Oracle Life Sciences ClearTrial
User Guide

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Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support

Documentation accessibility

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

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

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

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

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

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

1

Before Planning Any Studies

Oracle Life Sciences ClearTrial Cloud Service is subscription-based software as a service (SaaS) that leverages embedded industry intelligence and clinical knowledge to optimize clinical study planning and sourcing, as well as rationalize the deployment of R&D spending. The cloud-based software enables the compression of study timelines along with reduced costs, the accelerated delivery of accurate, defensible, achievable budgets, the reduction of outsourcing cycle times, and increased negotiation leverage.

This chapter covers setup and configuration tasks to perform before you start planning studies.

- Understand the ClearTrial Model
  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.

- Add Your Product to ClearTrial
  You must add your product or test article before you can create a study for it.

- Define Columns for List Screens
  The Configure List Options link appears in the upper right hand area of every list screen in ClearTrial (Plans, Studies, Products, Portfolios, RFPs, Bids, and so on) and allows you to select which columns to display.

- Define Filters for List Screens
  To help you quickly locate relevant items, such as plans, or to easily ignore items that are not applicable to you or your therapeutic area, you can filter lists to hide items based on some predefined or custom criteria. Every list screen has a Filter section.

- Manage your user profile
  This chapter provides information on how to view and edit your account details.

Understand the ClearTrial Model

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.

ClearTrial supports two assumption models—one for early phase trials (Phase I (Healthy Volunteers) and another for late stage trials (all variations of Phase I (patients) through Phase IV with or without IND).

Each model consists of:

- User input assumptions

- Default values

- Site Approval Schedule

- Subject Visit Schedule

- Monitoring Schedule

Before you can plan a trial, you (or another authorized user) must:

- Create the product to be tested.

- Create a study to uniquely represent the potential trial.

Only then can you create one or more plans for that study to estimate costs and durations according to your assumptions.

The optimal plan for each study for a product can be compiled into a portfolio to provide estimates for cost and time to bring a product to market. Portfolios can also be used to compile the optimal plan for each study expected in some time frame to estimate quarterly, yearly, or other long-range budgets across a suite of products.

Add Your Product to ClearTrial

You must add your product or test article before you can create a study for it.

A product is a compound, a medical device, or a combination product for which you conduct a study. You can conduct multiple studies on a product of varying phase, therapeutic area, and indication values for any user-defined product.

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

2. On the **Products** screen, click **New**.

3. On the **Create Product** screen, enter the information in the fields. For more information about a field, click the field label to display online help.

4. Click **Save**, then click **Close**.

Define Columns for List Screens

The Configure List Options link appears in the upper right hand area of every list screen in ClearTrial (Plans, Studies, Products, Portfolios, RFPs, Bids, and so on) and allows you to select which columns to display.

You can also control the sort order of the items displayed in the list and how may items to display on each page, if the list is lengthy.

1. On any list screen, click the **Configure List Options** link.

2. On the **Configure List Options** screen, in the **Configure Columns** section, select the check boxes 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.

   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 third sorting criterion.

> ✎ **Note:**
>
> You can always reorder a list by clicking the column header by which to order the list.

4. Click **Ok**.

Define Filters for List Screens

To help you quickly locate relevant items, such as plans, or to easily ignore items that are not applicable to you or your therapeutic area, you can filter lists to hide items based on some predefined or custom criteria. Every list screen has a Filter section.

1. On any list screen; for example the Plans screen, in the Filter section, choose all items, only active items, or those items matching your the filter you specify.

    • **All <items>**—Shows all items (no filter is applied).

    • **Active <items> Only**—Shows items that are not deleted or marked as Study complete or Archived status.

    • **<items> matching filter**—Shows only items that match the criteria you have defined in the selected custom filter.

2. To modify the filter in effect:

    a. Click the **Modify** link.

    b. Select the criteria to filter items by and save the filter as a user-defined filter by giving it a name.

3. Click **Ok**.

Manage your user profile

This chapter provides information on how to view and edit your account details.

Topics:

• Set Your User Preferences
  The User Profile screen stores the minimum required information necessary for you to use Oracle Life Sciences ClearTrial Cloud Service.

• View your user profile
  Your user profile stores the minimum information required to use ClearTrial. You can update your profile at any time.

• Edit your user profile
  You can edit the information in your user profile at any time.

• Change your password
  You can change your password on your user profile screen.

Set Your User Preferences

The User Profile screen stores the minimum required information necessary for you to use Oracle Life Sciences ClearTrial Cloud Service.

1. On the **Start** screen, click your name in the upper right of the menu bar.

2. Select **View My User Profile**.

3. Click **Edit Profile**, then make changes as necessary to the **User Preferences** fields:

    • **Login Name**—Only the System Administrator can change this.

    • **First Name, Last Name**—You can edit these.

    • **Email Address**—Update your email address if necessary. If you forget your password, you must supply this email address to reset it.

    • **Security Question**, **Security Answer**—Select a security question from the list and supply the answer. ClearTrial uses the question and answer for authentication purposes if you need to recover your password.

    • **Preferred Edit Mode**— Your selection controls how many clinical assumptions are displayed per tab in the plan. The tabs and set of clinical assumptions included vary by edit mode.

        – **Quick mode**—Includes the minimal required number of clinical assumptions a user has to enter to create a quick, ballpark budget. In Quick mode, some assumptions are hidden and ClearTrial defaults are used in your forecast.

        – **Basic mode**—Includes more assumptions than provided in Quick mode at every level. All tabs are enabled for you to accept or override the defaults.

        – **Advanced mode**—Includes the majority of clinical assumptions.

        – **Expert mode**—Includes all clinical assumptions. Use this mode 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.

    > 💡 **Tip:**
    >
    > If you change your preferred edit mode after setting some assumptions, Oracle recommends only changing it to a higher mode so that you can continue to view and edit all the assumptions from the previous mode.

    • **Preferred Home Page**—This is the screen that you have specified to appear after you log in. You can choose between various list screens, depending on what screen you plan on starting with or visiting most frequently.

    • **Preferred Locale**—Locale determines how dates and numbers are displayed and interpreted in the application. Use this setting to override your computer settings.

4. To receive emails about changes to the service, upcoming planned maintenance, new releases, and other relevant information, select the **Receive notifications about service updates** check box.

5. Select the **Participate in customer surveys to improve the service** check box if you agree to receive occasional surveys about your use of, and satisfaction with, ClearTrial.

6. Click **Save**.

View your user profile

Your user profile stores the minimum information required to use ClearTrial. You can update your profile at any time.

1. To view your user profile details, click your name in the upper right corner of the main menu bar.

    You will see all existing settings for your account, such as your login name, email address, preferred locale, and all your assigned roles, such as your primary role to access the service along with all existing additional roles/capabilities currently assigned to you.

2. To see the permissions associated with each role, click it.

Edit your user profile

You can edit the information in your user profile at any time.

1. Click your name in the upper right corner of the main menu bar.

2. On your user profile screen, click the **Edit Profile** button to display the **Edit User** screen.

3. On the **Profile** tab in the **User Preferences** section, edit the fields to reflect the most current and accurate information.

    For more information about a field, click on the field to display the online help.

4. Click **Save**.

Change your password

You can change your password on your user profile screen.

1. Click your name in the upper right corner of the main menu bar.

2. On your user profile screen, click the **Change Password** button to display the **Change Password** screen.

3. In the **Current Password** field, enter your password.

4. In the **New Password** field, enter your new password.

5. In the **Verify New Password** field, re-enter your new password.

6. Click **Save**.

2

Plan a Clinical Trial

Oracle Life Sciences ClearTrial Cloud Service leverages 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 costing methodology in ClearTrial encompasses the detailed tasks and costs required to plan a clinical study, enabling you to build study plans and Request for Proposal documents from the bottom up by entering in your clinical operational assumptions. Delivered as cloud-based, software-as-a-service (SaaS) applications, ClearTrial offers industry-proven algorithms for more than 200 therapeutic indications, specific clinical development data and clinical research organization (CRO) labor rates for 90 locations, and detailed clinical, fees and cost, and resource capacity reports.

- Create the Study
  You must create a new study for every new protocol before you can start planning each study.

- Create a Plan
  You can create multiple plans for a given study, as necessary, to determine the most cost-effective or time-efficient approach.

- Choose the User Edit Mode
  ClearTrial provides four edit modes that govern the assumptions you can enter for a plan and the default field values provided.

- Add Your Assumptions
  Once you have selected the template and clicked **Ok**, ClearTrial displays the Create Plan screen.

- Build a Portfolio
  A portfolio acts as a container to aggregate plans and calculate the total costs for the trials the plans represent.

- Create Templates
  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 assumption values and choices.

Create the Study

You must create a new study for every new protocol before you can start planning each study.

You can create multiple plans or clinical scenarios for any given study.

1. On the **Start** screen or your custom-defined Home screen, select the option to view the list of existing plans.

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

3. On the **Studies** screen, click **New**.

4. On the **Create Study** screen, complete the **General Information** section.

   • For more information about a field, click the field label to display online help.

   • 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.

   • Your choice of **Phase** determines the assumptions you can specify in the Therapeutic Area & Indication section.

5. Complete the **Therapeutic Area & Indication** section.

   Indications are classified into therapeutic areas. ClearTrial 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 for ClearTrial-defined assumptions. You can override these default values.

   > **✎ Note:**
   >
   > If you selected a Phase 1 study for either healthy volunteers or patients, you cannot choose a different therapeutic area.

   • By selecting **Substitute the names below for therapeutic area and indication**, you can specify an alias for the selected therapeutic area and indication for reporting purposes. The alias appears on the Studies screen, the plan header, and on all study-related reports.
   You should add a therapeutic area or indication alias if there are no therapeutic areas or indications included on the predefined list that match your particular study protocol when ClearTrial offers a similar indication.

   • To view a list of all therapeutic areas and their associated indications, from the Report 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).

6. Add a **description** or **note**.

7. Click **Save**.

Create a Plan

You can create multiple plans for a given study, as necessary, to determine the most cost-effective or time-efficient approach.

1. On the **Start** screen or your custom-defined Home screen, select the option to view the list of existing plans.

2. From the **Edit** menu, click **Plans** to open the **Plans** screen.

3. Click **New**.

4. On the **Choose Study and Plan Template** screen, specify the study you want to plan.

5. Next, choose a template upon which to base the new plan. Select either a template created by your organization from the list or use the ClearTrial default template by clicking the **Show ClearTrial Default System Template** link to add it to the top of the template list for selection.

> **Note:**
>
> To view descriptions of the templates, from the **Maintain** menu on the Plans screen, select **Templates**.

6. Select the cost model to apply from the **Cost Model Version** drop-down list.

> **Note:**
>
> If you select the default ClearTrial template, you cannot specify the cost model for the new plan.

7. Click **Ok**.

ClearTrial displays the Create Plan screen and you can begin to enter your assumptions.

Choose the User Edit Mode

ClearTrial provides four edit modes that govern the assumptions you can enter for a plan and the default field values provided.

For example, in Quick mode, you only need to answer about 25 questions to create a ballpark plan. In Advanced mode, you provide approximately 120 assumptions to fine tune the operational approach and budget for your study. Defining your plan in Advanced mode yields more accurate results than Quick mode.

You can set the edit mode for a specific plan or apply your preferred edit mode to all of your plans by specifying it on your user profile.

Set the edit mode for a specific plan

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

2. From the **Plans** screen, select the plan to edit, then click **Edit**.

3. At the top of the **Overview** tab, from the **Current Edit Mode** menu, select the edit mode. For example, to create a ballpark plan, select **Quick**.

   The plan updates to show or hide fields and tabs according to the chosen mode.

Plan or edit trials in a specific edit mode by default
Edit your user profile to make adjustments to Preferred and Maximum Edit modes by default.

1. On the main menu bar, click your **user name** to view your user profile settings.

2. Click **Edit Profile**.

3. From the **Preferred Edit Mode** drop-down list, select the desired edit mode; for example, *Quick* or *Advanced*.

4. Click **Save**.

Add Your Assumptions

Once you have selected the template and clicked **Ok**, ClearTrial displays the Create Plan screen.

The assumptions you can specify are grouped by category and each category is a separate tab. You can select the tabs in any order or enter your assumptions tab by tab, clicking Next to save your changes and advance to the next tab.

The first tab is the Overview tab. Any time you open or create a plan, the Overview tab is selected.

ClearTrial provides default values on each tab, but you can override these values. Some defaults vary by phase, therapeutic area, and indication, while others are dynamically updated based on your other choices specific to the plan.

- For more information about any field, click the field label to display context-sensitive help.

- For details on how your assumptions interact and can be configured to accomplish specific study goals, step through each tab section.

- Edit Basic Information on the Overview Tab
  The Overview tab includes general information about the plan such as start date, outsourcing options, currency selected, and exchange rates.

- Specify Investigation Sites on the Locations Tab
  On the Locations tab, specify the locations in which investigator sites will be established and subjects will be enrolled.

- Set Up Sites on the Site Tab
  The Site tab presents assumptions related to how sites in each location will be identified, qualified, and initiated.

- Define Trial Characteristics on the Treatment Tab
  On the Treatment tab, you can define various operational trial characteristics per treatment arm.

- Select Data Management Options on the Data Tab
  You specify how data is to be collected and managed for your study on the Data tab of a plan.

- Review and Adjust Monitored Data on the Monitoring Tab
  On the Monitoring tab you can specify information about the global and by location monitoring assumptions in a plan.

- Add Vendors and Service Providers on the Provider Tab
  On the Provider tab, you can add vendors to the list of possible service providers to use and designate a primary provider to which outsourced tasks are automatically assigned. However, you make the assignments to service providers on the Assignment tab.

- **Set Up Meeting Details and Attendees on the Meetings Tab**
  On the Meetings tab, add or remove meetings, specify meeting details and attendees, add notes for each meeting, and estimate meeting costs.

- **Define Outsourced Tasks on the Assignment Tab**
  On the Assignment tab, select which location the assignments apply to and a default service provider for outsourced tasks, then, for each task or assignment group, assign a service provider and billing rate location.

- **View Major Tasks and Adjust Labor Fees on the Labor Tab**
  On the Labor tab, review the major tasks in the plan and adjust the calculated labor unit costs and unit hours for each service provider if necessary.

- **Configure Indirect Costs on the Costs Tab**
  By default, the Costs tab of a plan displays the pass-through and miscellaneous costs calculated for the plan. Some of these costs are pre-calculated. Other costs are displayed as place-holder costs based on ClearTrial's embedded intelligence.

- **Define Provider Payment Schedules on the Payments Tab**
  On the Payments tab, you can configure the payment schedule for each provider performing work. Payments are defined as percentage values representing the portion of the total fees paid or received at the completion of each milestone.

- **View Expected Study Costs on the Summary Tab**
  The Summary tab provides a quick view of the plan's calculated budget forecast. While the Reports tab offer detailed reports, the summary is useful for "what-if" scenarios benchmarking against a vendor bid.

- **Run Reports on the Reports Tab**
  The Reports tab provides a list of reports grouped by reporting category, or as thumbnails, so you can quickly and easily identify or distinguish a particular report.

Edit Basic Information on the Overview Tab

The Overview tab includes general information about the plan such as start date, outsourcing options, currency selected, and exchange rates.

Your edit mode determines which fields are visible. For more information about any field, click its name to display context-sensitive help.

> **Note:**
>
> For CRO users, the Overview tab includes an additional assumption that gives you the option to include or exclude sponsor hours from your budget plan. By default, sponsor hours are excluded for CRO users.

1. In the **General Information** section, in the **Plan Name** field, enter a name for the plan.

   - Oracle recommends that your team establish a standard naming convention for plans and templates.

   - As you enter the plan name, it appears in the information about the plan displayed at the top of every page.

> **✏ Note:**
>
> For CRO users, the sponsor name appears within the plan header information at the top center of the screen.

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 begins billable work on the project. For studies conducted internally by the sponsor, it is the date on which project initiation activities begin requiring 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, all dates will be adjusted according to the new start date.

3. Select the plan 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 Assignment tab.

4. In the **Description** section, in the **Short Description** and **Long Description** fields, enter descriptions to help you recognize a particular scenario or remind you of the purpose of the plan when you view a list of plans. The **Long Description** field is optional.

5. In the **Currency Options** section, from the **Default Model 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.

6. 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.

7. Indicate the option to use for exchanging or converting between currencies:

- **As of (specified date)**—Select a specific date for calculating exchange rates. If ClearTrial doesn't 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. For more information, see User-defined Exchange Rate Tables.

- **As specified here...**—Override one or more exchange rates by selecting this link to display the **Override Currency Exchange Rates** screen. Enter the specific exchange rates ClearTrial should use when converting this plan's values to a currency other than the currency in which a value has been entered or calculated, and then click **Ok**.

- **As of plan created date**—This is the recommended option to specify if you are creating this plan as a template. For each plan created from the template, the exchange rates date defaults to the latest available date.

8. In the **Other Factors** section, from the **Drug Storage** drop-down list, define other factors, such as special handling considerations.

9. If the product or compound is radioactive, select the **Radio Labeled** check box.

10. Select the difficulty of the study.

    Study difficulty 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 or visit or additional interaction with several clinical investigators or their staff; for example, a 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. However, drug accountability might be atypical.

11. Enter values for any user-defined fields that appear. For more information about using and specifying user-defined fields, see Add Custom Fields to a Plan (Enterprise Edition).

12. Click **Next** to save your changes and advance to the next tab.

Specify Investigation Sites on the Locations Tab

On the Locations tab, specify the locations in which investigator sites will be established and subjects will be enrolled.

For each location, you are expected to specify the number of sites and subjects as well as the average investigator grant amount per subject. For more information about any field, click the column header to display online help.

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

2. Select the location(s) to add. You can choose regions, specific countries within the regions, or a combination of regions and countries.

> 💡 **Tip:**
>
> 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).

3. (Optional) In the **Filter** section, choose a template or plan from which to import location-specific overrides.

   This feature allows you to use a template your organization created that already has user-defined defaults such as assumption field values, assignments and pinning, GL code and department mapping, and adjustments to indirect costs.

   A description of the selected template or plan appears in a table below the filter.

4. Click **Ok**.

   The tab refreshes displaying a table showing the added locations.

5. For each location row, in the **Sites** column, enter the number of sites expected to be approved and activated.

6. In the **MOH/FDA Delay** column, estimate the number of days you expect the Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time delay to last.

   - This value represents the number of elapsed days required in each location to obtain approval to proceed with the study. ClearTrial uses this number with other statistical factors to forecast the number of sites that should be approved by any particular date.

   - ClearTrial also uses this forecast to suggest and validate assumptions regarding the first subject enrolled date (FSFT/FPFT), 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 override the suggested FSFT/FPFT 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 (FSFT/FPFT) 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 (FSFT/FPFT) 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.

   ClearTrial displays the First Site Approved date (FSA) per location based on the number of sites in that location and the expected regulatory delay.

7. Continue defining the plan locations by clicking **Add Language(s)**.

- Support Languages and Translations
  ClearTrial suggests languages based on the locations specified. You can add or remove languages and dialects as needed.

Support Languages and Translations

ClearTrial suggests languages based on the locations specified. You can add or remove languages and dialects as needed.

You can specify whether to translate (and back-translate) all documents, or no documents, or specify which documents are to be translated. Your edit mode determines the fields shown. For more information about any field, click the field name to display online help.

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

2. On the **Choose Additional Languages** screen, select the languages to add and click **Ok**.

   The selected languages appear in a table under the selected locations.

3. For each row, in the **Dialects/Variations** column, increase or decrease the number that appears to indicate the number of translations required.

4. For each language, specify which documents to translate: all, none, or specific documents.

   If you select **Specified Documents**, for each document select one or more translation options:

   • To translate the document, select the **Translate** check box.

   • 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.

   • Apply the document translations to additional languages by selecting the check boxes of the languages shown under the table.

5. Click **Ok** to add the translations required to the plan.

6. Click **Next**.

   ClearTrial advances to the Site tab.

Set Up Sites on the Site Tab

The Site tab presents assumptions related to how sites in each location will be identified, qualified, and initiated.

• Global Versus By Location Specifications
Because these assumptions can differ from location to location, you can specify values both globally and by location.

• Enter Site Management Assumptions for the Locations
On the Site tab, you specify detailed site-related information for each location in the study or all studies at the same time.

• Assign Responsibilities
You can assign tasks to specific service providers. In the **Assignments/Responsibilities** section of the Site tab you specify the outsourcing option for each location.

- Modify the Site Approval Schedule
  ClearTrial uses industry trends to calculate a default site approval schedule for
  each location. You can view or modify this schedule on the Site tab.

Global Versus By Location Specifications

Because these assumptions can differ from location to location, you can specify values
both globally and by location.

1. First, specify the values common to all locations. From the **Values apply to** drop-
   down list in the **Site Information** section, select **All Locations**.

2. Then, specify values for the locations whose assumptions differ. From the **Values
   apply to** drop-down list, select a specific location.

> **Note:**
>
> It is not necessary to save specific values for each location in the study,
> only those that differ from those specified for **All Locations**. This is
> termed *manage by exception*.

Enter Site Management Assumptions for the Locations

On the Site tab, you specify detailed site-related information for each location in the
study or all studies at the same time.

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

> **Note:**
>
> **All Locations** means those locations for which the user has not
> provided specific values or overridden the values. ClearTrial 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.
> In this context, think of **All Locations** as all locations other than those
> that have been overridden.

2. For each field, enter the percentage of sites to which the information applies. For
   more information about any field, click the field name to display context-sensitive
   help.

   ClearTrial calculates and displays the number of sites represented by applying the
   specified percentage value. Note that sites and subjects are atomic; half sites and
   half subjects do not exist. For this reason, values are always rounded up to the
   next whole number.

   - The **Percent of sites identified by sponsor** may apply to 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.

- Site visits add a significant cost to a trial. You can specify the percentage of the sites that require in-person visits versus remote 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%.

- 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. This value assumes quarterly payments (4), but you can override this value.

- **Percent of sites using 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).

- Many sites require a percentage to cover overhead expenses beyond the standard investigator grant. Specify overhead in the **Average percent overhead** field. 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 and the average percentage value.

3. Continue on the Site tab by entering personnel assignments and responsibilities. Click **Next** to enter treatment assumptions.

Assign Responsibilities

You can assign tasks to specific service providers. In the **Assignments/Responsibilities** section of the Site tab you specify the outsourcing option for each location.

Assign services providers and billing rates to tasks on the Assignment tab.

1. On the **Site** tab, in the **Assignments/Responsibilities** section, choose the outsourcing option for each group of assignable tasks. Setting an item to *N/A* excludes the associated tasks. Setting an item to *Mixed* implies you intend to assign each task uniquely on the Assignment tab or by using the Task Manager feature available to customers licensed for the Enterprise edition.

    - To assign a combination of responsibilities to sponsors and vendors, you must change the plan outsourcing 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*.

2. Click **Next** to specify treatment characteristics.

Modify the Site Approval Schedule

ClearTrial uses industry trends to calculate a default site approval schedule for each location. You can view or modify this schedule on the Site tab.

The Site Approval Schedule, in conjunction with the Subject Enrollment Schedule, Treatment Schedule, and Monitoring Frequency determines the level of effort and other costs required to collect and verify the CRF pages generated by each subject.

you can add or subtract weeks or days from the schedule and specify how many sites you expect to be approved each week or day. You can also restore the ClearTrial defaults.

> **Note:**
>
> If you are planning in Quick Edit Mode, the Site tab is disabled and ClearTrial uses default site assumption values for your budget forecast.

1. On the **Edit Plan** or **Create Plan** screen, select the **Site** tab to view the locations for which you can specify site-related information for the study.

2. From the **Site Approval Schedule** column, click a location's link to view or modify the schedule.
   The link will be labeled *ClearTrial Default* if the location is using the system-calculated schedule, or *User-Defined*, if you or another user has already modified the site approval schedule.

3. Edit the site approval schedule as described in Set Up Sites on the Site Tab.

Define Trial Characteristics on the Treatment Tab

On the Treatment tab, you can define various operational trial characteristics per treatment arm.

You can add, edit, copy, and delete one or more treatments within a plan. For more information about any field, click the field name to display online help.

- Define the Study Characteristics
  You can model single or multiple treatment arm trials, using either parallel or cross-over designs.

- Define Investigator Grants
  Specify investigator grants-related assumptions for each location in the Investigator Grants section of the Treatment tab.

- Define the Treatments
  In the Treatment(s) section, you can add up to 26 staggered treatment arms with various operational characteristics per plan.

Define the Study Characteristics

You can model single or multiple treatment arm trials, using either parallel or cross-over designs.

Your edit mode determines which fields are displayed and available to override to enter a different value than the default value provided.

1. On the **Treatment** tab, in the **Study Characteristics** section, select the **Trial Design**:

   • **Parallel**—A parallel design, also called a parallel group study, compares two or more treatments. Participants are randomly assigned to either group, treatments are administered, and then the results are compared.

   • **Crossover**— In a crossover trial design, each subject receives all defined treatments, but in a different order or sequence; such as, the subjects or patients cross over from one treatment to another during the course of the trial.
   If you select **Crossover**, you are prompted to enter in additional crossover-specific assumptions such as characteristics about the washout period.

2. From the **Measure enrollment periods in** drop-down list, specify how to measure enrollment periods. Choose between weeks and days to specify the enrollment period duration interval unit per treatment.

   > **Note:**
   >
   > This field and other enrollment-specific fields are hidden for Phase I (Healthy Volunteers) plans because all subjects are assumed to enroll on the same day they arrive at the Clinical Pharmacology Unit (CPU).

3. From the **Measure treatment duration in** drop-down list, choose between weeks and days to specify the treatment period duration interval unit per treatment.

4. Complete the next section to define the investigator grants.

Define Investigator Grants

Specify investigator grants-related assumptions for each location in the Investigator Grants section of the Treatment tab.

Specify the values in each column of the default top row to apply your assumptions to all locations except the ones you specifically enter assumptions for.

1. On the **Treatment** tab, in the **Investigator Grants** section, in the **Avg Grant/Subject** column, enter the grant amount to be paid to each investigator for each subject who completes the study. Select the appropriate currency from the drop-down list.

   • Do not include payments made for screen failures, university-related overhead, other overhead associated with certain sites, or inflation. Those assumptions are entered on the Site tab.

   • ClearTrial includes the total for investigator grant payments as a pass-through cost in the budget.

> **Tip:**
>
> 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.

2. In the **Stipend/Enrolled Subject** column, specify the amount paid to the subjects enrolled. The amount should cover all subjects.

3. In the **Payment/Screen Failure** column, specify the amount to pay an investigator for a subject that fails screening.

4. In the **% Screen Failures Paid** column, specify the percentage of failures that will result in the investigator not being paid. This represents a cap on the amount paid for subjects who do not become participants.

5. In the **Stipend/Screen Failure** column, specify the stipend to be paid to each potential subject that fails to pass the screening. This covers parking, transportation, and other nominal considerations.

6. For Phase I (Healthy Volunteers) study plans, two additional columns appear.

    *   In the **Stipend/Alternate Subject** column, specify the stipend provided to each alternative subject.

    *   In the **Special Procedure Cost** column, specify the amount paid to the CPU per subject to perform special or uncommon procedures required.

7. Define the treatments in the next section.

Define the Treatments

In the Treatment(s) section, you can add up to 26 staggered treatment arms with various operational characteristics per plan.

1. On the **Treatment** tab, in the **Treatment(s)** section, click **Add**.

    > **Note:**
    >
    > For every treatment you add, the treatment's name defaults to a letter of the alphabet, starting with *Treatment A* and continuing through *Treatment Z*. These names are configurable. You can name the treatment to align with what is stated in your specific protocol or to easily distinguish each one.

2. Define the treatment characteristics across the different segments or periods of a trial, including screening, treatment, and follow up to align with the protocol's schedule of assessments or events. For each treatment, specify:

    *   **Enrolled subjects**—Enter the number of subjects enrolling per treatment. If you have a cohort of subjects that are starting treatment before or after this treatment arm, then you can model that as a separate treatment arm.

    *   **Alternate Subjects**—Accept the default value or enter the number of subjects you need to enroll as alternate subjects for Phase I (Healthy Volunteers) plans.

- **FSFT/FPFT Date**—Specify the date that the First Subject/ Patient First Treatment (FSFT/FPFT) is expected to take place. ClearTrial 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.

- **Enrollment period**—Enter the Enrollment period for late-stage plans. The unit of weeks or days will depend on the value you chose to measure enrollment periods.

- **Enrollment rate**—This field displays the average rate at which subjects must be enrolled to meet the specified number of subjects randomized during the specified enrollment period. This value is measured in subjects per site per month.

- **Enrollment distribution**—Select the type of enrollment distribution from the ClearTrial-defined enrollment curves available for late-stage plans.

- **LSFT/LPFT Date**—This date is when the last subject or patient has their first treatment (intervention) visit post screening.

- **LSLT/LPLT Date**—This date is when the last subject or patient has their last treatment visit or data collection event before entering follow-up, if one exists.

- **Cost per bednight**—Enter the cost per bednight and the currency to be used, for subjects to stay overnight in the Clinical Pharmacology Unit (CPU) for Phase I (Healthy Volunteers) plans.

> **Note:**
>
> Enrollment-specific assumptions are not displayed for Phase I (Healthy Volunteers) plans because enrollment is expected to occur for all subjects in the same day they arrive at the Clinical Pharmacology Unit (CPU).

Screening

- **Screening period**—This is the screening period duration in weeks or days, depending on which value you chose for the **Measure treatment duration in** assumption.

- **Screening visits per subject**—This value represents the number of visits or data collection events that occur per subject during the screening period, as defined in the schedule of assessments in a protocol or study synopsis.

- **CRF Pages per screened subject**—This value represents the number of CRF pages collected per screened subject, during the screening period duration defined.

- **Screen failure rate**—Enter the percentage of screened subjects expected to fail to become study participants.

- **Number of subjects to screen**—This field displays the calculated number of subjects to be screened based on the percentage of subjects that are expected to fail screening and the number of subjects that are expected to be screened.

  The calculation for this field is as follows:

  ```
  Number of Screen Failures Expected = Number of Subjects Randomized/
  Enrolled / ( 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, this would be a screen

failure rate of 25%, yielding the need to screen at least 133 subjects. (133 * 0.25 = 33 screen failures, yielding a total of 100 subjects to randomize).

Treatment

*   **Treatment duration**—For each subject, enter the treatment period length in weeks or days, depending on the value you chose for the **Measure treatment duration in** assumption. For Phase 1 (Healthy Volunteers) trials, the treatment duration is modeled in days. For late-stage trials, the default is weeks but you have the flexibility to model the treatment period in days. ClearTrial allows you to model a minimum of one day or one week for the treatment duration.

    > **Note:**
    >
    > If you are modeling more visits to occur in one week for a parallel design trial, for example, if there are eight visits in a one-week treatment duration, ClearTrial recommends that you model the treatment duration in days and then configure the treatment schedule as needed for that treatment arm.

    > **Note:**
    >
    > For CRO users, the default treatment period interval unit is in days, with the flexibility to change to weeks, as needed.

*   **Visits per subject**—Specify the number of visits or data collection events for each subject during the treatment period. For Phase 1 (Healthy Volunteers) trials, because you are modeling in days, a visit is assumed to be on the day of treatment. A visit is a day for which one or more CRF pages or data are generated and collected. If you are modeling a trial in which patients are seen more than once per week, and still want to model the duration in weeks, add the number of pages collected at each of the visits into a single visit in the treatment schedule.

    For Phase 1 (Healthy Volunteers) studies, 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 ClearTrial costing algorithms.

    If your study has multiple visits per week, specify the duration of the treatment period in days. This allows CRO users to enter the actual number of visits so that the bid matches the RFP. Otherwise, visits occurring in the same week should be combined into a single visit. If the number of visits is greater than the number of weeks, you will see a warning.

    ClearTrial recommends planning in days, and not weeks, for these scenarios.

*   **Number of bednights**—For Phase 1 (Healthy Volunteers) trials, specify the number of nights subjects will be confined to the CPU during the treatment period duration. ClearTrial 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), you have the flexibility to specify the number of bednights during washout separately.

- **CRF pages per subject**—Specify the total number of Case Report Form (CRF) pages estimated to be collected for each subject during treatment. This value should include quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.

- **Number of cycles**—Specify the number of cycles or the number of times subjects will repeat this treatment before follow-up, as specified in the protocol.

- **Subject diary pages**—Specify how many of the pages collected during the treatment period are subject diary pages.

- **QOL Pages**—Specify how many of the pages collected during the treatment period are Quality of Life (QOL) pages.

- **Pharmacoeconomic pages**—Specify how many of the pages collected during the treatment period are pharmacoeconomic pages.

- **Subject drop rate**—Specify the percent of subjects expected to drop during the treatment period.

  ClearTrial uses this percentage as it calculates the data that needs to be monitored during treatment. For example, if you expect only three out of four subjects randomized to complete the treatment period, the treatment period's subject drop rate is 25%. If 100 subjects are randomized and you expect a 25% drop rate during treatment, only 75 subjects are expected to complete treatment.

- **Lab/Diagnostic tests/subject**—Specify the number of expected lab and diagnostic tests per subject per treatment arm. This field is only available in late-stage trials for cost model versions 5.5 and above. This assumption value drives the effort for the ClearTrial-defined task, *Review alert lab and diagnostic test results*.

- **Cohort escalation reviews**—Specify the number of dose escalation reviews per treatment arm. This field is only available for late-stage plans and in cost model versions 5.5 and above. This assumption's value drives the effort for the ClearTrial-defined task, *Review data to determine dose escalation*.

- **Monitoring minutes per page**—Specify the number of minutes to monitor one standard CRF page (excluding eDiary, QOL, and Pharmacoeconomic pages). If a study is complex, or you want the monitors to spend extra time performing additional activities, increase this assumption's default value. ClearTrial calculates the default value based on the study phase, therapeutic area, and indication.

Follow-Up

- **Follow subjects for**—Specify the follow-up period duration in years, weeks, or days.

- **% completed subjects followed**—Specify what percentage of subjects who completed treatment will enter the follow-up period.

- **First follow-up occurs after**—Specify when the first follow-up visit or data collection event occurs after the **Last Subject/Patient Last Treatment visit**, as defined in the protocol's schedule of events or assessments.

- **Follow-up visits occur every**—Specify how often visits occur or the frequency of visits where data is generated during the follow-up period.

- **Follow-up drop rate**—Specify the estimated drop date for subjects in the follow-up period.

- **CRF pages per follow-up visit**—Specify the number of CRF pages collected per visit during the follow-up period.

- **Subject diary pages per visit**—Specify the number of subject diary pages collected per visit during the follow-up period.

- **QOL pages per visit**—Specify the number of Quality of Life (QOL) pages collected per visit during the follow-up period.

- **Pharmacoeconomic pages per visit**—Specify the number of pharmacoeconomic pages collected per visit during the follow-up period.

- **LSLV/LPLV Date**—This is the last subject or patient last visit or last subject or last patient follow-up visit.

3. Select a treatment arm and click **Edit** to define all location-specific assumptions around subjects, enrollment, screening, treatment, follow-up, and grants/stipend amounts.

> **Note:**
>
> When you have overrides by location, such as FSFT, that exist in a plan for modeling when sites and subjects are coming on later, if you toggle to override at the global treatment arm level, then the global treatment level updates will be used downstream.

- **Subjects**—Manage FSFT/FPFT or the enrollment period by location or by treatment, or to override their default assumption values.

> **Note:**
>
> When you have multiple locations in a plan and treatment arms have sites and subjects expected to be approved and enrolled later, then for those location with zero subjects, select FSFT by location and adjust the FSFT date per location.

- **Enrollment**—Specify enrollment distribution values by location or by treatment. If you manage by location, select the specific plan location to view the number of subjects and the percentage of total subjects allocated, per period.
  Select the enrollment distribution from one of the default ClearTrial-defined enrollment distribution curves or select **Custom** to customize your own.

- **Screening**—Review all screening period-specific assumptions and override default values, if needed. You can also manage the screen failure rate by location.

- **Treatment**—Review all treatment period-specific assumptions and override them, if needed. You can also manage the subject drop rate during the treatment period by location.

- **Follow-Up**—Review all follow-up period-specific assumptions and override any if needed. You can also manage the follow-up subject drop rate or the percent of subjects not expected to complete the follow-up period, by location.

- **Schedule**—Review the entire trial's subject visit schedule across Screening, Treatment, and Follow-Up periods. Specify how much data is to be collected per period, the monitoring time in minutes, and the percent of the grant distributed for treatment and follow-up periods. If you have cycles defined, you can review those as well.

> **✎ Note:**
>
> The number of weeks or days displayed in the subject visit schedule is configurable and can be updated to display more data on one screen without having to go to the next page. You can override the default customer configuration that impacts all plans by asking your assigned System Administrator to change the setting using **Customer Preferences** launched by either selecting **Preferences** from the **Maintain** menu or by selecting **Customer Preferences** from the **Admin** menu.

- **Grants**—Specify grant/stipend amount details by location.
- **Notes**—Enter in any information you want to capture or track per treatment arm.

4. Click **Next** to specify data management assumptions.

Select Data Management Options on the Data Tab

You specify how data is to be collected and managed for your study on the Data tab of a plan.

For more information about any field, click the field name to display online help.

- Specify Data Management Assumptions
  Use the Data tab to specify options for collecting and managing study data.

- Specify Biostatistics Assumptions
  Biostatistics is the study of data analysis and statistical reasoning applied practically to medicine and public health.

- Specify Project Management Assumptions
  In the Project Management section of the Data Management tab, specify the media to be used to inform investigators and sponsors of overall study progress and how training is to be performed.

- Specify Electronic Master Trial File (eTMF) Assumptions
  These assumptions drive electronic Trial Master File indirect costs and fees estimated in a study plan budget.

- Specify Medical Writing Assumptions
  The medical writing assumptions you specify govern creation of an Investigator Brochure, manuscripts for industry journals, and the final study report.

- Specify End-of-Study Assumptions
  ClearTrial predicts end-of-study milestone dates such as Database Lock (EOS), Stat Report (EOS), Draft Report (EOS) and Final Report (EOS) based on the assumption values entered for these fields.

- Specify Safety and Medical Management Assumptions
  Enter your assumptions about anticipated Serious Adverse Events (SAEs) in the Safety and Medical Management section of the Data tab.

- Select Interactive Voice Response System Usage
  ClearTrial uses the term IVRS for any automated system or interactive response technology (IRT) used to randomize subjects, schedule drug shipments, or maintain an online subject diary.

- Anticipate Changes to the Protocol
  Updates to the protocol are common in clinical trials. You can account for anticipated changes in the form of protocol amendments added to the plan. Planning for these amendments makes the study budget more accurate.

- Assign Responsibilities
  You can identify an outsourcing option for each group of assignable tasks.

Specify Data Management Assumptions

Use the Data tab to specify options for collecting and managing study data.

1. On the **Plans** screen, select the check box to the left of your plan, and then click the **Edit** button to display the **Overview** tab on the **Edit Plan** screen.

2. Select the **Data** tab.

> **Note:**
>
> Many of the assumptions described below are available only in Advanced edit mode or higher.

3. In the **Data Management** section, from the **Data Collection Method** drop-down list, select the data collection method to use for the trial.

   - **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 **Assignments / Responsibilities** section, set monitoring responsibilities to **N/A**.

   - **Electronic Data Capture**—The sponsor or a vendor added to this plan is responsible for EDC management. ClearTrial 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**—Select this choice if you do not want ClearTrial 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, also, 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 is keyed into a data capture system or web-based system by someone at the site. This option is not the same as EDC and was formerly known as Remote Data Entry.

4. If you select **Electronic Data Capture** or **EDC - 3rd Party**, select the **EDC Maturity Level** . This drop-down list doesn't appear in Quick mode.

   - **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 grandfathered 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.

5. 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
   ```

6. In the **Percent of database data to audit** field, indicate the percent of the database information that must be audited.

   Typically, the vendor who manages the data is required to audit some percentage of the database. The default for this value is 10%.

7. In the **Minutes for Data Entry per CRF page** field, ClearTrial displays the number of minutes required to enter one CRF page into the database, assuming double data entry. ClearTrial calculates this value based on the phase, therapeutic area, and indication of the study. You can override this value.

8. In the **Minutes for Data Coordination per CRF page** field, ClearTrial displays the number of minutes required to coordinate CRF data and calculates this value based on the phase, therapeutic area, and indication of the study. You can override this value.

9. 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.

10. 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 analyses 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 analyses typically require 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.

11. In the **Number of 3rd 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.

12. In the **Total number of data imports from 3rd 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.

13. In the **Number of AE coded terms** field, enter the number of coded terms for adverse events in the study.

14. In the **Number of Concomitant Medication coded terms** field, enter the number of coded terms for concomitant medications in the study. Concomitant medications are prescription medications, over-the-counter drugs, or dietary supplements that a clinical trial participant happens to be taking at the time of the trial in addition to the drug under investigation.

15. In the **Number of Medical History coded terms** field, enter the number of codes for medical history terms.

16. In the **Number of Data Listings** field, accept the default shown (one data listing per month for the months the study is conducted) or override the default value.

17. In the **Number of Unique Pages** field, 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.

18. In the **Number of screens per CRF page** field, specify the number of screens needed to capture one paper CRF page.

19. Continue by specifying the assumptions in the Biostatistics section or click **Save**, and then **Next** to specify monitoring assumptions.

• Factors for Choosing the EDC Maturity Level
   Which EDC stage or maturity level you choose depends on if you have worked with that EDC vendor before for a trial.

Factors for Choosing the EDC Maturity Level

Which EDC stage or maturity level you choose depends on if you have worked with that EDC vendor before for a trial.

• If a customer or sponsor has not used an Electronic Data Capture (EDC) vendor before for any of their trials, they should select Stage 1 because it is more efficient that to start from scratch.

• The higher the maturity level chosen, the more efficient setting up data collection is. The EDC vendor doesn't have to rebuild data specifications and can use existing data points /schema objects from previous trials instead of starting from scratch.

Specify Biostatistics Assumptions

Biostatistics is the study of data analysis and statistical reasoning applied practically to medicine and public health.

1. On the **Data** tab, in the **Biostatistics** section, 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.

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

3. Continue by specifying the assumptions in the Project Management section or click **Save**, and then **Next** to specify monitoring assumptions.

Specify Project Management Assumptions

In the Project Management section of the Data Management tab, specify the media to be used to inform investigators and sponsors of overall study progress and how training is to be performed.

1. On the **Data** tab, in the **Project Management** section, in the **Number of newsletters** field, indicate how many times you expect to generate newsletters for the sites. 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.

   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. ICF refers to the International Classification of Functioning, Disability, and Health, a framework for describing and organizing information on functioning and disability.

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.

4. If you selected **Electronic Data Capture (EDC)** or **EDC - 3rd Party** in the Data Management section, specify the number of online EDC training sessions required.

   > ✐ **Note:**
   >
   > This is not the training that happens at the Investigator Meeting or the initial CRA training.

5. Continue by specifying the assumptions in the eTMF (Electronic Trial Master File) section or click **Save**, and then **Next** to specify monitoring assumptions.

Specify Electronic Master Trial File (eTMF) Assumptions

These assumptions drive electronic Trial Master File indirect costs and fees estimated in a study plan budget.

1. On the **Data** tab, in the **eTMF (Electronic Trial Master File)** section, specify the following assumptions:

   • **Number of eTMF Country/Region Files** - Specify the number of eTMF Country/Region files. ClearTrial defaults to one country/region file per location entered in a plan.
     This assumption value drives the defaults provided for the following tasks:

     – eTMF Country/Region File Setup

     – eTMF Country/Region File Maintenance

     – eTMF Country/Region File Close-out

     – The associated Sponsor Oversight tasks

   • **Number of eTMF Site Files** - Specify the number of eTMF site files. ClearTrial defaults to one eTMF site file per site entered in a plan. This assumption value drives the default included effort for the following tasks:

     – eTMF Site File Setup

     – eTMF Site File Maintenance

     – eTMF Site File Close-out

     – The associated Sponsor Oversight tasks, as well as the default pass-through cost

     – TMF Shipping

   • **Number of months for the Vendor to archive the eTMF** - Specify the number of months for the vendor to archive the eTMF.
     ClearTrial defaults this value to 12 months. This assumption's value drives the default pass-through cost for TMF Archival. If this pass-through cost is assigned to the sponsor, then it will calculate as zero.

2. Continue by specifying the assumptions in the Medical Writing / Timelines section or click **Save**, and then **Next** to specify monitoring assumptions.

Specify Medical Writing Assumptions

The medical writing assumptions you specify govern creation of an Investigator Brochure, manuscripts for industry journals, and the final study report.

1. On the **Data** tab, in the **Medical Writing / Timelines** section, in the **Number of pages in the Investigator Brochure** field, specify the number of pages for the *Investigator Brochure*, which can be a few pages to over 250 pages.

   • The *Investigator Brochure* describes 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 as well as precautions or special monitoring required.

   • You submit 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.

   • ClearTrial 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 you expect to effectively calculate the effort required to print and distribute the brochure.

- The default value for this field assumes that the sponsor requires that a full *Investigator Brochure* be written and edited for each new study.

- If the *Investigator Brochure*:

  – Has been previously written, you can exclude the **Write Investigator Brochure** task on the Assignment tab.

  – If the brochure has been written but needs updating, include **Edit Investigator Brochure** on the Assignment Tab.

  – If no updates are required, exclude **Edit Investigator Brochure**.

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 the study's primary data management cycle times if they vary from the default values displayed.

   ClearTrial's cycle time defaults are based on the study phase, data collection method, and EDC maturity level/stage. Based on the values entered for the following assumptions, ClearTrial predicts and displays the study's primary milestone dates for Database Lock, Stat Report, Draft Report, and the Final Clinical Study Report.

   - In the **Days from LSLT/LPLT until Database Lock** field, specify the number of estimated days from last subject last treatment until the database will be locked.

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

   - In the **Days from Database Lock until Draft Report due** field, specify the number of estimated 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 report completed, expressed in elapsed days from the database lock date.

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

4. Continue by specifying the assumptions in the End of Study section or click **Save**, and then **Next** to specify monitoring assumptions.

Specify End-of-Study Assumptions

ClearTrial predicts end-of-study milestone dates such as Database Lock (EOS), Stat Report (EOS), Draft Report (EOS) and Final Report (EOS) based on the assumption values entered for these fields.

These follow-up specific milestone/timeline assumptions are displayed only if you have defined one or more treatment arms in a plan with a follow-up period.

1. On the **Data** tab, in the **End of Study** section, in the **Will there be a Supplemental CSR?** field, specify if there will be another CSR to account for the data from the first follow-up visit to the study/budget end.

2. In the **Reduce effort for Supplemental CSR by** field, specify the percentage to reduce the default effort included in delivering the Supplemental CSR during follow-up.

3. In the **Days from LSLV/LPLV until Database Lock (EOS)** field, specify the number of days estimated from LSLV/LPLV until the Database Lock at the End-of-Study (EOS).

   This is the time (in days) from the last patient's last follow-up visit/data collection event until the Database Lock (EOS) that occurs after the follow-up or at the end of the study.

4. In the **Days from Database Lock (EOS) until Statistical Report (EOS) due** field, specify the number of estimated days from the Database Lock (EOS)/End-of-Study date until the Statistical Report (EOS)/End-of-Study is expected to be delivered.

5. In the **Days from Database Lock (EOS) until Draft Report (EOS) due** field, specify the number of estimated days from the Database Lock (EOS) / End-of-Study date until the Draft Clinical Report (EOS) / End-of-Study is expected to be delivered.

6. In the **Days from Database Lock (EOS) until Final Report (EOS) due** field, specify the estimated days from the Database Lock (EOS) / End-of-Study date until the Final Clinical Study Report (EOS) / End-of-Study is delivered.

7. ClearTrial determines when the costing for the planned trial will end, known as the Study/Budget End date.

   • When no treatment arms have follow-up periods defined, enter a value in the **Days from Final Clinical Study Report (CSR) to Study/Budget End** field. Enter 0 to stop accounting for all effort and costs at the date the final report is delivered.

   • When one or more treatment arms in a plan have a follow-up period defined, enter a value in the **Days from Final CSR (EOS) to Study/Budget End** field.

8. Continue by specifying the assumptions in the Safety and Medical Management section or click **Save**, and then **Next** to specify monitoring assumptions.

Specify Safety and Medical Management Assumptions

Enter your assumptions about anticipated Serious Adverse Events (SAEs) in the Safety and Medical Management section of the Data tab.

1. On the **Data** tab, in the **Safety and Medical Management** section, 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 SAEs across all subjects over the entire duration of the study.

   • When each subject is expected to experience multiple SAEs, this percentage can be greater than 100.

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 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. If applicable, 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).

5. Continue by specifying the assumptions in the IVRS (Interactive Voice Response System section or click **Save**, and then **Next** to specify monitoring assumptions.

Select Interactive Voice Response System Usage

ClearTrial uses the term IVRS for any automated system or interactive response technology (IRT) used to randomize subjects, schedule drug shipments, or maintain an online subject diary.

1. On the **Data** tab, in the **IVRS (Interactive Voice Response System)** section, select the **IVRS Usage** options that identify how the Interactive Voice Response System (IVRS) will be used.

    • Randomization

    • Drug Distribution

    • Subject Diary

    • Market Study

2. Continue by specifying the assumptions in the Expected Protocol Amendments section or click **Save**, and then **Next** to specify monitoring assumptions.

Anticipate Changes to the Protocol

Updates to the protocol are common in clinical trials. You can account for anticipated changes in the form of protocol amendments added to the plan. Planning for these amendments makes the study budget more accurate.

1. On the **Data** tab, in the **Expected Protocol Amendments** section, click the **Add an amendment** link.

2. In the **An amendment is expected to occur** field, 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.

    ClearTrial 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 and follow the instructions in Step 2.

Assign Responsibilities

You can identify an outsourcing option for each group of assignable tasks.

1. On the **Data** tab, in the **Assignments / Responsibilities** section, Select a radio button to specify the outsourcing option for each group of assignable tasks. The outsourcing option

(conducted Internally, Outsourced, or Combination) specified on the **Overview** tab, determines which options are enabled.

- If you want all the tasks in that assignment group to be assigned to the study sponsor, choose **Sponsor**.

- To initially assign all the tasks in that group to the primary provider specified on the Provider tab, select **Vendor**.

- If you want to assign some of the tasks in that group to a vendor and other tasks to the study sponsor, selected **Mixed**. Assignments at a more granular level by task can be made on the Assignment tab.

- If none of the tasks in that group will be performed or the service is excluded from the trial, select **N/A**.

2. Click **Save**, and then **Next** to specify monitoring assumptions.

Review and Adjust Monitored Data on the Monitoring Tab

On the Monitoring tab you can specify information about the global and by location monitoring assumptions in a plan.

Your edit mode determines the fields shown on the Monitoring tab. For more information about any field, click the field name to display online help.

- Specify the Monitoring Methods
  Specify whether monitoring will be performed on-site, remotely, centrally, or by a combination of these methods and whether to specify monitoring assumptions globally or by location.

- Accept or Modify the On-site Monitoring Schedule
  The default on-site monitoring schedule uses a frequency-based model to calculate the total number of on-site visits. The frequency impacts the length or duration of the visits.

- Review the Remote Monitoring Schedule
  If you chose **Remote** from the **Monitoring Methods** section of the **Monitoring** tab, the default schedule uses a frequency-based model to calculate the total number of remote visits.

- Review the Remote Monitoring Schedule for Centralized Monitoring
  If you chose **Centralized** from the **Monitoring Methods** section of the **Monitoring** tab, then corresponding default labor will be included in the budget.

- Define the Monitoring Approach
  In the Monitoring Approach section of the Monitoring tab, enter detailed assumptions about who will perform monitoring and how they will work.

- Specify Total CRF Pages Expected
  In the Monitored Data section of the Monitoring tab, enter the total number of CRF pages to be generated and monitored.

- Review and Adjust Medical Monitoring Assumptions
  In the Medical Monitoring section of the Monitoring tab, review and adjust the time for a medical monitor to serve as the team medical lead and provide support to the CRA monitoring staff and investigators for issues beyond safety reporting.

- Review and Adjust Separate Drug Accountability Visits
  Will there be additional drug accountability visits? Separate drug accountability generally applies to oncology and some vaccine studies and is done by someone other than the CRA that monitors the site.

Specify the Monitoring Methods

Specify whether monitoring will be performed on-site, remotely, centrally, or by a combination of these methods and whether to specify monitoring assumptions globally or by location.

Your edit mode determines which fields are displayed and available to override to enter a different value than the default value provided.

1. On the **Monitoring** tab, in the **Monitoring Methods** section, specify the types of monitoring to be performed.

   - **On-site**—On-site monitoring is linked to Source Data Verification (SDV) where the monitor (CRA) reviews the Case Report Form (CRF) data against the clinical source data (EMR/EHR data, lab data, imaging data, etc.) to verify accuracy and completeness in accordance with ICH GCP regulatory guidelines. Calculation of the on-site monitoring effort is based on the number of CRF pages planned per subject multiplied by the monitoring minutes per CRF page (driven by the therapeutic area and indication of a study) to determine the total effort to monitor/SDV the CRF data. In addition to the monitoring effort required for SDV, the effort for the visit preparation, travel time, on-site time not related to SDV (defined below), report/follow-up, is calculated by the frequency defined from the First Subject First Screening Visit to the Last Subject Last Follow-Up Visit (FSFV-LSLV).

     If you already know the total on-site monitoring visits and you don't want ClearTrial to calculate that for you, you can override the system-calculated value to use downstream and ignore the default or ClearTrial-defined on-site monitoring schedule.

   - **Remote**—Remote visits may be added on top of any on-site SDV monitoring strategy, but aren't linked to SDV. Remote monitoring supplements the on-site activities done by the monitor (CRA) and is calculated based on the assumption values you defined for the frequency or average hours per remote visit.
     If you already know the total remote monitoring visits and you don't want ClearTrial to calculate that for you, you can override the system-calculated value to use downstream and ignore the default or ClearTrial-defined remote monitoring schedule.

   - **Centralized**—Centralized monitoring is conducted centrally and performed by a centralized team by default, as opposed to a field-based monitoring team (CRAs). Incorporating centralized monitoring as part of a risk-based monitoring approach helps reduce risk and ensure quality by allowing potential anomalies or risks to be detected more quickly.
     Centralized monitoring looks across all subject data across all sites and identifies any outliers to determine if there is an anomaly. When an anomaly is detected, a query may be issued, closer examination of data at a site may be completed, an extra visit may be added, or some other Risk-based Monitoring (RBM) mitigation action may be performed.

     Activities include identifying Key Risk Indicators (KRIs) upfront at the beginning of a study and setting risk thresholds. During the study, activities include conducting and reviewing monthly KRI data dashboards and performing analyses across all subjects and sites to identify anomalies for action remediation.

     Sites with multiple issues detected through centralized monitoring can provide an early signal of a need for an on-site visit and corrective actions to minimize the likelihood of similar issues occurring during the remainder of the trial.

You can select all three options.

2. In the **Manage monitoring schedule values** field, specify whether to manage monitoring schedules globally or per location.

- If you manage monitoring schedules globally, ClearTrial applies all of the assumptions you enter in the **On-Site Monitoring Schedule** section or **Remote Monitoring Schedule** section 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. On the **Edit Per Location Monitoring Schedule** screen you can select each location and edit that location's monitoring methods, define the schedules by frequency, or override the total number of visits to be leveraged downstream.

3. Continue by reviewing and fine-tuning the on-site and remote monitoring schedules as necessary.

Accept or Modify the On-site Monitoring Schedule

The default on-site monitoring schedule uses a frequency-based model to calculate the total number of on-site visits. The frequency impacts the length or duration of the visits.

If you chose **on-site** from the **Monitoring Methods** section of the **Monitoring** tab, you can specify details about the on-site monitoring schedule.

1. In the **On-Site Monitoring Schedule** section of the **Monitoring** tab, in the **Monitor every** field, specify how frequently a monitor (CRA) will visit the sites in the study during each period of the monitoring schedule across screening, treatment, and follow-up sements (between FSFV and LSLV).

2. Choose the frequency:

- If visits will continue at the specified frequency throughout the study enrollment, treatment, and follow-up segments (FSFV to LSLV or Last Subject Last Follow-up Visit, select **until LSLV**.
  When there are no treatment arms with a follow-up treatment defined, then $LSLV = LSLT$. When there is a follow-up period defined for one or more treatment arms, then $LSLV = LSLFU$ (Last Subject Last Follow Up visit/data collection event).

- If the monitoring frequency will change during the treatment or follow-up period, select the **until week** radio button and define a new frequency for the next or remaining intervals.

- If you want to use a variable monitoring frequency; for example, visiting 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 **Monitor 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. Now, specify what happens in the next monitoring period. Enter a value for the **Monitor every** field and choose **until LSLV** or **until week**.

    d. Repeat as necessary to define each change in frequency over the course of the monitoring schedule.
ClearTrial calculates the total number of visits to be made, derived from the remote monitoring frequency and the subject enrollment rate, and displays it in the **Total Remote Visits** field.

    e. If you know the total on-site visits and you can't achieve it by adjusting the frequency of visits per interval, you can override the system-calculated value. The overridden value will be used downstream instead of the ClearTrial default or the user-defined on-site monitoring schedule values.

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

- ClearTrial derives the default value shown from the total number of sites, monitoring frequency, and subject enrollment rate, treatment, and follow-up periods (FSFV to LSLV). 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 ClearTrial calculates 1068 visits and there are 89 sites in the study of 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 entered be as close to the value calculated by ClearTrial as possible. That is, try to adjust the monitoring frequencies to arrive at the desired value and, only if you cannot achieve the desired number, enter a new value to override the calculated value.

4. From the **Monitoring Travel Strategy** drop-down list, specify the monitoring visit strategy to use for most of the monitoring trips.

- **Spoke monitoring**— The monitors return to their homes or offices between each visit.

- **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.
For studies that have slower enrollment, with slower data being generated and slower distribution, such as Oncology studies, Oracle recommends using the Spoke travel strategy because there will be less frequent visits but of longer duration.

  For studies with shorter enrollment periods and more even distribution and generation of CRF data across sites, use the Loop visit strategy to leverage more frequent visits of shorter durations. A local CRA can monitor multiple sites in one trip before returning home. ClearTrial defaults to Loop visits because they are more cost efficient.

- Use the Monitoring Schedule chart or the Monitoring sections of the Assumptions report to verify the schedule.

- Note that ClearTrial always assumes Spoke travel for closeout visits.

5. Set up the monitoring approach or click **Next** to open the Provider tab.

Review the Remote Monitoring Schedule

If you chose **Remote** from the **Monitoring Methods** section of the **Monitoring** tab, the default schedule uses a frequency-based model to calculate the total number of remote visits.

> **Note:**
>
> When you select **Centralized** monitoring, corresponding labor activities are included by default in the budget.

1. In the **Remote Monitoring Schedule** section of the **Monitoring** tab, in the **Monitor every** field, specify how frequently a monitor will contact the sites during each period of the monitoring schedule.

2. If the remote monitoring will continue at the specified frequency throughout the study enrollment, treatment and follow-up periods (FSFV to LSLV), select **until LSLV**.

   - If the monitoring frequency will change during the treatment or follow-up period, the select the **until week** radio button and define a new frequency for the next (or remaining) period.

   - If there are no treatment arms with a follow-up treatment defined, then `LSLV = LSLT`. When there is a follow-up period defined for one or more treatment arms, then `LSLV = LSLFU` (Last Subject Last Follow Up visit or data collection event).

3. If you want to use a variable monitoring frequency; for example, contacting 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 **Monitor every** field, select **until week** and enter the week at which this frequency ends and a new monitoring frequency begins.

   b. Now, specify what happens in the next monitoring period. Enter a value for the **Monitor every** field and choose **until LSLV** or **until week**.

   c. Repeat as necessary to define each change in frequency over the course of the monitoring schedule.
   ClearTrial calculates the total number of contacts to be made, derived from the remote monitoring frequency and the subject enrollment rate, and displays it in the **Total Remote Visits** field.

   d. If you know the total remote visits and you can't achieve it by adjusting the frequency of visits per interval, you can override the system-calculated value. The overridden value will be used downstream and instead of the ClearTrial default or the user-defined remote monitoring schedule values.

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

5. Set up the monitoring approach or click **Next** to open the Provider tab.

Review the Remote Monitoring Schedule for Centralized Monitoring

If you chose **Centralized** from the **Monitoring Methods** section of the **Monitoring** tab, then corresponding default labor will be included in the budget.

> **✎ Note:**
>
> If you also chose **Remote** from the **Monitoring Methods** section of the **Monitoring** tab, the default schedule uses a frequency-based model to calculate the total number of remote visits.

1. In the **Remote Monitoring Schedule** section of the **Monitoring** tab, in the **Monitor every** field, specify how frequently a monitor will contact the sites during each period of the monitoring schedule.

2. If the remote monitoring will continue at the specified frequency throughout the study enrollment, treatment and follow-up periods (FSFV to LSLV), select **until LSLV**.

   - If the monitoring frequency will change during the treatment or follow-up period, the select the **until week** radio button and define a new frequency for the next (or remaining) period.

   - If there are no treatment arms with a follow-up treatment defined, then `LSLV = LSLT`. When there is a follow-up period defined for one or more treatment arms, then `LSLV = LSLFU` (Last Subject Last Follow Up visit or data collection event).

3. If you want to use a variable monitoring frequency; for example, contacting 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 **Monitor every** field, select **until week** and enter the week at which this frequency ends and a new monitoring frequency begins.

   b. Now, specify what happens in the next monitoring period. Enter a value for the **Monitor every** field and choose **until LSLV** or **until week**.

   c. Repeat as necessary to define each change in frequency over the course of the monitoring schedule.
   ClearTrial calculates the total number of contacts to be made, derived from the remote monitoring frequency and the subject enrollment rate, and displays it in the **Total Remote Visits** field.

   d. If you know the total remote visits and you can't achieve it by adjusting the frequency of visits per interval, you can override the system-calculated value. The overridden value will be used downstream and instead of the ClearTrial default or the user-defined remote monitoring schedule values.

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

5. Set up the monitoring approach or click **Next** to open the Provider tab.

Define the Monitoring Approach

In the Monitoring Approach section of the Monitoring tab, enter detailed assumptions about who will perform monitoring and how they will work.

> **Note:**
>
> These monitoring assumptions are only available in Advanced or Expert Edit Mode.

1. On the **Monitoring** tab, in the **Monitoring Approach** section, enter the following details.

   - **Percentage of time monitors spend in the field**—Specify the percentage of time monitors spend in the field. It is assumed that the remainder of their time is spent on site-management activities. Adjusting the percentage modifies the default calculation for site management.

   - **Percentage of monitoring done by CRAs (vs. senior CRAs)**—Specify the percentage of monitoring and site management that will be done by staff CRAs versus senior CRAs. In more complex studies, you might prefer that a senior CRA perform a larger percentage of the monitoring. If this is the case, decrease this percentage to indicate that less of the monitoring will be done by CRAs. Enter 100% if all monitoring will be done by CRAs; enter 0% if all monitoring will be done by senior CRAs.

   - **Percentage of monitoring done by Regional Monitors**—Specify the percentage of monitoring that will be done by regional monitors. The remaining monitoring and site management-activities are split between CRAs and senior CRAs, according to the value indicated in the **Percentage of monitoring done by CRAs (vs. senior CRAs)** field. Even when 100% of monitoring is done by regional monitors, some site management activities are still performed by CRAs or SCRAs..

     > **Note:**
     >
     > The values in this field is not related to travel time or distance. This value is used to split the effort of monitoring and site-management tasks across resources that have different billing rates.

     When 100% of monitoring is done by regional monitors, some site management activities will still be performed by CRAs or SCRAs.

     When using regional monitors, time allocated for travel will be assigned to clean, monitored CRF and site management tasks.

   - **Average travel time (in hours) for site monitors**—Specify the average number of hours a monitor requires to travel to sites. This value should represent the average travel time from site to site as well as from a monitor's home.

- If you chose Loop visits for the monitoring travel strategy, this value is used to calculate the time from the monitor's home to the first site, then to the second site, and so on, until the monitor returns home.

- If you chose Spoke visits for the monitoring travel strategy, this value is multiplied by 1.75 to calculate the travel time to and from the monitor's home or office to the site. Note that close-out visits are assumed to always use the Spoke travel strategy, even if the interim monitoring visits are performed via Loop travel.

- **Percent of source documentation verification**—Specify the percent of data to be source-verified while monitoring the data. ClearTrial assumes and defaults to 100% of all data points per CRF page per study to be source-verified. You can define or override the default value and other related monitoring assumptions as needed based on their risk-based monitoring strategy.
  ClearTrial assumes 100% SDV by default, calculated by multiplying the Total Number of CRF Pages by the Monitoring Minutes per Page (driven by a study's Therapeutic Area and Indication) to determine the total amount of time related to on-site SDV. If you are performing targeted or reduced SDV, there are two factors you can leverage to model this.

  - **Adjusting the *Percent of source document verification* or SDV% assumption value**—For example, if only 70% of the data points per page of each CRF page will be reviewed, define 70% SDV, which will reduce the **Monitoring Minutes per Page** by 70%.

    > **✎ Note:**
    >
    > Reducing the SDV% does not drive or adjust the **Total CRF pages monitored** assumption value.

  - **Adjusting the *Total CRF pages monitored* assumption value**—For example, if only the significant data points per CRF page (efficacy and safety) will be reviewed, then define or leave 100% SDV and adjust the **Total CRF Pages monitored (accounting for subject drops)** assumption accordingly.

- **Time to review queries from previous visit (minutes)**—ClearTrial calculates this value representing the number of minutes required to re-review queries and CRF data from a previous monitoring visit, based on the phase, therapeutic area, and indication selected for the study. You can override this value.

- **Other (Non-SDV) hours on-site per visit**—Specify the number of hours expected during each visit to perform activities not directly related to source document verification. Example activities include reviewing logs (subject screening, subject visit, subject discontinuation and termination, drug accountability, and others), confirming site adequacy or site status, and verifying adequate study supplies exist. The default value for this field is based on Phase, Therapeutic Area, and Indication. You can override this value.

- **Manage location-specific values**—Enter monitoring approach assumptions per location by clicking the **Edit location-specific overrides** link. On the **Edit Per Location Monitoring Approach** screen, enter the monitoring approach assumptions for each location, overriding global default values where necessary, then click **Ok**.

2. Enter the details for monitoring data through CRF pages in the **Monitored Data** section or click **Next** to enter assumptions on the **Provider** tab.

Specify Total CRF Pages Expected

In the Monitored Data section of the Monitoring tab, enter the total number of CRF pages to be generated and monitored.

> **✎ Note:**
>
> These monitoring assumptions are only available in Advanced or Expert Edit Mode.

1. On the **Monitoring** tab, in the **Monitored Data** section, enter the following details.

   • **Total CRF pages generated (without subject drops)—**ClearTrial calculates this value as the total number of expected CRFs that will be generated assuming no subjects drop out of the study (ignoring subjects expected to drop via the subject drop rate per segment). It is a summation of all CRF pages completed for each subject visit across all subjects and sites, as defined on the Subject Treatment/Visit Schedule.

   • **Total CRF pages monitored (accounting for subject drops)**—This value represents or ClearTrial calculates this value as the expected CRFs that will be monitored, accounting for any subjects that drop out of the study during the screening, treatment, or follow-up segments. The default value is derived from the subject drop rate per segment, which is applied to each week of the study to calculate the subject retention rate.
   To determine the total number of CRFs including drops, ClearTrial assumes the following:

     – For the first two weeks of enrollment, ClearTrial assumes that no subjects drop. Therefore, retention for weeks 1 and 2 is 100% and ClearTrial assumes that all scheduled CRF pages are completed.

     – For each week after week 2 of enrollment; that is, the total enrollment period minus the first two weeks, the system starts correcting the total number of CRFs completed by the drop 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.

     – Finally, the system 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 described above to calculate the CRFs including drop outs.

   You may 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 drops.

2. Specify medical monitoring assumptions or click **Next** to enter assumptions on the **Provider** tab.

Review and Adjust Medical Monitoring Assumptions

In the Medical Monitoring section of the Monitoring tab, review and adjust the time for a medical monitor to serve as the team medical lead and provide support to the CRA monitoring staff and investigators for issues beyond safety reporting.

> **Note:**
>
> These monitoring assumptions are only available in Advanced or Expert Edit Mode.

1. On the **Monitoring** tab, in the **Medical Monitoring** section, select the **24/7 coverage** radio button to require 24/7 coverage by the medical monitor for the study. This means the medical monitor is *on call* to address any site- or subject-related questions including, but not limited to, subject inclusion/exclusion criteria in accordance with the protocol, protocol violations or deviations that may occur during the study, or any other general medical monitor-related questions.

2. In the **Number of medical data listing reviews** field, enter the number of reviews required for the particular study being planned.

3. Enter drug accountability options in the **Separate Drug Accountability** section or click **Next** to enter assumptions on the **Provider** tab.

Review and Adjust Separate Drug Accountability Visits

Will there be additional drug accountability visits? Separate drug accountability generally applies to oncology and some vaccine studies and is done by someone other than the CRA that monitors the site.

Separate drug accountability visits are required when the study drug or test article is visibly different or packaged differently than the placebo. If the unblinded monitor conducts their drug accountability review of the study drug or test article, it could cause unintentional unblinding of the study monitor. In this scenario, the drug accountability is done by someone other than the CRA that monitors the site to ensure that all involved in the study are completely blinded.

> **Note:**
>
> These monitoring assumptions are only available in Advanced or Expert Edit Mode.

1. On the **Monitoring** tab, in the **Separate Drug Accountability** section, specify the following details:
    *   **Will there be additional drug accountability visits?**—Specify whether drug accountability visits are required.
        Separate drug accountability visits are required when the study drug or test article is visibly different or packaged differently than the placebo. If the unblinded monitor conducts their drug accountability review of the study drug or test article, it could cause unintentional unblinding of the study monitor. In this scenario, the drug accountability is done by someone other than the CRA that monitors the site to ensure that all involved in the study are completely blinded.

- **Additional drug accountability visits performed by**—Specify who will perform additional drug accountability visits, if applicable.

- **Additional drug accountability visits per site**—Specify the number of additional drug accountability visits that will be made per site.

2. Save any changes you have already made.

3. Click **Next** to enter assumptions on the **Provider** tab.

Add Vendors and Service Providers on the Provider Tab

On the Provider tab, you can add vendors to the list of possible service providers to use and designate a primary provider to which outsourced tasks are automatically assigned. However, you make the assignments to service providers on the Assignment tab.

- Adding a provider does not automatically assign that provider to any tasks.

- Before assigning any tasks to a service provider, that service provider must be defined in your environment and have published billing rates.

- You can assign tasks by provider on the Assignment tab or in the Task Manager.

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

2. On the **Choose Service Providers** screen, select the check box associated with one or more service providers listed.

> **Note:**
>
> To be added to the plan, published billing rates must exist for the service providers. ClearTrial displays warning icons if published rates do not match the chosen rate year or no inflation profiles exists for the provider.

3. Click **Ok**.

   ClearTrial adds the selected providers to the list of providers associated with the plan.

4. Add details about the provider and an inflation profile by clicking the **Provider Name** of the newly added provider, or **Next** to add or remove meetings on the **Meetings** tab.

- Specify Provider-specific Information on the Details Tab
  Once you have added a provider to the plan, specify investigator meeting attendance and other details.

- Create or Edit 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 for user-defined providers from the Maintain menu.

- Designate a Primary Service Provider
  The Primary Service Provider is automatically assigned to tasks indicated as outsourced to Vendor. Additionally, tasks assigned to vendors who are removed get reassigned to the Primary Service Provider.

- Freeze and Unfreeze Rates for a Service Provider
  On the Provider tab, above the list of providers, is a Freeze Rates / Unfreeze Rates button that freezes or unfreezes billing rates for a selected service provider.

- Remove Service Providers from Plans
  You can remove service providers from plans.

- Replace a Service Provider
  If you have overridden several assumptions specific to a provider in your plan and want to use another provider instead, replace the provider rather than remove it.

Specify Provider-specific Information on the Details Tab

Once you have added a provider to the plan, specify investigator meeting attendance and other details.

1. On the **Provider** tab, click the **Provider Name** to display the **Details** tab on the **Specify Provider-Specific Details** screen.

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

   - **Rate Year in effect**—Specify which set of billing rates to use to calculate the provider's fees. ClearTrial uses the hourly rates published for this provider for the rate chosen, plus or minus any discount indicated, 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. ClearTrial 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 billing rate location for one or more tasks if necessary.

   - **Bottom Line Discount**—Specify any negotiated monetary discount established with this provider for the trial. Select the currency in which you have specified the discount from the drop-down list. If there is more than one provider for a plan, each may offer a different discount.

   - **Currency Exchange Rate**s—Choose an option to indicate which exchange rates ClearTrial uses to convert between currencies:

     – **Use rates defined on the Plan Overview tab**—Do not override any exchange rates specified for this specific provider.

     – **Use rates defined below**—This option opens 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, 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; that is:

- 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.

4. In the **Other** section, which in available only in Advanced edit mode or higher, in the **Number of sponsor affiliates** field, specify the number of sponsor affiliates with which this provider will work.

5. In the **Type of reporting to affiliates** field, select one or more kinds of reporting to affiliates required of sponsor affiliates: Safety, Monitoring, or Site Progress.

6. From the **Additional type of vendor with which this service provider will work** drop-down list, select the relationship that this vendor has with these other third parties. Don't include casual relationships where there is little or no daily interaction.

7. In the **Will this provider manage the CTMS** field, specify whether or not this provider enters data into the sponsor's Clinical Trial Management system.

8. Click **Ok**.

Create or Edit 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 for user-defined providers from the Maintain menu.

When using a ClearTrial built-in provider, or a user-defined 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 updates as needed.

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

1. On the **Provider** tab, click a **Provider Name** to display the **Specify Provider-Specific Details** screen.

2. Click the **Inflation** tab.

3. In the **Compound inflation annually** field, select **Yes** or **No**.

4. To change inflation rates for the selected service provider, enter the new rate for each location for each year.

5. To remove a single override, highlight the value in the cell and press the **Delete** key.

6. To remove all overrides, click **Clear Overrides**.

7. To reset the inflation rate to zero, click **Set Inflation to 0%**.

8. Click **Ok**.

> **Tip:**
>
> To quickly update the inflation table to your desired rates, override only the default inflation values for the locations included in the 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 a plan without inflation, click **Set Inflation to 0%**.

Designate a Primary Service Provider

The Primary Service Provider is automatically assigned to tasks indicated as outsourced to Vendor. Additionally, tasks assigned to vendors who are removed get reassigned to the Primary Service Provider.

1. On the **Provider** tab, select the check box of a service provider 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**.

Freeze and Unfreeze Rates for a Service Provider

On the Provider tab, above the list of providers, is a Freeze Rates / Unfreeze Rates button that freezes or unfreezes billing rates for a selected service provider.

- If there is a **Freeze Rates** button, no rates have been frozen.

- If there is an **Unfreeze Rates**, button, billing and inflation rates have been frozen for this plan.

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

The **Rate Year in Effect** column shows the rate year ClearTrial 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. If you click the icon, a message states that neither billing rates nor inflation rates have been published for the provider for the year the study is expected to start.

If you click the **Unfreeze Rates** button, ClearTrial deletes the copied rates and uses the current published rates for the service providers to calculate expected direct costs for this plan. The plan reflects any changes to the billing rates for its service providers.

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

Remove Service Providers from Plans

You can remove service providers from plans.

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

2. On the **Plans** screen, select the plan to edit, then click **Edit**.

3. On the **Provider** tab, select one or more service providers and click **Remove Provider(s)**.

   Tasks that have been assigned to a removed Service Provider are reassigned according to the following rules:

   • 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.

4. Click **Save**.

Replace a Service Provider

If you have overridden several assumptions specific to a provider in your plan and want to use another provider instead, replace the provider rather than remove it.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Provider** tab, select the service provider and click **Replace Provider**.

4. Choose a different service provider to replace the existing service provider in your plan.

5. Click **Ok**.

ClearTrial preserves all existing service provider assignments and provider-specific overrides and replaces the service provider with your new choice.

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

Set Up Meeting Details and Attendees on the Meetings Tab

On the Meetings tab, add or remove meetings, specify meeting details and attendees, add notes for each meeting, and estimate meeting costs.

You can plan recurring meetings, mixed attendance meetings (where some attendees travel and others join via web conference), and Investigator Meetings (with expected attendees from sites).

*   Add a Meeting
    You add meetings on the Meetings tab. After you specify the meeting type, you can add meeting details and attendees.

Add a Meeting

You add meetings on the Meetings tab. After you specify the meeting type, you can add meeting details and attendees.

1. On the **Meetings** tab, click **Add**.

2. On the **Define New Meeting** screen, 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** to define the meeting details and manage attendees on the **Meeting Details** screen.

*   Define the Meeting and Service Providers Attending
    On the Meeting Details screen, you can specify the location, schedule, attendees, and pass-through costs associated with the resources attending the meeting.

*   Add Meeting Attendees by Provider
    Once you have scheduled a meeting on the Meeting tab and provided details about the meeting and identified the providers attending on the Meeting Details screen, you can add the attendees for each provider that will be invited to attend the meeting on the Attendees tab.

*   Manage Attendees from Investigator Sites
    If the meeting type involves on-site attendees, you can specify on the Site Attendees tab the number of attendees per site, percentage of sites represented, location, attendance method, and indirect costs associated with the meeting.

Define the Meeting and Service Providers Attending

On the Meeting Details screen, you can specify the location, schedule, attendees, and pass-through costs associated with the resources attending the meeting.

1. Once you have added a meeting by giving it a name and assigning its type, click **Continue** to display the **Meeting Details** screen.

2. On the **Meeting Details** tab, in the **Meeting Definition** section, specify basic information about the meeting:

- Select the service provider responsible for planning and organizing the meeting from the **Organizer/Planner** drop-down list.

- Select the country where the meeting will occur from the **Location** drop-down list.

- In the optional **City** field, enter the name of the city where the meeting will take place.
  In the **Non-travel costs** field, enter your budget for audio-visual equipment rental, meeting space, and so on and select the currency for managing event costs.

  > **Note:**
  >
  > The default travel costs include all indirect costs for the resource traveling to the meeting, such as airfare and lodging, however, meals are not included.

3. In the **Schedule** section, enter the meeting frequency, start and end, and duration.

   - Select the frequency of the meeting from the **Occurs** drop-down list.

   - In the **Starts** field, specify the number of days before or after the selected project milestone that the meeting is expected to occur.

     > **Note:**
     >
     > The start date cannot be earlier than the pre-study planning date.

   - Use the **Until** field to create a recurring meeting. After selecting the frequency from the **Occurs** drop-down list and the start date, in the Until field specify the number of days before or after the selected project milestone the meeting reoccurs.
     ClearTrial calculates the number of meetings that will be scheduled.

   - Add the expected length of each meeting in the **Meeting Duration** field.

4. In the **Providers Attending** section, select the check box for each type of service provider to participate in the meeting.

5. Click **Save**.

6. To add the actual attendees, click the **Attendees** tab.

Add Meeting Attendees by Provider

Once you have scheduled a meeting on the Meeting tab and provided details about the meeting and identified the providers attending on the Meeting Details screen, you can add the attendees for each provider that will be invited to attend the meeting on the Attendees tab.

1. On the **Meeting Details** screen, click the **Attendees** tab.

2. From the **Service Provider** drop-down list, select a service provider, then click the **Add** button in the **Provider Attendees** section to display a list of resources you can include in the meeting.

3. Select the check box for each resource to include, then click **Ok** to add these resources to the **Provider Attendees** list for the meeting shown on the **Attendees** tab.

4. For each resource type, specify the number of attendees, the billing rate location (usually the country from which the attendees are traveling), how the attendees will join the meeting, the billable hours expected for meeting attendance, and applicable indirect costs.

   You can sort the table of meeting attendees by clicking any of the column headers or by clicking the ascending or descending arrows to change the sort order.

5. 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 shown in the **Billable Hours** column.

6. Click **Save**.

7. Repeat steps 2 through 6 for each service provider to be represented at the meeting.

8. Now, select the **Site Attendees** tab to add site attendees or click **Save & Close**.

Manage Attendees from Investigator Sites

If the meeting type involves on-site attendees, you can specify on the Site Attendees tab the number of attendees per site, percentage of sites represented, location, attendance method, and indirect costs associated with the meeting.

1. On the **Meetings** tab, select the check box associated with a Face to Face meeting and click **Edit**.

2. On the **Meeting Details** screen, 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** check box and click **Delete**.

   - To duplicate a site attendee, select the site attendee to duplicate and click **Duplicate**. ClearTrial adds the duplicated site attendee to the bottom of the page. You can modify the duplicated values.

   - To add a site attendee, click **Add**. ClearTrial adds another site attendee to the bottom of the page. You can modify the default values used.

3. Click **Save**.

4. Add notes on the **Notes** tab and click **Save** or click **Ok**.

Define Outsourced Tasks on the Assignment Tab

On the Assignment tab, select which location the assignments apply to and a default service provider for outsourced tasks, then, for each task or assignment group, assign a service provider and billing rate location.

> **✎ Note:**
>
> Tasks are added to the ClearTrial Work Breakdown Structure (WBS) with the ClearTrial Task Manager. Enterprise-licensed users can launch the Task Manager by clicking **New Major Task** or **Edit Major Task** from the **Labor** tab of a plan.

Select the location and default service provider for outsourced tasks

1. Select the **Assignment** tab.

2. In the **Task Assignments** section, from the **Values apply to** drop-down list, select the location to assign responsibility for a specific service provider to a specific country or region.

   - Select **Centralized Tasks/Location Defaults** if you want assignments to pertain to every location in the study.

   - Otherwise, select a specific location.

3. Choose the default service provider for outsourced tasks from the **Default Service Provider for outsourced tasks** drop-down list.

   - If all outsourced tasks are to be performed by a single service provider, select that service provider.

   - If outsourced tasks in the plan are performed by various service providers, select the service provider who performs most of the outsourced work.

     Examples

     – Example 1: If **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: If **Values apply to** is set to a country, for example, 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.

4. Click **Save**.

5. If a list of assignment groups and tasks doesn't appear at the bottom of the screen, click the **Show Tasks** link.

6. To see and assign individual tasks, click the triangle to the left of the assignment group or task.

   - To expand all task groups, in the table header bar, double click in the space to the left of the **Assignment Group/Task** column header.

- The **Included** column, which appears only if you expand the task groups, indicates whether this task is included in the study and allows you to exclude a task from the study. If this check box 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 a vendor. 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.

7. For each entry in the **Assignment Group/Task** column, 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, but some tasks are assigned to another provider.

8. From the **Billing Rate Location** drop-down list, select the billing rate location to use to calculate resource costs for this task or group of tasks.

   - You can specify a different billing rate location for each task group or individual 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...**. Choose the location where the work is performed (or from where the resources who will perform the task will come), and then click **Ok**.

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

9. To prevent cascading changes, pin the Service provider and billing rate location assignments by clicking the **Pushpin** in the **Pinned** column to highlight it.

   - As a reminder, the primary provider is distinguishable from other providers on the Provider tab by the ** next to its name.
     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.

- If an assigned provider is deleted from a plan, the task is automatically assigned to the primary provider in the plan.

10. Click **Save**.

11. 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.

12. Override selected resources and rates or click **Next** to view or adjust labor fees.

- Override Resources and Rates
  You can specify substitutions for each resource and/or override the billing rate location and rate by location, per provider.

Override Resources and Rates

You can specify substitutions for each resource and/or override the billing rate location and rate by location, per provider.

Show me how! ▶ Video

1. Select the **Assignment** tab.

2. Click **Save** to save any changes you have already made.

3. In the **Task Assignments** section, click the **Override Resources or Rates** link.

4. On the **Resource Overrides** screen, in the **Scope of Overrides** section, from the **For tasks assigned to** drop-down list, select a service provider.

5. In the **Resources / Overrides** section, specify your override for each default resource specification and pin your changes if desired. If you pin your changes, ClearTrial uses these choices throughout the plan instead of its defaults.

6. Click **Save & Close**.

7. Perform additional overrides, or click **Next** to view or adjust effort and labor fees.

View Major Tasks and Adjust Labor Fees on the Labor Tab

On the Labor tab, review the major tasks in the plan and adjust the calculated labor unit costs and unit hours for each service provider if necessary.

If you are licensed for an Enterprise edition, you also have the flexibility to create and edit major tasks and tasks, and to add and remove resources from tasks.

▶ Video

1. Click the **Labor** tab.

   Major tasks and their expected direct costs are associated with a specific service provider.

2. Choose a viewing option:

   - To view a provider's expected fees, 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 no effort is expected for them for the chosen provider, select the **Show major tasks with no planned effort for the selected provider** check box.

3. Review the hour and cost information for the major tasks listed for the plan. You can:

- Accept the calculated hours and costs, then click **Next** to advance to the Costs tab.

- Adjust the hours or fees by selecting a major task then clicking the **Adjust Hours or Fees** button.

- Add a major task by clicking the **New Major Task** button and following the instructions in Create a Major Task.

- Create a Major Task (Enterprise Edition Only)
  A major task is a ClearTrial term for a group of related tasks that share the same unit of measure, scope (location-scoped or study-scoped), and expected timeframe and distribution of units completed.

- Add a Task for a Major Task
  Tasks are activities performed to accomplish a major task. For each task, you can define its name, uniquely identify it with a code or mapping key, add it to an assignment group, and add resources.

- Configure Resources for User-defined Tasks
  Resources are the roles that people who work on the study are 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.

- Create a Custom Level-of-Effort (LOE) Algorithm
  With the appropriate role granted, user-defined algorithms can be created when you have custom labor activities you need to account for in the budget.

Create a Major Task (Enterprise Edition Only)

A major task is a ClearTrial term for a group of related tasks that share the same unit of measure, scope (location-scoped or study-scoped), and expected timeframe and distribution of units completed.

By default, the major tasks you create appear below the ClearTrial-defined major tasks on the Labor tab in the order you create them. However, you can change the sort order for all major tasks and tasks to align with your custom work breakdown structure.

ClearTrial applies inflation to all major tasks, whether user-defined or ClearTrial-defined, based on the inflation settings on the Provider tab.

▶ Video

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

2. On the **Task Manager** screen, 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. Use a noun or noun phrase. 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.

   - **Location of Labor**—Specify whether associated tasks vary by location (location-scoped) or are centralized (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, subjects, 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 for each location 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 unit of measure is usually the study itself. The unit of measure, also known as the work unit, should ideally be a value that does not vary by location; however, if you choose a value that varies by location as the unit of measure for a study-scoped major task, the number of units will be calculated as the sum across the locations in the trial.

- **Unit of Measure**—From the drop-down list, select the unit of measure for this major task. Both ClearTrial default and user-defined units of measure are available from this list. You can create a custom field and specify it to be used as a work unit and those user-defined work units are distinguishable in the list from the ClearTrial-defined ones. ClearTrial calculates all effort for associated tasks in terms of how many hours it takes to complete one such unit of work.

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

  – User-defined units of work appear in the drop-down list in italicized font followed by an asterisk so you can easily distinguish between custom and default units of measure.
  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.

> **Note:**
>
> Algorithms based on user-defined units of measure may become invalid if the Custom Field Model for the plan is changed.

3. Identify where to display the new major task. From the **Display this Major Task** drop-down list, select **before** or **after**. Then select the major task *before* or *after* which to display the major task.

4. Click **Save**.

5. Click **Close** or the **New Task** button to add a task to the new major task.

Add a Task for a Major Task

Tasks are activities performed to accomplish a major task. For each task, you can define its name, uniquely identify it with a code or mapping key, add it to an assignment group, and add resources.

1. On the **Edit Plan** screen, select the **Labor** tab.

2. Select the major task to which you want to add a task.

   - If you just created a new major task, on the **Major Task Details** tab, click **New Task**.

- If you are adding a task to an existing major task, on the **Labor** tab, select the radio button of the major task to which you want to add a task, click **Edit Major Task**, then, on the **Major Task Details** tab, click the **New Task** button.

3. On the **Task Details** tab, specify the details about the task, keeping in mind that all tasks inherit some characteristics, such as unit of measure, labor scope, and distribution, from their major task.

   - **Name**—Enter a descriptive name for the task.

   - **Grouping Code**—Including a grouping code allows you to quickly identify, organize, and map tasks to align with another WBS. Grouping Code appears as a column on the Summary Grid report.

   - **Mapping Key**—ClearTrial assigns a unique value to identify this task.

   - **Code**—ClearTrial uses your entry as a prefix to the selected task name.

   - **Sponsor Mapping Key**—Enter a unique mapping key that will appear in a **Sponsor Mapping Key** column on the Summary Grid report.

   - **Description**—The text you enter appears as the help text for this task on the Assignment tab.

   - **Assignment Group**—The assignment group is represented by choices in the **Responsibilities** section of various tabs throughout the plan and in drop-down lists on the Assignment tab. By choosing the appropriate assignment group, you can determine whether a task is performed by the sponsor or CRO, or is not performed at all for this trial. You can also manage the assignments of each task on the **Task Assignments** tab on this Task Manager screen.

   - **Summary Category**—Your selection from the **Summary Category** drop-down list determines which summary group the task will be displayed in on the Summary tab.

   - **Major Task**—From the **Major Task** drop-down list, select the major task under which this task should appear.

   - **Display this Task**—To sort the tasks, from the drop-down list, select **before** or **after**. From the drop-down list to the right, select the task before or after which to display this task.

4. Click **Save**.

5. Add a resource by clicking the **Add Resource** button, selecting one or more resources, and then clicking **Ok**

6. Click **Save**.

   ClearTrial assigns the new task a mapping key. Editable mapping keys are included in the Bid Grid exported when you create an RFP to allow vendors to programmatically map their costs to the Bid Grid format.

7. Click the **Task Assignments** tab.

8. Select the **Default Values** check box to assign a default service provider and billing location for the selected task.

9. To include the location, select the **Included** check box.

10. For each location, select the service provider and billing rate location from the drop-down lists.

11. To prevent cascading changes, pin the service provider and billing rate location assignments by clicking the **Pushpin** icon in the **Pinned** column.

12. Add one or more resources by clicking the **Add Resource** button, selecting addition resources, and then clicking **Ok**, or click **Save**.

13. Click **Close** to return to the **Edit Plan** screen to add or edit a major task. Click **Next** to assign pass-through or other indirect costs for this study on the **Costs** tab.

Configure Resources for User-defined Tasks

Resources are the roles that people who work on the study are 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.

1. On the **Labor** tab, select a major task, then click **Edit Major Task**.

2. Select the task whose resources you want to edit, then click **Edit Task**.

3. From the list of resources, select the **Resource**, and then click **Edit Resource**. ClearTrial displays information about the resource on four tabs (or three, if combined): Resource Details, Algorithm, Hours, and Rates & Substitutions. If your assigned ClearTrial system administrator has set the customer preference to combine the Algorithm and Unit Hours tabs, these two tabs are combined into just one tab called Algorithm / Hours. If you need information about a field, click its name.

> **Tip:**
>
> You can configure algorithms to calculate a resource's level-of-effort only for user-defined resources. You can adjust billing rate locations, billing rates, and unit hours for any resource.

4. 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.
   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. For more information, see Add a User-defined Description for a ClearTrial-defined Resource.

5. On the resource **Algorithm** tab (or **Algorithm / Hours** tab), configure custom algorithms using multiple expressions (requires the Advanced Algorithm Editor additional role/capability) or via script (requires the Expert Algorithm Editor additional role/capability). The scripting language should only be used if your algorithm cannot be accomplished via the expression functionality. You can switch between scripted (**Switch to Script**) and expression (**Use Expressions**) modes. When working with multiple expressions, select the cost driver (also known as work unit), a percentage to apply to the cost driver, and the number of hours per that percentage of the work unit for each expression. The complete algorithm should produce the level of effort in hours for the selected resource to produce one unit of work (as defined by its major task).

6. On the **Unit Hours** tab (or **Algorithm / Hours** tab), you can override the ClearTrial-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 or the unit hours percentage adjustment for the selected resource for all unpinned locations.

   • Use the **Unit Hours** 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 **% Adjust** field for the selected resource to specify a percentage adjustment to be applied to calculated hours.

7. On the **Rates & Substitutions** tab, you can assign the billing rate location for the selected resource when working on this task and override the billing rates for the selected resource when performing the task.
Each row displays the hourly billing rate for the selected resource based on its billing rate location.

   a. From the **Billing Rate Location** drop-down, select the location where this activity will be performed.

      - It is not necessary for the location to have active sites participating in the study. For example, you may have study sites in France, Germany, and Italy but perform all data management in the UK or India.

      - By default, ClearTrial calculates centralized tasks using the back-office billing rate location of the assigned provider.

   b. If the task is location-scoped, you can override the value in the **Rate** field for each location.

      - 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.

      - If you have overridden the billing rate location, the rate displayed reflects that choice rather than the local rate.

   c. (Optional) Select a resource to substitute from the **Substitute** drop-down.

      - By default, the billing 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.

   d. (Optional) Use the **% Adjust** field to specify a percentage adjustment to the rate for a selected resource on a case-by-case basis.

   e. To prevent cascading changes, pin the billing rate location assignment, substitute resource, and billing rate by clicking the **Pushpin** icon in the **Pinned** column to highlight it.

> **✎ Note:**
>
> Changes made to the billing rate location for the task or task group assignments do not override pinned billing rate locations for this resource for this task. Also, changes made to the billing rate or resource at the plan level or plan-location level do not override pinned billing rates or substitutions for this resource for this task. However, pinned settings are lost if the associated location and/or service provider are removed from the plan.

8. Click **Save**.

9. Click **Close**.

Create a Custom Level-of-Effort (LOE) Algorithm

With the appropriate role granted, user-defined algorithms can be created when you have custom labor activities you need to account for in the budget.

Multiple-expression algorithms can be used to calculate the level of effort required for a resource to complete a task.

1. From the **Labor** tab, click **Create New Major Task** or select a major task from the list and click **Edit Major Task**.

2. From **Task Manager**, select a major task from the left panel, to display its tasks on the **Major Task Details** tab in the right panel, and then click **New Task** or select a task and click **Edit Task**.

3. On the **Task Details** tab, click **Add Resource** to add a resource to the plan.

4. On the **Algorithm** tab, define a custom algorithm using multiple expressions or the scripting language.

   - Use the scripting language only if your algorithm cannot be accomplished via the expression functionality. You can switch between scripted and expression modes by clicking the **Switch to Script** and **Use Expressions** links.

   - When working with multiple-expressions, select 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 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 cost as location-scoped, then you can define an algorithm for each location or use the default algorithm for one or more locations.

   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 to drive the calculation for the expression. User-defined work units appear in the **of** drop-down list in italicized type followed by an asterisk.

d. Click **Save**.

e. Click **Add another expression** to add up to eight expressions.
ClearTrial 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 the cost or hours.

> **✎ 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.
> Generally, algorithms should avoid using the same work unit defined as the unit of measure for the associated major task. Level-of-effort algorithms should return unit hours, not total hours, for the task.

5. Click **Save**.

6. Click **Close**.

Configure Indirect Costs on the Costs Tab

By default, the Costs tab of a plan displays the pass-through and miscellaneous costs calculated for the plan. Some of these costs are pre-calculated. Other costs are displayed as place-holder costs based on ClearTrial's embedded intelligence.

1. Select the **Costs** tab.

2. Choose which costs to display:

   - To display only cost categories with a value, clear the **categories where costs total 0.00** filter option.

   - To display cost values for each location and assignments, select the **per location values and assignments** filter option. This will allow you to view all costs in the list by location and toggle through their provider, department, and GL Code assignments.

   - To display excluded costs as well as included costs in the list, select the **Show excluded costs** filter option.

     – If you exclude a cost, but it no longer includes the amount in the plan and its totals, the costs appear with a line drawn through them.

     – Restore an excluded cost by selecting the check box to the left of an excluded cost, and clicking **Include**.

   - 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.

3. You can accept the costs shown as is, add a cost that is needed, or review the costs and make adjustments to the algorithm and distribution. For instructions, see Create User-defined Indirect Costs.

- Create User-defined Indirect Costs
  On the Costs tab, enter information about the new cost on the Definition, Assignments, Algorithm, and Distribution tabs.

- Enter Cost Category Information
  Define the cost by categorizing the cost as pass-through, miscellaneous, or associated with a specific department and a GL code.

- Assign Costs to Service Providers
  After you have defined the category for the new indirect cost, select the Assignments tab the assign the cost to specific service providers.

- Distribute the Cost
  On the Distribution tab, select how the cost will be distributed for each location in your plan or study-wide.

Enter Cost Category Information

Define the cost by categorizing the cost as pass-through, miscellaneous, or associated with a specific department and a GL code.

1. Open the **Costs** tab and select the **New** button to display the **Definition** tab on the **Define New Category** screen.

2. In the **Category Information** section, in the **Name** field, enter a name for the cost. For any user-defined cost, specify a name of up to 60 characters that is unique for this plan. However, you cannot change the name of a ClearTrial-defined cost.

3. From the **Type** drop-down list, select the cost type.

   - **Pass Through**—These costs are incurred by an outsourced partner and will be passed through to the sponsor for reimbursement.

   - **Miscellaneous**—These costs are incurred by the sponsor as part of the overall study budget.

4. Specify whether the cost varies by location or will be the same for all locations.

   If you select **Costs vary by location**, you can specify a different amount for each location, 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 (on the Distribution tab), and express the cost in a different currency for one or more locations (Algorithm tab).

5. To make this cost part of the recurring payments plotted on the Cash Flow Chart, select the **Include in Payment Schedule** check box. ClearTrial 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**.

6. 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** check box. To include inflation for this cost in resulting calculations, select the **Apply inflation over time** check box.

7. To treat his as a credit item and disable the **Include inflation in results** option, select the **Treat as Credit** check box.

8. In the **Notes** section, enter details or comments about the new cost category. ClearTrial displays these notes as the help content for this cost.

9. Note the **History** section that shows who created the new category and when as well as who last modified it and when.

10. Click **Save**.

    ClearTrial 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.

11. Continue to define the new cost category by assigning costs to service providers on the **Assignments** tab, calculating algorithms on the **Algorithm** tab, and specifying how to distribute costs on the **Distribution** tab.

12. Click **Close**. To specify the payments schedule, click **Next** to open the **Payments** tab.

Assign Costs to Service Providers

After you have defined the category for the new indirect cost, select the Assignments tab the assign the cost to specific service providers.

1. Click the **Assignments** tab.

2. For each location or for the entire study:
   select the service provider, department, and GL Code from the drop-down lists.

   a. Select the responsible service provider or vendor from the **Provider** drop-down list.

   b. Map the cost to a specific department you select from the **Department** drop-down list.

   c. Map the cost to a specific code in the General Ledger by selecting it from the **GL Code** drop-down list.

3. Click **Save**, and then select the **Algorithm** tab.

Distribute the Cost

On the Distribution tab, select how the cost will be distributed for each location in your plan or study-wide.

1. On the **Define New Category** screen, after providing basic information on the **Definition** tab, assigning the cost to a service provider on the **Assignments** tab, and creating a custom algorithm on the **Algorithm** tab, select the **Distribution** tab.

2. From the **Distribute according to** drop-down list, select a predefined schedule or a custom approach to distributing the cost for each location in the plan.

   • If you select the **Site Approval Distribution**, **Subject Enrollment Distribution**, or **CRF Data Distribution**, in the **and shift** field specify an offset for the selected ClearTrial-defined distribution curve. You can shift a distribution to occur up to 999 days earlier or later than originally defined.

   • Select **An Even Distribution** to 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.

   • Select **A Custom Distribution** to 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** milestones for the cost distribution. These are used as the default start and end date for each location and specifies whether the offset is before or after the selected milestone.

   • 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.

   • For example, you can indicate that a cost is expected to spread from 30 days prior to FSI to 15 days after LSO.

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

4. Click **Save & Close** to return to the **Costs** tab.

Create User-defined Indirect Costs

On the Costs tab, enter information about the new cost on the Definition, Assignments, Algorithm, and Distribution tabs.

▶ Video

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

2. Enter information about the new cost on the Definition, Assignments, Algorithm, and Distribution tabs.

Define Provider Payment Schedules on the Payments Tab

On the Payments tab, you can configure the payment schedule for each provider performing work. Payments are defined as percentage values representing the portion of the total fees paid or received at the completion of each milestone.

You can define the payment terms to specify the number of days from the invoice that payment is expected. You can use the payment schedule with the Cash Flow Chart report to determine the cash flow characteristics of the payment plan. If some of the fees will be paid on a recurring schedule, you can specify that payment schedule. You can also tie payments to project milestones.

• Set Payment Terms
  Use the Set Payment Terms option to enter the expected number of days from the invoice date that payment will be made to a provider.

• Configure Recurring Payments
  Fees that are paid on a repeating schedule (for example, monthly) are recurring payments. You can choose the payment frequency for each item by service provider.

- Add a user-defined milestone
  If payments are paid in response to events or conditions not currently defined, you add user-defined milestones to the plan.

- Exclude Milestones
  Excluded milestones are excluded by default from the Milestone Dates and Milestone Payment Schedule reports. However, you cannot include milestones with zero payment amounts and show excluded milestones on the Milestone Payment Schedule report.

Set Payment Terms

Use the Set Payment Terms option to enter the expected number of days from the invoice date that payment will be made to a provider.

1. Select the **Payments** tab, and then select the **Set Payment Terms** button.

2. For each provider shown on the Payment Terms screen, enter the expected number of days from invoice date to the date of payment.

3. Click **Ok**.

> **Note:**
>
> Any bottom line discounts are allocated to the payment amounts based on the percentage values specified for each milestone payment.

4. Add recurring payments or define payments based on milestones or click **Save** and then **Next** to view a summary of hours, fees, and FTEs.

Configure Recurring Payments

Fees that are paid on a repeating schedule (for example, monthly) are recurring payments. You can choose the payment frequency for each item by service provider.

1. On the **Payments** tab, select the **Edit Recurring Payments** button.

2. For each item paid to each service provider, select the payment frequency from the drop-down list.

   For items whose fees and costs will be paid by milestones reached, rather than as regular recurring payments, select **Milestone** as the frequency.

3. Click **Ok**.

4. Add milestone payments or click **Save**, and then **Next** to view a summary of hours, fees, and FTEs.

Add a user-defined milestone

If payments are paid in response to events or conditions not currently defined, you add user-defined milestones to the plan.

1. On the **Payments** tab, select the **Add Milestone** button.

2. On the **Create Milestone** screen, in the **Milestone Definition** section, enter a name for the milestone. You can name the milestone anything appropriate as long as the milestone name is unique for this plan.

3. In the **Occurs** field, enter the number of days before or after the ClearTrial-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 ClearTrial-defined milestone or subsequent to a ClearTrial-defined milestone.

- From the milestone drop-down list, select the ClearTrial-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 ClearTrial-defined milestone selected.

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

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

6. Click **Ok** to return to the Payments tab.

   The provider for the new milestone is highlighted.

7. Enter the payment percentage for the new milestone provider.

8. Adjust the payment percentages of the other providers shown so that the payments add up to 100%.

9. Click **Save**, and then **Next** to view a summary of hours, fees, and FTEs.

Exclude Milestones

Excluded milestones are excluded by default from the Milestone Dates and Milestone Payment Schedule reports. However, you cannot include milestones with zero payment amounts and show excluded milestones on the Milestone Payment Schedule report.

1. On the **Payments** tab, view the list of ClearTrial-defined milestones.

2. If any one of these do not apply to your study, select the check boxes of the milestones to exclude and select the **Exclude Milestone** button.

> ✏️ **Note:**
>
> To include the excluded milestone on the milestone table, in the **Filter** section, in the **Show** field, select the **excluded milestones** check box.

3. Click **Save**.

View Expected Study Costs on the Summary Tab

The Summary tab provides a quick view of the plan's calculated budget forecast. While the Reports tab offer detailed reports, the summary is useful for "what-if" scenarios benchmarking against a vendor bid.

ClearTrial computes monetary values by converting each service provider's billing rate currency to the modeling currency, using the exchange rates specified on the Overview tab (or any overrides specified by provider).

- • Filter the Summary by Providers
  Begin your summary by selecting the providers to include.

- • View the Fees and Indirect Costs
  The Totals section provides a quick way to view the total study costs broken out by direct and indirect labor fees (pass-through or miscellaneous) and with and without inflation applied.

- • Group the Fees and Costs
  Select a grouping by which to summarize fees and costs.

- • Review Fees, Hours, and FTEs
  The values in the Fees, Hours, and FTEs section are displayed according to the grouping you selected.

- • Review Costs by Grouping
  The total indirect costs are displayed broken out by cost category type, and with or without inflation applied.

- • Review Dates and Duration
  This section summarizes study-related dates and durations.

- • Review Metrics
  This section includes the cost per completed subject and the average number of subjects per site per month.

Filter the Summary by Providers

Begin your summary by selecting the providers to include.

Displayed values include only those fees, costs, and hours associated with the selected providers.

1. Click the **Summary** tab.

2. In the **Included Providers** section, select the check boxes of the service providers to include.

3. Continue by viewing the total study costs with and without inflation in the Totals section. The values shown in the Totals section change to reflect the included providers.

View the Fees and Indirect Costs

The Totals section provides a quick way to view the total study costs broken out by direct and indirect labor fees (pass-through or miscellaneous) and with and without inflation applied.

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

1. After selecting the providers to include in the **Included Providers** section, view the values in the **Totals** section.
   The total study costs shown are a combination of all vender fees, pass-through costs, and sponsor internal costs.

2. Review and compare costs by grouping fees and costs.

Group the Fees and Costs

Select a grouping by which to summarize fees and costs.

1. After reviewing the fees and indirect costs with and without inflation, in the **Group By** section, select a way to group the fees and costs. Click the **Category**, **Department**, **GL Code**, or **Resource** button.

   Your choice determines how the values in the **Fees, Hours, and FTEs** and **Costs** sections are presented.

2. Review the fees, hours, and FTEs.

Review Fees, Hours, and FTEs

The values in the Fees, Hours, and FTEs section are displayed according to the grouping you selected.

1. After specifying the way to group fees, hours, and FTEs, view the summary in the **Fees, Hours, and FTEs** section.
   ClearTrial calculates the FTE (Full Time Equivalents) based on the forecasted resource effort. FTEs are based on planned resource hours and the available FTE working hours per resource.

2. Continue by reviewing the costs with and without inflation.

• FTE Calculation

FTE Calculation

ClearTrial calculates an FTE based on forecasted resource effort.

FTEs (or Full Time Equivalents) displayed are annual FTEs calculated by the application based on the planned resource hours required and the available FTE working hours per resource.

ClearTrial uses the level of effort estimated to complete each task per resource for each location and shows the sum of these hours per the grouping chosen (By Category, GL Code, Department, or Resource).

Monthly FTEs are calculated per month by determining the effort for a particular kind of resource expected that month and dividing by 1/12 th of the available FTE hours per year.

Annual FTEs are calculated per year by determining the effort for a particular kind of resource expected that year and dividing by the available FTE hours per year. By default, available hours per resource per year is calculated as:

> 6.5 dedicated hours per day
> x 5 work days per week
> x 50 weeks per year (accounting for minimal vacation and/or holidays)
> = 1,625 hours per year

If your organization uses a different value for the number of resource hours per year = 1 FTE, then users who are assigned the ClearTrial **System Administrator** primary role, can configure this for their organization by editing Customer Preferences. Customer Preferences can be launched from Start Page > Maintain > Preferences or from Admin > Customer Preferences. The preference is called "Hours per year resources are expected to perform billable work". This value will default to 1625 but you can update this value to align with what your organization uses.

Review Costs by Grouping

The total indirect costs are displayed broken out by cost category type, and with or without inflation applied.

1. After specifying the way to group costs, view the summary in the **Costs** section. Depending on the grouping, ClearTrial calculates totals with and without inflation.

2. Continue by reviewing the study dates and duration.

Review Dates and Duration

This section summarizes study-related dates and durations.

1. In the **Dates / Duration** section, review these 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 last activity on a task or study 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/Patient Last Treatment (LSLT/LPLT) minus the First Subject/Patient First Treatment (FSFT/FPFT).

2. Continue by reviewing the metrics associated with the study summary.

Review Metrics

This section includes the cost per completed subject and the average number of subjects per site per month.

1. In the **Metrics** section, review the costs per each subject who completed the study and the average expected number of subjects monitored at each site per month.
   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 site per month.

2. Print the summary if you wish, and then click **Next** to generate more detailed reports on the **Reports** tab.

Run Reports on the Reports Tab

The Reports tab provides a list of reports grouped by reporting category, or as thumbnails, so you can quickly and easily identify or distinguish a particular report.

ClearTrial reports output calculations based on the assumptions you entered into the ClearTrial model on the Edit Plan tabs.

Reports can be used to…

- Understand the forecast calculated from the plan's assumptions.
- Verify the trial budget.
- Manage resources.
- Compare fees and costs across plans.
- Build an RFP for a CRO.
- Build a bid for a sponsor.
- Create analyses in Excel (leveraging the format for excel analysis format option to build pivot tables).

You can view each report in the browser (as html), or export it to other formats.

- Report Types
  ClearTrial groups the reports into categories.
- Generate a Report
  Numerous reports are available from the Reports tab to provide details on clinical indicators, costs, FTE/Resources, and comparisons.

Report Types

ClearTrial groups the reports into categories.

You can view the report categories as thumbnail graphics or as a list. You click the thumbnail or list item to select it.

- Clinical Indicators
- Custom Reports (if applicable)

> ✎ **Note:**
>
> Please contact your account representative or Oracle Consulting Services (OCS) for further information on custom reporting for ClearTrial.

- Costs
- FTE/Resources
- Comparisons (to compare a plan to its template as opposed to comparing plans from the Plan list screen)

Each report provides customization opportunities such as which locations and providers to include, level of detail, grouping of information, and the reporting currency.

Generate a Report

Numerous reports are available from the Reports tab to provide details on clinical indicators, costs, FTE/Resources, and comparisons.

1. On the **Reports** tab, decide whether to view and select the available reports based on thumbnail graphics or from a list.

   • Click the **View as Thumbnails** button to see the content and format of the reports.

   • Click the **View as List** button to see a list of report names and descriptions.

   In either case, reports are grouped into:

   • Clinical Indicators

   • Costs

   • FTE/Resources

   • Comparisons

2. Select a report by clicking the thumbnail or name.

3. Specify content and formatting options for the report, and then click **Ok**.

   ClearTrial generates the report on a separate screen.

4. You can print the report, view it as PDF, export it to Excel, or export it to CSV.

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

Build a Portfolio

A portfolio acts as a container to aggregate plans and calculate the total costs for the trials the plans represent.

Possible uses for a portfolio include adding the final version plan for each study related to the same product (compound or medical device) to a portfolio to estimate the costs to bring the product to market. Other uses include adding the optimal plan for each study potentially executed over a certain time frame to do longer range planning for operating budgets.

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.

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 you can include it again.

The portfolio costs include any inflation and bottom -ine discounts that exist in a plan within the portfolio.

- Create a Portfolio
  Building a portfolio is a way to store multiple versions and forecasts for a study in one place and easily explore changes to the plan and outcomes from adjusting assumptions.

Create a Portfolio

Building a portfolio is a way to store multiple versions and forecasts for a study in one place and easily explore changes to the plan and outcomes from adjusting assumptions.

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

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

3. On the **Create Portfolio** screen, on the **Overview** tab, enter a name for the portfolio in the **Portfolio Overview** section, short and long descriptions in the **Description** section, and the currency to use for portfolio reports in the **Currency Options** section.
   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 select a different currency.

4. Click **Save**, and then **Next**.

5. Click **Add Plans**.

6. On the **Choose Plans** screen, select the check boxes of the plans to add to the portfolio, and then click **Ok**.
   The selected plans appear on the **Plans** tab of the **Create Portfolio** screen with information regarding their start date, the start offset specified, and the probability that the plan will come to fruition.

   - You can add up to 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 selecting the plan's check box and 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. ClearTrial reduces the costs associated with the plan according to the percentage. For example, if you set the probability to 50%, ClearTrial adds half of the plan's costs to the portfolio. The plan itself is not affected.

7. Click **Save**, and then **Next** to generate the portfolio and display a portfolio dashboard on the Summary tab.

8. On the **Summary** tab, review the portfolio dashboard.

   - 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 bottom line discounts exist in the plans included in the portfolio, inflation and bottom line discounts appear as separate line items.

9. Click **Next** to generate reports about the portfolio.

10. On the **Reports** tab, view the available reports as thumbnails or a list.

    - You can view each report in a separate window.

    - 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.

11. Select a report, specify any reporting parameters and generate the report.

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

13. Click **Close** to return to the **Portfolios** screen.

Create Templates

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 assumption 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. By default, plans are created from the ClearTrial Default System Template.

- Create a User-defined Template
  You can create multiple templates for your organization.

- Lock or Unlock a Template
  ClearTrial recommends locking plans and templates once you are satisfied with them.

Create a User-defined Template

You can create multiple templates for your organization.

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

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

3. On the **Select Template Defaults** screen, select the sponsor from the drop-down list.

4. Select the **Phase**, **Therapeutic Area**, and **Indication** from the drop-down lists to allow ClearTrial to calculate suggested values for your template.

   • You can override these values as you create the template.

   • You can override these values as you create the template or again in plans created from the template.

   • You can also create plans for studies in other indications from any template. Default values derived from the phase, therapeutic area, and indication reflect those of the study being planned. Values you have overridden in the template, however, are used instead of any of these defaults.

5. Click **Ok**.

6. On the **Create Template** screen, which is identical to the Create Plan screen, enter values as you would for any plan.

   > **Note:**
   >
   > The user-defined template will be created using the cost model for the current release.

   • Choose values that correspond to most of the plans for which this template will act as a source. You can then make plan-specific changes in each 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 label to display online help.

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

Lock or Unlock a Template

ClearTrial recommends locking plans and templates once you are satisfied with them.

However, locked templates cannot be edited unless they are unlocked.

Lock a Template

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

2. On the **Templates** screen, select the template to lock.

3. Click the **Other Actions** button, and then click **Lock Templates**.

A lock icon appears on the left, next to the check box, indicating that the template is now locked.

Unlock a Template

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

2. On the **Templates** screen, select the template to unlock.

3. Click the **Other Actions** button, and then click **Unlock Templates**.
   The lock icon disappears.

Why can't I unlock a template?

• You cannot unlock templates or plans that use a cost model of 4.1 or prior.

• Locked templates and plans have a red lock icon which indicates that they are permanently locked and cannot be unlocked.
  Locked templates and plans have a red lock icon which indicates that they are permanently locked and cannot be unlocked.

3

Configure Service Providers, Billing Rates, and Inflation Rates

This chapter describes how to configure service providers, define their resource hourly billing rates, and add them to plans.

To view the list of existing service providers in your environment, from the **Maintain** menu, select **Service Providers**.

The Service Providers screen displays all the providers currently available in your environment (including ClearTrial-defined and any user-defined providers) that can be added to plans and to which tasks can be assigned.

If you are a sponsor and an early ballpark budget planner, the service offers five types of out-of-the-box composite providers to select from to add to plans. The ClearTrial-defined composite providers include the following types depending on the type or level of provider you are interested in outsourcing to and generating a forecast:

- **Premium:** Global presence in all major regions. Studies can be fully outsourced to them; more expensive than other leading CROs.

- **Major:** Global presence, in all major regions. Studies can be fully outsourced to them.

- **Medium:** Incomplete global presence. Studies can be fully outsourced to them but they may have to sub-contract some of the work.

- **Niche:** Typically operate in only one country or region, and often only offer a subset of services.

- **Average All CROs**: Rates are an average across the other levels/types of composite providers.

For the most accurate budget forecast, attain the actual provider-specific billing rates by rate year from your providers and upload them by selecting **Billing Rates** from the **Maintain** menu.

- Define Service Providers
  You must add service providers to your environment before you can use them in your plans. Which service provider types you can add to your plans depends on your customer type.

- Define Resources
  Resources are the roles that people who work on the study are 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.

- Configure Billing Rates
  After you define and publish billing rates for service providers, ClearTrial shares the rates between plans. You cannot add service providers to a plan that does not have a set of published rates.

- Configure Inflation Rates
  You can define plan-neutral inflation profiles for service providers. Inflation profiles correspond to a set of expected inflation rates for the specified years.

- Map Labor and Costs to Departments
  By editing department mappings, you can manage all mappings of ClearTrial-defined labor and indirect costs to departments to apply to plans.

- Map Labor and Costs to GL Codes
  The GL Code screen lists the defined GL codes. You can create, edit, delete, and restore GL codes. You can also map GL codes to labor and costs.

- User-defined Exchange Rate Tables
  A user-defined exchange rate table allows you to create and define your organization's standardized rates for each currency to be used in your plans.

- Map Countries to Reporting Regions
  You can create user-defined reporting regions for use in your plans based on your global organizational structure and accounting practices. You can then map countries to those reporting regions.

Define Service Providers

You must add service providers to your environment before you can use them in your plans. Which service provider types you can add to your plans depends on your customer type.

The supported service provider types include Sponsors and Contract Research Organizations (CROs). If you are a sponsor, you can add CRO provider types to your plans. If you are a CRO, you can add sponsors.

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

2. On the **Service Providers** screen, click the **New** button.

3. On the **Create Provider** screen, in the **Service Provider Information** section, enter the provider name, select the type from the **Provider Type** drop-down list, and add a description.

4. From the **Billing Rates Currency** drop-down list, select the currency for the hourly billing rates associated with this service provider.

5. 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 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.

6. Click **Save**.

Define Resources

Resources are the roles that people who work on the study are 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 ClearTrial:

- **ClearTrial-defined resources**—Resources ClearTrial provides based on its embedded clinical intelligence. You can edit these resources. However, you cannot delete ClearTrial-defined resources.

- **User-defined resources**—Resources a user with the Resources Administrator role add to the service. The Resources Administrator can edit, delete, and restore these resources. If they delete a user-defined resource that is being used in a plan, that resource remains available in the plan.

> **Note:**
>
> To maintain resources, you must have the Clinical Administrator primary role and your assigned ClearTrial System Administrator must grant you the Resources Administrator additional role.

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

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

3. On the **Create Resource** screen, in the **Resource Summary** section, enter a resource code, name, and description.

   In the **Code** field, 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.

4. In the **Default Billing Rates** section, fill in the table. For each of the ClearTrial-defined service or composite providers, enter the hourly billing rate for the resource.

   - The ClearTrial composite providers include: Major CRO, Medium CRO, Niche CRO, Premium CRO, and Average All CROs.

   - 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 years you choose as the effective rate year when planning a study.

   - To populate the table automatically, click **Auto Fill**. On the **Auto-Populate Rates** screen, you can 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.

   - If you've already created rate cards, don't forget to enter the rates for the new resources you add.

5. Click **Ok**.

Configure Billing Rates

After you define and publish billing rates for service providers, ClearTrial shares the rates between plans. You cannot add service providers to a plan that does not have a set of published rates.

- You can save a draft version of a set of billing rates but you can't use draft versions in plans. You can also view the prior published rates and revert to those rates.

- To work with billing rates, your assigned ClearTrial System Administrator must grant you the ClearTrial Clinical or System Administrator role.

Video

- Define Billing Rates
  Defining billing rates is done from the Maintain menu.

- Publish Billing Rates
  After you publish the billing rates, ClearTrial shares the rates between plans. You cannot add service providers to a plan that do not have a set of published rates.

- Generate the Billing Rates Report
  The Billing Rates report displays the billing rates for the sponsor and the the rate year selected.

- Change Billing Rates
  You can edit and save billing rates in a draft state as many times as necessary prior to publishing them. When you are ready, publish that draft and replace the currently published rates.

- View the Billing Rate Revision History
  The Billing Rates Revision History screen shows previously published sets of billing rates.

- Revert to Previously Published Billing Rates
  If you revert the billing rates for a plan to a previous version and publish them, ClearTrial makes the rates available to all plans.

Define Billing Rates

Defining billing rates is done from the Maintain menu.

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

2. On the **Billing Rates** screen, click **New**. You can also copy an existing billing rates table by clicking **Copy** and editing the fields as described below.

3. From the **When** drop-down list, select the service provider for whom you want to enter billing rates.

4. 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 selected service provider is performing work for this sponsor or affiliate.

- If your organization is a CRO, select the sponsor for whom these billing rates apply.

5. From the **for Rate Year** drop-down list, select the year for which these rates apply and ClearTrial updates the table to match the selected year.

   When creating a plan, the effective rate year chosen in the Provider Details screen from the Provider tab determines which rates are used. Rates are inflated per any inflation percentages specified.

6. From the **Base Rate Location** drop-down list, select the country or region the rates that 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, ClearTrial 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.

7. 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, ClearTrial multiples the hourly rate supplied by the number of hours calculated to be necessary for employees of this type to complete the work.

   - ClearTrial 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 country or region shown in the **Base Rate** column. 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.

8. Click **Save**, then publish the rates so they can be used when calculating plans.

Publish Billing Rates

After you publish the billing rates, ClearTrial shares the rates between plans. You cannot add service providers to a plan that do not have a set of published rates.

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

2. From the list of defined rates, select the check box of a billing rate with a **Draft** status, and then click **Publish**.

3. On the **Confirm Publish Rates** screen, click **Publish**.

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

Generate the Billing Rates Report

The Billing Rates report displays the billing rates for the sponsor and the the rate year selected.

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

2. On the **Service Providers** screen, select the check box of a user-defined service provider or one that you created.

> **✎ Note:**
>
> You can only generate the ClearTrial Billing Rates report for user-defined service providers.

3. Click **Billing Rates Report** to display the report options in a separate window.

4. Change any options and click **Ok** to display the report.

5. Print, view, or export the report, and then click **Close**.

Change Billing Rates

You can edit and save billing rates in a draft state as many times as necessary prior to publishing them. When you are ready, publish that draft and replace the currently published rates.

You can also edit published rates and save them as a new draft that does not replace the published rates.

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

2. In the Filter section, select a specific provider from the **Show rates for** drop-down list, or **Any Provider** to view all billing rate schedules.

3. From the for **Rate Year** drop-down list, select a specific year or **Any** to include any years with data.

4. To include deleted rates, select the **Include Deleted Rates** check box.

5. On the Billing Rates table, select the check box for the rates to update, and then click **Edit**.

6. On the **Edit Billing Rates** screen, edit the hourly billing rates for the resources and locations as necessary.

7. Click **Save**.

8. To publish the changed rates, click **Publish**.

View the Billing Rate Revision History

The Billing Rates Revision History screen shows previously published sets of billing rates.

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

2. In the **Filter** section, select a specific provider from the **Show rates for** drop-down list, or **Any Provider** to view all billing rate schedules.

3. From the for **Rate Year** drop-down list, select a specific year or **Any** to include any years with data.

4. To include deleted rates, select the **Include Deleted Rates** check box.

5. Select the check box for a billing rate year, and then click **Show Revision History**.

   ClearTrial displays the modification information in a separate window.

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

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

8. Click **Close**.

Revert to Previously Published Billing Rates

If you revert the billing rates for a plan to a previous version and publish them, ClearTrial makes the rates available to all plans.

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

2. In the **Filter** section, select a specific provider from the **Show rates for** drop-down list, or **Any Provider** to view all billing rate schedules.

3. From the for **Rate Year** drop-down list, select a specific year or **Any** to include any years with data.

4. To include deleted rates, select the **Include Deleted Rates** check box.

5. Select the check box for a billing rate year, and then click **Show Revision History**.

   ClearTrial displays the modification information in a separate window.

6. To view the billing rates for a previously published set of billing rates, select an earlier rate schedule and then click the **Open as Draft** link.

7. On the **Edit Billing Rates** screen for the earlier billing rates, click **Save**.

8. To publish the reverted rates, click **Publish**.

9. Confirm that you want to make these rates available and effective by clicking **Publish**.

Configure Inflation Rates

You can define plan-neutral inflation profiles for service providers. Inflation profiles correspond to a set of expected inflation rates for the specified years.

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 user-defined 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.

ClearTrial suggests configuring rate variances by location so you can set the inflation rates for a base location, such as the USA, and then cascade those rates to other locations based on the variance % per location.

> ✎ **Note:**
>
> To use user-defined inflation rates only in specific locations, override the default ClearTrial values with your custom 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.

You can save draft versions of inflation profiles to continue to work on them until you have them finalized.

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

- Define an Inflation Profile
  An inflation profile includes an hourly rate plus a percentage to cover inflation for vendors to whom you may assign tasks to when planning a study.

- Publish Inflation Profiles
  Publishing the inflation rates saves and makes them available to ClearTrial to use to calculate fees and costs associated with tasks assigned to the chosen vendor.

- Change Inflation Profiles
  You can edit and save inflation profiles in a draft state as many times as necessary prior to publishing them. When you are ready, you can publish that draft and replace the currently published inflation profile.

- View the Inflation Profile Revision History
  The Inflation Profile Revision History screen shows previously published sets of inflation rates.

Define an Inflation Profile

An inflation profile includes an hourly rate plus a percentage to cover inflation for vendors to whom you may assign tasks to when planning a study.

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

2. On the **Inflation Profiles** screen, click **New**. You can also copy an existing inflation profile by selecting the profile's check box, clicking **Copy**, and then editing the fields as described below.

3. On the New Inflation Profile screen, from the **When** drop-down list, select the service provider to whom this inflation profile applies.

4. 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 CRO, select the sponsor to whom this inflation profile applies.

5. 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 selected in the **Provider Details** screen determines which billing rates are used. Rates are inflated per any inflation percentages specified.

   - A rate year is defined as January through 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, ClearTrial issues an alert and the inflation rate defaults to 0% for all years of the trial.

6. Click **Ok**.

7. On the **Create Inflation Profile** screen, from the **Base Rate Location** drop-down list, select the country or region to which the base rate applies.

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

- By default, ClearTrial 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 by 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 for each location to 100% so that ClearTrial applies the base rate values by year to every location.

8. For each **Year**, for each location column, enter the inflation rate as a percentage.

   - The default specification includes five years, because most studies 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 study and relative to each location.

9. Click **Save**. ClearTrial saves the inflation profile as a draft.

Publish Inflation Profiles

Publishing the inflation rates saves and makes them available to ClearTrial to use to calculate fees and costs associated with tasks assigned to the chosen vendor.

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

2. Select the check box of an inflation profile whose status is **Draft**.

3. Click **Publish**.

4. On the **Confirm Publish Profile** screen, click **Publish**.

   The inflation rates are immediately effective and available.

   Any unlocked plans that do not have frozen rates reflect these changes.

Change Inflation Profiles

You can edit and save inflation profiles in a draft state as many times as necessary prior to publishing them. When you are ready, you can publish that draft and replace the currently published inflation profile.

You can also edit published inflation profiles and save them as a new draft that does not replace the published inflation profile.

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

2. On the **Inflation Profiles** screen, select an inflation profile's check box, and then click **Edit**.

3. Edit the base rate and percentages applied to selected regions and countries for the years shown.

4. Click **Save**.

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

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

View the Inflation Profile Revision History

The Inflation Profile Revision History screen shows previously published sets of inflation rates.

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

2. On the **Inflation Profiles** screen, select an inflation profile's check box, and then click **Show Revision History**.
The revisions are shown on the Show Revision History screen.

3. You can view a profile by clicking its **Show Profile** link or edit a published profile by clicking the **Open as Draft** link.
The inflation profile appears in a separate window.

4. View or edit the inflation profile, and then click **Close**.

Map Labor and Costs to Departments

By editing department mappings, you can manage all mappings of ClearTrial-defined labor and indirect costs to departments to apply to plans.

Departments can be mapped to internal and outsourced providers for each task. To work with departments, your assigned ClearTrial System Administrator must grant you the Departments/GL Codes Administrator additional role/capability.

For use case scenarios, see the *Department and GL Code Manager Scenarios*, available on the Oracle Help Center.

• Add a User-defined Department
You can define and add a department to your plan.

• Edit Default Department Mappings
You can provide a default department for internal and outsourced providers for all tasks by setting departments in the Default Row, or for tasks within a task group by setting departments in a task group row.

Add a User-defined Department

You can define and add a department to your plan.

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

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

3. On the **Create Department** screen, in the **Code** field, enter a department code.

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

4. In the **Name** field, enter a unique department name.

5. In the **Description** field, describe the department.

6. Click **Save**.

7. To return to the **Departments** screen, click **Close**.

Edit Default Department Mappings

You can provide a default department for internal and outsourced providers for all tasks by setting departments in the Default Row, or for tasks within a task group by setting departments in a task group row.

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

2. On the **Departments** screen, click **Map Labor and Costs**.
   There are four department mapping tabs:

   - Labor (Late stage)

   - Labor (Phase I HV)

   - Costs (Late stage)

   - Costs (Phase I HV)

> **Note:**
>
> Phase I HV refers to the ClearTrial-defined Phase I (Healthy Volunteers) Work Breakdown Structure (WBS). Late stage refers to the ClearTrial-defined Phase I (Oncology/Vaccines) through Phase IV (with or without IND) WBS.

3. If you want to map at a different level or by a different dimension, click the **change** link to the right of the **Mapping by Task** field, and then, on the **Change Mode** screen, click the radio button for the level of mapping you want to conduct.

   - **Resource**—Map labor to departments by resource. You can map departments to internal and outsourced providers for each ClearTrial-defined resource.

   - **Location**—Map labor to departments by location. You can map departments to internal and outsourced providers per plan location.

   - **Task**—Map labor to departments by task. You can map departments to internal and outsourced providers for each task.

   - **Rule (Advanced Mode)**—Map labor to departments by your own criteria. For more information, see Add a Department Mapping Rule.

4. Click **Ok**.

5. On the **Edit Department Mapping screen** for the selected mode, do the following on each tab, saving your selections on each tab:

   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**.

- Restore Default Department Mappings
  You can restore the ClearTrial-default department mappings to their default settings.

- [Add a Department Mapping Rule](#)
  You can map labor to departments by your own criteria.

Restore Default Department Mappings

You can restore the ClearTrial-default department mappings to their default settings.

1. On the **Edit Department Mapping** screen, on each tab, click **Restore ClearTrial Defaults**.

2. Confirm that you accept that your user-defined mappings will be replaced with ClearTrial defaults by clicking **Yes**.

Add a Department Mapping Rule

You can map labor to departments by your own criteria.

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

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

3. Click the **change** link to the right of the **Mapping by Task** field, click the **Rule (Advanced Mode)** radio button, and then click **Ok**.

4. Click **Add Rule**. For more information about a field, click the field label to display online help.
   The options that appear on the **Create Department Mapping Rule** screen are determined by your mapping level/mode selection.

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

6. On the **Providers** tab, select the providers.

   - To include all of the internal and outsourced service providers, select the **Any Provider** check box.

   - To include all the service providers in the Internal group, select the **Internal** check box.

   - To include all the service providers in the Outsource group, select the **Outsource** check box.

   - To include specific providers, select their check boxes from the **Internal** and **Outsource** lists.

7. On the other tabs, select specific locations, costs, tasks, or resources or **Any** to include all.

8. Click **Ok** to add the rule.

9. Click **Save**.

Map Labor and Costs to GL Codes

The GL Code screen lists the defined GL codes. You can create, edit, delete, and restore GL codes. You can also map GL codes to labor and costs.

To work with GL codes, your assigned ClearTrial System Administrator must grant you the Departments/GL Codes Administrator additional role/capability.

- Add a User-defined GL Code
  You can add user-defined General Ledger (GL) codes for use in plans and map labor and costs to them.

- Edit Default GL Code Mappings
  You can map labor to GL codes by task. GL codes can be mapped for internal and outsourced providers for each task.

Add a User-defined GL Code

You can add user-defined General Ledger (GL) codes for use in plans and map labor and costs to them.

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

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

3. On the **Create GL Code** screen, in the **Code** field, enter an alphanumeric code that represents the GL code and will appear throughout ClearTrial for tasks and indirect costs.

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

5. In the **Description** field, describe the GL code.

6. Click **Save**.

7. To return to the GL Codes screen, click **Close**.

Edit Default GL Code Mappings

You can map labor to GL codes by task. GL codes can be mapped for internal and outsourced providers for each task.

You can also specify a default GL code for internal and outsourced providers for all tasks by setting GL codes in the default row, or for all tasks within a task group by setting GL codes in a task group row.

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

2. On the **GL Codes** screen, click the **Map Labor and Costs** button to display the **Edit GL Code Mapping** screen. There are four GL code mapping tabs:

   On the Edit GL Code Mapping screen, there are four GL code mapping tabs that correspond to the study type:

   - **Labor (Late stage)**

   - **Labor (Phase I HV)**

   - **Costs (Late stage)**

   - **Costs (Phase I HV)**

3. Select the tab corresponding to the study phase you want to map. The first line of the table shows the default mappings for the Internal and Outsourced task groups.

4. If you want to map at a different level than the default, click the **Mapping by task [change]** link to enter Change Mode, and then select the mapping mode by clicking the radio button for the level of mapping you wish to conduct.

   - **Resource**—Map labor to GL codes by resource. You can map GL codes to internal and outsourced providers for each ClearTrial-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 Add a GL Code Mapping Rule.

5. Click **Ok** to return to the **Edit GL Code Mapping** screen.

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

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

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

9. Click **Save**.

- Restore Default GL Code Mappings
  You can discard user-defined mappings and restore the ClearTrial default GL code mappings.

- Add a GL Code Mapping Rule
  You can map labor to GL codes by your own criteria.

Restore Default GL Code Mappings

You can discard user-defined mappings and restore the ClearTrial default GL code mappings.

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

2. On the **GL Codes** screen, click the **Map Labor and Costs** button to display the **Edit GL Code Mapping** screen.

3. Select the tab corresponding to the study phase containing the GL code mapping you want to restore.

4. At the bottom of the screen, click the **Restore ClearTrial Defaults** button.

5. Click **Close**.

Add a GL Code Mapping Rule

You can map labor to GL codes by your own criteria.

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

2. On the **GL Codes** screen, click the **Map Labor and Costs** button to display the **Edit GL Code Mapping** screen.

3. Click the **Mapping by task [change]** link to enter Change Mode to change the default mapping level.

4. On the **Change Mode** screen, select the **Rule (Advanced Mode)** radio button and click **Ok**.

5. Click **Add Rule** to display the **Create GL Code Mapping Rule** screen. The options are determined by your mapping level/mode selection. For more information about a field, click the field label to display online help.

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

7. On the **Providers** tab, select the providers to be assigned according to this rule or **Any Provider** to include both internal and outsourced service providers. Select the **Internal** and **Outsourced** check boxes to include all the service providers in that group.

8. On the other tabs, select specific locations, costs, tasks, or resources. Select **Any** to include all.

9. Click **Ok** to add the rule.

10. Click **Save**.

User-defined Exchange Rate Tables

A user-defined exchange rate table allows you to create and define your organization's standardized rates for each currency to be used in your plans.

- Exchange rate tables can be shared by multiple plans. If you designate one of the exchange rate tables as the default table, ClearTrial automatically applies that exchange rate table to new plans.

- Draft versions are not available for use in plans. Exchange rate tables must be published to be used in plans.

- To work with exchange rate tables, you must have Power User as a primary role and your assigned ClearTrial System Administrator must grant you the Exchange Rates Administrator role/capability.

- Create a User-defined Exchange Rate Table
  Defining exchange rates allows several plans to be updated in one step by updating the shared rates.

- Set the Default Exchange Rate Table
  You can specify a default exchange rate table for ClearTrial to use when a new plan is created.

- Edit an Exchange Rate Table
  You can edit an exchange rate table to tailor your plan to your organization's global structure and accounting practices.

Create a User-defined Exchange Rate Table

Defining exchange rates allows several plans to be updated in one step by updating the shared rates.

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

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

3. On the **Create Exchange Rate Table** screen, in the **Details** section, in the **Name** field, enter a name for the exchange rate table.

4. In the **Description** field, identify this exchange rate table.

5. 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 default values from that date.

   For each currency listed, ClearTrial calculates the equivalent value in that currency. If you change the exchange rate date and click **Apply**, ClearTrial recalculates the rates.

   Although you can override the rates shown, Oracle recommends that you accept the exchange rates automatically calculated by ClearTrial.

6. Note that the status of the new exchange rate table appears below the Currency Exchange section. The table may be in one of three states: To save the exchange rate table as a draft, click **Save Draft**.

   • **Draft**—A draft table is visible on the Exchange Rate Table screen, but not available when planning studies.

   • **Published**—A published table may be used for planning studies and represents the currently active conversion rates,

   • **Published with Draft**—This status means there is a pending draft version that is not yet available for planning studies. The previously published version remain active, available, and in use.

7. To make the exchange rate table available for use in plans, click **Publish**.

8. To return to the Exchange Rate Tables screen, click **Close**.

• Publishing Exchange Rate Tables
  To make the exchange rate table available for use in plans, you must publish it.

Publishing Exchange Rate Tables

To make the exchange rate table available for use in plans, you must publish it.

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

2. Select the check box of the draft exchange rate table you want to publish, and then click **Publish**.

   All new plans use the published exchange rate table.

   ClearTrial automatically updates all plans using the revised exchange table.

Set the Default Exchange Rate Table

You can specify a default exchange rate table for ClearTrial to use when a new plan is created.

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

2. Select the check box of the published exchange rate table you want to set as the default table, and then click **Set Default**.

   The default table name appears in **boldface** type.

Edit an Exchange Rate Table

You can edit an exchange rate table to tailor your plan to your organization's global structure and accounting practices.

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

2. On the **Exchange Rate Tables** screen, select the check box of an exchange rate table, and then click **Edit**.

3. Edit the details and the currency exchange rates as necessary.

4. Choose one of these options: .

   • To save the exchange rate table as a draft, click **Save Draft**

   • 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. ClearTrial automatically updates all plans using the exchange rate table with the new conversion rates.

5. Click **Close**.

Map Countries to Reporting Regions

You can create user-defined reporting regions for use in your plans based on your global organizational structure and accounting practices. You can then map countries to those reporting regions.

If you define reporting regions, you can view the Monthly Budget by Reporting Region report, available from the Reports tab of a plan.

To work with reporting regions, you must have Power User as a primary role and your assigned ClearTrial System Administrator must grant you the Reporting Regions Administrator role/capability.

• Add a Reporting Region
  By creating reporting regions, you can tailor your plan to your global organizational structure and accounting practices.

• Map Countries to Reporting Regions
  Once you have added reporting regions, you can map countries to those reporting regions.

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

Add a Reporting Region

By creating reporting regions, you can tailor your plan to your global organizational structure and accounting practices.

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

2. 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**.

3. In the row added to the bottom of the table enter a name for the new reporting region in the **Reporting Region Name** column. If this is the first reporting region being added, enter a name for the new reporting region and click **New Reporting Region**.

4. Click **Save**.

5. Continue adding reporting regions by clicking **New Reporting Region**, entering the reporting region name, and clicking **Save**.

Map Countries to Reporting Regions

Once you have added reporting regions, you can map countries to those reporting regions.

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

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

3. For each country shown on the **Map Countries to Reporting Regions** screen, select a reporting region from the drop-down list.

4. Click **Save and Close**.

View the Monthly Budget by Reporting Region Report

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

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

2. Select a plan and click **Edit**, and then select the **Reports** tab.

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

> ✎ **Note:**
>
> This is the only report that includes this information.

4. When you are finished reviewing the report, click **Close**.

4

Create and Edit Major Tasks with the Task Manager

The ClearTrial Task Manager provides the ability to add major tasks, subtasks, resources, and associated algorithms to the ClearTrial Work Breakdown Structure (WBS) or to delete major tasks and subtasks from the ClearTrial WBS.

> **✎ Note:**
>
> These changes apply to a specific plan. To share an updated WBS with many plans, create a template. Plans created from a user-defined template inherit the changes made to the template prior to the creation of a plan.

Enterprise-licensed users can launch the Task Manager from the Labor tab of a plan by clicking **New Major Task** or **Edit Major Task**.

Prerequisites

- You must work in Advanced or Expert mode. Task Manager options are not visible in Quick or Basic mode.
- You must be assigned one of these two roles:
  - **WBS Editor:** You can add and edit WBS elements in your own plans. Assigned ClearTrial power users automatically have this set of permissions by default.
  - **WBS Manager:** You can add and edit WBS elements in any plan. Assigned ClearTrial clinical administrators automatically have this set of permissions by default.

Task Manager actions

- Search for major tasks and subtasks
- Quickly move between major tasks, subtasks, and resources by leveraging the tree-grid structure.
- Create plan-specific, user-defined major tasks and subtasks.
- Edit and delete major tasks and/or subtasks or their properties (code, description, assignment group, summary group, sort order, etc.).
- Add, edit, or delete resources from tasks.
- Supply an algorithm, override, or adjust unit hours, rates, department, or GL code for each task or resource.
- Manage inclusion/exclusion and the billing rate location for tasks (task assignments).
- Apply floating adjustments for the number of units at the major task level and for hours at the resource level.
- Plan user-defined tasks before the Project Activity Start Date and after the Final Report Date (Final CSR).

Where tasks appear in ClearTrial

- **Task groups**—Tasks are grouped together because they are commonly assigned as a group, most often to the sponsor or a provider.
  Task groups appear throughout ClearTrial in the Responsibilities sections to specify whether to outsource the task and to whom. Task groups also appear on the Assignment tab, where you can adjust the tasks by group or individually.

- **Summary groups**—Fees, hours, and FTEs associated with the summary group or functional area are "rolled" up together on the Summary tab and Summary report.

- **Department**—Tasks are indirectly grouped by department, according to the department to which one or more of the tasks belong. Each resource is associated with a specific department, but you can also associate the same resource with a different department when performing specific tasks.

- **Assignments**—Each task can be assigned to a single provider. Location-scoped tasks perform differently in each trail location, allowing you to exclude tasks from selected locations.

- Move a User-defined Task from One Major Task to Another
  Moving a user-defined task from one major task to another allows you to apply a different unit of measure, distribution, and start and end dates without recreating the task, its assignments, and its resources and their algorithms.

- Rename or Reorder Major Tasks
  Within your plan, you can override the name and description of each ClearTrial-defined major task and specify the order in which it appears in the Task Manager tree and on reports.

- Copy a Major Task
  You can copy user-defined major tasks, including their associated subtasks and resources. However, the name of the copied task must be unique within the plan.

- Reorder Major Tasks from the Labor Tab
  The ClearTrial-defined major tasks appear in the order in which they are typically performed in a trial. You can control the order in which they are displayed on the Labor tab.

- Adjust Hours, Fees, or Units Distribution

- Copy a Task
  Copying a user-defined task (subtask) allows you to change time and budget cycles without losing your original plan's forecast and enables your organization to collect historical data to determine key metrics for planning better next time.

- Choose Assignment and Summary Groups for Tasks
  You can move tasks from one summary group to another to match your organization's hierarchy. The ClearTrial-defined summary groups appear on the Plan Summary tab and include the tasks assigned per summary group.

- Rename or Reorder Tasks
  Within your plan, you can edit the name and description of each Task and specify where it appears in reports and in the Task Manager tree.

- Delete ClearTrial-defined Major Tasks or Tasks
  To exclude ClearTrial-defined major tasks or subtasks from the specific trial you are planning, you can delete them.

Move a User-defined Task from One Major Task to Another

Moving a user-defined task from one major task to another allows you to apply a different unit of measure, distribution, and start and end dates without recreating the task, its assignments, and its resources and their algorithms.

- If the task is part of a study-scoped major task and is moved to a location-scoped major task, any values stored at the study scope become the default values for each location.

- If the task is location-scoped, but is moved under a study-scoped major task, ClearTrial warns you that location-specific values and algorithms will be lost.
  ClearTrial uses the defaults as the study-scoped values and algorithms for the moved task.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. Select a major task, and then click **Edit Major Task**.

5. From the list of tasks shown at the bottom of the **Major Task Details** tab, select the user-defined task and click **Edit Task**.

6. On the **Task Details** tab, select a different major task from the **Major Task** drop-down list.

7. Click **Save**.

   The user-defined task you moved appears in the pane on the left under the new major task.

Rename or Reorder Major Tasks

Within your plan, you can override the name and description of each ClearTrial-defined major task and specify the order in which it appears in the Task Manager tree and on reports.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. Select a major task, and then click **Edit Major Task**.

5. Type the new name.

6. Change the description.

7. Identify where the renamed major task should appear with respect to other major tasks when listed on reports or displayed in the Task Manager tree.

8. From the **Display this Major Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the major task before or after which to display the selected major task.

9. Click **Save & Close**.

Copy a Major Task

You can copy user-defined major tasks, including their associated subtasks and resources. However, the name of the copied task must be unique within the plan.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. From the list of tasks shown at the bottom of the **Major Task Details** tab, select the user-defined task and click **Copy Major Task**.

5. In the **Name** field, provide a unique name for the copied major task.

6. Enter a description, specify if it is study-scoped or varies by location, and select a unit of measure from the drop-down list.

7. Choose where to display the copied major task. The default is to add the new major task just below its original.

   a. From the **Display this Major Task** drop-down list, select **before** or **after**.

   b. From the drop-down list to the right, select the major task before or after which to display the copied major task.

8. Click **Save**.
   ClearTrial creates a copy of the major task, including its associated tasks and resources. You can see the copied major task in the pane on the left.

Reorder Major Tasks from the Labor Tab

The ClearTrial-defined major tasks appear in the order in which they are typically performed in a trial. You can control the order in which they are displayed on the Labor tab.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, select a major task that includes a user-defined task and click **Edit Major Task**.

5. On the **Major Task Details** tab, identify where the task should appear in list of tasks under the major task. From the **Display this Major Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the major task before or after which to display the task.

   > ✎ **Note:**
   >
   > Alternatively, use the mouse to highlight the major task and drag and drop it into the new position.

6. Click **Save**.

ClearTrial retains this user-defined sort order even if you change the cost model for your plan.

Adjust Hours, Fees, or Units Distribution

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. Select a major task and click the **Adjust Hours or Fees** button.

5. Click the **Distribution** tab.

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

6. In the **Distribute completed units of work according to** drop-down list, select the distribution approach. For more information, see Distribute the Cost.

   • The distribution of units over time determines when the related fees are incurred, how value is accrued, and how inflation rates are applied to work in the second and subsequent years of a trial.

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

7. Click **Save**.

Copy a Task

Copying a user-defined task (subtask) allows you to change time and budget cycles without losing your original plan's forecast and enables your organization to collect historical data to determine key metrics for planning better next time.

ClearTrial enables you to contribute to an analysis-driven culture with the flexibility to quickly and easily create copies of user-defined tasks and update the copy over time.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, select a major task that includes a user-defined task and click **Edit Major Task**.

5. On the **Task Manager** screen, from the list of tasks displayed at the bottom of the **Major Task Details** tab, select the user-defined task and then click **Copy Task**.

   • You can only copy tasks from major tasks of the same scope.

   • The copied task appears under the original in the left pane with _1 appended to its name.

6. On the **Task Details** tab, you can change the name of the copied task and other details about the task.

   • All tasks under a major task inherit its characteristics, such as the unit of measurement, the scope, distribution, and start and end dates.

   • ClearTrial 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 on the Assignments and Labor tabs.

- Select an assignment group for the task.

- Select a summary group for the task which corresponds to the summary grouping displayed on the Plan Summary tab.

7. Identify where the task should appear in list of tasks under the major task. From the **Display this Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the task before or after which to display the task.

8. Click **Save & Close**.

Choose Assignment and Summary Groups for Tasks

You can move tasks from one summary group to another to match your organization's hierarchy. The ClearTrial-defined summary groups appear on the Plan Summary tab and include the tasks assigned per summary group.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, select a major task and click **Edit Major Task**.

5. On the **Major Tasks Details** tab for the selected major task, select a task and click **Edit Task**.

> ✎ **Note:**
>
> The Major Task Details tab shows the assignment group and summary category for each task.

6. To change the assignment group, from the **Assignment Group** drop-down list select a different assignment group. Assignment groups are represented by radio buttons in the Responsibilities section of various tabs and as drop-down lists on the Assignment tab.

    Tasks are grouped by assignment groups only for the purposes of easier assignments or exclusions. Tasks are otherwise grouped by major task for the purposes of calculated effort.

7. Change the summary category by selecting a different category from the **Summary Category** drop-down list.

    Summary categories determine how the hours and fees are summarized ("rolled up") and displayed on the Summary tab of your plan and Plan Summary report. Tasks are otherwise grouped by major task for the purpose of calculated effort.

8. Click **Save**.

Rename or Reorder Tasks

Within your plan, you can edit the name and description of each Task and specify where it appears in reports and in the Task Manager tree.

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, select the major task and click **Edit Major Task**.

5. From the list of tasks shown at the bottom of the **Major Task Details** tab, select the check box of the task and click **Edit Task**.

6. On the **Task Details** tab, rename or reorder the task.

   - In the **Name** field, enter a new name.

     – Optionally, specify a code to appear as a prefix when this task appears. The code also determines the default position of the task within the Task Manager.

     – Change the description to describe the new name.

     – Specify where the renamed task should appear in task list. From the **Display this Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the task before or after which to display the task.

   - If reordering an existing task:

     – On the **Task Details** tab, from the **Display this Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the task before or after which to display the task.

     – Alternatively, use the mouse to highlight the task and drag and drop it into the new position.

7. Click **Save & Close**.

Delete ClearTrial-defined Major Tasks or Tasks

To exclude ClearTrial-defined major tasks or subtasks from the specific trial you are planning, you can delete them.

Deletion removes the major task or subtask only from the plan you're editing. It does not delete it from the template on which the plan is based. However, you will be prompted to confirm the deletion, as it cannot be undone.

> **✎ Note:**
>
> You cannot delete major tasks or subtasks for meeting labor. Instead, edit or delete the associated meetings.

To delete a ClearTrial-defined major task:

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, highlight the major task you want to delete by clicking its row.

5. Click **Delete Major Task**.

6. Confirm the deletion.

To delete a ClearTrial-defined task:

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

2. On the **Plans** screen, select the plan, and then click **Edit**.

3. On the **Edit Plan** screen, select the **Labor** tab.

4. On the **Labor** tab, select a Major Task and click **Edit Major Task**.

5. On the **Major Task Details** tab, select the task to be deleted from the list of tasks.

6. Click **Delete Task**.

   ClearTrial deletes the task without asking for confirmation. It appears crossed out in the list of tasks.

5
Refine a Plan

As you add more details or want to try different or more precise assumptions, you can update a plan to learn the impact of the changes.

ClearTrial offers extensive flexibility and configurability to tailor a plan to your organization's work breakdown structure, business processes, and the unique characteristics of individual trials.

If the plan was created in Quick Mode or Basic Mode, you can switch to Advanced or Expert Mode to change more granular assumptions or customize the work breakdown structure.

You may also want to update a plan in response to collaboration with a CRO (or sponsor if you work for a CRO), especially during the RFP/Bid process if you are also using ClearTrial to generate RFPs and import and compare bids.

If you want to maintain a forecast/scenario to compare against your changes, make a copy of the plan and edit the copy instead.

- Edit a Plan
  Refine a plan by editing the assumptions set on the tabs on the Edit Plan screen.

- Change the Cost Model for a Plan
  ClearTrial recommends upgrading plans to the latest available cost model available to take advantage of the clinical intelligence updates in each successive release.

- Working with Custom Field Models
  The DRAFT custom field model is considered the working copy and is the only version where changes can be made to custom fields.

- Add Custom Fields to a Plan (Enterprise Edition)
  If you have purchased the Enterprise Edition of ClearTrial, you can create custom fields and define default formulas for them when you need to add additional drivers to plans or use them as custom work units or variables when defining custom level-of-effort or cost algorithms.

- Define Custom Algorithms
  You can configure custom algorithms using multiple expressions (requires the Advanced Algorithm Editor additional role/capability) or via script (requires the Expert Algorithm Editor additional role/capability).

- User-defined Resources
  Resources are the roles that people who work on the study are assigned.

- Compare Plans
  When determining the optimal scenario, you can create several plans to compare and choose between. For example, you might test the impact of upgrading to a later cost model.

Edit a Plan

Refine a plan by editing the assumptions set on the tabs on the Edit Plan screen.

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

2. On the **Plans** screen, select the check box of the plan to edit, and then click the **Edit** button.

3. Enter or edit the information on each tab, clicking **Next** to save your changes and advance to the next tab.

> ✏️ **Note:**
>
> If a request for proposal (RFP) was created from a plan, the plan is permanently locked and a red lock icon is displayed next to the plan (or RFP) on the Plans screen.
> If you want to make changes to your RFP and have a new version to model from your vendor, make a copy of the plan, make those changes in the copy, and generate a new RFP from the copy.

> 💡 **Tip:**
>
> To make changes to a **template**, from the **Maintain** menu, click **Templates**. Select the template and click **Edit**.

- Copy a Plan
  Copying a plan facilitates comparing What If? scenarios and basing new plans off of existing plans.

- Lock and Unlock Plans
  Locking a plan ensures that your entered assumption values are preserved and not changed by other users and prevents ClearTrial from recalculating effort and costs.

Copy a Plan

Copying a plan facilitates comparing What If? scenarios and basing new plans off of existing plans.

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

2. On the **Plans** screen, select the plan you want to copy.

> ✏️ **Note:**
>
> You cannot copy a plan in an *Incomplete* status.

3. Click the **Copy** button.

4. On the **Copy Plan** screen, in the **Plan Name** field, enter a new, unique name for the new plan.

5. 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.

   For more information, see What is the Cost Model?

6. From the **Custom Field Model** drop-down list, select a custom field model or **None** to not assign a custom field model. The default selection is the current custom field model used by the plan.

7. Click **Ok**.

   ClearTrial displays the Overview tab on the Edit Plan screen for you to specify assumptions for the copied plan.

Lock and Unlock Plans

Locking a plan ensures that your entered assumption values are preserved and not changed by other users and prevents ClearTrial from recalculating effort and costs.

ClearTrial recommends locking any plan you have used to provide information or reports to other parties or represents the best scenario for executing that trial.

Lock a plan

1. On the **Plans** screen, select one or more plans.

2. Click the **Other Actions...** button, and then select **Lock Plans**.
   A Lock icon (

) appears next to the plan. Users cannot edit a locked plan until it is unlocked.

> **Note:**
>
> You can still change the status, name, and/or description of a locked plan with the Change Plan Attributes option from the **Other Actions...** menu.

Unlock a plan

1. On the **Plans** screen, select one or more locked plans.

2. Click the **Other Actions...** button, and then select **Unlock Plans**.
   ClearTrial unlocks the plan. The Lock icon disappears.

Why can't I unlock a particular plan?

Some plans cannot be unlocked; for example, permanently locked plans used to generate RFPs or legacy plans locked to cost models prior to 4.2.

If you need to make changes to a locked plan, copy the plan and make your changes to the copy.

> **Note:**
>
> When you unlock or copy an existing plan using a 5.2 or prior cost model, that plan defaults to use the latest available cost model. If you want to model the trial using a prior cost model, use the Change Attributes option to change the cost model (and/or other attributes of the plan).

Change the Cost Model for a Plan

ClearTrial recommends upgrading plans to the latest available cost model available to take advantage of the clinical intelligence updates in each successive release.

However, if you have plans with which you are satisfied, are currently using to negotiate with a CRO (or Sponsor), or are using to record changes to the plan during trial execution, you can continue to use the prior cost model so that the plan will calculate according to the algorithms defined at the time of its creation or last update.

To change the cost model for a plan:

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1. From the **Edit** menu, select **Plans**.
2. On the **Plans** screen, select the plan to edit.
3. Click the **Other Actions...** button, and then select **Change Attributes**.
4. On the **Change Plan Attributes** screen, from the **Cost Model** drop-down list, select a cost model.
5. Click **Save**.

While viewing or editing a plan, the cost model being used appears at the top right of the screen.

> 💡 **Tip:**
>
> You can select the cost model as a column to display on the Plans screen by selecting the **Configure List Options** link displayed at the upper right side of every list screen.

- What is the Cost Model?
  A ClearTrial Cost Model is the set of algorithms, default assumption values, task and cost definitions, and resources that are used to calculate and represent the expected timelines, effort, and cost estimates for a plan.

What is the Cost Model?

A ClearTrial Cost Model is the set of algorithms, default assumption values, task and cost definitions, and resources that are used to calculate and represent the expected timelines, effort, and cost estimates for a plan.

- When ClearTrial releases a new version, a new cost model is created to reflect the latest industry-standard costing algorithms. Plans using previous cost models continue to calculate and represent trial activities and effort exactly as they did prior to the new release.

- The Cost Model does NOT include billing and inflation rates. These values are maintained in a plan-neutral manner. If you want your plan to continue to use the billing and inflation rates which were used when the plan was created, you must freeze the rates.

Working with Custom Field Models

The DRAFT custom field 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:

- **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. To add custom fields, you must check out the DRAFT model.

- **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.

Don't worry, you can always cancel the checkout once you have it opened to discard your changes.

- Create a Custom Field Model
  To add a custom field model, start by checking out the DRAFT model.

- Publish a Custom Field Model
  Publishing the model makes it available for use in plans.

- Apply a Custom Field Model to a Plan
  To apply a custom field model to a plan, you must publish it and define attributes for applying it. Depending on the criteria you select, the custom fields appear in new plans.

Create a Custom Field Model

To add a custom field model, start by checking out the DRAFT model.

The DRAFT custom field model is considered the working copy and is the only version where changes can be made to custom fields.

1. From the **Maintain** menu, select **Custom Fields** to display the Custom Field Models screen.

   The Custom Field Models screen lists all the currently defined custom field models.

   - Each custom field model is identified by a unique version number.

   - If the model has been published and can be applied to new plans, the **Published Date** and **Published By** columns are populated.

2. Select the **DRAFT custom field model**, and click **Checkout**.

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

3. Click **New** to add a new field to that model.

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

   • ClearTrial provides on-screen help for each field as it gains focus.

   • For more information about any field, click the field label to display more help for the field and for the screen.

5. Click **Save**.

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

Publish a Custom Field Model

Publishing the model makes it available for use in plans.

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

2. Select the **DRAFT custom field model**, and then click **Publish**.

> ✎ **Note:**
>
> You can also open the Draft custom field model and click **Publish**.

3. On the **Publish Custom Fields** screen, in the **Description** field, you must type a short description for the new custom field model.

4. Click **Publish**, then **Close**.
   The published custom field model is assigned a version number and added to the list of custom fields on the custom field list screen.

   • You can now use the custom fields in your plans.

   • If a plan is using a custom field model, the version number is displayed in the upper right corner of each plan screen.

   • Custom Fields can be displayed on any of the following tabs of a plan:

     – Overview

     – Site

     – Subject

     – Treatment

     – Data

     – Monitoring

   • Custom fields are displayed in a separate data field set, labeled Custom Fields, below ClearTrial-defined assumptions on the tab specified, so you can easily locate them.

Apply a Custom Field Model to a Plan

To apply a custom field model to a plan, you must publish it and define attributes for applying it. Depending on the criteria you select, the custom fields appear in new plans.

1. On the **Plans** screen, select the check box of the plan to which to apply the custom field model.

2. Click the **Other Actions** button and select **Change Plan Attributes**.

3. On the **Change Plan Attributes**, from the **Custom Field Model** drop-down, select the custom field model to apply.

4. Click **Save & Close**.

Add Custom Fields to a Plan (Enterprise Edition)

If you have purchased the Enterprise Edition of ClearTrial, you can create custom fields and define default formulas for them when you need to add additional drivers to plans or use them as custom work units or variables when defining custom level-of-effort or cost algorithms.

Prerequisite: Custom Fields Designer: Users with this additional role/capability can create, edit, and delete custom fields within the DRAFT custom field model and check-out, check-in, and publish the custom field model. This additional role can only be granted to Clinical or System administrators.

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Definitions

- **Custom field**: A field in which to enter a custom assumption value.
  - 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 and use the custom fields of that model in your plan.
  - You can define the default value for a custom field by entering a static value or by using a formula to calculate the value.

- **Custom assumption**: The value(s) entered in a particular plan.
  - 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.
  - Custom Fields can be defined to appear in only certain plans (according to the study's phase, therapeutic area, and indication) and/or to appear on specific tabs and to be visible in specific edit modes.

Define Custom Algorithms

You can configure custom algorithms using multiple expressions (requires the Advanced Algorithm Editor additional role/capability) or via script (requires the Expert Algorithm Editor additional role/capability).

> **✎ Note:**
>
> Configuring custom algorithms using multiple expressions requires the Advanced Algorithm Editor role. Using a script requires the Expert Algorithm Editor role. Use the scripting language only if your algorithm cannot be accomplished via the expression functionality.

1. Open the **Costs** tab and select the **New** button to display the **Definition** tab on the **Define New Category** screen.

2. On the **Define New Category** screen, after providing basic information on the **Definition** tab and assigning the cost to a service provider on the **Assignments** tab, select the **Algorithm** tab.

3. To define an expression, make sure that the **Switch to Script** link is displayed.

4. in the **Calculate as** field, specify the per unit cost value and select the currency for the cost for all locations or each specific location from the currency drop-down list.

   - Editing this field does not convert a previously entered value. ClearTrial assumes that the value you entered is expressed in the chosen currency.

   - When the currency is edited, ClearTrial applies the change to the location-specific costs, 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 or decrease the number derived from the underlying assumption for the driver.

6. From the **of** drop-down list, select a unit-based assumption to drive the calculation of this cost.

   - Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption automatically adjust this cost.

   - User-defined cost drivers appear in the drop-down list in italicized type followed by an asterisk.

   ClearTrial 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. System-calculated cost values are displayed to the right of the **Calculated** field and cannot be changed.

7. You can create algorithms with up to eight individual expressions. To add another expression, click the Add another expression link, then specify the calculation information.

   - Each expression within the algorithm has the ability to use a different cost driver, also known as a Work Unit, a percentage to apply to the cost driver and monetary value.

- When working with multiple expressions, enter a per cost driver cost, currency, cost driver, and percentage to apply to the cost driver to evaluate to a specific monetary value in a specific currency.

- If you have specified that the cost varies by location, you can define a specific algorithm for each location.

8. If necessary, switch to Script mode by clicking the **Switch to Script** link, then type the expression in the **Calculate as** field and specify the currency in the **in** drop-down list.

> ✏️ **Note:**
>
> When working with expert algorithms, the scripting language is used to define mathematical formulas to calculate the monetary value of the cost item. Expert algorithms should only be used if you are unable to produce the right cost value using multiple expressions.

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

9. Click **Save**, and select the **Distribution** tab.

- About Custom Algorithms
  For user-defined resources and indirect costs, you can create custom algorithms to generate the level of effort hours (for resources) or monetary value (for costs).

- Define a Multi-expression Indirect Cost Algorithm
  Multiple-expression algorithms can be used to calculate or adjust the value of a cost item. If you have specified the cost as location-scoped, you can define an algorithm for each location.

- Define a Scripted Algorithm
  ClearTrial allows users licensed to Enterprise Edition and granted the Expert Algorithm Editor role to define algorithms using a scripting language.

- Create a Default Algorithm That Applies to All Locations
  For tasks or costs/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.

About Custom Algorithms

For user-defined resources and indirect costs, you can create custom algorithms to generate the level of effort hours (for resources) or monetary value (for costs).

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Prerequisites

- Only visible in Advanced and Expert Modes.

- User must be assigned one of these two roles:

  – **Advanced Algorithm Editor**: Users with this role have permissions to create or edit cost or resource algorithms with multiple expressions. This additional role/capability

can only be granted to Power User, Clinical Administrator, or System Administrator users.

– **Expert Algorithm Editor**: Users with this role have permissions to create or edit cost or resource algorithms by creating custom mathematical formulas via a scripting language. The scripting language used to define the formulas is based on JavaScript. This additional capability can only be granted to Power User, Clinical Administrator, or System Administrator users.

You can use the following to create your algorithms:

• Multiple Expressions (Advanced mode)

• Scripted Algorithms (Expert mode)

When defining a user-defined resource's algorithm in Task Manager or defining a user-defined pass-through cost on the Costs tab, in Advanced Edit Mode, you can build your custom algorithms using multiple expressions with multiple cost drivers, including a percentage of a cost driver, per expression.

Best practice is to use the multiple expressions functionality to define your algorithms, whenever possible. However, if you are unable to produce the correct level of effort in hours or monetary cost value using multiple expression algorithms, ClearTrial offers Enterprise Edition Expert Mode users the ability to create and define custom mathematical formulas via a scripting language.

The scripting language used to define the formulas is based on JavaScript.

ClearTrial exposes all of a plan's assumptions as variables to use in these formulas as well as a few precalculated values useful for creating algo-rithms.

When dealing with algorithms, there are two concepts to understand:

• **Expression**—Elements of an algorithm.

    For resources, the expression 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).

    For costs, the expression 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 evaluates to the level of effort in hours required for the resource to complete the task or whose total value evaluates to the monetary value in a specific currency for a cost item.

    Example of resource algorithm: 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).

    Example of cost algorithm: 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).

Define a Multi-expression Indirect Cost Algorithm

Multiple-expression algorithms can be used to calculate or adjust the value of a cost item. If you have specified the cost as location-scoped, you can define an algorithm for each location.

1. On the **Define New Category** screen, after providing basic information on the **Definition** tab and assigning the cost to a service provider on the **Assignments** tab, select the **Algorithm** tab.

2. To define an expression, in the **Calculate as** field, specify the per unit cost value and select the currency for the cost for all locations or each specific location from the currency drop-down list.

   - Editing this field does not convert a previously entered value. ClearTrial assumes that the value you entered is expressed in the chosen currency.

   - When the currency is edited, ClearTrial applies the change to the location-specific costs, unless they have been overridden to vary from the amount and currency entered in this section.

   a. In the **per** field, specify a percentage value to apply to the selected cost driver for the expression. This percentage will increase or decrease the number derived from the underlying assumption for the driver.

   b. From the **of** drop-down list, select a unit-based assumption to drive the calculation of this cost.

      - Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption automatically adjust this cost.

      - User-defined cost drivers appear in the drop-down list in italicized type followed by an asterisk.

      ClearTrial 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. System-calculated cost values are displayed to the right of the **Calculated** field and cannot be changed.

   c. You can create algorithms with up to eight individual expressions. To add another expression, click the **Add another expression** link, then specify the calculation information.

      - Each expression within the algorithm has the ability to use a different cost driver, also known as a Work Unit, a percentage to apply to the cost driver and monetary value.

      - When working with multiple expressions, enter a per cost driver cost, currency, cost driver, and percentage to apply to the cost driver to evaluate to a specific monetary value in a specific currency.

      - If you have specified that the cost varies by location, you can define a specific algorithm for each location.

   d. Click **Save**, and select the **Distribution** tab.

Define a Scripted Algorithm

ClearTrial allows users licensed to Enterprise Edition and granted the Expert Algorithm Editor role to define algorithms using a scripting language.

This scripting language is based on a simplified subset of JavaScript and uses the JavaScript engine built into Java itself to evaluate the formulas you have composed. There are various websites on the internet available to learn more about JavaScript, but you only need to know how to use those features specific to writing algorithms.

- Although you do not need to be a software developer or expert in JavaScript, ClearTrial does recommend that you review some of the available tutorial websites.

- There are basic rules you should understand to use the scripting features; for example, JavaScript is case sensitive, so a variable name like "numEdits" is not the same variable as "numedits" for example.

- **Arithmetic operations:**

  - Addition (+)

  - Subtraction (-)

  - Multiplication (*)

  - Division (/)

- **Conditional statements:**

  - if / else if / else

  - Switch / case

- **JavaScript comparison operators:**
  >, >=, <, <=, ==, !=, ===

- **JavaScript logical operators:**

  - &&, ||

- **JavaScript Math functions:**

  - Use Math.round(x) to return the value of x rounded to its nearest integer; Math.round(1.6) returns 2

  - Use Math.floor(x) to return the value of x rounded downward to its nearest integer; Math.floor(1.6) returns 1

  - Use Math.ceil(x) to return the value of x rounded up to its nearest integer; Math.ceil(1.2) returns 2

  - Use Math.max() to find the highest value in a list of arguments; Math.max(5, 10, 15) returns 15

  - Use Math.min() to find the lowest value in a list of arguments; Math.min(5, 10, 15) returns 5

  - The following are less common Math functions that are valid to use in ClearTrial:

    * Use Math.sqrt(x) to return the square root of x; Math.sqrt(144) returns 12

    * Use Math.pow(x,y) to return the value of x to the power of y; Math.pow(8,2) returns 64

    * Use Math.exp to return e (Euler's number) raised to the power of the value provided as parameter; Math.exp(1) returns 2.718

    * Use Math.log to return the logarithm of the given parameter; Math.log(10) returns 2.303

Scripted algorithms can use any valid variable to help drive hours or costs.

A variable represents a ClearTrial work unit/cost driver or a custom assumption.

For example, the number of weeks between study start date and final report is represented by the variable name *$numWeeks*.

Over 200 ClearTrial variables are exposed to be used in a custom algorithms.

- The ClearTrial variables that can be used in a plan depend upon the plan's assigned Cost Model and Custom Field Model.
- All ClearTrial variables start with a dollar sign ($).
- Variables based on custom assumptions are defined by the Custom Field Designer.
- For a list of all the ClearTrial variables available as well as more information on working with expert algorithms, see the *Script Variables Guide*, available for download on the Oracle Help Center.
- For the list of user-defined variables, consult the Custom Field Model for the plan.

Example 1: You want to create a scripted algorithm to calculate the level of effort in hours for a user-defined resource based on the EDC maturity level selected for the plan. If the EDC maturity level selected is 1, then the level of effort should be 2 hours; if the level selected is 2, then the level of effort should be 1.5 hours; for any other selected level, the level of effort should be 0.5 hours.

1. On the **Algorithm tab** for the task/resource, click **Switch to Script** to switch into script mode.

2. Using the ClearTrial variable that exists for the EDC maturity level, $edcMaturityLevel, specify, in the script box, the conditional task/resource algorithm script to be:

   if (1 == $edcMaturityLevel) {2;}

   else if (2 == $edcMaturityLevel) {1.5;}

   else {.5;}

Example 2: You want to create a new user-defined cost for annual fees to be calculated as $1000 for each year of the plan after year 1.

1. On the **Algorithm tab** for the indirect cost, click **Switch to Script** to switch into script mode.

2. Using the ClearTrial variable that exists for the number of weeks between study start date and final report (e.g., study duration), **$numWeeks**, specify in the script box the cost algorithm script as:

   1000 * Math.ceil(($numWeeks / 52) - 1)

- Auto-formatting and Auto-completion
  ClearTrial automatically formats your algorithm script to make it easier to read and understand.

- Validation As You Type
  ClearTrial helps you write valid scripts by providing information about the script's validity and performance as you create it. This prevents you from saving scripts that will not execute properly.

Auto-formatting and Auto-completion

ClearTrial automatically formats your algorithm script to make it easier to read and understand.

- For each line of a scripted algorithm, a unique line number displays as the first character for the row. The first line number will always be "1," and each subsequent line number will follow sequential numbering logic.

- ClearTrial indents a new line automatically when the user inserts **Enter** after a leading brace.

- Variable name and keyword suggestions are provided with related descriptions, so that you can quickly find and select items from a pre-populated list to ensure you use valid variable names or keywords in the script.

  – You can click a selection from the pre-populated list and the selection will be inserted into the script.

  – When a pre-populated list is displayed, a description displays next to each list item.

- Because braces and brackets are often troublesome, when you place the cursor near a parenthesis, brace, or bracket ("(",")"," { ", "} "), the matching pair of braces, brackets, or parentheses is highlighted.

Validation As You Type

ClearTrial helps you write valid scripts by providing information about the script's validity and performance as you create it. This prevents you from saving scripts that will not execute properly.

Validation checks include:

- Scripts must be valid JavaScript whose last statement evaluates to the value desired.

- Scripts must only use the following JavaScript keywords: **if**, **else**, **true**, **false**, **null**, **switch**, **case**, **break**, and **default**.

- Scripts must not contain double or single quotes or any characters other than: upper or lowercase letters of the alphabet, numbers, dot, comma, mathematical operators (+,-,*,/,%), underscore, ?, :, ;, =, <, >, !, $, &, |, (,), {, } , space, or newline.

- Scripts must not contain variables that are not defined/exposed with respect to the plan in which the scripts are created.

As you type your script, ClearTrial identifies any syntax that is invalid and highlights what has caused the error.

If the script is valid, ClearTrial provides an estimate of execution time, so you can adjust the run-time characteristics of your code.

Create a Default Algorithm That Applies to All Locations

For tasks or costs/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.

User-defined Resources

Resources are the roles that people who work on the study are assigned.

There are two types of resources in ClearTrial:

- **ClearTrial-defined resources** are the ClearTrial default resources working on tasks. You can edit these resources.

- **User-defined resources** are custom resources you create and define to more accurately reflect your or your CROs' organizations' staffing and costing structures.

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- Create a Resource
  You can add new resources and then assign these user-defined resources to both system-defined and user-defined tasks using the Task Manager.

- Add a User-defined Description for a ClearTrial-defined Resource
  You can update the description for ClearTrial-defined resources and user-defined resources so that it adequately provides other users the information they need to identify the correct resource to add to a task.

- Override Plan-level Resource Assignments
  When designing a trial, you can create alternative estimates by replacing all resources of one type with a different one.

Create a Resource

You can add new resources and then assign these user-defined resources to both system-defined and user-defined tasks using the Task Manager.

Prerequisite: You must be a Resources Administrator to assign, create, edit, or delete user-defined resources.

1. From the **Maintain** menu, select **Resources**.
2. On the **Resources** screen, click **New**.

3. On the **Create Resource** screen, in the **Resource Summary** section, enter a resource code, name, and description. For more information about a field, click the field label to display online help.

   Use the **Code** field to quickly identify your resource throughout the user interface and in reporting. Specify a unique alphanumeric code that represents the resource that will be displayed in the plan and on reports; for example, CRO1.

4. In the **Default Billing Rates** section, enter the hourly rate for each resource for work performed in North America or USA for the ClearTrial-defined composite providers by entering a value in each cell. Rates for other locations are derived based on ClearTrial-defined percentage variances.

   • For providers you have defined, use the Billing Rates Maintenance features to provide and publish specific rates for each location.

   • Click **Auto Fill** if you do not want to manually enter each of the U.S. rates for each of the rate years displayed. You will be prompted with options on how to auto-populate rates for the resource; for example, you can populate rates based on a yearly percentage increase. Choose an option, enter the values, click **Apply**, and then **Ok**.

5. Click **Save**.

Add a User-defined Description for a ClearTrial-defined Resource

You can update the description for ClearTrial-defined resources and user-defined resources so that it adequately provides other users the information they need to identify the correct resource to add to a task.

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

2. On the **Resources** screen, select the ClearTrial-defined resource, and then click **Edit**.

3. On the Edit Resource screen, click the **Edit** icon (

) to the right of the description.

4. Edit the description, and then click **Save**.

5. Click **Close**.

Override Plan-level Resource Assignments

When designing a trial, you can create alternative estimates by replacing all resources of one type with a different one.

For example, you might substitute junior programmers for senior clinical research associates (senior CRAs) to perform project management activities. You can substitute at the global level or for each task and override plan-level resource assignments per provider.

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

2. On the **Plan** screen, select the plan and then click **Edit**.

3. On the **Edit Plan** screen, select the **Assignment** tab.

4. Click the Task Assignments section, click the **Override Resources or Rates** link.

5. On the **Resource Overrides** screen, in the **Scope of Overrides** section, select a provider from the **For tasks assigned to** drop-down list.

6. In the **Resources/Overrides** section, specify your override for each default resource specification and pin your changes if desired.

7. Click **Save**.

8. To clear the overrides made in one click, click the **Clear Overrides** link**.**

Compare Plans

When determining the optimal scenario, you can create several plans to compare and choose between. For example, you might test the impact of upgrading to a later cost model.

Comparing copies of a plan to one another can pinpoint the areas in which costs and timelines are negatively or positively impacted by different strategies.

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

2. On the **Plans** screen, select two or more plans to compare. You cannot compare plans whose status is *Incomplete*.

3. Click **Compare**.

4. On the **Compare Plans** screen, in the **Available Comparisons** section, choose the type of comparison and any applicable options. You can compare:

   • **Assumptions**—Comparison of assumptions for two or more plans.

   • **Fees and Costs**—Differences in fees, bottom line 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 bottom line discounts) per resource for the selected plans.

   • **Milestone Dates**—Differences in milestone dates.

   Depending on the type of comparison, other reporting options are dynamically enabled.

5. In the **Providers To Include** section, select one or more of the providers to include or select **All Providers**.

6. In the **Reporting Currency** section, select the currency to use in the comparison from the drop-down list and whether to round values up to the nearest denomination.

7. Click **Ok**.

   ClearTrial display a comparison report in the currency specified and highlights the differences.

   > ✎ **Note:**
   >
   > ClearTrial does not include the variance column.

8. You can print the report, view it as a PDF, or export it to Excel or CSV by selecting the appropriate link at the bottom of the report.

9. To close the report, click the **Close** link.

- Compare a Copy of a Plan to its Original
  Use the Compare to Original report from the Reports tab of a plan to compare a
  copied plan to the original/source plan.

- Compare a Plan to its Template
  Generate the Compare to Template report to quickly determine how a plan has
  been changed from its template.

Compare a Copy of a Plan to its Original

Use the Compare to Original report from the Reports tab of a plan to compare a
copied plan to the original/source plan.

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

2. On the **Plans** screen, select the copied plan and click **Edit**.

> ○ **Tip:**
>
> Double-clicking anywhere in the row listing a plan on the Plan list screen
> also redirects you to the Edit Plan screen. This shortcut is available on
> any screen listing things that can be opened or edited.

3. On the **Edit Plan** screen, select the **Reports** tab.

4. Scroll down to the **Comparisons** section and select either the thumbnail report
   shown or the **Compare to Original** link.

5. On the **Compare Plans** screen, from the **Available Comparisons** section, choose
   the type of comparison and any applicable options.

6. Click **Ok**.

7. Print the report, view it as a PDF, or export it to Excel or CSV by selecting the
   appropriate link at the bottom of the report.

8. To close the report, click the **Close** link.

Compare a Plan to its Template

Generate the Compare to Template report to quickly determine how a plan has been
changed from its template.

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

2. On the **Plans** screen, select the copied plan and click **Edit**.

3. On the **Edit Plan** screen, select the **Reports** tab.

4. From the **Comparison** section, select **Compare to Template**.

5. On the **Compare Plans** screen, from the **Available Comparisons** section, choose
   the type of comparison and any applicable options.

6. Click **Ok**.

7. Print the report, view it as a PDF, or export it to Excel or CSV by selecting the
   appropriate link at the bottom of the report.

8. To close the report, click the **Close** link.

6

Create a Request for Proposal (RFP)

If you have purchased the Enterprise Edition of ClearTrial Plan and Source (for Sponsors), and you have the required additional roles assigned, you can create a request for proposal from a plan and send it to your vendors to bid.

> **Note:**
>
> The features described are available only to sponsors who have an Enterprise Edition license for ClearTrial Plan and Source Cloud Service.

▶ Video

If you are not a licensed user, you can still see the applicable options in menus, but they are inactive.
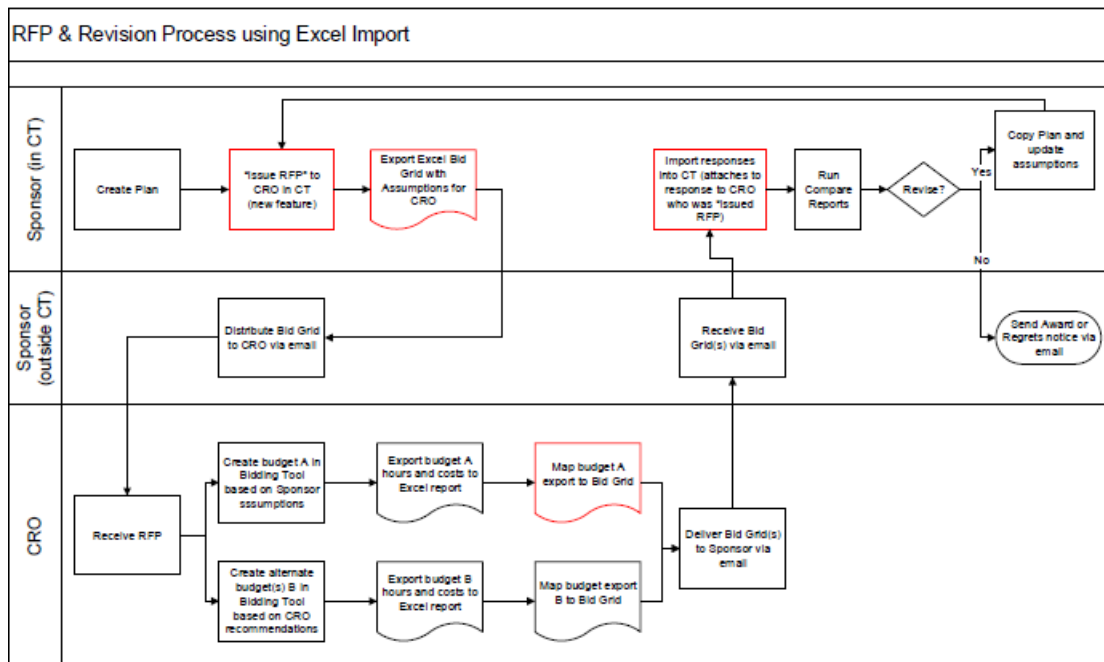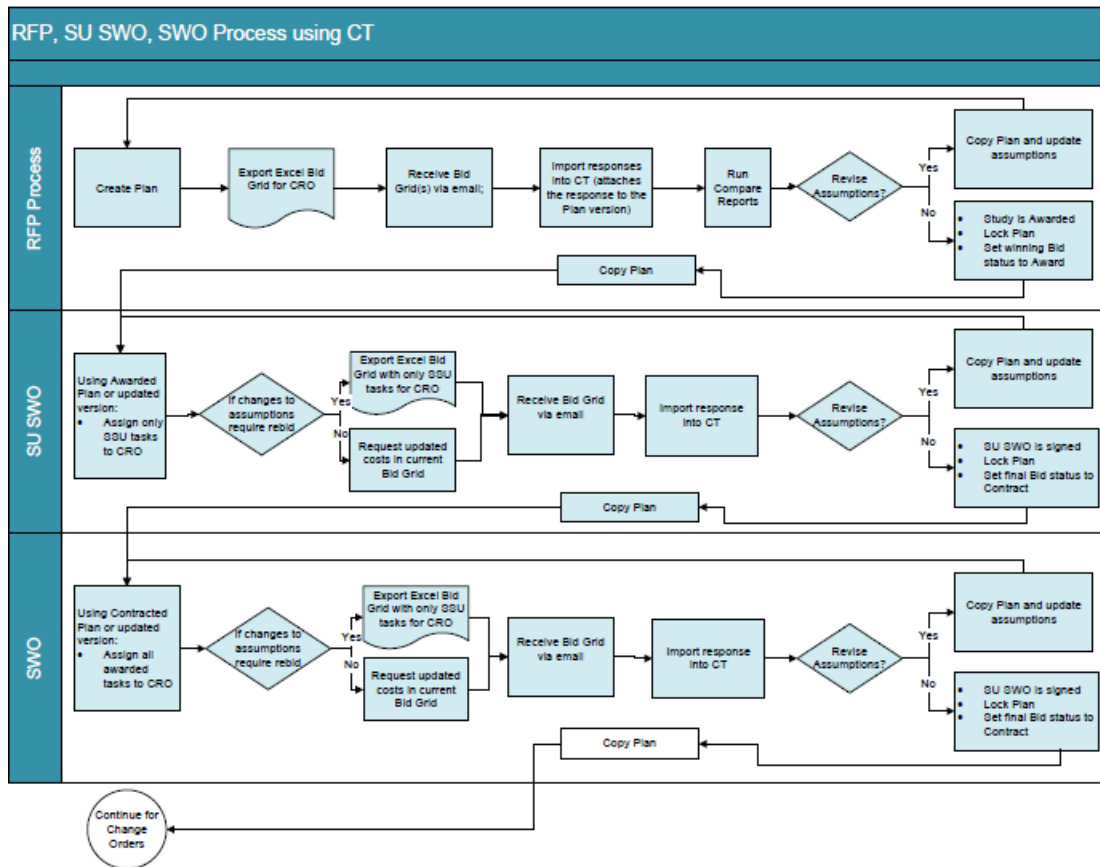
Figure 6-1   Process Flow Diagram

Figure 6-2   Process Flow Diagram

- Required Additional Roles and Capabilities
  To work with RFPs and bids in ClearTrial, users need one of the described roles or capabilities granted to their user accounts.

- Create an RFP from Your Plan and Download the Bid Grid
  From your final operational benchmark plan, you can create one or multiple RFP versions to send out to vendors.

- Work with the Bid Grid
  The Bid Grid is a Microsoft Excel workbook based on RFP data. Vendors fill in a bid grid to respond to your associated RFP.

- Work with Bids
  When your vendor completes the RFP and submits a bid to you offline, you can import the bid back into ClearTrial to do a thorough comparison against other bids or to the benchmark's planned values.

Required Additional Roles and Capabilities

To work with RFPs and bids in ClearTrial, users need one of the described roles or capabilities granted to their user accounts.

Please contact your assigned ClearTrial System Administrator to grant you these additional roles.

- **RFP Administrator**: Users with this role can create, edit, or delete Requests for Proposals (RFPs).
- **RFP/Bid Reader**: Users with this role have read-only access to RFPs and bids; they cannot make changes.

Create an RFP from Your Plan and Download the Bid Grid

From your final operational benchmark plan, you can create one or multiple RFP versions to send out to vendors.

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

   > **Tip:**
   >
   > Alternatively, you can create RFPs by clicking the **Edit** menu, selecting **RFPs**, and then clicking **New**.

   If you try to create another RFP for the same provider or scope of work, ClearTrial displays a warning message that an RFP already exists and asks if you want to continue.

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 vendor-completed bids later, upon upload each bid inherits the vendor name from the Bid Grid.

3. In the **RFP Info** section, a file name for the Bid Grid, a short description of the RFP, and any comments.

   - The Bid Grid file name is the name under which the downloaded Bid Grid is saved to your computer.

   - You can edit the short description for your RFP to efficiently identify or filter out specific RFPs.

   - The Comments field is a space to record any notes relevant to the RFP. For example, you might want to capture specific audit details, such as who you sent the grid to and when, or any contact details.
     The Bid Grid file name, short description, and comments you enter can be edited at any time from the Edit RFP Details screen (launched by clicking **Edit** for an existing selected RFP from the RFP screen).

4. In the **Bid Grid** section, select **Download Bid Grid**.

5. Click **Continue....**.

6. On the **Download Bid Grid** screen, select options from the various sections to set the level of detail for your bid grid so that it aligns with the precise level and scope of work you want to include for bidding.

> 💡 **Tip:**
>
> For details about the options, click the help icon in the top right of the screen.

7. Click **Download**.

   - ClearTrial generates the RFP and adds it to the RFPs list.

   - To see the RFPs, from the **Edit** menu, select **RFPs** .

   > ✎ **Note:**
   >
   > ClearTrial generates and downloads the Bid Grid as a Microsoft Excel file, which has an .xls extension. Do not change the extension as this is the only supported file type when uploading bids.

   - The plan is now locked and its status is updated to RFP. A red lock icon (

) appears next to the plan to indicate that it is now permanently locked.
     If you need to make changes to the plan (for example, after discussions and agreement of alternate scenarios with your vendor), copy the plan, make the updates in the copy, and create a second version of the RFP.

     You can always refer to the original or initial version of the RFP, which is locked as read-only.

- Ways to Generate the Bid Grid
  If an RFP already exists for a plan, you can generate the Bid Grid from additional workflows or locations in the service.

Ways to Generate the Bid Grid

If an RFP already exists for a plan, you can generate the Bid Grid from additional workflows or locations in the service.

1. On the **Plans** screen, open the **Edit** and select **RFPs** to display RFPs generated for all plans.

2. Generate the Bid Grid in one of the following ways:

   a. Click the **New** button, select the plan for which you want to generate the Bid Grid, and continue by completing the wizard.

   b. Click **Download Bid Grid** just above the RFP list.
      For help with the options, click the help icon in the top right of the Download Bid Grid screen.

   c. Select an existing RFP and click **Edit**. Then, on the **Details** tab, click the **Download Bid Grid** link in the **History** section.
      For help with the options, click the help icon in the top right of the Download Bid Grid screen.

Work with the Bid Grid

The Bid Grid is a Microsoft Excel workbook based on RFP data. Vendors fill in a bid grid to respond to your associated RFP.

Vendors:

1. Receive a bid grid from a provider user and download it.

2. Open the downloaded bid grid in Microsoft Excel.

3. Read and understand the instructions for using the bid grid that are included on the first sheet of the workbook. Vendors are instructed:

   • To not alter the workbook structure or format. If they do, it can't be imported by the provider user.

   • That the workbook is password protected.

4. Complete each sheet of the workbook, following the instructions on the first sheet.

   • Only cells that are shaded light blue can be edited.

   • The currency that must be used for the bid appears on each worksheet.

   • Default mapping keys are included in the bid grid and you can edit these values to map back to your client grids in internal/other costing tools/systems.

   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.

5. After filling in the bid grid, email it to the provider, who then imports it into ClearTrial and uses ClearTrial features and tools to evaluate and compare the bids received.

• Default Bid Grid Structure
  The Bid Grid contains default instructions for your vendors to follow to complete their bids.

• 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.

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 bottom line 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*.

• The first worksheet includes instructions to bidders.

• The Bid Grid Summary page is generated after you have entered your detailed bid.

- The Bid Grid Centralized page 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.

- Column headers and input fields
  Password-protected headers describe the data in each column of the bid grid.

Column headers and input fields

Password-protected headers describe the data in each column of the bid grid.

- **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. *This column is populated based on the RFP and is not editable.*

- **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. You 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. Enter the RFP currency format with two-decimal point precision.

- **Inflated Billing Rate**—Inflated billing rate for the ClearTrial-defined 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. Enter 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. Enter the unit hours with three-decimal point precision.

- **Total Hours**—This column is calculated based on the vendor's input and the number of units. Enter the total hours with three-decimal point precision.

- **Unit Cost**—This column is calculated based on the vendor's input. Enter the RFP currency format with two-decimal point precision.

- **Total Cost**—This column is calculated based on the vendor's input and the number of units. Enter the RFP currency format with two-decimal point precision.

- **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 ClearTrial.

Default Bid Grid Structure

The Bid Grid contains default instructions for your vendors to follow to complete their bids.

To add custom instructions for a specific vendor, you can delete the Instructions worksheet and add your own custom sheets, in any order.

ClearTrial also includes the study specifications by default. This worksheet is editable to customize the content or format to align with your organization's existing business processes. Review the contents of this sheet and add your contact information at the top of the worksheet so that vendors have a name, email, or phone number to contact.

> **Note:**
>
> The study duration displayed beneath the final milestone on the Timelines sheet is calculated as the duration between the first and last included milestone.

Work with Bids

When your vendor completes the RFP and submits a bid to you offline, you can import the bid back into ClearTrial to do a thorough comparison against other bids or to the benchmark's planned values.

- Import a Bid
  Once a vendor has submitted a bid, you must save the submitted bid grid to your computer, then upload it.

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

- Replace a Bid
  You can replace a bid associated with an RFP with another bid.

- Review Vendor Bids
  Once vendors submit bids, you can review the bids.

- Update the Status of a Bid
  You can manually update the status of a bid.

- Compare bids
  You can compare bids for a single RFP or bids across RFPs.

Import a Bid

Once a vendor has submitted a bid, you must save the submitted bid grid to your computer, then upload it.

Video

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

2. On the **RFPs** screen, select the RFP plan name and click **Import Bid**.

3. On the **Import Bid** screen, in the **Bid Information** section, choose the bid grid file to upload by clicking **Browse** and finding the files on your computer. ClearTrial assumes that you have saved the submitted bid grid to your computer.

4. Add a short description to identify the bid, the bid number supplied by the vendor, and any comments about the bid to efficiently identify the bid in the future. Upon successful bid import, ClearTrial displays and associates the vendor name with the bid.

5. Click **Ok**.

> **Tip:**
>
> If a bid already exists for the provider, ClearTrial creates a new bid version number for that provider.

ClearTrial generates warnings that you might want the vendor to correct, but will still successfully import the Bid Grid.

> **Tip:**
>
> For successful bid imports, warnings are allowed; fatal errors are not and must be fixed for successful imports.

6. To see or save the list of issues encountered, click the **Download Issues** link.

   - You can also see the list of bid issues from the **Edit Bid** screen launched by selecting a bid from the **Bids** screen, clicking **Edit**, and navigating to the **Issues** tab.

   - You can download the list of issues from this screen by clicking the **Download** link located at the upper right hand side of the screen.

7. Save the issues list to your computer and share it with the vendor.

8. After the vendor resolves the fatal errors, you can import the revised bid.

9. To complete the import action, click **Continue**.

10. Click **Close**.
    All imported bids are available on the Bid List screen where you can review and select them for comparison.

Replace a Bid

You can replace a bid associated with an RFP with another bid.

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

2. Select **Replace Existing Bid**, and then select the bid to replace from the list displayed.

3. In the **Bid Information** section, choose the Bid Grid file to upload by clicking **Browse** and browsing the files on your computer.

4. Add a short description to identify the bid, the bid number supplied by the vendor, and any comments about the bid.

5. Click **Ok**.

6. Click **Continue**.

7. Click **Close**.

Review Vendor Bids

Once vendors submit bids, you can review the bids.

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

2. Select a bid with a status of Pending Review, and then click **Edit** to display the **Edit Bid** screen.

   You now have access to four tabs: Details, Labor, Costs, and Issues.

3. On the **Details** tab, edit basic information about the bid including the short description, CRO bid number, status, and comments.

4. On the **Labor** tab, review the proposed effort and fees supplied by this vendor.

   If the selected bid includes information at the resource by location level, an **Include Inflation** option is available on the **Edit Bids Labor** and **Edit Bids** tabs. Also, if the vendor has submitted values for the inflated billing rate column, the Include Inflation option is selected by default.

5. On the **Costs** tab, review pass-through and miscellaneous costs supplied by this vendor.

6. On the **Issues** tab, you can review the warnings and issues ClearTrial found when importing the bid. These issues must be corrected by you or the vendor.

7. To view the Bid Grid, on the **Bids** screen, click the **Download** button.

8. Click **Close**.

Update the Status of a Bid

You can manually update the status of a bid.

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

2. On the **Bids** screen, select the bid, and then click **Update Status**.

3. On the **Change Bid Status** screen, from the **Status** drop-down list, select the status to assign to the selected bid.

4. To add this action to the bid history, select the **Update Bid History** check box.

5. Click **Save & Close**.

Compare bids

You can compare bids for a single RFP or bids across RFPs.

▶ Video

The information in the comparison report generated depends on the comparison scenario:

- When comparing a bid to the benchmark/planned values, the report shows the variance between the bid and the benchmark.

- When comparing two or more bids, ClearTrial generates the variances between the chosen baseline bid and the remaining bids.

- When comparing two or more bids and the RFP, ClearTrial generates the variances between one chosen baseline and the remaining bids or the RFP.

- Rules governing the comparisons include:

  - The baseline plan appears first.

  - Total hours variances are highlighted in blue if greater than the user-defined threshold. Total cost variances are highlighted in yellow if greater than the user-defined threshold.

  - Hours, dollars, and variances with negative values appear in parentheses; for example, (4.5).

  - Bottom line discounts are also compared across providers.

To compare bids:

Choose one of two ways to compare bids:

From the RFPs screen

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

2. Select an RFP plan name with two to five bids.

3. Click **Compare Bids**.

   ClearTrial 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

4. On the **Vendor Bid Comparison Options** screen, specify the options to include in the Bid Comparison report. Continue with the steps under **Vender Bid Comparison Options**.

From the Bids screen

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

2. Select the bids to compare and click **Compare**.

3. On the **Vendor Bid Comparison Options** screen, specify the options to include in the Bid Comparison report. Continue with the steps under **Vender Bid Comparison Options**.

Vendor Bid Comparison Options
When configuring the reporting parameters for comparison, you can choose the level of granularity, which values to compare, and whether or not to highlight variances above the user-defined threshold specified for costs and hours.
Available options depend on the granularity of bids selected for comparison. By default, bids are rolled up to the corresponding common lowest level of granularity. For more information about each option, you can also click the blue question mark icon in the upper right hand side of the screen.

1. In the **Level of Comparison** section, select the level of data for the comparison. Major task is selected and disabled by default since this high-level activity is static

in all bid grid formats. If the bids selected include data at the task-resource level, those options are available to choose from for values comparison.

2. In the **Location Options** section, if one bid is global and the other bid is by location, global is selected by default because comparisons can be done at their most common level.

3. In the **Values to Compare** section, select all the data points you want included for the bids comparison. Total Cost is always selected and included in the comparisons.

4. In the **Variance Display** section, specify whether or not you want to highlight costs and or hours variances above a user-defined (positive/negative) percentage threshold.

5. In the **Baseline for Comparison** section, you can include the planned values or a specific bid as the baseline, if you are comparing multiple bids. If you are comparing a single bid to the benchmark's planned values, then the planned values are always included in the comparison and selected.

6. Select the format for the report. Excel (.xls) is selected by default and the preferred format for comparison reporting.

7. Click **Ok**.

8. Click **Close**.

Map 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 ClearTrial to uniquely identify an activity by location, task, and resource. Mapping keys are in the format `[location code]-[task code]-[resource code]`.

- **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 ClearTrial 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 screen or as a prefix to a resource name in the Task Details screen in the Task Manager.