Oracle® Health Sciences ClearTrial Cloud Service

TRACK User Guide

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Oracle Health Sciences ClearTrial Cloud Service TRACK User Guide, Release 5.4

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Contents

3 Track Screen and Dialog Box Field Descriptions

Preface

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

Audience

This document is for users working with the Oracle Health Sciences ClearTrial Track Cloud Service application.

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Related Documents

For more information, see the following documents in the Oracle Health Sciences ClearTrial Cloud Service Release 5.4 documentation set:

- *Oracle Health Sciences ClearTrial Cloud Service 5.4 Release Notes*
- *Oracle Health Sciences ClearTrial Cloud Service 5.4 Plan and Source User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.4 System Administrator User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.4 Web Services API User Guide*
- *Oracle Health Sciences ClearTrial Cloud Service 5.4 Third Party Licenses and Notices*

1

Getting Started: Basics and Common Tools

This chapter covers the basic functions and tools you can use to manage clinical studies after they are underway.

Using ClearTrial Track to Manage a Study Budget

The ClearTrial Track module is used in conjunction with the ClearTrial Plan and Source module.

You can create plans and set them as baseline plans in Plan and Source, then use Track to manage the study budget. You can access the Track features and capabilities if your organization has a subscription.

The Baseline Plan Supplies the Values to Track

The baseline plan you create in Plan and Source populates the planned values in Track. The baseline plan is your estimate of how much a study is going to cost and how long it is going to take to complete. Tracking the baseline plan after a study is underway provides you with information to assess study progress.

Baseline Plans are Locked

When you set a plan as the baseline, it becomes locked and you can no longer edit it. If changes need to be made while the study is being tracked, the baseline plan can be unlocked from the Plans screen. Any changes made are reflected in the tracked study. For more information, see Locking and Unlocking Baseline Plans.

Planned vs. Actual Values

The planned values the application displays are supplied by the baseline plan you select to track.

The actual values are the values you enter as the study is underway. You can compare actual values with the planned values to assess your study performance.

Enter Actual Values

In the application, you can enter actuals by location or by study level. To avoid data entry errors while tracking by location, ensure you select the correct location before entering data. If you are tracking by study level, you do not have the option to select a location.

A Tabbed Interface Guides You through Tracking a Study

You enter actuals for a tracked study on the Edit Actuals screen. This screen provides access to a set of data entry screens accessed by clicking tabs on the left side of the screen. The tabs appear in a specific order that steps you through a logical approach to entering actuals.

As you complete a tab, you can click **Next** to go to the next tab. The application highlights the corresponding tab on the left.

Roadmap: Tracking a Study

Table 1–1 Roadmap: Tracking a Study

Step	Action	Description
1	Create a product.	1. From the Edit menu, select **Products**. The Products screen appears. 2. Click **New**. The Create Product screen appears. 3. Enter the product details. For more information about a field, click the field name. 4. Click **Save**.
2	Create a study.	1. From the Edit menu, select **Studies**. The Studies screen appears. 2. Click **New**. The Create Study screen appears. 3. Enter general information, therapeutic and indication information, and a description or note. For more information about a field, click the field name. 4. Click **Save**.
3	Create a plan	1. From the Edit menu, select **Plans**. The Plans screen appears. 2. Click **New**. The Choose Study and Plan Template dialog box appears. 3. Select the checkbox of the study for which you are creating a plan. 4. Select a template checkbox. 5. Click **Ok**. The Create Plan screen appears. 6. Enter the fields as necessary. For more information about a field, click the field name. 7. Click **Save**. The application adds the plan to the Plans screen.
4	Set the plan as the baseline plan.	The baseline plan is a plan that has been approved as the operational plan for the study and contains the final agreed-upon assumptions. There are two methods for setting the baseline plan. For more information, see Setting the Baseline Plan.

Table 1–1 (Cont.) Roadmap: Tracking a Study

Step	Action	Description
5	Select tracking settings.	The tracking settings must be selected before you can begin entering actuals. Select these settings on the Settings tab of the Edit Actuals screen. For more information, see Select Track Settings for a Study: Settings Tab.
6	Enter actuals on the Edit Actuals screen.	
7	Save.	

Working with Tracked Studies

This section provides information on how to perform tasks and functions that apply to all tracked studies.

Viewing Tracked Studies on the Studies Screen

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

   The Studies screen appears. Tracked studies have a tracking icon in the far right column.

Entering Actuals for a Tracked Study

1. On the Studies screen, select the checkbox of the study for which you want to enter actuals.
2. Click **Track** and select **Enter Actuals**.
3. Click **Ok**.

   The Edit Actuals screen appears.
4. Enter study actuals using the tabs on the left side of the screen. Click **Next** to proceed to the next tab.
   - For more information about a field, click the field name.
   - For more information about the fields for study actuals, see Chapter 3, "Track Screen and Dialog Box Field Descriptions.".
5. Click **Save**.

Locking and Unlocking Actuals

You can lock actuals for a tracked study to prevent users from editing data.

1. On the Studies screen, select the checkbox of the study for which you want to lock or unlock actuals.
2. Click **Track** and select **Lock Actuals** or **Unlock Actuals**.

Copying Actuals

1. On the Studies screen, select the checkbox of the study for which you want to copy actuals.
2. Click **Track** and select **Copy Actuals**.

   The Copy Actuals dialog box appears.

3. In the **Study Name** field, enter a study name.
4. In the **Plan Name** field, enter a plan name.
5. Click **Ok**.

   The application creates a new plan and study with the copied actuals.

Viewing the Tracked Study Summary

1. On the Studies screen, select the checkbox of the study for which you want to view a summary.
2. Click **Track** and select **View Summary**.

   The Summary screen appears. The Summary screen provides an overview of the study's budget health.

   - For more information, see Evaluate your Study's Progress: Summary Tab.

Viewing Reports for a Tracked Study

1. On the Studies screen, select the checkbox of the study for which you want to view study reports.
2. Click **Track** and select **View Reports**.

   The Reports screen appears. The Reports screen provides reports you can view to evaluate your study's progress.

   - For more information, see Generate Tracking Reports: Reports Tab.

Working with Baseline Plans

This section provides information on how to work with baseline plans.

Setting the Baseline Plan

There are two methods for setting the baseline plan.

To set the baseline plan from the Plans screen:

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

   The Plans screen appears.
2. Select the checkbox of the plan.
3. Click **Other Actions** and select **Set as Baseline**.

   The Set Baseline dialog box appears.
4. From the **Plan State** drop-down list, select a plan state.
5. Click **Ok**.

   The application sets the plan as a baseline plan and locks the plan.

To set the baseline plan from the Studies screen:

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

   The Studies screen appears.
2. Select the checkbox of the study.

3. Click **Track** and select **Enter Actuals**.

   The Choose a Plan to use as Baseline dialog box appears.

   or

   The Edit Actuals screen appears, if there is only one plan available to set as the baseline plan.

4. Select the checkbox of a plan to set as the baseline plan.

5. Click **Ok**.

   The Edit Actuals screen appears.

6. Edit the fields as necessary. For more information about the field, click the field name.

7. Click **Save**.

Locking and Unlocking Baseline Plans

A baseline plan is locked by default when it is set as a baseline plan. You can unlock a baseline plan to edit the plan. Edits made to the baseline plan are reflected in the associated tracked study.

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

   The Plans screen appears.

2. Select the checkbox of a baseline plan. Baseline plans have a baseline status.

3. Click **Other Actions** and select **Lock Plans** or **Unlock Plans**.

Reforecasting Baseline Plans

You can reforecast a plan and set it as the baseline plan while tracking a study. Reforecasting allows you to model 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 you to take into account the assumption changes that have occurred or are planned.

Reforecasting looks at tasks that are distributed over time and at the date you specify, and freezes the planned activity at that date.

Reforecasting a Baseline Plan

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

   The Plans screen appears.

2. Select the checkbox of the plan.

3. Click **Other Actions** and select **Create Reforecast**.

   The Create Reforecast dialog box appears.

4. In the **Reforecast Name** field, enter a reforecast name.

5. In the **Reforecast Date** field, select a reforecast date.

   The application calculates activities that have already occurred or costs that have already been incurred according to any tracking data available, allowing the application to predict the impacts of work remaining.

6. Select the **radio button**, either **Actual Values** or **Planned Values**.
7. Click **Ok**.

   The Edit Reforecast screen appears.
8. Edit the fields as necessary. For more information about a field, click the field name.
9. Click **Save**.

Setting the Reforecasted Plan as the Baseline Plan

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

   The Plans screen appears.
2. Select the checkbox of the plan you reforecasted. Reforecasted plans have a status of Reforecast Effective.
3. Click **Other Actions** and select **Set as Baseline**.

   A message appears, informing you that setting this plan as the new baseline allows you to track against the changes you made.
4. Click **Ok**.

   The reforecasted plan is set as the baseline plan.

2
Tracking Studies

This chapter provides information on tracking studies.

Select Track Settings for a Study: Settings Tab

The options on the Settings tab determine how you enter tracking data on the Edit Actuals screen.

Opening the Settings Tab

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

   The Studies screen appears.
2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Settings** tab.

   The Settings tab appears.

   For more information about the fields on this screen, see Settings Tab Fields.

Selecting a Tracking Interval

You can select either the monthly or weekly interval to track a study. This setting determines whether you can enter actuals weekly or monthly on the rest of the tabs on the Edit Actuals screen.

1. In the **Track this study** field, select **Monthly** or **Weekly**.
2. Click **Save**.

Entering a Study Status Date

The Study Status Date is the date through which progress reporting is complete. The application uses this date as the cutoff date for EVA calculations. Update this field as the study progress and actuals are entered.

1. In the **Study Status Date** field, enter the date or click the calendar icon to select a date.
2. Click **Save**.

Selecting a Tracking Level for Major Tasks and Miscellaneous Costs

1. Click the **Major Tasks** tab or the **Costs** tab.
2. Select a tracking level for each major task or miscellaneous cost. The application applies this setting to the rest of the tabs on the Edit Actuals screen.
   - **Study Level—**Track the major task or cost on a study-wide basis.
   - **Location Level—**Track the major task or cost on a per-location basis. You can enter actuals for each location in the study.
   - **Not Tracked—**Do not enter actuals for a major task or cost.
3. Click **Save**.

Selecting Earned Value Options for Miscellaneous Costs

1. Click the **Costs** tab.

   A list of miscellaneous costs appears.
2. In the Earned Value Options column, select an earned value option for each miscellaneous cost.
   - **Enter AP Only (sets AP to EV)—**Enter the values that have been paid. The application sets the earned value to be equal to what is entered for the actual payment.
   - **Enter EV and AP—**Track separately what is reported as earned based on completed work and what is actually paid.
   - **Derived—**The application selects this option by default for certain costs that are driven from completed work. You can only select derived for costs that are defined with a task-based cost driver.
3. Click **Save**.

Selecting How Payments are Tracked for each Service Provider

1. Click the **Payments** tab.

   A list of service providers in the study appears.
2. In the payment tracking options column, select a payment option for each service provider.
   - **Study Level—**Track the major task or cost on a study-wide basis.
   - **Location Level:** Track the major task or cost on a per-location basis. You can enter actuals for each location in the study.
   - **Pay for work completed upon milestone achieved—**Track actual costs according to the Milestone Payment schedule in the baseline plan and pay for work completed based on milestones achieved. This option is not available for tracking the sponsor’s internal costs.
   - **Pay fixed fee upon milestone achieved—**Track actual costs according to the Milestone Payment schedule in the baseline plan and pay a fixed fee based on milestones achieved.
   - **Enter AP Only (Sets AP to EV)—**Select this option if you do not need detailed cost tracking. If you select this option, the application sets the service provider’s payments to their completed work.

3. Click **Save**.

Enter Approved Sites: Sites tab

On the Sites tab, you enter the number of sites approved for each location, for each week, in the study. The application uses these values for the completed units of work for the sites approved major task.

If you opted to track enrollment on a Study Level basis on the Settings tab, you do not have the option to enter enrolled subjects on a Location Level basis.

The values in the Planned to Date and Planned Sites This Week columns are supplied by the baseline plan you selected to track.

Opening the Sites Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Sites** tab.

   The Sites tab opens, allowing you to enter the number of approved sites for each location in the study.

   For more information about the fields on this screen, see Sites Tab Fields.

Enter Approved Sites for each Week

1. From the **Location** drop-down list, select a location.
2. For each week in the study, in the **Approved Sites This Week** field, enter the number of sites approved.
3. Click **Save**.

Adding a Later Week

1. From the **Location** drop-down list, select a location.
2. Click **Add Later Week**.

   The application adds another week to the bottom of the weeks list.

3. Click **Save**.

Enter Enrolled Study Subjects: Subjects Tab

On the Subjects tab, you enter the number of enrolled, randomized subjects for each location, for each week, in the study. The application uses these values for the completed units of work for the subject/volunteer randomized major task.

If you opted to track enrollment on a Study Level basis on the Settings tab, you do not have the option to enter enrolled subjects on a Location Level basis.

The values in the Planned to Date and Planned Subjects This Week columns are supplied by the baseline plan you selected to track.

Opening the Subjects Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Subjects** tab.

   The Subjects tab appears, allowing you to enter the number of enrolled subjects per week.

   For more information about the fields on this screen, see Subjects Tab Fields.

Entering Enrolled Subjects for Each Week

1. From the **Location** drop-down list, select a location.
2. For each week, enter the number of enrolled subjects.
3. Click **Save**.

Adding Earlier and Later Weeks

1. From the **Location** drop-down list, select a location.
2. Click **Add Earlier Week** or **Add Later Week**.

   - By default, the last week shown is the week of the Last Subject/Patient In (LSI/LPI) milestone. To capture subjects that were enrolled after the planned LSI/LPI, click **Add Later Week**.
   - The first week shown is the week of the First Subject/Patient In (FSI/FPI) milestone. To capture subjects that were enrolled before the planned FSI/FPI click **Add Earlier Week**.

3. Click **Save**.

   The application adds another week to the list.

Enter Completed Case Report Forms: Monitoring Tab

On the Monitoring tab, you enter the number of Case Report Form (CRF) pages, or Electronic Data Capture (EDC) equivalent, collected for each week in the study. The application uses these values for the completed units of work for the Monitored, Clean CRF Page major tasks.

If you opted to track monitoring on a Study Level basis on the Settings tab, you do not have the option to enter completed CRF pages on a Location Level basis.

The values in the Planned to Date and Planned CRF Pages This Week columns are supplied by the baseline plan you selected to track.

Opening the Monitoring Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Monitoring** tab.

   The Monitoring tab appears, allowing you to enter the number of completed CRF pages per week.

   For more information about the fields on this screen, see Monitoring Tab Fields.

Entering the Number of Completed CRF Pages

1. From the **Locations** drop-down list, select a location.
2. For each week in the study, in the **Completed CRF Pages This Week** column, enter the number of completed CRF pages.
3. Click **Save**.

Adding Earlier and Later Weeks

1. From the **Locations** drop-down list, select a location.
2. Click **Add Earlier Week** or **Add Later Week**.
   - By default, the last week shown is the week of the Last Subject/Patient In (LSI/LPI) milestone. To capture subjects that were enrolled after the planned LSI/LPI, click **Add Later Week**.
   - The first week shown is the week of the First Subject/Patient In (FSI/FPI) milestone. To capture subjects that were enrolled before the planned FSI/FPI click **Add Earlier Week**.
3. Click **Save**.

   The application adds another week to the list.

Track Work Completed by Service Providers: Task Units Tab

On the Task Units tab, you enter the amount of work completed for each major task, for each service provider, at each location in the study. Major tasks are groups of tasks, or labor, that is being completed for the study.

The values in the planned fields for each major task are supplied by the baseline plan you selected to track.

Opening the Task Units Tab

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

   The Studies screen appears.
2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Task Units** tab.

The Task Units tab opens, allowing you to enter the amount of work completed for each major task.

For more information about the fields on this screen, see Task Units tab Fields.

Entering Completed Work for Major Tasks

1. From the **Service Provider** drop-down list, select a service provider.

   Major tasks assigned to the service provider appear.

2. From the **Locations** drop-down list, select a location.
3. For each major task, in the **Actual** field, enter the amount of work completed.
4. Click **Save**.

Track Dates for Work Completed by Service Providers: Task Dates Tab

On the Task Dates tab, you enter the start and end dates associated with each major task, for each service provider, at each location in your study.

Task dates are the start and end dates for when work was completed for a major task. Major tasks are groups of tasks, or labor, that is being completed for the study.

The started and completed dates in the Planned column are supplied by the baseline plan you selected to track.

The Variance (days) column displays the number of days that lapsed between the date you planned and the actual date.

Opening the Task Dates Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Task Dates** tab.

   The Task Dates tab appears, allowing you to enter the start and end dates associated with each major task.

   For more information about the fields on this screen, see Task Dates Tab Fields.

Entering the Start and Completed Dates

1. From the **Service Provider** drop-down list, select a service provider.

   Major tasks assigned to the service provider appear.

2. From the **Locations** drop-down list, select a location.
3. For each major task, in the Actual column, enter the date or click the calendar icon to select a date.
4. Click **Save**.

Track Dates for Study Milestones: Milestone Dates Tab

On the Milestone Dates tab, you enter the start dates for study milestones. Study milestones are major events that take place during a study. Milestones are populated by the baseline plan you selected to track.

The Variance (days) column displays the number of days that lapsed between the expected date and the actual date.

Opening the Milestone Dates Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.

3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Milestone Dates** tab.

   The Milestone Dates tab appears, allowing you to enter milestone start dates.

   For more information about the fields on this screen, see Milestone Dates Tab Fields.

Entering Dates Study Milestones Occur

1. For each milestone, in the Actual column, enter the date or click the calendar icon to select a date.

2. Click **Save**.

Track Payments Made Against the Milestone Payment Schedule: Milestone Payments Tab

On the Milestone Payments tab, you can enter the actual payments made against the milestone payment schedule for each service provider. Values displayed only include items you have chosen to track.

Milestone payments are made at a study milestone. All monetary values are displayed in US dollars.

Opening the Milestone Payments Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.

3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Milestone Payments** tab.

   The Milestone Payments tab appears, allowing you to enter milestone start dates.

   For more information about the fields on this screen, see Milestone Dates Tab Fields.

Entering Actual Payments

1. From the **Service Provider** drop-down list, select a service provider.

   Study milestones associated with the service provider appear.

2. For each milestone, in the Actual Payment column, enter the amount paid.
3. Click **Save**.

Track Labor for Service Providers: Labor Fees Tab

On the Labor Fees tab, you enter the fees accrued for each major task, for each service provider, at each location in the study.

The application provides the ability for you to capture unplanned costs. You can enter data for all service providers and locations in the study, regardless of whether planned fees exist for each combination. Oracle recommends that if you accumulate significant unplanned costs, you reforecast the baseline plan to ensure the earned value calculations are accurate. For more information about reforecasting, see Reforecasting Baseline Plans.

If your payment schedule indicates that a payment occurs later than the predicted study end date, the application moves that payment date to the study end date. Enter your actual payment on this date.

Opening the Labor Fees Tab

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

   The Studies screen appears.

2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.

4. Click the **Labor Fees** tab.

   A list of major tasks appears, allowing you to enter labor fees.

   For more information about the fields on this screen, see Labor Fees Tab Fields.

Entering Actual Fees for Major Tasks

1. From the **Service Provider** drop-down list, select a service provider.

   A list of major tasks associated with the service provider appears.

2. From the **Locations** drop-down list, select a location.
3. For each major task, in the **Actual** field, enter the labor fees.
4. Click **Save**.

Track Costs for Each Service Provider: Costs Tab

On the Costs tab, you enter costs accrued against the miscellaneous and pass-through costs in your study for each service provider, at each location in your study.

The application provides the ability for you to capture unplanned costs. You can enter data for all service providers and locations in the study, regardless of whether miscellaneous costs apply to each combination. Oracle recommends that if you accumulate significant unplanned costs, you reforecast the baseline plan to ensure the earned value calculations are accurate. For more information about reforecasting, see Reforecasting Baseline Plans.

If your payment schedule indicates that a payment occurs later than the predicted study end date, the application moves that payment date to the study end date. Enter your actual payment on this date.

The values in the planned fields are supplied by the baseline plan you selected to track.

Opening the Costs Tab

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

   The Studies screen appears.
2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Costs** tab.

   A list of costs appears, allowing you to enter labor fees.

   For more information about the fields on this screen, see Costs Tab Fields.

Entering the Actual/Earned Value for Costs

1. From the **Service Provider** drop-down list, select a service provider.

   A list of costs associated with the service provider appears.
2. From the **Locations** drop-down list, select a location.
3. For each miscellaneous and pass-through cost, in the **Actual/Earned Value** field, enter the costs accrued.
4. Click **Save**.

Evaluate your Study's Progress: Summary Tab

On the Summary tab, you evaluate your study's progress by selecting various service providers and data to include in the summary.

Opening the Summary Tab

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

   The Studies screen appears.
2. Select the checkbox of the study.
3. Click **Track** and select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Summary** tab.

   A summary of your study's progress appears.

   For more information about the fields on this screen, see Summary Tab Fields.

Select Data to Include in the Study Summary

The Summary tab allows you to select the data and service providers that appear in the summary.

Including and Excluding Data

1. In the **Summary Project Status & Earned Value Analysis (EVA)** section, check the checkbox of the data you want to include in the summary and uncheck the checkbox of the data to exclude.
2. Click **Save**.

Selecting Providers to Include in the Study Summary

1. From the **Providers** drop-down list, select a service provider.

   The application calculates the summary data based on the service provider you selected.
2. Click **Save**.

Selecting a View As Of date to Include in the Study Summary

1. In the **View As Of** field, enter the date or click the calendar icon to select a date.

   The application calculates the summary data based on the date you selected. You can click **Reset** to change the date back to the Study Status Date.
2. Click **Save**.

View Project Performance with the Project Health Data

The Project Health data provides an overview of the project performance for the labor fees and costs in your study. The cells containing these values are colored to indicate project health:

- **Green—**A healthy project. No changes need to be made and the project is proceeding according to plan.
- **Yellow—**A warning that the project is starting to deviate from the plan. The project's performance should be evaluated in detail.
- **Red—**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.
- **No color—**The study is exceeding expectations and data should be reviewed to ensure there are no errors.

View the Study Performance Trend Graph

The Study Performance Trend Graph, in the Study Performance data, shows the Actual Payments, Earned Value, and Planned Value across the entire timeline and costs of the study.

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

Viewing Project Performance Details

In the Project Health, Current Status, and Projected At Completion data, you can generate a report that provides a more detailed view of the project health.

1. In the Project Health, Current Status, or Projected At Completion data, click the **Detail** link.

   The Tracking Detail Report appears.
2. Enter details you want to include in the report.
3. Click **Ok**.

Generate Tracking Reports: Reports Tab

On the Reports tab, you can generate detailed reports that provide valuable information related to study progress and overall health.

Opening the Reports Tab

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

   The Studies screen appears.
2. Select the checkbox of the study.
3. From the Track menu, select **Enter Actuals**.

   The Edit Actuals screen appears.
4. Click the **Reports** tab.

   A list of available reports appears.

   For more information about the reports on this screen, see Report Descriptions.

Generating a Report

1. Click a report link.

   If applicable, a dialog box appears.
2. Enter details you want to include in the report.
3. Click **Ok**.

3 Track Screen and Dialog Box Field Descriptions

This chapter provides help descriptions for fields throughout the ClearTrial Track module.

Costs Tab Fields

Table 3–1 Costs Tab Fields

Field	Description	Notes
Service Provider	Service provider who is completing work on the study.	
Location	Location in which you are tracking costs for the selected service provider.	The available locations are derived from the baseline plan being tracked.
Columns		
Cost	Assigned costs in a study.	The assigned costs are from the Costs tab of the baseline plan.
Month	Month in which you are tracking costs.	
Total	Total amount of planned and actual payments made for the duration of a study.	

Labor Fees Tab Fields

Table 3–2 Labor Fees Tab Fields

Field	Description	Notes
Service Provider	Service provider who is completing work on the study.	
Location	Location in which you are tracking labor fees for work completed on major tasks.	The available locations are derived from the baseline plan being tracked.
Planned	Budget for the selected service provider in the associated location, derived from the baseline plan.	

Table 3–2 (Cont.) Labor Fees Tab Fields

Field	Description	Notes
Earned Value	Earned value for the selected service provider in the associated location.	
Actual	Labor fees for the selected service provider in the associated location.	
Columns		
Major Task	Major tasks included in a study	
Month	Month in which you are tracking labor fees for a major task.	
Total	Total amount of planned, earned value, and actual payments for the duration of the study.	

Milestone Dates Tab Fields

Table 3–3 Milestone Dates Tab Fields

Field	Description	Notes
Milestone	Milestones derived from the baseline plan that is being tracked.	
Expected	Expected dates derived from the baseline plan that is being tracked.	
Actual	Actual date the study milestone began.	
Variance (days)	Difference between the expected milestone dates and the actual milestone dates.	

Milestone Payments Tab Fields

Table 3–4 Milestone Payments Tab Fields

Field	Description	Notes
Service Provider	Service provider who is completing work on the study.	You can only enter milestone payments for service providers that were selected to have payments tracked by milestone on the Settings tab.
Columns		
Milestone	Milestones derived from the baseline plan that is being tracked.	
Planned Date	Planned dates derived from the baseline plan that is being tracked.	
Actual Date	Actual date the milestone payment was made.	The displayed date is the date from the Milestone Dates tab.
Scheduled Payment	Planned payment amounts according to the milestone payment schedule in the baseline plan being tracked.	

Table 3–4 (Cont.) Milestone Payments Tab Fields

Field	Description	Notes
Earned Value to Date	Summation of the earned values entered from the beginning of the study to each milestone.	The application calculates the earned value by applying the ratio of units of work completed to planned units to the planned value.
Actual Payment	Amount paid to the service provider.	

Monitoring Tab Fields

Table 3–5 Monitoring Tab fields

Field	Description	Notes
Location	Location in which you are tracking completed CRF pages.	If you are tracking on a study level basis, this field is unavailable.
Add Earlier Week	Subjects enrolled before the First Subject/Patient In (FSI/FPI) milestone.	By default, the first week shown is the FSI/FPI milestone.
Add Later Week	Subjects enrolled after the Last Subject/Patient Out (LSO/LPO) milestone.	By default, the last week shown is the LSO/LPO milestone.
Total	Number of CRF pages, or EDC equivalent, collected for the designated location, or for all locations, if you are tracking on an all location basis.	
Columns		
Week Of	Week in which you can track completed CRFs for a study.	
Planned To Date	Number of planned completed CRFs, or EDC equivalent, from the baseline plan.	
Planned CRF Pages This Week	Number of planned completed CRFs, or EDC equivalent, for the indicated week from the baseline plan	
Completed CRF Pages This Week	Number of completed CRFs, or EDC equivalent, for the indicated week.	

Report Descriptions

Table 3–6 Report Descriptions

Field	Description	Notes
Site Approval Schedule	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.	

Table 3–6 (Cont.) Report Descriptions

Field	Description	Notes
Subject Enrollment	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	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	Project milestone dates from Project Activity Start Date to Final Report. This report shows both the planned and actual values.	
Study Performance Trend Report	Earned Values (EV), Planned Values (PV), and Actual Payments (AP) over time.	
Milestone Payment Schedule	Printable view of the detailed milestone payment history.	
Tracking Summary	Printable view of the Project Health, Current Status, Cash Flow Analysis, and Projected At Completion. This report can be run for all service providers or a selected one.	
Tracking Detail	Provides a granular view of the project health. Providers and locations can be filtered to be included or excluded. The report can be run with major tasks, miscellaneous costs, or both, and earned value metrics.	
Accruals	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.	

Settings Tab Fields

Table 3–7 Settings Tab Fields

Field	Description	Notes
Tracking Interval	Interval at which you track actuals for the study.	You can track weekly or monthly.
Study Status Date	Date the application uses as the cut-off for EVA calculations.	You must update this field as actuals are entered.
Major Tasks		
Major Tasks	Major tasks included in a study.	

Table 3–7 (Cont.) Settings Tab Fields

Field	Description	Notes
Track	Level at which major tasks are tracked.	You can select Not Tracked for major tasks that are not included in the study.
Costs		
Miscellaneous Cost	Miscellaneous and pass-through costs that are included in a study.	
Track	Level at which costs are tracked.	
Earned Value Options	Earned value tracking option.	
Payments		
Service Provider	Service providers for which you are tracking payments made for work completed on the study.	
Payment scheduled	Interval at which payments are made to service providers.	

Sites Tab Fields

Table 3–8 Sites Tab Fields

Field	Description	Notes
Location	Location in which you are tracking approved sites.	If you are tracking on a study level basis, this field is unavailable.
Add Later Week	Site approvals that occur after the last site is approved.	By default, the first week displayed is the week of the Project Activity Start Date and the last week shown is the week of the Last Site Approved milestone.
Total	Total number of Planned Sites and Approved sites for the designated location, or for all locations if you are tracking on an all location basis.	
Columns		
Week Of	Week in which you can track approved sites for a study.	
Planned To Date	Number of planned sites approved from the baseline plan.	
Planned Sites This Week	Number of sites approved for the week from the baseline plan.	
Approved Sites This Week	Number of sites approved for the week.	

Studies Screen Fields

Table 3–9 Studies Screen Fields

Field	Description	Notes
Filter	Search through the studies included on the Studies screen.	
Modify	Modify the filter for the Studies screen.	
New	Create a new study.	
Edit	Edit a study.	
View	View study details.	
Delete	Delete studies.	Deleted studies can be restored before they are purged from the application.
Restore	Restore deleted studies.	
Create Plan	Create a new plan for a study.	
Track	Track studies.	
Columns		
Study Name	Available studies in the application.	
Product/Compound	Product or compound being studied.	
Phase	Study phase.	
Therapeutic Area	Therapeutic area targeted for the study.	
Indication	Indication targeted for the study.	
Status	Study status.	

Subjects Tab Fields

Table 3–10 Subjects Tab Fields

Field	Description	Notes
Location	Location in which you are tracking enrolled subjects.	If you are tracking on a study level basis, this field is unavailable.
Add Earlier Week	Subjects enrolled before the First Subject/Patient In (FSI/FPI) milestone.	By default, the first week displayed is the week of the FSI/FPI milestone.
Add Later Week	Subjects enrolled after the Last Subject/Patient In (LSI/LPI) milestone.	By default, the last week displayed is the week of the LSI/LPI milestone.
Total	Number of Planned Subjects and Enrolled Subjects for the designated location, or for all locations if you are tracking on an all location basis.	
Columns		

Table 3–10 (Cont.) Subjects Tab Fields

Field	Description	Notes
Week Of	Week in which you can track enrolled subjects for a study.	
Planned To Date	Number of planned enrolled subjects from the baseline plan.	
Planned Subjects This Week	Number of enrolled subjects for the indicated week from the Baseline plan.	
Enrolled Subjects This Week	Number of enrolled subjects for the week.	

Summary Tab Fields

Table 3–11 Summary Tab Fields

Field	Description	Notes
Providers	Service providers included in the study summary.	
View As Of:	Date through which you want to view study data.	
Study Status Date	Date the application uses as the cut off for EVA calculations.	The provided date is from the Settings tab.
Project Health		
Schedule Performance	Predicts 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	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	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.
Current Status		
Planned Value (PV)	Budgeted cost for the work scheduled to be completed on an activity or work breakdown structure component.	
Earned Value (EV)	Budgeted amount for the work actually completed on the schedule activity or work breakdown structure component.	

Table 3–11 (Cont.) Summary Tab Fields

Field	Description	Notes
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)	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.	
Projected at Completion		
Estimate to Complete (ETC)	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.
Budget at Complete (BAC)	Total original planned project budget. The BAC represents the sum of all Planned Values (PV) for the project at completion.	
Estimate at Complete (EAC)	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).
Variance at Complete (VAC)	Difference between the original planned project Budget at Complete (BAC) and the Estimate at Complete (EAC), calculated based on your current performance.	
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).	

Task Dates Tab Fields

Table 3–12 Task Dates Tab Fields

Field	Description	Notes
Service Provider	Service provider who is completing work for major tasks in a study.	
Location	Location in which you are tracking dates for work completed on major tasks.	The available locations are derived from the baseline plan being tracked.

Table 3–12 (Cont.) Task Dates Tab Fields

Field	Description	Notes
Started	Date on which activity related to the major task began.	
Completed	Date one which activity related to the major task is completed.	
Columns		
Major Task	Major tasks included in a study.	
Planned	Planned values derived from the baseline plan that is being tracked.	
Actual	Actual dates for when work was started and completed on a major task.	
Variance (days)	Difference between planned and actual values for both the started and completed dates.	

Task Units tab Fields

Table 3–13 Task Units Tab Fields

Field	Description	Notes
Service Provider	Service provider who is completing work for major tasks in a study.	
Location	Location in which you are tracking work completed for major tasks.	The available locations are derived from the baseline plan being tracked.
Planned	Planned values derived from the baseline plan that is being tracked.	Major tasks that have a single completed unit of work, the Planned Value displays as a percentage. For other major tasks, the planned value displays the number of planned units of work.
Actual	Completed units of work for the major task, for the associated service provider in the selected location.	If the major task has a single completed unit of work, you enter the percentage of work that was completed in the time period. Otherwise, enter numeric values to represent the number of units completed in the corresponding time period. For major tasks that have a single completed unit of work, the percentages you enter are adjusted as you switch from Per-Location to All Location. The application factors in the number of locations when it displays rolled-up percentages.
Columns		
Major Task	Major tasks included in a study	

Table 3–13 (Cont.) Task Units Tab Fields

Field	Description	Notes
Unit	Unit of work used to measure a major task’s progress.	
Month	Month in which you are tracking work completed for a major task.	