Oracle® Health Sciences ClearTrial Cloud Service

Plan and Source User Guide

Release 5.1

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Preface

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

Audience

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

Documentation Accessibility

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

Access to Oracle Support

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

Resetting a Forgotten Password

If you have forgotten your password, click the "Forgot Your Password?" link on the ClearTrial login screen. Enter your Customer ID, login name, and email address. You will receive an email with further instructions on how to reset your password.

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

Accessing ClearTrial Help

Within the ClearTrial application, users have several options for accessing help resources.

- **ClearTrial Support Center:** Click the Visit Support Center link on any screen within ClearTrial to access additional documentation and resources.

- **ClearTrial Support Team:** Contact the ClearTrial Support Team at cleartrial-support_ww@oracle.com or +1 (877) 206-4846.
- **On-Screen Help:** From any screen within ClearTrial, click the label for a specific field to view the on-screen help window.

Finding Oracle Documentation

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

Finding Oracle Health Sciences Documentation

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

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

or, for the documentation for this product, to:

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

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

Related Documents

For more information, see the following documents in the Oracle Health Sciences ClearTrial Cloud Service Release v5.1 documentation set:

- *Oracle Health Sciences ClearTrial Cloud Service v5.1 Release Notes*
- *Oracle Health Sciences ClearTrial Track Cloud Service User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service System Administrator User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service Web Services API User Guide*

Part I

Working with ClearTrial

Part I provides information on how to create and edit products, plans, and studies in ClearTrial. Part I also includes information on how to create templates and portfolios.

Part I contains the following chapters:

1

Products

Before working with studies or plans, you have to add products in ClearTrial, with the Product List Screen. Studies are conducted based on products entered into ClearTrial, while plans are potential scenarios for completing a study.

- **Product:** A compound, combination compound, medical device, or product that is the subject of a clinical study.
- **Study:** A clinical study for a product. You may have multiple studies for a single product.
- **Plan:** A potential scenario that might be used to conduct a study. You may have multiple plans for a single study.

Working with Products

To work with Products, select Products from the Maintain menu to view the Product List Screen. This screen allows you to add, edit, delete, and restore products.

Roles

To work with products, you must have either the Clinical Administrator or System Administrator Role. These are additional roles that can be granted by your System Administrator.

Creating Products

To create a product:

1. Navigate to the Products List Screen.
2. Click the New button.
3. Enter all required product detail information in the Create Product Screen.
4. Click Save.

Editing Products

To edit a product:

1. Navigate to the Products List Screen.
2. Select a product from the list. Click the Edit button and make changes as needed.
3. Click Save.

Deleting Products

To delete a product:

1. Navigate to the Products List Screen.
2. Select one or more products from the list. Click the Delete button.

Restoring Products

To restore a product:

1. Navigate to the Products List Screen.
2. Select one or more deleted products from the list. If needed, adjust the filter to show deleted products.
3. Click the Restore button.

2

Studies

After a product has been added to ClearTrial, a study can be created for that product. Studies are maintained from the Study List Screen. This screen allows you to create, edit, delete, and restore studies.

Working with Studies

Studies are created from the Study List Screen.

Study Phases

ClearTrial supports study phases II, IIa, IIb, III, IIIb, phase IV with an IND, and phase IV without an IND. ClearTrial also supports Phase I for oncology and vaccine studies, as well as Phase I studies for healthy volunteers.

The study phase is selected when a new study is created.

Creating Phase II-IV Studies

When Phase II through IV studies are created, assumptions pertaining to these phases are provided.

To create a study:

1. Navigate to the Study List Screen.
2. Click the New button to display the Create Study Screen.
3. In the Study Name field, type the study name.
4. In the Protocol field, type the protocol ID number.

   The protocol ID number identifies the protocol for this study.
5. In the Product/Compound field, select a product from the drop-down list. This list is populated with products that are created on the Product List Screen.
6. In the Phase field, select a study phase, II through IV, from the drop-down. If this is a Phase I study, see Section , "Creating Phase I Studies".
7. In the Sponsor field, select a study sponsor for the study.
8. In the Status field, specify the status of this study from the drop-down list.

   The status can be set to one of the following: Planning, Contract Negotiation, In Progress, Complete, or Archived.
9. In the Billing Code field, enter a billing code.

This field allows you to specify a special billing code that may be applicable, or an abbreviation or short name for this study.

10. In the Therapeutic Area and Indication fields, select a therapeutic area from the drop down menu. To see a list of ClearTrial Therapeutic Areas and Indications, select “Therapeutic Area / Indications Mapping” from the Report menu.

    If the Therapeutic Area and Indication you need is not included, pick one that best represents the complexity of the study and substitute it with an alias name. The alias you enter will appear on all plans and reports for the study. Consult with your ClearTrial Clinical Services Manager to choose the appropriate Therapeutic Area and Indication in these situations.

11. In the Description/Notes field, enter a description that provides other users with additional information about the study.

12. Click Save.

13. To begin creating a plan for this study, click the Create Plan button at the bottom of the page to launch the Choose Template dialog box. Pick a template and click OK to begin entering assumptions for the plan.

    The other option you have for creating a plan for your study is to start from the Plan List Screen. For more information, see Working with Plans.

Creating Phase I Studies

ClearTrial supports Phase I studies for healthy volunteers and Phase I for oncology and vaccine studies.

To create a Phase I study:

1. Navigate to the Study List Screen.

2. Click the New button to display the Create Study Screen.

3. In the Study Name field, type the study name.

4. In the Protocol field, type the protocol ID number.

   The protocol ID number identifies the protocol for this study.

5. In the Product/Compound field, select a product from the drop-down list. This list is populated with products that are created on the Product List Screen.

6. In the Phase field, select either Phase I Healthy Volunteers or Phase I oncology/vaccines.

   If Phase I Healthy Volunteers is selected, the Therapeutic Area and Indication fields are set to Healthy Volunteers.

   If Phase I Oncology/vaccines is selected, you can select either "oncology" or "other" for the Therapeutic Area.

   If needed, you can select the check-box for "Substitute the names below for therapeutic area and indication" to enter an alias name for "Healthy Volunteers," "Oncology," and "Other." Consult with your ClearTrial Clinical Services Manager to choose the appropriate Therapeutic Area and Indication in these situations.

7. In the Sponsor field, select a study sponsor for the study.

8. In the Status field, specify the status of this study from the drop-down list.

   The status can be set to one of the following: Planning, Contract Negotiation, In Progress, Complete, or Archived.

9. In the Billing Code field, enter a billing code.

   This field allows you to specify a special billing code that may be applicable, or an abbreviation or short name for this study.

10. In the Description/Notes field, enter a description that provides other users with additional information about the study.

11. Click Save.

12. To begin creating a plan for this study, click the Create Plan button at the bottom of the page to launch the Choose Template dialog box. Pick a template and click OK to begin entering assumptions for the plan.

    The other option you have for creating a plan for your study is to start from the Plan List Screen. For more information, see Working with Plans.

Editing Studies

To edit a study:

1. Navigate to the Study List Screen.
2. Select a study and click the Edit button.
3. Make changes as needed and click Save.

Deleting Studies

To delete a study:

1. Navigate to the Study List Screen.
2. Select select one or more studies and click the Delete button.

Restoring Studies

To restore a study:

1. Navigate to the Study List Screen.
2. Select one or more deleted studies. If needed, adjust the filter to display deleted studies.
3. Click the Restore button.

3

Plans

After a study has been added to ClearTrial, one or more plans can be created based on that study.

Working with Plans

Plans are created on the Plan List Screen. While editing plans, there are several tabs that allow you to enter assumptions about various aspects of a study. These tabs include: Overview Tab, Locations Tab, Site Tab, Subject Tab, Treatment Tab, Data Tab, Monitoring Tab, Provider Tab, Translations Tab, Meetings Tab, Assignment Tab, Labor Tab, Costs Tab, Payments Tab, Summary Tab, and Reports Tab.

There are entry fields in several sections on each tab. The number of fields displayed depends on which Edit Mode you are in. The Edit Mode can be controlled from the drop down box in the upper-right hand corner.

Entering Notes

To help communicate further clarification related to your input assumptions, you can use the ClearTrial notes function.

To record notes with your plan, click the Notes button in the upper right corner of each tab. Use Public notes to share with your business partners. Private notes may be limited to share with only your internal team. All notes appear on the Assumptions Report (see Reports Tab), below the table of assumptions for each functional area. You can control whether public and private notes are displayed when you print the Assumptions Report.

Warnings and Advice

The ClearTrial software provides warnings and guidance as you enter assumptions about a plan. This information is based on ClearTrial's industry information. Advice is available when a symbol appears to the right of a value. Double click the symbol to read the advice.

- A blue "i" means additional information is available.
- A yellow "!" indicates that a value or piece of data may be outside of standard ranges.
- A red "!" signifies an entry is invalid.

Edit Modes

ClearTrial allows you to plan your studies in one of four Edit Modes, which are Quick, Basic, Advanced, and Expert. An Edit Mode controls how many input questions are displayed. Your current Edit Mode is shown in the upper right corner of the page when you are editing a plan. To change it, click on the drop down menu to select a different mode.

- **Quick Mode:** Quick Mode displays the least amount of input questions, which is helpful when you have minimal information about a study you are planning.
- **Basic Mode:** Basic Mode allows you to input information for all of the same fields as Quick Mode, with some additional fields.
- **Advanced and Expert Modes:** Advanced and Expert Modes include all of the same fields as Basic Mode. These modes enable you to control all of the ClearTrial input assumptions to customize the operational approach and budget for your study. These are typically used prior to submitting an RFP bid, or for a final budgeting exercise, when you have specific information about how the study will be conducted.

Preferred and Maximum Edit Modes

You have a Preferred Edit Mode and a Maximum Edit Mode, which are set when your user account is added to ClearTrial. Your Maximum Edit Mode is the highest edit mode you are authorized to use. Contact your System Administrator to request a change to your Maximum Edit Mode.

ClearTrial defaults you to your Preferred Edit Mode every time you create a new study or plan. You can change your Preferred Edit Mode by using the Edit Profile button.

To change your Preferred Edit Mode:

1. Login to the application.
2. Select your name on the menu bar.
3. Click Edit Profile button.
4. Choose your Preferred Edit Mode from the drop-down menu and click Save.

Preferred Home Page

You have a preferred home page that is set when your user account is added to ClearTrial. The preferred home page is the screen you will view upon logging into ClearTrial. You can edit your preferred home page by editing your user profile.

To change your Preferred Home Page:

1. Login to the application.
2. Select your user name in the upper right corner.
3. Click the Edit Profile button.
4. In the Preferred Home Page drop down, select your desired home page and click Save.

Preferred Locale

You have a preferred locale that is set when your user account is added to ClearTrial. The preferred locale determines how dates and numbers are displayed within ClearTrial. You can edit your preferred locale by editing your user profile.

To change your Preferred Locale:

1. Login to the application.
2. Select your user name in the upper right corner.
3. Click the Edit Profile button.
4. In the Preferred Locale drop down, select your desired locale and click Save.

Creating Plans

To create a new plan:

1. Navigate to the Plan List Screen.
2. Click the New button.
3. Select the study for which you are creating a plan. You must also select a template to use as a starting point for your plan.
4. Click Ok. The Create Plan page is displayed, with the Overview Tab open. All of the tabs are unavailable, except for the Overview Tab. The tabs become available as information is entered.
5. Enter a name and description for your plan.
6. Complete the fields on the Overview Tab.
7. Input the assumptions for your plan in the series of tabs down the left side of the page. Use the Next button to navigate from one tab to the next. The plan is complete once you have reached the Summary Tab.

Saving Plans

ClearTrial allows you to save plans while you are editing them. You can save plans by clicking the Save button at the bottom of each tab, or you can click the Next button to save your work and navigate to the next tab.

Editing Plans

To edit a plan:

1. Navigate to the Plan List Screen.
2. Select a plan and click the Edit button to view the Edit Plan Screen. From the Edit Plan Screen, you can work with all of the tabs and adjust all plan assumptions as needed.

Deleting Plans

To delete a plan:

1. Navigate to the Plan List Screen.
2. Select one or more plans and click the Delete button.

Copying Plans

To copy a plan:

1. Navigate to the Plan List Screen.

2. Select a plan and click the Copy button. Enter a new name for the copied plan.

   Note: Do not select "Copy as Template," if you want to be able to work with the copied plan. If you need to create a template, see Chapter 4, "Templates".

3. Click OK to view the Edit Plan Screen.

Restoring Plans

To restore a plan:

1. Navigate to the Plan List Screen.
2. Select one or more plans. If needed, adjust the filter to display deleted plans.
3. Click the Restore button.

Comparing Plans

To compare plans:

1. Navigate to the Plan List Screen.
2. Select two or more plans you wish to compare and click the Compare button.
3. Specify the information to include in the report. The information available for comparisons include: Assumptions, Fees and Costs, Fixed Unit Prices, Resources, and Milestone Dates. You can include provider details, location details, and inflation.
4. Select a currency and Click OK to view the comparison.

Locking Plans

If you need to prevent other users from editing a plan, you can lock the plan with the Other Actions button. You can also lock plans to prevent them from being updated with each new release of ClearTrial when there are task and algorithm changes.

Note: You cannot lock a plan that is "incomplete." Locked plans can be copied and the copy uses the current algorithms and calculations.

To lock a plan:

1. Navigate to the Plan List Screen.
2. Select one or more plans to lock.
3. Click the Other Actions button at the top of the list and select Lock Plan. A locked symbol appears next to any plan that is locked. These plans are available for viewing, but cannot be changed.

   To view the version of ClearTrial that the plan is locked to, hover your mouse over the locked symbol. Information about which version of ClearTrial the plan was locked in is displayed.

Unlocking Plans

Plans that have been locked can be unlocked to be updated with the current algorithm and task changes.

1. Navigate to the Plan List Screen.
2. Select one or more plans to unlock
3. Select "Unlock Plan" from the Other Actions menu. The lock symbol is removed from your plan(s) and recalculated with any updated task and/or algorithm changes in the current release of ClearTrial.

Editing Attributes of a Locked Plan

The status and long description of a locked plan can be edited from the Plan List Screen, without unlocking the plan.

To edit attributes of a locked plan:

1. Navigate to the Plan List Screen.
2. Select a locked plan to edit.
3. Click the Other Actions button and select "Change Attributes" from the menu. Edit the plan status and long description as needed. Click Save.

View, Print, and Export a Plan

After you enter all of your plan assumptions, you can view the results and generate reports. Plan results can be viewed on the Summary Tab. Reports can be exported and printed from the Reports Tab.

To view plan results:

1. Navigate to the Plan List Screen.
2. Select the plan for which you want to generate a report.
3. Click the Edit button and navigate to the Reports Tab.
4. Select a report and specify the information you need included. Click OK and the report will be generated. From the report screen, you can print the report, view it as a PDF, or export it to a CSV or Excel file format.

Freezing Billing Rates for a Plan

ClearTrial allows you to freeze billing rates for plans, while allowing changes to other input specifications. This should be done prior to new releases of ClearTrial if you do not want your billing rates to be updated with the release.

To freeze a plan:

1. Navigate to the Plan List Screen.
2. Click the check box for the plan(s) for which you want to freeze the billing rates.
3. Click the Other Actions button and select "Freeze Billing Rates" from the menu. Any updates or changes to your Service Provider billing rates will not affect the output of these frozen plans.

Recalculate a Plan with Service Provider Billing Rates

ClearTrial allows you to recalculate plans with updated billing rates by unfreezing plans that were previously frozen. Plans should be unfrozen prior to new releases of ClearTrial if you want your billing rates to be updated with the release.

To unfreeze a plan:

1. Navigate to the Plan List Screen.
2. Select the plans you want to recalculate.
3. Click the Other Actions button and select “Unfreeze Billing Rates” from the submenu. These plans will now use the most current billing rates for the rate year specified in the Service Provider detail page.

4

Templates

ClearTrial allows you to create templates for plans that can be used by other users. Templates are created to reflect your standard practices for certain types of studies, which can be used as a starting point when creating new plans.

Working with Templates

To work with templates, select Templates from the Edit menu to display the Template List Screen. This screen displays the currently defined templates and provides the ability to create, edit, delete, restore, copy, and lock templates.

Roles

To work with templates, you must have either the Power User or Clinical Administrator Role. Users without these roles can only view the templates. These are additional roles that can be granted by your System Administrator.

Creating Templates

There are two options for creating templates. You can use an existing plan and save it as a template or you can create a template on the Template List Screen.

To create a template with the Template List Screen:

1. Navigate to the Template List Screen.
2. Click the New button.
3. Specify the Sponsor, Phase, Therapeutic Area, and Indication for the template.
4. Click OK to display the Edit Plan Screen. Enter all of the assumptions you want to be used in the template and save the plan. Once saved, the template will be listed on the Template List Screen.

   Upon completion, your template is visible to other users and they can use it as a starting point for creating new plans.

To copy a plan as a template:

1. Navigate to the Plan List Screen.
2. Select a plan to copy as a template. Click the Other Actions... button and select “Copy as Template” to display the Copy Plan dialog box.
3. Enter a name for the template and ensure the Copy as Template check-box is marked.

4. Click OK. Enter and adjust assumptions as needed and save the plan. Once saved, the plan will be added as a template on the Template List Screen.

Editing Templates

Templates can be edited from the Template List Screen. When a template is edited, plans that were created based on that template are not affected.

To edit a template:

1. Navigate to the Template List Screen.
2. Select the template you need to edit and click the Edit button to view the Edit Template Screen. Modify your input assumptions and click Save.

Deleting and Restoring Templates

Templates can be deleted and restored from the Template List Screen. When a template is deleted or restored, plans created based on that template are not affected.

To delete and restore a template:

1. Navigate to the Template List Screen.
2. Select the template you need to delete and click the Delete button.
3. To restore a template, select it and click the Restore button. If the template you need to restore is not on the list, adjust the filters to display all templates.

Copying Templates

Templates can be copied to create new ones from the Template List Screen. When a template is copied, plans created based on that template are not affected.

To copy a template:

1. Navigate to the Template List Screen.
2. Select the template you need to copy and click the Copy button to display the Copy Template dialog box. Enter a name for the copy and click OK to view the Edit Template Screen. Edit the copied template as needed and click Save.

Locking and Unlocking Templates

Templates can be locked and unlocked from the Template List Screen, to prevent other users from modifying them. When a template is locked or unlocked, plans created based on that template are not affected.

To lock and unlock a template:

1. Navigate to the Template List Screen.
2. Select the template you need to lock and click the Lock Templates button. A lock symbol will appear next to locked templates. If you need to unlock a template, select it and click the Unlock Templates button.

5

Portfolios

ClearTrial allows you to group several plans together by study, product, phase, or indication with the Portfolio feature. Portfolios provide aggregate forecasts, such as monthly budget, monthly resource demand, and time lines across multiple plans. They also allow you to see the effect of adjusting start and end dates.

Working with Portfolios

Portfolios can be created and edited from the Plan List Screen or the Portfolio List Screen. In addition, you can view which portfolios a plan belongs to from the Overview Tab while editing a plan in Advanced or Expert Edit Mode.

The Plan List Screen allows you to select plans from the list and add them to an existing portfolio, or create a new portfolio, with the "Other Actions" button.

The Portfolio List Screen is accessed by selecting Portfolios from the Edit drop-down menu. This screen displays the currently defined portfolios and provides the ability to create, edit, delete, restore, and copy portfolios.

Roles

To work with portfolios, you must have either the Power User or Clinical Administrator Role. Users without these roles cannot edit other users' portfolios. These are additional roles that can be granted by your System Administrator.

Creating Portfolios

Portfolios can be created from the Plan List Screen.

To create a portfolio:

1. Navigate the Plan List Screen.
2. Choose one or more plans and select "Add to Portfolio(s)" from the Other Actions menu.
3. From the "Add Plans to Portfolio(s)" dialog box, you can select plans to add to an existing portfolio or create a new one. To create a new portfolio, select "Also create a new portfolio and add the selected plans to it" to enable the create New Portfolio fields.
4. Click OK to view an updated portfolio list.

Portfolios can also be created from the Portfolio List Screen.

To create a portfolio:

1. Navigate the Portfolio List Screen.
2. Click the New button.
3. On the Overview Tab, enter a portfolio name, description, and currency options. Click Next.
4. On the Plans Tab, click the Add Plans button to view the Choose Plans dialog screen. Select one or more plans to include in the portfolio. Click OK.

   If you need to remove plans from the portfolio, select them from the list and click the Remove Plans button. If you want to exclude plan(s) from the portfolio, but do not want to remove them, you can use the Include and Exclude buttons.
5. On the Refine Tab, you can choose to include or exclude plans from the portfolio and view a summary of the costs. You can also adjust the Start and End dates for the portfolio. Click next.
6. The Reports Tab allows you to view, export, and print reports for your portfolio. These reports include:
   - Portfolio Milestone Timeline Chart
   - Portfolio Summary
   - Fees by Major Task
   - Monthly Budget
   - Resource Demand Summary
   - Resource Demand by Date
   - Resource Demand Chart

Editing Portfolios

Portfolios can be edited from the Portfolio List Screen.

To edit a portfolio:

1. Navigate the Portfolio List Screen.
2. Select Portfolios from the Edit menu to view the portfolio list.
3. Select the portfolio(s) from the list that you need to edit and click the Edit button to view the Edit Portfolio Screen. Make changes as needed and click Save.

Deleting Portfolios

Portfolios can be deleted from the Portfolio List Screen.

To delete a portfolio:

1. Navigate the Portfolio List Screen.
2. Select one or more portfolios from the list and click the Delete button.

Copying Portfolios

Portfolios can be copied from the Portfolio List Screen.

To copy a portfolio:

1. Navigate the Portfolio List Screen.

2. Select a portfolio to copy and click the Copy button. Enter a name for the portfolio and click OK to view the Edit Portfolio Screen.

6

Reports

ClearTrial allows you to view several reports from the Reports menu. These reports provide information that is maintained outside of individual plans.

Working with Reports

To work with reports, select the Report drop-down menu on the main menu bar within the application. Click the report you need to view and the report dialog screen is displayed. If needed, you can select report assumptions to be displayed.

All reports can be printed and viewed as a PDF. They can also be exported to Microsoft Excel and CSV.

> **Note:** The User Report, Inactive Users Report, Planned Trials, Tracked Trials Report, and Plan Inventory Report are only available to system administrators. For more information about system administrators, see the *Oracle Health Sciences ClearTrial Cloud Service System Administrator User Guide.*

Reports

Described below are the reports on the Reports menu.

- **Bid Grid (Late Stage):** The Bid Grid report for late stage studies displays the start and end dates for each major task. The report also shows the unit hours, unit cost, units, extended hours, and extended costs for each major task.
- **Bid Grid (Phase I - Healthy Volunteers):** The Bid Grid report for Phase I Healthy Volunteers studies displays the start and end dates for each major task. The report also shows the unit hours, unit cost, units, extended hours, and extended costs for each major task.
- **Therapeutic Area / Indications Mapping:** The Therapeutic Area/Indications Mapping report displays a list of all the therapeutic areas that are supported by ClearTrial.
- **Study Performance Summary:** The Study Performance Summary report displays the Overall Performance (OP), Schedule Performance (SP), and Budget Performance (BP) for all studies in ClearTrial. This report allows you to select date range options and study attributes of plans to be included in the report.
- **User Report:** The User Report displays a list of users with user accounts. This report is only available to system administrators.

- **Inactive Users Report:** The Inactive Users Report displays a list of users who have not logged into the application. This report is only available to system administrators.
- **Plan Inventory Report:** The Plan Inventory report provides a summary of all the studies and plans currently in ClearTrial. This report is only available to system administrators.
- **Planned Trials:** The Planned Trials Report displays all of the currently planned trials in the application. This report is only available to system administrators.
- **Tracked Trials:** The Tracked Trials Report displays all of the currently tracked trials in the application. This report is only available to system administrators.

Part II

Entering Plan Assumptions for Studies

After you have created a plan and you are ready to begin entering assumptions, you can begin entering specifications for your study with the tabs on the Edit Plan Screen. The tabs allow you to specify all information related to your study, such as data collection methods, assigning service providers, entering costs, etc.

Part II provides information how to work with all of the ClearTrial tabs.

> **Note:** Before you can begin entering assumptions, you must create a product and study. For more information, see Chapter I, "Working with ClearTrial".

Part II contains the following chapters:

7

Overview Tab

The Overview Tab is used to enter basic information about a plan, including name, project activity start date, description, status and currency preferences for your plan.

Plan Name

The plan name is a name that identifies a plan. Your organization should decide on a standard naming convention, but it is recommended that plan names be a combination of the study name and the version of the plan that you are creating.

Plan Status

The Status field allows you to indicate the state of a plan. However, if a plan has been set as the baseline plan, the status cannot be edited. This field is unavailable for baselined plans.

The available plan statuses include the following:

1. **Incomplete:** An incomplete plan does not have all of the input questions answered and the results are not expected to be accurate.
2. **Draft:** A draft plan has all of the input questions answered, but the plan owner may still be working on the plan.
3. **Final:** A final plan has all of the input questions answered and the plan owner believes that the plan will be used to conduct the clinical study, however the plan has not yet been approved by a person authorized to approve a study plan.
4. **Approved:** An approved plan has been authorized for use in conducting a clinical study, or to be a part of an RFP or a proposal.
5. **RFP:** A plan marked RFP, means that it has been approved and has been included as part of an RFP.
6. **Agreement reached; not started:** A plan marked Agreement reached means that an agreement has been reached on the plan and it is under contract (if an outsourced study) or ready for study activities to begin (if an internal sponsor-executed study).
7. **In progress:** A plan marked In progress means that the study has begun and is operating.
8. **Study Complete:** A plan marked Study Complete means that the study has completed execution.
9. **Archived:** A plan marked Archived means that this plan is being preserved for historical purposes only.

Project Activity Start Date

For outsourced studies, this is the date that any Service Providers on the study will begin billable work.

> **Note:** This field impacts fees for project management and start up fees for vendors based on the FSI date.

For studies conducted internally by the sponsor, this is the date on which Project Initiation activities will begin utilizing sponsor personnel. This does not include Pre-Study Planning as that date is accounted for separately; (see Pre-Study Planning).

If you decide to change the Project Activity Start Date after other data has been entered and saved, the following items may need to be addressed:

- If you accepted the default First Subject Enrolled (FSI) date (on the Subject Tab), this date is updated automatically according to the changed Project Activity Start Date. But if you or another user has changed (overridden) the First subject enrolled date, then any change in the Project Activity Start Date will not automatically update the First Subject Enrolled date that was selected.
- ClearTrial will require you to re-visit and revise any dates you have overridden.
- If you select a start date that is greater than the user-specified FSI date then a warning appears in the FSI date indicating that the date is before the Project Activity Start Date.

Start Pre-Study Planning

The Pre-Study Planning date is the date, prior to the project start date, on which a sponsor begins pre-planning activities. The value for this date 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. This date does not currently drive any calculations of effort or costs for your study.

Study will be

The plan outsourcing option, or "Study will be" field, allows you to identify how the plan will be outsourced.

- **Outsourced:** Select Outsourced if the entire study will be outsourced to an external Service Provider (excluding oversight of that Service Provider). This will set all responsibility radio buttons to 'Vendor' through-out the tabs of the plan.
- **Conducted Internally:** Select Conducted Internally if the study will be performed internally by the sponsor only, with no outside Service Providers. This will set all responsibility radio buttons to 'Sponsor' throughout the tabs of the plan.
- **Combination:** Select Combination if 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.

Short Description

The short description field allows you to enter information that will be displayed when viewing a list of plans. This information may help you recognize a particular scenario or purpose of the plan.

Long Description

The long description field allows you to enter a detailed explanation of the assumptions upon which this plan is based.

Default Modeling Currency

This field allows you to select the Default Modeling Currency. The Default Modeling Currency is the currency in which you expect to enter most costs and determines the default value for the currency selection of monetary assumptions. If the plan has been set as the Baseline Plan, you will not be able to edit this field.

The default modeling currency also determines the currency in which values will be displayed on the Labor, Costs, Payments, and Summary Tabs.

Regardless of the chosen modeling currency, you can enter any monetary assumption in the currency of your choice as is appropriate to the assumption.

Default Reporting Currency

This field allows you to select the Default Reporting Currency, which is the default currency used to generate reports. You can also choose any supported currency when you generate a report.

Use Exchange Rates

There are three options to indicate which exchange rates are used to convert between currencies:

1. **As of (specified date):** This option allows you to select a specific date from which exchange rates should be used. If you enter or select a date that ClearTrial does not have exchange rates, the date defaults to the next prior date for which ClearTrial does have exchange rates. You will receive a message indicating the date that is used and the field is updated accordingly.
2. **As specified here...:** This option allows you to override one or more exchange rates to values you supply. The label for this option is an active link. When clicked, it launches the Override Currency Exchange Rates dialog to enable you to view and/or override exchange rates.

   Note: If you change the exchange rate date, by selecting the "as of (specific date)" option, and you have previously overridden exchange rates, ClearTrial removes the overridden values and restores all values to the exchange rates for the newly selected date.

3. **Defined in:** This options allows you to select a user-defined exchange rate table from the drop down list. This option is recommended when you need to use your own exchange rates, rather than the ClearTrial defined rates. User-defined exchanges tables are created with the Exchange Rates functionality available on the Maintain Menu.

   When creating templates, another option is available:

4. **As of plan created date:** Selecting this option indicates that for each plan created from the template, the exchange rates date defaults to the latest available date for which ClearTrial has obtained exchange rates as of the date that plan is created.

This is the recommended option for templates, unless the purpose of the template includes storing pre-negotiated exchange rates that every plan created using this template should use.

Drug Storage

This field allows you specify special handling considerations that must be considered.

Radio Labeled

This checkbox allows you to indicate whether the compound is radioactive.

Portfolio List

The Portfolio List displays all of the portfolios that contain this plan. For more information on portfolios and how to create them, see Working with Portfolios.

History

The History section displays information regarding the version history of a plan. This information can be used to keep track of when a plan was created, what template was used, who created it, what template was used, and it was last modified by.

8

Locations Tab

The Locations Tab is used to specify the locations in which investigator sites will be established and subjects will be enrolled.

For each location you need to specify the number of sites and subjects expected, as well as the average investigator grant amount per subject.

Adding Locations

On the Locations Tab, the Add Location(s) button is used to identify countries and regions in a study.

When adding locations in which you will conduct a study, it is recommend that you select regions if you are not sure of the exact countries. Or, you can select specific countries if you do know which countries the study will be conducted in.

For budgeting purposes, you can map reporting locations to regions with the Reporting Regions feature; for more information see Section 29, "Maintaining Reporting Regions".

To add locations to a study:

1. Navigate to the Locations Tab.
2. Click the Add Location(s) button to display the Choose Locations dialog screen. Select the regions and countries you want to include in the study. Click OK.
3. In the Number of Sites field, enter the number of sites expected at each location.
4. In the Subjects to Randomize field, enter the number the number of subjects to randomize for each location.

   Subjects to randomize is the number of subjects that will be given either the study drug/test article or an alternative treatment (e.g. placebo) in this Location. Drop rates and screen failure rates are accounted for on the Subject Tab.

   This field should contain only the number of subjects that will actually be enrolled in the trial. For instance, if the protocol calls for 1000 subjects to be randomized, enter 1000 here.
5. In the Avg Grant amount field, enter the average grant amount.

   The average grant amount is the amount of money that will be paid to each investigator in this location for each subject they enroll into the study. This should include only the amount paid to the investigator for each subject.

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

The total for investigator grant payments will be included as a Pass-Through Cost in the budget. If you do not know the grant amount for a location, enter either your best estimate or zero. If needed, you may enter zero for the grant amount for all locations and the final budget will not include the grant.

Furthermore, costs are estimated 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 because ClearTrial expects the average to be closer to 75% of all visits completed since dropped subjects must return for the termination visits (generally a repeat of the last subject visit is regardless of where they terminate).

These Pass-Through Costs can be adjusted if specific knowledge of the prorated grant budget is known.

For endpoint studies, you should be sure to include the grant costs for both the standard treatment and full extended treatment schedules.

6. In the MOH/FDA Delay field, enter the expected Ministry of Health (MOH) or Federal Drug Administration (FDA) approval time frame for each location.

   This value represents the number of elapsed days required in each location to obtain approval to proceed with the study and is used to help forecast the number of sites that should be approved by any particular date.

7. Enter information for each location and Click Save.

Removing Locations

On the Locations Tab, the Remove Location(s) button is used to remove a location from a study. Removing a location will delete all of the data associated with it.

To remove a location:

1. Navigate to the Locations Tab.
2. Select one or more locations.
3. Click the Remove Location(s) button.

9

Site Tab

The Site Tab is used to enter site management information for each location in a study. This tab identifies details regarding how sites will be recognized, initiated, monitored, and closed out.

In addition, this tab allows you to specify the subject screen failure rate, drop rate, and other values that determine effort and costs related to investigator sites and monitoring. Because these values may differ from location to location, this screen allows you to specify values both globally and by location.

Editing Site Approval Schedule

The Site Tab allows you edit the Site Approval Schedule for each location in the study.

To edit the Site Approval Schedule:

1. Navigate to the Site Tab.
2. In the Site Approval section, choose a location from the list and click the Site Approval Schedule link.

   The Edit Site Approval Schedule dialog is displayed. This dialog is used to customize the site approval schedule for a particular location.
3. The Site Approval Schedule field displays the type of site approval schedule being used for this location.

   If the schedule has been modified, the Site Approval Schedule field will say "User-Defined." If this location is using a ClearTrial calculated schedule "ClearTrial Default" is displayed.
4. The Default Site Approval Period field displays the default length of the site approval period. Additional weeks can be added to the schedule by entering a value in the Additional Site Approval Weeks field and clicking the Apply button.
5. In the Site Approval Table, adjust the number of site approvals for each week in the study.
6. Click Save.

Entering Site Information

The Site Tab allows you to enter information regarding subject and site information, and apply it to all locations or a specific location in the study.

To enter site information:

1. Navigate to the Site Tab.

2. In the Values apply to field, select either a location or All Locations from the Values apply to drop down. The site information entered will be applied to the location(s) selected in this field.
3. Enter site information for each location, or all locations, in the study and click Save.
4. Click Save to keep the values for the selected location, before selecting another location from this drop-down.

Responsibilities

The Responsibilities section includes radio buttons that allow you to indicate the outsourcing option for each group of assignable tasks. The outsourcing options include:

- **Sponsor:** Assigns all of the tasks in that group to the study sponsor.
- **Vendor:** Initially assigns all of the tasks in that group to the Primary Vendor specified on the Provider Tab.
- **Mixed:** Indicates that you would like to assign some of the tasks in that group to a vendor and other tasks in that group to the study sponsor; this can be done on the Assignment Tab.
- **N/A:** Indicates that none of the tasks in that group will be performed, if they are optional.

If you have selected "Conducted Internally" on the Overview Tab, you will not be able to assign any of the responsibilities to Vendor. Similarly, if you have selected "Outsourced" on the Overview Tab, you will not be able to assign any of the responsibilities to Sponsor.

If you determine that you want a combination of some responsibilities assigned to the Sponsor and some assigned to a Vendor, then change your selection on the Overview Tab to "Combination."

10

Subject Tab

The Subject Tab is used to enter information about the expected enrollment period and subject enrollment rate, the treatment schedule, and the First Subject In Date (FSI/FPI).

Define the Enrollment Period

The Subject Tab allows you to activities related to the enrollment period.

- **Project Activity Start Date:** This date is displayed here as an aid for entering or evaluating the First subject enrolled date (FSI/FPI).Click the icon to the right of the First subject enrolled date (FSI/FPI) field for more information about that value.

  For studies which are outsourced (in whole or in part), the Project Activity Start Date is the date on which a service provider will begin billable work on the project. For studies conducted internally by the sponsor, the Project Activity Start Date is the date on which Project Initiation activities will begin.

- **First subject enrolled date (FSI/FPI):** This value represents the date that the first subject first visit (FSFV) is expected to take place. ClearTrial estimates this date based on the expectation of study sites approval, however, you can override the suggested value with any date later than the Project Activity Start Date.

- **First Subject In Date Calendar Control:** The calendar icon represents a popup calendar which may be used to select a date as an alternative to typing the date into the corresponding field. Click the icon to display the popup calendar.

- **Enrollment Period:** The value entered in this field represents the number of weeks during which subjects will be enrolled in the trial. This is defined as the time from the first enrolled subject's first visit to the last enrolled subject's first visit.

- **Enrollment Rate:** This field displays the average rate at which subjects must be enrolled to meet the specified number of subjects randomized during the specified enrollment period.

- **Manage Location-specific values:** You may choose to specify the expected First Subject In (FSI) date for each location in one of two ways.

  If you choose to manage the location-specific dates and enrollment periods globally, changes you make to the system-suggested FSI date will be applied to each location based on the number of days you shifted the date.

  If you choose to manage the location-specific dates and enrollment periods per location, a dialog box will be displayed to allow the entry of a specific date and/or enrollment period for each location.

Define the Enrollment Distribution

The Subject Tab allows you to select an enrollment distribution.

- **Type of enrollment distribution:** This field allows you to specify the expected enrollment distribution. The enrollment distribution specifies the percentage of subjects expected to enroll in each quartile (fourth) of the enrollment period.

  Select one of the predefined Enrollment Distribution Rates from the drop-down box for a fast way of entering you enrollment expectations.

  The predefined Enrollment Distributions include:

  1. **Acute:** Use Acute distribution for indications where the subjects must present with the condition and will not be found by searching the medical records (Generally, when investigators can only estimate their ability to enroll by looking at empirical data and projecting potential enrollment numbers based on this empirical data) and if you expect that most of the sites will be approved before the first subject first visit (FSFV/FPFV) is expected to take place.

     For example, Anti-infective trials might experience an Acute or Acute Short Startup enrollment distribution. See Acute Short Startup, below, for the difference between Acute and Acute Short Startup.

  2. **Acute Short Startup:** Use this for Acute indications and when you expect that less than 75% of the sites will be approved at the time when the first subject will enroll.

  3. **Bell Curve:** This is used only when you are unsure of the enrollment type and want to get an estimate of the study using something other than an even distribution of subjects across the enrollment period.

  4. **Block Enroll:** This is used specifically for things like allergy studies where it is expected that patients will be enrolled quickly over the first two quartiles of the enrollment period and stragglers over the last two quartiles.

  5. **Chronic:** Use a Chronic enrollment for studies where the subjects that meet the criteria are generally known by the investigator and can be readily found by reviewing the patient charts and if you expect all or most of the sites will be approved before the first subject visit takes place.

     For example, Chronic illness like diabetes, Alzheimer's, AIDs are examples of an indications that might experience a Chronic or Chronic Short Startup enrollment distribution, unless the study requirements for these disorders are to be newly diagnosed. In this case, they should be considered acute.

  6. **Chronic Short Startup:** Use a Chronic Short Startup distribution for chronic indications and when you expect that less than 75% of the sites will be approved at the time when the first subject will enroll.

  7. **Even Distribution:** Even distribution is rarely used, usually only for general estimations when you have no idea what the enrollment distribution will be.

  8. **Custom...:** This option allows you to enter the percentage of the total subject population expected to be enrolled during each quartile of the enrollment period. This will depend on the number of sites that are approved at the start of subject enrollment (FSFV), availability of subjects, and the therapeutic indication.

- **Manage Location-specific values:** This field allows you to choose the expected enrollment distribution for each location, either globally or per location. If you

choose to manage location-specific enrollment globally, changes you make will be applied to every location.

If you choose to manage the enrollment distribution per location, a dialog box will be displayed to allow you to choose a different distribution for each location. Additionally, if you choose to manage enrollment per location, you may choose to create a custom weekly enrollment schedule.

Screening and Drops

The Subject Tab allows you to specify the number of subjects to be screened and estimate the subject drop rate.

- **Subjects to randomize:** This field displays the number of subjects expected in the selected location or for All Locations whose values are being displayed.
- **Screen failure rate:** This field allows you to enter the percentage of screened subjects expected to fail to become study participants.
- **Number of subjects to screen:** This field displays the number of subjects to screen based on the screen failure rate.
- **Investigator payment per screen failure:** This field allows you to enter the investigator payment per screen failure.
- **Percent of screen failures paid for:** This field allows you to enter the percentage of screen failures for which payment will be made.
- **Stipend per screen failure:** This field allows you to enter the subject stipend for screen failures.
- **Number of CRF pages per screen failure:** This field allows you to indicate the number of CRF pages that will be collected per screen failure.
- **Subject drop rate:** This field allows you to enter the percentage of subjects that will not complete a full CRF due to early termination.
- **Subjects expected to complete all study visits:** This field displays the number of subjects expected to complete the study based on the drop rate.
- **Manage location-specific values:** This field allows you to edit location-specific values, if needed. You can manage the expected enrollment distribution for each location in one of two ways.

  If you choose to manage location-specific enrollment globally, changes you make will be applied to every location. If you choose to manage the enrollment distribution per location, a dialog box will be displayed to allow you to choose a different distribution for each location.

  Additionally, if you choose to manage enrollment per location, you may choose to create a custom weekly enrollment schedule.

11

Treatment Tab

The Treatment Tab allows you to add, edit, copy, and delete one or more treatments within a plan.

Using the fields on this tab, 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.

Trial Design

The Treatment Tab allows you specify whether this study uses a parallel or cross-over design with the Trial Design field.

Parallel designs are those in which some subjects receive only one of the defined treatments, while other subjects receive only one of the other defined treatments and these subjects receive treatments during the same period.

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

Cross-over designs are more common than Phase I trials, but can be used for some later stage trials as well. Cross-over designs are generally used to reduce the number of subjects required to obtain statistically valid results. When subjects act as their own controls, variability based on age, gender, ethnicity, and lifestyle, for example, is eliminated.

Adding Treatments

The Treatment Tab allows you to add treatments for Parallel or Cross-over trials.

Adding Treatments for Parallel Trial Design Studies - Phase I Healthy Volunteers

Treatments can be added to phase I healthy volunteer studies with a parallel trial design.

To add one or more treatments:

1. Navigate to the Treatments Tab.
2. In the Trial Design field, select Parallel.
3. In the Electronic subject diary field, select yes or no.

   This field allows you to indicate whether an electronic subject diary is to be expected.
4. In the Cost per bednight field, enter the cost per bednight.

5. Click the Add button.

   Another treatment will be added to the list of treatments.

6. In the Number of subjects field, enter the number of subjects that will receive the treatment.

7. In the Treatment Duration field, enter the treatment length for each subject. The duration is specified in weeks for late stage trials and in days for Phase 1 trials.

8. In the Visits per subject field, specify the number of visits for each subject during the treatment.

   A visit is a week (late stage) or day (Phase 1) in which one or more CRF pages are collected.

   For Phase 1 Healthy Volunteers trials in which subjects are confined and procedures are performed throughout the day on most or all days of treatment and/or washout, each day would be considered a visit.

9. In the Number of Bednights field, enter the number of nights study subjects will stay on site.

10. In the Number of CRF pages per subject field, enter the number of Case Report Form (CRF) pages that will be collected for each subject during this treatment.

    This value should be inclusive of quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.

11. In the Number of QOL pages field, enter how many Quality of Life (QOL) pages will be collected during the treatment period.

    QOL pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.

12. In the Number of Subject Diary Pages field, enter how many subject diary pages will be collected during the treatment period.

13. In the Number of Pharmacoeconomic pages field, enter the number of pharmacoeconomic pages that will be collected during the treatment period.

    These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.

14. Click the Save button. Click the Add button to add more treatments or Next to continue to the next plan tab.

Adding Treatments for Parallel Trial Design Studies - Late Stage and Phase I Oncology/Vaccine

Treatments can be added to phase II through IV studies and phase I oncology/vaccines studies with a parallel trial design.

To add one or more treatments:

1. Navigate to the Treatments Tab.

2. In the Trial Design field, select Parallel.

3. In the Electronic subject diary field, select yes or no.

   This field allows you to indicate whether an electronic subject diary is to be expected.

4. In the Endpoint Study field, select yes or no.

The Endpoint Study field is only available for phase II through IV studies and phase I oncology/vaccine studies. This field allows you to indicate whether the study being modeled is an endpoint study.

In ClearTrial, an endpoint study is a study in which all patients conclude their participation in the study on, or around, the same calendar date.

5. Click the Add button.

   Another treatment will be added to the list of treatments.

6. In the Number of subjects field, enter the number of subjects that will receive the treatment.

7. In the Treatment Duration field, enter the treatment length for each subject. The duration is specified in weeks for late stage trials and in days for Phase 1 trials.

8. In the Visits per subject field, specify the number of visits for each subject during the treatment.

   A visit is a week (late stage) or day (Phase 1) in which one or more CRF pages are collected.

   For Phase 1 Healthy Volunteers trials in which subjects are confined and procedures are performed throughout the day on most or all days of treatment and/or washout, each day would be considered a visit.

9. In the Number of CRF pages per subject field, enter the number of Case Report Form (CRF) pages that will be collected for each subject during this treatment.

   This value should be inclusive of quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.

10. In the Number of QOL pages field, enter how many Quality of Life (QOL) pages will be collected during the treatment period.

    QOL pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.

11. In the Number of Subject Diary Pages field, enter how many subject diary pages will be collected during the treatment period.

12. In the Number of Pharmacoeconomic pages field, enter the number of pharmacoeconomic pages that will be collected during the treatment period.

    These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.

13. Click the Save button. Click the Add button to add more treatments or Next to continue to the next plan tab.

Adding Treatments for Cross-Over Trial Design Studies - Phase I Healthy Volunteers

Treatments can be added to phase I healthy volunteer studies with a cross-over trial design.

To add one or more treatments:

1. Navigate to the Treatments Tab.

2. In the Trial Design field, select Cross-over.

   The available fields displayed will pertain to cross-over trial design studies.

3. In the Electronic subject diary field, select yes or no.

This field allows you to indicate whether an electronic subject diary is to be expected.

4. In the Cost per bednight field, enter the cost per bednight.
5. In the Number of CRF pages collected in the baseline visit field, enter the number of CRF pages that are to be collected during the screening and baseline visits.

   The value entered in this field should be the total number of CRF pages collected for enrolled subjects during their screening visits and during the baseline visit. Only enter the number of pages that are collected at the beginning of the study, not the number collected at the beginning of each treatment period.

   Note: The pages collected for candidates that do not pass screening is a value captured on the Subject tab.

6. The Baseline visit monitoring time required (in minutes) field displays the number of minutes required to monitor pages collected during the screening and baseline visit(s). The value displayed can be overridden.
7. In the Washout period duration field, enter the length of the washout period.

   The duration is specified in weeks for late stage trials and in days for Phase 1 trials.

   The washout period is the time between treatments in a cross-over trial in which subjects are not treated in an effort to reduce or avoid residual effects of the prior treatment from skewing the data or compromising the validity of the subsequent treatment(s).

   If data are collected during the washout period, you will need to configure that by clicking the link labeled, "Configure washout period."
8. In the Treatment Duration field, enter the treatment length for each subject. The duration is specified in weeks for late state trials and in days for Phase 1 trials.
9. In the Visits per subject field, specify the number of visits for each subject during the treatment.

   A visit is a week (late stage) or day (Phase 1) in which one or more CRF pages are collected.

   For Phase 1 Healthy Volunteers trials in which subjects are confined and procedures are performed throughout the day on most or all days of treatment and/or washout, each day would be considered a visit.
10. In the Number of bednights field, enter the number of nights study subjects will stay on site.
11. In the Number of CRF pages per subject field, enter the number of Case Report Form (CRF) pages that will be collected for each subject during this treatment.

    This value should be inclusive of quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.
12. In the Number of QOL pages field, enter how many Quality of Life (QOL) pages will be collected during the treatment period.

    QOL pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring

13. In the Number of Subject Diary Pages field, enter how many subject diary pages will be collected during the treatment period.
14. In the Number of Pharmacoeconomic pages field, enter the number of pharmacoeconomic pages that will be collected during the treatment period.

    These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.
15. Click the Save button. Click the Add button to add more treatments to study.
16. In the Cross-Over Design field, select a cross-over design to determine the specific sequences of treatments to which subjects will be randomized.

    ClearTrial currently supports either Latin Square or Balaam's Design. Balaam's Design is only applicable to a trial with two treatments.
17. Click Save.

Adding Treatments for Cross-Over Trial Design Studies - Late Stage and Phase I Oncology/Vaccine

Treatments can be added to phase II through IV studies and phase I oncology/vaccine studies with a cross-over trial design.

To add one or more treatments:

1. Navigate to the Treatments Tab.
2. In the Trial Design field, select Cross-over.

   The available fields displayed will pertain to cross-over trial design studies.
3. In the Number of CRF pages collected in the baseline visit field, enter the number of CRF pages that are to be collected during the screening and baseline visits.

   The value entered in this field should be the total number of CRF pages collected for enrolled subjects during their screening visits and during the baseline visit. Only enter the number of pages that are collected at the beginning of the study, not the number collected at the beginning of each treatment period.

   Note: The pages collected for candidates that do not pass screening is a value captured on the Subject tab.
4. The Baseline visit monitoring time required (in minutes) field displays the number of minutes required to monitor pages collected during the screening and baseline visit(s). The value displayed can be overridden.
5. In the Washout period duration field, enter the length of the washout period.

   The duration is specified in weeks for late stage trials and in days for Phase 1 trials.

   The washout period is the time between treatments in a cross-over trial in which subjects are not treated in an effort to reduce or avoid residual effects of the prior treatment from skewing the data or compromising the validity of the subsequent treatment(s).

   If data are collected during the washout period, you will need to configure that by clicking the link labeled, "Configure washout period."

6. In the Treatment Duration field, enter the treatment length for each subject. The duration is specified in weeks for late state trials and in days for Phase 1 trials.
7. In the Visits per subject field, specify the number of visits for each subject during the treatment.

   A visit is a week (late stage) or day (Phase 1) in which one or more CRF pages are collected.

   For Phase 1 Healthy Volunteers trials in which subjects are confined and procedures are performed throughout the day on most or all days of treatment and/or washout, each day would be considered a visit.
8. In the Number of CRF pages per subject field, enter the number of Case Report Form (CRF) pages that will be collected for each subject during this treatment.

   This value should be inclusive of quality-of-life (QOL), pharmacoeconomic, and subject diary pages collected.
9. In the Number of QOL pages field, enter how many Quality of Life (QOL) pages will be collected during the treatment period.

   QOL pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring
10. In the Number of Subject Diary Pages field, enter how many subject diary pages will be collected during the treatment period.
11. In the Number of Pharmacoeconomic pages field, enter the number of pharmacoeconomic pages that will be collected during the treatment period.

    These pages are reviewed to see if they have been filled out by the study subjects, but usually require little or no monitoring.
12. In the Cross-Over Design field, select a cross-over design to determine the specific sequences of treatments to which subjects will be randomized.

    ClearTrial currently supports either Latin Square or Balaam's Design. Balaam's Design is only applicable to a trial with two treatments.
13. Click Save.

12

Data Tab

The Data Tab is used to specify information regarding the collection and management of study data.

Data Collection

The Data Tab allows you to indicate how data will be collected by selecting a data collection method.

Data Collection Method

The Data Collection Method selected on the Data Tab determines which pieces of data need to be collected and managed. If there will be no monitoring for the study, select "Paper (Traditional Monitoring)" and set monitoring responsibilities to N/A.

The Data Collection Methods include:

1. **Paper (Traditional Monitoring):** Select this method if monitors will visit the sites to collect data.
2. **Electronic Data Capture (EDC):** Select this method if a Sponsor, CRO or other provider added to this plan is responsible for EDC management. ClearTrial will calculate associated direct labor fees and indirect costs based on the level of EDC proficiency.
3. **EDC-3rd Party:** Select this method only 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 providers added to this plan are responsible for EDC management. Use the Assignment Tab to include and assign individual tasks that have been excluded by default for EDC 3rd Party.
4. **Faxed CRFs:** Select this method if the Case Report Forms (CRFs) will be completed at the Investigator Site and faxed to the CRO, or to the location where data management is performed.
5. **Investigator Site Data Entry:** Select this method if data will be keyed into a data capture system or web-based system by someone at the site. (Note: This option is not the same as EDC and was formerly known as Remote Data Entry.)

EDC Maturity Level

If "Electronic Data Capture (EDC)" is selected as the data collection method, then the EDC Maturity Level field will become available. This field allows you to specify the level of EDC proficiency for a study.

The default value for this field is Stage 1 for "Electronic Data Capture (EDC)" and Stage 4 for "EDC- 3rd Party." Stage 1 represents the least level of proficiency and Stage 4 indicates expert level. Effort, costs, and study duration will be greater for lower levels of proficiency. Each option is explained below:

- **Stage 1: Pilot/Single Study:** Select Pilot/Single Study if 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 achievable for you.
- **Stage 2: Limited Standardization:** Select Limited Standardization if you have moved past piloting EDC and have recognized its potential value. Stage 2 is used to test EDC abilities to full scale and to assess its reliability. EDC deployment is typically expanded to other trial phases or different therapeutic areas during this stage.
- **Stage 3: Standardization:** Select Standardization if you have an established standardization for EDC on all new trials over all phases and therapeutic areas. Most clinical trials using paper are doing so only because they began prior to initial EDC implementation and are grandfathered until they conclude. There is a high level of integration between EDC and other systems such as CTMS, laboratory systems, project management systems, payment systems, and IVRS. During this stage, companies commit to a preferred EDC solution vendor and willingly entertain discussions about forming long-term partnerships with vendors.
- **Stage 4: Enterprise Deployment:** Select Enterprise Deployment if 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. All note taking is done directly in the system, and all signatures are done electronically. A small number of clinical trials, or certain portions of a trial, may still require the use of paper. EDC solutions found in Stage 4 provide hybrid paper/electronic features that support a limited number of paper records.

Query Rate

This field allows you to specify the average number of queries expected per every 100 pages of CRF data.

Percent of database data to audit

This field allows you to indicate what percent of the database information must be audited. The default value for this field is 10%, however, you may override this value.

Minutes for data entry per CRF page

This field displays the number of minutes required to enter one CRF into the database and assumes double data entry. This value is calculated based on the phase and therapeutic indication of the study. You can override this value.

Minutes for data coordination per CRF page

This field displays the number of minutes required to coordinate CRF data. This value is calculated based on the phase and therapeutic indication of the study. You can override this value.

Total number of data transfers

This field allows you to specify the number of data transfers expected. The vendor who manages the data will be required to transfer the data in electronic format to the Sponsor. If the Sponsor is performing data management, enter 0.

Number of interim analyses to be performed

This field allows you to specify the number of interim analyses to be performed. An interim analysis is a preliminary look at the study data to determine if there are large differences between treatment groups.

Number of third-party vendors/data sources

This field allows you to specify the number of third-party vendors or data sources used to capture study-related data.

Total number of data imports from third-party vendors

This field allows you to 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.

CRF Design

The Data Tab allows you to enter details about the Case Report Forms (CRFs).

Number of unique pages

This field allows you to enter the number of unique pages in the Case Report Form (CRF) that are not duplicates for another CRF page/screen.

CRF page NCR ply

This field allows you to specify the number of screens needed to capture one paper Case Report Form (CRF) page.

Number of screens per CRF Page

This field allows you to specify the number of screens needed to capture one paper Case Report Form (CRF) page when either Electronic Data Capture or EDC - 3rd Party is selected as the Data Collection Method.

Cost per page to print CRF

This field allows you to specify the cost to print a Case Report Form (CRF) page. The costs for printing a CRF page are dependent on the number of NCR plies of the CRF page and the binding method.

Biostatistics

The Data Tab allows you to enter specifics about data based on biostatistics for the study.

Number of unique data tables

This field allows you to enter the number of unique tables, based on biostatistics estimates in support of the study.

Number of unique data listings

This field allows you to enter the number of unique data listings, based on biostatistic estimates for the study.

Number of unique figures and graphs

This field allows you to enter the number of unique figures or graphs, based on biostatistics estimates for the study.

Project Management

The Data Tab allows you to enter specifics about project management.

Number of newsletters per site

This field allows to you indicate the number of newsletters expected per site.

Will there be an ICF Video/DVD?

This field allows you specify whether there will be an ICF Video.

Number of years to archive data

This field allows you specify the number of years the study data must be kept after completion of the study. After a study is concluded, the data are required to be archived for some period of time.

Number of online EDC training sessions

This field allows you to specify the number of online EDC training sessions that will be required, if you selected "Electronic Data Capture (EDC)" or "EDC - 3rd Party" as the data collection method.

Medical Writing / Timelines

The Data Tab allows you to specify details about medical writing and timelines.

Number of pages in the Investigator brochure

This field allows you to enter the number of pages expected to be in the Investigators Brochure (IB).

Number of manuscripts

This field allows you specify the number of manuscripts to be created.

Days from LSO/LPO until database lock

This field allows you to enter the number of elapsed days from last subject observation (LSO/LPO) until the expected database lock.

Days from database lock until statistical report is due

This field allows you to enter the number of elapsed days from the database lock date until the statistical report is expected to be delivered.

Days from database lock until draft report is due

This field allows you to enter the number of elapsed days from the database lock date until the draft clinical report is expected to be delivered.

Days from database lock until final report is due

This field allows you to 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 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 will be calculated based on the EDC maturity level.

SAE Management

The Data Tab allows you to specify information about SAE Management.

SAE rate as a percent of randomized subjects

This field allows you to indicate the number of anticipated Serious Adverse Events (SAEs) in terms of a percent of the total subject population.

Hours medical monitor will spend with each SAE

This field allows you specify the number of hours a medical monitor will spend with regard to each Serious Adverse Event (SAE).

Expected percent of SAE reports to be expedited

This field allows you to enter the expected percentage of SAE reports to be expedited to regulatory agencies and ethics committees.

Provide data to the DSMB

This field allows you indicate how often data will be reported to the Data Safety Monitory Board (DSMB).

IVRS (Interactive Voice Response System

The Data Tab allows you to enter specifics about how an IVRS will be used.

Responsibilities

The Responsibilities section includes radio buttons that allow you to indicate the outsourcing option for each group of assignable tasks. The outsourcing options include:

- **Sponsor:** Assigns all of the tasks in that group to the study sponsor.
- **Vendor:** Initially assigns all of the tasks in that group to the Primary Vendor specified on the Provider Tab.
- **Mixed:** Indicates that you would like to assign some of the tasks in that group to a vendor and other tasks in that group to the study sponsor; this can be done on the Assignment Tab.
- **N/A:** Indicates that none of the tasks in that group will be performed, if they are optional.

If you have selected "Conducted Internally" on the Overview Tab, you will not be able to assign any of the responsibilities to Vendor. Similarly, if you have selected "Outsourced" on the Overview Tab, you will not be able to assign any of the responsibilities to Sponsor.

If you determine that you want a combination of some responsibilities assigned to the Sponsor and some assigned to a Vendor, then change your selection on the Overview Tab to "Combination."

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Monitoring Tab

The Monitoring Tab is used to enter information about the expected monitoring frequency, approach, and to specify which responsibilities will be outsourced or conducted internally.

Monitoring Methods

The Monitoring Methods section allows you to indicate whether monitoring is done in-person and/or by phone, as well as how you want to manage the monitoring schedule values.

- **Monitoring will be performed:** This field allows you to specify whether monitoring will be done in-person or by phone or by a combination of these methods. Typically phone-based monitoring is done only for Phase IV studies or during long follow-up periods.
- **Manage monitoring schedule values:** This field allows you to specify whether monitoring schedule values are managed globally or per location. If monitoring schedules are managed globally, all of the assumptions entered on the Monitoring Tab are applied to all the plan locations in the study.

  If monitoring schedules are managed per location, schedules can be modified for each location within the study. The Edit Per Location Monitoring Schedule dialog box allows you to select each location and edit their monitoring schedule.

On-Site Monitoring Schedule

The On-site Monitoring Schedule section allows you to configure the schedule for on-site monitoring.

- **Monitor Every:** This value indicates how frequently a monitor visits the sites in the study during each period of the monitoring schedule.
- **Until LSO/LPO:** Selecting this radio button indicates that site monitoring continues at the specified frequency to the end of the treatment period.
- **Until week:** Selecting this radio button indicates that the monitoring frequency changes during the treatment period and a new frequency will be defined for the next or remaining period. This value represents the week number of the start of the next monitoring period and must be greater than or equal to the value for the monitoring frequency for the prior period.
- **Total number of on-site monitoring visits:** This value is derived from the total number of sites, monitoring frequency, and subject enrollment rate. You may

increase this number if you would like to add more monitoring visits. You may also wish to lower the total number of monitoring visits.

- **Monitoring Travel Strategy:** This field allows you to specify the travel strategy to be used for the majority of the monitoring trips. Spoke monitoring is when the monitors return to their home/office between each site visit. Loop monitoring is when monitors travel to site 1, then to site 2, then to site 3, etc. before returning to their home/office.

Monitoring Approach

The Monitoring Approach section allows you to indicate the amount of time monitors spend in the field, as well as which resources are responsible for monitoring.

- **Percentage of time Monitors spend in the field:** This field allows you to indicate the percentage of time monitors spend in the field. It is assumed that the remainder of their time is then spent on site management activities.
- **Percentage of monitoring done by CRAs (vs. Senior CRAs):** This field allows you to indicate the percentage of monitoring and site management that is done by Clinical Research Assistants (CRAs) versus Senior Clinical Research Assistants (SCRAs).
- **Percentage of monitoring done by Regional Monitors:** This field allows you to indicate the percentage of monitoring that is done by Regional Monitors. The remaining monitoring and site management activities is split between CRAs and Senior CRAs according to the value indicated in the field, "Percentage of monitoring done by CRAs (vs. Senior CRAs)."

> **Note:** The value in this field is not related to travel time or distance. This value is used to split the effort of monitoring and site management tasks across various resources who have different billing rates. Even when 100% of monitoring is done by RMs, some site management activities is still performed by CRAs or SCRAs.

- **Avg travel time (in hours) for site monitors:** This field allows you to enter the average number of hours a monitor needs to travel to sites.
- **Percent of source document verification:** This field allows you to specify the percent of key safety and efficacy data to be source verified while monitoring the data. Most studies require all of the key safety and efficacy data to be verified against the source. Some Phase III and Phase IV studies may not require this level of monitoring for study data.
- **Time to review queries from previous visit (minutes):** This is a calculated value representing the number of minutes required to review queries/CRF data from a previous monitoring visit based on the therapeutic area and indication selected for the study.
- **Manage location-specific values:** Upon clicking Edit Location specific overrides, you can enter monitoring approach assumptions per location. All location-specific values can be overridden from their global default value.

Monitored Data

The Monitoring Data section displays the total number of CRF pages that are generated, with and without subject drops.

- **Total CRF pages generated (without subject drops):** This value is the total number of predicted CRF pages generated, assuming that no subjects drop. It is a summation of all CRF pages entered for each subject visit across all subjects and sites, as defined on the subject treatment schedule.
- **Total CRF pages monitored (accounting for subject drops):** This value represents the predicted CRF pages that are monitored, accounting for any subjects that drop out of the study. This value is derived from the subject drop rate, which is applied to each week of the study in order to calculate the subject retention rate.

Medical Monitoring

The Medical Monitoring section allows you to estimate the number of full-time medical monitors that are needed.

- **Estimated number of FTE (full-time equivalent) Medical Monitors:** This field includes time for a Medical Monitor (MD) to serve as the team medical lead and provide support to the CRA monitoring staff as well as to the Investigators for issues beyond safety reporting.

Separate Drug Accountability

The Separate Drug Accountability section allows you to account for separate drug accountability visits.

- **Will there be additional drug accountability visits?** Allows you to indicate whether additional drug accountability visits are required.
- **Additional Drug Accountability visits performed by:** This field allows you to indicate who performs additional drug accountability visits (if applicable). 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/test article.
- **Additional Drug Accountability Visits Per Site:** This field allows you to indicate the number of additional drug accountability visits that are made per site. Separate drug accountability generally applies to oncology and some vaccine studies and is done by someone other than the CRA that monitors the site.

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Provider Tab

The Provider Tab allows you to add one or more vendors to the list of possible service providers for a plan. Adding providers to this list does not assign them to any tasks, but makes them available to do work within a plan. For information on maintaining service providers, see Section 23, "Maintaining Service Providers".

This tab allows you to designate the Primary Provider, to which outsourced tasks will be automatically assigned. These assignments can be changed using the Assignments Tab.

Provider Specific Details

This tab allows you to override default rates and responsibilities for service providers by clicking on the provider name from the list. The Provider Detail page dialog allows you to control provider assumptions, including:

- Rate Year in Effect
- Inflation Rates
- Project level discounts extended by this provider
- Back Office Billing Rate Location
- Currency Exchange Rates
- Project Management FTEs assigned by this provider
- Affiliates
- Meetings with this provider
- Who will manage the CTMS (Clinical Trial Management System) for the study

Working with Providers

The Provider Tab allows you to add and remove providers, as well as assign the primary provider and freeze billing rates.

Adding Providers

To add a provider:

1. Navigate to the Provider Tab.
2. Click the Add Provider(s) button to display the Choose Service Providers dialog box.

3. Select a provider.
4. Click OK.

   Selected providers are displayed on this screen and allow specification of investigator meeting attendance and other details. However, these providers and associated information will not become part of this plan until you have clicked Save or Next. Adding a provider to this screen does not automatically assign the provider to any tasks.

Removing Providers

To remove a provider:

1. Navigate to the Provider Tab.
2. Select a provider and click the Remove Provider button.
3. The provider is removed from the list. Providers selected are removed from the display, but they are not removed from the plan until you click Save or Next.
4. Click OK.

   Tasks that may have been previously assigned to a removed provider will be reassigned according to the following rule: If the task assignment has been made for subject data from a location whose assignments have been overridden, the task will be reassigned to the default provider for that location. Otherwise, the task will be reassigned to the provider specified as the primary provider.

Primary Providers

You can select a provider to be the default provider for tasks.

To select a primary provider:

1. Navigate to the Provider Tab.
2. Select a provider and click the Set as Primary Provider button.
3. The Primary Provider button will become grayed out.

   The primary provider is automatically assigned to tasks indicated as outsourced (by selecting the “Vendor” radio button for responsibilities on one or more of the other tabs). The primary provider also becomes assigned to any tasks assigned to a vendor who is later removed from the plan.

Replacing Providers

The Provider Tab allows you to replace providers with the Replace Provider button.

When you replace a provider, any resource, rate, or unit hours overrides, as well as provider-specific details, such as inflation, they are transferred to the newly chosen provider.

To replace a provider:

1. Navigate to the Provider Tab.
2. Select a provider and click the Replace Provider button. Choose a new provider and click OK. All of your current provider-level assumptions will be saved and the selected provider will be replaced with your new choice.

Freezing Billing Rates

The Provider Tab allows you to freeze billing rates for a selected provider.

To freeze billing rates:

1. Navigate to the Provider Tab.
2. Select one or more provider from the list and click the Freeze Billing Rates button.
3. The button will change to say “Unfreeze Billing Rates.”

   This button may read either “Freeze Billing Rates” or “Unfreeze Billing Rates” depending on whether rates are currently frozen for this plan.

   Clicking this button to freeze the rates for this plan copies the current rates for the current providers and stores them with this plan.

   Changes to these providers’ billing rates will no longer impact this plan. If additional providers are added, their current rates will also be copied to this plan.

   When the button reads “Unfreeze Billing Rates,” rates have been frozen for this plan; clicking the button in this case deletes the copied rates and uses the current rates for the providers to calculate costs for this plan. Changes to providers billing rates will be reflected in this plan.

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Translations Tab

The Translations Tab displays the languages into which it is likely that study documents will need to be translated and allows you to add or remove languages or dialects as needed.

This tab also allows you to designate exactly which study documents will need to be translated into the specified languages. ClearTrial calculates the suggested languages based on the locations specified.

Adding Languages

To add a language:

1. Navigate to the Translations Tab.
2. Click the Add Language button.
3. Select a language from the list and click OK. The language is added to list of languages that study documents will need to be translated.

   Once the language is added to the list, use the Translations field to enter the number of dialects into which study documents will be need to be translated.
4. Next, after a language is added, you need to select the document type that needs to be translated, as well as if it needs to be back-translated and if it will be accounted for as a pass-through cost.

   Select a language from the list and check the box next to each type of document that needs to be translated. Next, indicate if the translation will need to be translated back and if the translation will be accounted for as a pass-through cost.
5. Click Save.

Removing Languages

To remove a language:

1. Navigate to the Translations Tab.
2. Select one or more languages to delete and click the Remove Language button.
3. Click Save.

Document Translations

The Translations Tab allows you to specify the types of documents that need to be translated, as well as if they need to be back translated and if they need to be treated as

a pass-through cost. Select the checkboxes next to the document types that are going to be translated.

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Meetings Tab

The Meetings Tab allows you to plan and track meetings in order to account for their associated costs.

On this tab, you have the ability to add and edit meetings, such as Kick-off, Internal Team, Face-to-Face, Status Update to Sponsor, End of Study, and Investigator Meetings. You can specify meeting details, attendees and notes for each meeting.

Meetings

The Meetings section is used to add, edit, copy, delete, and include and exclude meetings with the Meetings Details dialog.

Adding Meetings

Meetings are added with the Add button that launches the Meeting Details dialog.

To add a meeting:

1. Navigate to the Meetings Tab.
2. Click the Add button to launch the Edit Meetings Details dialog, which displays the Meetings Detail, Attendees, Site Attendees, and Notes Tabs. Each tab allows you to specify information about your meeting.
   - **Meeting Details:** The Meeting Details Tab is used to specify the meeting name, schedule, and Providers attending. For meetings that include Investigator Site Personnel, you can specify the number of sites attending from each location.
   - **Attendees:** The Attendees Tab allows you to specify the number of resources, hours, and costs associated with meeting participants from each provider.
   - **Site Attendees:** The Site Attendees Tab allows you to add attendees from investigator sites to the meeting. This tab is used to identify the number of attendees per site, as well as their method of travel and indirect costs.
   - **Notes:** This Tab allows you to enter notes pertaining to the meeting. The notes can be viewed and edited by anyone who has permission to work with this plan.
3. Input your assumptions on each tab and click Save to add the meeting.

Editing Meetings

To edit a meeting:

1. Navigate to the Meetings Tab.
2. Select a meeting and click the Edit button, which displays the Meetings Detail, Attendees, Site Attendees, and Notes Tabs. Each tab allows you to specify information about your meeting.
3. Edit the meeting information as needed and click Save.

Copying Meetings

To copy meetings:

1. Navigate to the Meetings Tab.
2. Select a meeting and click the Copy button.
3. The Meeting Details Dialog is displayed. Make edits as needed and click Save.

Including and Excluding Meetings

Meetings can be included or excluded from a plan with the Include and Exclude buttons. Excluding a meeting will not delete it, but the costs associated with it will not be calculated with the rest of the plan costs.

To include and exclude meetings:

1. Navigate to the Meetings Tab.
2. Select a meeting and click the Exclude button to remove the meeting from plan costs. If you need to include a meeting, select it and click the Include button.
3. Click Save.

Deleting Meetings

To delete a meeting:

1. Navigate to the Meetings Tab.
2. Select a meeting and click the Delete button to remove the meeting from the list.
3. Click Save.

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Assignment Tab

The Assignment Tab is used to assign a service provider and billing rate location to outsourced tasks in a plan.

Task Assignments

This section allows you to assign locations and responsibilities to specific service providers. If all outsourced tasks in your plan are performed by a single provider, select that provider for the "Default service provider for outsourced tasks" field and click Save or Next to continue to the next tab.

For each task performed by a different provider, depending on location, select the location in the "Values apply to" drop-down menu and assign the appropriate provider to the tasks in that location.

If outsourced tasks in your plan are performed by various providers in the study, then follow the steps below.

Assigning Outsourced Tasks

Outsourced tasks can be assigned to various providers on the Assignment Tab.

To assign outsourced tasks to various providers:

1. Choose your primary provider who performs most of the outsourced work in the "Default service provider for outsourced tasks" drop-down and click Save.
2. Click the Show Tasks link and assign tasks to the appropriate non-primary providers as necessary.
3. Choose the appropriate location in the "Values apply to" drop-down and assign Service Provider location dependent tasks. You can also specify a different billing rate location for each task group or task.

Including and Excluding Tasks

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 (grayed out).

You can save the Service Provider and billing rate location assignments for any task by clicking the pin icon. Pinning allows you to protect and ensure that your current assignments for each task will not be lost due to other changes. For example, changes made to the group of tasks such as task groups in the Assignment Tab will override

the assignments made for individual tasks included in the group, if the latter changes are not pinned.

If an assigned provider has been deleted from the plan, then the task assignment will be changed to the primary provider in the plan. Any changes to tasks are pinned by default.

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Labor Tab

The Labor Tab is used to view and adjust the calculated labor unit costs or unit hours for each major task, or unit, for each service provider. This tab can be used to align your plan with the study's contract, bid, and internal tasks and costs.

This tab also allows you to launch Task Manager, where you can add and/or edit major tasks, tasks, resources, assign project tasks to specific service providers and billing rate locations, and override unit hours and the billing rate of a specific resource.

Adjusting Unit Hours and Fees

The Labor Tab allows you to adjust unit hours and fees for ClearTrial defined major tasks with the Adjust Hours or Fees button.

The Adjust Hours or Fees button displays a dialog screen for the selected major task and service provider, if you are a Standard Edition user. Enterprise Edition users can adjust hours and fees within Task Manager by selecting the Adjust Hours or Fees button or launching Task Manager.

To adjust hours or fees for a major task:

1. Navigate to the Labor Tab.
2. Select a major task and click the Adjust Hours or Fees button to display the dialog screen.

   If you are a Standard Edition user, the Adjust Hours or Fees dialog is displayed. If you are an Enterprise Edition user, the Major Task Adjustments Tab in Task Manager is displayed.
3. Within the Adjust Hours or Fees dialog, in the Hours row, enter either a value in hours in the Per Unit field or a percent adjustment in the% Adjustment field. In the fees row, enter either a value in hours in the Per Unit field or a percent adjustment in the% Adjustment field. Adjust each location as needed.
4. In the Major Task Adjustments Tab, within Task Manager, select the arrow for a location that needs to be adjusted. Clicking the arrow allows you to modify the number of units, unit hours, and unit costs for that major task. Adjust each location as needed.

   Next, navigate to the Major Task Distribution Tab to modify the distribution method for the Service Provider completing work on the assigned major task.
5. Click Save.

Bulk Pinning Labor for Major Tasks

The Labor Tab allows you to pin, or save, all major task adjustment values for a major task by selecting the Pin Labor link above the major task list. The Pin Labor link allows you to bulk pin labor for all of the major tasks in a plan.

Pinning Labor for Major Tasks

Bulk pinning major task adjustments for major tasks in a plan ensures the values will be protected from inheriting edits made in the plan. Pinning guarantees the adjusted values remain aligned with the study contract, bid, or internal tasks.

To bulk pin labor major tasks in a plan:

1. Navigate to the Labor Tab.
2. Click the "Pin Labor" link. Click OK to confirm you wish to pin all labor units, costs, hours, and distributions.

Unpinning Labor for Major Tasks

The Labor Tab allows you to unpin all major task adjustment values by selecting the Unpin Labor link above the major task list. When labor is unpinned, the major task adjustments will be recalculated to reflect the plan's original major task number of units, unit hours, unit cost, and distribution.

To unpin labor for a major task:

1. Navigate to the Labor Tab.
2. Click the "Unpin Labor" link. Click OK to confirm you wish to unpin all labor units, costs, hours, and distributions.

Task Manager

To increase control over budgeting capabilities, user-defined major tasks and tasks can be created using Task Manager on the Labor Tab. The Labor Tab is used to view and adjust the calculated labor unit fees or unit hours for each major task, or unit, for each service provider.

Task Manager allows you to add and edit major tasks, tasks, resources, assign project tasks to specific service providers and billing rate locations, and override unit hours and the billing rate of a specific resource.

Definition of a Major Task

In ClearTrial, a major task is a collection of related tasks that share the same unit of measure, labor scope, and expected distribution of units completed. Major tasks have three basic attributes:

- **Labor Distribution:** Labor Distribution of a major task determines whether its associated tasks are expected to be performed in a centralized location or multiple locations at which sites and subjects are found.
- **Cost Allocations:** Cost allocations allow you to spread costs evenly between two milestones or distribute the labor costs by a curve, such as subject enrollment.
- **Unit of Measure (Unit of Work):** The unit of measure is calculated in terms of hours required to complete one unit of the major task.

Roles

To work with Task Manager, you must have either the WBS Editor or WBS Manager additional roles/capabilities assigned. Users without these roles cannot create user-defined major tasks. These are additional roles that can be granted by your System Administrator.

Searching for Major Tasks

A search box appears above the navigation panel and allows locating a major task or task quickly. Type one or more characters into the field and either click the icon or press the "Enter" key. The screen displays the total number of matches found for the keyword. The matches are highlighted and you can navigate through the list of occurrences by clicking on the "previous" or "next" links.

Task Manager Tabs

Within Task Manager, there are three tabs that are used for creating new major tasks and editing major tasks.

- **Major Task Details Tab:** This tab is used to define the basic attributes of a major task. When a new major task is created, you must specify the name, unit of measure, labor scope, and units distribution.
- **Major Task Adjustments Tab:** This tab allows you to edit the number of units, unit hours and unit costs for a specific major task.

  The major task unit adjustment capability is available for all system defined and user-defined major tasks, except for the Site Approved, Subject/Volunteer Randomized, and Monitored Clean CRF Pages Major Tasks. These major tasks can be aligned to your study's contract, bid, and internal tasks and costs by adjusting the unit hours and unit costs by location and by provider.
- **Major Task Distribution Tab:** This tab allows you to edit the distribution method for the Service Provider completing work on the assigned major task.

  The major task distribution adjustment capability is available for all system defined and user-defined major tasks, except for the Site Approved, Subject/Volunteer Randomized, and Monitored Clean CRF Pages Major Tasks. These major tasks are limited to distribution adjustments at a by location level only.

Location-Scoped vs. Study-Scoped Tasks

Location-scoped tasks can be assigned to different service providers in different locations. 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. Study-scoped tasks can only be assigned to one service provider.

For a location-scoped task, you can create different algorithms to determine the level of effort required to complete the task in that location. 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.

Working with User-Defined Major Tasks

Task Manager allows you to edit and create user-defined major tasks.

Creating User-Defined Major Tasks

Creating user-defined major tasks involves specifying attributes for a major task and then assigning tasks beneath it to complete the work. The tasks have service provider(s) and billing rate location(s) assigned to them, as well as resources that are expected to complete the work.

When user-defined major tasks are added, they appear beneath the ClearTrial defined major tasks on the Labor Tab in the order they were created. They are also listed on the Payments Tab and on all pertinent reports.

To create a user-defined major task:

1. Navigate to the Labor Tab.
2. Click the New Major Task button to display the Task Manager. The Major Task Details, Adjustments, and Distribution Tabs are shown.

   On the Major Task Details Tab, enter a name and description. Specify if the labor is going to be varied by location or centralized. ClearTrial considers tasks as being location-scoped or study-scoped; see "Location-Scoped vs. Study-Scoped Tasks" for more information. Select a Unit of Measure from the drop-down menu.

   Note: Consult with your Clinical Services Manager if the Unit of Measure is not applicable to your major task.

3. Click Save.

   Now that your major task has been defined and created, you can begin assigning tasks by selecting the New Task button. You can search for major tasks and tasks with the navigation panel in Task Manager. See Searching for Major Tasks for more information.
4. Next, go to the Major Task Adjustments Tab to adjust the number of units, unit hours, and unit costs for providers assigned to this major task.
5. Navigate to the Distribution Tab to edit the distribution method for the Service Provider completing work on the assigned major task.
6. Click Save.

Editing User-Defined Major Tasks

User-defined major tasks be edited with the Task Manager.

To edit a user-defined major task:

1. Navigate to the Labor Tab.
2. Select the major task you want to edit and click the Edit Major Task button.
3. Make your changes and click Save.

Deleting User-Defined Major Tasks

Major tasks created by users can be deleted with the Task Manager (ClearTrial defined major tasks cannot be deleted).

To delete a user-defined major task:

1. Navigate to the Labor Tab.
2. Select the Major Task you want to delete and click the Delete Major Task button.

Working with Tasks

User-defined major tasks and ClearTrial defined major tasks can have tasks added beneath them in order to assign work to be completed. Tasks can be modified and deleted from Task Manager on the Labor Tab.

Creating Tasks

To create a task:

1. Navigate to the Labor Tab.
2. Select the major task for which you want to add a new task and click the Edit Major Task button to launch the Task Manager.
3. On the Major Task Details Tab, click the New Task button to display the Task Details and Task Assignments Tabs. Enter the task name, code, and description. Specify the Assignment Group and the Summary Category that the task belongs to from the drop-down menus.

   Assignment Groups are represented by radio-button choices in the Responsibilities section of various tabs throughout the plan and as drop-down lists in the Assignment Tab. You can determine whether a task is performed by the sponsor or an external vendor (CRO) (or is not performed at all for this trial) by choosing the appropriate radio-button for its assignment group.

   You can also manage the assignments of each specific task on the Task Assignments Tab in the Task Manager or in the Assignment Tab.
4. Click Save and go to the Task Assignments Tab to assign the task to a service provider and billing rate location.
5. After you enter information for the task, you can add resources by selecting the Add Resource button to display a list of resources. To add one, click the check-box and click OK.

Deleting Tasks

Tasks that have been assigned to major tasks can be deleted with from the Task Manager.

To delete a task:

1. Navigate to the Labor Tab.
2. Select a major task to edit and click the Edit Major Task button to launch the Task Manager.
3. Select a task and click the Delete Task button.

Editing Tasks

You can edit task descriptions and assign resources with the Task Manager. You can also adjust the default billing rate for resources performing the task.

To edit a task:

1. Navigate to the Labor Tab.
2. Select a major task to edit and click the Edit Major Task button.
3. Select a task and click the Edit Task button.
4. Make your changes and click Save.

   Task Manager allows you to only edit task descriptions for user-defined tasks and major tasks.

To modify task descriptions:

1. Navigate to the Labor Tab.
2. Select a major task to edit and click the Edit Major Task button. Tasks for this major task are listed on the Major Task Details Tab.
3. Select a task and click the Edit Task button to view the Task Details Tab. From this tab, you can edit the task description.

Pinning Service Provider and Billing Rate Location Assignments

While working with the Task Assignments Tab in Task Manager, you can save the service provider and billing rate location assignments for tasks by clicking the pin icon. Pinning allows you to protect and ensure that your current task assignments will not be lost due to other changes.

For example, changes made to the group of tasks, such as assignment groups on the Assignment Tab, will override the assignments made for individual tasks included in the group if the latter changes are not pinned. Any changes made to tasks are "pinned" by default.

The order of precedence for pinning is as follows:

1. Assignments made at the task-resource level.
2. Assignments made at the task level.
3. Assignments made at the Assignment group level.
4. Location assignments made at the plan level.
5. All location assignments made at the plan level.

Working with Resources

In Task Manager, resources are assigned to tasks to allocate work to be completed. Resources can be added to tasks that are assigned to user-defined major tasks or ClearTrial defined major tasks.

Add a Resource to a Task

Resources can be assigned to tasks in the Task Manager. You can also specify resource details, algorithms, unit hours and billing rate locations for resources.

To add a resource:

1. Navigate to the Labor Tab.
2. Select the Major Task and click the Edit Major Task button.

3. On the Major Task Details Tab, click the Edit Task button to view the Task Details and Task Assignments Tabs. In the Task Details Tab, click the Add Resource button and select a resource. Click OK.
4. Click Save. Select the resource and click the Edit Resource button to view the resource tabs. For more information about the functions of each tab, see Resource Tabs below.
5. Modify the resource on each tab as needed and Click Save.

Resource Tabs

When adding resources to tasks in Task Manager, you can specify information about each resource with the tabs described below.

- **Resource Details:** Select a department name from the drop-down menu. The department is the name of the department to which this resource belongs when performing this task.

  Note: If the Major Task you are editing is ClearTrial defined, you will not be able to select a department.

- **Algorithm:** Specify the cost driver and the level-of-effort in hours for the selected resource to produce one unit of the particular work product (major task unit-of-measure). You can only define algorithms for resources you add. System-defined algorithms cannot be depicted.
- **Billing Rate Location:** Assign the billing rate location for the selected resource. You may select any location where this activity or activities will be conducted. It is not necessary for the location to have active sites participating in the study.
- **Rates & Substitutions (Billing Rates Overrides Tab):** Override billing rates for the selected resource when performing a specified task. If the task is location scoped, you can override the rate for each location. Each row displays the hourly billing rate for the selected resource based on the applicable billing rate location, which may differ from the location listed. You can also substitute resources on this tab.
- **Unit Hours:** Observe and/or override system-calculated unit hours for the selected resource. For location-scoped tasks, you can override the unit hours expected for each location.

Delete a Resource from a Task

Resources that have been assigned to tasks can be deleted by using the Edit Task button.

To delete a resource:

1. Navigate to the Labor Tab.
2. Select a Major Task and click the Edit Major Task button.
3. Select the task with the resource assigned to it that needs to be deleted and click the Edit Task button.
4. Click the resource you need to delete and click the Delete Resource button.

Edit a Resource for a Task

Resources that have been assigned to tasks can be edited using Task Manager. You can modify billing rates, billing rate locations, and substitute resources at the task level.

Modify the Billing Rate of a Resource

To modify the billing rate of a resource:

1. Navigate to the Labor Tab.
2. Select a major task to edit, and click the Edit Major Task button.
3. Select a task to modify the billing rate of its resource and click the Edit Task button. Click the resource you want to edit and select the Edit Resource button. Navigate to the Rates & Substitutions Tab.
4. On the Rates & Substitutions Tab, you can use the Rate and% Adjust columns to modify the billing rate for the resource. You can edit the predefined ClearTrial numbers by entering your own information into these columns. When finished, click Save.

Modify the Billing Rate Location of a Resource

To modify the billing rate location of a resource:

1. Navigate to the Labor Tab.
2. Select a major task to edit, and click the Edit Major Task button.
3. Select a task to modify the billing rate location of its resource and click the Edit Task button. Click the resource you want to edit and select the Edit Resource button. Navigate to the Billing Rate Location Tab.
4. On the Billing Rate Location Tab, you can override the billing rate location by selecting different locations from the drop down menu. In order to save your overrides, you can click the pin icon in the pinned column. This column displays an icon that you can click to protect, or "pin", your current settings for this resource for this task.
5. When the icon is blue, the billing rate location is pinned, and changes made at more general levels will not affect that value. For example, 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.

   Note: Your pinned settings will be lost if the associated locations and/or service providers are removed from the plan. However, if you replace a provider, your pinned settings are maintained and transferred to the replacement.

6. Click Save.

Substitute a Resource

To substitute a resource:

1. Navigate to the Labor Tab.
2. Select a major task to edit and click the Edit Major Task button.

3. Select the task with the resource that needs to be substituted and click the Edit Task button. Highlight the resource to edit and click the Edit Resource button. Navigate to the Rates & Substitutions Tab.
4. On the Rates & Substitutions Tab, you can substitute resources with the Substitute column. This column allows you to select a different resource to perform this task in the listed location. By default, the billing rate used will be the effective billing rate (which may have been overridden at the plan level or plan-location level) of the selected resource.
5. 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 specified in that context as the rate for the selected resource when performing the work of the originally expected resource.
6. Click Save.

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Costs Tab

The Costs Tab allows you to edit cost details and create user-defined costs for studies. You can also include and exclude costs for a plan.

The Costs Tab displays a list of pass-through and cost categories that can be adjusted based on your plan assumptions. Some of these costs are pre-calculated, while the rest are assumed study costs that cannot be derived from study characteristics or your assumptions.

Including and Excluding Costs

The Costs Tab allows you to include and exclude costs from a study. To exclude a cost, select one or more costs and click the Exclude Cost(s) button.

Excluded costs are not deleted, but their amounts are not included in the plan totals. Excluded costs can be restored by selecting the checkbox to left of each excluded cost and clicking the Include Cost(s) button.

Inflation

The Costs Tab allows you to include or exclude inflation for selected pass-through and miscellaneous costs across the length of the trial on all reports that display the cost. You can choose to exclude inflation by clicking on the Edit Cost button and uncheck the inflation checkbox.

Working with Costs

Costs can be created and edited on the Costs Tab.

Adding New Costs

To add a new cost:

1. Navigate to the Costs Tab.
2. Click the New Cost button. On the Definition Tab, enter a cost name and select the cost type, pass-through or miscellaneous. Select a Department and GL Code for the cost. Determine if you want to include inflation, include this cost in the payment schedule, and/or include it in the Resources by Department Report. You can also treat the cost as a credit. Click Save.
3. Navigate to the Algorithm Tab. Indicate if this cost varies by location or at the study level. If the cost varies by location, use the “Calculate as” field to specify a

per unit cost. This value will be the default for each location if you have chosen to vary this cost by location.

The total value for each location, or the study-level cost, is calculated as this value multiplied by the number of units expected for the chosen assumption.

Next, specify the currency in which you have expressed a per unit amount. Editing this field will not convert a previously entered value. It is assumed the value you have entered is expressed in the chosen currency.

When the currency is edited, the change is applied to the location-specific costs unless those costs have been overridden to vary from the amount and currency entered in this section.

Then, select a unit-based assumption by which to drive the calculation of this cost. The number of units derived for the chosen assumption is multiplied by the amount entered to produce the total cost. Changes to assumptions that result in an increase or decrease in the number of units for the chosen assumption are adjusted for this cost.

Click Save.

4. The Distribution Tab allows you to determine how costs will be distributed for each location in your plan with the "Distribute according to:" field. The options for cost distribution include:
   - Spread costs according to one of the pre-defined schedules: Site Approval Distribution, Subject Enrollment Distribution, or CRF Data Distribution.
   - 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, will be modified accordingly.
   - Spread costs according to a custom distribution where you can enter an absolute value per period between available milestones and an optional off-set. Custom Distribution timeline period, or intervals, include: week, month, and quarter.
5. Click Save.

Editing Costs

To edit a cost:

1. Navigate to the Costs Tab.
2. Select a cost and click the Edit button.
3. Make changes as needed and save.

Deleting Costs

To delete a cost:

1. Navigate to the Costs Tab.
2. Select one or more costs and click the Delete button.

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Payments Tab

The Payments Tab is used to configure the payment schedule for each provider performing work. This payment schedule drives the Cash Flow report on the Reports Tab. The payment schedule can be used in conjunction with the Cash Flow Chart report to determine the cash flow characteristics of the payment plan.

Payments are defined as percentage values representing the portion of the total fees that will be paid or received at the completion of each milestone. If some of the fees will be paid on a recurring schedule and not based on a milestone achievement, you can specify these by clicking the “Edit Recurring Payments” button.

Creating a Milestone Payment Schedule

If payments will be paid in response to events or conditions not currently defined, you may add milestones. Defining the frequency as “Milestone” indicates that the fees associated with that item are included in payments made in response to the occurrence of one or more milestones.

Specifying Recurring Payment Items

The Payments Tab allows you to specify terms for recurring payments, tasks, that are not based on milestone achievements. For information on how to edit these payments, see Section , "Editing Payment Schedules".

Setting Payment Terms

The Payments Tab allows you to set payment terms for each provider in your study. The Payment Terms screen provides options for each provider to specify the number of days from invoice to payment expected.

To set payment terms:

1. Navigate to the Payments Tab.
2. Click the Set Payment Terms button to display the Payment Terms dialog box, which allows you to specify the payment terms negotiated between the sponsor and each provider performing work.
3. For each provider, choose the closest available option to define the number of days from the time an invoice is received to the time the payment should be received, with the drop-down menu. These terms are considered when plotting the cash flow characteristics of the payment schedule. The terms identified are only applied to the provider listed in the provider column.
4. Click OK.

Editing Payment Schedules

Recurring payments can be edited with the Recurring Payments button, which allows you to specify which items' fees are paid at regular intervals instead of as per the milestone payment schedule. For each item whose fees are to be paid on a recurring basis, you may define the frequency at which these payments will be made or received. You may also indicate whether payments are expected in advance of the period for which the fees apply or only after the period has ended.

To edit recurring payments:

1. Navigate to the Payments Tab.
2. Click the Edit Recurring Payments button to display the Recurring Payments dialog box. This screen lists all of the major tasks, or specially marked pass-through costs, that can be configured as a recurring milestone or payment. To configure them, define the frequency of payments for each item with the drop-down menus.

Adding Milestones

The Provider Tab allows you to add user-defined milestones with the Add Milestone button. User-defined Milestones are listed on the Provider Tab in the Milestone column and can have their payment schedules adjusted.

To add user-defined milestones:

1. Navigate to the Payments Tab.
2. Click the Add Milestone button to display the Create Milestone dialog box.
3. Enter a name for the milestone. Next, select the system-defined milestone before or after which this milestone is expected to occur from the drop-down menu. The calculated date for this milestone will be the number of days specified prior or subsequent to the system-defined milestone selected.

   In the Code field, enter a short 3-6 character abbreviation for this milestone. This value is used to display the milestone on reports where the full name will not fit or display properly. The Description field allows you to enter any additional information to help describe this milestone or its purpose for this plan.
4. Click OK.

Deleting User-Defined Milestones

To delete user-defined milestones:

1. Navigate to the Payments Tab.
2. Select the user-defined milestone to be deleted and click the Delete Milestone button to remove the milestone from the list.

   Note: Only user-defined milestones can be removed. If you do not intend to make a payment at a system-defined milestone, define the percentage as zero.
3. Click OK.

Editing User-Defined Milestones

To edit user-defined milestones:

1. Navigate to the Payments Tab.
2. Select the user-defined milestone to be edited and select the Edit Milestone button to display the Edit Milestone dialog box. You can edit a previously added milestone to change its name and/or the properties which determine when it is expected to occur.
3. Click OK.

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Summary Tab

The Summary Tab provides an overview of study costs. You can view costs based on individual or all Service Providers, by selecting which ones you want to include above the list of costs.

All fees and costs are displayed in the modeling currency. These values are calculated by converting from each provider's billing rate currency to the modeling currency, using the exchange rates specified on the Plan Overview Tab (or any overrides specified at the Provider level).

Fee Descriptions

Below is a description of the fees included on the Summary Tab.

Fees, Hours, and FTEs

- **Startup Fees:** This value represents all fees, hours, and FTEs associated with study start-up. It includes all fees associated with the start up of the study from Project Activity Start Date to the First subject enrolled (FSFV).
- **Clinical Monitoring Closeout and Site Audit Fees:** This value represents all fees associated with the site monitoring, site management, telephone monitoring, query resolution, SAE management, site close outs and clinical compliance audits.
- **Data Management:** This value represents all fees associated with the database design, data entry data coordination, cleaning the data, database audits and the annual IND update.
- **Biostatistics:** This value represents all fees associated with Table listings and graphs, randomization procedures, stat and analysis plan, and the interim analysis.
- **Project Management / Study Oversight:** This value represents all fees associated with the project management of the study from beginning to end.
- **Medical Writing / Final Report:** This value represents all fees associated with delivering the stat report, draft report, and final report (CSR).
- **Other:** This value represents all fees associated with other tasks not included any other line item.
- **Total Fees:** Total of all Fees associated with the study.
- **Total Pass-Through Costs:** All third-party, pass-through, and miscellaneous costs in the study.

- **Total Study Costs:** These are a combination of all vendor fees, pass through costs, and Sponsor internal costs.

Dates / Duration

- **Project Activity Start Date:** This is the date that the study is expected to begin, defined as the date that vendors and/or the sponsor start identifying sites and any vendors start billable activity on the study.
- **Study End Date:** This is the date by which the study is expected to be complete, defined as the date that all activity stops (usually the date the final report (CSR) is finalized). This does not include any post study follow-up by the sponsor.
- **Total Study Duration:** This value represents the total expected study duration (in elapsed days), defined as the end date minus the start date.
- **Duration of Active Treatment Phase:** This value 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).

Metrics

- **Cost per Completed Subject:** This value represents the expected cost per each completed subject. This is calculated as the total study costs divided by the number of subjects expected to complete all scheduled subject visits.
- **Number of Subjects/Site/Month:** This 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.

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Reports Tab

The Reports Tab provides links to several reports based on data from the current plan you are working on.

Each report can be printed and converted to Adobe Portable Document Format (PDF). Reports can also be exported to Microsoft Excel and CSV file formats. There are three types of reports in ClearTrial: Clinical Indicator Reports, Costs Reports, and FTE/Resources Reports.

Clinical Indicator Reports

- **Assumptions:** Clinical assumptions based on the data entered in each page. This is your scope of work, and follows the flow of how you input the data into the system via the tabs.
- **Currency Exchange Rates:** Currency exchange rates based on data entry.
- **Responsibilities:** Responsibilities for tasks, based on the data entered. Driven by the assignments on the Overview and Assignments Tabs.
- **Site Approval Schedule - Cumulative:** Cumulative site approval curve for the entire study, by week.
- **Site Approval Schedule by Location:** Site approval curve by week for each location in the study.
- **On-Site Monitoring Schedule - Total Hours:** Total hours for all on-site monitoring visits for the entire study.
- **On-Site Monitoring Schedule by Location:** Average hours per on-site monitoring visit for each location in the study.
- **CRF Pages - Cumulative:** Cumulative CRF pages generated per week for each location in the study.
- **CRF Pages by Location:** CRF pages generated per week for each location in the study.
- **Subject Enrollment - Cumulative:** Cumulative subject enrollment per week.
- **Subject Enrollment by Location:** Subject enrollment per week by location for each location in the study.
- **Metrics:** Shows various performance and cost metrics.
- **Milestone Dates:** Critical dates in the study. Used in the RFP process, it is in the typical format of CRO Bid proposals.

- **Milestone Timeline Chart:** Graphically represents the entire plan and identifies crucial milestones.

Cost Reports

- **Plan Summary:** A printable view of the Summary Tab with a roll-up of costs by major functional area. You can show all costs or just vendor costs you want to see. If you have not entered Sponsor billing rates, you will just see hours and resources, but not costs.
- **Fees by Major Task:** A breakdown of fees associated with the study, sorted by major task (such as Site Initiation or Medical Monitoring). Unit costs are not included on this report. Use the Fixed Unit Prices report for unit costs. Use this report as a high level RFP review.
- **Fixed Unit Prices:** A breakdown of study Fixed Unit Prices. The report can displayed by summary or detail, and by provider or department.
- **Pass-Through and 3rd Party Costs:** All study pass-through and 3rd party costs. View is customizable by summary and detail, or by provider.
- **Monthly Budget:** A detailed monthly budget report. View is customizable by provider and other details, such as inflation.
- **Monthly Budget by Reporting Region:** A summary of the study costs by month over the duration of the study, categorized up by reporting region.
- **Labor Adjustments:** Breakdown of unit level adjustments by Major Task.
- **Cash Flow:** This report displays the planned value (PV) versus payments.
- **Milestone Payment Schedule:** A schedule of payments at each milestone.
- **Meetings Report:** A breakdown of costs and hours associated with meetings.
- **Bid Grid:** This report shows a plan-specific bid grid of labor fees and costs for a selected service provider.

FTE / Resource Reports

- **Resource / FTE Demand Summary:** A breakdown of hours, fees, and FTEs by specific resources involved in the study.
- **Resources by Major Task:** A detailed view of resource unit hours and other information by Major Task. View is customizable by provider, location, and other details.
- **Resources by Department:** Resource usage by department. View is customizable by provider, location, and other details. In addition, this report displays overrides at the task-resource level. It shows the ClearTrial default calculated values vs. the overridden values with the variance at the task-resource level.
- **Resources by GL Code:** This report shows the resource effort for each area of work grouped by GL Code.
- **Resource Demand by Date:** Details of resource usage over time. View is customizable by provider, time line (quarterly or monthly view), hours, costs, and Major Tasks.
- **Resource Demand Chart:** Demand for each resource over time. You can run the report by hours or FTE.
- **Billing Rates by Resource Name:** Billing rates listed for a Service Provider.

Part III

Maintenance Outside of ClearTrial Plans

In addition to maintaining plans, studies, and products in ClearTrial, there are several items that are managed outside of individual plans for use in all plans. These items include service providers, resources, billing rates, departments, GL codes, exchange rates, and reporting regions.

Part III provides information on working with items outside of plans.

Part III contains the following chapters:

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Maintaining Service Providers

ClearTrial allows you to add, select, edit, and delete service providers that can be included in a plan with the Service Provider List Screen. For information on how to add service providers to a study, see Chapter 14, "Provider Tab".

Supported Providers

Sponsor and Contract Research Organizations (CRO) are the only types of providers currently supported. The types of CROs ClearTrial supports include:

- **Premium:** Global presence in all major regions. Studies can be fully outsourced to them; more expensive than other leading CROs.
- **Major:** Global presence, in all major regions. Studies can be fully outsourced to them.
- **Medium:** Incomplete global presence. Studies can be fully outsourced to them, but they may have to sub-contract some of the work.
- **Niche:** Typically operates in only one country or region and often only offers a subset of services.

Working with Service Providers

Select service providers from the Maintain drop-down menu to display the Service Providers List Screen. This screen allows you to add, edit, delete, and restore service providers.

Roles

To work with service providers, you must have either the Clinical Administrator or System Administrator Role. Users without these roles cannot edit or delete service providers. These are additional roles that can be granted by your System Administrator.

Adding Service Providers

The Service Providers List Screen allows you to add service providers with the New button.

To add a service provider:

1. Navigate to the Service Providers List Screen.
2. Click the New button. Enter the provider name, description, and identify the provider type.

The Billing Rates Currency field allows you to select the currency of the billing rates associated with this service provider. All billing rates used for this provider must be expressed in this currency.

The Back-Office Billing Rate Location field determines the default billing rates for tasks which are typically centralized or conducted at a central location, such as Protocol Preparation and Data Management. Choose the country from the list in which these tasks usually occur for this service provider.

For example, if this service provider is headquartered in the USA but conducts all of its Data Management, Biostatistics, and Medical Writing tasks in India, then choose India for the default Back Office Billing Rate Location.

Note: You can override the default Back-Office Billing Rate Location for any specific task on the Assignment Tab when you create or edit a plan.

3. Click Save. Next, enter billing rates for this service provider by clicking the "Update Billing Rates" link to view the Create Billing Rates Screen.

   Enter rates for each resource. Click Save to preserve the values in a draft state or click Publish to make the rates available for use in plans. Publishing rates will make them active rates that can be used by ClearTrial to calculate fees and costs associated with tasks assigned to the chosen vendor.

   For guidance on working with billing rates, see Billing Rates.

Editing Service Providers

Service providers, without assigned billing rates, can be edited on the Service Providers List Screen with the Edit button.

To edit a service provider:

1. Navigate to the Service Providers List Screen.
2. Choose a service provider and click the Edit button. Make changes as needed and update the billing rates.
3. Click Save.

Delete and Restore Service Providers

To delete and restore a service provider:

1. Navigate to the Service Providers List Screen.
2. Select one or more service providers and click the Delete button to remove them from the list.
3. To restore a deleted service provider, change the filter to display deleted providers. Select one or more deleted providers and click the Restore button.

Billing Rates Report

To view the Billing Rates Report for the selected service provider:

1. Navigate to the Service Providers List Screen.
2. Select a service provider and click the Billing Rates Report button.

3. Click Ok to view the report.

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Maintaining Resources

ClearTrial allows you to edit default resources and add user-defined resources with the Resource Maintenance feature, which can be launched by selecting “Resources” from the Maintain Menu.

Working with Resources

To work with resources, select “Resources” from the Maintain menu to display the Resource List Screen. This list displays currently defined resources and the ability to create, edit, and delete user-defined resources, as well as edit ClearTrial defined resources.

Roles

To work with the resource maintenance capabilities, you must have the Resources Administrator additional role/capability granted by your System Administrator.

Editing ClearTrial Resources

ClearTrial defined resources can be edited from the Resource List Screen. You can edit resource names, codes, and departments to match your specific resources.

To edit a resource:

1. Navigate to the Resources List Screen, by selecting “Resources” from the Maintain Menu.
2. Select a ClearTrial defined resource and click the Edit button. Make edits to the resource as needed and click Save to apply the changes.

Adding User-Defined Resources

User-defined resources can be added on the Resource List Screen. You can provide your own code, name, department, and description. In addition, you can enter the base rates for ClearTrial defined service providers by using the Auto-fill capability.

To add a resource:

1. Navigate to the Resources List Screen.
2. Click the New button and enter a code and name for the resource.
3. Select a Department for which this resource belongs. Fees and costs associated with this resource will be included by department in the correlating reports.

4. Enter a description for the resource. The description should include information such as responsibilities and activities generally handled by this resource.
5. Next, use the table to enter billing rates for this resource. The table allows you to assign hourly billing rates for ClearTrial defined Service Providers. If no rates are assigned, they will default to zero.

> **Note:** You will need to enter your internal rates within the Billing Rates Maintenance Feature for Non-ClearTrial defined Service Providers.

6. To quickly enter an hourly billing rate for one or more providers, and to apply a percentage increase, select the Auto Fill... button to open the Auto-Populate Rates dialog. Using this dialog, you have two options that allow you to apply an hourly rate and adjust it with a percentage increase as needed.
7. After entering rates for this resource, click Save to make this resource available for use in plans.

Editing User-Defined Resources

User-defined resources that have been added to the resource list can be edited.

To edit a user-defined resource:

1. Navigate to the Resources List Screen.
2. Click the Edit button to view the Edit Resource Screen. Edit the resource as needed and click Save to apply the changes.

Deleting and Restoring User-Defined Resources

User-defined resources that have been added to the resource list can be deleted and restored. ClearTrial defined resources cannot be deleted.

To delete and restore a user-defined resource:

1. Navigate to the Resources List Screen.
2. Select one or more resources to be deleted and click the Delete button. The resource(s) are removed from the list and are not available for use in new plans. Plans currently using the deleted resource(s) will not be affected.
3. To restore a deleted resource, adjust the list filter to display deleted resources. Next, select one or more deleted resources and click the Restore button.

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Maintaining Billing Rates

ClearTrial allows you to define billing rates for specific service providers who will be assigned work to complete a study with the Billing Rates List Screen.

This screen displays currently defined billing rates and provides the ability to create, edit, delete, restore, copy or publish billing rates. Billing rates defined on this screen can be shared by multiple plans.

Working with Billing Rates

To work with billing rates, select Billing Rates from the Maintain menu. This screen displays currently defined reporting regions and the ability to create, edit, and delete rates.

Roles

To work with billing rates, you must have either the Clinical or System Administrator Role. Users without these roles can only view billing rates. This is an additional role that can be granted by your System Administrator.

Drafts

The Billing Rates feature allows you to save draft versions of billing rates if the rates are not ready to use. Draft versions are not available for use in plans; rates must be published in order to be used in plans.

Previously published billing rates can be edited and the pending edits will remain in a Draft state until ready to be published.

The application will continue to use the previously published values until the new rates are published, replacing the prior values.

Revision History

The Billing Rates Lists Screen allows you to view previously published rates with the Show Revision History button.

Billing Rate Resource Descriptions

ClearTrial multiplies the hourly rate supplied for each resource by the number of hours calculated to be necessary for employees of this type to complete the work. The Billing Rates feature allows you to define hourly billing rates for each resource for specific service providers you may assign to work on a study.

To help guide you in providing the appropriate hourly rates you have negotiated with your vendor(s), see Chapter 30, "Resource Descriptions". This section describes the responsibilities of each resource.

Adding Billing Rates

To add billing rates:

1. Navigate to the Billing Rates List Screen.
2. Click the New button.
3. Select the service provider, sponsor, and rate year combination to complete the sentence... “When [vendor] performs works for [sponsor] for rate year [year].”
4. Choose the country or region for which your base rates apply. Enter the hourly rate for each resource in that country in the base rate location column. ClearTrial calculates the country-specific rates as per the variance value listed in the rate variance row.

   You may change the variance for any country to produce the expected rates and/or override any specific rate for any particular resource in any location.

   Note: For guidance on providing the appropriate hourly rates you have negotiated with your vendor(s), see Chapter 30, "Resource Descriptions". This document is also available in the online help for maintaining Billing Rates.

5. When you have entered rates for each resource, for each country, click Save to preserve the values in a draft state or click Publish to make the rates available for use in plans. Publishing rates will make them active rates that can be used by ClearTrial to calculate fees and costs associated with tasks assigned to the chosen vendor.

   Previously published billing rate worksheets can be edited and will remain in the Published with Draft state until ready to be published.

   The application will continue to use the previously published values until the new draft is published, replacing the prior values.

Editing Billing Rates

To edit billing rates:

1. Navigate to the Billing Rates List Screen.
2. Select a billing rate worksheet and click the Edit button.
3. Adjust rates as needed and click Save to preserve changes or click Publish to make the new rates available for use in plans.

Copying Billing Rates

To copy billing rates:

1. Navigate to the Billing Rates List Screen.
2. Select a billing rate worksheet and click the Copy Button. Select either the draft or published version to be copied. Also, you may apply a percent adjustment to the rates if needed.

3. Click OK and begin editing the copied the billing rates.

Publishing Billing Rates

To publish billing rates:

1. Navigate to the Billing Rates List Screen.
2. Select a billing rate worksheet in the Draft state and Click the Publish button. Confirm you want the rates published. The rates are now available for use in plans.

Deleting and Restoring Billing Rates

To delete and restore billing rates:

1. Navigate to the Billing Rates List Screen.
2. Select a billing rate worksheet in the Draft or Published state and click the Delete button to delete them.
3. To restore a set of billing rates, check the checkbox for "Include Deleted Rates." Deleted rates will be displayed with a line through them. Select the deleted billing rates you need and click the Restore button.

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Maintaining Departments

ClearTrial allows you to add, edit, and delete departments with the Department Maintenance feature, which can be launched by selecting "Departments/Functional Areas" from the Maintain Menu.

This feature also allows you to map departments to labor fees and costs.

Working with Departments

To work with departments, select Departments/Functional Areas from the Maintain Menu. The Department List Screen displays the currently defined departments.

Roles

To work with the department maintenance capabilities, you must have the Departments/GL Codes Administrator additional role/capability granted by your System Administrator.

Creating User-Defined Departments

To create a user-defined department:

1. Navigate to the Department List Screen.
2. Click the New button. Enter a code, name, and description for the department.
3. Click Save.

Editing Departments

To edit a department:

1. Navigate to the Department List Screen.
2. Select a department and click the Edit button. Make changes as needed and Click Save.

Deleting and Restoring Departments

To delete a department:

1. Navigate to the Department List Screen.
2. Select one or more departments and click the Delete button.
3. To restore a deleted department, adjust the filter to display deleted departments. Select one or more deleted departments and click the Restore button.

Mapping Departments

ClearTrial defined and user-defined departments can be mapped to labor fees and costs by resource, task, location, or a combination of user-defined rules.

Mapping by Resource

To map by resource:

1. Navigate to the Department List Screen.
2. Select a department and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure “resource” is selected.
4. Next, in the internal column for each resource, select the department to apply when the resource performs work for an internal provider.
5. In the outsourced column for each resource, select the department to apply when the resource performs work for an outsourced provider.

   If you do not need to select a department for each resource, you can provide a default department for internal and outsourced providers for all resources by selecting departments in the Default Row.
6. Click Save.

Mapping by Location

To map by location:

1. Navigate to the Department List Screen.
2. Select a department and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure “location” is selected.
4. Next, in the internal column for each location, select the department to apply when an internal provider is assigned to that location.
5. In the outsourced column for each location, select the department to apply when an outsourced provider is assigned to that location.

   If you do not need to select a department for each location, you can provide a default department for internal and outsourced providers for all locations by selecting departments in the Default Row.
6. Click Save.

Mapping by Task

To map by task:

1. Navigate to the Department List Screen.
2. Select a department and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure “task” is selected.
4. Next, in the internal column for each task and task group, select the department to apply when an internal provider is assigned to that task or task group.
5. In the outsourced column for each task and task group, select the department to apply when an outsourced provider is assigned to that task or task group.

If you do not need to select a department for each task or task group, you can provide a default department for internal and outsourced providers for all tasks by selecting departments in the Default Row, or for all tasks within a task group by selecting departments in a task group row.

6. Click Save.

Mapping by Rule (Advanced Mode)

To map by Rule (Advanced Mode):

1. Navigate to the Department List Screen.
2. Select a department and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure "Rule (Advanced Mode)" is selected.

   The Edit Department Mapping Screen allows you to map labor to departments by user-defined rules/criteria. Mapping in this mode allows you to define your own rules to fit your organization's business needs with the Add Rule button.
4. Click the Add Rule button to create a rule for mapping labor to departments.

   The Create Department Mapping Rule screen allows you to select the department for which labor should be mapped with the Department drop-down field in the upper left corner.
5. Select a department for which labor should be mapped.
6. Next, navigate to the Providers Tab and select providers to be matched when this rule is applied. Selecting the Internal and Outsource check boxes will include all of the service providers in that group.
7. Go to the Locations Tab and select locations to be matched when this rule is applied. Checking the Any Location field will include study-scoped items as part of the match.
8. Next, go to the Tasks Tab and select tasks to be matched when this rule is applied. Checking the Any Task field will include all task groups and tasks. ClearTrial defined and user-defined tasks can be included in the rule by selecting their associated task or task group.
9. Lastly, navigate to the Resources Tab and select resources to be matched when this rule is applied. Checking the Any Resource check box will include all resources.
10. Click OK to add the rule.
11. If you have more than one rule added to the list, you can click and drag the rules to create a hierarchy for which rules should take precedence over others.

    To re-order the rules, go to the Drag to Order column and select a rule. Drag it up or down the list to put it in the desired order.
12. Click Save.

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Maintaining GL Codes

ClearTrial allows you to add, edit, and delete GL Codes with the GL Code Maintenance feature, which can be launched by selecting “GL Codes” from the Maintain Menu.

This feature also allows you to map GL Codes to labor fees and costs.

Working with GL Codes

To work with GL Codes, select GL Codes from the Maintain Menu. The GL Code List Screen displays the currently defined GL Codes.

Roles

To work with the GL Code maintenance capabilities, you must have the Departments/GL Codes Administrator additional role/capability granted by your System Administrator.

Creating User-Defined GL Codes

To create a user-defined GL Code:

1. Navigate to the GL Code List Screen.
2. Click the New button. Enter a code, name, and description for the GL Code.
3. Click Save.

Editing GL Codes

To edit a GL Code:

1. Navigate to the GL Code List Screen.
2. Select a GL Code and click the Edit button. Make changes as needed and Click Save.

Deleting and Restoring GL Codes

To delete and restore GL Codes:

1. Navigate to the GL Code List Screen.
2. Select one or more GL Codes and click the Delete button.
3. To restore a deleted GL Code, adjust the filter to display deleted GL Codes. Select one or more deleted departments and click the Restore button.

Mapping GL Codes

ClearTrial defined and user-defined GL Codes can be mapped to labor fees and costs by resource, task, location, or a combination of user-defined rules.

Mapping by Resource

To map by resource:

1. Navigate to the GL Code List Screen.
2. Select a GL Code and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure "resource" is selected.
4. Next, in the internal column for each resource, select the GL Code to apply when the resource performs work for an internal provider.
5. In the outsourced column for each resource, select the GL Code to apply when the resource performs work for an outsourced provider.

   If you do not need to select a GL Code for each resource, you can provide a default GL Code for internal and outsourced providers for all resources by selecting GL Codes in the Default Row.
6. Click Save.

Mapping by Location

To map by location:

1. Navigate to the GL Code List Screen.
2. Select a GL Code and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure "location" is selected.
4. Next, in the internal column for each location, select the GL Code to apply when an internal provider is assigned to that location.
5. In the outsourced column for each location, select the GL Code to apply when an outsourced provider is assigned to that location.

   If you do not need to select a GL Code for each location, you can provide a default GL Code for internal and outsourced providers for all locations by selecting GL Codes in the Default Row.
6. Click Save.

Mapping by Task

To map by task:

1. Navigate to the GL Code List Screen.
2. Select a GL Code and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure "task" is selected.
4. Next, in the internal column for each task and task group, select the GL Code to apply when an internal provider is assigned to that task or task group.
5. In the outsourced column for each task and task group, select the GL Code to apply when an outsourced provider is assigned to that task or task group.

If you do not need to select a GL Code for each task or task group, 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 Code in a task group row.

6. Click Save.

Mapping by Rule (Advanced Mode)

To map by Rule (Advanced Mode):

1. Navigate to the GL Code List Screen.
2. Select a GL Code and click the Map Labor and Costs button.
3. Click the Change link in the upper right corner and ensure "Rule (Advanced Mode)" is selected.

   The Edit GL Code Mapping Screen allows you to map labor to GL Codes by user-defined rules/criteria. Mapping in this mode allows you to define your own rules to fit your organization's business needs with the Add Rule button.
4. Click the Add Rule button to create a rule for mapping labor to GL Codes.

   The Create GL Code Mapping Rule screen allows you to select the GL Code for which labor should be mapped with the GL Code drop-down field in the upper left corner.
5. Select a GL Code for which labor should be mapped.
6. Next, navigate to the Providers Tab and select providers to be matched when this rule is applied. Selecting the Internal and Outsource check boxes will include all of the service providers in that group.
7. Go to the Locations Tab and select locations to be matched when this rule is applied. Checking the Any Location field will include study-scoped items as part of the match.
8. Next, go to the Tasks Tab and select tasks to be matched when this rule is applied. Checking the Any Task field will include all task groups and tasks. ClearTrial defined and user-defined tasks can be included in the rule by selecting their associated task or task group.
9. Lastly, navigate to the Resources Tab and select resources to be matched when this rule is applied. Checking the Any Resource check box will include all resources.
10. Click OK to add the rule.
11. If you have more than one rule added to the list, you can click and drag the rules to create a hierarchy for which rules should take precedence over others.

    To re-order the rules, go to the Drag to Order column and select a rule. Drag it up or down the list to put it in the desired order.
12. Click Save.

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Maintaining Exchange Rates

ClearTrial supports the use of multiple currencies within a plan. 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 are defined outside of a plan.

Working with Exchange Rates

To work with the exchange rate tables, select Exchange Rates from the Maintain menu to display the Exchange Rate Tables List Screen. This screen displays the currently defined exchange rate tables and provides the ability to create, edit, delete, restore, publish, or set the default exchange rate table.

Roles

To work with exchange rate tables, you must have the Exchange Rates Administrator Role. Users without this role can only view the Exchange Rate Tables. This role is an additional role that can be granted by your System Administrator.

State

The State column indicates the published and draft tables.

- **Published:** A published exchange rate table can be applied to a plan from the Overview Tab. When you edit a published exchange rate table, those changes will be applied to all unlocked plans that are associated with that table.
- **Draft:** A draft exchange rate table cannot be applied to any plans and can only be edited by users with the Exchange Rates Administrator Role.

Creating Exchange Rate Tables

To create an exchange rate table:

1. Navigate to the Exchange Rates List Screen.
2. Click the New button. Enter a name and description.
3. Next, select a date for the "use rates as of:" field. This field allows you to choose a date from which to populate the exchange rates. After you select a date, each field is filled for every country on the list. You can override individual rates with your own by deleting the ClearTrial rate and entering a different rate.

> **Note:** The "use rates as of:" field is optional. If needed, you can enter your own exchange rates for each currency.

4. Click the Save Draft button to save the Exchange Rate Table without publishing it.

Editing Exchange Rate Tables

Exchange rate tables can be edited from the Exchange Rate Tables List Screen. When rates are edited and published, all of the plans associated with that table will be updated based on the new rates.

To edit an exchange rate table:

1. Navigate to the Exchange Rates List Screen.
2. Select Exchange Rates from the Maintain menu to display the Exchange Rate Tables List Screen.
3. Select an exchange rate table and click the Edit button.
4. Make changes to the rates as needed and click either the Click the Save Draft button or Publish button.

Deleting Exchange Rate Tables

Exchange Rate Tables that have been published, or saved as drafts, can be deleted from the Exchange Rate Tables List Screen. When published exchange rate tables are deleted, the plans using those rates will not be affected. However, newly created plans will not have access to the deleted exchange rate tables.

To delete an exchange rate table:

1. Navigate to the Exchange Rates List Screen.
2. Select one or more exchange rate tables and click the Delete button to remove it from the list.

Restoring Exchange Rate Tables

To restore an exchange rate table:

1. Navigate to the Exchange Rates List Screen. Deleted tables should be shown with a gray line through them. If not, adjust the filter to show deleted tables.
2. Select one or more deleted exchange rate tables and click the Restore button.

Publishing Exchange Rate Tables

User-defined exchange rate tables must be published in order to be applied to plans. Published exchange rate tables can be used in a plan by choosing the “defined in” option on the Overview Tab and selecting the table from the menu.

To publish an exchange rate table:

1. Navigate to the Exchange Rates List Screen.
2. Select Exchange Rates from the Maintain menu to display the Exchange Rate Tables Screen.
3. Select the exchange rate table you want to publish and click the Publish button.

Setting Default Exchange Rate Tables

You can designate an exchange rate table to be the Default. This table will be the default exchange rate table when you select the "defined in" option in the Overview Tab of a plan.

To set a default exchange rate table:

1. Navigate to the Exchange Rates List Screen.
2. Select the exchange rate table you want to set as the default and click the Default button.

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Maintaining Reporting Regions

ClearTrial allows you to group reporting regions for studies based on your company's global organizational structure and accounting practices with the Reporting Regions List Screen.

This screen allows you to create, edit, and delete reporting region names and to map countries to reporting regions. Mapping allows you to view the budget by location with the Monthly Budget by Reporting Region Report on the Reports tab for a plan.

Working with Reporting Regions

To work with Reporting Regions, select Reporting Regions from the Maintain drop-down menu. This screen displays currently defined reporting regions, along with the ability to create, edit, and delete them.

Roles

To work with Reporting Regions, you must have the Reporting Regions Admin Role. Users without this role can only view reporting regions. This role is an additional role that can be granted by your System Administrator.

Adding and Mapping Reporting Regions

The Reporting Regions List Screen allows you to add new reporting regions and map them to countries.

To add and map a reporting region:

1. Navigate to the Reporting Regions List Screen.
2. Click the New Reporting Region button or type a reporting region name in the list. You can also press enter on the keyboard to add groups.
3. Click the Map Countries to Reporting Regions button and select a reporting region for each country on the list.
4. Click OK.

Editing Reporting Regions

To edit a reporting region:

1. Navigate to the Reporting Regions List Screen.
2. Click the pencil icon next to the reporting region you need to edit and make changes. Click Save.

Deleting Reporting Regions

To delete a reporting region:

1. Navigate to the Reporting Regions List Screen.
2. Select Reporting Regions from the Maintain menu.
3. Click the trash icon to delete reporting regions.
4. Click Save.

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Resource Descriptions

This chapter describes the ClearTrial system-defined resources. ClearTrial resources represent job titles, or types of employees, who may be expected to perform work during a study.

ClearTrial multiplies the hourly rate supplied for each resource by the number of hours calculated to be necessary for employees of this type to complete the work.

The Billing Rates feature allows you to define hourly billing rates for each resource for specific service providers you may assign to work on a study.

To help guide you in providing the appropriate hourly rates you have negotiated with your vendor(s), this chapter describes the responsibilities of each resource.

Resource Descriptions

Described below are resources and their responsibilities.

CR01 - Clinical Research Associate (CRA)

- Supports negotiations with the central laboratory, if applicable, for costs, billing, and other details regarding the central labs involvement in the study.
- Assists with establishing the Data Safety Monitoring Board, which requires meeting schedules, report formats for receipt of safety data, etc.
- Supports the production and distribution of the subject information video (where required).
- Participates in the development of necessary documents for the study, such as forms for monitoring and site management.
- Performs an initial review of the protocol.
- Supports the Medical Writing team with writing the initial Investigator Brochure (IB).
- Participates in editing drafts of the Investigator Brochure, when a draft is provided.
- When performed in-house, translate various documents, such as the Informed Consent Form (ICF), Protocol, CRFs, IB, and Subject Diary.
- Assists in the development, distribution and collection of investigator meeting materials.
- Print and Distribute IB and Protocol.
- Produce and critique country-specific Informed Consent Forms.

- Support investigator sites with clinical trial application and exemptions, as well as IRB approvals.
- Interact with a central IRB on behalf of many sites in the study that do not require their own local IRB.
- Assist the Data Management group with the instructions for each CRF page, or the EDC equivalent, that guides the study coordinator in providing the data that is being collected.
- Attends Kick-Off, Investigator and Internal Team meetings and teleconferences as appropriate.
- Participates in identifying and screening investigators.
- Conducts on-site Pre-Study, Initiation, Monitoring and Close-out visits.
- Perform the negotiation of the investigator contract agreement and the fees to be paid per completed subject.
- Facilitate the collection of the 1572 and other regulatory documents required under the guidelines of ICH/GCP.
- Based on the study, facilitate the collection of other study documents that may be required.
- Assists the regulatory group to set up the regulatory files at the sites in accordance with GCP.
- Ensures all regulatory docs are approved and the site agreement is signed prior to drug release.
- Assists with procedures required for import, ship, certify, package, tracking and label of study drug.
- Performs monitoring visits to collect and verify data at the site against source documents.
- Perform weekly telephone contact with the study sites to check on enrollment, SAEs, and any problems, etc.
- Validates data at site to facilitate investigator and/or central lab payments.
- Supports the Project Manager in the production of periodic site newsletters.
- Resolve any questions about the CRF or EDC data with the study sites that have been raised by the data group on input of the data into the database.

CR02 - Senior Clinical Research Associate (SCRA)

In addition to activities performed by a CRA, responsibilities may include implementation and management of one or more clinical trials and project team members as appropriate.

The SCRA solves complex issues requiring in-depth analysis and provides recommendations to management.

- Supports negotiations with the central laboratory, if applicable, for costs, billing, and other details regarding the central labs involvement in the study.
- Assists with establishing the Data Safety Monitoring Board, which requires meeting schedules, report formats for receipt of safety data, etc.
- Supports the production and distribution of the subject information video (where required).

- Participates in the development of necessary documents for the study, such as forms for monitoring and site management.
- Performs an initial review of the protocol.
- Supports the Medical Writing team with writing the initial Investigator Brochure (IB).
- Participates in editing drafts of the Investigator Brochure, when a draft is provided.
- When performed in-house, translate various documents, such as the Informed Consent Form (ICF), Protocol, CRFs, IB and Subject Diary.
- Assists in the development, distribution and collection of investigator meeting materials.
- Print and Distribute IB and Protocol.
- Produce and critique country-specific Informed Consent Forms.
- Support investigator sites with clinical trial application and exemptions and IRB approvals.
- Interact with a central IRB on behalf of many sites in the study that do not require their own local IRB.
- Assist the Data Management group with the instructions for each CRF page (or the EDC equivalent) that guide the study coordinator in providing the data that is being collected.
- Attends Kick-Off, Investigator and Internal Team meetings and teleconferences as appropriate
- Participate in identifying and screening investigators.
- Conducts on-site Pre-Study, Initiation, Monitoring and Close-out visits.
- Perform the negotiation of the investigator contract agreement and the fees to be paid per completed subject.
- Facilitate the collection of the 1572 and other regulatory documents required under the guidelines of ICH/GCP.
- Based on the study, facilitate the collection of other study documents that may be required.
- Assists the regulatory group to set up the regulatory files at the sites in accordance with GCP.
- Ensures all regulatory docs are approved and the site agreement is signed prior to drug release.
- Assists with procedures required for import, ship, certify, package, tracking and label of study drug.
- Performs monitoring visits to collect and verify data at the site against source documents.
- Perform weekly telephone contact with the study sites to check on enrollment, SAEs, and any problems, etc.
- Validates data at site to facilitate investigator and or central lab payments.
- Supports the Project Manager in the production of periodic site newsletters.

- Resolve any questions about the CRF or EDC data with the study sites that have been raised by the data group on input of the data into the database.

CR03 - Regional Clinical Research Associate (Regional CRA)

Responsibilities are similar to those for a Senior CRA. Due to the regionalized nature of the role, this individual works independently and may require some additional experience.

- Provides clinical monitoring expertise, leadership, and management for clinical trials.
- Individual is responsible for the planning and delivery of the clinical component of the project in accordance with the scope of work and contracted timelines and for managing the clinical portion of the study budget.
- Coordinates monitoring activities on projects.
- Reviews site visit reports for accuracy, completion, and proper distribution in accordance with the applicable SOPs and requirements.
- Adheres to project scope-of-work guidelines, approved budget, and timelines.

CR04/CR05 - Senior Vice President Clinical or Senior Director Clinical/Therapeutic

- Strategic and tactical leader of the clinical group, accountable for the designated clinical area and for communication to corporate management.
- Leader of the project management team for assigned projects, providing input to other functions in the organization.
- Retains overall responsibility and accountability for defining the strategy and clinical operating plans for assigned projects.
- Collaborate with the development project teams for integration of the global strategy.
- Direct the selection of clinical investigators and study sites and oversee the evaluation.
- Work closely with country medical directors to incorporate the country needs and expertise into the development plans.
- Develop professional relationships with opinion and thought leaders.
- Represent the company at meetings with external attendees.
- Lead the clinical component of contract review and the due diligence process to evaluate product licensing opportunities; make recommendations on acquisitions and the work/resources required.

CR06 - Project Manager

- Responsible for management and organization of the clinical group including:
  - Define and provide direction to the group, including establishing goals, timelines, and deliverables.
  - Manage budget for the assigned group, assume responsibility for protocol design, clinical activities, and the clinical section of submissions.
  - Review and approve clinical scientific documents and SOPs, author scientific documents.

- Liaise with safety and regulatory organizations for coordination of global activities.
- Ensure the comprehensive product development plan is optimized and addresses key issues for the successful commercialization of the product (including R&D, manufacturing, and commercialization globally).
- Lead the articulation of product strategy and present/defend to the Executive Committee as required.
- Manage and execute the tactical plan supporting all elements of the product development plan and provide a detailed timeline and budget.
- Lead team to problem solve, engaging all relevant parts of the organization and escalating to appropriate higher levels within the company.
- Work effectively with overall functional leaders across the company.
- Lead the presentation of periodic budget proposals to the executive committee, including preparation of "next-year budget," the conduct of portfolio analysis, etc.
- Assist in the preparation of study reports, investigator brochures, and publications.

CR07/CR08 - Project Admin Assistant or Secretarial Support

- Request and process legal documents. (Confidentiality and Consulting Agreements)
- Schedule meetings and prepare meeting materials, logistics, and meeting minutes.
- Prepare international and domestic travel expense reports.
- Maintain company critical records, including files pertaining to the copy approval and labeling processes, documents developed under an electronic document management system, central product file and official adverse event report and complaint files.
- Create/maintain Word documents, Excel spreadsheets, Power Point presentations and the company's databases.
- Maintain files, fax, and photocopy.
- Organize internal events and guest accommodations.
- Provide support for word processing; faxing, photocopying, and invoice tracking.

DM01 - Data Coordinator

- Provide solid core and some comprehensive data management expertise to data management team to provide efficient, quality data management products that meet customer needs.
- Provide leadership to the team as Lead Data Manager or in the role of back-up.
- Develop and maintain good communications and working relationships with CDM team.
- Assist other team members in training and developing data management expertise.
- Independently bring project solutions to the CDM team.
- Interact with corporate team and CDM team members to negotiate timelines and responsibilities (if desirable).

DM02 - Data Entry Clerk

- Perform clinical data entry and validation to ensure legibility, completeness, and accuracy of data.
- Assist users with requests for clinical documents.
- Assist with the development and evaluation of clinical record forms.
- Maintain internal record-keeping system(s) in conjunction with CRAs and internal staff, including maintaining and auditing data, and providing status and activity reports as required.

DM03 - Data Manager

- Provide expertise in data management.
- Lead team in data management plan development and/or act as Data Team Lead.
- Develop/maintain good communications and working relationships with Clinical and other functional teams.
- Train other team members in data management expertise.
- Attend/present at professional conferences and/or publish articles in professional journals.
- Bring project solutions to the Clinical Team.

DM04/ST03 - Senior Programmer or Statistical Programmer

- Direct, review, and manage all programming deliverables including major deliverables of analysis data sets; databases; QC plans; table, listing, and graph tracking plans; and other components of submissions.
- Direct, review and manage specifications of databases; data transfers; data definition tables; analysis files; table, listing and graph generation.
- Direct, review, and manage timelines and contracts of statistical programming activities with CROs and Sponsors in coordination with other departments.
- Attend and participate in project, departmental, and interdepartmental meetings.
- Provide programming and technical support to the principal statistician in the creation of the analysis file specifications documents.
- Develop analysis files, table, listing, and graph outputs in accordance with the statistical analysis plan (SAP) guidelines.
- Provide, as needed, QC programming support of analysis files, table, listing, and graph outputs.
- Maintain responsibility and accountability for the statistical programming integrity of various study results including ad-hoc requests, analysis files used for TLG production, TLG outputs, and various other clinical reports.
- Develop, review and maintain Global Standard Operating Procedures (SOP) for the Statistics and Data Management department.
- Understand, comply, and document compliance with Global SOPs, including training CRO personnel in statistics and data management SOPs.
- Provide programming support for ad-hoc requests from other groups, as well as, publications and other sales activities.

DM05 - Program Analyst

This position is primarily for performing SAS programming in a data management environment.

- Plan and coordinate database design, development, implementation, and maintenance.
- Support of clinical systems for local, regional, or transnational use.
- Provide technical expertise in conjunction with internal and external clients in EDC database design in support of SAS deliverables.
- Produce dataset and listing specifications.
- Reformat and restructure data for analysis.
- Program edit checks.
- Produce ad-hoc listings.
- Program transfers of data to sponsors and Biostatistics Department.
- Import data from EDC system and external vendors.
- Program, test, and document databases in accordance with programming standards and validation procedures.
- Program database manipulation and transfers of data for internal and external clients.
- May assist in developing and implementing new technologies.
- May assist IT in testing and evaluating new upgrades to technologies.
- May assist in developing, revising, and maintain core operating procedures and working instructions.
- May serve as Lead Programmer on the corporate team.

DM06 - Senior Program Analyst

- Plan and lead the development of project-related solutions for all statistical programming tasks.
- Provide technical expertise to the Statistical Programming department.
- Specific responsibilities include programming, analysis, files, tables, listings, graphs/plots and process improvement work.
- The senior program analyst may also serve as an SP lead representing Statistical Programming on the corporate team and may plan and coordinate programming, testing, and documentation of statistical programs for use in creating statistical tables, graphics, and experience-listing summaries.

DM07 - Help Desk Support Specialist

- Supervised by the Help Desk Manager.
- Provide accessible clinical hotline support in the local language.
- Prequalify the sites elected to participate in a trial based on EDC readiness.
- Verify connectivity connection and functionality of the EDC hardware/software.
- Connect sites via conference call to a designated on-call clinician when required.

- Record and document calls.
- Qualify requests that need to be escalated by gathering and confirming the necessary information to be sent to the next level.
- Assist with Inclusion/Exclusion Criteria.
- Address questions relative to the entry of data into the EDC database.
- Provide eCRF Guidance.
- Address or forward Drug/Device Questions to CRO monitoring staff.
- Provide AE and SAE Support in the absence of CRO Medical or monitoring staff.
- Address any technical issues relative to problems with data entry.
- Add new problem solutions to the knowledge database for future reference.

DM08 - Help Desk Manager

- Manage the Help Desk Support Specialist and their duties.
- Provide accessible clinical hotline support in the local language.
- Prequalify the sites elected to participate in a trial based on EDC readiness.
- Verify connectivity connection and verify functionality of the EDC hardware/software.
- Connect sites via conference call to your designated on-call clinician when required.
- Record and document calls.
- Qualify requests that need to be escalated by gathering and confirming the necessary information to be sent to the next level.
- Assist with Inclusion/Exclusion Criteria.
- Address questions relative to the entry of data into the EDC database.
- Provide eCRF Guidance.
- Address or forward Drug/Device Questions to CRO monitoring staff.
- Provide AE and SAE Support in the absence of CRO Medical or monitoring staff.
- Address any technical issues relative to problems with data entry.
- Add new problem solutions to the knowledge database for future reference.

DM09 - EDC Trainer

- Provide eLearning through web-based programs.
- Provide web-based training for individuals and/or small groups.
- Develop on-site training in a classroom setting.
- Provide customized role-based training.
- Conduct Investigator Meeting training for EDC when appropriate.
- Develop and lead “Train the Trainer” programs.
- User training management, including delivery of training certificates upon completion.

- Develop and provide instruction for Ad-hoc or customized training programs.

DS01 - Medical Monitor

- In house review of Case Report Forms (CRFs), including query resolution and addenda writing, and QA of data listings.
- Provide support for Adverse Event Reporting and/or Medical Communication, which includes writing standard and custom responses to communication requests.
- Provide in-depth assistance to the medical and lay community by responding to inquiries with medical/scientific information that is more complex and requires more data than is supplied in the package insert or the standard letter database.
- Off-label information would be disseminated at this level.
- Provide training internally and at investigator meetings on safety issues.
- Assume responsibility for serious adverse events and CRF completion.
- Write study summaries and review protocols, study summary investigator brochures, and IND annual updates for safety data verification.

GA01 - Records Clerk

- Provide technical, administrative, and clerical support for records management.
- Set-up, maintain, and track project, study, and CRF "files of record" for clinical, research, post-marketing, and regulatory affairs divisions in accordance with regulatory authority and Standard Operating Procedures (SOPs) set forth by CRO and its sponsor clients.
- Set up the project, tracking system at the beginning of a project for study, investigator and CRF page entries.
- Maintain tracking information for study and regulatory documents, correspondence submitted for filing by project staff, and CRFs delivered to CRO from CRAs following a monitoring visit.
- Maintain and provide a list of official copies of documents to specific authorized CRO personnel as they are superseded.
- Generate project specific or overall tracking reports for authorized CRO personnel.
- Maintain compliance with CRO policies and procedures, including security, safety, and general work rules.
- Attend related continuing education programs, professional meetings, and career development activities sponsored by CRO.
- Assist in assuring the secure and timely, verbal, electronic, or physical delivery of CRFs, project documents (or copies) to authorized personnel.
- At the end of the project, participate in checking inventory records, and packing and shipping project documents designated as the "files of record" to the sponsor. Monitor the retention schedule for CRO project documents.

GA02 - Records Manager

- Provide reference services to all departments and levels of personnel.

- Ensure effective security, storage, and retrieval of all proprietary and client information in accordance with established procedures.
- Create files according to established classification system.
- Process incoming information; sort, classify and verify coded material for filing and integration into systems.
- Provide reference services to internal clients in accordance with SOPs and maintaining accurate charge-out systems.
- Create and maintain logs, computerized indexes, and databases to provide accurate status, and retrieval of information.
- Operate scanning equipment and process and organize scanned images.

Medical Writer

- Manage the preparation of clinical and pre-clinical manuscripts, abstracts, posters, slide presentations, and other scientific documents.
- Supervise the development of medical education materials and strategic marketing documents.
- Manage and review documentation generated by external communications agencies and company resources.

PK01 - Clinical Pharmacokineticist

- Provide modeling and simulation strategy and clinical development plan.
- Plan, design, analyze, and interpret PK and PK/PD data from clinical studies.
- Provide expert advice on dose/regimen selection and issues relating to clinical pharmacology (PK, PK/PD, ADME, DDI, special populations (i.e., pediatrics, hepatic and renal impairment, elderly, etc.)).
- Investigate relationships between PK and clinical endpoints, biomarkers and adverse effects; perform simulations to predict clinical response and study outcomes.
- Perform population PK and PK/PD analyses, provide interpretation and simulations.
- Interpret and present results and recommendations to management and relevant teams/committees.
- Prepare and/or review PK, PK/PD and clinical pharmacology components of study protocols, study reports, investigator's brochure, development plans, project summaries/internal documents, and regulatory briefing and submission documents.
- Prepare appropriate responses to regulatory agencies on PK, PK/PD and clinical pharmacology related issues, including regulatory advisory meetings.
- Interact cross-functionally with company departments and groups.
- Prepare, review, publish and present scientific publications and abstracts.

PK02 - Senior Pharmacokineticist

- Manage DMPK aspects of projects and negotiate an optimal PK/PD strategy for early and full development in liaison with line functions and Management.

- Responsible for PK, PK/PD, and Modeling and Simulation components of study protocols, reports, project summaries and development plans that meet regulatory requirements.
- Work across DMPK non-clinical and clinical groups to embed PK/PD into groups and projects, liaising closely with other functions supporting PK/PD.
- Preparation of submission documents and responses to Health Authority (HA) inquiries.
- Interpretation and presentation of study results to project teams and management.
- Lead appropriate PK and biopharmaceutical studies.

QA01 - Compliance/QA Manager

- Serve as a point person with all governmental regulatory organizations.
- Develop excellent working relationships that will result in rapid, worldwide approvals for internal and external (client) projects.
- Build a strong foundation for corporate credibility.
- Maintain vigilance over proposed changes and new regulatory legislation.
- Evaluate the impact of proposed changes and devise strategies and to ensure efficient regulatory functions.
- Provide regulatory assessments and conducts regulatory due diligence for new opportunities.
- Ensure optimal acceptable regulatory strategies for worldwide compliance and submissions from development through marketing, including advertising, promotion, and labeling.
- Develop and implement regulatory strategies for new products, product improvements, and new indications.
- Provide regulatory strategy and direction that will accomplish results for worldwide registrations and regulatory product maintenance activities in a positive manner.
- Help manage and participate in the processes to achieve regulatory agency input into research and development programs.
- Communicate and negotiate all activities pertaining to assigned therapeutic areas with applicable regulatory agencies to ensure efficient drug development and drug approvals.
- Ensure that all regulatory documents are prepared in accordance with regulatory guidelines and internal standards and SOPs.
- Interact with Regulatory Affairs personnel and project team members to define submission logistics and scheduling; coordinate priorities for submissions.
- Manage regulatory therapeutic areas and direct reports.
- Establish, manage, and mentor therapeutic area team.
- As a member of Regulatory Affairs management team, evaluate functional strengths and developmental areas of the department.
- Identify and recommend solutions to improve departmental efficiency and effectiveness.

- Maintain a high level of expertise through reading and attendance at professional seminars and workshops.

QA02 - Compliance/QA Auditor

- Plan, conduct, and report quality assurance audits as scheduled.
- Support QA management in promoting and assessing compliance of contracted functions with regulations, guidelines and corporate policies of CRO and customers through the conduct of independent audits of projects and processes as applicable.
- Provide quality assurance oversight, under the direction of QA management or senior staff, of assigned projects through interaction and consultation with customers, project and study teams, and associated development groups.
- Conduct GXP audits (GXP= GCP/GLP/GMP) and/or consultancy projects for customers, as applicable, according to CRO departmental and/or customer policies and procedures, within budget and agreed timelines.
- Schedule, prepare, conduct, report, and close out all assigned audits under the supervision of QA management. This may include audits of clinical study documents (protocol amendments, informed consent, clinical study reports, and advertisements) project set-up, Project In-Life, investigator sites, databases, study reports, sub-contractors, etc.
- Plan, conduct, and report audits of clinical research activities in any of the countries involved in CRO contracts to assess compliance with customer requirements, CRO core operating procedures, work instructions, and project specific guidelines/instructions.
- Participate in reviewing corrective actions.
- Represent QA on customer/project teams under the direction of QA management.
- Document and report quality/compliance issues, relating to the product, process or quality system, to line management within specified regional timelines.
- Advise/communicate to QA management the perceived need for audits of CRO systems.
- Develop a working knowledge of current GXP regulations, guidelines, and related auditing techniques.
- Assist in the conduct of customer audits, mock regulatory inspections and regulatory facility inspections.
- May host customer audits and work with responsible parties to prepare corrective action plan as applicable.

RG01 - Regulatory Submissions Specialist

- In collaboration with the Regulatory Operations team, coordinate the preparation, compilation, and publishing of global regulatory submission documents (briefing documents, INDs, CTAs, PSURs, NDAs, MAAs amendments, etc.).
- Assist with global electronic and paper records systems, to include electronic document management system.
- Assist archiving of hard-copy files in regulatory records centers in the US and the UK to include management of off-site archives.

- Help develop and maintain SOPs, work instructions, and training documents and help train others in the use of document-authoring and publishing tools.
- Work with Quality Assurance to facilitate the review and approval of documents for submission to regulatory authorities by performing QA checks on submission documents to ensure content quality and compliance with regulatory guidelines.
- Assist in maintaining regulatory registration databases and tracking systems.
- Operate as record management liaison with internal and external partners and ensure that all contractual obligations are met.
- Support the preparation of regulatory correspondence and slides for regulatory meetings.

RG02 - Regulatory Submissions Manager

- Review and approve routine regulatory submissions, including annual reports, periodic safety reports, and expedited safety reports.
- Assume primary responsibility in defining requirements, developing the content, and compiling more complex submissions, including: INDs, CTXs, NDAs, MAAs, technically complex amendments, supplements, and variations in collaboration with regulatory project leader, and regulatory operations team to be ready for review and approval.
- Serve as liaison with regulatory authority at the direction of the Director of Regulatory Affairs.
- Assume primary responsibility for assuring quality assurance of regulatory submissions, including managing the schedule for QA, Audit-CRO, and suppliers.
- Assume responsibility for providing regulatory authorization for release of clinical supplies for shipment to US study sites, if required.
- Prepare and maintain policies and SOPs for regulatory processes relative to regulatory affairs. Review and contribute regulatory perspective for SOP from other functions.
- Review and recommend protocols and development documents for approval.
- Take meeting minute notes during meetings with regulatory agencies.
- Provide regulatory input and perspective into regulatory strategies, development plans, reports, and submission documents.
- Maintain responsibility for assigned activities with the project team.
- Represent regulatory affairs in due diligence activities as required, write reports of due diligence activities, and provide recommendations.

RG03 - Director Regulatory Affairs

- Manage a Regulatory Affairs (RA) unit that provides scientific and regulatory expertise.
- Provide preclinical research, toxicology, manufacturing, and clinical trials support for both internal CRO customers and external clients, for investigational drugs, biologicals, and medical devices.
- Provide support for the development of RA business from pharmaceutical, biological and medical device companies, in accordance with the RA business plan.

- Participate in project-related work as required.
- Line management responsibilities include professional development, performance appraisals, and employee counseling for Junior Regulatory staff.
- Assigns project work and reviews workload for all direct reports.
- Takes leadership role in the coordination of products and resources.
- May serve as a team member or as a Project Manager if assigned, assures appropriate technical training will be provided to and taken by all RA unit members.
- Keeps abreast of current regulatory knowledge, trends, and developments in the US, Canada, Europe, and emerging markets.
- Participates in the RA Management Unit meetings, making reports as required.
- Provides advice to client pharmaceutical companies on developing new pharmaceutical products, including drugs and biologics.
- Interacts with FDA by phone, face to face meetings, mail, and email.
- Participates on behalf of Regulatory Affairs in business development meetings with potential clients.
- Prepares written reports and memoranda as needed.

ST01 - Junior Biostatistician

- Develop and implement programming specifications, database evaluation, and analysis plan drafting.
- Provide statistical review of program output, tables, figures, and listings resulting from the specifications.
- Provide statistical consulting for analysis file QC and generation of data listings.
- Perform statistical evaluation of databases including creation of consistency queries, summaries of database characteristics, and routine statistical summaries.
- May run non-production SAS programs to explore database characteristics in preparation for statistical analysis (upon direction of lead biostatistician).

ST02 - Senior Biostatistician

- Direct, review, and manage CROs in terms of all statistics deliverables including: major deliverables of CRFs, databases, protocols, statistical analysis and surveillance plans, data management plans, QC plans, clinical study reports, integrated summaries, and other components of submissions.
- Direct, review and manage specifications of databases, data dictionaries including coding tools, data transfers, data definition tables, analysis files and table, and listing and graphs generation.
- Direct, review, and manage timelines and contracts of statistics and data management activities with CROs in coordination with other departments.
- Attend and participate in project, departmental, and inter-departmental meetings.
- May assume responsibility for programming and data analysis of various clinical databases.
- Provide statistics and programming support for publications and other sales activities.

- Assume responsibility and accountability for the statistical integrity of various plans (including the randomization and analysis plans) and the interpretation of results as represented in clinical study reports, publications, and various other clinical reports.
- Assist with the evaluation and selection of CROs for the statistical and data management aspects of clinical studies; review contracts.
- Liaise with clinical and safety and regulatory organizations to coordinate global activities.
- Manage long-term database CRO archives following completion of projects and retrieve information as required.
- Develop, review, and maintain Global Standard Operating Procedures (SOPs) for the Statistics and Data Management department.
- Understand, comply, and document compliance with Global SOPs including training CRO personnel in the department's Statistics and Data Management SOPs.

ST04 - Director Biostatistics/Data Management

- Responsible for Data Management and biostatistics department, including P&L, quality, personnel and strategic direction.
- Manage regional Directors/Managers who are responsible for data management personnel and activities within their regions or sites.
- Assist regional Directors/Managers with planning, organizing, and resourcing projects to assume compliance with contractual obligations and to ensure optimum efficiency.
- Assist regional Directors/Managers in ensuring adherence to global standard operating procedures and working practices for all data management areas.
- Ensure all personnel related matters in Data Management are being addressed appropriately by regional Directors/Managers, including: creating position descriptions, hiring, managing, and training Data Management departmental personnel, supervising managers and senior staff, establishing performance and quality standards for Data Management, initiating personnel actions, evaluating performance of associates, and maintaining training records.
- Work collaboratively with other senior data management leaders in other countries to establish global data management processes and systems.
- Function as a member of the senior management team and assist in determining the strategic direction of the organization.
- Collaborate with management of other functional areas, including but not limited to: biostatistics, medical writing, and clinical to ensure consistency in approach and success on all projects.
- Approve Statistical and Analysis Plans.
- Support pricing, bid defenses, RFI development and capabilities presentations.
- Develop and manage sponsor relationships and partnerships.
- Work collaboratively with IT on the implementation and management of data management systems, including: establishing user requirements for data management systems, developing and executing validation plans, ensuring the

development of processes to support the use of new technologies, and ensuring systems meet regulatory requirements.

- Maintain current knowledge of industry trends and information relevant to data management processes through literature reviews and attendance at industry meetings and conferences.
- Ensure staff is in compliance with all appropriate CDISC and other regulatory requirements.