** and **Custom Field Model** fields are disabled.
- You cannot change the status of a deleted template or a template that is incomplete.
- You cannot change the status of templates you did not create unless you are assigned a role that grants you permission to edit other users' templates.
- You can only change the cost model and custom field model for unlocked templates.
- Oracle recommends that you select the **Update last modified date and user (template history)** checkbox. However, if you often filter by the last modified date, deselect the checkbox to prevent bulk updates from changing your view.
- For more information, see Change Template Attributes Dialog Box Fields

4. Click **Save & Close**.
   - Changes are made without opening or unlocking the templates.
   - What you can change depends on the number of templates selected and the status of the templates.

Maintain Service Providers on the Service Provider Screen

You maintain service providers on the Service Providers screen. The service providers on this screen are sponsor and Contract Research Organizations (CROs) and 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.

Viewing the Service Providers

1. From the Maintain menu, select **Service Providers**.

   The Service Providers screen appears.
2. In the Filter section, specify which services providers to include: sponsors, vendors, deleted providers.

Creating a Service Provider

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

   The Create Provider screen appears.
2. In the Service Provider Information section, 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).

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

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 country in which these tasks usually occur for this provider.
   - The back-office billing rate location determines the default billing rates for tasks that are typically centralized or conducted at a central location.
   - 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 History section appears.

   If no rates have been published for this provider, the **Update Billing Rates** link appears.

Enter Billing Rates for the Provider

You can enter hourly billing rates for the service provider.

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

   The Create Billing Rates screen appears.

2. Enter hourly billing rates for the service provider. For more information on entering billing rates, see Create/Edit 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. For more information on updating billing rates, see Create/Edit Billing Rates Screen.

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, in the Filter section, 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 in a separate window.
3. Click **Close**.

Define Resources to Add to Your Plan on the Resources Screen

Resources are the roles that people who work on the study will be assigned. Associated with each resource are a code for tracking the resource through the study, a job title or classification, and a set of responsibilities. There are two types of resources in the application:

- **System-defined resources—**Resources the application provides. You can edit these resources. However, 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.

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.

Viewing Resources

1. From the Maintain menu, select **Resources**.

   The Resources screen appears.

2. You can filter the Resources 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. In the Resource Summary section, enter a resource code, name, and description.

   Use the Code field to specify an alphanumeric code that represents the resource; for example, CRO1. If your company intends to use the RFP and bid management feature, you must include a code for every resource.

3. In the **Default Billing Rates** section, fill in the table. For each of the application-provided service providers, enter the hourly billing rate for the resource.

   - This table establishes a base rate for the ClearTrial-defined providers. You can enter or edit the U.S. hourly rate for this resource for each of the y ears you choose as the effective rate year when planning a study. Use the Maintain Billing Rates feature to provide and publish specific rates for each location.
   - 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. For user-defined resources, edit the code, name, description, and default billing rates.

   or

   For system-defined resources, edit the code and name.

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

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

Deleting User-Defined Resources

You cannot delete system-defined resources.

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

Restoring User-Defined Resources

1. On the Resources screen, in the Filter section, select the **All Resources** to display the deleted resources.

   Deleted resources appear with a line through them.
2. Select the checkbox of the resource to restore.
3. Click **Restore**.

   The application removes the line through the resource and the resource becomes active.

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. This screen displays currently defined billing rates and provides the ability to create, edit, delete, restore, copy, and publish billing rates. After you publish the billing rates, the application shares the rates between plans. If the rates are not ready to use, you can save a draft version of a set of billing rates. However, you cannot use draft versions in plans. You can also view the prior published rates and revert to those rates.

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

Viewing Billing Rates

1. From the Maintain menu, select **Billing Rates**.

   The Billing Rates screen appears.
   - For more information about a field, click the field name.
   - For more information about the screen, see Billing Rates Screen Fields.
2. Filter the Billing Rates screen to display only those rates associated with a selected provider or a selected year. For information see, Define Resource Filter Dialog Box Fields.
   a. 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**.
   b. 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. You use this screen to create, edit, export, and publish hourly billing rates for service providers to whom you assign tasks in a study.

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

2. From the **When** drop-down list, select a service provider doing work for a sponsor.
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. These rates are used when the chosen service provider is performing work for this sponsor or affiliate.
   - If your organization is a service provider (for example, a CRO), select the sponsor for whom these billing rates apply or --Any Sponsor-- if these rates apply to all sponsors for which you do not load specific rates.
   - If you have not creates rates to charge a specific sponsor, the application uses the rates you created for --Any Sponsor--.

4. From the **for Rate Year** drop-down list, select the year for which these rates apply.

   - 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.

   - 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.
   - 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.

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. You can view and download a list of the resource descriptions

from the Help topic associated with the Create Billing Rates screen. User-defined resources are included.

- Note the column whose Rate Variance % value is 100%. That is the location serving as the base rate. The rates for all other locations are derived as a percentage of the variance value of the base rate. You can change any variance or override any specific rate value.

7. Click **Save**.
   - To publish the rates, click **Publish**.
   - To view or save the rates as a Microsoft Excel spreadsheet, click the **Export rates to Excel** link.
   - To define billing rates for another service provider, select the service provider from the **When** drop-down list and repeat this procedure.

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**.

   The rates are immediately effective and available. Any unlocked plans that do not have frozen rates will reflect these changes.

Editing Billing Rates

You can edit and save rates in a draft state as many times as necessary prior to publishing them. You can also edit published rates and save them as a new draft that does not replace the published rates. When you are ready, you can publish that draft and replace the currently published 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.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Billing Rates Screen.
4. Click **Save**.

Deleting Billing Rates

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

   The application does not permanently delete the service provider billing rates. The deleted service provider appears with a line through it. You can restore the deleted rates.

Restoring Billing Rates

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

   Service providers with 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.

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

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 (positive or negative) to reflect inflation or other negotiated changes to the fees charged by selecting the checkbox and entering a percentage.

   This is useful for creating rates for a number of years for the same vendor when you expect the rates to increase or decrease by a certain percentage each year.

5. Click **Ok**.

   The Edit Billing Rates screen appears.

6. Edit the hourly billing rates as necessary.

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

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. To view the billing rates for a previously published set of billing rates, click the **Show Rates** link.

   The billing rates appear in a separate window.

   or

   Click the **Open as Draft** link to open the Edit Billing Rates screen to edit the billing rates, save them as a draft, or publish them.

4. Click **Close**.

Reverting to Previously Published Billing Rates

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.
4. Click **Close**.

Draft and Publish Inflation Profiles on the Inflation Profiles Screen

You define inflation profiles for service providers to whom you assign work on the Inflation Profiles screen. After you publish the inflation profile, the application shares the rates between plans. Inflation profiles correspond to a set of billing rates for the specified rate year. The application suggests rate variances by location so you can set inflation rates for a base location and the application translates those rates to other locations based on economic forecasts by region.

Note: To use your predicted inflation rates only for specific locations, overwrite the default ClearTrial values with your values for those specific locations. Leave the ClearTrial defaults in the remaining locations in the event one of those remaining locations is later included in a plan.

Many sponsors and CROs negotiate inflation rates, along with billing rates, as part of a Master Services Agreement or a Statement of Work. You can create custom inflation profiles by provider to match these negotiated rates. Each time you create a plan, you can then apply the profiles to create a more accurate estimate of the costs you expect to see in the provider bids.

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

Viewing Inflation Profiles

1. From the Maintain menu, select **Inflation Profiles**.

   The Inflation Profiles screen appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Inflation Profiles Screen Fields.
2. Filter the Inflation Profiles screen to display only those inflation profiles associated with a selected provider or a selected year. For information see, Inflation Profiles Screen Fields.

   a. From the **Show Profile for** drop-down list, select a vendor. To see inflation profiles for all vendors, select **Any Provider**.

   b. From the **for Rate Year** drop-down list, select a rate year. To see inflation profiles for all years, select **Any**.

   Inflation profiles matching your filter criteria appear.

Draft vs. Published Inflation Profiles

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

You can edit published inflation profiles and save them as drafts until you click **Publish**. The application continues to use the previously published inflation profiles until the new ones are published. You can view past inflation profiles and revert to these by clicking **Show Revision History**. For more information, see Viewing the Inflation Profiles Revision History.

Defining New Inflation Profiles

1. On the Inflation Profiles screen, click **New**.

   The New Inflation Profile dialog box appears.

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

2. From the **When** drop-down list, select the service provider for which this inflation profile applies.

3. From the **performs work for** drop-down list, select the sponsor that will be charged these rates.

   - If your organization is a sponsor, select your organization or an affiliate from the drop-down list.
   - If your organization is a service provider, select the sponsor for whom this inflation profile applies.

4. From the **for Rate Year** drop-down list, select the rate year to which to apply this inflation profile.

   - When creating a plan, the effective rate year chosen in the Provider Details dialog determines which billing rates are used. Rates are inflated per any inflation percentages specified.
   - A rate year is defined as January - December for the relevant year.
   - The Rate Year in effect determines the correct Billing Rate table and which Inflation Profile is used in that plan.
   - If there is no Inflation Profile for the sponsor/provider combination and Rate Year, the application issues an alert and the inflate rate defaults to 0% for all years in the plan.

5. Click **Ok**.

   The Create Inflation Profile screen appears.

   All the countries supported for the ClearTrial application are shown and the fields prepopulated with any already defined rates. Note that your selections from the New Inflation Profile dialog box appear at the top of the table.

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

6. From the **Base Rate Location** drop-down list, select the country or region for which the base rate applies.

- 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.
- You can change any variance or override any specific percentage.
- If you want to use the same inflation rate values in all locations, enter the values once in the Base Rate column and change the Rate Variances by location to 100% so that the application applies the base rate values by year to every location.

7. For each **Year**, for each location column, enter the inflation rate as a percentage.
   - The default specification includes five years, because most trials planned are five years. You can add years by clicking **Add Year.** You can specify inflation rates for up to 30 years.
   - To exclude an inflation calculation, enter a zero.
   - You can include a different rate for every year of the trial and relative to each location.
8. Click **Save**.

The ClearTrial application saves the inflation profile as a draft. To publish the draft, click **Publish**.

Publishing Inflation Profiles

1. On the Inflation Profiles screen, select the checkbox of an inflation profile with a Draft status.
2. Click **Publish**.

   The Confirm Publish Profile dialog box appears.
3. Click **Publish**.

   The inflation rates are immediately effective and available. Any unlocked plans that do not have frozen inflation rates will reflect these changes.

Editing Inflation Profiles

You can edit and save inflation profiles in a draft state as many times as necessary prior to publishing them. You can also edit published inflation profiles and save them as a new draft that does not replace the published inflation profile. When you are ready, you can publish that draft and replace the currently published inflation profile.

1. On the Inflation Profiles screen, select the checkbox of the inflation profile to edit.
2. Click **Edit**.

   The Edit Inflation Profile screen appears.
   - For more information about a field, click the field name.
   - For more information about the screen, see Create/Edit Inflation Profile Screen Fields.
3. Edit the base rate and percentages applied to selected regions and countries for the years shown as necessary.
4. Click **Save**.

If your profile matches an existing profile, the application asks you to confirm that you want to overwrite the existing values rather than create a new profile.

Deleting Inflation Profiles

1. On the Inflation Profiles screen, select the checkbox of the inflation profile to delete.
2. Click **Delete**.

   The application does not permanently delete the inflation profile. The deleted inflation profile appears with a line through it. You can restore the deleted inflation profile.

Restoring Inflation Profiles

1. On the Inflation Profiles screen, in the Filter section, select the **Include Deleted Profile** checkbox.

   Deleted inflation profiles appear with a line through them.
2. Select the checkbox of a deleted inflation profile.
3. Click **Restore**.

Copying Inflation Profiles

You can copy a draft, published, or prior published inflation profile.

1. On the Inflation Profiles screen, select the checkbox of the inflation profile to copy.
2. Click **Copy**.

   The Copy Inflation Profile dialog box appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Copy Inflation Profile Dialog Box Fields.
3. Enter the details for the copy of the inflation profile.

   a. From the **When** drop-down list, select a vendor.

   b. From the **performs work for** drop-down list, select the sponsor for whom the inflation profile applies.

   c. From the **for Rate Year** drop-down list, select the billing rate year to use.

   d. From the **Copy from** drop-down list, select the version of the inflation profile to copy. If there is only one option, this field is read-only.
4. Click **Ok**.

   The Create Inflation Profile screen appears. All the countries supported for the ClearTrial application are shown and the fields prepopulated with any already defined rates. Note that your selections from the New Inflation Profile dialog box appear at the top of the table.
5. Click **Save**.

   The application saves the changes to the copy of the inflation rate profile and adds the draft to the Inflation Profiles screen.

Note: Both the source and the copied inflation profiles will be identical except with respect to the years, which will start with the new effective rate year +1. The inflation rate values will be the same with respect to the years' offset within that profile as within the source.

Viewing the Inflation Profiles Revision History

1. On the Inflation Profiles screen, select the checkbox of the inflation profile.
2. Click **Show Revision History**.

   The Show Revision History dialog box appears displaying the profile status, last modified date, and user who last modified the profile.
3. To view the profile, click the **Show Profile** link.

   The inflation profile appears in a separate window.

   or

   To edit a published inflation profile, click the **Open as Draft** link to open the Edit Inflation Profile screen.

   a. Edit the profile as necessary.

   b. Click **Save**.
4. Click **Close**.

Map Departments to Labor and Costs on the Departments Screen

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

For more information, see Departments Screen Fields.

Viewing Departments and Mappings

1. From the Maintain menu, select **Departments/Functional Areas**.

   The Departments screen appears.
2. In the Filter section, specify whether to include all departments, active departments only, or departments matching a selected filter.
3. To create or modify a filter, click the **Modify** link.

   The Define Department Filter dialog box appears.

   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.

   This alphanumeric code represents the department and appears throughout the application. For example, the code for the Biostatistics department might be ST.

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 description of the department.
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**.

   The application does not permanently delete the department. The deleted department appears with a line through it. You can restore the deleted department

Restoring Departments

1. On the Departments screen, in the Filter section, select **All Departments** .

   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

Use this feature to map labor to departments by resource. You can map departments to internal and outsourced providers for each resource. You can also provide a default department for internal and outsourced mappings by selecting departments in the Default row.

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

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, select the mapping mode by clickingthe **Change** link in the upper right corner.

   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 can map departments to internal and outsourced providers for each ClearTrial-defined and user-defined resource.
   - **Location**—Map labor to departments by location. You can map departments to internal and outsourced providers for each location.
   - **Task**—Map labor to departments by task. You can map departments 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 for the selected mode appears.

5. For each tab, do the following:

   a. In the **Default** row, select default department mappings for internal and outsourced tasks from the drop-down lists.

   b. In the **Internal** column, select a department mapping for each resource, location, or task.

   c. 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. There are tabs for Labor or Costs for Phase 1 and Late Phase.

5. Click **Add Rule**.

   The Create Department Mapping Rule dialog box appears.

   - For more information about a field, click the field name.
   - For more information about the screen, see Create Department Mapping Rule Dialog Box

6. Do the following. Which choices you have are determined by your choice in step 4.

   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.

      Select **Any Provider** to include both Internal and outsourced service providers. Select the **Internal** and **Outsource** checkboxes to include 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 **Costs** tab, select the checkboxes of costs to be matched according to this rule.

      Selecting the **Any Cost** checkbox includes all costs.

   f. 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**.

Editing and Deleting Department Mapping Rules

You can edit or delete 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 General Ledger (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. You can create, edit, delete, and restore GL codes.

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

Viewing GL Codes and Mappings

1. From the Maintain menu, select **GL Codes**.

   The GL Codes screen appears.

2. You can filter the GL Codes screen to include all GL codes, active codes only, or specific criteria you have defined.

   For more information, see Define GL Code Filter Dialog Box Fields.

Adding a GL Code

You can edit ClearTrial-defined GL codes and user-defined GL codes.

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 of the GL code.
5. Click **Save**.
6. To return to the GL Code screen, click **Close**.

Editing a GL Code

You can edit both ClearTrial-defined GL codes and user-defined codes.

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**.

   Deleted GL codes appear with a line through them.

Restoring GL Codes

1. On the GL Codes screen, in the Filter section, select **All GL Codes**.

   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

You can map labor categories to GL codes by resource. For each resource you can map GL codes to internal and outsourced providers. You can also enter a default GL code for internal and outsourced providers for all resources by setting GL codes in the Default row.

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

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, select the mapping mode by clicking the **Change** link in the upper right corner.

   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 can map GL codes to internal and outsourced providers for each ClearTrial-defined and user-defined resource.
   - **Location**—Map labor to GL codes by location. You can map GL codes to internal and outsourced providers for each location.
   - **Task**—Map labor to GL codes by task. You can map GL codes 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 for the selected mode appears.

5. For each tab, do the following:

   - In the **Default** row, select default GL code mappings for internal and outsourced tasks from the drop-down lists.
   - 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**.

Restoring Default GL Codes Mappings

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

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.

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

- For more information about the screen, see Create GL Code Mapping Rule Dialog Box.

6. On the Create GL Code Mapping Rule dialog box, do the following. Which choices you have are determined by your choice in step 4.

   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. If you designate one of the exchange rate tables as the default table, the application automatically applies that exchange rate table to new plans.

- 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 can save a draft version of the exchange rate table if the values are not ready for use. Draft versions are not available for use in plans. Exchange rate tables must be published to be used in plans. You can edit previously published exchange rate tables, save the table as a draft, and later publish it. The application continues to use the previously published values until the new draft is published. When you update an exchange rate table, all plans using the table automatically update with the new conversion rates. You apply a published exchange rate table to a plan on the Overview tab.

Viewing Exchange Rates

1. From the Maintain menu, select **Exchange Rates**.

   The Exchange Rate Tables screen appears.

2. In the Filter section, specify whether to use all exchange rate tables, actives tables only, or tables matching a selected filter.
3. To create or modify a filter, click the **Modify** link.

   The Define Exchange Rate Table Filter dialog box appears.

   For more information, 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.

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

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 short description to identify this 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 with ClearTrial default values from a certain date.
5. In the **Currency Exchange Rate**, fields, enter what one unit of the currency equals in each of the other locations.
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. The application automatically updates all plans using the exchange rate table 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**.

   Deleted exchange rate tables appear with a line through them.

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**.

   All new plans use the published exchange rate table. The application automatically updates plans using the revised exchange table.

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

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

You then 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 Screens and Dialog Boxes.

Viewing Reporting Regions

1. From the Maintain menu, select **Reporting Regions**.

   The **Edit Reporting Regions** screen appears showing each reporting region defined and the number of countries mapped.

Adding a Reporting Region

1. On the Edit Reporting Regions screen, click **New Reporting Region.** If this is the first reporting region being added, enter a name for the new reporting region and click **New Reporting Region**.

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

2. Enter a reporting region name.
3. Click **Save**.
4. Continue adding reporting regions by clicking **New Reporting Region**, entering the reporting region name, and clicking **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

Map countries to the reporting regions you defined to view the Monthly Budget by Reporting Region report for a plan.

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. Select a plan and on the Edit Plan screen, click the **Reports** tab.

   A list of available study reports appear.

2. In the Costs section, click **Monthly Budget by Reporting Region**.

   If you have locations in the plan that are mapped to reporting regions, the Monthly Budget By Reporting Region report appears and shows the study costs by month by reporting region over the duration of the study.

3. Click **Close**.

Purging Deleted Items

When items are deleted, they are not actually removed from the application database. Instead the application marks them as deleted and stamps them with a date indicating when they were marked as deleted. This allows restoration of items that were deleted in error.

The application, however, permanent removes, or purges, deleted items regularly to conserve data storage space and to insure maximum application responsiveness. Purging takes place automatically at night to permanently remove items that have been deleted more than 30 days prior to the current date.

If you are a system administrator, however, you can override the 30-day deletion setting or initiate immediate purging of deleted items.

1. From the Maintain menu, select **Purge Deleted items**.

   The Purge Deleted screen appears.

2. Select the checkboxes of the item types to be purged.
3. In the deleted at least n days ago field, specify the number of days since an item of the selected type was deleted and should now be purged.

   To purge all deleted items of the selected type, enter 0.

4. Click **Purge Selected Items**.

   The application finds all selected items that were deleted within the specified number of days and purges them.

Draft and Publish Custom Field Models on the Custom Field Models Screen

The Custom Field Models screen displays a DRAFT model and any published custom field models. A published custom field model represents a set of custom fields that can be used in plans by other users. Any published model will have a version number assigned. You can open or change the description on published models, but the custom fields in a published model cannot be modified.

The DRAFT model is considered the working copy and is the only version where changes can be made to custom fields. You can perform the following actions on the DRAFT model: open, check out, check in, cancel checkout, and publish. The DRAFT model is not available to use in plans unless you have the Custom Fields Designer permission.

- **Checkout—**Reserves the DRAFT model so that changes can be made to it. When the DRAFT is checked out by one custom field designer, other custom field designers are not able to modify it; however, the other custom field designers can still view it in read-only mode.

- **Check-in**—Commits any changes made during a checkout session. This also makes the DRAFT model available to be checked out and modified by another custom field designer. Changes that have been made during a checkout session, but have not yet been checked-in, cannot be viewed or modified by other custom field designers.
- **Publish**—Creates a new Custom Field Model version that consists of the custom fields that existed in the DRAFT model at the time of publishing. Publishing also releases the new Custom Field Model version for use in plans.

Viewing the List of Custom Field Models

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

   - If a displayed custom field model has been published, the Version field contains a numeric value and the Published Date and Published By columns are populated.
   - If the DRAFT custom field model is checked out for editing, the Checkout Date and Checkout By columns are populated.
   - For more information about a button or column name, click the **Help menu** and select **With the Current Screen**.
   - For more information about the screen, see Custom Field Models Screen Fields.

Viewing the Custom Fields for a Custom Field Model

You can open a custom field model to display the custom fields that exist within the model and view custom field definitions, display criteria, and designer notes.

1. On the Custom Field Models screen, select the radio button associated with a custom field model and click **Open**.

   The Custom Fields screen for the selected custom field model appears and displays all the custom fields that exist in the selected model. The information displayed is read only and cannot be modified on this screen.

2. To view the field definitions, display criteria, and design notes of a custom field, select the checkbox for a custom field and click **View**.

   The View Custom Field screen appears. The information displayed is read-only and cannot be modified in view mode.

3. To return to the Custom Fields screen, click **Close**.
4. Once on the Custom Fields screen, to return to the Custom Field Models screen, click **Return to Custom Field Models**.

Checking Out the DRAFT Custom Field Model

You can check out the DRAFT model to add new or modify existing custom fields.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

2. Select the radio button associated with the DRAFT custom field model.
3. Click **Checkout**.

   The Custom Fields screen for the DRAFT custom field model appears.
4. To return to the Custom Field Models screen, click the **Return to Custom Field Models** link.

Checking In the DRAFT Custom Field Model

If you have finished making changes to the DRAFT model, you can check in your updates to make them available to other custom field designers.

1. On the Custom Field Models screen, select the radio button associated with the DRAFT custom field model.

   The Custom Field Models screen appears.
2. Click **Check-In**.

   The Checkout Date and Checkout By columns are blanked out.

   Or:

   On the Custom Fields screen for the DRAFT custom field model, click **Check-in.**

   Any changes made to the DRAFT custom field model are saved and you are returned to the Custom Field Models screen.

> **Note:** Once you have checked in the DRAFT model, if you decide you no longer want the changes that were just checked in, you must check out the DRAFT and delete or manually update the DRAFT custom fields and related field definitions back to the desired state.

Cancelling a Checkout Session

If you have the DRAFT model checked out and decide you no longer need any of changes you made in that checkout session, you can cancel that checkout session. Cancelling a checkout removes any changes you made during that checkout session and restores the DRAFT model to the last checked in state.

1. On the Custom Field Models screen, select the radio button associated with the DRAFT custom field model.

   The Custom Field Models screen appears.
2. Click **Cancel Checkout**.

   Or

   On the Custom Fields screen for the DRAFT custom field model, click **Cancel.**

   All changes made in the last checkout session are removed and the custom fields in the DRAFT custom field model are restored to the last checked in state.

Note: You are not able to cancel another custom field designer's checkout session; you can only cancel your own checkout sessions. If the custom field designer who has the DRAFT checked out is unavailable for an extended period of time, you can contact your system administrator to cancel the checkout. Any change that was not checked in will be lost.

Creating a Custom Field

You can create new custom fields within the DRAFT custom field model.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

2. Select the radio button associated with the DRAFT custom field model, and click **Checkout**.

   Or:

   If the DRAFT custom field model is already checked out, click **Open**.

   The Custom Fields screen for the checked out DRAFT custom field model appears.

3. Click **New**.

   The Create Custom Field screen appears.

4. Define the custom field by completing the **Field Definition**, **Display Criteria**, and **Designer Notes** sections.

   - For more information about a field, click the text box in which you enter the information.
   - For more information about the screen, click the field name to see a help topic.
   - For field descriptions see View/Create/Edit Custom Field Screen Field Descriptions.

5. Click **Save**.

6. To return to the Custom Fields screen, click **Close**.

Editing a Custom Field

You can change the field definitions, display criteria, and designer notes for existing custom fields within the DRAFT custom field model.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

2. Select the radio button associated with the DRAFT custom field model, and click **Checkout**.

   Or:

   If the DRAFT custom field model is already checked out, click **Open**.

   The Custom Fields screen for the DRAFT custom field model appears.

3. Select the checkbox for the custom field you want to edit, and click **Edit**.

   The Edit Custom Field screen appears.

4. Modify the custom field values in the Field Definition, Display Criteria, and Designer Notes sections.
   - For more information about a field, click the text box in which you enter the information.
   - For more information about the screen, click the field name to see a help topic.
   - For field descriptions see View/Create/Edit Custom Field Screen Field Descriptions.
5. Click **Save**.
6. To return to the Custom Fields screen, click **Close**.

Deleting Custom Fields

You can delete custom fields from the DRAFT custom field model that are no longer required for your standard operating procedures.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.
2. Select the radio button associated with the DRAFT custom field model, and click **Checkout**.

   Or:

   If the DRAFT custom field model is already checked out, click **Open**.

   The Custom Fields screen for the DRAFT custom field model appears.
3. Select the checkbox for the custom field you want to delete, and click **Delete**.

   Deleted custom fields are preserved and are not purged by the application.

Restoring Deleted Custom Fields

You can restore custom fields to the DRAFT custom field model that were deleted in the past.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.
2. Select the radio button associated with the DRAFT custom field model, and click **Checkout**.

   Or:

   If the DRAFT custom field model is already checked out, click **Open**.

   The Custom Fields screen for the DRAFT custom field model appears.
3. In the Filter section, select **All Custom Fields**.

   Deleted custom fields appear with a line through them.
4. Select the checkbox of a deleted custom field, and click **Restore**.

   The application removes the strike-through line from the restored field.

Copying a Custom Field

You can create a new custom field based on a copy of another custom field.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

2. Select the radio button associated with the DRAFT custom field model, and click **Checkout**.

   Or:

   If the DRAFT custom field model is already checked out, click **Open**.

   The Custom Fields screen for the DRAFT custom field model appears.

3. Select the checkbox for the custom field you want to copy, and click **Copy**.

   The Edit Custom Field screen appears that is a copy of the selected custom field.

4. Modify the custom field values in the **Field Definition**, **Display Criteria**, and **Designer Notes** sections. You must change the Name, Label, and Unit of Measure (Singular) fields.

   - For more information about a field, click the text box in which you enter the information.
   - For more information about the screen, click the field name to see a help topic.
   - For field descriptions see View/Create/Edit Custom Field Screen Field Descriptions.

5. Click **Save**.

6. To return to the Custom Fields screen, click **Close**.

   The copied field appears on the Custom Fields screen.

Publishing Custom Fields as a Custom Field Model

Once you have made your changes to the DRAFT custom field model and are ready to make it available to be used in plans, you can publish the DRAFT.

1. From the Maintain menu, select **Custom Fields**.

   The Custom Field Models screen appears.

2. Select the radio button associated with the DRAFT custom field model, and click **Publish**.

   Or:

   On the Custom Fields screen for the DRAFT custom field model, click B.

   The Publish Custom Fields dialog box appears.

3. In the **Description** field, you must type a short description for the new custom field model.

4. Click **Publish**.

   The Custom Field Models page appears.

   A new published custom field model is created that consists of the custom fields that existed in the DRAFT model at the time of publishing. The new model is assigned a version number.

   If the DRAFT custom field model was in a checked-out state at the time you clicked **Publish**, all changes made during that checkout session are saved and incorporated into the new published custom field model. The DRAFT custom field model is returned to a checked in state.

You can now use the custom fields in your plans.

Changing the Description of a Custom Field Model

You can change the description on any published custom field model.

1. On the Custom Field Models screen, select the radio button of the published custom field model whose description you want to change.
2. Click **Change Description**.

   The Change Description dialog box appears.
3. In the **Description** field, change the short description of the custom field model.
4. Click **Save & Close**.

   The description on the Custom Field Models screen changes.

Reviewing the DRAFT Custom Field Model within a Plan

If you have the custom field designer permission, you can assign a plan to the DRAFT model to review the impacts before you publish it.

For more information on assigning a custom field model to a plan, see Change Attributes.

Only those updates made to the DRAFT custom field model that have been checked in can be seen in plans.

ClearTrial recommends that the DRAFT model is not assigned to live plans to minimize any disruptions to other users who might be using those plans. You should create a copy of the live plan and then apply the DRAFT custom field model to the copy.

5

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,"Chapter 3, "Creating Requests for Proposals and Reviewing Bids," and Chapter 4, "Maintaining Resource Information and Settings."

Home Page Fields

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

Table 5–1 Home Page Fields

Field	Description	Notes
Edit menu	Add or edit plans, studies, products, templates, and portfolios.	There are no notes.
Report menu	Generate standard reports that are not plan-specific.	There are no notes.

Table 5–1 (Cont.) Home Page Fields

Field	Description	Notes
Maintain menu	Define, select, and edit: **Templates**—A reusable plan that serves as a starting point when planning any study. **Service providers**—The service providers to whom you can assign work in a plan. **Resources**—Manage system-defined resources and add, edit, and delete user-defined resources. **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. **Departments and functional areas**—Map departments to labor and costs. Choose a mapping mode. **GL codes**—Map labor and costs to the general ledger. **Exchange rates**—Create and define your organization's standardized rates for each currency to be used in your plans. **Reporting Regions**—Group reporting regions for studies based on your global organizational structure and accounting practices. **Custom Fields**—Manage custom field models and custom fields.	Select **Purge Deleted Items** to permanently remove items.
Admin menu	**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.	There are no notes.
Help menu	Display a Help screen associated with the screen currently displayed. View version and product information on the About Oracle Health Sciences ClearTrial Cloud Service dialog box. Contact technical support.	There are no notes.
User Name	View your user profile.	You can edit your profile and change your password.

Table 5–1 (Cont.) Home Page Fields

Field	Description	Notes
Visit Support Center	Displays the application Support Center to access release information, documentation, and reference material or to contact Oracle Support.	There are no notes.
Logout	Sign out of the application.	There are no notes.
Show	Show or hide items based on selected criteria. ▪ **All <items>**—No filter is applied. All items appear. ▪ **Active <items> Only**—Items that are not deleted or marked as Study Complete or Archived appear. ▪ **<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.	There are no notes.

Plans Screens, Tabs, and Dialog Boxes

This section documents the screens, tabs, and dialog boxes associated with plans.

Plans Screen

Table 5–2 Plans Screen Fields

Field	Description	Notes
New button	Create a new plan.	There are no notes.
Edit button	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.
Delete button	Delete the selected plan.	Deleted plans are removed at a later time and can be restored.
Restore button	Restore a deleted plan.	To use this option, adjust the filters so that you can see inactive as well as active items.
Copy button	Make a copy of the selected plan.	There are no notes.
Compare button	Compare selected plans. You can specify service provider and location details and change the currency used to generate the costs and comparison reports.	There are no notes.
Other Actions... button	Access additional features, such as locking and unlocking plans, freezing, and unfreezing billing rates, copying a plan as a template, and so on.	There are no notes.

Table 5–2 (Cont.) Plans Screen Fields

Field	Description	Notes
Plan name column	Unique identifier of plans.	There are no notes.
Study Name column	Name of study.	There are no notes.
Description column	Short description of the plan.	There are no notes.
Status column	Status of the plan: ■ **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.	You cannot choose another plan status until you enter information on all tabs through the Provider tab.
Last Modified column	Date a user last modified this plan.	There are no notes.

Plans Screen Dialog Boxes

The following dialog boxes are associated with the Plans screen.

Define Plan Filter Dialog Box

Table 5–3 Define Plan Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes plans last edited and saved the specified number of days.	There are no notes.
Include deleted plans	Includes plans that have been previously deleted.	There are no notes.
Plan name starts with	Includes plans whose names start with the specified text.	There are no notes.
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 as	Name assigned to the filter.	There are no notes.

Configure List Options Dialog Box - Plans Screen

Table 5–4 Configure List Options Dialog Box Fields - Plans Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.
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 5–5 Choose Study and Plan Template Dialog Box Fields

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

Table 5–5 (Cont.) Choose Study and Plan Template Dialog Box Fields

Field	Description	Notes
Phase study column	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. The application supports Phase I for oncology and vaccine studies, as well as Phase I studies for healthy volunteers. Phase I Oncology or Phase I Vaccine studies more closely resemble Phase IIa trials.	Read-only.
Therapeutic Area study column	The therapeutic area or body system for which this study will be conducted. 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 study column	The reason selected to perform this study. Indications are classified into therapeutic areas. 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 Name template column	Name of a plan or partial plan that can be used as a starting point for new plans for a study.	Read-only. Inactive template statuses (Deleted, Archived, Study Complete) are not available for selection.
Description template column	Information describing the template to help you recognize a particular scenario or purpose for the plan.	Read-only.
Applicable For template column	Study phase(s) for which the template has been defined.	Read-only.

Copy Plan Dialog Box

Table 5–6 Copy Plan Dialog Box Fields

Field	Description	Notes
Plan Name	Name of the copy.	There are no notes.
Use Cost Model from	Cost model to apply to the copy.	The default is the cost model of the plan being copied. The list includes all supported cost models beginning with 5.3.
Custom Field Model	Custom field model to apply to the copy.	There are no notes.

Compare Plan Dialog Box

Table 5–7 Compare Plan Dialog Box Fields

Field	Description	Notes
Available Comparisons	Comparisons to be made and details to include.	There are no notes.
Providers To Include	Service providers to include in the comparison.	There are no notes.
Reporting Currency	Currency to use for the comparison report.	There are no notes.

Copy Plan as Template Dialog Box Fields

Table 5–8 Copy Plan as Template Dialog Box Fields

Field	Description	Notes
Template Name	Name of the new template based on the plan.	There are no notes.
Use Cost Model from	Cost model to apply to the template.	The default is the cost model of the plan being copied. The list includes all supported cost models beginning with 5.3.
Custom Field Model	Custom field model to apply to the template.	There are no notes.

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 5–9 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.

Table 5–9 (Cont.) Change Plan Attributes Dialog Box Fields

Field	Description	Notes
Status	Status of the plan: ▪ **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.	There are no notes.
Cost Model	Cost model to apply to the plan.	The list includes all supported cost models beginning with 5.3.
Custom Field Model	Custom field model to apply to the plan.	There are no notes.
Short Description	Short description of the plan that appears on the Plans screen.	There are no notes.
Long Description	Detailed plan description.	There are no notes.
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.	There are no notes.

Add Plans to Portfolio(s) Dialog Box

Table 5–10 Add Plans to Portfolio(s) Dialog Box Fields

Field	Description	Notes
Name column	Portfolios to which you can add the selected plan(s).	There are no notes.
Description column	Short description of the portfolio.	There are no notes.
# Plans Now column	Number of plans in the portfolio before adding the selected plan(s).	There are no notes.
# Plans After column	Number of plans in the portfolio after adding the selected plan(s).	There are no notes.
Also create a new portfolio and add the selected plans to it column	Create a new portfolio.	There are no notes.
Portfolio Name	Name for the new portfolio.	There are no notes.
Short Description	Short description of the portfolio. This description appears on the Portfolios screen.	There are no notes.
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 5–11 Create Reforecast Dialog Box Fields

Field	Description	Notes
Reforecast Name	Name of the new forecast.	There are no notes.
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.	There are no notes.
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).	There are no notes.
Use Cost Model from	Cost model to apply to the reforecast.	The list includes all supported cost models beginning with 5.3.
Custom Field Model	Custom field model to apply to the reforecast.	There are no notes.
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 5–12 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. ■ To reforecast based on exchange rates as of a particular date, choose the first radio button and then specify that date. ■ 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.	There are no notes.
Use Exchange Rates: as of (date)	Date from which to obtain exchange rates as they were at the close of market on that day.	There are no notes.
Use Exchange Rates: defined in (published exchange rates table)	Published set of exchange rates to apply.	There are no notes.
Reforecast Name column	Suggested name for each reforecast. You can either accept this name or type a new name.	There are no notes.
Prior Forecast Date column	Date of the last forecast per plan.	The new reforecast date must be later than this date.
Study End Date column	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).	There are no notes.
Reforecast Date column	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 column	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 or Template Screen (Overview Tab)

Table 5–13 Overview Tab fields

Field	Description	Notes
Plan Name	Unique name that identifies the plan.	There are no 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.	There are no notes.

Table 5–13 (Cont.) Overview Tab fields

Field	Description	Notes
Status	Plan status.	There are no 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: ▪ **Conducted Internally**—Study is performed internally. Sets all responsibility radio buttons to Sponsor throughout the plan. ▪ **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. ▪ **Combination**—Study tasks are divided between an external service provider and the sponsor.	There are no notes.
Short Description	Short description of the plan that appears on the Plans screen.	There are no notes.
Long Description	Detailed plan description.	There are no notes.
Default Modeling Currency	Currency used to enter plan costs.	There are no notes.
Default Reporting Currency	Currency the application uses to generate reports.	There are no notes.
Use Exchange Rates	Exchange rates to use when converting between currencies. ▪ **As if (specified date)**—Exchange rates from a specific date. ▪ **Defined in**—User-defined exchange rate table. For more information on creating exchange rate tables, see Creating an Exchange Rate Table. ▪ **As specified here**—Override of one or more exchange rates with values you supply. ▪ **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.
Drug Storage	Special handling considerations.	There are no notes.
Radio Labeled	Compound is radioactive.	Optional.

Table 5–13 (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.
Created By	Displays the name of the user who created the plan.	There are no notes.
Last Modified By	Displays the name of the user who last modified the plan.	There are no notes.
Created Date	Displays the date the plan was created.	There are no notes.
Last Modified	Displays the date the plan was last modified.	There are no notes.
Created as a copy of	Displays the plan that was copied.	There are no notes.
Original Template	Displays the template from which the plan was created.	There are no notes.

Override Currency Exchange Rates Dialog Box

Table 5–14 Override Currency Exchange Rates Dialog Box Fields

Field	Description	Notes
Currency Exchange Rates	Currency exchange rates based on data entry.	There are no notes.
1 US Dollar (USD) equals...	Default exchange rates for 1 US dollar as of the current date.	There are no notes.

Locations Tab

Table 5–15 Locations Tab Fields

Field	Description	Notes
Add Location(s) button	Add one or more locations on the Choose Locations dialog box.	There are no notes.
Remove Location(s) button	Remove selected location(s).	Removing a location from a plan does not delete that location from the application.
Add Language(s) button	Add one or more languages not suggested for the plan by the application.	There are no notes.
Remove Language(s) button	Remove a selected user-specified language.	There are no notes.
Location column	Name of a location (either the country or the region) where sites will be located and subjects enrolled.	There are no notes.

Table 5–15 (Cont.) Locations Tab Fields

Field	Description	Notes
Number of Sites column	Number of sites for the location.	There are no notes.
Subjects to Randomize column	Number of subjects to randomize in this location. 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 column	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. Must be a value between 0.00 and 500,000.00 USD (or the equivalent in another currency).
MOH/FDA Delay column	Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time frame for each location.	Must be a value between 0 and 999.
Total/Avg column	Averages of the total sites, subjects to randomize, grant amount and MOH/FDA time delay.	There are no notes.
Language	Language into which study materials might need to be translated.	There are no notes.
Dialects/Variations	Number of dialects or variants of this language into which to translate study documents.	There are no notes.
Document Translations	Which documents are to be translated into the languages specified.	There are no notes.
Number of Translations/ Dialects	Total number of translations required.	There are no notes.

Choose Location Dialog Box

Table 5–16 Choose Locations Dialog Box Fields

Field	Description	Notes
Regions filter	Include locations by region.	There are no notes.
Countries filter	Include locations by country.	There are no notes.
Remove Language(s) filter	Remove the selected languages.	There are no notes.
Region column	Regions available for selection.	There are no notes.
Country column	Countries available for selection.	There are no notes.
Primary Language column	Primary language of the selected region or country.	There are no notes.
Primary Currency column	Primary currency of the selected region or country.	There are no notes.

Table 5–16 (Cont.) Choose Locations Dialog Box Fields

Field	Description	Notes
MOH/FDA Delay column	Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time for each location.	There are no notes.

Choose Additional Languages Dialog Box

Table 5–17 Choose Additional Languages Dialog Box Fields

Field	Description	Notes
Language column	Languages available.	There are no notes.
ISO Code column	Internationally recognized country code associated with the language.	There are no notes.

Document Translations Required Dialog Box

Table 5–18 Document Translations Required Dialog Box Fields

Field	Description	Notes
Document Type	Type of document.	There are no notes.
Translate	Translates the document type to the languages indicated.	There are no notes.
Back Translate	Translates the document back into the language of the original text, from the translated version.	There are no notes.
As Pass-Through Cost	Translation costs are to be considered pass-through costs, not calculated costs.	There are no notes.
Apply these choices for:	Applies selected translation choices to other languages.	There are no notes.

Site Tab

Table 5–19 Site Tab Fields

Field	Description	Notes
Location column	Name of a location where sites will be located and subjects enrolled.	There are no notes.
Number of Sites column	Number of sites within the selected location.	There are no notes.
Site Approval Schedule column	Type of site approval schedule for the location. ■ **User Defined Schedule**—Site approval schedule has been modified. ■ **ClearTrial Default Schedule**—Site approval follows the application-defined schedule.	There are no notes.

Table 5–19 (Cont.) Site Tab Fields

Field	Description	Notes
Values apply to	Location for which the values apply. 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.	There are no notes.
Percent of sites identified by sponsor	Percentage of study sites that the study sponsor identifies. The application calculates the number of sites.	There are no notes.
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.	There are no notes.
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 of sites.	There are no notes.
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 of sites.	There are no notes.
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.	There are no notes.
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.	There are no notes.
Percent of sites requiring only phone-based close-outs	Percentage of sites that require only phone-based close-outs. The application calculates the number of sites.	There are no notes.
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 of sites.	There are no notes.
Percent of sites requiring overhead	Percentage of sites requiring overhead above the standard investigator grant. The application calculates the number of sites.	There are no notes.
Average percent overhead	Average overhead percentage for sites requiring overhead.	There are no notes.
Number of drug shipments per site	Estimated number of drug shipments for each site.	There are no notes.

Table 5–19 (Cont.) Site Tab Fields

Field	Description	Notes
Percent of sites requiring a QA audit	Percentage of sites requiring a quality assurance audit. The application calculates the number of sites.	There are no notes.
Percent of regulatory documents collected	Enter the percentage of regulatory documents to collect during the investigator approval process.	There are no notes.
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.
Task Group column	Assignment group to which outsourcing responsibilities are applied.	For a list of tasks, see the online Help for the Sites tab.
Sponsor column	Assign all of the tasks in that group to the study sponsor.	There are no notes.
Vendor column	Assign all of the tasks in that group to the primary vendor assigned on the Provider tab.	There are no notes.
Mixed column	Assign some of the tasks to the sponsor and some to the vendor.	Make these assignments on the Assignment tab.
N/A column	None of the tasks in the group will be performed.	There are no notes.

Edit Site Approval Schedule Dialog Box

Table 5–20 Edit Site Approval Schedule Dialog Box Fields

Field	Description	Notes
Site Approval Schedule	Type of site approval schedule for the location. **User Defined Schedule**—Site approval schedule has been modified. **ClearTrial Default Schedule**—Site approval follows the application-defined schedule.	There are no notes.
Default Site Approval Period	Default length of the site approval period.	There are no notes.

Table 5–20 (Cont.) Edit Site Approval Schedule Dialog Box Fields

Field	Description	Notes
Additional Site Approval Weeks	Number of weeks added to the application-defined approval period.	There are no notes.
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.	There are no notes.
Week # column	Week number. within the site approval schedule.	There are no notes.
Week Of column	Start date of each week of the site approval period.	There are no notes.
Sites (Default) column	Number of sites expected to be approved (according to the ClearTrial Default Site Approval Schedule) each week.	Cumulative totals appear inside parentheses.
% (Default) column	Percentage of sites expected to be approved (according to the ClearTrial Default Site Approval Schedule) each week.	There are no notes.
Sites (User Defined)	Number of sites expected to be approved (according to the user-defined Site Approval Schedule) each week.	There are no notes.
% (User Defined) column	Percentage of sites expected to be approved (according to the user-defined Site Approval Schedule) each week.	There are no notes.
Total column	Total for each column.	There are no notes.
Restore Defaults button	Restore the default site approval schedule for this location.	There are no notes.
Apply button	Add the specified number of weeks to the site approval schedule.	There are no notes.
Copy Default Value button	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 5–21 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.	There are no notes.

Table 5–21 (Cont.) Subject Tab Fields

Field	Description	Notes
Manage location-specific values	Manage location-specific values for the First Subject In (FSI) date. ▪ **Globally**—Changes you make to the application-calculated FSI date apply to each location based on the number of days you shift the date. ▪ **Per Location**—Enter the dates and enrollment periods for each location in the study on the Edit Subject Arrival Dates dialog box.	There are no notes.
Subjects to randomize	Number of subjects in the selected location or all locations.	There are no notes.
Additional percent of randomized subject as alternates	Percentage of the total subjects randomized to be screened as alternate subjects.	There are no notes.
Stipend per alternate subjects	Stipend provided each alternate subject.	There are no notes.
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.	There are no notes.
Investigator payment per screen failure	Amount paid to the investigator for a subject that fails study screening.	There are no notes.
Percent of screen failures paid for	Percentage of the expected screen failures for which investigators are paid.	There are no notes.
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.	There are no notes.
Number of CRF pages per screen failure	Number of CRF pages collected for each screen failure.	There are no notes.
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.	There are no 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.	There are no notes.

Edit Subject Enrollment Dialog Box

Table 5–22 Edit Subject Enrollment Dialog Box Fields

Field	Description	Notes
Update study level enrollment period to	Study-level enrollment period.	There are no notes.
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).	There are no notes.
FSI column	First Subject In. Date that the First Subject First Visit (FSFV) is expected to take place.	There are no notes.
Enrollment Period column	Number of weeks during which subjects will be enrolled in the trial.	There are no notes.
Last Subject In Date column	Location -specific First Subject In date plus the enrollment period.	There are no notes.
Enrollment Rate column	Number of subjects expected to be enrolled per site per month.	There are no notes.

Edit Subjects Arrival Dates Dialog Box Fields

Table 5–23 Edit Subjects Arrival Dates Dialog Box Fields

Field	Description	Notes
Enrollment per Location	Defines subjects arrival dates per location.	There are no notes.
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.	There are no notes.
Apply button	Applies the FSI date shift value to the selected locations.	There are no notes.
Location column	Subject arrival region.	There are no notes.
FSI column	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 column	Location-specific First Subject In date plus the enrollment period.	There are no notes.

Edit Enrollment Distribution Dialog Box

Table 5–24 Edit Enrollment Distribution Dialog Box Fields

Field	Description	Notes
Location option	Location for which the subject enrollment distribution is managed.	There are no notes.

Table 5–24 (Cont.) Edit Enrollment Distribution Dialog Box Fields

Field	Description	Notes
Type of enrollment distribution option	Expected enrollment distribution. ■ **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. ■ **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. ■ **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.	There are no 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. ■ **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. Example: Chronic illness like diabetes, Alzheimer's, AIDs. ■ **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. ■ **Even Distribution**—Rarely used, and then only for general estimations. ■ **Custom...**—To enter the percentage of the total subject population expected to be enrolled during each quartile of the enrollment period.	There are no notes.

Table 5–24 (Cont.) Edit Enrollment Distribution Dialog Box Fields

Field	Description	Notes
Distribution resolution option	Resolution at which to manage the subject enrollment distribution.	There are no notes.
Period column	Period, quartile, or study week, during which subjects are planned to enroll.	There are no notes.
Subjects column	Number of subjects expected to enroll during a particular period or quartile.	There are no notes.
Percentage column	Percentage of subjects expected to enroll during a particular period or quartile.	There are no notes.

Edit Location-specific Screening and Drop Rate Assumptions Dialog Box

Table 5–25 Edit Location-specific Screening and Drop Rate Assumptions Dialog Box Fields

Field	Description	Notes
Location	Screening and drops region.	There are no notes.
Subjects to randomize	Number of subjects expected in the selected location or for All Locations.	There are no notes.
Additional percent of randomized subjects as alternates	Percentage of the total subjects randomized to be screened as alternate subjects.	There are no notes.
Stipend per Alternate subject	Stipend provided each alternate subject.	There are no notes.
Screen failure rate	Percentage of screened subjects expected to fail to become study participants.	Must contain a value between 0 and 99.99. Cannot be greater than 99.99%. 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: 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.	There are no notes.
Stipend per screen failure	Stipend to be paid to each potential subject that fails to pass the screening.	There are no notes.
Percent of screen failures paid for	Percentage of the expected screen failures investigators will still be paid.	There are no notes.
Number of screen failures allowed	Maximum number of screen failures for which investigators will compensated in this location.	There are no notes.

Table 5–25 (Cont.) Edit Location-specific Screening and Drop Rate Assumptions Dialog Box Fields

Field	Description	Notes
Subject drop rate	Percent of subjects that will not complete a full CRF due to early termination.	There are no notes.

Treatment Tab

Table 5–26 Treatment Tab Fields

Field	Description	Notes
Trial Design	Parallel or Cross-over study design. ■ **Parallel**—Different subjects receive different treatments during the same period. ■ **Cross-over**—Each subject receives all of the defined treatments, but in a different sequence.	Your choice determines which fields and sections appear. For example, if you select Parallel, you can also identify this as an endpoint study and select additional assumptions.
Will there be an electronic subject diary?	Whether there is an electronic subject diary.	There are no notes.
Is this an endpoint study?	Yes or No	An endpoint study is a study in which all patients conclude their participation on or around the same calendar date.
Weeks from FSI to endpoint	The number of weeks from the time the first subject is enrolled until the endpoint is expected to occur.	Must be a value between 0 and 999.
Subjects will visit every <n> weeks during the extended treatment period	The frequency of subject visits during the extended treatment period.	Must be a value between 0 and 999.
Endpoint date	The date the endpoint is expected to occur according to your entry for the number of weeks until the endpoint.	This is a display field.
Cost per bednight	Cost per night that a subject is confined to a study center during the treatment period.	Only applicable to PHIHV plans.
Currency drop-down list	Currency of the Cost per bednight.	Only applicable to PHIHV plans.
Number of CRF pages collected in the baseline visit	Total number of CRF pages collected for enrolled subjects during their screening visits and during the baseline visit.	Appears if the Trial Design is Cross-over. Must be a value between 0 and 99. If two or more patient visits occur in the same week, treat them as a single visit for calculation purposes.

Table 5–26 (Cont.) Treatment Tab Fields

Field	Description	Notes
Baseline visit monitoring time required (in minutes)	Minutes required to monitor pages collected during screening and baseline visits.	Appears if the Trial Design is Cross-over. Must be a value between 0 and 9,999.99.
Washout period duration	Length of the washout period, specified in weeks for late stage trials and in days for Phase 1 trial.	Appears if the Trial Design is Cross-over. 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). Must be a value between 0 and 999.
Configure washout period	Link that displays the Edit Washout Period dialog box., where you can specify how much data is collect during the washout period between each treatment.	There are no notes.
Number of CRF Pages	The number of Case Report Form (CRF) pages that will be collected for each subject during this period.	Must contain a value between 0 and 999.
Monitoring Time (minutes)	Display of the calculated amount of time, in minutes, required to monitor the pages collected during this period.	You can override this value if necessary. Must be a value between 0 and 9,999.99.
Total number of CRF pages	Display of the total number of CRF pages to be collected for a single subject during each washout period.	There are no notes.
Number of bednights during the washout period	Number of nights that a subject is confined to a study center during the washout period.	Only applicable to PHIHV plans when Cross-over selected.
Add button	Add a new treatment.	You can add up to five treatments to the study.
Edit button	Edit a treatment on the Treatment Details dialog box.	There are no notes.
Copy button	Duplicate an existing treatment.	There are no notes.
Delete button	Remove a treatment.	Deleting a treatment removes all of its associated assumptions.
ID	Alphabetic identifier for the treatment entry.	There are no notes.
Number of subjects	Number of subjects to receive the treatment.	Included for parallel studies. Not included for cross-over studies because all subjects receive all treatments. Treatment sequence varies). Must be a value between 1 and 999,999.

Table 5–26 (Cont.) Treatment Tab Fields

Field	Description	Notes
Treatment duration	Treatment length, or time-on-trial, for each subject. For late-stage trials, specified in weeks. 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. For late-stage trials, a visit is a week. For Phase I trials, a visit is a day on which one or more CRF pages are collected. For Phase I (Healthy Volunteers) trials, in which subjects are confined, each day is a visit.	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. For PHIHV plans only.
CRF pages per subject	Number of Case Report Form (CRF) pages collected for each subject during this treatment.	Must be a value between 2 and 9,999.
QOL pages	Number of Quality of Life (QOL) pages collected during the treatment period.	Must be a value between 0 and 9,999.
Subject diary pages	Number of subject diary pages collected during the treatment period.	Must be a value between 0 and 9,999.
Pharmacoeconomic pages	Number of pharmacoeconomic pages collected during the treatment period.	Must be a value between 0 and 9,999.
Lab and diagnostic tests per subject.	Number of expected lab and diagnostic tests per subject per treatment arm.	Must be a value between 0 and 999. Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Cohort escalation review.	Number of dose escalation reviews per treatment arm.	Must be a value between 0 and 999. Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Average CRF pages per extended visit	The average number of CRFs that will be collected during each visit after a subject has completed the standard treatment.	This value should be inclusive of QOL (Quality-of-Life), pharmacoeconomic, and subject diary pages collect. Must contain a value between 0 and 99.
QOL pages per extended visit	How many of the pages collected during the extended treatment period are Quality-of-Life (QOL) pages.	Must contain a value between 0 and 99.

Table 5–26 (Cont.) Treatment Tab Fields

Field	Description	Notes
Subject diary pages per extended visit	How many of the pages collected during the extended treatment period are subject diary pages.	Must be a value between 0 and 99. Available in Advanced Edit Mode or higher.
Pharmacoeconomic pages per extended visit	How may of the pages collected during the extended treatment period are pharmacoeconomic pages.	Must be a value between 0 and 99. Available in Advanced Edit Mode or higher.
Monitoring minutes per CRF page	Number of minutes to monitor one regular CRF page. This field does not apply to monitoring for pages generated during the baseline visit. The application calculates the default value based on the study phase and therapeutic indication. You can override this value for each treatment. Overridden values do not affect minute per page values for the baseline visit or washout period for a crossover study. ■ If endpoint study, applies to both the standard treatment period and the extended treatment period for the treatment arm. ■ Does not apply to pages collected at baseline visit or during washout period. Those values can be configured through the washout configuration option or on the treatment schedule.	Available in Expert mode only. Must be a value between 1 and 100. Precision up to three decimal places appears. If the default value has more than 3 decimal places, the full numeric value appears when you hover the mouse over the field.
Name	Cross-over design that determines the sequences of treatments to which subjects are randomized. The application supports Latin Square and Balaam's Design. Balaam's design is only applicable to trials with exactly two treatments.	There are no notes.
Treatment Sequence	Order in which treatments are administered.	There are no notes.

Edit Washout Period Dialog Box

Table 5–27 Edit Washout Period Dialog Box Fields

Field	Description	Notes
Day	Integer representing day within washout period.	There are no notes.
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.

Table 5–27 (Cont.) Edit Washout Period Dialog Box Fields

Field	Description	Notes
Monitoring Time (minutes)	Calculated 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.	There are no notes.

Edit Treatment Dialog Box (Details Tab, Schedule Tab, Notes Tab)

Table 5–28 Edit Treatment (Details Tab) Fields

Field	Description	Notes
Treatment duration	Treatment length for each subject. For late-stage trials, specified as weeks. 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.
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. This number should be inclusive of QQL, pharmacoeconomic, and subject diary pages collected.
QOL pages	Number of Quality of Life (QOL) pages collected during the treatment period.	Must be a value between 0 and 9,999.
Subject diary pages	Number of subject diary pages collected during the treatment period.	Must be a value between 0 and 9,999.
Pharmacoeconomic pages	Number of pharmacoeconomic pages collected during the treatment period.	Must be a value between 0 and 9,999.
Lab and diagnostic tests per subject	Number of expected lab and diagnostic tests per subject per treatment arm.	Must be a value between 0 and 999. Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Cohort escalation reviews	Number of dose escalation reviews per treatment arm.	Must be a value between 0 and 999. Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Location column	Location to which the treatment cost is applied.	There are no notes.

Table 5–28 (Cont.) Edit Treatment (Details Tab) Fields

Field	Description	Notes
# Subjects column	Number of subjects expected to be randomized to this treatment in each location.	There are no notes.
Average 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. Must be a value between 0.00 and 500,000.00 USD (or the equivalent in another currency).
Procedure Cost column	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). Only appears for PHIHV plans.
Special Procedure Cost column	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). Only appears for PHIHV plans.
Stipend Per Enrolled Subject column	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 5–29 Edit Treatment (Schedule Tab) Fields

Field	Description	Notes
Monitoring minutes per CRF page	Number of minutes to monitor one regular CRF page. This field does not apply to monitoring for pages generated during the baseline visit. The application calculates the default value based on the study phase and therapeutic indication. You can override this value for each treatment. Overridden values do not affect minute per page values for the baseline visit or washout period for a crossover study.	Must be a value between 1 and 100.
Use example grant amount	Select to enter numeric values for each visit. The application converts these into percentage values.	The value is not saved; only the percentage is saved.
Day	Day within the treatment period, represented by an integer.	There are no 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. The number of CRF pages per visit must be a value between 0 and 999.
Monitoring Time (minutes)	Number of minutes required for this visit.	There are no notes.

Table 5–29 (Cont.) Edit Treatment (Schedule Tab) Fields

Field	Description	Notes
Percent of Grant	Percentage of the grant amount allocated to each visit.	Change the percentages to control how grants are accrued and payments distributed over the course of the trial.
Total Number of CRF Pages	Total number of CRF pages to be collected for a single subject during the course of this treatment.	There are no notes.
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.
Clear CRF Defaults link	Overrides the entire calculated schedule.	There are no notes.
Restore CRF Defaults link	Restores default values for CRF pages and monitoring time.	There are no notes.
Clear Grant Overrides link	Restores default values for grant allocations.	There are no notes.

Table 5–30 Edit Treatment (Notes Tab) Fields

Field	Description	Notes
Notes	Information relevant to the treatment that you want to be available to other people who view this plan or reports.	There are no notes.

Data Tab

Table 5–31 Data Tab Fields

Field	Description	Notes
Data Collection Method	Data collection method for the study. ■ **Paper (Traditional Monitoring)**—Monitors visit the sites to collect data. ■ **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. ■ **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. ■ **Faxed CRFs**—Case Report Forms (CRFs) are completed at the investigator site and faxed to the data management location. ■ **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. Electronic Data Capture (EDC) is the default data collection method.
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. ■ **Stage 1: Pilot/Single Study**—Actively conduct experimental EDC implementations within a single study or within a limited number of trials. ■ **Stage 2: Limited Standardization**—Use EDC in a limited number of studies. ■ **Stage 3: Standardization**—Use EDC for all new trials. ■ **Stage 4: Enterprise Deployment**—EDC is fully integrated for all of your trials.	Default data collection method is EDC Maturity Level 3 for all new plans.
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.

Table 5–31 (Cont.) Data Tab Fields

Field	Description	Notes
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.	There are no notes.
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. 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.	Must be a value between 0 and 9,999.
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.
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).
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 Repeat Data Tables	Number of repeat data tables.	The application calculates a default based on the Number of Unique Pages field. Must be a value between 0 and 99.
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 Repeat Data Listings	Number of repeat data listings.	The application calculates a default number based on the Number of Unique Pages field.

Table 5–31 (Cont.) Data Tab Fields

Field	Description	Notes
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 Repeat Figures and Graphs	Number of repeat figures and graphs.	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.	There are no notes.
Number of Repeat PK/PD Data Tables	Number of repeat PK/PD related tables.	There are no notes.
Number of Unique PK/PD Data Listings	Number of unique PK/PD related listings.	There are no notes.
Number of Repeat PK/PD Data Listings	Number of repeat PK/PD data listings.	There are no notes.
Number of Unique PK/PD Figures and Graphs	Number of unique PK/PD related figures or graphs.	There are no notes.
Number of Repeat PK/PD Figures and Graphs	Number of repeat PK/PD figures and graphs.	There are no notes.
Number of newsletters per site	Number of newsletters to provide per site.	Indicate how many timed the newsletters will be generated. For example, if the study has 120 sites and there will be 12 newsletters, enter 12.
Will there be an ICF Video/DVD?	Whether there will be an ICF Video/DVD.	There are no notes.
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	Additional training sessions that occur for EDC. This is not the training at the Investigator meeting or initial CRA training.	Default value is 3. Required if you selected EDC or EDC-3rd Party as the data collection method.
Number of pages in the Investigator Brochure	Number of pages in the Investigator Brochure.	The Investigator Brochure can be a few pages or more than 250 pages. Deselect the Write IB task on the Assignment tab if the Investigator Brochure was previously written.
Number of manuscripts	Number of documents, other than the final Clinical Summary Report.	Must be a value between 0 and 99.
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. 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. Minimum value is 1.

Table 5–31 (Cont.) Data Tab Fields

Field	Description	Notes
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.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.Minimum value is 1.
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.	There are no notes.
Hours medical monitor will spend with each SAE	Number of hours a medical monitor spends with each serious adverse event (SAE).	There are no notes.
Expected percent of SAE Reports to be expedited	Percentage of serious adverse event (SAE) reports to be expedited to regulatory agencies and ethics committees.	There are no notes.
Expedited SAEs	Number of expedited serious adverse events (SAEs) calculated by the application.	There are no notes.
Provide data to the DSMB	How often data is reported to the Data Safety Monitoring Board (DSMB).	There are no notes.
IVRS Usage	Tasks for which an Interactive Voice Response System (IVRS) is used.	There are no notes.
Expected Protocol Amendments	Add one or more protocol amendments.	There are no notes.
An amendment is expected to occur	The number of days before or after a specific milestone this amendment is expected to occur	There are no notes.
Milestone nearest to the protocol amendment	The selected milestone from which the application calculates the approximate date of the amendment.	There are no notes.
Add another amendment	Add additional protocol amendments to the study.	There are no notes.
Task Group column	Assignment groups to which outsourcing responsibilities are applied.	For a list of tasks, see the online Help for the Sites tab.
Sponsor column	Assign all of the tasks in that group to the study sponsor.	There are no notes.
Vendor column	Assign all of the tasks in that group to the primary vendor assigned on the Provider tab.	There are no notes.

Table 5–31 (Cont.) Data Tab Fields

Field	Description	Notes
Mixed column	Assign some of the tasks to the sponsor and some to the vendor on the Assignment tab.	There are no notes.
N/A column	None of the tasks in the group will be performed.	There are no notes.

Monitoring Tab

Table 5–32 Monitoring Tab Fields

Field	Description	Notes
Monitoring will be performed	Whether monitoring will be done in-person, by phone, or by a combination of these methods.	There are no notes.
Manage monitoring schedule values	Management of monitoring schedules. ■ **Globally**—Assumptions entered on the Monitoring tab apply to all the locations in the study. ■ **Per Location**—Modify schedules for each location within the study by clicking the **Per Location** link.	There are no notes.
Monitor every	Frequency, in weeks that a monitor visits the study sites during each period of the monitoring schedule.	There are no notes.
Until LSO/LPO	Site monitoring continues at the entered frequency until the end of the treatment period.	There are no notes.
Until Week	The week during the study the monitoring frequency changes.	There are no notes.
Total visits	Total number of monitoring visits during the study. 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. **Spoke**—Monitors returns to their home or office between each site visit. **Loop**—Monitor travels to each site before returning to their home or office.	There are no notes.
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.

Table 5–32 (Cont.) Monitoring Tab Fields

Field	Description	Notes
Percentage of monitoring done by CRAs (vs. Senior CRAs)	Percentage of monitoring and site management conducted by Clinical Research Assistants (CRAs) versus Senior CRAs.	There are no notes.
Percentage of monitoring done by Regional Monitors	Percentage of monitoring regional monitors complete.	There are no notes.
Avg travel time (in hours) for site monitors	Average travel time, in hours, for site monitors.	There are no notes.
Percent of source document verification	Percentage of safety and efficacy data to be source verified while monitoring the data.	There are no notes.
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 Schedule Dialog Box dialog box.	There are no notes.
Total CRF pages generated (without subject drops)	Number of predicted Case Report Form (CRF) pages generated, assuming no subjects drop out of the study.	There are no notes.
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.	There are no 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.	In cost models 5.5 and above, field only available to Phase I (Healthy Volunteer) trials.
24/7 coverage	Indicates the number of times the medical monitor will perform medical data listing reviews.	Only available in cost models 5.5 and above. Not available in Phase I (Healthy Volunteers) trials.
Number of medical data listing reviews	The number of times the medical monitor will perform medical data listing reviews.	Must be a value between 0 and 999. Only available in cost models 5.5 and above. Not available in Phase I (Healthy Volunteers) trials.
Will there be additional drug accountability visits?	Whether additional drug accountability visits are required.	There are no notes.
Additional drug accountability visits performed by	Who will perform additional drug accountability visits, if applicable.	There are no notes.

Table 5–32 (Cont.) Monitoring Tab Fields

Field	Description	Notes
Additional drug accountability visits per site	Number of additional drug accountability visits to be made per site.	There are no notes.

Edit Per Location Monitoring Schedule Dialog Box

Table 5–33 Edit Per Location Monitoring Schedule Dialog Box Fields

Field	Description	Notes
Monitoring will be performed	Whether monitoring will be done in-person or by phone or by a combination of these methods.	There are no notes.
Monitor every	Frequency, in weeks that a monitor visits the study sites during each period of the monitoring schedule.	There are no notes.
until LSO/LPO	Indicates that site monitoring will continue at the specified frequency throughout the end of the treatment period.	There are no notes.
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.	There are no notes.
Monitoring Travel Strategy	Travel strategy to be used for most of the monitoring trips.	There are no 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.	There are no notes.
Total Visits	Total number of visits across all locations.	There are no notes.
Total Calls	Total number of calls across all locations.	There are no notes.
Manage location-specific values	Monitoring approach assumptions for each location.	There are no notes.

Edit Per Location Monitoring Approach Dialog Box

Table 5–34 Edit Per Location Monitoring Approach Dialog Box Fields

Field	Description	Notes
Restore Defaults	Click to restore the monitoring assumptions to the global values for a specific location.	There are no notes.
Restore All Defaults	Click to restore the monitoring assumptions to the global values for all locations.	There are no notes.
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.	There are no notes.
Percent of source document verification	Specify the percent of key safety and efficacy data to be source verified while monitoring the data.	There are no notes.
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).	There are no notes.
Percentage of monitoring done by Regional Monitors	Indicates the percentage of monitoring that will be done by Regional Monitors.	There are no notes.
Avg travel time (in hours) for site monitors	The average number of hours a monitor will need to travel to sites	There are no notes.

Provider Tab

Table 5–35 Provider Tab Fields

Field	Description	Notes
Add Provider(s) button	Add providers.	There are no notes.
Remove Provider(s) button	Remove providers.	There are no notes.
Set as Primary Provider button	The primary, or default, provider for tasks.	There are no notes.
Replace Provider button	Replace the selected provider with another provider.	There are no notes.
Freeze Billing Rates/Unfreeze Billing Rates button	Freeze or unfreeze the rates for the plan.	The application copies the current rates for the current providers and stores them with this plan.
Provider Name column	Provider name.	There are no notes.
Provider Type column	Provider type.	There are no notes.

Table 5–35 (Cont.) Provider Tab Fields

Field	Description	Notes
Rate Year in Effect column	Rate Year used to look up billing rates for the resources for this service provider for this plan.	There are no notes.
Back-Office Billing Rate Location column	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 5–36 Choose Service Providers Dialog Box Fields

Column	Description	Notes
Name	Name of the service provider.	There are no notes.
Type	Provider type.	There are no notes.
Last Updated	Date and time when service provider was last updated.	There are no notes.
Updated By	User who last updated the service provider.	There are no notes.

Specify Provider-Specific Details Dialog Box

Table 5–37 Specify Provider-Specific Details Dialog Box Fields

Field	Description	Notes
Rate Year in effect	Rate year, associated with the billing rate, selected from the drop-down list.	There are no notes.
Discount rate to apply to this study	Discount rate negotiated for the study, as a percentage.	There are no notes.
Inflation rate to apply to year 2 of study	Percentage to be added to billing rates in year 2 to offset inflation.	There are no notes.
Inflation rate to apply to subsequent years of study	Percentage to be added to billing rates after year 2 to offset inflation.	There are no notes.
Compound inflation annually	Whether or not to calculate inflation by compounding it annually.	There are no notes.
Back-Office Billing Rate Location	Location used to determine the default billing rates for centralized tasks or tasks conducted at a central location.	There are no notes.

Table 5–37 (Cont.) Specify Provider-Specific Details Dialog Box Fields

Field	Description	Notes
Line Item Discount	Negotiated line-item discount established with this particular provider.	Must be a positive value between 0 and 999,999 USD (or equivalent value if non-USD). Default is 0. If there is more than one provider for a plan, each could offer a different discount.
Currency	Currency in which line-item discount is calculated.	If provider is replaced, currency selection remains in effect.
Billing Rate Currency	Currency type for billing rate.	There are no notes.
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.	There are no notes.
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.
Project Manager utilization prior to FSI/FPI	Percentage of project manager resources required before the first patient has enrolled.	There are no notes.
Project Manager utilization after FSI/FPI	Percentage of project manager resources required after the first patient has enrolled.	There are no notes.
Resource Allocation Factor	Percentage of each full workday that the service provider’s team works on the project.	There are no notes.
Number of sponsor affiliates	The number of affiliates that the provider is to work with.	There are no notes.
Type of reporting to affiliates	The types of reporting to sponsor affiliates by the provider.	There are no notes.
Additional type of vendor with which this service provider will work	Relationship this service provider has with another provider.	There are no notes.
Will this provider manage the CTMS	Whether or not this service provider will enter data into the sponsor’s Clinical Trial Management System.	There are no notes.

Choose Replacement Provider Dialog Box

Table 5–38 Choose Replacement Provider Dialog Box Fields

Column	Description	Notes
Name	Name of the service provider.	There are no notes.
Type	Provider type.	There are no notes.
Last Updated	Date and time when service provider was last updated.	There are no notes.

Table 5–38 (Cont.) Choose Replacement Provider Dialog Box Fields

Column	Description	Notes
Updated By	User who last updated the service provider.	There are no notes.

Meetings Tab

Table 5–39 Meetings Tab Fields

Field	Description	Notes
Edit button	Edit a meeting.	There are no notes.
Copy button	Copy a meeting.	There are no notes.
Include button	Include a meeting.	There are no notes.
Exclude button	Exclude a meeting.	There are no notes.
Delete button	Delete a meeting.	There are no notes.
Name column	Meeting name.	There are no notes.
Type column	Meeting type.	There are no notes.
Location column	Meeting location.	There are no notes.
Occurs column	Meeting frequency.	There are no notes.
Planner column	Meeting organizer.	There are no notes.

Define New Meeting Dialog Box

Table 5–40 Define New Meeting Dialog Box Fields

Field	Description	Notes
Name	Meeting name.	There are no notes.
Type	Meeting type.	There are no notes.

Meeting Details Dialog Box: Meeting Details Tab, Attendees Tab, Site Attendees Tab

Table 5–41 Meeting Details Dialog Box (Meeting Details Tab) Fields

Field	Description	Notes
Name	Meeting name.	There are no notes.
Type	Meeting type.	There are no notes.
Code	Meeting code.	The application uses the code as a prefix for the task associated with the meeting type.
Organizer/Planner	Meeting planner.	There are no notes.
Location	Meeting location.	There are no notes.
City	Name of the city where the meeting takes place.	There are no notes.
Non-travel event costs	Non-travel meeting costs.	There are no notes.
Occurs	Meeting frequency.	There are no notes.

Table 5–41 (Cont.) Meeting Details Dialog Box (Meeting Details Tab) Fields

Field	Description	Notes
Starts	Meeting start date.	There are no notes.
Until	Meeting end date.	There are no notes.
# Meetings	Displays the number of meetings.	There are no notes.
Meeting Duration	Enter the number of hours each meeting lasts.	There are no notes.
Provider	Service providers attending the meeting.	There are no notes.
Location	Personnel from sites in the chosen location attending the meeting.	There are no notes.
% Sites Attending	Percentage of sites in this location sending participants to the meeting.	There are no notes.
# Sites Attending	Number of sites attending the meeting from this location.	There are no notes.

Table 5–42 Meeting Details Dialog Box (Attendees Tab) Fields

Field	Description	Notes
Service Provider	Service provider for which you are editing or viewing meeting attendees.	There are no notes.
Add button	Add additional meeting attendees.	There are no notes.
Delete button	Delete meeting attendees.	You can only delete user-defined attendees.
Duplicate button	Copy a meeting attendee.	There are no notes.
Expand All Billable Hours link	View details about billable hours for each meeting attendee.	There are no notes.
Attendees column	Number of meeting attendees for the associated resource type.	There are no notes.
Resource Type	The resource type attending the meeting.	There are no notes.
Billing Rate Location column	The billing rate location for the meeting attendee.	There are no notes.
Attendance Method column	Attendee travel method.	There are no notes.
Billable Hours column	Number of billable hours for the meeting attendee.	There are no notes.
Preparation column	Number of hours of preparation expected by this resource.	Appears if the Expand All Billable Hours or Edit links are selected. Must contain a value between 0 and 999.99.
Travel column	Number of hours of travel expected by this resource.	Appears if the Expand All Billable Hours or Edit links are selected. Must contain a value between 0 and 999.99.

Table 5–42 (Cont.) Meeting Details Dialog Box (Attendees Tab) Fields

Field	Description	Notes
Attendance column	Number of hours that this resource is expected to attend the meeting.	Appears if the Expand All Billable Hours or Edit links are selected. Must contain a value between 0 and 999.99.
Follow Up column	Number of follow up hours expected by this resource.	Appears if the Expand All Billable Hours or Edit links are selected. Must contain a value between 0 and 999.99.
Indirect Costs column	Indirect costs for the meeting attendee.	There are no notes.
Travel column	Total travel indirect costs for each meeting attendee.	There are no notes.
Other column	Other indirect costs for each meeting attendee.	There are no notes.

Table 5–43 Add Provider Attendees Dialog Box Fields

Field	Description	Notes
Resource Name	Resource you can add to the task.	There are no notes.
Code	Code for a resource you can add to the meeting.	There are no notes.

Table 5–44 Site Attendees Tab Fields

Field	Description	Notes
Attendees/Site	Number of attendees attending from each site for the selected location.	There are no notes.
% Sites	Percentage of sites attending that send this number of attendees by this attendance method.	There are no notes.
# Sites	Number of sites attending that send this number of attendees by this attendance method.	There are no notes.
Source Location	Location from which each meeting attendee is coming.	There are no notes.
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.	There are no notes.
Other Cost	Miscellaneous other costs expected by the site attendees for this location.	There are no notes.
Total Costs	Total indirect costs for each meeting attendee.	There are no notes.

Table 5–45 Meeting Details Dialog Box (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 5–46 Assignment Tab Fields

Field	Description	Notes
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. 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.	There are no notes.
Show Tasks link	List of assignment groups and tasks.	There are no notes.
Hide Tasks link	List of assignment groups and tasks.	There are no notes.
Override Resources or Rates	Override Resources or rates.	There are no notes.
Assignment Group/Task column	Available assignment groups and tasks.	There are no notes.
Assign to column	Service provider to which the task is assigned.	There are no notes.
Billing Rate Location column	Billing rate location.	The application uses this location to calculate resource costs for the task.
Pinned column	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. Pinned settings are lost if the associated locations or service providers are removed from the plan. If you replace a service provider, your pinned settings are saved.

Resource Overrides Dialog Box

Table 5–47 Resource Overrides Dialog Box Fields

Field	Description	Notes
Values apply to	Locations affected by the overrides.	There are no notes.

Table 5–47 (Cont.) Resource Overrides Dialog Box Fields

Field	Description	Notes
Default service provider for outsourced tasks	Service provider whose resources or rates are to be overridden.	There are no notes.
Resource Name	Resource name.	There are no notes.
Billing Rate Location	Billing Rate Location.	There are no notes.
Rate	Billing rate.	This field must contain a value between 0.00 and 9,999 USD or the equivalent in another currency.
% Adjust	Percentage adjustment applied to the billing rate.	This field must contain a value between 0 and 999.99.
Pinned	Save overridden values.	There are no notes.
Clear Overrides link	Restore the default resources and rates for the associated service provider.	There are no notes.

Labor Tab

For details about the ClearTrial-defined major tasks, see the Help topic for the Labor tab.

Table 5–48 Labor Tab Fields

Field	Description	Notes
Show hours and fees for	Service provider for which hours and fees appear.	There are no notes.
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. **Deselect**—Only major tasks assigned to the selected service provider appear.	There are no notes.
New Major Task button	Create a major task. Opens the Task Manager dialog box.	There are no notes.
Edit Major Task button	Edit the selected major task. Opens the Task Manager dialog box.	There are no notes.
Delete Major Task button	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 button	Adjust the labor unit hours and fees for the selected major task and service provider on the Task Manager dialog box.	There are no notes.
Pin Labor button	Pin all labor units, costs, hours and distributions.	There are no notes.
Unpin Labor button	Unpin all labor units, costs, hours and distributions.	There are no notes.

Table 5–48 (Cont.) Labor Tab Fields

Field	Description	Notes
Major Task column	Major task type.	For a description of each major task, see the online Help for the Labor tab.
Unit Hours column	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.
Unit Cost column	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 column	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 column	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. Displayed values are rounded to the nearest 10th. Hover over the value to see the actual value.
Ext Cost column	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 column	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 column	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 5–49 Task Manager Dialog Box (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.	There are no notes.
Labor	Whether associated tasks vary by location or centralized. If you select **varies by location**, the associated tasks are completed at the study sites.	There are no notes.
Unit of Measure	Unit of work this major task represents.	Custom units of work appear in italicized type followed by an asterisk.
New Task button	Create a new task for the selected major task.	There are no notes.
Edit Task button	Edit the selected task.	There are no notes.

Table 5–49 (Cont.) Task Manager Dialog Box (Major Task Details Tab) Fields

Field	Description	Notes
Delete Task button	Delete the selected task.	There are no notes.
Edit Assignments button	Edit service provider assignments for the selected task.	There are no notes.

Table 5–50 Task Manager Dialog Box (Adjustments Tab) Fields

Field	Description	Notes
Show hours and fees for	Service provider, whose unit hours or fees are to be adjusted.	There are no notes.
Expand All	View all hours and fees in each location for the selected service provider.	There are no notes.
Collapse All	Close the expanded view of hours and fees and display only planned and adjusted extended hours and extended cost.	There are no notes.
Clear Overrides	Restore all fields to the application default values.	There are no notes.
Location column	Location (countries/regions or centralized) where the service provider is conducting work on the major task.	There are no notes.
Planned column	Planned number of units, unit hours, and unit cost for the major task.	There are no notes.
Adjusted column	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 column	Saves the number of units, unit hours, and unit costs preventing changes from cascading through the plan.	There are no notes.
Extended Hours column	Total plan hours for each location.	The application calculates this number based on plan assumptions.
Extended Cost column	Total cost for each location.	The application calculates this number based on plan assumptions.

Table 5–51 Task Manager Dialog Box (Distribution Tab) Fields

Field	Description	Notes
Distribute completed units of work according to	How to distribute completed units of work across time.	There are no notes.
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 5–51 (Cont.) Task Manager Dialog Box (Distribution Tab) Fields

Field	Description	Notes
Start	Number of days before or after a selected milestone to start the distribution.	There are no notes.
End	Number of days before or after a selected milestone to end the distribution.	There are no notes.
Service Provider	Service provider to which these assumptions apply.	There are no notes.
Location	Location to which to apply these distribution assumptions.	There are no notes.
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.
Period column	Period during which the number or percentage of units are expected to be completed.	There are no notes.
Percentage column	Percentage of units expected to be completed during the associated period.	There are no notes.
Total column	Total percentage of work completed during the work periods.	There are no notes.

Task Manager: New Task Dialog Box (Task Details Tab, Task Assignments Tab)

Table 5–52 Task Manager: New Task Dialog Box (Task Details Tab) Fields

Field	Description	Notes
Name	Name for the task.	There are no notes.
Code	Code for the task that the application will use as a prefix to the selected task name.	There are no notes.
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.
Summary Category	Summary category to which the task belongs.	Determines how the hours and fees are summarized on the Summary tab and Summary report.
Add Resource button	Add a resource to this task.	There are no notes.

Table 5–52 (Cont.) Task Manager: New Task Dialog Box (Task Details Tab) Fields

Field	Description	Notes
Edit Resource button	Change details about the resource effort or rates for this task. resource	There are no notes.
Delete Resource button	Remove a resource from this task.	There are no notes.
Resource Name column	Resource typically assigned to this task.	There are no notes.
Substitutions column	Resource overrides for a resource.	There are no notes.

Table 5–53 Task Manager: New Task Dialog Box (Task Assignments Tab) Fields

Field	Description	Notes
Location column	Location in which task is performed.	For centralized tasks, All Locations appears.
Included column	If selected, the task is included in the study, for the location.	Deselect to exclude a task for a specific location.
Service Provider column	Service provider who performs the task for this location.	There are no notes.
Billing Rate Location column	Billing rate location for each location. If you select Local, the application uses the location from where the subject data are collected for the billing rate calculations. If you select a country, the application uses the billing rate data for that country. 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 column	Saves your task settings so that changes made at general levels do not affect the task.	There are no notes.
Add Resource button	Add a resource to this task.	There are no notes.
Edit Resource button	Change details about the resource effort or rates for this task. resource	There are no notes.
Delete Resource button	Remove a resource from this task.	There are no notes.
Resource Name column	Resource typically assigned to this task.	There are no notes.
Substitutions column	Resource overrides for a resource.	There are no notes.

Task Manager: Select Resources Dialog Box

Table 5–54 Task Manager: Select Resources Dialog Box Fields

Field	Description	Notes
Resource Name	Resource you can add to the task.	There are no notes.
Code	Code for a resource you can add to the task.	There are no notes.

Task Manager: Edit Resource Dialog Box (Resource Details Tab, Algorithm Tab, Billing Rate Location Tab, Rates & Substitutions Tab, Unit Hours Tab)

Table 5–55 Task Manager: Edit Resource Dialog Box (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.	There are no notes.
Location column	Location in which the resource performs the work.	There are no notes.
Service Provider column	Service provider to which the resource belongs.	There are no notes.
Department column	Department to which this resource belongs when performing the task.	There are no notes.
GL Code column	General Ledger code for fees associated with this resource when performing the task.	There are no notes.

Table 5–56 Task Manager: Edit Resource Dialog Box (Algorithm Tab) Fields

Column	Description	Notes
Location	Location to which the algorithm applies.	There are no notes.
Calculate as hours	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 10,000.000.
per (percentage)	Percentage amount to increase or decrease the number of units for the selected unit-based assumption.	There are no notes.
of (cost driver)	Work unit to use for this Level of Effort (LOE) algorithm.	Custom units of work appear in italicized type followed by an asterisk.
Unit Hours	Number of unit hours the selected resource must spend performing this task to complete one unit-of-measure for this location.	There are no notes.

Table 5–56 (Cont.) Task Manager: Edit Resource Dialog Box (Algorithm Tab) Fields

Column	Description	Notes
(hours) Ext. Hours	Total hours for the selected resource to complete the task for this location.	There are no notes.

Table 5–57 Task Manager: Edit Resource Dialog Box (Billing Rate Location Tab) Fields

Column	Description	Notes
Location	Name of the location where sites and subjects are located.	There are no notes.
Service Provider	Service provider assigned to handle this task for sites and subjects in the listed location.	There are no notes.
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 5–58 Task Manager: Edit Resource Dialog Box (Rates & Substitutions Tab) Fields

Column	Description	Notes
Location	Location where sites and subjects are located.	There are no notes.
Service Provider	Name of the service provider assigned to this task for the listed location.	There are no notes.
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.	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 5–59 Task Manager: Edit Resource Dialog Box (Unit Hours Tab) Fields

Column	Description	Notes
Location	Location where sites and subjects are located.	There are no notes.
Service Provider	Service provider assigned to this task for the listed location.	There are no 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.

Table 5–59 (Cont.) Task Manager: Edit Resource Dialog Box (Unit Hours Tab) Fields

Column	Description	Notes
% 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.	There are no notes.
Ext. Hours	Extended hours for this location.	The application calculates this number by multiplying the unit hours by the number of units expected.

Task Manager: Major Task Descriptions

Table 5–60 Task Manager: Major Task Descriptions

Field	Description	Notes
Project Initiated	Activities associated with getting the study started for all sites at all locations	There are no notes.
Study Setup	Centralized start up activities such as negotiation of the all the central labs, design of study documents, development of Investigator Brochure, ICF, diary and protocol translations, and design of the randomization system.	There are no notes.
Study Setup Per-Location	Start up activities that are specific to individual locations, such as printing and distribution of the IB; distribution and collection of training materials and investigator meeting materials; development of country-specific ICF; clinical trial application approvals and negotiation of central IRB/IEC.	There are no notes.
A Written Protocol	For a protocol provided by the sponsor or CRO, create, edit, and review the protocol draft.	There are no notes.
Protocol Amendment	Amendments to the protocol.	There are no notes.
Protocol Amendment per Location	Amendment to the protocol by location.	There are no notes.
Unique CRF Page Developed	The development of a single unique CRF page or the electronic equivalent, including creation of the edit specifications.	There are no notes.
CRF Book Printed	Activities associated with the printing of the CRF; does not apply to electronic data capture.	There are no notes.
Meetings - Kickoff Meeting	Activities for kickoff meetings.	There are no notes.

Table 5–60 (Cont.) Task Manager: Major Task Descriptions

Field	Description	Notes
Meetings - Investigator Meeting	Activities for investigator meetings.	There are no notes.
Meetings - Face to Face Meeting	Activities for face to face meetings.	There are no notes.
Meetings - Status Update to Sponsor (Teleconference Meetings)	Activities for teleconference meetings.	There are no notes.
Meetings - Internal Team Meeting	Activities for internal team meetings.	There are no notes.
Meetings - Other	Other tasks related to meetings.	There are no notes.
Meetings - End of Study	Activities for end of study meetings.	There are no notes.
Site Identified by Sponsor	Sites that have been identified and screened by the sponsor and not by the vendor.	There are no notes.
Site Identified by Vendor	Sites that have been identified and screened by the CRF provider and not by the sponsor.	There are no notes.
Pre-study Site Visit (PSSV)	The activities that are associated with a pre-qualification visit to an investigator site; includes preparation, follow-up, and travel time.	There are no notes.
Pre-study Site Visit (PSSV) by phone	Pre-study site qualification activities conducted by telephone versus in person.	There are no notes.
Site Approved	Activities for the identification and approval of an investigative site. Includes regulatory document preparation, collection and approval, site contract negotiation, and drug shipment to site. It does not include the Pre-study or Site Initiation Visits.	There are no notes.
Site Initiation Visit	The activities for the initiation of a study investigator site and staff; includes preparation, follow-up and travel time.	There are no notes.
Site Initiation Visit by Phone	Site initiation by phone.	There are no notes.
Drug Packaging and Supply Audit	Audit activities of the drug packaging and supply facility.	There are no notes.
Study Drug Shipment Tracked	Tracking of the drug shipment to all study sites.	There are no notes.
Completed Statistics & Analysis Plan (SAP)	Development of the Statistical Analysis plan for the final report and performance of the analysis.	There are no notes.
Database Designed	Activities for the design and programming of the clinical data base.	There are no notes.

Table 5–60 (Cont.) Task Manager: Major Task Descriptions

Field	Description	Notes
Data Entry Screen Developed	The development of a data entry screen for the internal or external data entry for the CRF pages or EDC equivalent.	There are no notes.
IVRS Setup	The set up and management of an interactive voice response system.	There are no notes.
Subject/Volunteer Randomized	Tracking the randomization of subjects in any given study.	There are no notes.
Project Management Week prior to FSI	The project management activities that are associated with the clinical trial from study start through First Subject Enrolled.	There are no notes.
Project Management Week after FSI	The project management activities that are associated with the clinical trial from First Subject Enrolled through the Final Report.	There are no notes.
SAE Database Programmed	SAE Database Programmed (an independent activity from Safety and Medical Management).	No longer available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
SAE Processed	All of the tasks for the reporting of Serious Adverse Events, including writing the relevant narratives.	In cost models prior to 5.5, still named SAE Report Completed. Renamed in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Expedited Safety Report Completed	Preparation of SAEs that are reportable events to health authorities. These are events that are being reported for the first time.	In cost models prior to 5.5, still named Expedited SAE Report Completed. Renamed in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Medical Data Listing Review	Review data from the clinical database, safety database, or other source to identify the presence or lack of safety issues with respect to the protocol.	Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Subject Monitored	Subject-specific monitoring.	Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Cohort Escalation Review	Medical safety review to determine appropriate changes in dosage.	Must be a number between 0 and 999. Available in cost models 5.5 and above for all trials except Phase I (Healthy Volunteers) trials.
Monitored Clean CRF Page	The on-site Source Document Verification (SDV) and retrieval of paper CRF pages, or the review of electronic equivalents, and related on-site activities.	There are no notes.
Onsite Monitoring Visit - Prep, Travel, Reporting, and Follow-up	The non-source document verification tasks associated with monitoring visits, including preparation, travel, and follow-up.	There are no notes.

Table 5–60 (Cont.) Task Manager: Major Task Descriptions

Field	Description	Notes
One Hour of Phone-based Monitoring	One hour of phone-based monitoring, in lieu of on-site monitoring. Formal trip reports will be completed.	There are no notes.
Separate Drug Accountability Visit	A separate visit to an investigator site to account for drug to keep the CRO vendor monitor blinded to the study drug.	There are no notes.
Newsletter Prepared	The preparation and distribution of newsletters to clinical investigators.	There are no notes.
CRF Page Entered into Database	The double keyed data entry of a paper CRF into the data base; tracking and logging of CRF pages, coding and data coordination, which does not apply to electronic data capture.	There are no notes.
Query Resolution - by Monitor	Resolution of Data Clarifications Forms (DCF) by the study monitor. Can be conducted on-site or remotely. Does not include resolution by the data management group.	There are no notes.
Interim Analysis	All activities for the development of an interim analysis of the study data.	There are no notes.
Site Audited	All activities for performing a clinical compliance audit of an investigator site.	There are no notes.
Annual IND Report Activities	Preparation of the annual IND safety update tables and listings for each active year of the study.	There are no notes.
Site Close-out Visit	Activities associated with study close out of an investigator site.	There are no notes.
Site Close-out by Phone	Site close out activities completed by phone versus in person.	There are no notes.
Third-party Data Import	Import of third party data at a defined frequency throughout the life of the study.	There are no notes.
All Data Cleaned and Database Locked	The ongoing data query process and cleaning of the clinical data from first patient enrolled through database lock.	There are no notes.
Data Transfer	The transfer of clinical data to the sponsor one or more times.	There are no notes.
Final Data Audit	An internal audit of the database, conducted by the provider responsible for data management, defaulted to 10% of the data, but can be edited by you.	There are no notes.
Issued Unique PK/PD Summary Table	Activities required to issue a unique summary table.	There are no notes.

Table 5–60 (Cont.) Task Manager: Major Task Descriptions

Field	Description	Notes
Issued Unique PK/PD Summary Listing	Activities required to issue a unique data listing.	There are no notes.
Issued Unique PK/PD Summary Figure/Graph	Activities required to issue a unique data figure or graph.	There are no notes.
Issued Repeat PK/PD Summary Table	Activities required to issue a unique summary table.	There are no notes.
Issued Repeat PK/PD Summary Listing	Activities required to issue a unique data listing.	There are no notes.
Issued Repeat PK/PD Summary Figure/Graph	Activities required to issue a unique data figure or graph.	There are no notes.
Issued Unique Summary Table	Includes activities for specifications, programming, and quality control to issue unique tables.	There are no notes.
Issued Unique Summary Listing	Includes activities for specifications, programming, and quality control to issue unique data listings.	There are no notes.
Issued Unique Summary Figure/Graph	Includes activities for specifications, programming, and quality control to issue unique data figures/graphs.	There are no notes.
Issued Repeat Summary Table	Includes activities for specifications, programming, and quality control to issue repeated tables.	Tasks include: ■ Complete Repeat Summary Table Specification ■ Complete Repeat Summary Table Programming ■ Complete Repeat Summary Table Quality Control
Issued Repeat Summary Listing	Includes activities for specifications, programming, and quality control to issue repeated summary listings.	Tasks include: ■ Complete Repeat Summary Listing Specifications ■ Complete Repeat Summary Listing Programming ■ Complete Repeat Summary Listing Quality Control
Issued Repeat Summary Figure/Graph	Includes activities for specifications, programming, and quality control to issue repeated figures or graphs.	Tasks include: ■ Complete Repeat Summary Figure/Graph Specifications ■ Complete Repeat Summary Figure/Graph Programming ■ Complete Repeat Summary Figure/Graph Quality Control

Table 5–60 (Cont.) Task Manager: Major Task Descriptions

Field	Description	Notes
PK/PD Report	Activities required to issue the PK/PD Report.	There are no notes.
Stat Report	The development of the statistical report section of the Clinical Summary Report.	There are no notes.
Draft Report	All of the activities associated with one draft of the Clinical Summary Report.	There are no notes.
Final Report (CSR)	The activities associated with taking the draft report and finalizing it for publication/submission.	There are no notes.
Prepared Publication	Manuscripts or journal articles other than the Clinical Summary Report that are prepared for publication.	There are no notes.
EDC Help Desk	Set-up of the software and necessary hardware for the study. Assist the investigator site personnel with access to the on-call clinical expert or medical monitor to address questions related to trial matters.	There are no notes.
EDC Training	Responsible for activities related to EDC training management. Includes initial and one round of refresher training.	There are no notes.
Sponsor Oversight	All of the management activities associated with oversight of the outsourced tasks. This does not include time that a sponsor spends on any of the project tasks conducted internally.	There are no notes.

Costs Tab

Table 5–61 Costs Tab Fields

Field	Description	Notes
Show: Excluded Cost(s) filter	Displays costs that have been previously excluded.	Excluded costs are not included in the plan budget.
Show: Categories where costs total 0.00 filter	Displays cost categories where the total cost equals 0.00. Deselect to hide cost categories where the total cost equals 0.00.	There are no notes.
New button	Opens the Define New Category dialog box to create a user-defined cost.	There are no notes.
Edit button	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.

Table 5–61 (Cont.) Costs Tab Fields

Field	Description	Notes
Exclude button	Excluded the selected costs from the plan budget totals.	Excluded costs are not deleted. They appear with a line through them.
Include button	Restores the selected excluded costs.	Set the filter to show excluded costs.
Delete button	Permanently delete the selected user-defined costs.	You cannot delete default application costs. You cannot restore deleted user-defined costs.
Name column	Name referring to a specific cost or cost type.	For a description of each cost, see the online Help for this tab.
Type column	Whether the cost type is a pass-through or another type of indirect cost.	There are no notes.
Calculated column	Application-calculated cost based on the assumptions entered on other tabs.	There are no notes.
Adjustment column	Total amount of adjustments entered on the Adjustments tab of the Edit or Adjust Dialog box.	There are no notes.
Total column	Total calculated cost, including any adjustments.	Must be zero or greater.

Define New/Edit Category Dialog Box (Definition Tab, Assignments, Algorithm/Adjustments Tab, Distribution Tab)

Table 5–62 Define New /Edit Category Dialog Box (Definition Tab) Fields

Field	Description	Notes
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.	There are no notes.
Costs or Cost and Adjustments	Whether the cost or credit varies by location or is calculated at study-level.	There are no notes.
Mapping Key	System-defined code that is included as part of the mapping key in the bid grid export found in the RFP feature.	There are no notes.
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.	There are no notes.

Table 5–62 (Cont.) Define New /Edit Category Dialog Box (Definition Tab) Fields

Field	Description	Notes
Apply inflation over time	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 **Apply inflation over time** checkbox.
Notes	Additional notes or comments about the cost.	Displayed as help content for user-defined costs.
Created By	Name of the user who created the cost.	There are no notes.
Created Date	Date the cost was created.	There are no notes.
Last Modified By	Name of the user who last modified the cost.	There are no notes.
Last Modified	Date the cost was last modified.	There are no notes.

Table 5–63 Define New/Edit Category Dialog Box (Assignments Tab) Fields

Field	Description	Notes
Provider	Service provider associated with a cost.	There are no notes.
Department	Department associated with the cost.	There are no notes.
GL Code	Association of a cost or set of costs with a particular entry in the General Ledger.	There are no notes.

Table 5–64 Define New/Edit Category Dialog Box (Algorithm Tab) Fields

Field	Description	Notes
Calculate as: or Apply adjustment of:	Per unit cost.	Must contain a value between 0 and 99,999,999 USD (or the equivalent in another currency).
Currency	Currency of the per unit cost.	There are no notes.
per (percentage amount)	Specify a percentage amount that will increase/decrease the number derived from the underlying assumption for the driver.	Must contain a value between 0 and 999.99.
of (cost driver)	Unit-based assumptions that drive this cost calculation.	Custom units of work appear in italicized type followed by an asterisk.
Location	Location with which a cost is associated.	Applies only to costs that are defined to vary by location.
Calculated (cost)	System-calculated cost value.	There are no notes.

Table 5–64 (Cont.) Define New/Edit Category Dialog Box (Algorithm Tab) Fields

Field	Description	Notes
Costs	Cost or credit value calculated for each location- or study-level expression as the monetary value multiplied by the specified percentage of the number of units expected for the chosen assumption.	There are no notes.
Total	Total calculated costs or credits for all expressions in the algorithm, including any adjustments made by you or another user.	Must be zero or greater.

Table 5–65 Define New/Edit Category Dialog Box (Distribution Tab) Fields

Field	Description	Notes
Distribute according to	How a cost will be distributed for each location in your plan. 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.	There are no notes.
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.	There are no notes.
Percentage	Percentage of the total cost paid during the associated period.	There are no notes.
Total	Displays the total of the cost distribution.	There are no notes.

Cost Category Descriptions

Table 5–66 Cost Category Descriptions Fields

Field	Description	Notes
Advertising (additional)	Advertising costs for finding subjects, not included in the investigator grants.	The application does not calculate this cost.
Call Center	Costs associated with a subject enrollment call center.	The application does not calculate this cost.
Clinical Trial Insurance	Costs based on the location of the sites and the number of sites for a particular clinical trial. The total clinical trial insurance is the sum of these costs for all sites you select on the Locations tab and are entered as Pass Through Costs.	There are no notes.
Consultants	Fees associated with outside consultants that are not part of CRO Vendor fees.	The application does not calculate this cost.
CRF Printing	Costs for printing the CRF books, based on the number of pages per CRF book, the number of subjects in the study, the ply of the NCR paper, and the cost per page that you indicate on the Data tab. The costs for CRF distribution are the costs to package and ship the CRF books to each site.	The application assumes you print an average of fifteen percent of CRF Books. The application calculates this cost, however, you can enter adjustments to raise or lower this value.
Drug Distribution - Special Handling	These costs apply to special costs associated with shipping the study drug/test article. Examples include the use of dry ice, custom fees, and central pharmacy shipping fees.	The application does not calculate this cost.
Drug Distribution - Standard Shipping	The application bases these costs on the location of the sites and which company is handling the distribution of the study drug or device being studied. These are estimated costs for storing and distribution of the study drug (test article) to the sites based on the frequency of shipments of the material being shipped.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Drug Packaging	Costs associated with the actual packaging and storage of the test article prior to routing to the distribution center. The application bases these costs on the location of the sites and which company is handling the packaging of the study drug. The method of packaging is a significant driver of these costs.	If your study drug or device requires special packaging and labeling, Oracle recommends that you override the estimate the application calculates. The application calculates these costs, however, you can enter adjustments to raise or lower this value.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
DSMB Reporting	Costs associated with compiling and reporting information to the Data Safety Monitoring Board (DSMB).	The application calculates these costs based on several factors, including how often you report data to the Data Safety Monitoring Board. This assumption is on the Monitoring Tab. The application calculates these costs, however, you can enter adjustments to raise or lower this value.
EDC - 3rd Party Costs	Costs associated with Electronic Data Capture (EDC) that is managed by a third party.	There are no notes.
EDC Hosting	Costs associated with Electronic Data Capture (EDC) Hosting. This is a centralized cost and calculates based on the EDC maturity level you select. The start date is 28 days prior to the First Subject In (FSI) and the End Date is the date of the Database Lock.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
EDC Licensing	Costs associated with Electronic Data Capture (EDC) Licensing. This is a centralized cost and calculated based on the EDC maturity level selected. The Start Date is the Project Activity Start Date and the End Date is the Final Report Date.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
EDC Setup	Costs associated with setting-up Electronic Data Capture (EDC) with a Third Party. This is a centralized cost and is calculated based on the EDC maturity level selected. The start date is 30 days prior to the global First Subject In (FSI) date and the End Date is the FSI date.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Electronic Data Capture (EDC)	Costs associated with Electronic Data Capture (EDC), including hardware costs, configurations costs, training costs, telecommunication fees, and monthly maintenance fees.	This cost category only applies to plans that were created prior to ClearTrial release 4.2.0. As of release 4.2.0, this item is replaced by tasks and costs covering setup, hosting, and licensing.
Event Committee Costs	Costs associated with Event Committee costs, not including Initial and Annual IRB fees estimates.	The application does not calculate this cost.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
FDA Audits	Costs associated with FDA audits. Actual FDA audits are not typically covered in bids from CROs, as these audits are typically conducted by the sponsor. When the FDA requires an audit, the CRO or sponsor handles this as a change order. If you know or expect a certain number of audits to occur, enter an estimated value here.	The application does not calculate this cost.
Investigator Grants - Grant Payments	All fees paid per subject to the investigator sites for enrollment into the study and in accordance with the study protocol. The application calculates this value based on the grant amount you enter on the Locations tab, by country, specifically for the numbers of subjects in each country. The grant amount calculation includes the number of subjects to randomize and the subject drop rate. The grant calculation for dropped subjects assumes each dropped subject only completes 75% of a completed CRF book. The grant calculation for a completed subject assumes 100% of the CRF is complete.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Investigator Grants - Overhead	All fees paid to sites requiring overhead and the percentage of overhead allowed per site specified on the Site tab.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Investigator Grants - Screen Failures	Screen failure payments made to the investigator sites. The application calculates this value based on various user input including the screen failure rate and the payment per screen failure.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
Investigator Meetings	Costs associated with the Investigator meetings as specified on the Meetings tab. The application calculates this cost category based on the number of attendees from each site plus the expected vendor staff and sponsor staff as specified on the Meetings tab for each Investigator Meeting. This calculated value does not include any meeting planning fees, but does include the travel costs for the meeting planner, in addition to all other meeting attendees. If you plan to use a third-party meeting planner, the fees associated with the third party vendor should be added as a separate pass through cost. The pass through costs for investigator meetings include travel costs to and from the meeting venue(s) for the Vendor, Sponsor and Investigator and his or her representatives (study coordinator, sub investigator, etc). They also cover costs for the meals, meeting rooms, and other miscellaneous travel expenses for all parties. These costs are apportioned by vendor and the bulk of these expenses are apportioned to the planner of the investigator meeting as specified for each Investigator Meeting on the Meetings tab.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
IRB and Annual Renewal Fees	Initial and annual renewal fees for IRB or Ethics Committee Submissions. These are not part of the investigator grant and are paid by the sponsor for each site. These fees are calculated based on the number of Local and Central IRBs that are required for the study, specified on the Site tab, and the number of sites participating in the study.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
IVRS - Central Randomization	Includes IVRS Fees. If IVRS is not assigned to one of the plan providers, you should enter the costs associated with the IVRS or Central Randomization vendor here. This cost should include the setup, maintenance and close out of the IVRS system.	If IVRS is assigned to a CRO, the application calculates these costs, however, you can enter adjustments to raise or lower this value. If IVRS is assigned to the sponsor or a third-party vendor, the application does not calculate these costs.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
IVRS - Hardware Only	Any costs directly associated with an Interactive Voice Response System (IVRS). This value should not include other costs associated with an IVRS.	The application does not calculate this cost.
Labs - Central Lab	All fees paid to the Central Lab for analysis of safety labs. The application calculates these costs based on the number of subject visits, factors specific to the locations in which the sites and subjects are being treated, and the number of subjects being treated. These fees are an estimate for central laboratory analyses for standard safety labs (CBC, chemistry panel and urinalysis) and assumes that safety labs are done on all subjects at least 66.667% of all visits. These fees do not include costs that some Central Labs may charge for shipment of samples. You should add lab shipment fees either by adjusting this cost line item or entering costs under the Pass-Through Line Item labeled Drug Distribution - Special Handling.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Labs - Core Labs (e.g., Holter monitoring)	These costs are typically different than the central lab costs. They may include PK analysis, Central EKG Lab, Holter monitoring, specialized lab analysis, etc.	The application does not calculate this cost.
Labs - Efficacy Labs (not included in Central lab)	The application calculates and estimates the Central Safety lab costs, however, there may be additional costs that need to be included in the costs of the study. For example, costs related to efficacy.	The application does not calculate this cost.
Labs - Other Lab Costs	Lab fees not covered in core lab fees.	The application does not calculate this cost.
Meeting - Face to Face Meeting (CT Internal Training Sponsor)	All costs associated with face to face meetings for the internal training sponsor.	There are no notes.
Meeting - Face to Face Meeting (Major CRO)	All costs associated with face to face meetings for the major CRO.	There are no notes.
Meeting - Investigator Meeting (CT Internal Training Sponsor)	All costs associated with investigator meetings for the internal training sponsor.	There are no notes.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
Meeting - Investigator Meeting (Major CRO)	All costs associated with investigator meetings for the major CRO.	There are no notes.
Meeting - Kickoff Meeting (CT Internal Training Sponsor)	All costs associated with kick-off meetings for the internal training sponsor.	There are no notes.
Meeting - Kickoff Meeting (Major CRO)	All costs associated with kick-off meetings for the major CRO.	There are no notes.
Meeting - Primary Provider Internal Team Meeting (CT Internal Training Sponsor)	All costs associated the primary provider internal team meeting for the internal training sponsor.	There are no notes.
Meeting - Primary Provider Internal Team Meeting (Major CRO)	All costs associated the primary provider internal team meeting for the Major CRO.	There are no notes.
Meeting - Status Update to Sponsor (Major CRO)	All costs associated with meetings for status updates to sponsor for the major CRO.	There are no notes.
Meeting - Status Update to Sponsor (CT Internal Training Sponsor)	All costs associated with meetings for status updates to sponsor for the internal training sponsor.	There are no notes.
Meeting - Status Update to Sponsor (Major CRO)	All costs associated with meetings for status updates to sponsor for the major CRO.	There are no notes.
Miscellaneous Costs	Costs associated with miscellaneous minor expenses, such as copying, faxing, and sending letters to sites.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Other Costs	Any other known or expected costs that are not part of a pre-defined or user-added category.	The application does not calculate this cost.
Printing (not including CRF Printing)	Applies to any printing costs other than printing the CRF. This covers the cost of printing Investigator Brochures, newsletters, and other general correspondence.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Protocol Amendment IRB Submissions	Covers costs associated with submissions to Institutional Review Boards or Ethics Committees with respect to changes in the protocol.	There are no notes.
Protocol Distribution	Distribution of the protocol. Costs are driven by the number of sites to which each provider is distributing the protocol.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Recruitment Costs (additional)	Subject recruitment costs not included in the investigator grants	The application does not calculate this cost.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
Regulatory Approval Outside the USA	Any fees to be paid to other regulatory bodies if required. For instance, if there are fees assessed by a local MOH, then you should adjust this cost by that amount.	The application does not calculate this cost.
Shipping (not including study drug/test article shipping)	Applies to costs associated with shipping for CRFs, Investigator Brochures, and other printed media (both to and from the site). These costs are separate from shipping related to the study drug/test article. Note that additional costs are added to this category when a third-party vendor is expected to perform translations. Translated documents must be printed and shipped to all sites.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Shipping - Central Lab Test Kits	Includes costs associated with shipping test kits to the central lab prior to treatment start. Test kits include supplies for use during treatment.	There are no notes.
Stability Studies Fees & Expenses	Stability studies are routinely performed throughout the drug development process. If stability studies are a part of the protocol being modeled, those costs should be captured here.	The application does not calculate this cost.
Subject Stipends - Enrolled	Payments made to enrolled subjects to pay for travel and parking.	There are no notes.
Subject Stipends - Screen Failures	Accounts for costs associated with subjects who fail the screening to cover travel and parking.	There are no notes.
Translation Services - 3rd Party	Applies to translations being done by a third-party Vendor. If you specified any of the document translations as pass-through costs (see the Locations tab), those costs should be entered here.	The application does not calculate this cost.

Table 5–66 (Cont.) Cost Category Descriptions Fields

Field	Description	Notes
Travel - Monitoring Travel Expenses	Applies to costs associated with all travel to and from investigator sites for monitoring, including Pre-Study Site Visits (PSSV), Site Initiation Visits, Interim Monitoring, and Site Close-out Visits. Travel for Site Audits are not included here, but are calculated separately under Travel Fees for Site Audits. Travel costs are determined in part by the monitoring frequency (more trips require more travel costs, however multiple-day monitoring visits require more overnight accommodations), as well as the monitoring strategy (loop visits tend to decrease travel costs, but increase costs associated with overnight accommodations; spoke visits tend to require more travel). You should examine the Monitoring Schedule reports to help plan the optimal frequency and strategy.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Travel - Other Travel Expenses	Other travel costs, such as drug accountability travel. The application calculates these costs separately from other travel costs.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.
Travel - Site Audit Travel Expenses	Travel costs specifically for site audits. The application calculates these separately from other travel costs.	The application calculates these costs, however, you can enter adjustments to raise or lower this value.

Payments Tab

Table 5–67 Payments Tab Fields

Field	Description	Notes
Set Payment Terms button	Open the Payment Terms dialog box to specify the number of days from invoice to payment is expected for each service provider.	
Edit Recurring Payments button	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 button	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.

Table 5–67 (Cont.) Payments Tab Fields

Field	Description	Notes
Edit Milestone button	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 button	Delete a user-defined milestone.	To not make a payment at a system-defined milestone, define the percentage as 0.
Milestone column	The milestone at which payments can be made or received.	There are no notes.
Inv. Date column	Displays the date on which the milestone is expected to occur and trigger an invoice.	There are no notes.
Service Provider (Payment Percentage and Amount) column	The payment percentages and amounts to be received by the service provider.	For example, Major CRO, Medium CRO, Premium CRO.
Total column	Total amount paid to all service providers at this milestone.	Includes line-item discounts for the providers. The discounted values are allocated to the milestones based on the default or overwritten percentages.
Budget Total column	Total payment percentage and amount for all plan milestones.	Includes line-item discounts for the providers.

Payment Terms Dialog Box

Table 5–68 Payment Terms Dialog Box Fields

Column	Description	Notes
Provider	Service provider.	There are no notes.
Payment Term	Number of days between the invoice date and the date of payment.	There are no notes.

Recurring Payments Dialog Box

Table 5–69 Recurring Payments Dialog Box Fields

Column	Description	Notes
Item Name	Major task or pass-through cost that can be set as a milestone triggering a recurring payment.	There are no notes.
Specific Service Provider	For each service provider, the milestone when the recurring payment is to be made.	There are no notes.

Create/Edit Milestone Dialog Box

Table 5–70 Create/Edit Milestone Dialog Box Fields

Field	Description	Notes
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.	There are no notes.
Milestone	The application-defined milestone before or after which this user-defined milestone occurs.	There are no notes.
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.	There are no notes.

Summary Tab

Table 5–71 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.
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).	There are no notes.
Clinical Monitoring Closeout and Site Audit Fees	All fees associated with site monitoring, site management, telephone monitoring, query resolution, site close outs, and clinical compliance audits	SAE Management. activity falls under the Safety and Medical Management summary group for cost models 5.5 and above, but is included here for cost models prior to 5.5.
Safety and Medical Management	All fees associated with medical monitoring, SAE processing and safety oversight.	Available in late phase plans with cost models 5.5 and above.
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.	There are no notes.

Table 5–71 (Cont.) Summary Tab Fields

Field	Description	Notes
Biostatistics	All fees, hours, and FTEs associated with table listings and graphs, randomization procedures, statistical and analysis plans, and interim analysis.	There are no notes.
Project Management/ Study Oversight	All fees, hours, and FTEs associated with project management of the study from beginning to end.	There are no notes.
Medical Writing/ Final Report	All fees, hours, and FTEs associated with delivering the statistical report, draft report, and final report (CSR).	There are no notes.
Other	All fees, hours, and FTEs associated with other tasks not included in any other line item.	There are no notes.
Total Fees	Which line item appears depends on the criteria met.	Possible line items: ▪ Total Fees without inflation and discount ▪ Inflation (Fees) ▪ Line-Item Discounts ▪ Total fees before discount ▪ Total fees before inflation
Total Fees	All fees associated with the study.	There are no notes.
Total Hours	Total hourly effort associated with the study.	There are no notes.
Total FTEs	Total of all FTEs associated with this study, by functional area.	There are no notes.
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.	There are no notes.
Total Pass-Through Costs	All third-party, pass-through, and miscellaneous costs in the study.	There are no notes.
Inflation (Pass-Through Costs)	Costs incurred due to inflation applied to pass-through costs.	There are no notes.
Total Study Costs	Total study costs, including vendor fees, pass-through costs, sponsor internal costs, and any applicable inflation and line-item discount.	There are no notes.
Pre-Study Activity Start Date	Date on which the earliest activity or cost occurs.	There are no 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.	There are no notes.

Table 5–71 (Cont.) Summary Tab Fields

Field	Description	Notes
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).	There are no notes.
Total Study Duration	The total study duration (in elapsed days), defined as the end date minus the start date.	There are no 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).	There are no notes.
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.	There are no notes.

Reports Tab

There are three types of reports in the application: Clinical Indicator, Costs, and FTE/Resources Reports.

Clinical Indicators Reports

Table 5–72 Clinical Indicator Reports Descriptions

Field	Description	Notes
Assumptions	Assumptions based on data entry.	Includes custom assumptions.
Currency Exchange Rates	Currency exchange rates based on data entry.	There are no notes.
Responsibilities	Responsibilities based on data entry.	There are no notes.
Site Approval Schedule - Cumulative	Cumulative site approval curve for the entire study by week.	There are no notes.
Site Approval Schedule By Location	Site approval curve by week for each location in the study.	There are no notes.
On-Site Monitoring Schedule - Total Hours	Total hours for all on-site monitoring visits for the entire study.	There are no notes.
On-Site Monitoring Schedule By Location	Average hours per on-site monitoring visit for each location in the study.	There are no notes.
CRF Pages - Cumulative	Cumulative CRF pages generated per week.	There are no notes.
CRF Pages By Location	CRF pages generated per week for each location in the study.	There are no notes.

Table 5–72 (Cont.) Clinical Indicator Reports Descriptions

Field	Description	Notes
Subject Enrollment - Cumulative	Cumulative subject enrollment per week.	There are no notes.
Subject Enrollment by Location	Subject enrollment per week by location.	There are no notes.
Metrics	Various performance and cost metrics.	The following metrics include line-item discount and inflation, if report parameters are selected for inclusion: ■ Direct fees per Enrolled Subject ■ Cost per subject per site per week ■ Total study cost per on-site monitoring day ■ Total study cost per CRF page
Milestone Dates	Critical dates in the study.	There are no notes.
Milestones Timeline Chart	Graphical view of key milestones.	There are no notes.

Costs Reports

Table 5–73 Costs Reports Descriptions

Field	Description	Notes
Plan Summary	Printable view of the Plans Summary Tab.	Includes line-item discount and inflation.
Fees by Major Task	Fees by major task.	Includes inflation (when selected for inclusion) and line-item discount.
Fixed Unit Prices	Fixed unit prices.	Includes inflation (when selected for inclusion) and line-item discount.
Pass-Through and 3rd Party Costs	Pass-through and 3rd party costs.	There are no notes.
Monthly Budget	Monthly budget.	Includes inflation (when selected for inclusion) and line-item discount.
Monthly Budget By Reporting Region	Monthly budget by reporting region.	Includes inflation (when selected for inclusion) and line-item discount.
Labor Adjustments	Breakdown of unit level adjustments by major task.	Includes inflation (when selected for inclusion) and line-item discount.
Cash Flow	Planned value (PV) versus payments.	Includes inflation and line-item discount.
Milestone Payment Schedule	Schedule of payments at each milestone.	Includes inflation and line-item discount.
Meetings Report	Meeting costs and assumptions.	There are no notes.

Table 5–73 (Cont.) Costs Reports Descriptions

Field	Description	Notes
Summary Grid by Major Task	Plan/Provider-specific report showing selected values by major task.	Includes line-item discount.
Inflation Rates	Inflation rates by location and year.	There are no notes.

FTE/Resources Reports

Table 5–74 FTE/Resources Reports Descriptions

Field	Description	Notes
Resource/FTE Demand Summary	Summary of the plan resources and FTE demands.	Includes inflation (when selected for inclusion) and line-item discount.
Resources By Major Task	Resources by major task.	Includes inflation (when selected for inclusion) and line-item discount.
Resources By Department	Resources by department.	Includes inflation (when selected for inclusion).
Resources By GL Code	Resources by GL code.	Includes inflation (when selected for inclusion).
Resource Demand by Date	Resources by demand date.	Cost view includes inflation (when selected for inclusion) and line-item discount.
Resource Demand Chart	Graphical view of resource demand by date.	There are no notes.
Billing Rates by Resource Name	Billing rates by resource name.	There are no notes.

Studies Screen Fields

The following screens and dialog boxes are associated with studies.

Studies Screen Fields

Table 5–75 Studies Screen Fields

Field	Description	Notes
New button	New study.	There are no notes.
Edit button	Edit a study.	There are no notes.
Delete button	Delete a study.	There are no notes.
Restore button	Restore a deleted study.	There are no notes.
Create Plan button	Create a plan based on a study.	There are no notes.
Study Name column	Studies in the application.	There are no notes.
Product/Compound column	Product or compound the associated study is based on.	There are no notes.
Phase column	Study phase of the associated study.	There are no notes.

Table 5–75 (Cont.) Studies Screen Fields

Field	Description	Notes
Therapeutic Area column	Therapeutic area the associated study is based on.	There are no notes.
Indication column	Indication the associated study is based on.	There are no notes.
Status column	Study status.	There are no notes.

Create/Edit Study Screen Fields

Table 5–76 Create/Edit Study Screen Fields

Field	Description	Notes
Study Name	Study name.	There are no notes.
Protocol	Protocol ID.	The protocol ID number identifies the protocol for this study.
Product/Compound	Product or compound the associated study is based on.	There are no notes.
Phase	Study phase.	There are no notes.
Sponsor	Study sponsor.	There are no notes.
Status	Study status.	There are no notes.
Billing Code	Study billing code.	There are no notes.
Therapeutic Area	Therapeutic area the study is based on.	There are no notes.
Indication	Indication the study is based on.	There are no notes.
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	Study description	There are no notes.

Define Study Filter Dialog Box Fields

Table 5–77 Define Study Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes studies created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted studies	Includes studies that have been previously deleted.	There are no notes.

Table 5–77 (Cont.) Define Study Filter Dialog Box Fields

Field	Description	Notes
Study name starts with	Includes studies whose names begin with the text entered. Filters out all other studies.	There are no notes.
Created by	Includes studies created by the selected users.	To display all studies regardless of who created them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Last Modified by	Includes studies last edited and saved by the selected users.	To display studies regardless of who last updated them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Status	Includes studies with the selected statuses.	To display studies regardless of their status, select **Any Status**.
Phases	Includes studies pertaining to the selected phases.	To display studies regardless of the phase, select **Any Phase**.
Therapeutic Areas	Includes studies pertaining to the selected Therapeutic Areas	To display studies regardless of the Therapeutic Area, select **Any Therapeutic Area**.
Sponsors	Includes studies for the selected sponsors.	To display studies regardless of the sponsor, select **Any Sponsor**.
Save filter as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Studies Screen

Table 5–78 Configure List Options Dialog Box Fields - Studies Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.
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 5–79 Create Product Dialog Box Fields

Field	Description	Notes
Product ID	Unique product identifier, typically and alphanumeric code used to identify the product/compound.	There are no notes.
Name	Name used to refer to the product.	There are no notes.
Description	Description of the product.	There are no notes.

Products Screen Fields

The following screens and dialog boxes are associated with products.

Product Screen Fields

Table 5–80 Product Screen Fields

Field	Description	Notes
New button	Add a product.	There are no notes.
Edit button	Edit a product.	There are no notes.
Delete button	Delete a product.	There are no notes.
Restore button	Restore a deleted product.	There are no notes.
Product Name column	Products in the application.	There are no notes.
Description column	Product description.	There are no notes.
Last Updated column	Date and time the product was lasted modified.	There are no notes.
Updated By column	User who modified the product.	There are no notes.

Create/Edit Product Screen Fields

Table 5–81 Create/Edit Product Screen Fields

Field	Description	Notes
Product ID	Product ID.	There are no notes.
Name	Product name.	There are no notes.
Description	Product description.	There are no notes.

Define Product Filter Dialog Box Fields

Table 5–82 Define Product Table Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes products created or modified within the number of days selected from the drop-down list..	There are no notes.
Include deleted products	Includes products that have been previously deleted.	There are no notes.
Product name starts with	Includes products whose names begin with the text entered. Filters out all other products.	There are no notes.
Created by	Includes products created by the selected users.	To display all products regardless of who created them, select **Any User**. To display more users to choose from, click the **Expand list...** link.

Table 5–82 (Cont.) Define Product Table Filter Dialog Box Fields

Field	Description	Notes
Last Modified by	Includes products last edited and saved by the selected users.	To display products regardless of who last updated them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Save filter as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Products Screen

Table 5–83 Configure List Options Dialog Box Fields - Products Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.
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.

Portfolios Screens, Tabs, and Dialog Boxes

The following screens and dialog boxes are associated with portfolios.

Portfolio Screen

Table 5–84 Portfolio Screen Fields

Field	Description	Notes
Show filter	Show or hide portfolios based on selected criteria: ■ **All Portfolios**—No filter is applied. All portfolios appear.? ■ **Active Portfolios Only**—Portfolios that are not deleted or marked as Study Complete or Archived appear. ■ **Portfolios matching filter**—Only portfolios that match the criteria you selected from the custom filter drop-down list appear.	There are no notes.
Modify link	Define a custom filter on the Define Portfolio Filter dialog box.	There are no notes.
New button	Create a new portfolio on the Create Portfolio screen (Overview tab).	There are no notes.

Table 5–84 (Cont.) Portfolio Screen Fields

Field	Description	Notes
Edit button	Edit the selected portfolio or open it to view details, the summary, or reports.	There are no notes.
Delete button	Delete the selected portfolio.	Deleted portfolios are permanently removed at a later time.
Restore button	Restore a deleted portfolio.	To use this option, adjust the filters so that you can see inactive as well as active items.
Copy button	Make a copy of the selected portfolio.	There are no notes.
Portfolio Name column	Name of the portfolio.	There are no notes.
Description column	Description of the portfolio.	There are no notes.
Number of plans column	Number of plans included in the portfolio.	There are no notes.
Last Modified column	Date a user last modified this portfolio.	There are no notes.

Portfolio Screen Dialog Boxes

Define Portfolio Filter Dialog Box

Table 5–85 Define Portfolio Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes portfolios created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted portfolios	Includes portfolios that have been previously deleted.	You can recover, or restore, portfolios that have been deleted. 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.	There are no notes.
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 as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Portfolio Screen

Table 5–86 Configure List Options Dialog Box Fields - Portfolio Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.
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 5–87 Create/Edit Portfolio Screen (Overview Tab) Fields

Field	Description	Notes
Portfolio Name	Unique name for the portfolio.	There are no notes.
Short Description	Details that appear on the Portfolios screen to help you recognize the portfolio.	There are no notes.
Long Description	Detailed description of the portfolio.	There are no notes.
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.
Created By	Name of the user who created the portfolio.	Edit Portfolio screen only.
Created Date	Date the portfolio was created.	Edit Portfolio screen only.
Last Modified By	Name of the user who last modified the portfolio.	Edit Portfolio screen only.
Last Modified	Date the portfolio was last modified.	Edit Portfolio screen only.

Create/Edit Portfolio Screen (Plans Tab) Fields

Table 5–88 Create/Edit Portfolio Screen (Plans Tab) Fields

Field	Description	Notes
Add Plans button	Add plans to the Portfolio on the Choose Plans dialog box.	You cannot add more than 200 plans.
Remove Plans button	Remove plans from a portfolio.	There are no notes.
Include Plans button	Restores an excluded plan to a portfolio.	There are no notes.
Exclude Plans button	Excludes a plan from the portfolio.	Excluded plans have a line through them on the Plans tab.

Table 5–88 (Cont.) Create/Edit Portfolio Screen (Plans Tab) Fields

Field	Description	Notes
Plan Information column	Plan name and description.	There are no notes.
Start Date column	Plan project activity start date.	There are no notes.
Start Offset column	Effects of beginning a plan, or plans, earlier or later than originally scheduled. 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 column	Likelihood that the plan is going to occur on schedule, expressed as a percentage.	There are no notes.

Create/Edit Portfolio Screen (Summary Tab)

Table 5–89 Create/Edit Portfolio Screen (Summary Tab) Fields

Field	Description	Notes
Start	By default, start date of the earliest plan in the portfolio, including any offset dates.	There are no notes.
End	By default, end date of the final plan in the portfolio.	There are no notes.
Cost Distribution Graph	Graphical view of when costs occur over the time range specified. Costs inclusive of line-item discount and inflation.	The blue shaded area represents the time frame selected in the Summary Portfolio dialog box.
Reset button	Resets Start and End values to portfolio defaults.	There are no notes.
Plan Name column	Displays the plan name.	There are no notes.
Study Name column	Displays the study for the plan.	There are no notes.
Plan Cost column	Displays the total plan cost inclusive of inflation and line-item discount.	There are no notes.
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).	There are no notes.
Clinical Monitoring Closeout and Site Audit Fees	All fees, hours, and FTEs associated with site monitoring, site management, telephone monitoring, query resolution, site closeouts, and clinical compliance audits.	SAE Management activity falls under the Safety and Medical Management summary group for cost models 5.5 and above, but is included here for cost models prior to 5.5.
Safety and Medical Management	All fees associated with medical monitoring, SAE processing, and safety oversight.	Available in late phase plans with cost models 5.5 and above.

Table 5–89 (Cont.) Create/Edit Portfolio Screen (Summary Tab) Fields

Field	Description	Notes
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.	There are no notes.
Biostatistics	All fees, hours, and FTEs associated with table listings and graphs, randomization procedures, statistical and analysis plans, and interim analysis.	There are no notes.
Project Management / Study Oversight	All fees, hours, and FTEs associated with project management of the study from beginning to end.	There are no notes.
Medical Writing / Final Report	All fees, hours, and FTEs associated with delivering the statistical report, draft report, and final report (CSR).	There are no notes.
Other	All fees, hours, and FTEs associated with other tasks not included in any other line item.	There are no notes.
Total Fees	All fees associated with the study.	There are no notes.
Total Hours	Total hourly effort associated with the study.	There are no notes.
Total Pass-Through Costs	All third-party, pass-through, and miscellaneous costs in the study.	There are no notes.
Total Portfolio Costs	Total portfolio costs, including vendor fees, pass-through costs, and sponsor internal costs.	There are no notes.

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 5–90 Create/Edit Portfolio Screen (Reports Tab), Clinical Indicator Reports Descriptions

Field	Description	Notes
Portfolio Milestones Timeline Chart	Displays a graphical view of key milestones in the portfolio.	There are no notes.

Costs Reports Descriptions

Table 5–91 Create/Edit Portfolio Screen (Reports Tab), Costs Reports Descriptions

Field	Description	Notes
Portfolio Summary	Displays a printable view of the Portfolio Summary Tab.	There are no notes.

Table 5–91 (Cont.) Create/Edit Portfolio Screen (Reports Tab), Costs Reports

Field	Description	Notes
Fees by Major Task	Displays fees by major task.	Includes inflation (when selected for inclusion) and line-item discount.
Monthly Budget	Displays monthly budget.	Includes inflation (when selected for inclusion) and line-item discount.

FTE/Resources Reports Descriptions

Table 5–92 Create/Edit Portfolio Screen (Reports Tab), FTE/Resources Reports Descriptions

Field	Description	Notes
Resource Demand Summary	Displays a summary of the portfolio resources demands.	Includes inflation (when selected for inclusion) and line-item discount.
Resource Demand by Date	Displays a summary of the portfolio date demands.	Includes inflation (when selected for inclusion) and line-item discount.
Resource Demand Chart	Displays resources demand chart.	There are no notes.

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 5–93 Portfolio Reports, Clinical Indicator Reports Descriptions

Field	Description	Notes
Portfolio Milestones Timeline Chart	Graphical view of key milestones in the portfolio.	There are no notes.

Portfolio Costs Reports Descriptions

Table 5–94 Portfolio Reports, Costs Reports Descriptions

Field	Description	Notes
Portfolio Summary	Printable view of the Portfolio Summary Tab.	There are no notes.
Fees by Major Task	Fees by major task.	Includes inflation (when selected for inclusion) and line-item discount.
Monthly Budget	Monthly budget.	Includes inflation (when selected for inclusion) and line-item discount.

Portfolio FTE/Resources Reports Descriptions

Table 5–95 Portfolio Reports, FTE/Resources Reports Descriptions

Field	Description	Notes
Resource Demand Summary	Summary of the portfolio resources demands.	There are no notes.
Resource Demand by Date	Summary of the portfolio date demands.	Includes inflation (when selected for inclusion) and line-item discount.
Resource Demand Chart	Resources demand chart.	Includes inflation (when selected for inclusion) and line-item discount.

RFPs and Bids Screens, Tabs, and Dialog Boxes

The following screens and dialog boxes are associated with RFPs and bids.

RFPs Screen

Table 5–96 RFPs Screen Fields

Field	Description	Notes
New button	Create a new request for proposal.	There are no notes.
Edit button	Edit the selected RFP or open it to view details, the summary, or reports.	You can also a open an RFP by double-clicking the plan name.
Delete button	Delete the selected RFP(s).	Deleted RFPs are removed at a later time and can be restored.
Restore button	Restore a deleted RFP.	To use this option, adjust the filters so that you can see inactive as well as active items.
Import Bid button	Upload a bid received from a vendor.	There are no notes.
Compare Bids button	Compare the bids associated with the selected RFPS.	There are no notes.
Download Bid Grid button	Generate and download the Bid Grid for the selected RFP.	There are no notes.
Plan name column	Unique identifier of plans.	There are no notes.
Scope/Provider column	Provider representing the scope of work on which the RFP is based.	There are no notes.
Description column	Short description of the RFP.	There are no notes.
Number of Bids column	The number of bids associated with the RFP.	There are no notes.

RFPs Screen Dialog Boxes

The following dialog boxes are associated with RFPs.

Define RFP Filter Dialog Box

Table 5–97 Define RFP Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes RFPs last edited and saved the specified number of days.	There are no notes.
Include deleted RFPs	Includes RFPs that have been previously deleted.	When you delete an RFP, the application does not permanently delete and purge it until 30 days later.
Created by	Includes only RFPs created by one of the selected users.	To include all RFPs, select **Any User**.
Last Modified by	Includes only RFPs last edited and saved by the selected user.	To include all RFPs, select **Any User**.
Save filter as	Name assigned to the filter.	There are no notes.

Configure List Options Dialog Box - RFPs Screen

Table 5–98 Configure List Options Dialog Box Fields - RFPs Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.
Sort By	Orders the RFPs based on your selections.	Change the order by clicking a column heading.
Show n RFPs per page	Number of RFPs displayed on each page.	Use the paging tool to move to the next or previous page or directly to a page number.

Choose Plan for RFP Dialog Box

Table 5–99 Choose Plan for RFP Dialog Box Fields

Field	Description	Notes
Plan Name column	Unique name given to the plan by its creator.	Read-only.
Study Name column	Name of the study with which the plan is associated.	Read-only.
Phase column	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. The application supports Phase I for oncology and vaccine studies, as well as Phase I studies for healthy volunteers. Phase I Oncology or Phase I Vaccine studies more closely resemble Phase IIa trials.	Read-only.

Table 5–99 (Cont.) Choose Plan for RFP Dialog Box Fields

Field	Description	Notes
Indication column	The reason selected to perform this study. Indications are classified into therapeutic areas. The application uses this selection to calculate monitoring time required, time for query resolution, data entry, and to provide other default values.	Read-only.
Status column	The status of the plan: ■ **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.	Read-only.
Template Name column	Name of a plan or partial plan that can be used as a starting point for new plans for a study.	Read-only.
Description column	Information describing the template to help you recognize a particular scenario or purpose for the plan.	Read-only.

Table 5–99 (Cont.) Choose Plan for RFP Dialog Box Fields

Field	Description	Notes
Applicable For column	Study phase(s) for which the template has been defined.	Read-only.

Create RFP Dialog Box

Table 5–100 Create RFP Dialog Box Fields

Field	Description	Notes
Scope of Work/Assigned to Provider	Name of the service provider assigned to the desired scope of work in the plan associated with this RFP.	There are no notes.
Short Description	Label by which you will recognize this RFP on the RFPs screen.	Must be between 8 and 40 characters. Not included on the bid grid.
Bid Grid Title	Header that will appear on every page of the bid grid.	There are no notes.
Comments	Notes relevant to this RFP.	There are no notes.

Edit RFP Screen (Details Tab)

Table 5–101 Edit RFP Screen (Details Tab fields)

Field	Description	Notes
Short Description	Label by which you will recognize this RFP on the RFPs screen.	Must be between 8 and 40 characters. Not included on the bid grid.
Bid Grid Title	Header that will appear on every page of the bid grid.	There are no notes.
Comments	Notes relevant to this RFP.	There are no notes.
History section	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.
Created By	User who created this RFP.	There are no notes.
Created Date	Date and time the RFP was created.	There are no notes.
Last Modified By	Name of the user who last changed this RFP.	There are no notes.
Last Modified	Date and time this RFP was last changed.	There are no notes.
Download Bid Grid link	Regenerate the bid grid with the most recently saved Bid Grid Title.	There are no notes.

Edit RFP Screen (Labor Tab)

Table 5–102 Edit RFP Screen (Labor Tab Fields)

Field	Description	Notes
Include Inflation Checkbox	Include the impact of inflation in the values displayed	There are no notes.
Major Task column	Major task type.	For a description of each major task, see the online Help for the Labor tab.
Unit Hours column	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 thousandth. Hover over the value to see the actual value.
Unit Cost column	Total cost for the selected service provider to complete one unit of work for the major task.	Displayed values are rounded to the hundredths or according to the conventions of the currency.
# Units column	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 column	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. Displayed values are rounded to the nearest thousandth. Hover over the value to see the actual value.
Ext Cost column	Total cost for the selected service provider to complete the major task.	Displayed values are rounded to the hundredths or according to the conventions of the currency.
Total Ext Hours column	Total level of effort in hours for the selected service provider to complete the major task.	There are no notes.
Total Ext Cost column	Total cost for the selected service provider to complete the major task.	There are no notes.

Edit RFP Screen (Costs Tab)

Table 5–103 Edit RFP Screen (Costs Tab Fields)

Column	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.
Total	Total calculated cost, including any adjustments.	There are no notes.
Inflated Total	Total calculated cost, including applicable inflation.	There are no notes.

Edit RFP Screen (Bids Tab)

Table 5–104 Edit RFP Screen (Bids Tab Fields)

Field	Description	Notes
Compare button	Compare the selected bids.	There are no notes.
Delete button	Delete the selected RFPs.	There are no notes.
Restore button	Restore the selected deleted RFPs.	There are no notes.
Download button	Download the bid grid file received from the vendor.	There are no notes.
Update Status button	Display a dialog box from which to choose a new status for the selected bid(s).	There are no notes.
Version column	The version of the bid, if you imported more than one bid for the same RFP from the same vendor.	There are no notes.
Created Date column	The date the bid was imported.	There are no notes.
Status column	The current status of the bid. Active statuses include: ■ Pending Review ■ Proposal - Under Review ■ Proposal - Pending vendor action ■ Proposal - Selected ■ Contract - Under Review ■ Contract - Pending vendor action ■ Change Order - Under Review ■ Change Order - Pending vendor action ■ Change Order - Accepted Final Inactive statuses include: ■ Proposal - Rejected ■ Proposal - On Hold ■ Proposal - Canceled ■ Contract - Rejected ■ Contract - Complete ■ Change Order - Rejected ■ Change Order - Complete	Upon vendor bid upload, the default status is Pending Review.
Total Fees column	The total fees for each bid inclusive of line-item discounts.	There are no notes.
Total PTC column	The total pass-through costs for each bid.	There are no notes.

Import Bids Screen and Dialog Boxes

Import Bid Dialog Box

Table 5–105 Import Bid Dialog Box Fields

Field	Description	Notes
Vendor Name	Vendor who submitted the bid.	There are no notes.
Bid Grid File to Upload	Name of bid file to upload. Browse for file on your PC.	There are no notes.
Short Description	Label by which you will recognize this bid on the RFPs screen.	Must be between 8 and 40 characters. Not included on the bid grid.
CRO Bid Number	Number by which the vendor can identify this bid.	Optional
Comments / CRO Information	Notes relevant to this RFP.	Up to 4000 characters.

Import Bid Issues Dialog Box

Table 5–106 Import Bid Issues Dialog Box Fields

Field	Description	Notes
Severity column	Status of the issue.: Warning, Serious, Fatal.	Fatal errors will prevent the file from successfully importing. Warnings or Serious issues will not prevent a successful import.
Message column	Type of issue and how it will be handled by the application.	There are no notes.
Sheet column	Sheet within bid grid workbook on which error appears.	There are no notes.
Row column	Number of row on sheet that error appears.	There are no notes.
Download Issues link	Saves the list of issues in a spreadsheet.	There are no notes.
Cancel button	Abort the loading of the bid.	There are no notes.
Continue button	Load the bid with the issues uncorrected.	The bid will fail to load if any of the issues have a severity level of Fatal.

Vendor Bid Comparison Options Dialog Box

Table 5–107 Vendor Bid Comparison Options Dialog Box Fields

Field	Description	Notes
Major Task and Cost Summary	Compare values aggregated by major task and cost.	Includes line-item discount comparison.
Detailed Fees and Costs by Location, Task, Resource	Compare values by resource per task per location.	Includes line-item discount comparison.

Table 5–107 (Cont.) Vendor Bid Comparison Options Dialog Box Fields

Field	Description	Notes
Include RFP i n comparison	Include the RFP values in the comparison.	Selected by default.
Show variances relative to RFP	Compare the selected bids to the RFP values.	Selected by default when the user uses the RFP as the baseline. If selected, turns off Show variances relative to a selected bid.
Show variances relative to a selected bid	Compare bids to the bid selected. The following data is displayed: ■ Service Provider ■ Version ■ Short Description ■ Created Date	Enabled when user selects a bid as baseline. You can select a single bid to compare other bids to. Turns off Show variances relative to RFP.
Variance Analysis Section	Assumptions displayed depend on which comparison is selected.	There are no notes.
Include Variance Analysis	For Major Task and Cost Summary comparison, includes: ■ Highlight total cost variances above (user-defined %). Default is 10%. ■ Highlight total hours variances above (user-defined %). Default is 10%. When turned off, all options below it are disabled and all % fields contain either the default or overridden value as read-only. For Detailed Fees and Costs by Location, Task, Resource comparison, includes: ■ Highlight unit cost variances above (user-defined %). Default is 10%. ■ Highlight unit hours variances above (user-defined %). Default is 10%. ■ Highlight base billing rate variances above (user-defined %). Default will be 10%. ■ Highlight inflated billing rate variances above (user-defined %). Default will be 10%. ■ Highlight total cost variances above (user-defined %). Default is 10%. ■ Highlight total hours variances above (user-defined %). Default is 10%. When turned off, all options below it are disabled and all % fields contain either the default or overridden value as read-only.	There are no notes.

Table 5–107 (Cont.) Vendor Bid Comparison Options Dialog Box Fields

Field	Description	Notes
Highlight total cost variances above	Highlights the unit cost variances outside the specified range.	There are no notes.
Highlight total hours variances above	Highlights the unit hours variances outside the specified range.	There are no notes.
Highlight base billing rate variances above	Highlights the billing rates variances outside the specified range.	There are no notes.
Highlight inflated billing rate variances above	Highlights the inflated billing rates variances outside the specified range.	There are no notes.
Report Format	Formats include HTML, PDF, XLS, and CSV.	There are no notes.

Bids Screens and Dialog Boxes

Bids Screen

Table 5–108 Bids Screen Fields

Field	Description	Notes
Edit button	Edit the selected bid.	You can also a open a bid by double-clicking the plan name.
Delete button	Delete the selected bid(s).	Deleted bids are removed at a later time and can be restored.
Restore button	Restore a deleted bid.	To use this option, adjust the filters so that you can see inactive as well as active items.
Update Status button	Display a dialog box in which to choose a new status for the selected bids.	There are no notes.
Compare button	Compare the selected bids or a single bid with the RFP.	There are no notes.
Download button	Download the original bid grid (Excel file) that was uploaded.	There are no notes.
Plan name column	Unique identifier of plans.	There are no notes.
Scope column	Provider representing the scope of work on which the bid is based.	There are no notes.
Vendor column	The name of the vendor from which each bid was received.	There are no notes.
Version column	The version of the bid, if you imported more than one bid for the same RFP from the same vendor.	There are no notes.
Description column	Label by which you will recognize this bid on the RFPs screen.	There are no notes.

Table 5–108 (Cont.) Bids Screen Fields

Field	Description	Notes
Status column	The current status of the bid. Active statuses include: ▪ Pending Review ▪ Proposal - Under Review ▪ Proposal - Pending vendor action ▪ Proposal - Selected ▪ Contract - Under Review ▪ Contract - Pending vendor action ▪ Change Order - Under Review ▪ Change Order - Pending vendor action ▪ Change Order - Accepted Final Inactive statuses include: ▪ Proposal - Rejected ▪ Proposal - On Hold ▪ Proposal - Canceled ▪ Contract - Rejected ▪ Contract - Complete ▪ Change Order - Rejected ▪ Change Order - Complete	Upon vendor bid upload, the default status is Pending Review.
Created Date column	The date the bid was imported.	There are no notes.

Edit Bid Screen (Details Tab)

Table 5–109 Edit Bid Screen (Details Tab fields)

Field	Description	Notes
Short Description	Label by which you will recognize this bid on the Bids screen.	Must be between 8 and 40 characters. Not included on the bid grid.
CRO Bid Number	A vendor-defined value to identify this bid.	There are no notes.
Status	Status to assign to the bid.	There are no notes.
Comments	Notes relevant to this bid.	There are no notes.
Created By	User who created this bid.	There are no notes.
Created Date	Date and time the bid was created.	There are no notes.
Last Modified By	Name of the user who last changed this bid.	There are no notes.
Last Modified	Date and time this bid was last changed.	There are no notes.

Table 5–109 (Cont.) Edit Bid Screen (Details Tab fields)

Field	Description	Notes
Download Imported Bid link	Download the file that was imported to create this bid.	There are no notes.

Edit Bid Screen (Labor Tab)

Table 5–110 Edit Bid Screen (Labor Tab Fields)

Field	Description	Notes
Include Inflation Checkbox	Include the impact of inflation in the values displayed.	There are no notes.
Major Task column	Group of tasks related to a specific unit of work.	For a description of each major task, see the online Help for the Labor tab on the Edit Plans screen.
Unit Hours column	Level of effort (in hours) the vendor requires to complete one unit of work for the major task.	Displayed values are rounded to the nearest thousandth. Hover over the value to see the actual value.
Unit Cost column	Total fees the vendor requires to complete one unit of work for the major task.	Displayed values are rounded to the nearest hundredths or according to the conventions of the currency.
# Units column	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 column	Total level of effort (in hours) the vendor requires to complete the major task.	The application multiplies the Unit Hours by the # Units. Displayed values are rounded to the nearest thousandth. Hover over the value to see the actual value.
Ext Cost column	Total fees the vendor requires to complete the major task.	Displayed values are rounded to the nearest hundredth or the conventions of the currency.
Total Ext Hours column	Total level of effort in hours the vendor requires to complete the major task.	There are no notes.
Total Ext Cost column	Total fees the vendor requires to complete the major task.	There are no notes.

Edit Bid Screen (Costs Tab)

Table 5–111 Edit Bid Screen (Costs Tab Fields)

Column	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 on the Edit Plans screen.

Table 5–111 (Cont.) Edit Bid Screen (Costs Tab Fields)

Column	Description	Notes
Total	Total calculated cost, the vendor expects to incur.	If line-item discounts have been entered in the bid by the service provider, the Total Fees and Total columns include the applicable line-item discount value. The Bid Labor tab footer will include any line-item discount imported from the bid grid.

Edit Bid Screen (Issues Tab)

Table 5–112 Edit Bid Screen (Issues Tab Fields)

Field	Description	Notes
Download link	Download the file that was imported to create this bid.	There are no notes.
Severity column	Level of concern for the issue encountered. ■ WARNING—Identifies missing information or data entry that differs from expected format. ■ SERIOUS—Warrants inspection of the bid to ensure it accurately reflects the file that was uploaded. ■ FATAL—Prevents the bid from being imported. Must be fixed for the import to proceed.	There are no notes.
Message column	Description of the issue.	There are no notes.
Sheet column	Name of the worksheet on which the issue was encountered.	There are no notes.
Row column	The row number where the issue was encountered.	There are no notes.

Change Bid Status Dialog Box

Table 5–113 Change Bid Status Dialog Box Fields

Field	Description	Notes
Status	Status of the bid.	There are no notes.
Update Bid History	Add to the history section included on the Edit Bid screen.	There are no notes.

Maintain Menu Screens and Dialog Boxes

Template Screen Fields and Dialog Boxes

Template Screen Fields

Table 5–114 Template Screen Fields

Field	Description	Notes
New button	Add template.	There are no notes.
Edit button	Edit a template.	There are no notes.
Delete button	Delete a template.	There are no notes.
Restore button	Restore a deleted template.	There are no notes.
Copy button	Copy a template.	There are no notes.
Lock Templates button	Lock templates.	There are no notes.
Unlock Templates button	Unlock templates.	There are no notes.
Template Name column	Template name.	There are no notes.
Phase column	Study phase.	There are no notes.
Therapeutic Area column	Therapeutic area of the associated template.	There are no notes.
Indication column	Indication of the associated template.	There are no notes.

Define Template Filter Dialog Box Fields

Table 5–115 Define Template Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes templates created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted templates	Includes templates that have been previously deleted.	There are no notes.
Template name starts with	Includes templates created or modified within the number of days selected from the drop-down list.	There are no notes.
Created by	Includes templates created by the selected users.	To display all templates regardless of who created them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Last Modified by	Include templates last edited and saved by the selected users.	To display templates regardless of who last updated them, select **Any User**. To display more users to choose from, click the **Expand list...** link.

Table 5–115 (Cont.) Define Template Filter Dialog Box Fields

Field	Description	Notes
Status	Include templates with the selected statuses.	To display templates regardless of their status, select **Any Status**.
Phases	Include templates pertaining to the selected phases.	To display templates regardless of the phase, select **Any Phase**.
Therapeutic Areas	Include templates pertaining to the selected Therapeutic Areas.	To display templates regardless of the Therapeutic Area, select **Any Therapeutic Area**.
Sponsors	Includes templates for the selected sponsors.	To display templates regardless of the sponsor, select **Any Sponsor**.
Save filter as	Name to assign to the filter.	There are no notes.

Configure Lists Options Dialog Box Fields - Templates Screen

Table 5–116 Configure Lists Options Dialog Box Fields - Templates Screen

Field	Description	Notes
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 5–117 Select Template Defaults Dialog Box Fields

Field	Description	Notes
Sponsor	Default sponsor for the template.	There are no notes.
Phase	Phase from which to derive values when creating the 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.	There are no notes.

Copy Template Dialog Box Fields

Table 5–118 Copy Template Dialog Box Fields

Field	Description	Notes
Template Name	Name of the copied template.	There are no notes.
Use Cost Model from	Cost model to apply to the templates.	The default is the cost model of the template being copied.

Table 5–118 (Cont.) Copy Template Dialog Box Fields

Field	Description	Notes
Custom Field Model	Custom field models to apply to the plan.	There are no notes.

Change Template Attributes Dialog Box Fields

Table 5–119 Change Template Attributes Dialog Box Fields

Field	Description	Notes
Template Name	Unique name that identifies the template.	Disabled if multiple templates are selected.
Status	State of the template: ■ **Incomplete**—Not all input questions have been addressed and the results are not expected to be accurate. ■ **Draft**—All input questions have been answered, but the template owner or creator is still working on the template. ■ **Final**—All input questions have been answered; however, the template is waiting approval by a person authorized to approve study templates. ■ **Approved**—The template is approved and ready to go out as part of an RFP or proposal, or to be used to conduct the trial. ■ **RFP**—The template has been approved and has been included as part of an RFP. ■ **Agreement reached; not started**—An agreement has been reach on the template 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 begin and is operating according to this template. ■ **Study Complete**—The study has completed execution. ■ **Archived**—This template is being preserved for historical purposes only.	There are no notes.
Cost Model	Cost model to apply to the template.	There are not notes.
Custom Field Model	Custom field model to apply to the template.	There are not notes.

Table 5–119 (Cont.) Change Template Attributes Dialog Box Fields

Field	Description	Notes
Short Description	Information displayed when viewing a list of templates.	If multiple templates are selected, this field is disabled.
Long Description	Detailed explanation of the assumptions upon which this template is based.	If multiple templates are selected, this field is disabled.
Update last modified date and user (template history)	If checkbox is selected, updates the selected templates' last modified date and last modifier (user) when you apply changes to the name, status, cost model, custom field model, or descriptions.	Oracle recommends that you select this option. However, if you or other users often filter by the last modified date or user and do not want bulk changes to status, clear the checkbox before saving.

Service Providers Screen Fields

Service Providers Screen Fields

Table 5–120 Service Providers Screen Fields

Field	Description	Notes
Show filter	Service providers that appear on the Service Providers screen.	You can select sponsors, vendors, and deleted service providers.
New button	Create a service provider.	There are no notes.
Edit button	Edit a service provider.	There are no notes.
Delete button	Delete a service provider.	There are no notes.
Restore button	Restore a service provider.	There are no notes.
Billing Rates Report button	Display the Billing Rates report for a service provider.	There are no notes.
Name column	Service provider name.	There are no notes.
Type column	Service provider type.	There are no notes.
Last Modified column	Date and time the service provider was last edited.	There are no notes.
Last Modified By column	User who last edited the service provider.	There are no notes.

Create/Edit Service Provider Screen Fields

Table 5–121 Create/Edit Service Provider Screen Fields

Field	Description	Notes
Provider Name	Name that will appear in reports and on screens when you assign work to this provider.	There are no notes.
Provider Type	Type of service provider: Sponsor or Contract Research Organization (CRS).	There are no notes.

Table 5–121 (Cont.) Create/Edit Service Provider Screen Fields

Field	Description	Notes
Description	Description to differentiate this provider.	Oracle recommends that you not particular specialties or limitations of this provider.
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, such as Protocol Preparation and Data Management.	You can override the billing rate location in a plan for any specific task in the Task Manager or on the Assignment tab.
Created By	User who created the service provider.	There are no notes.
Created Date	Date and time this service provider was created.	There are no notes.
Last Modified By	User who last edited the service provider information.	There are no notes.
Last Modified	Date the service provider information was last modified.	There are no notes.
Update Billing Rates link	Enter and publish billing rates for this service provider.	There are no notes.

Resources Screen Fields

Define Resource Filter Dialog Box Fields

Table 5–122 Define Resource Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes resources created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted resources	Includes previously deleted resources.	You can restore resources that have been deleted until they are permanently purged.
Resource name starts with	Includes resources with names starting with the specified text.	There are no notes.
Save filter as	Name assigned to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Resources Screen

Table 5–123 Configure List Options Dialog Box Fields - Resources Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Plans screen.	There are no notes.

Table 5–123 (Cont.) Configure List Options Dialog Box Fields - Resources Screen

Field	Description	Notes
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 5–124 Resources Screen Fields

Field	Description	Notes
Show filter	Resources that appear on the Resources screen.	You can include All Resources, Active Resources Only, or resources matching a filter.
New button	Add a resource.	There are no notes.
Edit button	Edit a resource.	There are no notes.
Delete button	Delete a resource.	There are no notes.
Restore button	Restore a resource.	There are no notes.
Name button	Resources in the application.	There are no notes.
Name column	Resource name.	There are no notes.
Last Updated column	Date and time the resource was last updated.	There are no notes.
Updated By column	User who last modified the resource.	There are no notes.

Create/Edit Resource Screen

Table 5–125 Create/Edit Resource Screen Fields

Field	Description	Notes
Code	Alphanumeric code representing this resource.	Example: CRO1.
Name	Job title or classification. Not the name of an individual resource.	Example: Medical Monitor. Two resources cannot have the same name.
Description	List of job responsibilities.	For system-defined resources, the list is read-only.
Rate Year	Rate year for each service provider.	Applies only to the Create Resource screen.
Auto Fill	Billing rates for each service provider.	Applies only to the Create Resource screen.

Billing Rates Screen Fields

Billing Rates Screen Fields

Table 5–126 Billing Rates Screen Fields

Field	Description	Notes
Show rates for	Service provider for which billing rates appear on the Billing Rates screen.	There are no notes.
For Rate Year	Year for which billing rates appear on the Billing Rates screen.	There are no notes.
Include Deleted Rates	Include deleted rates.	There are no notes.
New button	Add billing rates.	There are no notes.
Edit button	Edit billing rates.	There are no notes.
Delete button	Delete billing rates.	There are no notes.
Restore button	Restore deleted billing rates.	There are no notes.
Copy button	Copy billing rates.	There are no notes.
Publish button	Publish billing rates.	There are no notes.
Show Revision History button	Revision history of the selected billing rates.	There are no notes.
Rates for column	Service provider who charges the billing rates.	Service providers can charge different rates to different sponsors.
When performing work for column	Organization for whom the service provider is performing the work when these rates apply.	There are no notes.
Rate Year column	Billing rate year.	There are no notes.
Status column	Billing rate status.	Billing rates can be published or drafts.
Last Modified column	Date and time the billing rates were last edited.	There are no notes.
Last Modified By column	User who edited the billing rates.	There are no notes.

Create/Edit Billing Rates Screen

Table 5–127 Create/Edit Billing Rates Screen Fields

Field	Description	Notes
When	Service provider who charges these billing rates.	Required when creating a new set of billing rates.
Performs work for	Sponsor that will be charged these rates.	There are no notes.
For Rate Year	Year for which these billing rates apply.	There are no notes.

Table 5–127 (Cont.) Create/Edit Billing Rates Screen Fields

Field	Description	Notes
Base Rate Location	Location chosen by the user for initial data entry of billing rates by resource. The ClearTrial application suggests values for all other locations based on the rate variance percentages. You can accept these suggested values or override either the rate variance percentages or the resource billing rates for one or more locations.	The country or region whose RATE VARIANCE % is 100.00% is the base rate location. The application derives all other locations' rates as a variance of the base rate.
Currency	Currency in which the billing rates are expressed.	There are no notes.
RATE VARIANCE %	The application calculates the country-specific rates per the variance value that appears in this row.	You can change the variance for any country or override a specific rate for a particular resource in any location.
REGION	Country or region for which the base rate applies.	There are no notes.
Resource	Each row represents a job title or type of employee who performs work during a study.	The application multiples the hourly rate by the number of hours calculated to be required for the resource to complete the work. See the online Help for a list of responsibilities associated with each resource.
Country/Region columns	Enter the hourly rate for each resource for each country and region.	Regional rates represent the average billing rates for all locations within a defined region.
Export rates to Excel link	Export the billing rates you defined to a Microsoft Excel spreadsheet.	There are no notes.
Save button	Preserves the values in a draft state.	There are no notes.
Publish button	Publish the currently displayed set of billing rates and makes them available as the active rated used by the application to calculate fees and costs associated with tasks assigned to the chosen vendor.	There are no notes.

Copy Billing Rates Dialog Box Fields

Table 5–128 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, positive or negative, to apply to the copied billing rates.	Must contain a value between -999 and 999.

Show Revision History Dialog Box Fields

Table 5–129 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.	There are no notes.
Last Modified By	User who last edited the billing rates.	There are no notes.
Show Rates	Billing rates of the prior versions.	There are no notes.

Inflation Profiles Screen Fields

Inflation Profiles Screen Fields

Table 5–130 Inflation Profiles Screen Fields

Field	Description	Notes
Show Profile for filter	Include only those inflation profiles associated with the selected provider.	To display inflation profiles for all providers, select **Any Provider**.
for Rate Year filter	Include rates associated with the selected year.	To display inflation profiles for all years, select **Any Year.**
Include Deleted Rates filter	Select to include inflation profiles that have been deleted.	There are no notes.
New button	Define a new inflation profile.	There are no notes.
Edit button	Edit the selected inflation profile.	There are no notes.
Delete button	Delete the selected inflation profiles.	There are no notes.
Restore button	Restore the selected deleted inflation profile.	There are no notes.
Copy button	Copy the selected inflation profile.	There are no notes.
Publish button	Make the currently selected draft inflation profile active and available to all plans using the associated vendor and effective rate year.	There are no notes.
Show Revision History button	View a history of the revisions made to the selected inflation profile.	There are no notes.
Profile for column	Provider with whom the inflation profile is associated	Multiple profiles can be associated with a service provider.
When performing work for column	Organization for whom the service provider is performing the work when this inflation profile applies.	There are no notes.
Rate Year column	Billing rate year associated with the inflation profile.	There are no notes.

Table 5–130 (Cont.) Inflation Profiles Screen Fields

Field	Description	Notes
Status column	Status of the inflation profile: Published or Draft.	There are no notes.
Last Modified column	Date and time the inflation profile was last edited.	There are no notes.
Last Modified By column	User who edited the inflation profiles.	There are no notes.

New Inflation Profile Dialog Box Fields

Table 5–131 New Inflation Profile Dialog Box Fields

Field	Description	Notes
When	The vendor for which this inflation profile applies.	There are no notes.
Performs work for	The sponsor that will be charged these rates.	There are no notes.
For Rate Year	The year for which these rates apply	There are no notes.

Create/Edit Inflation Profile Screen Fields

Table 5–132 Create/Edit Inflation Profile Screen Fields

Field	Description	Notes
When	The vendor for which this inflation profile applies.	There are no notes.
Performs work for	The sponsor that will be charged these rates.	There are no notes.
For Rate Year	The year for which these rates apply	There are no notes.
Base Rate Location	The country or region for the rates in the Base Rate column.	The country or region whose RATE VARIANCE % is 100.00% is the base rate location. The application derives all other locations' rates as a variance of the base rate.
Add Year button	Copy the contents of the last row to a row added to the bottom of the grid.	There are no notes.
Delete Year button	Delete the selected year row.	There are no notes.
Publish button	Publish the currently displayed inflation profile.	There are no notes.
Export rates to Excel button	Export the data to a Microsoft Excel spreadsheet.	There are no notes.

Copy Inflation Profile Dialog Box Fields

Table 5–133 Copy Inflation Profile 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.	There are no notes.

Show Revision History Dialog Box Fields

Table 5–134 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.	There are no notes.
Last Modified By	User who last edited the billing rates.	There are no notes.
Show Rates	Billing rates of the prior versions.	There are no notes.

Departments Screen Fields

Departments Screen Fields

Table 5–135 Departments Screen Fields

Field	Description	Notes
Show filter	Departments that appear on the Departments screen.	You can show all departments, active departments only, or select a department filter.
New button	Add a department.	There are no notes.
Edit button	Edit a department.	There are no notes.
Delete button	Delete a department.	There are no notes.
Restore button	Restore a deleted department.	There are no notes.
Map Labor and Costs button	Edit department mappings.	There are no notes.
Name column	Department name.	There are no notes.
Code column	Department code.	There are no notes.
Description column	Department description.	There are no notes.
Last Updated column	Date and time the department was last edited.	There are no notes.
Updated By column	User who last edited the department.	There are no notes.

Define Department Filter Dialog Box Fields

Table 5–136 Define Department Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes departments created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted departments	Include departments that have been previously deleted.	There are no notes.
Department name starts with	Includes departments with names starting with the specified text.	There are no notes.
Save filter as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Departments Screen

Table 5–137 Configure List Options Dialog Box Fields - Departments Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Departments screen.	There are no notes.
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.

Create/Edit Department Screen Fields

Table 5–138 Create/Edit Department Screen Fields

Field	Description	Notes
Code	Alphanumeric code representing the department.	There are no notes.
Name	Department name.	Two departments cannot have the same name.
Description	Description of the department.	There are no notes.

Edit Department Mapping Screen Fields

Table 5–139 Edit Department Mapping Screen Fields

Field	Description	Notes
Mapping by <> Change	Displays the currently active mapping mode: resource, location, task, or rule.	To change modes, click the **change** link.
Restore ClearTrial Defaults	Restore department mappings to the application default mappings.	Discards any mappings you created.
Resource	Resources to which departments can be mapped.	Includes ClearTrial-defined and user-defined resources.

Table 5–139 (Cont.) Edit Department Mapping Screen Fields

Field	Description	Notes
Internal	Department to apply when the resource performs work for an internal provider.	Includes ClearTrial-defined and user-defined departments
Outsourced	Department to apply when the resource performs work for an outsourced provider.	Includes ClearTrial-defined and user-defined departments
Location	Locations to which departments can be mapped.	There are no notes.
Internal	Department to apply when an internal provider is assigned to the location.	Includes ClearTrial-defined and user-defined departments.
Outsourced	Department to apply when an outsourced provider is assigned to the location.	Includes ClearTrial-defined and user-defined departments.
Task Group	Task groups to which departments can be mapped.	The application applies the department selected for a task group as the default for all tasks in that group.
Task	Tasks to which departments can be mapped.	Includes only ClearTrial-defined tasks.
Internal	Department to apply when an internal provider is assigned to the task or task group.	Includes ClearTrial-defined and user-defined departments.
Outsourced	Department to apply when an outsourced provider is assigned to the task or task group.	Includes ClearTrial-defined and user-defined departments.
Add Rule button	Add a rule for mapping labor to departments.	There are no notes.
Edit Rule button	Edit a selected rule.	There are no notes.
Delete Rule button	Delete a selected rule.	There are no notes.
Criteria column	Criteria that determine which department is applied.	There are no notes.
Department column	The department associated with the rule.	There are no notes.
Drag to Order column	Use the mouse to reorder the rules by your own priority.	Rules at the top of the list take priority over the bottom.

Create Department Mapping Rule Dialog Box

Table 5–140 Create Department Mapping Rule Dialog Box Fields

Field	Description	Notes
Department	The department to be assigned when the rule matches the criteria.	There are no notes.
Providers (Any) tab	Select providers to be matched according to this rule.	Selecting the **Internal** and **Outsource** checkboxes include all the service providers in that group. Selecting **Any Provider** includes all providers.

Table 5–140 (Cont.) Create Department Mapping Rule Dialog Box Fields

Field	Description	Notes
Locations (Any) tab	Select locations to be matched according to this rule.	Select **Any Location** to include study-scoped locations as part of the match.
Tasks (Any) tab	Select tasks to be matched according to this rule.	Select **Any Task** to include all tasks and task groups. Include ClearTrial-defined and user-defined tasks by selecting their associated task or task group.
Resources (Any) tab	Select resources to be matched according to this rule.	Select **Any Resource** to include all resources.

GL Codes Screen Fields

GL Codes Screen Fields

Table 5–141 GL Codes Screen Fields

Field	Description	Notes
Show filter	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 button	Create a new GL code.	There are no notes.
Edit tab	Edit the selected GL code.	There are no notes.
Delete tab	Delete the selected GL code.	There are no notes.
Restore tab	Restore the selected deleted GL code.	There are no notes.
Map Labor and Costs tab	Edit GL code mappings.	There are no notes.
Name column	GL code name.	There are no notes.
Code column	Code associated with the GL code.	There are no notes.
Description column	GL code description.	There are no notes.
Last Modified column	Date and time the GL code was last edited.	There are no notes.
Modified By column	User who last edited the GL code.	There are no notes.

Define GL Code Filter Dialog Box Fields

Table 5–142 Define GL Code Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes GL codes created or modified within the number of days selected from the drop-down list.	There are no notes.
Include deleted GL Codes	Includes GL Codes that have been previously deleted.	There are no notes.

Table 5–142 (Cont.) Define GL Code Filter Dialog Box Fields

Field	Description	Notes
GL Code name starts with	Includes GL codes with names starting with the specified text.	There are no notes.
Save filter as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - GL Codes Screen

Table 5–143 Configure List Options Dialog Box Fields - GL Codes Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the GL Codes screen.	There are no notes.
Sort By	Order the list of GL codes 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.

Create/Edit GL Code Screen Fields

Table 5–144 Create/Edit GL Code Screen Fields

Field	Description	Notes
Code	Alphanumeric code representing the General Ledger code.	There are no notes.
Name	GL code name.	You cannot create two GL codes with the same name.
Description	GL code description.	There are no notes.

Edit GL Code Mapping Screen Fields

Table 5–145 GL Code Mapping Screen Fields

Field	Description	Notes
Mapping by <>Change	Displays the currently active mapping mode: resource, location, task, or rule.	To change modes, click the change link.
Restore ClearTrial Defaults	Restore GL code mappings to the application default mappings.	Discards any mappings you created.
Mapping by Resource	Displays the mapping mode currently being used.	To change modes, click the change link.
Resource	Resources to which GL codes can be mapped.	Includes ClearTrial-defined and user-defined resources.
Internal	GL code to apply when the resource performs work for an internal provider.	Includes ClearTrial-defined and user-defined resources.
Outsourced	GL code to apply when the resource performs work for an outsourced provider.	Includes ClearTrial-defined and user-defined resources.

Table 5–145 (Cont.) GL Code Mapping Screen Fields

Field	Description	Notes
Location	Locations to which GL codes can be mapped.	There are no notes.
Internal	GL code to apply when an internal provider is assigned to the location.	Includes ClearTrial-defined and user-defined GL codes.
Outsourced	GL code to apply when an outsourced provider is assigned to the location.	Includes ClearTrial-defined and user-defined GL codes.
Task Group	Task groups to which GL codes can be mapped.	The application applies the GL code selected for a task group as the default for all tasks in that group.
Task	Tasks to which departments can be mapped.	Includes only ClearTrial-defined tasks.
Internal	GL code to apply when an internal provider is assigned to the task or task group.	Includes only ClearTrial-defined GL codes.
Outsourced	GL code to apply when an outsourced provider is assigned to the task or task group.	Includes ClearTrial-defined and user-defined GL codes.
Map by Rule Advanced Mode	Map labor to GL codes by user-defined criteria.	There are no notes.
Add Rule button	Add a rule for mapping labor to GL codes.	There are no notes.
Edit Rule button	Edit a selected rule for mapping labor to GL codes.	There are no notes.
Delete Rule button	Delete a selected rule for mapping labor to GL codes.	There are no notes.
Criteria column	Criteria that determine which GL code is applied.	There are no notes.
GL Code column	The GL code associated with the rule.	There are no notes.
Drag to Order column	Use the mouse to reorder the rules by your own priority.	Rules at the top of the list take priority over the bottom.

Create GL Code Mapping Rule Dialog Box

Table 5–146 Create GL Code Mapping Rule Dialog Box Fields

Field	Description	Notes
GL Code	The GL code to be assigned when the rule matches the criteria.	There are no notes.
Providers (Any) tab	Select providers to be matched according to this rule.	Selecting the **Internal** and **Outsource** checkboxes include all the service providers in that group. Selecting **Any Provider** includes all providers.

Table 5–146 (Cont.) Create GL Code Mapping Rule Dialog Box Fields

Field	Description	Notes
Locations (Any) tab	Select locations to be matched according to this rule.	Select **Any Location** to include study-scoped locations as part of the match.
Tasks (Any) tab	Select tasks to be matched according to this rule.	Select **Any Task** to include all tasks and task groups. Include ClearTrial-defined and user-defined and user-defined tasks by selecting their associated task or task group.
Resources (Any) tab	Select resources to be matched according to this rule.	Select **Any Resource** to include all resources.

Exchange Rate Tables Screen Fields

Exchange Rate Tables Screen Fields

Table 5–147 Exchange Rate Table Screen Fields

Field	Description	Notes
Show filter	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 button	Add an exchange rate table.	There are no notes.
Edit button	Edit an exchange rate table.	There are no notes.
Delete button	Delete an exchange rate table.	There are no notes.
Restore button	Restore a deleted exchange rate table.	There are no notes.
Publish button	Publish an exchange rate table.	There are no notes.
Set Default button	Set the default exchange rate table.	There are no notes.
Description column	Exchange rate table description.	There are no notes.
Status column	Exchange rate table status.	Exchange rate tables can be published or drafts.
Last Updated column	Date and time the exchange rate table was last edited.	There are no notes.
Updated By column	User who last edited the exchange rate table.	There are no notes.

Define Exchange Rate Table Filter Dialog Box Fields

Table 5–148 Define Exchange Rate Table Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes exchange rates created or modified within the number of days selected from the drop-down list.	There are no notes.

Table 5–148 (Cont.) Define Exchange Rate Table Filter Dialog Box Fields

Field	Description	Notes
Include deleted exchange rate tables	Includes exchange rate tables that have been previously deleted.	There are no notes.
Exchange Rate Table name starts with	Includes exchange rates with names starting with the specified text.	There are no notes.
Created by	Includes exchange rate tables created by he selected users.	To display all exchange rate tables regardless of who created them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Last Modified by	Includes exchange rate tables last edited and saved by the selected users.	To display exchange rate tables regardless of who last updated them, select **Any User**. To display more users to choose from, click the **Expand list...** link.
Save filter as	Name to assign to the filter.	There are no notes.

Configure List Options Dialog Box Fields - Exchange Rate Tables Screen

Table 5–149 Configure List Options Dialog Box Fields - Exchange Rate Tables Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Exchange Rate Tables screen.	There are no notes.
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.

Create/Edit Exchange Rate Table Screen Fields

Table 5–150 Create/Edit Exchange Rate Table Screen Fields

Field	Description	Notes
Name	Name for this set of exchange rates.	This name appears as a choice in the defined in drop-down list on the Overview tab. If you change the name and save the changes as a draft table, the draft name does not appear on the Exchange Rate Tables screen. Only published tables appear.

Table 5–150 (Cont.) Create/Edit Exchange Rate Table Screen Fields

Field	Description	Notes
Status	Status of the exchange rate table: ■ Draft—Visible only on the Exchange Rate Tables screen and not available when you create a plan. ■ Published—Available for use when planning studies and represents the currently active conversion rates. ■ Published with Draft—Has pending draft version associated with it that is not yet available for plans, while the previously published version remains active, available, and it use. When editing an exchange rate table in this state, the currently published values appear in a column to the right of the pending changes.	There are no notes.
Description	Short description that identifies the exchange rate table.	The description appears only on the Exchange Rate Tables screen.
Use rates as of	Populates the exchange rates as of the chosen date.	This might be a starting point for specifying custom exchange rates.
Apply button	Apply the specified date to establish the values in the exchange rate fields.	There are no notes.
1 <currency> equals...	Fields for specify the conversion rate from the source currency rate to each destination currency.	The source currency is the currency used for the exchange rate table.

Reporting Regions Screens and Dialog Boxes

Edit Reporting Regions screen

Table 5–151 Reporting Regions Screen Fields

Field	Description	Notes
New Reporting Region button	Add a reporting region.	There are no notes.
Map Countries to Reporting Regions button	Select a reporting region for a country.	There are no notes.
Reporting Region Name column	Reporting regions.	There are no notes.
# of Countries Mapped column	Number of countries that are mapped to the associated reporting regions.	There are no notes.

Table 5–151 (Cont.) Reporting Regions Screen Fields

Field	Description	Notes
Total Number of Countries Mapped to Reporting Regions column	Total number of countries mapped to reporting regions.	There are no notes.

Map Countries to Reporting Regions Dialog Box

Table 5–152 Map Countries to Reporting Regions Dialog Box Fields

Field	Description	Notes
Country button	Country to be mapped.	There are no notes.
Reporting Region button	User-defined reporting regions that you can map the country to.	There are no notes.

Purge Deleted... Screen

Table 5–153 Purge Deleted... Screen Fields

Field	Description	Notes
Purge Selected Items button	Perform the purge.	There are no notes.
Items to delete column	Item type to be purged.	There are no notes.
deleted at least n days ago column	Number of days since an item of the selected type was deleted and will be purged when you select the Purge Selected Items button.	To purge all deleted items of the selected type, enter 0.

Custom Field Models Screen Fields

Custom Field Models Screen Fields

Table 5–154 Custom Field Models Screen Fields

Field	Description	Notes
Open button	Display the custom fields defined for the selected model on the Custom Fields screen.	There are no notes.
Checkout button	Check out the DRAFT custom field model for editing.	Enabled only if no other user has checked out the draft model.
Check-In button	Save any changes made to the DRAFT custom field mode.	Enabled only for the user who checked out the DRAFT model and the system administrator.
Cancel Checkout button	Cancel the checkout of the DRAFT custom field model.	Enabled only for the user who checked out the DRAFT model and the system administrator.
Publish button	Publish the DRAFT custom field model.	Enabled only for the user who checked out the DRAFT model and the system administrator.

Table 5–154 (Cont.) Custom Field Models Screen Fields

Field	Description	Notes
Change Description button	Change the description associated with a published custom field model.	Maximum of 32 characters.
Version column	Status or rendition number of the custom field model.	Can be DRAFT, PUBLISHED, or a version number from 1 to n.
Description column	Short description associated with a published custom field model.	32 characters maximum.
Published Date column	Date and time that the custom field model was published.	There are no notes.
Published By column	Who published the custom field model.	There are no notes.
Checkout Date column	Date and time that the DRAFT custom field model was last checked out.	There are no notes.
Checkout By column	Who currently has the DRAFT custom field model checked out.	There are no notes.

Custom Field Screen Fields

Table 5–155 Custom Field Screen Fields

Field	Description	Notes
New button	Create a new custom field.	There are no notes.
View button	Display the field definitions, display criteria, and designer notes for the selected custom field.	There are no notes.
Delete button	Delete the selected custom fields.	Deleted custom fields are not removed permanently.
Restore button	Restore the selected deleted custom fields.	There are no notes.
Copy button	Make a copy of the selected custom field.	There are no notes.
Checkout button	Check out the DRAFT custom field model.	Enabled only if no other user has checked out the DRAFT model.
Cancel checkout button	Cancel the checkout of the DRAFT custom field model.	Enabled only for the user who checked out the DRAFT model.
Publish button	Publish the DRAFT custom field model.	Enabled only for the user who checked out the DRAFT model.
Name column	Name of the custom field.	There are no notes.
Label column	How custom field appears on screens and in reports.	There are no notes.
Unit Of Measure column	Unit of Measure for the custom field.	There are no notes.
Tab column	Plan assumption tab on which the custom field appears.	There are no notes.
Last Modified column	Date and time that the custom field was last modified.	There are no notes.

Table 5–155 (Cont.) Custom Field Screen Fields

Field	Description	Notes
Last Modified By column	Who last modified the custom field.	There are no notes.

Define Custom Field Filter Dialog Box Fields

Table 5–156 Define Custom Field Filter Dialog Box Fields

Field	Description	Notes
Created or modified in the last n days	Includes custom fields modified and saved within the number of days selected from the drop-down list.	There are no notes.
Include deleted custom fields	Includes custom fields that have been previously deleted.	There are no notes.
Custom Field name starts with	Includes only custom fields with names starting with the specified text.	There are no notes.
Created by:	Includes only those custom fields that were created by one of the selected users.	To see custom fields regardless of who created them, select Any User.
Last Modified by:	Includes only those custom fields that were last edited and saved by one of the selected users.	To see custom fields regardless of who last updated them, select Any User.
Save filter as	Name to assign to the filter.	

Configure List Options Dialog Box Fields - Custom Fields Screen

Table 5–157 Configure List Options Dialog Box Fields - Custom Fields Screen

Field	Description	Notes
Configure Columns	Selected columns appear on the Custom Fields screen.	There are no notes.
Sort By	Order the custom fields according to your selection, rather than by the first displayed column.	Change the order by clicking a column heading.
Show n custom fields per page	Number of custom fields to be displayed on each page.	Use the paging tool to move to the next or previous page or directly to a page number.

View/Create/Edit Custom Field Screen Field Descriptions

Table 5–158 View /Create/Edit Custom Field Screen Fields

Field	Description	Notes
Name	The programmatic variable name by which the application will refer to this assumption in custom algorithms.	Must start with a letter and contain only letters, numbers, or the underscore (_) character. The value must be unique.
Data Type	The type of data users can enter when populating the custom field.	Currently, custom field values are restricted to positive whole numbers.

Table 5–158 (Cont.) View /Create/Edit Custom Field Screen Fields

Field	Description	Notes
Label	The name that appears on a plan's assumption tab to the left of the input element for this custom field.	Should be terse, but meaningful. The name must be unique.
Prompt	Include to provide additional instructions to users populating the field in a plan.	Displayed in the status area of a plan's assumption tab (lower left corner of the screen).
Help Text	Include to provide additional instructions to users populating the custom field in a plan.	Displayed when a user invokes context-sensitive help for this custom field by clicking its label on a plan's assumption tab.
Values vary by location	Defines whether users can provide location-specific or centralized values for this assumption.	Fields that will vary by location display a small icon to the right of their input element. Clicking the icons displays the location-specific values dialog box for the associated field.
Minimum Value	Lowest acceptable value for this assumption.	Must be a value between 0 and 99,999,999.
Maximum Value	Highest acceptable value for this assumption.	Must be a value between 0 and 99,999,999.
Unit of Measure Name, Singular	Name for this assumption to appear in the Unit of Measure drop-down lists in the Task Manager/Major Task panel, Resource Algorithm pane, and the Cost Details Algorithm tab.	Must be a unique value. Custom unit of measures appears in italicized type followed by an asterisk.
Unit of Measure Name, Plural	Plural form for the name for this assumption.	There are no notes.
Sort Order Rank	Order in which custom fields appears on a plan's assumption tab.	There are no notes.
Display on the <tab>	The plan assumption tab on which this custom field will appear.	Only custom fields that are location-scoped can appear on the Site tab.
Edit Mode	Specified the minimum edit mode in which the custom field will be displayed.	To make this field unavailable to novice users or when performing less detailed planning, specify Advanced or Expert mode.
Phase	Specified which phase(s) a plan must be associated to display the custom field.	There are no notes.
Therapeutic Area	Specifies which therapeutic area(s) a plan must be associated to display the custom field.	There are no notes.
Indication	Specifies which indication(s) a plan must be associated with to display the custom field.	There are no notes.
Designer Notes	Use this field to document the purpose of the custom field.	This description does not appear to users in plans. It only displays on the View/Edit/Create Custom Fields screen.

Admin Menu

User Profile Screen Fields

User Profile Screen Fields

Table 5–159 Edit User (Profile Tab, User Preferences) Screen Fields

Field	Description	Notes
Login Name	Name or phrase you use to log in.	There are no notes.
First Name	Your first name.	There are no notes.
Last Name	Your last name.	There are no notes.
Email Address	Your email address.	This email address allows users to use the Forgot Your Password? feature. If users forget their password, they need to supply this email address to reset their password.
Security Question	Security question used for authentication purposes.	There are no notes.
Security Answer	Security answer used for authentication purposes.	There are no notes.
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.

Change Password Screen Fields

Table 5–160 Change Password Screen Fields

Field	Description	Notes
Current Password	Your currently valid password.	Required to authorize the password change request.
New Password	The password to use for subsequent logins.	Passwords must be at least eight characters and contain at least one letter, one number, and one of the following special characters: !$*+-.=?@^_|~. Passwords must not contain the login name or any of the following words: password, oracle, guest, admin, administrator, or Cleartrial.

Table 5–160 (Cont.) Change Password Screen Fields

Field	Description	Notes
Verify New Password	The new password retyped to ensure that you have not mistyped the password.	There are no notes.

Reset Password Screen Fields

Table 5–161 Reset Password Screen 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: !$*+-.=?@^_|~. Passwords must not contain your login name or any of the following words: password, oracle, guest, admin, administrator, or cleartrial. 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.	There are no notes.