

**Oracle® Health Sciences ClearTrial Cloud Service**

Track User Guide

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# Preface

The Oracle Health Sciences ClearTrial Track Cloud Service User Guide is a reference for ClearTrial users who are tracking studies for their organization.

## Audience

This document is intended for users working with the Oracle Health Sciences ClearTrial Track 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>.

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## Related Documents

For more information, see the following documents in the Oracle Health Sciences ClearTrial Cloud Service Release v4.8 documentation set:

- *Oracle Health Sciences ClearTrial Cloud Service v4.8 Release Notes*
- *Oracle Health Sciences ClearTrial Plan and Source Cloud Service User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service System Administrator User Guide*





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## Baseline Plans

Plans created in the Oracle Health Sciences ClearTrial Plan and Source Cloud Service module can be tracked in the Oracle Health Sciences ClearTrial Track Cloud Service module, after they have been set as the baseline plan. The Track module allows you enter actuals against a study.

### 1.1 Identifying the Baseline Plan

Before a plan can be tracked, it should be set as the baseline plan and adjusted to reflect the final negotiated contract in the Oracle Health Sciences ClearTrial Plan and Source Cloud Service module. The baseline plan should be the plan that has been approved as the operational plan for the study and contains the final agreed-upon assumptions of the study.

After a plan has been set as the baseline, it is locked and cannot be modified. However, if changes need to be made while the study is being tracked, the baseline plan can be unlocked from the Plan List Screen. Any changes made will be reflected in the tracked study.

If a plan is reforecasted and set as the baseline plan, it will be locked and cannot be unlocked. Reforecasted baseline plans cannot be modified. For more information about reforecasting and how to set a reforecasted plan as a baseline, see Reforecasting.

#### 1.1.1 Baseline Plan

A plan selected as the baseline plan is the operational plan for the study against which you will track actual progress, costs, accruals, and earned value.

A study can only be tracked once. If multiple plans are associated with the study, only one may be selected as the baseline to track against. Once a plan is set as the baseline, you will be able to modify all plan assumptions except for the plan status and the modeling currency.

#### 1.1.2 Adjusting the Baseline Plan to Reflect the Negotiated Contract

If any portion of your study is outsourced to a service provider, you may need to adjust the unit costs, unit hours, resource billing rates, etc. in the plan to reflect the final negotiated contract values. This ensures you are tracking against the budget and plan that is in the final negotiated contract. All adjustments can be made in Oracle Health Sciences ClearTrial Plan and Source Cloud Service module.

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**Note:** If you need information on creating and editing plans for a study, refer the Oracle Health Sciences ClearTrial Plan and Source Cloud Service User Guide.

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To adjust a plan:

1. Login to the application.
2. From the Plan List Screen, choose a plan that is going to be set as the baseline plan and click the Edit button.
3. Adjust the major tasks' number of units, unit hours, and unit costs to reflect the final contracted value:
  1. Click the Labor Tab and select a major task
  2. Click the Adjust Hours or Fees button to open the Major Task Adjustments Tab in ClearTrial Task Manager. Use the Adjustments Tab to edit the number of units, unit hours, and unit costs for the selected major task.
  3. Navigate to the Major Task Distribution Tab and edit the distribution method for the Service Provider completing work on the assigned major task.
  4. Click Save.

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**Note:** It is recommended that after adjustments are made to the number of units, unit hours, and unit costs, you bulk pin labor for all the major tasks in the plan. This can be done by clicking the "Pin Labor" link at the top of the major task list. Labor should be pinned in case if adjustments need to be made to the baseline plan.

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.

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4. After all of the major tasks for a plan have been adjusted, ensure the plan costs are correct. To adjust a cost to reflect the final contracted value:
  1. Navigate to the Costs Tab. Select the cost from the list and click the Edit Cost button to open the Edit or Adjust Dialog. Use the Cost Algorithm Tab to adjust how costs will be calculated in each location.
  2. Click the Distribution Tab and make adjustments to the cost distribution as needed.
  3. Click Save.
5. Once the plan has been adjusted and saved, it can be set as the baseline plan.

## 1.2 Setting the Baseline Plan

There are two methods for setting the baseline plan, from either the Study List Screen or the Plan List Screen.

To set the Baseline Plan from the Study List Screen:

1. Login to the application.
2. Select Studies from the Edit menu to display the Study List Screen.

3. Select a study that has a plan you need to set as the baseline. Click the Track... button and select Enter Actuals.

If the study has multiple plans, you are prompted to select the designated baseline plan from a list of available plans. The Edit Actuals screen is displayed and you can begin entering actuals.

The baseline plan becomes locked and cannot be modified unless if it is unlocked from the Plan List Screen. Any modifications made to the baseline plan will be reflected in the tracked study.

4. Enter your actuals and click save when finished.

To set the Baseline Plan from the Plan List Screen:

1. Login to the application.
2. From the Plan List Screen, select the plan to be tracked. Click the Other Actions... button and select Set as Baseline. This plan is the baseline and any subsequent tracking of actual progress and costs are performed against this plan.

The baseline plan becomes locked and cannot be modified unless if it is unlocked from the Plan List Screen. Any modifications made to the baseline plan will be reflected in the tracked study.

3. To start entering actual study progress data, navigate to the Study List Screen and select your study. Click the Track... button and select Enter Actuals to begin tracking. Click save when finished.

### 1.2.1 Editing a Baseline Plan

Once a plan is set as the baseline, it is locked. However, it can be unlocked from the Plan List Screen and you can modify all of the plan assumptions except for the plan status and the modeling currency.

To edit a baselined plan, select it from the Plan List Screen and click the the Other Actions... button to unlock it. Click the Edit button to begin modifying assumptions.

If the baseline plan is a reforecasted plan that was set as the baseline, it cannot be modified. For more information about reforecasting and how to set a reforecasted plan as a baseline, see Reforecasting.

## 1.3 Tracking a Study

After you set the baseline plan and you are ready to enter actuals, the tracked study must be accessed from the Study List Screen.

To open a tracked study:

1. Navigate to the Study List Screen.
2. Select the tracked study and click the Track button. From the drop down menu, select Enter Actuals to view the study tabs and to enter actuals.

### 1.3.1 Viewing a Tracked Study Summary

After a plan has been set as the baseline and actuals have been entered, you can view a summary of the study's project health from the Study List Screen.

To view a tracked study's project health:

1. Navigate to the Study List Screen.

2. Select the graph icon next to the tracked study to open the Summary Tab. From here, you can view the project health, study performance trend graph, and projected at completion conditions. See the Summary Tab for more information.

### 1.3.2 Study Performance Summary Report

The Study Performance Summary Report, available from the Reports Menu, allows you to see the project health of all your tracked studies.

To generate the Study Performance Summary Report:

1. Navigate to the Study List Screen.
2. Select “Study Performance Summary Report” from the Reports Menu. Select the information you need included in the report. Click Ok to view the report.

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## Entering Actuals

Before you begin entering and tracking actuals, you should be familiar with the tabs in the Oracle Health Sciences ClearTrial Track Cloud Service module and the notes function.

### 2.1 Track Tabs

Similar to entering assumptions for plans in the Oracle Health Sciences ClearTrial Plan and Source Cloud Service module, there are tabs to enter information for studies that are being tracked.

- **Settings:** The Settings Tab is used to configure how actuals will be entered for a study. The Tracking Interval and Study Status Date can be set, as well as the tracking level for major tasks, costs, and payments.
- **Sites:** Enter the number of sites approved for each location, for each week, in your study. ClearTrial uses these values for the completed units of work for the Sites Approved Major Task.
- **Subjects:** Enter the number of enrolled, randomized subjects for each location, for each week in your study. These values for the completed units of work are used for the Subject/Volunteer Randomized Major Task.
- **Monitoring:** Record the number of monitored, cleaned CRF pages (or EDC equivalent) collected for each week of a study. These values are used for units of work for the Monitored, Clean CRF Page Major Task.
- **Task Units:** Enter the amount of work completed for each major task, for each service provider, at each location in a study.
- **Task Dates:** Enter the actual start and end dates for each major task, for each service provider, at each location in a study.
- **Milestone Dates:** Enter the actual dates on which study-level milestones will occur.
- **Milestone Payment:** Enter the actual payments made against the milestone payment schedule for each service provider in the study.
- **Labor Fees:** Enter the fees, or Actual Cost accrued for each major task, for each service provider, at each location in a study.
- **Costs:** Enter the actual costs acquired against the Miscellaneous Costs in your plan, for each service provider at every location in the study for Pass-Through Costs.

- **Summary:** This tab provides a project dashboard of your study's progress, with four portlets: Project Health, Study Performance Trend, Current Status, and Projected At Completion.
- **Reports:** This tab provides links to Track reports. Each report can be viewed in a separate window, printed, exported to Microsoft Excel, or converted to Adobe Portable Document Format (PDF).

## 2.2 Entering Notes

To help communicate further clarification related to your tracked actuals to other users, you can use the ClearTrial notes function. To record notes while entering actuals, click the Notes button in the upper right corner of each tab.

Notes can be public or private. Public notes can be included on reports that are generated from the Reports Tab. Private notes are only visible to users who are entering actual data for the tracked study.

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## Settings Tab

The Settings Tab allows you to establish tracking settings for a study, such as the tracking interval, study status date, and tracking payments for major tasks. All of these decisions are made in the Settings Tab, which includes three sub-tabs: Major Tasks, Costs, and Payments.

### 3.1 Tracking Settings

The default tracking settings are determined by your baseline plan, but these settings can be altered to fit your tracking needs.

#### 3.1.1 Tracking Interval

You have two options for the time interval you can use to track the study progress: weekly or monthly. Monthly means your data is entered by month and weekly allows you to enter data for each week in the study. The option you pick affects the Study Status Date and how actuals are entered.

#### 3.1.2 Study Status Date

The Study Status Date is the date through which you have complete study status information. Study status information includes data such as invoices received or the number of CRF pages collected. The date selection is bound by the selected tracking interval, either weekly or monthly.

The date you enter into the Study Status Field is the date you want ClearTrial to use as the cut-off date for earned value calculations. This date keeps incomplete data from being reported. Using an accurate Study Status Date ensures that earned values are accurately reflected.

If you prematurely advance the Study Status Date before you have entered a complete picture of your study's status, your results may be inaccurate. For example, if you have entered only half of the activity data for the month of September, leave the Study Status Date set to August 31.

### 3.2 Setting the Level of Detail for Tracking Tasks and Costs

For each cost, you have two options regarding the level of detail at which you want to track tasks and costs. These options affect how you view project performance and enter both actual progress and actual cost.

On the Settings Tab, use both the Major Tasks and Costs sub-tabs to select the following settings for each tracked study.

- **Study Level:** Select “Study Level” to track the major task, or cost, on a study-wide basis. (i.e. not tracking progress/cost for individual locations)
- **Location Level:** Select “Location Level” to track the major task, or cost, on a per location basis, making a separate entry for each location.
- **Not Tracked:** Select “Not Tracked” if you do not need to enter actuals for this major task, or cost. Note that once “Not Tracked” is selected, you cannot enter data or change the tracking settings once actuals have been entered.

### 3.2.1 Tracking Earned Value for Costs

The Cost sub tab has additional settings to designate how to capture Earned Value (EV) for miscellaneous or pass-through costs. EV is the amount of value (expressed in monetary terms) that has been earned, based on the work completed by a service provider.

- **Enter AP Only (sets AP to EV):** Select “Enter AP Only (sets AP to EV)” for a cost if you only need to enter what has been paid. For this selection, ClearTrial will set the earned value to be equal to what was entered for actual payment.
- **Enter EV and AP:** Select “Enter EV and AP” for a cost if you want to track separately what was reported as earned based on work completed and what is actually paid.
- **Derived:** Derived is defaulted for certain costs that are driven from other work that is completed. Only costs that are defined with a task-based cost driver are eligible for Derived.

### 3.2.2 Payment Tracking Options

The Payments sub-tab allows you to set your payment tracking options for each service provider included in the study.

Payments can be tracked at either the task or study level:

- **Task Level:** Select Task Level if you need to track actual payments at the Major Task Level. This option allows you to enter actual payments, for each of the Major Tasks in your study.
- **Study Level:** Select Study Level if you need to track payments at the Study Level. This option allows you to make one entry for labor fees and one entry for Costs (pass through and miscellaneous costs) for the entire study.

There are three options for how payments can be tracked:

- **Pay for work completed upon milestone achieved:** Select this option if you need to track actual payments according to the Milestone Payment schedule in the Baseline Plan and are paying for work completed upon milestone achieved. Note that this option is not available for tracking the sponsor’s internal costs.
- **Pay fixed fee upon milestone achieved:** Select this option if you wish to track actual payments according to the Milestone Payment schedule in the Baseline Plan and are paying a fixed fee upon milestone achieved. Note that this option is not available for tracking the sponsor’s internal costs.
- **Enter AP Only (sets AP to EV):** Select this option if you do not need to have detailed cost tracking. If you select this option, ClearTrial sets the service provider’s payments to their completed work.



The Sites Tab allows you to enter the number of sites approved for each location, for each week, in your study. These values are included in the Sites Approved Major Task.

Note that if you opted to track site approvals on a Study Level basis on the Settings Tab, you do not have the option to enter site approvals on a Location Level basis.

## **4.1 Entering Sites Approved**

To enter the number of sites that have been approved:

1. Navigate to the Sites Tab.
2. In the location drop down box, select the location you want to enter data in. This says “All Locations” if, on the Settings Tab, you chose to track at the Study Level for all site approval tasks.
3. Scroll down to the week(s) you are entering actual progress, and enter the number of sites approved during that week. If your enrollment period runs longer than the number of weeks listed, click the “Add Later Week” button to add more weeks.
4. Click Save once you have entered actual progress for each location.



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## Subjects Tab

The Subjects Tab allows you to enter the number of enrolled, randomized subjects for each Location, for each week, in your study. These values are included the Subject/Volunteer Randomized Major Task.

Note that if you opted to track enrollment on an Study Level basis on the Settings Tab, you will not have the option to enter enrolled subjects on a Location Level basis.

### 5.1 Entering Randomized Subjects

To enter the number of subjects that have been randomized:

1. Navigate to the Subjects Tab.
2. In the location drop down box, select the location for which you need to enter data. If you chose to track all locations on a Study Level basis for the Subject/Volunteer Randomized Major Task, the location drop down will say "All Locations."
3. Scroll down to the week(s) you are entering actual progress and enter the number of subjects enrolled during that week.

If your enrollment period starts earlier than you planned, click the Add Earlier Week button to append more weeks to the beginning of the site approval period.

If your enrollment period runs longer than you originally planned, click the Add Later Week button to append more weeks to the end of the site approval period.

4. Click Save.

Repeat the preceding steps to enter all of your data. Once you have entered actual progress for each location, click Next to save your entries and advance to the Monitoring Tab.



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## Monitoring Tab

The Monitoring Tab allows you to record the number of monitored cleaned CRF pages, or EDC equivalent, collected for each week of your study. These values are included in the Clean CRF Page Major Task.

Note that if you opted to track monitoring on an Study Level basis on the Settings Tab, you will not have the option to enter completed CRF pages on a “Per Location” basis.

### 6.1 Entering Collected CRF Pages

To enter the number of clean monitored CRF pages that have been collected:

1. Navigate to the Monitoring Tab.
2. In the location drop down box, select the location for which you need to enter data. If you chose to track all locations on a Study Level basis for the Clean Monitored CRF Page task, the location drop down will say “All Locations.”
3. Scroll down to the week(s) for which you are entering actual progress and enter the number of clean, monitored CRF pages collected during that week.
4. Repeat the preceding steps for each location in the study for which you are entering data.

If your treatment period starts earlier than you had originally planned, click the Add Earlier Week button to append more weeks to the beginning of the site approval period.

If your treatment period runs longer than you originally planned, click the Add Later Week button to append more weeks to the end of the site approval period.

5. Click Save.

Once you have entered actual progress for each location, click Next to save your entries and advance to the Task Units Tab.



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## Task Units Tab

The Task Units Tab allows you to enter the amount of work completed for every major task, for each service provider, for all locations in your study.

To avoid data entry errors, ensure you have selected the desired location before entering data. All actual values entered will be tracked against all Service Providers performing work for the selected location.

### 7.1 Entering Actual Data for Major Tasks

To enter actual data:

1. Navigate to the Task Units Tab.
2. Select the appropriate location from the Locations drop down list, or select All Locations.

If “All Locations” is selected in the drop down, only tasks that were selected to be tracked at the Study Level on the Settings Tab will be applicable for data entry. Any tasks being tracked at a Location Level basis will be grayed out and uneditable. To enter actuals for individual locations, select the location from the Locations drop down.

3. Enter the actual data for each week, or month, for each major task. Data is entered by week or month depending on the track setting selected on the Settings Tab.

The Task Units Tab displays actual data for three months, or three weeks, at a time. To navigate through dates, either use the arrows and the bottom of the columns or select a date from the calendar by clicking the displayed date.

4. Enter all actual data as needed and Click Save when finished.





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## Task Dates Tab

The Task Dates Tab allows you to enter the start and end dates associated with each major task, for every service provider, in all study locations.

### 8.1 Entering Start and End Task Dates

To track the dates that major tasks start and end:

1. Navigate to the Task Dates Tab.
2. Select the service provider for which you are entering data, from the service provider drop down box.
3. Select the location for which you are entering data, from the Location drop down box.
4. For any major task for which you have begun entering work completed, enter the date that task began in the “Started” field. If you have already entered work completed, a start date has been entered automatically by the system. You can override this date with a more exact date if you wish.
5. In the Completed field, enter the date when the major task was completed.



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## Milestone Dates Tab

The Milestone Dates Tab allows you to enter the actual dates for study milestones.

### 9.1 How Payment Settings Affect the Milestone Dates Tab

The payment settings you selected on the payments sub-tab of the Settings Tab affect how dates are entered on the Milestone Dates Tab.

- **Pay Monthly for Work Completed:** If you selected pay monthly for work completed, at either the task or study level, the Milestone Dates Tab will allow you to enter the actual dates that milestone events occurred.
- **Pay for Work Completed upon Milestone Achieved or Pay Fixed Fee upon Milestone Achieved:** If you selected to pay for work completed upon milestone achieved or to pay a fixed fee upon milestone achieved, you will need to enter the actual dates on the Milestone Dates Tab.
- **Enter AP Only (sets AP to EV):** If you selected Enter AP Only, you will need to enter the actual dates on the Milestone Dates Tab.

### 9.2 Entering Milestone Dates

The Milestone Dates Tab is used to enter actual dates for milestones that have been achieved during a specific time period.

To enter milestone dates:

1. Navigate to the Milestone Dates Tab.
2. Review the list of milestones. For any milestones that have been achieved during this period, enter the date the milestone was met by typing the date in the box or by clicking the calendar icon to select a date.
3. The expected milestone date is provided for reference and comes from the plan currently designated as the Baseline Plan for the study you are tracking.
4. Enter all dates as necessary and click Save. The far right column displays the variance between the expected and actual dates.



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## Milestone Payments Tab

The Milestones Payments Tab allows you to enter the actual payments made against the milestone payment schedule for each service provider in your study, if you are paying one or more service providers upon milestones achieved.

### 10.1 How Payment Settings Affect the Milestone Payments Tab

The payment settings you selected on the payments sub-tab of the Settings Tab affect how dates are entered on the Milestone Payments Tab.

- **Pay Monthly for Work Completed:** If you selected pay monthly for work completed, at either the task or study level, the Milestone Payments Tab will be unavailable. Since work is being paid monthly, the actual payments for each milestone do not need to be entered.
- **Pay for Work Completed upon Milestone Achieved or Pay Fixed Fee upon Milestone Achieved:** If you selected to pay for work completed upon milestone achieved or to pay a fixed fee upon milestone achieved, you will need to enter the actual payments on the Milestone Payments Tab.
- **Enter AP Only (sets AP to EV):** If you selected Enter AP Only, the Milestone Payments Tab will be unavailable.

#### 10.1.1 Other Task Payments

The tasks that are not paid per milestone payment schedule are accounted for on the Labor Fees Tab. Enter payments for these tasks on the Labor Fees Tab.

Tasks are included or excluded from the milestone payment schedule based on your selections in the baseline plan on the Payments Tab, in ClearTrial Plan and Source. To view your selections, you can select Plans from the Edit Menu and open the baseline plan.

### 10.2 Entering Milestone Payments

Use the Milestone Payments Tab to enter actual payments for each service provider in your study, based on the milestone payment schedule.

To enter milestone payments:

1. Navigate to the Milestone Payments Tab.
2. Ensure all work has been entered for the reporting period on the Sites, Subjects, Monitoring, and Task Units Tab. This information is used in the Earned Value to

Date column, which is the total cumulative amount you should have paid, in aggregate, at the time the milestone is achieved.

3. Select a service provider from the drop-down box.
4. Review the list of milestones payments. For any milestones that have been achieved during this period, enter the payment in the Actual Payment column.

The Scheduled Payment Column shows the planned payment amounts according to the Milestone Payment Schedule in the Baseline Plan.

The Earned Value to Date Column contains the summation of the earned values entered from the beginning of the study to each milestone.

5. Enter all payments and click Save. The Total row provides totals for both the scheduled and actual payment amounts.

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## Labor Fees Tab

The Labor Fees Tab allows you to enter the fees, or actual payments, accrued for every major task for each service provider at all locations in your study.

This tab allows you to capture recurring payments that are paid outside of the milestone payment schedule and payments for all tasks if you are paying monthly for completed work.

### 11.1 How Payment Settings Affect the Labor Fees Tab

The payment settings you selected on the payments sub-tab of the Settings Tab affect how actual payments are entered on the Labor Fees Tab.

- **Pay Monthly for Work Completed:** If you selected pay monthly for work completed, at either the task or study level, enter the actual payments for each major task for every month included in the study.
- **Pay for Work Completed upon Milestone Achieved or Pay Fixed Fee upon Milestone Achieved:** If you selected pay for work completed upon milestone achieved or pay a fixed fee upon milestone achieved for any of the service providers in your study, you cannot enter the actual payments. These payments are accounted for on the Milestone Payments Tab.
- **Enter AP Only (sets AP to EV):** If you selected enter payments only for any of the service providers in the study, Labor Fees Tab is unavailable because their payments are not being tracked at the major task level.

### 11.2 Recording Labor Fees

To record labor fees:

1. Navigate to the Labor Fees Tab.
2. Select the service provider and Location for which you are entering fees.
3. Enter (or scroll to) the date period for which you are entering fees.

Most invoices state that “fees are for work completed during the period of September 2010” or something similar. Be sure that you are entering fees into the month that corresponds with what is stated on the invoice. This is usually not the invoice date, as invoices often lag work performed by a month or more.

4. On the Actual line, enter the amount invoiced for each item.
5. When finished entering fees for one location, select the next location (at the top of the page) that this service provider is servicing, and repeat the preceding steps.

6. When finished entering fees for all locations for the service provider, select the next service provider for whom you have an invoice, and repeat the preceding steps.



The Costs Tab allows you to enter the actual costs accrued against the miscellaneous costs in your plan, for each service provider, at each location in your study.

## 12.1 How Cost Settings Affect the Costs Tab

The cost settings you selected on the costs sub-tab of the Settings Tab affect how actual costs are entered on the Costs Tab.

- **Enter AP Only (sets AP to EV):** If you selected “Enter AP Only (sets AP to EV),” ClearTrial will set the earned value for a tracking period to be the actual value entered. This option requires less data entry, but may not be as accurate when determining the tracking progress of the study.
- **Enter EV and AP:** If you selected “Enter EV and AP” for how a cost will be tracked, then the earned value and payment are entered on the Costs Tab. This option allows you to track the earned value and actual payment against the planned value.
- **Derived:** Any miscellaneous, or pass-through costs, that are derived cannot be edited on the Costs Tab. Derived costs are determined by the baseline plan.

## 12.2 Entering Costs

To enter costs:

1. Navigate to the Costs Tab.
2. Select the appropriate service provider from the service provider drop down list.
3. Select the appropriate location from the locations drop down list, or select All Locations.

If “All Locations” is selected in the drop down, only tasks that were selected to be tracked at the Study Level on the Settings Tab will be applicable for data entry. Any tasks being tracked at a Location Level basis will be grayed out and uneditable. To enter actuals for individual locations, select the location from the Locations drop down.

4. Enter actual costs as needed. Costs are entered per week or month depending on your track settings.

For miscellaneous costs that you selected to Enter EV and Payments on the Settings Tab, there is a field to enter the earned value and another field to enter the actual payment.

For costs that you selected Enter Payments Only on the Settings Tab, there is one field to enter the actual value. The earned value will be automatically set to equal the actual value entered.

5. Enter actuals for all service providers, in each location in the study.

To avoid data entry errors, please ensure you have selected the desired service provider and location before entering data. Note that ClearTrial provides the ability for you to enter data for any possible combination of service provider and location for all of the service providers and locations in the study, regardless of whether or not miscellaneous costs apply to each combination. This allows you to capture unplanned costs.

If you accumulate any significant amount of unplanned costs, it is recommend that you reforecast the baseline plan to ensure the most accurate earned value calculations.

6. Click Save when finished.

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## Summary Tab

The Summary Tab provides a project dashboard view of your study's progress. The Summary Tab contains four portlets: Project Health, Current Status, Summary Performance Trend, and Projected At Completion.

### 13.1 Arranging Summary View

The Summary Tab allows you to hide any portlets from your view. To hide a portlet, remove the check from the box next to the name of the portlet at the top of the page, or click the Close button on the portlet.

### 13.2 Detailed Summary View

For a detailed view of study performance, click the Detail link in the lower right-hand corner of the Project Health, Current Status, or Projected At Completion portlets. These links will take you to the control panel for the Tracking Detail Report.

### 13.3 Project Health Portlet

The Project Health Portlet provides the Schedule Performance (SP), Budget Performance (BP), and the Overall Performance (OP) for the labor fees and costs in your study. The cells containing these values are colored green, yellow, or red to indicate project health.

If you have any values that do not have a color, it means the study is exceeding expectations. If this is the case, your data should be reviewed to ensure there are no errors.

- **Green:** Indicates a healthy project. No changes need to be made and the project is proceeding according to plan.
- **Yellow:** Indicates a warning that the project is starting to deviate from the plan. The project's performance should be evaluated in detail.
- **Red:** Indicates a warning that the project has significantly deviated from the plan. Operational changes are needed to bring the project back in alignment with the plan.
- **Schedule Performance (SP):** The Schedule Performance (SP) is used to predict the completion date and is sometimes used in conjunction with the Budget Performance (BP) to forecast the project completion estimates. An SP value less than 1.0 indicates the project is behind schedule. An SP value greater than 1.0 indicates the project is ahead of schedule.

- **Budget Performance (BP):** The Budget Performance (BP) is a commonly used cost-efficiency indicator. A BP value less than 1.0 indicates a cost overrun of the estimates. A BP value greater than 1.0 indicates a cost underrun of the estimates.
- **Overall Performance (OP):** The Overall Performance combines the Schedule Performance (SP) and the Budget Performance (BP) to provide an overall project health indicator.

An Overall Performance (OP) value less than 1.0 indicates composite cost or schedule overruns. An OP value greater than 1.0 indicates composite cost or schedule underruns.

## 13.4 Current Status Portlet

The Current Status Portlet provides the fundamental earned value metrics for your project.

- **Planned Value (PV):** PV is the budgeted cost for the work scheduled to be completed on an activity or work breakdown structure component.
- **Earned Value (EV):** EV is the budgeted amount for the work actually completed on the schedule activity or work breakdown structure component.
- **Actual Payments (AP):** Total costs actually incurred and recorded in accomplishing work performed for a schedule activity or work breakdown structure component. Actual cost can sometimes be direct labor hours alone, direct costs alone, or all costs including indirect costs.
- **Cost Variance (CV):** The cost variance at the end of the project will be the difference between the budget at completion (BAC) and the actual amount spent.
- **% Complete:** Percent complete equals the Earned Value to date divided by total project budget, or BAC.

## 13.5 Study Performance Trend Portlet

The Study Performance Trend Portlet shows the Actual Payments (red), Earned Value (blue), and the Planned Value (green) across the entire timeline and costs of the study.

To see the value at any point on one of the lines, place your mouse pointer over the line. To zoom in to a section of the chart, click and drag your mouse over a desired section. To return to the all-study view, double click within the chart.

## 13.6 Projected at Completion Portlet

The Projected at Completion Portlet provides you with predictions of conditions in the project's future based on the current information available.

- **Estimate to Complete (ETC):** The Estimate to Complete (ETC) is the estimated cost required to complete the remainder of the project given your current actual payments for the project and your current budget performance.

To calculate the ETC, the Budget at Complete (BAC) is divided by the current Budget Performance (BP), and the current Actual Payments (AP) are subtracted. Formula:  $ETC = (BAC / BP) - AP$

- **Budget at Complete (BAC):** The Budget at Complete (BAC) is the total original planned project budget. The BAC represents the sum of all Planned Values (PV) for the project at completion.

- **Estimate at Complete (EAC):** Estimate at Complete (EAC) is the total estimated cost at the end of the project.

To calculate the EAC, the Budget at Complete (BAC) is divided by the current Budget Performance (BP). Formula:  $EAC = BAC / BP$

- **Variance at Complete (VAC):** Variance at Complete (VAC) is the difference between the original planned project Budget at Complete (BAC) and the Estimate at Complete (EAC), calculated based on your current performance.

Formula:  $VAC = BAC - EAC$ .

- **Study Completion Date:** The Planned Study Completion Date is the Final Report milestone date from the Baseline Plan.

The Estimated Study Completion Date is calculated by using your original planned study duration and applying your current Schedule Performance (SP). Formula:  $(Planned\ Start\ Date) + (Planned\ Study\ Duration / SP)$

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**Note:** The estimated date calculation is capped at 4 times the study length. If the date exceeds this cap, N/A will be displayed.

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The Reports Tab contains detailed reports that provide valuable information related to study progress and overall health.

## 14.1 Reports

Described below are the ClearTrial Track reports.

- **Site Approval Schedule:** The Site Approval Schedule Report shows the site approval curve for the entire study over time. It displays both the planned and actual values. This report can be run at the study level or per location.
- **Subject Enrollment:** The Subject Enrollment Report shows the subject enrollment curve for the entire study over time. It displays both the planned and actual values. This report can be run at the study level or per-location.
- **CRF Pages:** The CRF Pages Report shows the distribution of collected CRF pages over time. It displays both the planned and actual values. This report can be run at the study level or per-location.
- **Milestone Dates:** The Milestone Dates report displays the project milestone dates from Project Activity Start Date to Final Report. This report shows both the planned and actual values.
- **Study Performance Trend Report:** The Study Performance Trend Report displays Earned Values (EV), Planned Values (PV), and Actual Payments (AP) over time.
- **Milestone Payment Schedule:** This report displays a printable view of the detailed milestone payment history.
- **Tracking Summary:** The Tracking Summary Report displays a printable view of the Project Health, Current Status, Cash Flow Analysis, and Projected At Completion from the ClearTrial TRACK Summary Tab. This report can be run for all service providers or a selected one.
- **Tracking Detail:** The Tracking Detail Report provides a granular view of the project health. Providers and locations can be filtered to be included or excluded. The report can be rung with major tasks, miscellaneous costs, or both, and earned value metrics can be selected. This report displays locations and providers that are not performing well, and the major tasks that cause the underperformance.
- **Accruals:** The Accruals Report provides a view of work performed, actual payments, and the remaining cost accrual for work that has been performed but for which has not been paid. It can be displayed to show a period of time, cumulative for a project to date, for one or more providers and other parameters.





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## Utilizing Reports

The reports available on the Reports Tab can be used to produce sets of data that can help determine if a tracked study is on schedule with the baseline plan.

### 15.1 Identifying Underperforming Locations and Tasks

Use the Tracking Detail Report to determine the most significant causes of an underperforming study and to get information to help you make a decision on how to respond.

The Tracking Detail Report provides a granular view of the project health. Providers and locations can be filtered to be included or excluded. The report can be rung with major tasks, miscellaneous costs, or both, and earned value metrics can be selected.

This report displays locations and providers that are not performing well, and the major tasks that cause the underperformance.

#### 15.1.1 Generating the Tracking Detail Report

To generate the Tracking Detail Report:

1. Login to the application.
2. Select Studies from the Edit menu to display the Study List Screen. Open a tracked study and navigate to the Reports Tab. Select the Tracking Detail Report.
3. Select the following report options to focus on a specific location's performance:
  - Select Roll-up by Location
  - Verify the View as of Date
  - Select Show Earned Value Metrics
  - Select report data based on what you want to include in your assessment
  - Check All Locations
  - Check All Providers
4. Click OK.
5. Scroll down to the location being evaluated and review the overall row of the Tracking Detail Report to view the location's performance.

If Overall Performance (OP), Schedule Performance (SP), and Budget Performance (BP) are red, the location may be underperforming.

### 15.1.2 Deciding What to Update in the Plan

After it has been determined that the location(s) and major task(s) are causing the performance issues, the changes needed to get the plan back on schedule should be discussed. These changes can be modeled with the reforecasting feature to see how each scenario will affect the budget.

## 15.2 Reconciling Service Provider Invoices and Work Performed

The Accruals Report can be used to reconcile provider invoices against actual work performed.

The Accruals Report provides a view of work performed, actual payments, and the remaining cost accrual for work that has been performed but for which has not been paid. It can be displayed to show a period of time, cumulative for a project to date, for one or more providers and other parameters.

### 15.2.1 Generating the Accruals Report

To generate the Accruals Report:

1. Navigate to the Study List Screen.
2. Open a tracked study and navigate to the Reports Tab.
3. Open the Accruals Report. Select the provider from whom the invoice was received.
4. Under the Level of Detail:
  - Select Summary to see an aggregate figure for labor and costs. This option is recommended if this is the first comparison of this invoice in ClearTrial
  - Select Detail for more detail, or to included or exclude any combination of labor and costs. This option is recommended if a discrepancy between the invoice amount and the records in ClearTrial are being investigated.
5. Confirm the Study Status Date is the same or later than the billing period date on the invoice.
6. Set the Time Line Options on the Accruals Report to be the same as the billing period start and end dates.

Note the start and end dates are the period being billed. This often says “for work performed from xx/xx to xx/xx” on the invoice.
7. Verify the include / exclude options are consistent with what appears on the invoice.
8. Confirm the reporting currency is consistent with the invoice.
9. Click Ok.

## 15.3 Comparing Invoice Amounts and Earned Value

Earned Value (EV) and the Actual Payment (AP) can be viewed on the Accruals Report. Earned Value should be the same as the amount on the invoice for work performed in the period displayed. Actual Payment is the amount that has been paid or invoiced by the provider for the period displayed.

### 15.3.1 If Invoice Amount Equals EV

To pay an invoice if total EV equals the amount on the invoice:

1. Mark the invoice as “approved to pay.”
2. Enter the invoiced amounts into the Labor Fees and Costs Tabs.
3. Route the invoice to finance as “approved to pay.”

Finance can then schedule the invoice for payment in the A/P system.

### 15.3.2 If Invoice Amount Does Not Equal EV

To pay an invoice if total EV does not equal the amount on the invoice:

1. Open the Accruals Report on the Reports Tab.
2. Select Detail under the Level of Detail section.
3. Compare the earned value for each major task against the line item detail on the invoice to determine the discrepancy.

### 15.3.3 Using ClearTrial Invoice and Activity Report Templates

In addition to the Accruals Report for approving invoices, other reports can be used to benefit the finance department.

- Milestone Payment Schedule Report
- Tracking Summary Report

## 15.4 Generating Project Cost Accruals

The reports in ClearTrial TRACK can be used to quickly and accurately report project cost accruals. This is the cost incurred, but has not been invoiced. This accrual is a financial liability that must be accounted for in most company’s financial reporting.

### 15.4.1 Prepare the Accruals Report

The Accruals Report provides a view of work performed, actual payments, and the remaining cost accrual for work that has been performed but for which has not been paid. It can be displayed to show a period of time, cumulative for a project to date, for one or more providers and other parameters.

To prepare the Accruals Report:

1. Login to the application.
2. Select Studies from the Edit menu to display the Study List Screen. Open a tracked study and navigate to the Reports Tab. Open the Accruals Report.
3. Select All Providers.
4. Determine the level of detail to be displayed on the report:
  - Select Summary to see aggregate figures for labor and costs
  - Select Detail to see more detail or to include / exclude any combination of these
5. Confirm the Study Status Date is the same or later than the accrual period being reported.

6. Set a specific date under the Time Line Options so the Start Date is the beginning of the study and the end date is the date through when accrual is being reported.
7. Confirm the reporting currency.
8. Click Ok.

#### **15.4.1.1 Viewing Costs Accrued During a Time Window**

The Accrual Column on the left side of the Accrual Report displays the fees and costs accrued during the date period shown.

#### **15.4.1.2 Viewing Cost Accrual as of the Latest Work Performed**

The right side of the Accrual Report displays the accrual from inception of the project to the latest date of progress entries. This accrual value is what is typically reported as the current accrual.

#### **15.4.1.3 Viewing Cost Accrual Through a Specific Date**

To view what the accrual was from project inception up until a specific date, set the start date to be the beginning of the project and the end date to be the accrual date desired.

## **15.5 Assessing Provider Performance**

ClearTrial Track Reports can be used to measure provider performance on a project. Below is a recommended method for how to measure performance.

To assess provider performance:

1. Login to the application.
2. Select Studies from the Edit menu to display the Study List Screen.
3. Select the study being evaluated. Click TRACK and select View Summary.
4. On the Summary Tab, select the provider being evaluated.
5. Click Detail at the bottom of any summary panel to view the Tracking Detail Report.
6. On the report options page, select Roll-up by Provider.

Depending on what is considered when assessing a provider's performance, it may also be appropriate to include or exclude pass-through costs.

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## Reforecasting

While working with tracked studies in Oracle Health Sciences ClearTrial Track Cloud Service, you may need to reforecast a plan and set it as the baseline plan. A plan might need to be reforecasted due to protocol amendments or changes in actuals that need to be tracked.

### 16.1 Reforecasting a Plan

Any plan can be reforecasted. Reforecasting enables users to model one or more multiple assumption changes, with the impact being applied from a chosen point in time.

All sequential reforecasting events can be captured as the project progresses, allowing the user to see the updated planned value of a trial and to take into account the assumption changes that have occurred or are planned to occur.

Reforecasting looks at tasks that are distributed over time and at the date the user specifies, freezes the planned activity at that date. This allows the user to then modify the remaining distribution based on changes that they make to the drivers.

#### 16.1.1 Generate a Reforecast

To reforecast a plan:

1. From the Plan List Screen, select the plan to be reforecasted.
2. Click the Other Actions button and choose Create Reforecast from the drop down menu.
3. Enter a name for the reforecasted plan and select a reforecast date. Click Ok.
4. Make any necessary edits to the plan and click save.

### 16.2 Setting the Reforecasted Plan as the Baseline

After a plan has been reforecasted and adjusted, it can be set as the baseline plan if the plan needs to be tracked. However, when a reforecasted plan is set as the baseline plan, it is locked and can no longer be edited in the Oracle Health Sciences ClearTrial Plan and Source Cloud Service module.

To set a reforecasted plan as the baseline plan:

1. Navigate to the Plan List Screen and select your reforecasted plan.
2. Click the Other Actions... button and choose Set as Baseline from the drop down list.

A warning message is displayed, informing you that setting this plan as the new baseline will allow you to track against the changes to the operational plan reflected in the reforecast. Once the plan is baselined, it is locked and can no longer be edited.

3. Click Ok.
4. Go the Study List Screen and select your study.
5. Click the Track button and choose Enter Actuals to begin tracking.