Oracle® Health Sciences ClearTrial Cloud Service

Plan and Source User Guide

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ORACLE®

Oracle Health Sciences ClearTrial Cloud Service Plan and Source User Guide, Release 5.7

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Preface

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

Audience

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

Revision History

- **June 2018:** Second version of this book. The content of the following notes has been updated:
  - Note on page 4-1
  - Note on page 4-2.
- **April 2018:** First version of this book.

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Before you start your plan

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

ClearTrial Cloud Service integrates clinical operations, resource planning, project management, and R&D finance into a single service that provides your organization with dramatic efficiencies and cost savings.

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

Set your user preferences

1. Click your user name in the upper right corner of the screen to view or configure your user profile.
2. To edit profile settings, click **Edit Profile**, then click **Save**.
   - **Login Name**—Only the System Administrator can change this.
   - **First Name, Last Name**—You can edit these.
   - **Email Address**—If you forget your password, you must supply this email address to reset it.
   - **Security Question**, **Security Answer**—ClearTrial uses the question and answer for authentication purposes when you 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 amount of clinical assumptions a user has to enter to get a quick, ballpark budget. In Quick mode, site-level 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, we recommend 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 appears after you log in. You can choose between various screens, depending on what screen you plan on starting with or visiting most frequently. Typically, this is a list of all of the plans you can view or edit, known as the Plans List screen.
- **Preferred Locale**—Locale determines how dates and numbers are displayed and interpreted. Use this setting to override your computer settings.

Add the product to ClearTrial

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

1. From the **Edit** menu, select **Products**.
2. On the **Products** list screen, click **New**.
3. Enter the information in the fields. For more information about a field, click the field name to display online help.
4. Click **Save,** then click **Close**.

Create a study

You must add a study before you can start a plan. You can create multiple plans for a study.

1. From the **Edit** menu, select **Studies**.
2. Click **New**.
3. Enter **general information**.
   - For more information about a field, click the field name 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.
   - The selections you make on this Overview tab cascade throughout the plan and affect the defaults used on subsequent data entry screens and the hours and dollars that make up the default budget.
4. Enter **therapeutic area** and **indication information.**

   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 calculated values if you do not agree with the ClearTrial default.

   - By selecting **Substitute the names below for therapeutic area and indication**, you can specify an alias for the selected therapeutic area and/or indication. The alias appears on the Studies list 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 describe your particular study.

- To view a list of all therapeutic areas and their associated indications, from the Reports menu, select **Therapeutic Area/Indications Mapping**.
- When no therapeutic area or indication seems to fit, choose the most appropriate body system/therapeutic area for the study you are planning. If you cannot find the specific therapeutic area or indication you need:
  - Select a similar therapeutic area or indication from the available list and then use the Alias fields to substitute the name of the actual therapeutic area or indication.
  - Select **Other** from the list of therapeutic areas and choose either a similar indication or Other (Complex), Other (Routine), Other (Simple), or Other (Very Complex).

5. Add a **description** or **note**.
6. Click **Save**.

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Creating a plan

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

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

Create a ballpark plan

Show me how! 

Creating a plan in Quick mode allows you to enter the minimal number of clinical assumptions to quickly get an early or ballpark budget forecast.

Choose Quick mode

By choosing Quick mode, you will skip over the Site and Labor tabs. ClearTrial fills in default values on the various tabs, but you can override them.

1. On the main menu bar, click your **user name** to view or edit your user profile settings.
2. Click **Edit Profile**.
3. From the **Preferred Edit Mode** drop-down list, select **Quick**.
4. Click **Save**.

Create the study and plan

You must create and define a study before you can create and define a plan. Then, you can create as many plans, or scenarios, for a given study as necessary to determine the most cost-effective or time-efficient approach.

- To create the study, follow the instructions in Create a study.

- To create the plan, see Create the plan.

  Tip: If your organization has created a template containing predefined values for basic assumptions, select that template.

  If not, select the ClearTrial default template and set up the basic assumptions as described in Before your start your plan beginning with defining the service providers.

Create the ballpark plan by stepping through the tabs

ClearTrial creates the plan and opens the **Create Plan** screen to the **Overview** tab. You will enter your assumptions tab by tab, clicking **Save** and then **Next** to go to the next tab.

Because you are working in Quick mode, you will skip the Site and Labor tabs and not see all the options described for creating a detailed plan. ClearTrial also fills in default values on various tabs, but you can override these values as described in this chapter.

- For more information about a field, click the field name to display online help.
- For details on how your assumptions interact and can be configured to accomplish specific study goals, step through each tab section.

Create a detailed plan

Creating a plan in Advanced mode yields more accurate results than working in Quick mode. In Advanced mode, you control approximately 120 input assumptions to fine-tune the operational approach and budget for your study. To work effectively, you need to have detailed specifications about how you will conduct the study and are ready to prepare an RFP or bid for a project or need to submit your budget to management for review and approval.

Choose Advanced mode

1. On the main menu bar, click your **user name** to edit your user profile settings.
2. Click **Edit Profile**.
3. From the **Preferred Edit Mode** drop-down list, select **Advanced** or **Expert** mode. This changes the setting for each and every plan.
4. Click **Save**.

Alternatively, you can select the **Current Edit Mode** drop-down menu in the upper right corner to select the mode specifically for the plan you are working on.

Tip: If you change your edit mode after setting some assumptions, we recommend only changing it to a higher mode so that you can continue to view and edit all the assumptions from the previous mode.

Create the study

You must create and define a study before you can create and define a plan. Then, you can create as many plans, or scenarios, for a given study as necessary to determine the most cost-effective or time-efficient approach. To create the study, follow the instructions in Create a study.

Tip: If your organization has created a template containing predefined values for basic assumptions, select that template.

If not, select the ClearTrial default template and set up the basic assumptions as described in Before your start your plan beginning with defining the service providers.

Create the plan

1. From the **Edit** menu, click **Plans** to navigate to the Plans List screen.
2. Click **New**.
3. On the **Choose Study and Plan Template** dialog, select your study.

   To view the templates you can use:

   1. From the **Maintain** menu, select **Templates**.
   2. View the descriptions of the templates to determine their application. You can also use the ClearTrial default template to create a plan and apply the built-in ClearTrial defaults.
4. Select the default **ClearTrial Template** or a template created by your organization containing predefined values for many of the assumptions to be entered.
5. Click **Ok**.

   ClearTrial creates the plan and opens the **Create Plan** screen to the Overview tab. You will enter your assumptions tab by tab, clicking **Save** and then **Next** to go to the next tab.

Tip: By choosing Quick mode, you will skip over the Site and Labor tabs. ClearTrial fills in default values on the various tabs, but you can override them.

Enter overall information on the Overview tab

The Overview tab includes basic information about the plan. Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click the field name to display online 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.
   - We recommend that a plan name be a combination of the study name and the version of the plan that you are creating. Your team should establish a standard naming convention for your plans and templates.

     For example, if you create multiple plans for a study named CLARITY, you might name the first version of the study, Clarity version 1. The second version would be Clarity version 2, and so on.

- 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 will begin billable work on the project. For studies conducted internally by the sponsor, it is the date on which project initiation activities will begin utilizing sponsor personnel.

   - The value for the **Start pre-study planning** field defaults to three months prior to the Project Activity Start Date. However, you can override this date to any date prior to the Project Activity Start Date.
   - If you change the project activity start date after entering other information, a warning icon appears. Clicking the icon displays a message stating all dates will be adjusted according to the new start date.

3. Select an **outsourcing** option.

   – **Conducted Internally**—The study will be performed internally by the sponsor, with no outside service providers. This sets all responsibility radio buttons to Sponsor throughout the tabs for the plan.

   – **Outsourced**—The entire study will be outsourced to an external service provider (excluding oversight of that service provider). This sets all responsibility radio buttons to Vendor.

   – **Combination**—Some of the study tasks (in addition to Oversight) will be performed by the sponsor, while others will be done by one or more external service providers that you specify on the Assignments tab.

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

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

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

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.
- **As specified here...**—Override one or more exchange rates by clicking the link to display the Override Currency Exchange Rates dialog box. If you have previously overridden exchange rates, ClearTrial removes the overridden values and restores all values to the exchange rates for the newly selected date.
- **As of plan created date**—This is the recommended option for templates. Indicates that, for each plan created from the template, the exchange rates date defaults to the latest available date.

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** checkbox.
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, pharmacy or hospital medical unit or record room.
    - Sites might be approved and ready to receive a study drug in a very short time, requiring exceptional effort on the part of the vendor. Drug accountability 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 assumptions to your plan.
12. Click **Next**.

Specify investigation site locations on the Locations tab

On the Locations tab, you specify locations for investigation sites and enrolling subjects. Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

1. On the **Locations** tab, click **Add Location(s)**.
2. Check **Regions**, **Countries**, or both.

   Tip: We recommend 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. Select the locations to add.
4. 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.

- If you remove a country, then add it back later, the user-defined defaults associated with that location will be reactivated.

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

   This field should contain only the number of subjects that will actually be enrolled in the trial. For example, if the protocol calls for 1000 subjects to be randomized, enter 1000.
8. In the **Avg Grant Amount** box, enter the amount to be paid to each investigator in this location for each subject enrolled in the study. Select the currency from the drop-down list.

   - Do not include payments made for screen failures, university-related overhead, or other overhead associated with certain sites, or inflation. All of these items are accounted for on the Site tab.

     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, we recommend that you enter your best estimate or zero. If you enter zero for the grant amount for one location, we recommend that you enter zero for all locations, so that the final budget does not include the grant.

   - ClearTrial estimates costs based on completed and partially completed subjects. A completed subject gets 100% of the investigator grant amount. A dropped subject is estimated to require payment to an investigator of 75% of the grant. We expect the average to be closer to 75% of all visits completed since dropped subjects must return for a termination visits (generally a repeat of the last subject visit regardless of where the subject terminates).
   - You can adjust these pass-through costs if specific knowledge of the prorated grant budget is known. For endpoint studies, be sure to include the grant costs for both the standard treatment and the full extended treatment schedules.
   - For some rare disease trials, grants might run as high as 500,000 USD per subject. However, this is not typical. Check that you have entered a per-subject amount. This field must contain a value between 0 and 500,000 USD (or the equivalent in another currency).
9. For a **Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time delay** for the location, add the number of days you expect the 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 uses this forecast to suggest and validate assumptions regarding the first subject enrolled date (FSI/FPI), the enrollment distribution type, and the first quartile enrollment objectives You can override this value if necessary to

reflect changes or other knowledge concerning the regulatory delay in any particular location.

- You can override the suggested FSI date, enrollment distribution type, and first quartile objectives, which are based on the site approval forecast derived in part from this value.
- If a large number of sites are in countries with very long MOH/FDA approval times, there may not be enough sites approved at the First Subject Enrolled date to meet enrollment targets. This could require extending the enrollment period, reducing the expectation of enrollment by the first quartile, or moving the First Subject Enrolled date to a later date. Alternatively, this could suggest that the study would benefit from the addition of sites in locations with shorter MOH/FDA delays.

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

10. Add languages and translation assumptions, or click **Next**.

Add languages to the plan on the Locations tab

ClearTrial suggests languages based on the locations specified. You can add or remove languages/dialects as needed. You can translate (and back-translate) all documents, or no documents, or specify which documents are to be translated. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

1. On the **Locations** tab, click A**dd Language(s)**.
2. Select the languages to add.
3. Click **Ok**.
4. In the **Dialects/Variations** column, increase or decrease the number that appears to indicate the number of translations required.
5. For each language, specify which documents to translate: all, none, or specific documents.

   If you select **Specified Documents**, for each document:

   - To translate the document, select the **Translate** checkbox.
   - To translate the document back into the original language, select **Back Translate**. Comparison of a back-translation with the original text is sometimes used as a check on the accuracy of the original translation.
   - To prevent the translation cost from being automatically calculated, select **As Pass-Through Cost**. You can then add the translation cost on the Costs tab.
6. Click **Ok** to add the number of translations required to the plan.
7. Click **Next**.

Provide a site approval schedule and details on the Site tab

On the Site tab, you can accept the default site approval schedule or modify it and specify details regarding how sites are identified, initiated, monitored, and closed out. For more information about a field, click the field name to display online help.

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

Global versus by location specifications

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

Accept or define the site approval schedule for a location

1. Click the **Site** tab.
2. In the **Site Approval Schedule** column for a location, click the **ClearTrial Default** link.
3. Accept the default schedule shown, or add a site approval period and configure the number of sites to approve each week. For further information or help, click the field label or the column headers in the Site Approval Schedule table.

   Tip: To configure in days, rather than weeks for late-stage plans, click the **Switch to Days** link. To switch back, click **Switch to Weeks**.

   If you specify the schedule details, the number of sites you include must match the number of sites involved.
4. Click **Save & Close**. The **Values apply to** field now displays All Locations other than those locations you changed.

Enter site information for a location

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.

2. For each field, enter the percentage of sites to which the information applies. For more information about a field, click the field name to display online help.

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

   - 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 your plan. You can specify the percentage of the sites that require in-person visits versus phone-based visits.
  - **Pre-study visits**—If a site was used within the last year, by either the sponsor or the monitoring vendor, it usually does not need a pre-study site visit. Refer to your own SOPs regarding pre-study visits.
  - **Site-initiation visits**—This is normally equal to or less than the number of sites expected to participate in the study. On rare occasions, the study project manager might allow additional sites to be initiated (as back-ups) but, generally, will not approve the drug to be shipped unless the plan is to activate the sites later in the enrollment period.
  - **Close-out visits**—Normally, all sites participating in the study need a close-out visit when all subjects have completed the study. Therefore, the default for the field is 100%. However, there are some studies where this does not apply. For example, in Phase IV trials not done under an IND, it may not be necessary to close out the sites. In that case, the value for onsite close-out visits is 0%.
- 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 tis value.
- **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 an **overhead** beyond the standard investigator grant. For example, university sites and other independent sites without university affiliations might require overhead. If you have not included this in the investigator grant amount on the Locations tab, specify the percentage of sites that require this additional overhead. For example, if you entered an investigator grant of $10,000 with 50% overhead at 4 of 10 sites requiring overhead and 25% overhead at the remaining 6 sites, the percentage is 35%.

3. Enter site approval outsourcing responsibilities, or click **Next**.

Assign site approval outsourcing responsibilities

1. On the **Site** tab, in the **Responsibilities** section, enter the outsourcing option for each group of assignable tasks.
   - To assign a combination of some responsibilities to Sponsor and some to Vendor, you must change your selection on the Overview tab to **Combination**.
   - If you selected **Conducted Internally** on the Overview tab, you cannot assign any of the responsibilities to Vendor. If you have selected **Outsourced**, you cannot assign any of the responsibilities to Sponsor.
2. Click **Next**.

Specify the study enrollment details on the Subject tab

The Subject tab includes information about the enrollment period, enrollment distribution, and screening and drop rates. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

Enrollment period

1. Select the **Subject** tab.
2. In the **Define the Enrollment Period** section, define the relationship between the Project Activity Start Date and the First Subject In (FSI) date.
   - For studies that are outsourced (in whole or in part), the **Project Activity Start Date (PASD)** is the date on which a service provider begins billable work on the project. You selected this date on the Overview tab. For studies conducted internally by the sponsor, the Project Activity Start Date is the date on which project initiation activities begin.
   - The **First Subject In date (FSI/FPI)** value is the date that the First Subject First Visit (FSFV) 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.
   - If you change the Project Activity Start Date after this section has been completed and saved, the following might have to be addressed:
     - If you or another user accepted the default First Subject In (FSI) date, ClearTrial updates this date according to the changed Project Activity Start Date.
     - If you or another user changed the FSI date, any change in the Project Activity Start Date updates the FSI date that was entered. You must revisit and revise any dates that have been overridden.
     - If you select a start date that is greater than the user-specified FSI date, a warning appears in the FSI date indicating that the date is before the Project Activity Start Date.
3. Enter the **Enrollment period** in weeks or days, for late-stage plans. This is the time from the first enrolled subject's first visit to the last enrolled subject's first visit. ClearTrial displays the Last Subject In (LSI) date per location, which is defined as the last subject enrolled date. The enrollment period must be at least 18 weeks.
4. Specify how to **manage location-specific values**—either **Globally** or **Per Location**.
   - If you can specify the expected First Subject In (FSI) date for each location **globally**, ClearTrial applies changes you make to the ClearTrial-defined FSI date per location based on the number of days you shifted the date.
   - If you choose **Per Location**, you can make study-level adjustments and configure enrollment by location.
5. Define the enrollment distribution or click **Next**.

Enrollment distribution

1. Select the **Subject** tab.
2. In the **Define Enrollment Distribution** section, select the **type of enrollment distribution** from the drop-down list.

   Your choice is reflected in the percentages shown by quartile. If you choose **Custom**, you can enter the quartile values.
3. Specify how to **manage location-specific values**—either **Globally** or **Per Location**.

   When managing globally, if you edit the enrollment period, the calculated LSI date updates accordingly.

4. Define screen failures and drops or click **Next**.

Screening failures and drops

1. Select the **Subject** tab.
2. In the **Screening and Drops** section, the **Subjects to randomize** field displays the number of subjects expected in the selected location or for all locations. You can specify a percentage of the total subjects randomized to be screened as alternate subjects and a stipend to pay to alternate subjects.
3. In the **Screen failure rate** field, enter the percentage of screened subjects expected to fail to become study participants.

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

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

   For example, if the protocol requires 100 subjects to be randomized, and it is expected that for every four subjects screened, one will fail, the screen failure rate is 25%. You would need to screen at least 133 subjects. 33 screen failures = 100 subjects to randomize / 133 * 0.25.
4. In the **Subject drop rate** field, indicate the percent of subjects you expect to not complete a full CRF due to early termination. ClearTrial uses this percentage as it calculates the data that needs to be monitored and entered into the database.

   For example, if you expect only three out of four subjects randomized to complete the study, the drop rate is 25%. If 100 subjects are randomized and you expect a 25% drop rate, only 75 subjects are expected to complete the study. Sponsors likely do not have a schedule developed during the bidding or budgeting phase, so ClearTrial estimates 75% of the costs will be incurred for dropped subjects. These are pass-through costs and can only be estimated. However, you can easily adjust these costs if more exact amounts are known.

   Note: The actual costs per subject are based on a prorated schedule that is given to the investigator prior to the study start.
5. Enter location-specific overrides or click **Next**.

Location-specific screening, drop rates, and stipends

1. Select the **Subject** tab.
2. In the **Screening and Drops** section, click the **Edit location-specific overrides** link.
3. Per location, override the screen failure rate and subject drop rate assumptions. For more information about a field, click the field name to display online help.
4. Click **Ok**, then **Next**.

Specify study characteristics and subject treatments on the Treatment tab

On the Treatment tab, you define study characteristics and each treatment. Your edit mode determines the fields shown. For more information about a 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. For late-stage parallel design trials, you can also model endpoint studies. Your edit mode determines the fields available. For more information about a field, click the field name to display online help.

1. Select the **Treatment** tab.
2. In the **Study Characteristics** section, select the trial design:
   - **Parallel**—Parallel designs are those in which some subjects receive one of the defined treatments while other subjects receive one of the other defined treatments, and all subjects receive treatments during the same period. You can add treatments to Phase II through IV studies and Phase I oncology and vaccines studies with a parallel trial design.

     If you select Parallel, specify whether or not this is an endpoint study. An endpoint study is a study in which all patients conclude their participation in the study on or near the same calendar date. The **Endpoint Study** field is only available for Phase II through IV studies and Phase I oncology and vaccine studies.
   - **Cross-over**— In a cross-over trial design, each subject receives all defined treatments, but in a different order or sequence

     If you select **Crossover** in the **Trial Design** field, you can also enter baseline and washout assumptions and configure the washout period. For more information, click one of the field names to see the online help
   - **Will there be an electronic subject diary**?—Many studies require the subject to keep a daily diary. When these diaries are electronic, the data can be uploaded directly into the study database. Data entry and monitoring review of electronic diaries require less time than for paper-based diaries. The ED pages are part of the total CRF pages collected. Third-party vendors provide the electronic diaries.
   - **Last subject out date (LSO/LPO)**—Displayed based on the Treatment Duration (period) that is configured per treatment arm.
3. If you selected a **Parallel** study, specify whether this is an endpoint study. An endpoint study is a study in which all patients conclude their participation in the study on or near the same calendar date. The **Endpoint Study** field is only available for Phase II through IV studies and Phase I oncology and vaccine studies.
   a. In the **Endpoint Details** section, enter the number of weeks from the first subject enrolled until the endpoint. ClearTrial displays the endpoint date after you click **Save**.
   b. Specify the number of weeks between subject visits during the extended treatment period.
   c. Click **Save**.
   d. Add the treatments, or click **Next**

4. If this is a **Cross-over** study, specify the baseline and washout options.
   a. In the **Baseline and Washout** section, specify the number of CRF pages to be collected during the screening and baseline visits. Don't include the number collected at the beginning of each treatment period.
   b. Accept or override the number of minutes shown in the **Baseline visit monitoring time required** field.
   c. Specify the **washout period** in weeks.
   d. Click the **Configure washout period** link to view or edit the number of CRF pages collected during the washout period.
5. Add the treatments or click **Next**.

Define the treatments

1. Select the **Treatment** tab.
2. In the **Treatment(s)** section, click **Add** to add up to five treatment arms per plan. A ClearTrial-defined treatment arm is not equivalent to a cohort in your study. You can specify per-location assumptions for the selected treatment, customize the treatment schedule, and record notes relevant to the treatment.
3. Define the treatment parameters.
   - **Treatment duration**—For each subject, enter the treatment period length (time-on-trial). For Phase 1 (Healthy Volunteers) trials, the treatment duration is modeled in days. For all late-stage trials, the default is weeks but you have the option to model the treatment period in days. ClearTrial allows you to model a minimum of one day or one week for the treatment duration.
   - **Visits per subject**—Specify the number of visits for each subject during the treatment. For Phase 1 (Healthy Volunteers) trials, since 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 are generated or collected. For late-stage trials, it is assumed there is a visit per day of the week; therefore, one week has seven visits. For example, if you are modeling a trial in which patients are seen twice a week, add the number of pages collected at each of the two visits into a single visit in the treatment schedule.

     For Phase 1 (Healthy Volunteers) 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 planning 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 are combined into a single visit. If the number of visits is greater than the number of weeks, you will see a warning. Make sure you are planning in days and not weeks for this specific scenario.
   - **Number of bednights**—For Phase 1 (Healthy Volunteers) trials, specify the number of nights subjects will be confined to the CPU during the treatment. 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), specify the number of bednights during washout separately.

- **CRF pages per subject**—Specify the number of Case Report Form (CRF) pages to be collected for each subject during this treatment. This value should include quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected. ClearTrial considers the Number of CRF Pages Per Subject, the treatment period, the enrollment period, subject visits, and other factors to estimate the treatment schedule. Baseline visits and final visits are estimated differently than interim visits. ClearTrial calculates interim visits based on the average number of pages remaining and spread evenly throughout the first to last subject visit.
- **QOL pages**—Specify how many of the pages collected during the treatment period are Quality of Life (QOL) pages, reviewed to see if they have been filled out by the study subjects. These usually require little or no monitoring.
- **Subject diary pages**—Specify how many of the pages collected during the treatment period are subject diary pages.
- **Pharmacoeconomic pages**—Specify how many of the pages collected during the treatment period are pharmacoeconomic pages. These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.
- **Lab and diagnostic tests per subject**—Specify the number of expected lab and diagnostic tests per subject per treatment arm. This field is only available in cost models 5.5 above.
- **Cohort escalation reviews**—Specify the number of dose escalation reviews per treatment arm. This field is only available in cost models 5.5 above.
- **Monitoring minutes per CRF page**—Specify the number of minutes to monitor one regular CRF page. If a study is complex, or you want the monitors to spend extra time onsite performing additional activities, increase the monitoring time. This field does not apply to monitoring pages generated during the baseline visit. ClearTrial calculates the default value based on the chosen phase and therapeutic indication of the study. You can override this value for each treatment arm. Overridden values do not affect minute-per-page values for the baseline visit or washout period for a crossover study.

  The default or user-defined monitoring minutes per CRF page applies to both the treatment and extended treatment period for the treatment arm.

4. For endpoint studies, define the extended treatment parameters.
   - **Average CRF pages per extended visit**—Specify the average number of CRFs that will be collected during each visit after a subject has completed the standard treatment. This value should include quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.
   - **QOL pages per extended visit**—Specify how many of the pages collected during the extended treatment period are Quality of Life (QOL) pages.
   - **Subject diary pages per extended visit**—Specify how many of the pages collected during the extended treatment period are subject diary pages.
   - **Pharmacoeconomic pages per extended visit**—Specify how many of the pages collected during the extended treatment period are pharmacoeconomic pages.
5. To add per location grant and stipend amounts, change the monitoring schedule, and add notes about a treatment, select the treatment and click **Edit**.

a. On the **Details** tab, optionally modify the treatment details and the average grant amounts and stipends per enrolled subject for the various locations.

b. On the **Schedule** tab, optionally specify how many CRF pages are to be collected each week, the monitoring time in minutes, and how to distribute investigator costs.

c. On the **Notes** tab, enter any additional information about the treatment.

6. Click **Save**.

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

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

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

Set study data collection and management options on the Data tab

You specify how data is to be collected for your study on the Data tab. For more information about a field, click the field name to display online help.

Define how data is collected

1. Select the **Data** tab.

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

   - **Paper (Traditional Monitoring)**—Monitors will visit the sites to collect data. To specify that there will be no monitoring, select this data collection method, but in the **Responsibilities** section, set monitoring responsibilities to **N/A**.
   - **Electronic Data Capture**—A sponsor, CRO, or other service provider added to this plan is responsible for EDC management. 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 if none of the service providers added to this plan are responsible for EDC management. You can include and assign individual tasks that are excluded by default for EDC 3rd Party on the Assignment tab.
   - **Investigator Site Data Entry**—Data will be keyed into a data capture system or web-based system by someone at the site. This option is not the same as EDC.
   - **Faxed CRFs**—CRFs will be faxed.

3. In step 2, if you selected Electronic Data Capture or EDC-3rd Party, from the **EDC Maturity Level** drop-down list select the stage to apply to the plan. 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 grand-fathered until they conclude. There is a high level of integration between EDC and other systems such as CTMS, laboratory systems, project management systems, payment systems, and IVRS. During this stage, companies commit to a preferred EDC solution vendor and entertain discussions about forming long-term partnerships with vendors.
- **Stage 4: Enterprise Deployment**—You have an established enterprise-wide standardization on a single integrated EDC solution and all clinical management systems are fully integrated with the EDC system. EDC solutions found in Stage 4 provide hybrid paper/electronic features that support a limited number of paper records. All note taking is done directly in the system, and all signatures are recorded electronically. A small number of clinical trials, or certain portions of a trial, might still require the use of paper.

4. 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
5. 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%.
6. 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 and therapeutic indication of the study. You can override this value.
7. 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 and therapeutic indication of the study. You can override this value.
8. 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.
9. 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 we recommend that the value should not be greater than 3.

   An interim analysis is a preliminary look at the study data to determine if there are large differences between treatment groups. Interim analysis can be planned for

specified calendar times (for example, quarterly) or when specific numbers of subjects have enrolled in the study to ensure that a sufficient amount of data is available for review.

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

10. 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.
11. 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.
12. In the **CRF Design** section, specify the number of Case Report Form (CRF) pages that are not duplicates of another CRF page or screen.

    For example, the same AE page that is required at each visit counts as one unique page. The minimum field value is 1.
13. Define the **number of screens per CRF page**. This is the number of screens needed to capture one paper CRF page.
14. In the **Biostatistics** section, enter biostatistical study assumptions.
    - In the **Biostatistics** section, enter the number of unique and repeat data tables, listings, and figures and graphs for the study.
    - 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.
15. Enter project management options or click **Next**.

Specify project management options

1. Select the **Data** tab.
2. In the **Project Management** section, in the **Number of newsletters per site** field, indicate how many times you expect to generate newsletters. 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.
3. Specify whether to include an **ICF Video/DVD**.
4. After a study is concluded, you must archive the data for some period of time. In the **Number of years to archive data** field, enter the number of years. Check with your regulatory department for the most current regulations regarding data archiving. The default value is 5 years.

5. If you selected **Electronic Data Capture (EDC)** or **EDC- 3rd Party** as the data collection method, specify the number of online EDC training sessions required. This is not the training that happens at the Investigator Meeting or the initial CRA training. The default value is 3.
6. Enter medical writing and timelines options or click **Next**.

Enter medical writing choices and timelines

1. Select the **Data** tab.
2. In the **Medical Writing/Timelines** section, in the **Number of pages in the Investigator Brochure** field, specify the number of pages, which can be a few pages to over 250 pages.
   - The Investigator Brochure provides a description of the drug substance or device and the formulation, a summary of the pharmacological and toxicological effects, a summary of information relating to safety and effectiveness in humans, and a description of possible risks and adverse reactions to be anticipated and precautions or special monitoring required.
   - You provide the brochure to investigators and, ultimately, to ethical committees for review. You can use a vendor to help write, edit, print, translate, or distribute the brochure to clinical investigators.
   - ClearTrial uses the approximate size of this brochure to calculate costs for the activities related to the production, translation, and distribution of the brochure.
   - We recommend that you enter the total number of pages of your full Investigator Brochure to calculate the effort required to print and distribute the brochure.
   - The default value for this field assumes that the sponsor requires that the full Investigator Brochure be written and edited for each new study.
   - If the Investigator Brochure:
     - Has been previously written, you can de-select the **Write IB** task on the Assignment tab.
     - If the brochure has been written but needs updating, check **Edit IB** on the Assignment Tab.
     - If no updates are required, de-select **Edit IB**.
3. 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.
4. Set milestones and due dates related to clinical data. When you change the number of days in the fields below, the corresponding calculated dates appear in a new field and shows the offset in days for the specific milestone. When you make changes, you don't have to click **Save** to see the updated dates. If you change the default assumption value for any of the assumptions below, the date dynamically updates and displays based on what you entered.
   - In the **Days from LSO/LPO until Database Lock** field, enter the number of elapsed days from last subject observation (LSO/LPO) until the expected database lock. This typically occurs at least eight days after LSO (due to the

possibility of a late reportable SAE) and must occur before the Statistical Report date.

If you selected Electronic Data Capture (EDC) or EDC- 3rd Party as the data collection method, ClearTrial calculates the default value based on the EDC maturity level. The default values are 30 days for Stage 1; 20 days for Stage 2; 12 days for Stage 3; and 8 days for Stage 4. The minimum value this field can accept is 1.

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

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

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

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

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

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

5. Enter safety and medical management options or click **Next**.

Specify safety and medical management options

1. Select the **Data** tab.
2. 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 Serious Adverse Events (SAEs) across all subjects over the entire duration of the study.
3. In the **Hours medical monitor will spend with each SAE** field, specify the number of hours a medical monitor will spend with regard to each Serious Adverse Event (SAE).

4. 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.
5. 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).
6. Select an IVRS option or click **Next**.

Select uses for an Interactive Voice Response System

1. In the **IVRS (Interactive Voice Response System)** section, select the **IVRS Usage** checkbox that identifies how the Interactive Voice Response System (IVRS) will be used.
2. Check all choices that apply.
3. Specify whether or not protocol amendments are expected or click **Next**.

Anticipate changes to the plan

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

1. Select the **Data** tab.
2. In the **Expected Protocol Amendments** section, click the **Add an amendment** link.
3. 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.
4. To add additional protocol amendments, click the **Add another amendment** link.
5. Specify the outsourcing responsibilities for data collection or click **Next**.

Assign outsourcing responsibilities for data collection

1. On the **Data** tab, in the **Responsibilities** section, use the radio buttons to enter the outsourcing option for each group of assignable tasks.
   - To assign a combination of some responsibilities to Sponsor and some to Vendor, you must change your selection on the Overview tab to **Combination**.
   - If you selected **Conducted Internally** on the Overview tab, you cannot assign any of the responsibilities to Vendor. If you have selected **Outsourced**, you cannot assign any of the responsibilities to Sponsor.
2. Click **Next**.

Specify monitoring methods, schedule, and approach on the Monitoring tab

On the Monitoring tab, specify information about the monitoring methods, schedule, and approach. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

Select the monitoring methods

1. Select the **Monitoring** tab.
2. In the **Monitoring Methods** section, specify the types of monitoring to be performed.
   - **On-site**—Monitoring is done in person.
   - **Via phone**—Monitoring is done by phone. Phone-based monitoring is typically done only for Phase IV studies or during long follow-up periods.
   - **Combination**—Select both the on-site and via phone checkboxes.
3. 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 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.

If you selected managing globally:

1. In the **On-Site Monitoring Schedule** section, in the **Monitor every** field, specify the frequency of monitoring visits to the sites in the study during each period of the monitoring schedule.
   - If the monitoring will continue at the specified frequency through the end of the treatment period, select the **until LSO/LPO** radio button. For example, if a monitor will visit each site every 4 weeks, enter 4 in this field.
   - If you want to use a variable monitoring frequency, for example, monitoring every 4 weeks in the beginning of the study, every 2 weeks in the middle of the study, and every 6 weeks at the end of the study, in the **Monitor every** field, enter the frequency for the first period.
     - Select the **until week** radio button and enter the week at which this frequency ends and a new monitoring frequency begins. This value specifies the week at which the specified frequency for monitoring changes. This is the week number corresponding to the start of the next monitoring period and must be greater than or equal to the value for the monitoring frequency for the prior period.
     - In the next **Monitor every** field, enter the frequency to be used for the next period (or until the end of the treatment period).
     - Repeat as necessary to define each change in frequency over the course of the monitoring schedule.
2. Override the total number of monitoring visits in the **Total Visits** field, if necessary (for example, if the value in the RFP is different from the generated value).

- ClearTrial derives the default value shown from the total number of sites, monitoring frequency, and subject enrollment rate. You can increase this number to add more monitoring visits. You can also lower the total number of monitoring visits.
- If you are working with new sites that have limited research experience or where you know that there is a need to accelerate monitoring for some reason, add monitoring visits. For example, if 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.
- We recommend that the total number of visits selected be as close to the value calculated by ClearTrial as possible.

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

If you selected managing per location:

1. To select each location and edit the associated monitoring methods and monitoring schedule, in the **Monitoring Methods** section, in the **Manage monitoring schedule values**, click the **Per Location** link.
2. Choose the locations from the navigation tree.
3. For each location, specify the monitoring methods and the associated on-site and phone-based monitoring schedules.
4. Click **Ok**.
5. Set up the phone-based monitoring schedule or click **Next**.

Set up the phone-based monitoring schedule

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

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

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

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

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

5. In the **Average hours per visit** field, specify the average number of hours required to perform a phone-based monitoring visit, including preparation and follow-up activities. When in Quick mode, the **Average hours per visit** field is only available when managing by location, not globally.
6. Set up the monitoring approach or click **Next**.

Define the monitoring approach

These options are not available in Quick mode.

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

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

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

   - **Avg travel time (in hours) for site monitors**—The average number of hours a monitor requires to travel to sites.
   - **Percent of source documentation verification**—Specify the percent of key safety and efficacy data to be source verified. For most studies, this is 100%. Some Phase III and Phase IV studies might not require a level of monitoring the study data this rigorous.
   - **Time to review queried from previous visit (minutes)**—ClearTrial calculates a value representing the number of minutes required to re-review queries and CRF data from a previous monitoring visit, based on the therapeutic area and indication selected for the study. You can override this value.

- **Manage location-specific value**—Enter monitoring approach assumptions per location by clicking the **Edit location specific overrides** link. In the **Edit Per Location Monitoring Approach** dialog box, enter the monitoring approach assumptions by location, overriding global default values.

3. Enter the details for monitoring data through CRF pages or click **Next**.

Monitor data through CRF pages

1. Select the **Monitoring** tab.
2. In the **Monitored Data** section, enter the following details.
   - **Total CRF pages generated (without subject drops)—**Displays the predicted CRF pages that will be monitored, accounting for subjects that drop out of the study. ClearTrial derives this value from the subject drop rate, which is applied to each week of the study to calculate the subject retention rate.
   - **Total CRF pages monitored (accounting for subject drops)**—Displays the predicted CRF pages that will be monitored, accounting for subjects that drop out of the study. ClearTrial derives this value from the subject drop rate, which is applied to each week of the study to calculate the subject retention rate.

     To determine the number of total CRFs for a study, including a correction for dropped subjects, ClearTrial does the following:

     – For the first two weeks of enrollment, ClearTrial assumes that no subjects drop. Retention for weeks 1 and 2 is 100% and all scheduled CRFS are completed. ClearTrial assumes the drop rate is linear and calculates the weekly reduction rate as the overall drop rate divided by the number of weeks after week 2.

     – ClearTrial takes the number of CRFs that would have been generated each week if no subjects had dropped and multiplies it by the retention rate percentages to calculate the CRFs including drop out.

       You can increase or decrease this value. The percentage change of your adjustment is applied to the CRF pages generated during each week of treatment to produce the total number of CRF pages, including drop outs.

     – For each week after week 2 of enrollment (for example, the total enrollment period minus the first two weeks), ClearTrial starts correcting the total number of CRFs completed by the drop rate.
3. Specify medical monitoring options or click **Next**.

Include medical monitoring

1. Select the **Monitoring** tab.
2. Specify the medical monitoring options. The cost model applied to your plan determines the fields available. For more information about a field, click the field name to display online help.
3. Enter drug accountability options or click **Next**.

Cost Models Prior to 5.5

1. In the **Estimated number of FTE (full-time equivalent) Medical Monitors** field, you can accept or change the time for a Medical Monitor (MD) to serve as the team medical lead and provide support to the CRA monitoring staff and investigators

for issues beyond safety reporting. Tasks include the following, and others as appropriate:

- Developing protocol entry criteria.
- Developing abnormal lab data.
- Interpreting the protocol and discussing potential deviations.
- Medical discussion with Investigators.

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

ClearTrial supplies a calculated default value based on the study indication, the number of subjects, and the phase of the plan being modeled.

2. You can override the calculated default value. ClearTrial calculates the FTEs required based on 1800 hours per FTE per year. This task appears under the Site Management/Monitoring Task Group on the Assignment tab.
3. Enter drug accountability options or click **Next**.

Cost models 5.5 and above

1. In the **24/7 coverage** field, specify whether monitoring will be provided 24 hours per day, 7 days per week.
2. In the **Number of medical data listing reviews** field, enter the number of times the medical monitor will perform medical data listing reviews during the course of the trial.
3. Enter drug accountability options or click **Next**.

Add separate drug accountability visits

1. Select the **Monitoring** tab.
2. In the **Separate Drug Accountability** section, indicate whether additional drug accountability visits are required, who performs these visits, and how many visits per site to perform.

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

Add service providers to your plan on the Provider tab

Show me how! Video

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

- **Premium**—Provide a global presence in all major regions. You can fully outsource studies to them, but premium CROs are more expensive than other CRO types.
- **Major**—Provide a global presence in all major regions. You can fully outsource studies to them.

- **Medium**—Provide an incomplete global presence. You can fully outsource studies to them, but they may have to sub-contract some of the work.
- **Niche**—Operate in only one country or region and often offer only a subset of services.

Adding a provider does not automatically assign that provider to any tasks. You assign tasks to providers on the Assignment tab. Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

Add service providers to a plan

1. On the **Provider** tab, click **Add Provider(s)**.
2. Select one or more service providers.
3. Click **Ok**.

   Although the service provider appears on the screen, a service provider does not become part of this plan until you click **Save** or **Next**.

Specify provider-specific Information on the Details tab

1. Click a **provider name** to display the **Details** tab.
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 rats to use to calculate the provider's fees. ClearTrial uses the hourly rates published for this provider for the rate chosen as the base rate, plus or minus any discount indicated here, then applies the specified inflation percentages over the course of the study.
   - **Discount rate to apply to this study**—Specify any negotiated percentage discount established with this provider.
   - **Back-Office Billing Rate Location**—Specify the location where centralized or regionalized tasks or functions are performed. 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 location for one or more centralized tasks if necessary.
   - **Bottom Line Discount**—Specify any negotiated monetary discount established with this provider for the plan. This discount is only applied to the provider's labor fees. Select the currency in which to calculate the discount from the drop-down list. If there is more than one provider for a plan, each could offer a different discount.
   - **Currency Exchange Rate**s—Choose an option to indicate which exchange rates ClearTrial uses to convert between currencies:
     - **Use rates defined on the Plan Overview tab**—Do not override any exchange rates specified.
     - **Use rates defined below**—Open a new section on the screen to override exchange rates for this provider. If you have overridden exchange rates on the Overview tab, those values appear. To override these rates, type the exchange rate that is equal to one unit of the provider's billing rate currency. Overridden values appear with a shaded background. To restore the default value, delete the value in the field.

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

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

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

   - We recommend that you review the values if the number of sites or locations change or if tasks are reassigned.

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

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

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

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

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

   - **Number of sponsor affiliate**s—Enter the number of your affiliates with which this vendor will be working.
   - **Type of reporting to affiliates**—Select those items you want the vendor to do.
   - **Additional type of vendor with which this service provider will work**—From the drop-down list, select the type of provider with which this provider will work. This indicates the relationship that this vendor has with these other third parties. Do not include relationships where there is little or no daily interaction. For example, if the vendor only collects data from the central lab and does not interact with the central laboratory on a daily basis, do not include this interaction. If the vendor is managing the activities of another vendor, however, include this relationship.

- **Will this provider manage the CTMS**—Indicate whether or not this provider will enter data into the sponsor's Clinical Trial Management System (CTMS).

6. 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 by selecting **Service 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 your updates as needed.

> **Note:** To use your plan-specific inflation rates only for specific locations, overwrite 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. Click a **provider name** to display the **Details** tab.
2. Click the **Inflation** tab.
3. In the **Compound inflation annually** field, select **Yes** or **No**.
4. To change inflation rates for the provider, enter the new rate for each location for each year.
5. To remove your overrides, click **Clear Overrides**.
6. To reset the inflation rate to zero, click **Set Inflation to 0%**.
7. Click **Ok**.

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

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 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

If there is an **Unfreeze Rates**, button, billing and inflation rates have been frozen for this plan. If there is a **Freeze Rates button**, no rates have been frozen. 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, ClearTrial also copies their current rates to this plan.

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

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

Note: You cannot freeze billing rates for templates.

Plan and track the cost of meetings on the Meetings tab

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

Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

Add a meeting

1. Select the **Meetings** tab.
2. To add a meeting, click **Add**.
3. In the **Name** field, enter a name for the new meeting.
4. From the **Type** drop-down list, select the meeting type.
5. Click **Continue** to define the meeting details.

Define the meeting and providers attending

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

4. Click **Save**.
5. To add attendees, click the **Attendees** tab.

Add service provider attendees

1. Click the **Attendees** tab.

   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.
2. From the **Service Provider** drop-down list, select a service provider type.
3. Click **Add**.
4. Select the resources to include.
5. Click **Ok** to add these service providers to the Provider Attendees list for the meeting.
6. For each resource type, specify the number of attendees, the back office billing rate location, how the attendee will attend the meeting, the billable hours expected for meeting attendance, and indirect costs.
7. To divide the billable hours into preparation, travel, attendance, and follow-up costs, click the **Expand All Billable Hours** link and enter a value into each field.
8. Click **Save**.
9. Repeat steps 3 through 8 for each service provider type.
10. Select the **Site Attendees** tab to add site attendees or click **Save & Close**.

Manage attendees from investigator sites

1. Select an **Investigator** meeting and click **Edit**.
2. Click the **Site Attendees** tab.

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

   - To change site attendee settings, modify the values in the fields.
   - To delete a site attendee, select the **Attendee/Site** checkbox and click **Delete**.
   - To duplicate a site attendee, select the 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 or click **Next**.

Assign tasks to service providers on the Assignment tab

Use this tab to assign the service provider and billing rate location to tasks. Enter assumptions in the fields that appear. This option is not available in Quick mode.

1. Select the **Assignment** tab.

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

   Or

   If outsourced tasks in your plan are performed by various service providers, select the service provider who performs most of the outsourced work.
   - Example 1: **Values apply to** is set to **Centralized Tasks/Location Defaults**. To assign all outsourced tasks for all locations to Major CRO, select Major CRO.
   - Example 2: **Values apply to** is set to Chile. To assign all outsourced tasks in Chile to Medium CRO, select Medium CRO.
   - If a service provider is not available for selection, return to the Provider tab and add the service provider.
4. Click **Save**.
5. If the 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 blue triangle to the left of the assignment group.
   - The **Included** column indicates whether this task is included in the study and, in some cases, allows you to exclude a task from the study. If this checkbox is grayed out, the task must be included (or excluded) from the plan based on other input assumptions you have made or other study characteristics.
   - You can exclude selected tasks from the plan, which eliminates the effort and costs associated with these tasks. Tasks that cannot be excluded or specifically assigned, or whose billing rate location cannot be different from the location of subject data, are presented with the associated option(s) disabled.
   - If, on the Overview tab, you selected **Outsourced**, you can only assign tasks to 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 **Assignment Group/Task**, from the **Assign to** drop-down list, select the service provider.

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

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

     For example, if assignments made for individual tasks included in the group are not pinned, changes made to the assignment group or to the location defaults override these assignments.
   - Pinned settings are lost if you remove the associated locations or service providers from the plan. However, if you replace a provider, your pinned settings are maintained.
   - Task overrides migrated from plans created in earlier versions of the application are pinned by default.
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**.

Override resources and rates

Show me how! 

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

1. **Save** the entries you have already made.
2. Click the **Override Resources or Rates** link.
3. In the **Scope of Overrides** section, from the **For tasks assigned to** drop-down list, select a service provider.
4. In the **Resources/Overrides** section, specify your override for each default resource specification and pin your changes if desired. ClearTrial pulls in any location-specific resource overrides.
5. Click **Save and Close**.
6. Click **Next**.

Define Major Task efforts and labor fees on the Labor tab

Show me how! Video

On the Labor tab, review the Major Tasks in your plan and adjust the calculated labor unit costs and unit hours for each service provider if necessary. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

1. Click the **Labor** tab.
   - To see the Major Tasks associated with a specific service provider, in the **Filter** section, from the **Show hours and fees for** drop-down list, select the service provider.
   - To view all Major Tasks, even if the selected service provider is not assigned to any of the tasks, select the **Show major tasks with no planned effort for the selected provider** checkbox.
2. Review the hour and cost information for the Major Tasks included in your plan.
   - To accept the calculated hours and costs, click **Next** to go on to the Costs tab.
   - To adjust the hours or fees, select a **Major Task** and click **Adjust Hours or Fees**.
   - To add a Major Task, click **New Major Task** and create a Major Task.

Create a Major Task

Show me how! Video

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

By default, the Major Tasks you add appear below the ClearTrial-defined Major Tasks in the order you create them. However, you can specify where to display them. See . ClearTrial applies inflation to all Major Tasks, whether user-defined or ClearTrial-defined, based on inflation settings on the Provider tab.

1. On the **Labor** tab, click **New Major Task**.
2. In the **Task Manager,** on the **Major Task Details** tab, define the basic attributes of the new Major Task.
   - **Name**—We recommend naming the Major Task with the explicit deliverable or unit of work expected. Major Task names must be unique within a plan.
   - **Description**—We recommend providing a description to help others understand the purpose of the Major Task.
   - **Labor**—Specify whether associated tasks are location-scoped or study-scoped.

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

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

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

- **Unit of Measure**—From the drop-down list, select the unit of work this Major Task represents. Both ClearTrial default and user-defined units of work are listed. ClearTrial calculates all effort for associated tasks in terms of hours to complete one such unit.

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

  The 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 type followed by an asterisk.

- When creating a reforecast, you cannot change the unit of measurement, labor scope, and distribution of a user-defined Major Task defined in the prior forecast.

3. Identify where to display the new 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 to display the Major Task.
4. Click **Save**.
5. Click **Close** or **New Task** to add a task to the new Major Task.

Add a task to a new Major Task

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

   Or:

   Click the **Labor** tab, select the **Major Task** you created, and click **Edit Major Task.**
2. On the **Task Manager** dialog box, click **New Task**.
3. On the **Task Details** tab, specify the details about the task.
   - All tasks inherit major characteristics, such as unit of measure, labor scope, and work units distribution, from their Major Task.
   - 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 Assignment tab.
   - 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. You can determine whether a task is performed by the sponsor or CRO, or is not performed at all for this trial, by choosing the appropriate assignment group. You can also manage the assignments of each task on the Task Assignments tab on the Task Manager dialog box or on the Assignment tab.

- The **summary category** determines how ClearTrial summarizes the hours and purposes of display and report fees or the resources on the Summary tab.
- Identify where the task should appear in the list 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 to display the Major Task.
- Which Major Task to add the task to and the sort order.

4. Click **Save**.

   ClearTrial assigns the new task a mapping key. Mapping keys are included in the Bid Grid export when you create an RFP to allow vendors to programmatically map their costs to the Bid Grid format. For more information, see Map bids to RFPs using mapping keys.

5. Click the **Task Assignments** tab.
6. For each location, select the service provider and billing rate location.
7. To include the service provider, select the **Included** checkbox.
8. To prevent cascading changes, pin the service provider and billing rate location assignments by clicking the **Pushpin icon** in the **Pinned** column to highlight it.
9. Click **Save & Close**.
10. Click **Add Resource**.
11. Select one or more resources.
12. Click **Ok**.
13. Click **Save & Close**.
14. Click **Next**.

Configure resource data for user-defined tasks

1. Select a **user-defined Major Task**, then click **Edit Major Task**.
2. Select the task, then click **Edit Task**.
3. Select the **Resource Name** checkbox, and 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 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 an input field, click the field name.

   Tip: You can specify or change the algorithms to calculate this resource's level-of-effort only for resources that are not part of the ClearTrial default model. You can adjust billing rate locations, billing rates, and unit hours for any resource.

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.
   - If you overwrote the resource with another resource on the Billing Rates tab, or at the plan- or location-level, the name of the original resource appears.

- Different providers can use different names for the resources that perform tasks. Review and change the description to make sure it identifies the appropriate resource. For more information, see Add a user-defined description for a ClearTrial-defined resource.

5. On the **Algorithm** tab (or **Algorithm / Hours** tab), enter algorithms using either expressions (Advanced Algorithm Editor permission) or the scripting language (Expert Algorithm Editor permission). 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 multi-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. For more information, see Apply algorithms to resources.

6. Click **Save**.

7. On the **Unit Hours** tab (or **Algorithm / Hours** tab), override 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 and 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. We recommend 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.

8. Click **Save**.

9. 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 might 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 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. You can 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. You can 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.

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

10. Click **Save**.

11. Click **Close**.

Specify pass-through and indirect cost categories on the Costs tab

The Costs tab displays the pass-through and miscellaneous cost categories calculated for your plan. Some of these costs are pre-calculated. Other costs appear because many studies require costs of these types, but ClearTrial cannot derive these amounts from study characteristics or custom assumptions. You can increase or decrease each cost listed by editing the cost details.

Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click a field name. The help describes each cost.

1. Select the **Costs** tab.

- To display only cost categories with a value, de-select the **categories where costs total 0.00** checkbox.
- You can include or exclude costs and make adjustments.
  - ClearTrial does not delete the cost, but it no longer includes the amount in the plan and its totals and the cost appear with a line drawn through them.
  - To show costs that have been previously excluded, in the **Show** field in the **Filter** section, select the **excluded cost(s)** checkbox.
  - Restore an excluded cost by selecting the checkbox 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.

2. 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.

   If you make no changes to the costs, the ClearTrial defaults will drive the budget.

3. Define a new cost category or click **Next**.

Define a new cost category

Show me how! 

1. On the **Costs** tab, click **New**.
2. Enter information about the new category on the **Definition**, **Assignments**, **Algorithm**, and **Distribution** tabs. For more information about a field, click the field name to display online help.

Enter category information

1. On the **Definition** tab, in the **Name** field, define a name for the cost.
   - For any user-defined cost, specify a name of up to 60 characters that is unique for this plan.
   - You cannot change the name of a ClearTrial-defined cost.
2. From the **Type** drop-down list, select the cost type.
   - **Pass Through**—The cost is incurred by an outsourced partner and will be passed through to the sponsor for reimbursement.
   - **Miscellaneous**—Costs are incurred by the sponsor as part of the overall study budget.
3. In the **Costs** or **Credits** field, choose whether to vary the cost or credit by location or treat as a study-level cost or credit.

   If you choose **Costs vary by location**, you can specify a different per-unit amount for one or more locations, assign the responsibility for the cost to a different provider for each location (on the Assignments tab), override the start and end dates over which to distribute the costs or credit (on the Distribution tab), and express the per-unit cost or credit in a different currency for one or more locations (Algorithm tab).
4. To make this cost part of the recurring payments plotted on the Cash Flow Chart, select the **Include in Payment Schedule** checkbox. 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**.
5. To treat indirect costs as billable items or to allocate one or more resources to manage the costs, select the **Include in Resources by Department/GL Code report** checkbox. To include inflation for this cost in resulting calculations, select the **Apply inflation over time** checkbox. This selection clears the **Treat as credit** checkbox, if selected.

   Or

   To treat the cost as a credit item, select the **Treat as Credit** checkbox. This selection disables the **Apply inflation over time** checkbox. This option is not available to all users.
6. In the **Notes** section, enter details or comments about the new cost category. ClearTrial displays these notes as the help content for this cost.

7. 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.

8. Define assignments, algorithms, and cost distribution, or click **Next**.

Define assignments

1. Click the **Assignments** tab.
2. For each location or for the entire study, select the service provider, department, and GL Code.
   a. Assign the responsible provider, if applicable.
   b. Map the cost or credit to a specific department.
   c. Map the cost or credit to a GL Code.
3. Click **Save**.
4. Define algorithms and cost distribution, or click **Next**.

Define the algorithm

1. Click the **Algorithm** tab.
2. Enter algorithms for the new cost category using expressions or a scripting language. You must have Advanced Algorithm Editor permission or Expert Algorithm Editor permission, respectively. Don't use the scripting language unless your algorithm cannot be accomplished via the expression functionality. For details on using the scripting language, see Customize resources and costs with expressions and scripting.

   - You can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different cost driver, percentage to apply to the cost driver and monetary value.

     When working with multi-expressions, enter a per unit 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 the cost as location-scoped, then you can define an algorithm for each location.
   - 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 multi-expressions.

   a. In the **Calculate as** field, specify the per unit cost value.
   b. From the **currency** drop-down list, select the currency for the cost.

      Editing this field does not convert a previously entered value. ClearTrial assumes that the value you entered was expressed in the chosen currency.

      When the currency is edited, ClearTrial applies the change to the location-specific costs or credits, unless they have been overridden to vary from the amount and currency entered in this section.

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

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

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

   Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption automatically adjust this cost or credit.

   User-defined cost drivers appear in the drop-down list in italicized type followed by an asterisk.

e. Click **Save**.

   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 next to the **Calculated** field and cannot be changed.I n the **Total** field, ClearTrial displays the total calculated costs or credits, including any adjustments made by you or another user.

3. Distribute the costs or click **Next**.

Distribute the costs

1. Click 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 your plan.
   - If you select the **Site Approval Distribution**, **Subject Enrollment Distribution**, or **CRF Data Distribution**, in the **and shift** field specify an offset for a 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** milestone for the cost distribution. These are used as the default start and end date for each location.
   - For example, you can indicate that a cost is expected to spread from 30 days prior to FSI to 15 days after LSO.
   - Use the **Start** and **End** offset drop-down lists to specify whether the offset is before or after the selected milestone occurs.
   - From the **Start** and **End** milestone drop-down lists, select a milestone to which to anchor the start and end of the cost distribution. You can start the cost on this milestone or some number of days before or after this milestone. Changes to the assumptions in this plan that revise the predicted milestone date automatically revise the distribution of this cost. However, the calculated distribution start date cannot be earlier than the pre-study planning date.

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

4. Click **Save**.
5. Click **Next**.

Specify payment schedules on the Payments tab

Payments are defined as percentage values representing the portion of the total fees paid or received at the completion of each milestone. You can also define the payment terms to specify the number of days from the invoice that payment is expected. You can use the payment schedule with the Cash Flow Chart report to determine the cash flow characteristics of the payment plan.

Enter assumptions in the fields that appear. Your edit mode determines the fields shown. For more information about a field, click the field name to display online help.

Set payment terms

1. On the **Payments** tab, click **Set Payment Terms**.
2. From the **Payment Term** drop-down list, select the payment term negotiated with each service provider.
3. Click **Ok**.

   Any bottom line discount will be allocated to the payment amounts based on the percentage values specified for each milestone payment.
4. Add recurring payments or milestones or click **Next**.

Set recurring payments

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

1. On the **Payments** tab, click **Edit Recurring Payments**.
2. For each unit of work or pass-through cost, from the **service provider** drop-down lists, select the payment frequency for each milestone.

   Or

   To indicate that the fees associated with that item are included in payments made in response to the occurrence of one or more milestones, select **Milestone**.
3. Click **Ok**.
4. Add milestones or click **Next**.

Add a milestone

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

1. On the **Payments** tab, click **Add Milestone**.
2. Enter the **Milestone Definition**.

- You can name the milestone anything appropriate as long as the milestone name is unique for this plan.
- In the **Occurs** field, enter the number of days before or after the 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.

3. Add a **Description**.
   - In the **Code** field, specify a 3-6 character abbreviation for this milestone. The code appears on reports where the full name does not fit or display properly.
   - In the **Description** field, enter additional information to describe this milestone or its purpose for this plan.
4. Click **Ok**.
5. For each service provider of the new milestone, enter the payment percentage. Because the percentages of all the milestones must add up to 100%, you will have to reduce percentages paid for other milestones to add this payment.
6. Click **Save**.
7. Click **Next**.

Get a quick overview of study costs on the Summary tab

The Summary tab provides a one-page overview of the plan. ClearTrial calculates these values by converting from each service provider's billing rate currency to the modeling currency, using the exchange rates specified on the Overview tab (or any overrides specified at the service provider level).

Select the providers included

1. Click the **Summary** tab.
2. Select the **service providers** to include.
3. Deselect the **service providers** to exclude.
4. Review the information and click **Next** to generate reports providing additional information about your plan.

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

Review fees, hours, and FTEs

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

FTE calculation

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

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

Inflation and bottom line discount

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 overall fees.

Pass-through costs

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

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

Review dates and duration

The **Dates/Duration** section summarizes study-related dates and durations. Which metrics appear depend on the study type.

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

Review metrics

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

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

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

Reports appear on the Reports tab

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

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

Report types

ClearTrial groups the reports into the following categories:

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

Generate a report

1. On the **Reports** tab, click a report name.
2. If the application prompts you to select report-related options, make your selections and click **Ok**.
3. Select report printing and viewing options.
   - Print
   - View as PDF
   - Export to Excel
   - Export to CSV
4. When you are finished working with the report, click **Close**.

Group related plans into a portfolio

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

After you have created a portfolio, you can:

- Develop a forecast for a full set of studies within a given budget cycle (1-year, 3-years, 5-years, and so on).
- Assess the impact on your budget of including, excluding, or delaying a particular plan or study.
- View the resulting monthly budgets, resource requirements, cycle times, and milestones across a group of studies.
- Account for the likelihood that a plan will come to fruition by discounting the costs associated with the plan.
- Make on-the-fly adjustments and see the immediate impacts on budgets and resource requirements.

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

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

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

Create a portfolio

1. From the **Edit** menu, select **Portfolios**.
2. On the **Portfolios** list screen, click **New**.
3. On the **Overview** tab, enter a name for the portfolio, short and long descriptions, and the currency to use for portfolio reports.

   Portfolio reports show all values for all plans in the portfolio rolled up into the single default reporting currency. Each plan in the portfolio uses its own exchange rate rules to convert from the plan values to the reporting currency. When you generate a report, you can override the currency.
4. Click **Save**, then **Next**.
5. Click **Add Plans**.
6. Choose the plans to add to the portfolio and click **Ok**.

   The selected plans appear on the Plans tab with information on their start date, the start offset specified, and the probability that the plan will come to fruition.

   - You cannot add more than 200 plans to a portfolio.
   - After a plan has been added to a portfolio, it is automatically included, which means that the costs and milestones associated with the plan are added into the portfolio.
   - You can see the effect of postponing one or more plans by specifying a **Start Offset**.
     - To adjust the start date forward (earlier), enter a negative number.
     - To postpone a plan, enter a positive number.
     - This feature does not make adjustments for inflation. This is because the billing rate year associated with a plan does not change when you use Start Offset.

- In the **Probability** field, you can specify the probability of a plan being implemented. 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**, then **Next**.
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 discount exist in the plans included in the portfolio, inflation and bottom line discounts appear as separate line items.
9. Click **Next**.
10. On the **Reports** tab, you can generate additional reports about the portfolio.
    - You can view each report in a separate window, print it, export it to Microsoft Excel, or convert it to PDF.
    - The reports reflect only costs and hours from included plans. Costs and hours from excluded plans are not added to the costs and hours of the portfolio and, therefore, do not appear in reports.
    - If any of the included plans have a probability of less than 100%, the costs and hours are reduced accordingly. For example, if you set probability to 50%, the costs and hours reflect only half of the plan's costs and hours. If any of the included plans has an offset start date, the costs and hours associated with the plan begin on the offset date, not on the original start date.
11. Select a report, specify any details, and click **OK**.
12. When you are finished with the report, click **Close**.
13. Click **Close**.

3

Creating Requests for Proposal (RFPs) and reviewing bids

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

If you have licensed the ClearTrial Plan and Source Enterprise edition, you have the required permissions.If you are not a licensed user, you will see these features on menus; however, they are disabled.

Show me how! Video

Create an RFP from your plan

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

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, click **Other Actions...**, and choose **Create RFP**.
3. In the **Scope of Work/Assigned to Provider** section, select the provider representing the scope of work on which the RFP is based.
   - The provider does not have to correlate in any way with the vendors to which you plan to send the RFP.
   - The selected provider is used to model the trial and scope the tasks and costs that vendors bid on.
   - When you import the bids at a later time, each bid is associated with an actual vendor.
4. In the **RFP Info** section, enter a short description of the RFP, a title for the bid grid, and any comments.
   - The short description does not appear on the bid grid. Use it to recognize the RFP in the RFP list.
   - ClearTrial includes the bid grid title in the header on the bid grid. You can customize this value for each vendor by editing the RFP and regenerating the bid grid.
   - The Comments field is a space in which to record any notes relevant to the RFP. For example, you might record who you send the bid grid to and on what date.

5. Click **Ok**.

   - ClearTrial generates the RFP and adds it to the RFPs list. To see the RFPs, from the **Edit** menu, select **RFPs**.

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

   - ClearTrial also downloads the bid grid as a Microsoft Excel spreadsheet. Send this spreadsheet to the vendors you want to bid on this plan.
   - A lock icon appears next to the plan name checkbox on the Plans list screen to indicate that the plan is now locked and cannot be changed. You can used the ClearTrial-generated fees and costs as a benchmark for your vendor bids.

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

Work with bids

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

Import a bid

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

1. From the **Edit** menu, select **RFPs**.
2. Select the **RFP** plan name and click **Import Bid**.
3. On the **Import Bid** dialog box, in the **Vendor Name** section, select the vendor whose bid you want to import.
4. In the **Bid Information** section, choose the bid grid file to upload by clicking **Choose File** and browsing the files on your computer. ClearTrial assumes that you have saved the submitted bid grid to your computer.
5. Add a short description to identify the bid, the bid number supplied by the vendor, and any comments about the bid.
6. Click **Ok**.

   ClearTrial generates warnings that you might want the vendor to correct, but will still import the bid grid. The import action fails if there are fatal issues.

   a. To see or save the list of issues encountered, click the **Download Issues** link.
   b. Import the revised bid grid.
   c. Save the issues list to your computer and share it with the vendor.

   d. You or the vendor must correct the bid grid prior to import if you encounter fatal errors. Non-fatal warnings are listed for your review. You can decide if they require a correction from the vendor.

7. To complete the import action, click **Continue**.
8. Click **Close**.

Replace a bid

1. From the **Edit** menu, select **RFPs**.
2. Select **Replace Existing Bid**, 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 **Choose File** 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 the vendor's bid

1. From the **Edit** menu, select **Bids**.
2. Select the bid, and click **Edit**.

   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.

   To include the impact of inflation on the values, select the **Include Inflation** checkbox.
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 have not been corrected.
7. To view the bid grid, click the **Download** link.
8. Click **Close**.

Updating the status of a bid

You can manually update the status of a bid.

1. From the **Edit** menu, select **Bids**.
2. Select the bid, and click **Update Status**.
3. 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** checkbox.
5. Click **Save & Close**.

Compare bids

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

- When comparing a bid to the RFP, the report shows the variance between the bid and the RFP.
- When comparing two or more bids, ClearTrial generates the variances between one 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.
  - All variances greater than the options specified are shaded yellow.
  - Hours, dollars, and variances with negative values appear in parentheses; for example, (4.5).
  - Variance percentages with negative values are denoted by a minus (-) sign.
  - Bottom line discounts are also compared across providers.

1. From the **Edit** menu, select **RFPs**.
2. Select the **RFP** plan name.
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.

Or

1. From the **Edit** menu, select **Bids**.
2. Select the bids to compare and click **Compare Bids**.
3. In the **Available Comparisons** section, select the level of detail for the comparison:
   - **Major Task and Cost Summary**—Compare values aggregated by Major Task and cost.
   - **Detailed Fees and Costs by Location, Task, Resource**—Compare values by resource per task per location. This report is only available when comparing bids for a single RFP.
4. In the **Compare Options** section, specify whether or not to include the RFP itself in the comparison and whether to show the variances to the RFP or to a selected bid.
5. In the **Variance Analysis** section, specify whether or not to include variance analysis and the percentage of total costs and total hours above which to highlight variances.
6. In the **Reporting Currency** section, select the currency to use to render the report to ensure that all monetary values displayed are in the same currency.
7. Click **Ok**.

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

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 list screen or as a prefix to a resource name in the Task Details screen in the Task Manager.

Work with the bid grid

The bid grid is a Microsoft Excel workbook based on RFP data. Vendors can use the bid grid to respond to the associated RFP.

1. Receive the bid grid from a provider user and download it.
2. Open the downloaded bid grid in Microsoft Excel.
3. Read and understand the rules governing use of the bid grid outlined on sheet 1.
   - You must not alter the workbook structure or format. If you do, it can't be imported by the provider user.
   - The workbook is password protected.
4. Complete each sheet of the workbook.
   - Instructions for completing the bid grid appear as the first page of the workbook.
   - Only cells that are shaded light blue can be edited.
   - The currency that must be used for the bid appears on each worksheet.

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

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 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. 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.

Header section

Each worksheet contains a header section, comprised of:

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

Column headers and input fields

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

- **Cost Type**—Either Labor or Cost, depending on the row. *This column is populated based on the RFP and is not editable.*
- **Location**—Centralized or the plan's location. This column indicates the location of the sites/patients related to this task. *This column is populated based on the RFP and is not editable.*
- **Major Task/Cost**—Name. *This column is populated based on the RFP and is not editable.*
- **Task**—Name. *This column is populated based on the RFP and is not editable.*
- **Resource**—Resource Name. *This column is populated based on the RFP and is not editable.*
- **Mapping Key**—Prepopulated with a ClearTrial-defined key for mapping tasks and costs between the RFP, bids, and plans. *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.

4

Customizing your plan

ClearTrial offers extensive flexibility and configurability to align your plan to your organization's work breakdown structure and business processes.

Change your plan by editing it

1. From the **Edit** menu, click **Plans**.
2. From the **Plans** list screen, select the **plan** to edit, then click **Edit**.
3. Enter or edit the information on each tab.
4. Click **Save** before moving on to the next tab.

Note: If you have created a request for proposal (RFP) from a plan, the plan is permanently locked and you see a red lock icon next to your plan (or RFP) on the Plan List 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 and make those changes in the copy.

Tip: To make changes to a **template**, from the **Maintain** menu, click **Templates**. Select the template and click **Edit**.

You can work on a copy of your plan

1. From the **Edit** menu, click **Plans**.
2. On the **Plans** list screen, select the plan you want to copy. You cannot copy a plan in an *Incomplete* status.
3. Click **Copy**.
4. In the **Plan Name** field, enter a 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.
6. From the **Custom Field Model** drop-down list, select a custom field model.
7. Click **Ok**.

   The copied plan opens in Edit Plan mode on the Overview tab.

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

Pin your changes

Show me how! 

To prevent cascading changes, click the **Pushpin** icon in the **Pinned** column to highlight it. Subsequent changes at the plan level or plan-location level will not override pinned values for this task. However, pinned settings will be lost if the associated location and/or service provider are removed from the plan.

Lock and unlock plans

When you lock a plan, changes made to the cost model do not affect that plan. RFPs are locked plans that cannot be unlocked.

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

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

> **Note:** If the locked plan uses the 5.2 cost model version or an earlier one, the plan is upgraded to use the latest available cost model when you unlock it.

Change the cost model

Show me how! 

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan to edit.
3. From the **Other Actions...** menu, click **Change Attributes**.
4. In the **Plan Name** field, enter a different name if you don't want to overwrite this plan.
5. From the **Use Cost Model from** drop-down list, select a cost model.
6. Click **Ok**.

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

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

> **Tip:** You can add the cost model as a column on the Plans list screen. For more information, see Customize lists.

Compare two or more plans

You can compare plans by from the Plans list screen.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plans to compare. Do not include incomplete plans.
3. Click **Compare**.
4. On the **Compare Plans** dialog box, from the **Available Comparisons** section, select a comparison type.
   - **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 your selection, other options and sections appear.
5. Select the providers to include. To include all the providers, select the **All Providers** checkbox.
6. Select the currency to be used in the comparison report and whether to round values to the nearest unit of currency.
7. Click **Ok**.

   ClearTrial generates a Fee and Cost Comparison of the selected plans.

   You can print the report, view it as a PDF, export it to Microsoft Excel, or export it to CSV.
8. Click **Close**.

Quickly compare a copied plan to its original

Use the Compare to Original report to compare your copied plan to the plan from which it was copied.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the copied plan and click **Edit**.

   Tip: You can also double-click the plan you want to edit.
3. Select the **Reports** tab.
4. From the **Comparison** section, select **Compare to Original**.
5. On the **Compare Plans** dialog box, from the **Available Comparisons** section, select a comparison type.
   - **Assumptions**—Comparison of assumptions of the plans. You can limit the comparison to differences only by selecting **Only Show Differences**.
   - **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 your selection, other options and sections appear.

6. Select the options. For more information about a field, click the field name to display online help.
7. Click **Ok**.

   ClearTrial generates the comparison report. The copied plan and original plan values appear side by side so that you can quickly identify changes or discrepancies between the two plans. If fees, costs, unit prices, resources, or milestones are involved, ClearTrial calculates the differences between the two versions and, if applicable, the percent differences.

   You can print the report, view it as a PDF, export to Microsoft Excel, or export it to CSV.
8. Click **Close**.

Compare your plan to the template on which it was based

Use the Compare to Template report to quickly see how the plan has been changed from its template.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan to compare to its template and click **Edit**.
3. Select the **Reports** tab.
4. From the Comparison section, select **Compare to Template**.
5. On the **Compare Plans** dialog box, from the **Available Comparisons** section, select a comparison type.
   - **Assumptions**—Comparison of assumptions of the plans. You can limit the comparison to differences only by selecting **Only Show Differences**.
   - **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 your selection, other options and sections appear.
6. Select the options. For more information about a field, click the field name to display online help.
7. Click **Ok**.

   ClearTrial generates the comparison report. The plan and its associated template's values are displayed side by side so that you can quickly identify changes or discrepancies between the two templates. If fees, costs, unit prices, resources, or milestones are involved, ClearTrial calculates the differences between the two versions and, if applicable, the percent differences.

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

8. Click **Close**.

Customize resources

Show me how! Video

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

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

Resources can be assigned to complete work on tasks using the Task Manager. For more information about the Task Manager, see Adjust task effort and labor fees.

Create a user-defined resource

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

1. From the **Maintain** menu, select **Resources**.
2. On the **Resources** list screen, click **New**.
3. In the **Resource Summary** section, enter a resource code, name, and description. For more information about a field, click the field name to display online help.

   Use the **Code** field to specify a unique 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-provided service providers, enter the hourly billing rate for the resource.
   - This table establishes a base rate for the ClearTrial-defined providers. You can enter or edit the U.S. hourly rate for this resource for each of the years you choose as the effective rate year when planning a study. Use the **Maintain Billing Rates** feature to provide and publish specific rates for each location.
   - Enter the hourly rates for each of the years chosen as the effective rate year when planning a study. For service providers you added to ClearTrial, provide specific rates per location on the **Billing Rates** screen.
   - To populate the table automatically, click **Auto Fill**. The **Auto-Populate Rates** dialog box appears. Apply an hourly rate for a selected service provider or a percentage increase for each year based on the rate specified in the selected starting year. Click **Apply**, then **Ok**.
5. Click **Save**.

Add a user-defined description for a ClearTrial-defined resource

You can make the descriptions of ClearTrial-defined resources more accurately reflect your organization's staffing and costing structures by editing the resource description.

1. From the **Maintain** menu, select **Resources**.
2. On the **Resources** list screen, select the ClearTrial-defined resource, and click **Edit**.
3. Click the **Edit** icon (pencil) to the right of the description.
4. Edit the description, then click **Save**.
5. Click **Close**.

Override resources assigned to your plan

You can override task assignments for a specific service provider. You can save the overrides by clicking the **Push Pin** icon to ensure that they are not lost due to other cascading changes.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the **plan**, then click **Edit**.
3. Select the **Assignment** tab.
4. Click the **Override Resources or Rates** link.
5. In the **Scope of Overrides** section, from the **For tasks assigned to** drop-down list, select a service provider.
6. In the **Resources/Overrides** section, specify your override for each default resource specification and pin your changes if desired. For more information about a field, click the field name to display online help.
7. Click **Save**.
8. To clear the overrides, click the **Clear Overrides** link**.**

Add custom assumptions to your plan

Show me how! 

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

There are two concepts related to user-defined assumption:

1. **Custom field**—Where you enter a custom assumption value.
   - You must have the additional role/capability of Custom Fields Designer to create custom fields. This capability is available only if you already have the Clinical or System Administrator role.
   - Custom fields, which are developed and published for use in plans, are grouped and versioned as a *custom field model*. You can assign a custom field model to a plan 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.
2. **Custom assumption**—The value of the assumption.

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

Work with custom field models

To display the Custom Field Models list screen, from the **Maintain** menu, select **Custom Fields.**

ClearTrial displays a DRAFT model and any published custom field models.

The DRAFT model is considered the working copy and is the only version where changes can be made to custom fields. You can perform the following actions on the DRAFT model:

- **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.

In addition, you can open a model and cancel the checkout. The DRAFT model is not available to use in plans unless you have the Custom Fields Designer permission.

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

Create a custom field model

1. From the **Maintain** menu, select **Custom Fields** to display the Custom Field Models list screen.
   - If a displayed custom field model has been published, the **Version** field contains a numeric value and the **Published Date** and **Published By** columns are populated.
   - If the **DRAFT** custom field model is checked out for editing, the **Checkout Date** and **Checkout By** columns are populated.
2. Select the **DRAFT** custom field model, and click **Checkout**.

   Or

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

4. Define the custom field by completing the **Field Definition**, **Display Criteria**, and **Designer Notes** sections.
   - For more information about a field, click the text box in which you enter the information.
   - For more information about the screen, click a field name to see a help topic.
5. Click **Save**.
6. To return to the Custom Fields list screen, click **Close**.

Publish a custom field model

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

1. From the **Maintain** menu, select **Custom Fields**.
2. Select the **DRAFT custom field model**, and click **Publish**.

   Or

   On the **Custom Fields** screen for the DRAFT custom field model, click **B**.
3. On the **Publish Custom Fields** dialog box, in the **Description** field, you must type a short description for the new custom field model.
4. Click **Publish**, then **Close**.

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

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

   You can now use the custom fields in your plans.

Apply a custom field model to a plan

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

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

If custom fields exist for a tab, they appear in a separate section, labeled **Custom Fields**, that appears below the ClearTrial default assumptions. If you do not see an expected assumption, change your edit mode to the highest level of detail available to you.

You can create multiple custom fields; that is, more than a single custom field can be associated with a tab. Taken collectively, all the custom fields you create for the plan become the custom field model

Centralized vs. local-scope custom fields

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

- Custom fields that vary by location, but use a static value as their default, can be overridden either per location or from a global context. When such fields are overridden in a global context, the value entered by the user becomes the default value for each location.
- Custom fields that vary by location and use a formula to calculate the default value can only be overridden per-location. The sum of each location's values is displayed as a read-only field when viewed in a global context on a tab.

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

Customize the Task Manager

The **Task Manager** is a ClearTrial-defined set of categories (**Major Tasks**) that groups tasks together under a category because they are commonly assigned as a group. The **tasks** in a Major Task represent the detailed work to be completed.

Tasks appear in several places in ClearTrial.

- **Task groups**—Tasks 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

You can move a user-defined task from one Major Task to another. This allows you to apply a different unit of measure, distribution, and start and end dates to a user-defined task without having to recreate the task, its assignments, and its resources and their algorithms.

- If the task was part of a study-scoped Major Task, any values stored at the study scope become the default values for each location.
- If the task was location-scoped, but is moved under a study-scoped Major Task, ClearTrial warns you that location-specific values/algorithms will be lost.

ClearTrial uses the defaults as the study-scoped values/algorithms for the moved task.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, then click **Edit**.
3. Select the **Labor** tab.
4. Select a **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 **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 & Close**.

   The user-defined task you moved appears in the pane on the left under the new Major Task.

> **Note:** You can only move tasks to different Major Tasks if the source and destination Major Task has the same scope (study-scoped or location-scoped). For example, you can move a task that exists under a study-scoped Major Task to another Major Task that is also study-scoped.

Rename and reorder plan-specific Major Tasks and descriptions

Within your plan, you can customize the name and description of each ClearTrial-defined Major Task and specify where it appears in the Task Manager list. To apply these customizations to future plans, create a template with these settings and any plans created from the template will inherit the configurations/settings made.

1. On the **Labor** tab, select the **Major Task** and click **Edit Major Task**.
2. Type the new **name**.
3. Change the **description**.
4. Identify where the renamed Major Task should appear int he Task Manager. 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 to display the Major Task.
5. Click **Save & Close**.

Copy a user-defined Major Task

You can copy user-defined Major Tasks, including their associated tasks and resources. However, the name must be unique per Major Task.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, then click **Edit**.
3. Select the **Labor** tab.
4. Select a **user-defined Major 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 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 duplicated Major Task in the pane on the left.

Copy a user-defined task

You can copy a user-defined task so that you can make more changes without having to recreate the entire task from scratch.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, then click **Edit**.
3. Select the **Labor** tab.
4. Select a **Major Task** that includes a **user-defined task** and click **Edit Major Task**.
5. From the list of tasks displayed under that **Major Task**, select the **user-defined task** and click **Copy Task**.

   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.
7. Change any 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 Assignment tab.
   - Select an assignment group for the task.
   - Select a summary group for the task. The summary group categorizes the labor on the Plan Summary tab.
8. 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 to display the Major Task. You can only copy tasks rom Major Tasks of the same scope.
9. Click **Save & Close**.

Task renaming and reordering

Within your plan, you can customize the name and description of each task within a Major Task and specify where it appears in the Task Manager list.

1. On the **Labor** tab, select the **Major Task** and click **Edit Major Task**.

2. From the list of tasks shown at the bottom of the **Major Task Details** tab, select the checkbox of the task and click **Edit Task**.
3. On the **Task Details** tab, type the new **name**.
4. 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.
5. Change the **description**.
6. Identify where the task should appear in list of tasks under the Major Task by specifying whether to display before or after a specific task.
7. Click **Save & Close**.

Reorder the Major Tasks on 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 these Major Tasks are displayed on the Labor tab.

1. On the **Labor** tab, highlight the Major Task you want to move by clicking and holding the mouse button.
2. Drag the Major Task to where you want it to appear in the Major Task list and release the mouse button.
3. Click **Save**.

ClearTrial retains this user-defined sort order even if you change the cost model for your plan.

Change the task sorting order in the Task Manager

Within the Task Manager, you can also reorder the tasks within a ClearTrial-defined Major Task.

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

   Or

   Open the Task Manager by selecting any task to display the Major Task details and the tasks under that Major Task.
2. Highlight the task you want to move by clicking and holding the mouse button.
3. Drag the task to where you want it to appear in the Task list and release the mouse button.
4. Click **Save**.

Delete default Major Tasks or Tasks

If there are ClearTrial-defined Tasks or Major Tasks that you don't need, delete them from your plan.

The deletion removes it only from the plan you're editing, it does not delete it from the template on which the plan is based. However, you can't undo the deletion.

Note: You cannot delete Major Tasks or Tasks for meeting labor.

To delete a default Major Task:

1. On the **Labor** tab, highlight the Major Task you want to delete by clicking its row.
2. Click **Delete Major Task**.

To delete a default Task:

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

   Or

   Open the Task Manager by selecting any task to display the Major Task Details tab, where you can see the tasks under that Major Task.
2. Highlight the Task you want to delete by clicking its row.
3. Click **Delete Task**.

Adjust hours and fees associated with Major Tasks

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the **plan**, then click **Edit**.
3. Select the **Labor** tab.
4. Select a **Major Task**, and click **Adjust Hours or Fees**.
5. From the **Show hours and fees for** drop-down list, select the service provider whose unit hours or fees are to be adjusted.
6. To make adjustments, click the **Expand All** link.

   The Extended Hours section expands to show the # Units, Unit Hours, and Unit Cost.
7. Edit the **# Units** field and the **Unit Hours** field to align your plan with the study's contract, bid, and internal tasks and costs.

   ClearTrial recalculates the unit cost.
8. Click **Save**.

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

Redistribute completed hours and fees

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, then click **Edit**.
3. Select the **Labor** tab.
4. Select a **Major Task**, and click **Adjust Hours or Fees**.
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.

   Note: This tab lists only service providers assigned to work on the selected Major Task.

6. In the **Distribute completed units of work according to** field, specify the distribution approach by selecting the appropriate value from the drop-down list.

For more information, see Distribute the costs.

- The distribution of units over time determines how the related fees are incurred, how value is accrued, and what units are expected to be completed as of the reforecast date when reforecasting according to planned values.
- Changes to the assumptions in this plan that revise the predicted milestone date automatically revise the distribution of this work.

7. Click **Save**.

Adjust task effort and labor fees

On the Labor tab, you can adjust the calculated labor unit costs and unit hours for each Major Task for each service provider. Your edit mode determines the fields available. For more information about a field, click the field name to display online help.

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the **plan**, then click **Edit**.
3. Select the **Labor** tab.
4. Click a **Major Task**, then click **Edit Major Task**.
5. On the **Task Manager**, you can edit **Major Task Details**, add resources to the tasks associated with this Major Task, adjust hours or fees on the **Adjustments** tab, change the distribution of work units on the **Distribution** tab, define algorithms to calculate the unit hours for additional resources, and override resources, rates, or unit hours for resources.
6. Click **Save**.

Choose assignment and summary groups for ClearTrial-defined tasks

You can move tasks from one summary group to another to match your organization's summary grouping. The ClearTrial-defined summary groups appear on the Plan Summary tab and include the tasks assigned per summary group.

1. On the **Labor** tab, select a **Major Task** and click **Edit Major Task**.
2. Select a **task** and click **Edit Task**.

   On the Task Detail tab you can see the Assignment Group and Summary Category with which this Major Task is associated.
3. To change the **Assignment Group**, select a different assignment group from the drop-down list. Assignment groups are represented by radio buttons in the Responsibilities section of various tabs and as drop-down lists on the Assignment tab.
4. To change the **Summary Category**, select a different category from the drop-down list. Summary categories determine how the hours and fees are summarized ("rolled up") and displayed on the Summary tab and Summary report.
5. Reorder the tasks by specifying whether this task should appear before or after the other task you select from the drop-down list. 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 to display the Major Task.
6. Click **Save**.

   You can see the changes in the left-hand pane showing each Major Task and the tasks under it.

Customize resources and costs with expressions and scripting

Show me how! Video

You can customize the cost algorithms when adding cost categories and resources.

Best practice for algorithms is to use multi-expressions whenever possible. However, if you are unable to produce the correct level of effort in hours or monetary cost value using multi-expression algorithms, ClearTrial offers Plan Enterprise license users the Expert Algorithm Editor role. The expert algorithm functionality provides greater flexibility by giving users the ability to create user-defined mathematical formulas via a scripting language. The scripting language used to define the formulas is based on JavaScript.

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 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).

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

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.

Apply algorithms to resources

Multi-expression algorithms can be used to calculate the level of effort required for a resource to complete a task. You can only define algorithms for resources that are not part of the ClearTrial default model; that is, resources you added.

1. On the **Labor** tab, select a **Major Task** and click **Edit Major Task**.
2. Select a **task** and click **Edit Task**.
3. Choose a **user-defined resource** and click **Edit Resource**.

   ClearTrial displays information about the resource on five tabs, including Resource Details, Algorithm, Billing Rate Location, Rates & Substitutions, and Unit Hours.

   You can specify or change the algorithms to calculate this resource's level-of-effort only for resources that are not part of the ClearTrial default model. You can adjust billing rate locations, billing rates, and unit hours for any resource.
4. On the **Algorithm** tab, enter algorithms using either expressions (Advanced Algorithm Editor permission) or the scripting language (Expert Algorithm Editor permission). 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 multi-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.

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

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

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

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

      User-define units of work 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, clicking **Save** each time.

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 this cost or credit.

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

5. Click **Save**.
6. Click **Close**.

Apply algorithms to costs

Multi-expression algorithms can be used to calculate the value of a cost item. If you have specified the cost as location-scoped, you can define an algorithm for each location.

1. From the **Edit** menu, select **Plans**.
2. From the **Plans** list screen, select your plan, then click **Edit**.
3. On the **Costs** tab, create a new cost category. Follow the instructions in Define a new cost category. You can change the algorithm only for a user-defined cost category.
4. Select the **user-defined cost category** and click **Edit**.
5. Click the **Algorithm** tab.
6. Enter algorithms for the new cost category using expressions or a scripting language. You must have Advanced Algorithm Editor permission or Expert Algorithm Editor permission, respectively. Don't use the scripting language unless your algorithm cannot be accomplished via the expression functionality. For details on using the scripting language, see Customize resources and costs with expressions and scripting.

   - You can create algorithms with up to eight individual expressions. Each expression within the algorithm has the ability to use a different percentage to apply to the cost driver and monetary value.

     When working with multi-expressions, enter a per unit 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 the cost as location-scoped, then you can define an algorithm for each location.

   a. In the **Calculate as** field, specify the per unit cost value.

   b. From the **currency** drop-down list, select the currency for the cost.

Editing this field does not convert a previously entered value. ClearTrial assumes that the value you entered was expressed in the chosen currency.

When the currency is edited, ClearTrial applies the change to the location-specific costs or credits, unless they have been overridden to vary from the amount and currency entered in this section.

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

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

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

Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption automatically adjust this cost or credit.

User-defined cost drivers appear in the drop-down list in italicized type followed by an asterisk.

e. Click **Save**.

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. ClearTrial-calculated cost values are displayed next to the **Calculated** field and cannot be changed. In the **Total** field, ClearTrial displays the total calculated costs or credits, including any adjustments made by you or another user.

Work with expert algorithms

There are various websites on the internet available to learn more about JavaScript. There are specific rules you should understand to use JavaScript; for example, JavaScript is case sensitive. Although you do not need to be a software developer or expert in JavaScript, review of some of these websites is recommended.

The JavaScript-based formulas can use the following:

- **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

Expert algorithms can use any valid variable to help drive hours or costs. A variable represents a ClearTrial work unit/cost driver or a custom field. For example, the number of weeks between study start date and final report is represented by the variable name *$numWeeks*.

- Over 200 ClearTrial variables exist that can be used in a plan's script formula. The ClearTrial variables that can be used in a plan depend upon the plan's assigned cost model. All ClearTrial variables start with a dollar sign ($). For a list of all the ClearTrial variables available as well as more information on working with expert algorithms, see *Oracle ClearTrial - Working with Expert Algorithms*, posted in the ClearTrial Support Center.
- Custom fields can also be used in a plan's script formula. The custom fields that can be used in a plan will depend upon the plan's assigned custom field model.

Example 1: You want to create a scripted algorithm to drive 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)

Autoformatting and autocompletion

- ClearTrial automatically formats your algorithm script to make it easier to read and understand.
  - For each row 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 will indent a new line/row automatically when the user presses **Enter** after a leading bracket.
- 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 brackets often are troublesome, when you place the cursor near a bracket ("(",")"," { ", "} "), the matching pair of the bracket 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, 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.

Customize lists

The **Configure List Options** link appears along with the **Filter** section and allows you to select which columns you want to display on a list screen. You can also specify the order of the columns displayed from left to right.

1. On any screen with a **Filter** section, click the **Configure List Options** link.
2. From the **Configure Columns** section, select the checkboxes of the columns to include in listings.
3. In the **Sorting** and **Paging** section, specify up to three sort levels.
   a. From the **Sort By** drop-down list, select a field or category by which to group the items in the listing. Available choices appear in boldface type.
   b. From the first **and then** drop-down list, select a sort order within the first sorting criterion selected.
   c. From the second **and then** drop-down list, select a sorting order for the second sorting criterion.
4. Click **Ok**.

Use filters to show or hide items

On any screen with a **Filter** section, primarily the choices from the **Maintain** menu, select which items to show:

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

  The screen refreshes to show the selected items.

To modify the filter in effect:

1. Click the **Modify** link.
2. Complete the **Filter Criteria** and **Save Filter** sections. For more information about a field, click the field name to display online help.
3. Click **Ok**.

To create a new filter:

1. From the **Products matching filter** drop-down list, click **New**.
2. Complete the **Filter Criteria** and **Save Filter** sections. For more information about a field, click the field name to display online help.
3. Click **Ok**.

5

Configuring service providers and their rates

This chapter describes how to configure service providers and their billing rates, inflation rates, exchange rates, and costs. To reuse these configuration settings, we recommend that you define these settings, then create a template to use for subsequent plans.

Define the service providers

Service providers are sponsors and Contract Research Organizations (CROs) and must be added to the overall environment before they are available for use in a plan.

> **Note:** A published billing rate card must also be created before you can add service providers to your plan. For more information, see Set the billing rates.

1. From the **Maintain** menu, select **Service Providers**.
2. On the Service Providers list screen, click **New**.
3. In the **Service Provider Information** section, enter a service provider name, description, and select the type of service provider. For more information about a field, click the field name to display online help.
4. From the **Billing Rates Currency** drop-down list, select the currency in which you will enter the hourly billing rates for 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**.

Remove service providers

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list 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

1. From the **Edit** menu, select **Plans**.
2. On the **Plans** list screen, select the plan, then click **Edit**.
3. On the **Provider** tab, select a service provider and click **Replace Provider**.
4. Choose a different service provider to replace the currently selected service provider.
5. Click **Ok**.

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

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

Define the resources

Resources are the roles that people who work on the study will be assigned. Associated with each resource are a code for tracking the resource through the study, a job title or classification, and a set of responsibilities. There are two types of resources in 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 you add to the service. You can edit, delete, and restore these resources. If you delete a user-defined resource that is being used in a plan, that resource remains available in the plan.

Resources are assigned to complete work on tasks using the Task Manager. For more information about the Task Manager, see Define Major Task efforts and labor fees on the Labor tab.

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

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

2. On the **Resources** list screen, click **New**.
3. In the **Resource Summary** section, enter a resource code, name, and description.

   Use the Code field to specify an alphanumeric code that represents the resource; for example, CRO1. If your company intends to use the RFP and bid management feature, you must include a code for every resource.
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**. 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 the rate card, don't forget to enter the rates for the new resources you add.
5. Click **Ok**.

Set the billing rates

Show me how! Video

You can define billing rates for service providers. After you publish the billing rates, ClearTrial shares the rates between plans. You cannot use a service provider in a plan without a published rate card.

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 system administrator must grant you the Clinical or System Administrator role.

Define billing rates for a service provider

1. From the **Maintain** menu, select **Billing Rates**.
2. On the **Billing Rates** list 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 a service provider doing work for a sponsor.
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 chosen service provider is performing work for this sponsor or affiliate.
   - If your organization is a service provider (for example, a CRO), select the sponsor for whom these billing rates apply.
5. From the **for Rate Year** drop-down list, select the year for which these rates apply.

When creating a plan, the effective rate year chosen in the Provider Details dialog 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 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 column whose Rate Variance % value is 100%. That is the location serving as the base rate. The rates for all other locations are derived as a percentage of the variance value of the base rate. You can change any variance or override any specific rate value.
8. Click **Save**, then publish the rates.

Publish billing rates

1. From the **Maintain** menu, select **Billing Rates**.
2. Select **billing rates** with a **Draft** status.
3. Click **Publish**.
4. On the **Confirm Publish rates** dialog, click **Publish**.

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

Generate the Billing Rates report

1. From the **Maintain** menu, select **Service Providers**.
2. On the **Service Providers** list screen, select a service provider.

   Note: You can only generate a Billing Rates report for service providers you added.

3. Click **Billing Rates Report** to display the report in a separate window.
4. Change any options and click **Ok** to display the report.
5. 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. You can also edit published rates and save them as a new draft that does not replace the published rates. When you are ready, you can publish that draft and replace the currently published rates.

1. From the **Maintain** menu, select **Billing Rates**.
2. Select a specific **provider** from the **Show rates for** drop-down list, or view all billing rate schedules.
3. Select the **billing rate plan**, then click **Edit**.
4. On the **Billing Rates** screen, select the **billing rates schedule**, and click **Edit**.
5. On the **Edit Billing Rates** screen, edit **hourly billing rates** as necessary. For more information about a field, click the field name to display online help.
6. Click **Save**.

View the billing rate revision history

1. From the **Maintain** menu, select **Billing Rates**.
2. Select a specific **provider** from the **Show rates for** drop-down list, or view all billing rate schedules.
3. Select the **billing rate plan**, then click **Show Revision History**.
4. To view the billing rates for a previously published set of billing rates, click the **Show Rates** link.

   The billing rates appear in a separate window.

   Or

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

Revert to previously published billing rates

1. From the **Maintain** menu, select **Billing Rates**.
2. Select a specific **provider** from the **Show rates for** drop-down list, or view all billing rate schedules.
3. Select the **billing rate plan**, then click **Show Revision History**.
4. To view the billing rates for a previously published set of billing rates, select an earlier **rate schedule** and click the **Open as Draft** link.
5. Click **Save**.
6. Select the billing rates schedule you just saved and click **Publish**.
7. Confirm that you want to make these rates available and effective by clicking **Publish**.

Set the inflation rate

You can define inflation profiles for service providers. Inflation profiles correspond to a set of billing rates for the specified rate year. 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.

After you publish the inflation profile, ClearTrial shares the rates between plans. ClearTrial suggests rate variances by location so you can set inflation rates for a base location and the service translates those rates to other locations based on economic forecasts by region.

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

You can save draft versions of inflation profiles but you can't use draft versions in plans. You can also view the past inflation profiles and revert to those profiles.

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

Define an inflation profile

1. From the **Maintain** menu, select **Inflation Profiles**.
2. On the **Inflation Profiles** list screen, click **New**. You can also copy an existing inflation profile by clicking **Copy** and editing the fields as described below.
3. 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 service provider, 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 chosen in the Provider Details dialog determines which billing rates are used. Rates are inflated per any inflation percentages specified.
   - A rate year is defined as January - December for the relevant year.
   - The Rate Year in effect determines the correct Billing Rate table and which Inflation Profile is used in that plan.
   - If there is no Inflation Profile for the sponsor/provider combination and Rate Year, ClearTrial issues an alert and the inflate rate defaults to 0% for all years in the plan.
6. Click **Ok**.
7. 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 dialog box 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 any specific percentage.
- If you want to use the same inflation rate values in all locations, enter the values once in the Base Rate column and change the Rate Variances by location to 100% so that 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

1. From the **Maintain** menu, select **Inflation Profiles**.
2. Select **billing rates** with a **Draft** status.
3. Click **Publish**.
4. On the **Confirm Publish rates** dialog, click **Publish**.

   The rates are immediately effective and available. Any unlocked plans that do not have frozen rates will 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. You can also edit published inflation profiles and save them as a new draft that does not replace the published inflation profile. When you are ready, you can publish that draft and replace the currently published inflation profile.

1. From the **Maintain** menu, select **Inflation Profiles**.
2. On the **Inflation Profiles** list screen, select the **inflation profile**, then click **Edit**.
3. Edit the **base rate** and **percentages** applied to selected regions and countries for the years shown, as necessary. For more information about a field, click the field name to display online help.
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 system administrator must grant you the Clinical or System Administrator role.

View the inflation profiles revision history

1. From the **Maintain** menu, select **Inflation Profiles**.
2. On the **Inflation Profiles** list screen, select the **inflation profile**, then click **Show Revision History**.
3. To view the profile, click the **Show Profile** link.

   The inflation profile appears in a separate window.

   Or

   To edit a published inflation profile, click the **Open as Draft** link.

   a. Edit the profile as necessary. For more information about a field, click the field name to display online help.

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

Map departments to labor and costs

You can map departments to internal and outsourced providers for each resource. These settings will flow into your plans. To work with departments, your system administrator must grant you the Departments/GL Codes Administrator additional role.

Add a department

1. From the **Maintain** menu, select **Departments/Functional Areas**.
2. On the **Departments** list screen, click **New**. For more information about a field, click the field name to display online help.
3. 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 list screen, click **Close**.

Map labor and costs to departments

You can provide a default department for internal and outsourced labor and indirect cost mappings by selecting departments in the Default row.

1. From the **Maintain** menu, select **Departments/Functional Areas**.
2. On the **Departments** list screen, click **Map Labor and Costs**.

   There are four department mapping tabs:

   - **Labor (Late stage)**
   - **Labor (Phase I)**
   - **Costs (Late stage)**

- **Costs (Phase I)**

> **Note:** Phase I 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 and without IND WBS.

3. For each department mapping tab, select the mapping mode by clicking the **Change** link in the upper right corner.
4. Select one mapping mode by clicking the radio button.
   - **Resource**—Map labor to departments by resource. You can map departments to internal and outsourced providers for each ClearTrial-defined and user-defined resource.
   - **Location**—Map labor to departments by location. You can map departments to internal and outsourced providers per location.
   - **Task**—Map labor to departments by task. You can map departments to internal and outsourced providers for each task. You can provide a default department for internal and outsourced providers for all tasks by setting departments in the Default row, or for all tasks within a task group by selecting departments in a task group row.
   - **Rule (Advanced Mode)**—Map labor to departments by your own criteria. For more information, see Add a department mapping rule.
5. Click **Ok**.
6. On the **Edit Department Mapping** screen for the selected mode, do the following 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.
7. Click **Save**.

Restore default department mappings

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

Add a department mapping rule

1. From the **Maintain** menu, select **Departments/Functional Areas**.
2. On the **Departments** list screen, click **Map Labor and Costs**.
3. Select a department mapping tab and click the **Change** link in the upper right corner.
4. Click the **Rule (Advanced Mode)** radio button and click **Ok**.
5. Click **Add Rule**. For more information about a field, click the field name to display online help.

6. Do the following. Which choices you have are determined by your mapping mode choice.
   a. From the **Department** drop-down list, select the department to be assigned when this rule is applied.
   b. On the **Providers** tab, select providers to be matched according to this rule or **Any Provider** to include both Internal and outsourced service providers. Select the **Internal** and **Outsource** checkboxes to include all the service providers in that group.
   c. On the other tabs, select specific locations, costs, tasks, or resources or **Any** to include all.
7. Click **Ok** to add the rule to the department mapping tab.
8. Click **Save**.

Map GL codes to labor and costs

You can add General Ledger (GL) codes and map them to labor and costs. To work with GL codes, your system administrator must grant you the Departments/GL Codes Administrator additional role.

Add a GL code

1. From the **Maintain** menu, select **GL Codes**.
2. On the **GL Codes** list screen, click **New**.
3. In the **Code** field, enter an alphanumeric code that represents the GL code and will appear throughout ClearTrial.
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 list screen, click **Close**.

Map labor and costs to GL codes

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

1. From the **Maintain** menu, select **GL Codes**.
2. On the **GL Codes** list screen, click **Map Labor and Costs**. There are four GL code mapping tabs:
   - **Labor (Late stage)**
   - **Labor (Phase 1)**
   - **Costs (Late stage)**
   - **Costs (Phase 1)**
3. For each GL code mapping tab, select the mapping mode by clicking the **Change** link in the upper right corner.

4. Select a mapping mode by clicking the radio button.
   - **Resource**—Map labor to GL codes by resource. You can map GL codes to internal and outsourced providers for each ClearTrial-defined and user-defined resource.
   - **Location**—Map labor to GL codes by location. You can map GL codes to internal and outsourced providers for each location.
   - **Task**—Map labor to GL codes by task. You can map GL codes to internal and outsourced providers for each task. You can provide a default GL code for internal and outsourced providers for all tasks by selecting GL codes in the Default row, or for all tasks within a task group by selecting GL codes in a task group row.
   - **Rule (Advanced Mode)**—Map labor to GL codes by your own criteria. For more information, see Add a GL code mapping rule.
5. Click **Ok**.
6. On the **Edit GL Code Mapping** screen for the selected mode do the following:
   - In the **Default** row, select default GL code mappings for internal and outsourced tasks from the drop-down lists.
   - In the **Internal** column, select a GL code mapping for each resource, location, or task.
   - In the **Outsourced** column, select a GL code mapping for each resource, location, or task.
7. Click **Save**.

Restore default GL codes mappings

To restore the GL code mappings back to the ClearTrial default configuration because you have configured your organization's GL codes and need to start over or discard all of the updates made previously, click **Restore ClearTrial Defaults**.

Add a GL code mapping rule

1. From the **Maintain** menu, select **GL Codes**.
2. On the **GL Codes** list screen, click **Map Labor and Costs**.
3. Select a GL code mapping tab and click the **Change** link in the upper right corner.
4. Click the **Rule (Advanced Mode)** radio button and click **Ok**.
5. Click **Add Rule**. For more information about a field, click the field name to display online help.
6. Do the following. Which choices you have are determined by your mapping mode choice.
   a. From the **GL Code** drop-down list, select the GL code to be assigned when this rule is applied.
   b. On the **Providers** tab, select providers to be matched according to this rule or **Any Provider** to include both Internal and outsourced service providers. Select the **Internal** and **Outsource** checkboxes to include all the service providers in that group.
   c. On the other tabs, select specific locations, costs, tasks, or resources or **Any** to include all.

7. Click **Ok** to add the rule to the department mapping tab.
8. Click **Save**.

Define exchange rates on the Exchange Rate Tables list screen

An exchange rate table allows you to create and define your organization's standardized rates for each currency to be used in your plans. 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 system administrator must grant you the Exchange Rates Administrator role.

Create an exchange rate table

1. From the **Maintain** menu, select **Exchange Rates**.
2. On the **Exchange Rate Tables** list screen, click **New**. For more information about a field, click the field name to display online help.
3. 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 ClearTrial default values from a certain date.
6. In the **Currency Exchange Rate** fields, enter what one unit of the currency equals in each of the other locations.
7. To save the exchange rate table as a draft, click **Save Draft**.

   or

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

Publishing Exchange Rate tables

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

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

Set the default exchange rate table

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

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

   The default table name appears in **boldface** type.

Edit an exchange rates table

1. From the **Maintain** menu, select **Exchange Rates**.
2. On the **Exchange Rate Tables** list screen, select the checkbox of the **exchange rate table**, then click **Edit**.
3. Edit the exchange rates as necessary. For more information about a field, click the field name to display online help.
4. To save the exchange rate table as a draft, click **Save Draft**.

   Or

   To make the exchange rate table available for use in plans, click **Publish**.

   Clicking **Publish** replaces values in any plans currently using the exchange rate table. ClearTrial automatically updates all plans using the exchange rate table with the new conversion rates.
5. Click **Close**.

Apply different sets of exchange rates

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

1. From the **Edit** menu, select **Plans**.
2. Select the **plan**, click **Other Actions...**, and then click **Reforecast Exch Rates**.
3. In the **Reforecast Exchange Rates** dialog box, specify reforecast details. For more information about a field, click the field name to display online help.
   - We recommend naming each reforecast after its prior forecast.
   - If you base the reforecast on the planned values, ClearTrial calculates the work remaining as though the study is progressing exactly as was originally forecast.
   - When you reforecast exchange rates on a plan with a cost model version that is earlier than the latest, ClearTrial applies the latest cost model to the reforecast. If the cost model of the plan being reforecast is 5.6 or above, the reforecast inherits the cost model from the source plan.
   - You do not have the ability to manually apply a different cost model or custom field model when using this feature.
4. Click **Ok**.
5. Click **Close**.

Change department and GL code information

1. From the **Maintain** menu, select **Departments/Functional Areas** or **GL Codes**.
2. Select a **department** or **GL code**, the click **Edit**.
3. Edit the **department** or **GL code information** as necessary. For more information about a field, click the field name to display online help.
4. Click **Save**.
5. Click **Close**.

Change how labor and costs are mapped to departments and GL codes

1. From the **Maintain** menu, select **Departments/Functional Areas** or **GL Codes**.
2. Select a **department** or **GL code**, then click **Map Labor and Costs**.
3. For each **department** or **GL codes** mapping tab, click the **change** link in the upper right corner.
4. Select a **mapping mode.** There are four mapping modes:
   - **Resource**—Map labor to department or GL codes by resource. You can map to internal and outsourced providers for each ClearTrial-defined and user-defined resource.
   - **Location**—Map labor by location. You can map to internal and outsourced providers for each location.
   - **Task**—Map labor by task. You can map to internal and outsourced providers for each task. You can provide a default department or GL code for internal and outsourced providers for all tasks by selecting Department or GL codes in the Default row, or for all tasks within a task group by selecting Department or GL codes in a task group row.
   - **Rule (Advanced Mode)**—Map labor to department or GL codes by your own criteria. For more information, see Add a department or GL Code Mapping Rule.
5. Click **Ok**.
6. For each tab, do the following:
   - In the **Default** row, select default department or GL code mappings for internal and outsourced tasks from the drop-down lists.
   - In the **Internal** column, select a department or GL code mapping for each resource, location, or task.
   - In the **Outsourced** column, select a department or GL code mapping for each resource, location, or task.
7. Click **Save**.
8. Click **Close**.

Add a department or GL Code Mapping Rule

1. From the **Maintain** menu, select **Departments/Functional Areas** or **GL Codes**.
2. On the **Departments** or **GL Codes** list screen, click **Map Labor and Costs**.
3. Select a **department** or **GL code** mapping tab and click the **Change** link in the upper right corner.
4. Select **Rule (Advanced Mode)**.
5. Click **Ok**.
6. Click **Add Rule**.
7. On the **Create Department Mapping Rule** or **Create GL Code Mapping Rule** dialog box, do the following. Which tabs appear are determined by whether you are working with departments or GL codes.
   a. From the **Department** or **GL Code** drop-down list, select the department or GL code to be assigned when this rule is applied.

b. On the **Providers** tab, select providers to be matched according to this rule or click **Any Provider** to include all providers.

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

c. On the **Locations (Any)** tab, select **Any Locations** or specific locations to be matched according to this rule.

d. On the **Costs (Any)** tab, select the costs to be matched or **Any Cost**.

e. On the **Tasks** tab, select the tasks to be matched according to this rule or Any Task.

f. On the **Resources** tab, select resources to be matched according to this rule or **Any Resource**.

8. Click **Ok**.
9. Click **Save**.

Edit and delete your mapping rules

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

Map countries to reporting regions

You can create reporting regions for studies based on your global organizational structure and accounting practices. You can then map countries to reporting regions. Mapping allows you to view the budget by location with the **Monthly Budget by Reporting Region** report, available from the Reports tab.

To work with reporting regions, you must have Power User as a primary role and your system administrator must grant you the Reporting Regions Administrator role.

Add a reporting region

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 blank **Reporting Region Name** column, enter a reporting region name.
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

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, from the **Reporting Region** drop-down list, select a reporting region.
4. Click **Save and Close**.

View the Monthly Budget by Reporting Region report

1. From the **Edit** menu, select **Plans**.
2. Select a plan and click **Edit**, then select the **Reports** tab.
3. In the **Costs** section, click **Monthly Budget by Reporting Region**.

   If you have locations in the plan that are mapped to reporting regions, the Monthly Budget By Reporting Region report appears and shows the study costs by month by reporting region over the duration of the study. This is the only report that includes this information.
4. Click **Close**.

Create a template for your organization to share

A template is a reusable plan that serves as a starting point. Using a template to create a plan saves time by storing frequently used values and choices. Templates also enforce standard operating procedures. Unlike a copy of a plan, which remains linked to its original study, you can create a plan based on a template for any study. In fact, when you create a plan, selecting a template is one of your first actions.

To create a template as you configure the service providers and their rates, define your plan assumptions, create a template, as described below.

Create a new template

1. From the **Maintain** menu, select **Templates**.
2. On the **Templates** list screen, click **New**.
3. Select the **sponsor** from the drop-down list.
4. Identify the **Phase**, **Therapeutic Area**, and **Indication** to allow ClearTrial to calculate suggested values for your plan. You can override these values as you create the template.
5. Click **Ok**.

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

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

   - Choose values that correspond to most of the plans to which this template will apply. You can then modify the plan as necessary.
   - You can select this template to plan studies even if the study to be planned is for a different phase, therapeutic area, or indication.
   - For more information about a field, click the field name to display online help.
7. Work through the tabs until you have completely defined the template.

Lock a template

Locking a template freezes the template. It cannot be edited unless you unlock it.

1. From the **Maintain** menu, select **Templates**.
2. On the **Templates** list screen, select the template to lock.
3. From the **Other Actions** menu, click **Lock Templates**.

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

Purge deleted items

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

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

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

1. From the **Maintain** menu, select **Purge Deleted items**.
2. Select the **item types** to be purged. To see a description, click the item name.
3. In the **deleted at least n days ago** field, specify the number of days since an item of the selected type was deleted and should now be purged.

   To purge all deleted items of the selected type, enter 0.
4. Click **Purge Selected Items**.