Oracle® Health Sciences ClearTrial Cloud Service

Change Log

Release 5.7

E95838-01

April 2018

If you haven't used ClearTrial in a while and want to know what's changed beyond the most recent update, this document has the information you need. This document is a collection of information from the Release Notes for previous versions of ClearTrial, from oldest to most recent, excluding the current version.

Changes in Update 5.3

Update 5.3 includes enhancements to the Oracle ClearTrial Plan and Source Cloud Service. This section highlights changes from the previous release of the software, 5.2.

New Assumption for Monitoring Minutes for CRF Pages

ClearTrial 5.3 provides an additional treatment assumption to accommodate monitoring minutes needed for CRF pages. On the Edit Plan screen, from the Treatment tab, you now have the option to enter the monitoring minutes per CRF page for each treatment in the study.

The application calculates the default value for the Monitoring Minutes per CRF Page field based on the study phase and therapeutic indication. You can override this value for each treatment. Overridden values do not affect minute per page values for the baseline visit or washout period for a crossover study.

Enhancements to Assumptions and Metrics Reports

The Assumptions report now includes an assumption for the monitoring minutes per CRF page for each treatment included in your study.

The Metric report now includes an assumption for the average number of minutes to monitor one CRF page.

The Assumption and Metrics reports are available on the Edit Plan screen, from the Reports tab.

Enhancement to the Compare Plans Report

The Compare Plans report now includes an assumption for the Monitoring Minutes per CRF page for each treatment included in you study, in the Treatment Details section of the Report. The Compare Plans report is available on the Plans screen.

New Data Assumptions for Repeat Tables, Listings, and Figures

ClearTrial 5.3 provides new assumptions that allow you to accommodate repeated data tables, data listings, and figures and graphs. These fields are available from the Edit Plan screen, on the Data tab. The application calculates a default value for these

fields based on the Number of Unique Pages field, however, you can override this value. These new assumptions are available for all study phases.

In addition, the repeat data tables, listings, and figures and graphs appear as work units you can select within task manager. These work units are available from the Edit Plan screen, from the task manager on the Labor tab.

This release also incorporates new assumptions for repeated PK/PD data tables, listings, and figures and graphs. These fields are available from the Edit Plan screen, on the Data tab.

Enhancements to Assumptions and Compare Assumptions Report

The Assumptions report now includes assumptions for repeated data tables, data listings, and figures and graphs. The Assumptions report is available on the Edit Plan screen, from the Reports tab.

The Compare Assumptions report also includes assumptions for repeated data tables, data listings, and figures, and graphs. The Compare Assumptions report is available from the Plans screen by selecting two or more plans and clicking the **Compare** button.

User Configurable Columns

Users can select which columns the application displays with the Configure List Options dialog box available from the Filter section on the Plans, Studies, Products, Templates, Portfolios, Resources, Departments, GL Codes, and Exchange Rate Tables screens. To access this feature, click the **Configure List Options** link.

New Default Data Collection Method

ClearTrial 5.3 has been updated to provide a new default data collection method on the Data tab, available from the Edit Plan screen. The new default when creating new plans is Electronic Data Capture (EDC). You can override this value by selecting another data collection method from the drop-down list.

Rounding Values

ClearTrial 5.3 includes changes for how values are rounded throughout the application.

Rounding Values in Plans

On the Edit Plan screen, from the Summary tab, the application rounds to the thousandths place for hours by department.

All rates, unit costs, and extended costs that appear on the Edit Plan screen are now rounded to the number of decimal places that is the standard convention for the relevant currency. The application uses these rounded values for all calculations.

Rounding Values in Task Manager

In the Task Manager, on the Unit Hours tab, Major Task Adjustments tab, and the Adjustments tab, the default unit hours and unit hours round to thousandths place. The rounded value appears in the application and is used to calculate the unit cost and extended unit hours. Overridden values are also rounded to the thousands place.

Changes in Update 5.4

This section includes enhancements and updates to Oracle ClearTrial Plan and Source Cloud Service from the previous version, 5.3.

Important Note on Freezing Billing Rates

Oracle ClearTrial 5.4 includes updates to composite billing rates for years 2017 – 2039.

Freezing rates remains an Oracle ClearTrial release best practice to preserve existing rates in 5.3 (or earlier) plans.

Locking Plans Best Practice Update

Locking plans preserves assumption values and freezes resource billing rates and inflation rates in existing plans.

Upon the release of 5.4, existing plans will no longer be automatically upgraded to the cost model associated with the latest release of ClearTrial Cloud Service.

Therefore, locking plans is no longer required to preserve values prior to a ClearTrial release. Locking plans is now strictly a method to prevent users from making inadvertent changes to an existing plan.

Important Points on Existing Locked Plans that Are Unlocked/Copied

- When a plan that is locked to a version earlier than 5.3 is unlocked, it will be upgraded to the first supported cost model.
- Copies of a locked plan, locked to a version earlier than 5.3 will be upgraded to the first supported cost model.
- Copies of 5.3 locked plans will continue to use the 5.3 cost model, but users have the ability to upgrade per plan, on demand.

For more information, see Locking Plans: Information and Guidelines and Freezing Billing Rates: Information and Guidelines.

Clinical Intelligence Updates

Oracle ClearTrial 5.4 includes updates to composite billing and inflation rates.

Composite Billing Rate Updates

Oracle ClearTrial 5.4 introduces composite billing rate updates for years 2016 to 2029, based on estimated inflation, observed provider billing rates by location, and industry salary projections. ClearTrial will adjust future years for inflation, according to the ClearTrial-defined inflation profiles, by location and year.

ClearTrial continuously monitors and aggregates changes in provider billing rates. These composite rates are reviewed annually and updated to ensure that the most current and accurate composite rates are available.

Composite Inflation Rate Updates

Oracle ClearTrial 5.4 introduces composite inflation rate updates for years 2016 to 2039, based on global economic data.

ClearTrial continuously monitors and aggregates changes in global inflation rates. These composite rates are reviewed annually and updated to ensure that the most current and accurate composite rates are available.

Introduction of Cost Model Versioning from 5.3+

Oracle ClearTrial plans calculate level of effort, costs, distributions, and timelines logic, default values, and a work breakdown structure referred to as a "cost model." A new cost model is created with every ClearTrial release and will now be referred to using the release version number. For example, upon release of 5.4, the cost model will be called "cost model 5.4." **Oracle ClearTrial will now support multiple cost models simultaneously.**

All cost models from 5.3 and forward will be preserved and available for use in plans.

Existing Plans and Templates

Users will have the ability to decide whether or not to apply a cost model to a plan.

For example, users can choose to leave a plan (or template) created in cost model 5.3 in its current state. Should the user later choose to update an assumption or a default value in that plan, the plan values will recalculate using the logic from the 5.3 cost model.

Conversely, the user can choose to update a plan (or template) created in cost model 5.3 to cost model 5.4. In this case, the user's overwritten values will be preserved but all default values, logic, and tasks will be based on cost model 5.4. The plan labor and cost values will change to reflect the new model.

Cost models prior to version 5.3 have not been preserved; therefore, plans (or templates) locked to earlier versions (5.2 and less) when upgraded, will be upgraded to 5.3 at minimum, with the capability to upgrade to 5.4 on demand.

Updating Plans to a new Cost Model: Best Practice

If you have an existing plan or template that was locked prior to 5.3, you should not unlock it unless you are prepared to accept the changes that will occur as the plan adjusts to the oldest preserved cost model, which is the 5.3 cost model. Once the cost model is updated, you will not be able to revert the cost model back to a version prior to 5.3.

If you want to assess the potential impacts of a newer cost model on fees and costs without impacting your original plan, ClearTrial recommends that you:

1. Copy the plan.
2. Updating the cost model of the copy.
3. Compare the copy to the original plan.

If you do not like the resulting changes, you can delete the updated copy and your original plan will still be available.

New Plans and Templates

If a user creates a new plan based on a custom template, the new plan will reflect the cost model of the template.

If a user creates a new plan based on the ClearTrial default template, the new plan will reflect the current version cost model.

If a user wants to create a new plan using an old custom template and the newest cost model, the user can either:

- Create the plan based on the old custom template and then upgrade the plan to the newest cost model, or
- Upgrade the template to the newest cost model and then create the plan from the upgraded template.

Maintaining Templates: Best Practices

As of 5.4, the following best practices are recommended upon release of the new cost model:

- Copy your custom templates.
- Upgrade them to the current cost model version.
- Review the impact of ClearTrial's new cost model version.
- Edit your templates, if necessary.
- Instruct your users to create new plans based on the new templates.

You can leave templates based on older cost models available for users or you can archive them.

> **Note:** If you want the billing rates to remain the same from release to release, ClearTrial still recommends that you freeze rates prior to a new Oracle ClearTrial release because billing rates are not preserved as part of a cost model.

Custom Assumptions

Oracle ClearTrial 5.4 allows Oracle Health Sciences ClearTrial Plan Enterprise Edition Cloud Service users to create their own custom assumptions. Users might want to create a custom assumption when ClearTrial does not have a defined assumption that meets their need for calculating a custom task or for use as a unit of measure for billing.

User Additional Roles/Capabilities

Oracle ClearTrial 5.4 includes the additional role/capability of Custom Field Designer. This permission can be granted to users who need access to create custom fields and publish custom field models for use in plans. A training video is available for users who will be designated as custom field designers.

ClearTrial system administrators have this additional permission by default and can grant it to any user who is already assigned the Clinical Administrator or System Administrator primary role.

Bid Comparison across RFPs

In 5.3, you could only compare bids that existed within the same RFP. Oracle ClearTrial 5.4 provides the ability to compare bids from different RFPs. This allows you to perform a comparison of bids that have been generated from copies of plans to see how bids have changed when the same trial's scenario is updated in response to vendors' alternatives.

Line-item Discount Support

Oracle ClearTrial 5.4 provides the ability to apply line-item discounts per plan per provider. Line-item discounts are not associated with any particular major task, task, resource, or rate. This kind of discount is a negotiated amount at the plan level that gets applied against the overall labor fees for a particular plan provider.

If you configure a line-item discount in your plan, all ClearTrial-defined reports have been updated to display discount impact to total fees. For the Metrics report, you can specify that the metric calculations consider line-item discount.

New Units of Measurement/Cost Drivers

Oracle ClearTrial 5.4 exposes additional items to be used as units of measurements when creating task-resource algorithms in Task Manager or as cost drivers when creating user-defined miscellaneous or pass-through costs on the Costs tab. The items below are now available to be used as units of measurements or cost drivers.

- Pre-study Site Visit*
- Site Initiation Visit*
- Site Close-out Visit*
- Newsletter
- Publication

*Related to onsite visits only, not phone visits.

Increased Transparency for Meetings Labor

Oracle ClearTrial 5.4 provides increased transparency for meetings. In 5.3, meeting tasks were created for each unique provider attending the meeting. Regardless of billing location, multiple occurrences of the same resource for a meeting were merged together into one resource in the WBS. The billing rates for those resources were blended to derive the associated fees.

In 5.4, meeting tasks will now be created for each unique provider, resource, and billing location combination. When the associated fees are calculated, the billing rates are no longer blended. The actual billing rate for the resource's billing location will be used to derive the associated fees.

Metrics Updated to Include Inflation

Oracle ClearTrial 5.4 provides increased flexibility by allowing the user to apply inflation to metrics. Because ClearTrial-defined metric calculations are not versioned, metrics with the option to include inflation will be available in 5.3 plans.

The following metrics have been updated with the ability to include inflation on the ClearTrial-defined Metrics Report:

- Total study cost per CRF page (includes drop rate).
- Data management cost per CRF page (excludes Biostatistics).
- Total study cost per on-site monitoring day.
- Cost to monitor all sites for one additional month.
- Average cost per monitoring trip (excludes pass-through costs).

- Average cost for a single monitoring day (excludes pass-through costs).
- Cost per site per week.
- Study startup costs per site per week.
- Cost per subject per site per week.
- Cost per completed subject.
- Direct Fees per Enrolled Subject.

Bid Grid Versioning

Oracle ClearTrial 5.4 introduces bid grid versioning, which preserves the format and metadata of a bid grid generated from ClearTrial RFPs even if bid grid changes occur in the next ClearTrial release. This feature allows you to continue to produce bid grids for negotiations that may span multiple releases with the same format and metadata.

Usability Enhancements

Usability enhancements are ongoing to enhance the ClearTrial user experience.

Sort Plans by Protocol and Product/Compound

Oracle ClearTrial 5.4 provides additional data display options to sort by on List screens. Launched by clicking the **Configure List Options** link in the upper right-hand corner of the Plan List screen, Protocol and Product/Compound have been added as options for you to select from to display as columns by which to sort your plans As a reminder, if you have a large amount of plans, spanning multiple pages, you can also configure how many plans are shown per page by increasing the value for the **Show number of plans per page** assumption, located at the bottom of the same dialog box.

Select All Option

Oracle ClearTrial 5.4 allows you to quickly select all list items with a single click for the following:

- Locations on the Location tab.
- Languages on the Location tab.
- Providers on the Provider tab.
- Meetings on the Meetings tab.

Inactive Templates Removed from New Plan Dialog Box

Oracle ClearTrial 5.4 no longer displays Archived or Study Complete templates as choices when creating a new plan. This keeps the template list focused on active templates only.

Enhanced Reporting Options for Metrics Report

Oracle ClearTrial 5.4 provides new reporting options for the Metrics Report. New options control whether line-item discounts and inflation are included in your metric calculations. The option for line-item discounts is displayed only if a line-item discount exists in your plan.

Web Services API Enhancements

Oracle ClearTrial 5.4 includes enhancements to the Web Services API.

- Inclusion of study ID of each plan's parent study in the Plan Resource API.
- New RFP Resource API to obtain RFPs and related details.

Freezing Billing and Inflation Rates: Information and Guidelines

Oracle ClearTrial 5.4 includes changes to composite billing rates for years 2016 - 2029 and composite inflation rates for years 2017 - 2039. If you do not want these new rates applied to your existing plans, you can freeze your rates.

How to Freeze Billing and Inflation Rates for a Plan

On the Plans screen, select the plan, click **Other Actions**, and select **Freeze Billing Rates**. You can freeze billing and inflation rates for a single plan or multiple plans in the same step.

How to Unfreeze Billing and Inflation Rates for a Plan

On the Plans screen, select the plan, click **Other Actions**, and select **Unfreeze Billing Rates**. You can unfreeze billing and inflation rates for a single plan or multiple plans in the same step.

Changes in Update 5.5

This section includes enhancements and updates made to Oracle ClearTrial Plan and Source Cloud Service since version 5.4.

Advanced Algorithms

Configurability capabilities currently exist at the labor and indirect cost levels to allow you to align to your organizational hierarchy or the mutually agreed upon work breakdown structure determined between you and your service provider(s). Oracle ClearTrial has become the platform that triggers contract negotiation discussions for complete alignment and transparency between both sides (sponsor, vendor) of the ecosystem.

Oracle ClearTrial 5.5 expands on existing user-defined algorithm building capabilities by allowing the configuration of multiple expressions with multiple cost drivers accessible per expression, per algorithm. This enhancement provides increased control and flexibility over how custom fees and costs are specified to align to their respective clinical trial scenario.

ClearTrial 5.5 also includes a new configurable assumption within each expression to apply a percentage of, per cost driver, per expression. This percentage will increase/decrease the number derived from the underlying assumption for the driver.

There may be ClearTrial-defined costs and fees included by default at a different level of granularity than those in which your organization needs or for your planned trial's budget. You can leverage the 5.5 advanced algorithm capabilities so that you can include those specific fees or costs in your budget, when you need them (on demand).

New User Role/Additional Capability

Oracle ClearTrial 5.5 includes the additional role/capability of Advanced Algorithm Editor. This permission is for users who need write access to create or edit task-resource /cost algorithms with multiple expressions.

Assigned ClearTrial System Administrators have this additional permission by default and can grant it to any user who is already assigned the Power User, Clinical Administrator, or System Administrator primary role.

New Medical Monitoring and Safety Assumptions

Oracle ClearTrial 5.5 includes updates to existing medical monitoring and safety algorithms, including new, configurable assumptions used to calculate monitoring-related fees and costs accessible for late-stage studies, for users in Advanced/Expert mode.

All new assumptions/cost drivers will be displayed on associated out-of-the-box reports and accessible as a unit of measure to select from when creating user defined algorithms.

- **Lab and Diagnostic Tests** per subject, per treatment arm located on the Plan Treatment tab. This assumption's value is used to calculate the amount of time the medical monitor will spend reviewing lab and diagnostic test results.
- **Cohort Escalation Reviews** per treatment arm located on the Plan Treatment tab. This assumption's value is used to calculate the time required for the medical monitor and medical associate to determine appropriate changes in dosage.
- **24/7 Coverage for Medical Monitoring** located on the Plan Monitoring tab. This assumption’s value is used to increase the estimated time the medical monitor and medical associate will spend performing subject eligibility reviews, answering specific inclusion/exclusion criteria questions, and reviewing subject management and protocol issues that require medical judgment.
- **Medical Data Listing Reviews** located on the Plan Monitoring tab. This assumption's value is used to calculate the amount of time the medical monitor and medical associate will spend assessing point-to-point data, data across visits per subject, data across subjects per site, and data across the entire study.

Refined Assumption Defaults

Oracle ClearTrial 5.5 includes intelligent default value updates for the assumptions listed below.

- **Hours medical monitor will spend with each SAE**
- **Expected percent of SAE reports to be expedited**

Renamed Assignment Groups

Oracle ClearTrial 5.5 includes new and updated ClearTrial-defined Major Tasks, Tasks, and resources for late-stage studies. Please refer to the tables below for detailed updates.

Table 1 Renamed Assignment Groups in 5.5

5.4 Assignment Group	5.5 Assignment Group
SAE Management	Safety and Medical Management

Work Breakdown Structure Updates

Oracle ClearTrial 5.5 includes new and updated ClearTrial-defined Major Tasks, Tasks, and resources for late-stage studies. Please refer to the following tables for detailed updates.

Table 2 New Major Tasks and Tasks in 5.5

New Major Tasks	Associated Tasks
Medical Data Listing Review	Review medical data listings
Subject Monitored	Review clinical data and CRFs
Subject Monitored	Review alert lab and diagnostic test results
Cohort Escalation Review	Review data to determine dose escalation

Table 3 Existing Labor Updates in 5.5

Existing Major Tasks	Associated Tasks
Study Setup	Safety system setup
Study Setup	Develop SAE management plan
Study Setup	Prepare therapeutic training materials
Project Management Week after FSI	Post-FSI — Manage safety processes
SAE Processed	Process SAE
SAE Processed	Enter data and perform quality review
SAE Processed	SAE reconciliation
Expedited Safety Report Completed	Produce expedited safety report
Expedited Safety Report Completed	Expedite safety reports to central ethics committees
Expedited Safety Report Completed	Expedite safety reports to local ethics committees
Expedited Safety Report Completed	Expedite safety reports to sites
Sponsor Oversight	Oversee — Cohort escalation review
Sponsor Oversight	Oversee — Medical data listing review
Sponsor Oversight	Oversee — Subject monitored

Table 4 New Resources Available in 5.5

Resource Name	Resource Code
Medical Associate	DS02
Safety Specialist	PV01
Safety Coordinator	PV02

Table 4 (Cont.) New Resources Available in 5.5

Resource Name	Resource Code
Safety Database Administrator	PV03

Table 5 New Resource Effort in 5.5

Tasks	Resources
Develop scope of work, timeline, work assignment	Safety Specialist
Review protocol	Medical Monitor
Coordinate DSMB setup activity	Medical Monitor
Coordinate DSMB setup activity	Medical Associate
Internal Team Meeting	Medical Associate
Medical monitoring	Medical Monitor
Medical monitoring	Medical Associate
Expedite safety reports to regulatory agencies	Regulatory Submissions Specialist
Expedite safety reports to regulatory agencies	Safety Specialist
Write the SAE narrative	Safety Specialist
Write the SAE narrative	Medical Monitor
Conduct medical review of the SAE	Medical Monitor
Design study documents	Safety Specialist
Design study documents	Safety Coordinator
Oversee — Study Setup	Clinical Research Associate
Oversee — Study Setup	Safety Specialist
Oversee — Project Management Week after FSI	Medical Monitor
Oversee — Project Management Week after FSI	Medical Associate
Oversee — Project Management Week after FSI	Safety Coordinator
Oversee — SAE Processed	Safety Specialist
Oversee — SAE Processed	Safety Coordinator
Oversee — Expedited Safety Report Completed	Safety Specialist
Oversee — Expedited Safety Report Completed	Safety Coordinator.

Table 6 Resource Effort Removed in 5.5

Tasks	Removed Resources
Produce and distribute subject information video	Medical Monitor
Review CRF (or EDC equivalent)	Medical Monitor
Conduct medical review of the SAE	Senior Vice President Clinical
Conduct medical review of the SAE	Project Manager
Collect the SAE data from the investigator	Medical Monitor
Write the SAE Narrative	Senior Director, Clinical/Therapeutic

Table 6 (Cont.) Resource Effort Removed in 5.5

Tasks	Removed Resources
Expedite safety reports to regulatory agencies	Director, Regulatory Affairs
Oversee — SAE Processed	Clinical Research Associate
Oversee — SAE Processed	Project Admin Assistant

Important Note for New Resource Department Assignments

If your organization has never created custom department mappings prior to using the Maintain Departments capability, accessible from the Maintain menu, then the new resources available in 5.5 will contain a ClearTrial pre-defined default department mapping.

However, if your organization has previously taken advantage of/leveraged this ability to manage and maintain your custom department mappings over time for your plans, then please review the mappings per resource post release. The new resources available in 5.5 will have "Unmapped" as their default department assignment. Please meet with your users and determine if the new resources need updated mappings based on your current organizational structure.

Medical Monitoring Algorithm Updates

Oracle ClearTrial 5.5 updates the ClearTrial-defined algorithm to calculate the level of effort required for medical monitoring to be based on the site weeks and number of patients per location. This updated algorithm includes impact to the resources listed below, who are performing work on this task.

- **Medical Associate** (new in 5.5)
- **Medical Monitor**

This algorithm update also affects an existing assumption from 5.4 and prior and removes Number of FTE (full-time equivalent) Medical Monitors from the 5.5 cost model.

Renamed Safety Tasks

Oracle ClearTrial 5.5 includes renamed existing tasks to remain current with industry-standard terminology:

Table 7 Renamed Safety Major Tasks

5.4 Major Task Name	5.5 Major Task Name
Expedited SAE report completed	Expedited safety report completed
SAE report completed	SAE processed

Table 8 Renamed Safety Tasks

5.4 Task Name	5.5 Task Name
Expedite SAE reports to regulatory agencies and ethics committees	Expedite safety reports to regulatory agencies
Oversee — Expedited SAE report	Oversee — Expedited safety report completed

Table 8 (Cont.) Renamed Safety Tasks

5.4 Task Name	5.5 Task Name
Oversee — SAE report completed	Oversee — SAE processed

Safety Task Updates

The following safety tasks included in ClearTrial 5.4 and prior cost models are not included in the 5.5 cost model.

- **SAE Database programmed**
- **Program the SAE database**
- **Collect the SAE data from the investigator**
- **Enter the SAE data**
- **Code the SAE report**
- **Send final SAE report to sponsor**
- **Oversee — SAE database programmed**

New Units of Measurement

New accessible work units in 5.5 cost model when creating task-resource algorithms and user-defined miscellaneous or pass-through costs include:

- **Medical Data Listing Review** (related to new medical monitoring assumptions)
- **Cohort Escalation Review** (related to new medical monitoring assumptions)
- **Grant Payment**

New Plan Summary Group

Oracle ClearTrial 5.5 includes a new summary group for Safety and Medical Management, displayed primarily on the Plan Summary tab and associated reports. This new summary group includes the following direct labor fees:

- **Post-FSI - Manage safety processes**
- **Process SAE**
- **Enter data and perform quality review**
- **Conduct medical review of the SAE**
- **SAE reconciliation**
- **Produce expedited safety report**
- **Expedite safety reports to regulatory agencies**
- **Expedite safety reports to central ethics committees**
- **Expedite safety reports to local ethics committees**
- **Expedite safety reports to sites**
- **Review medical data listings**
- **Review clinical data and CRFs**
- **Review alert lab and diagnostic test results**

- **Review data to determine dose escalation**
- **Medical monitoring**

Indirect Cost Usability Enhancements

Oracle ClearTrial 5.5 provides several usability enhancements to the Plan Costs tab.

- New Cost Assignments tab when creating/editing a user defined cost.
- All cost assignments, including provider, department, and GL Code assignments will be accessible from the Cost Assignments tab.
- Existing cost specifications, such as the scope of the cost (by study or by location), have been relocated to the existing Cost Definition tab.
- Plan Cost tab includes a cost selection indicator to indicate to the user how many cost items have been selected from the list.
- Increased number of characters allowed for user-defined cost names.

Expanded Browser Support

Oracle ClearTrial 5.5 provides support for Microsoft Internet Explorer 11.

For inquiries on supported browsers and Oracle ClearTrial recommendations, refer to the Oracle ClearTrial 5.5 Technical Requirements available from the ClearTrial Support Center.

Web Services API Enhancements

Oracle ClearTrial 5.5 Web Services API includes enhancements to provide additional endpoints available for Plan Enterprise Edition customers. As a reminder, if you are a Plan Enterprise customer and your development/IT team would like additional technical information, please refer to the *Web Services API User Guide* by release accessible from the ClearTrial Support Center.

Changes in Update 5.6

This section includes enhancements and updates made to Oracle ClearTrial Plan and Source Cloud Service since version 5.5. This release offers the ability to upgrade existing plans and templates to the latest ClearTrial cost model. As a reminder, upgrading to the latest cost model ensures you are working with the latest industry updates to both early- and late-stage ClearTrial-defined Work Breakdown Structures (WBSs) and indirect cost calculations.

To access ClearTrial Cloud Service documentation and videos, please visit the new `Oracle Help Center`.

Update to Responsibilities/Assignment Groups

ClearTrial's 5.6 cost model offers the latest updates to the ClearTrial Responsibilities, also known as ClearTrial-defined Task/Assignment groups, and the tasks under each group.

Updates include new Responsibilities/Assignment groups and updates to existing ClearTrial Responsibilities group names and the order in which they are displayed on

various tabs. The new task groups displayed for plans using the ClearTrial 5.6 cost model include:

Phase I (Oncology/Vaccines) through Phase IV or Late-Stage Plans:

- Site Startup (New)
- Medical Management (New)
- Safety/Pharmacovigilance (Update to existing group Safety and Medical Management)
- Quality Assurance (Update to existing group Site Auditing)
- DSMB (New)

Phase I (Healthy Volunteers) Plans:

- Site Startup (New)
- Safety/Pharmacovigilance (New)
- Quality Assurance (Update to existing group Site Auditing)
- DSMB (New)

Additionally, existing ClearTrial-defined tasks have moved and will reside by default under different Responsibilities/Assignment groups in ClearTrial 5.6 cost model plans for both WBSs. As a result, default assignments for ClearTrial's Responsibilities have also changed when compared to plans using the ClearTrial 5.5 cost model.

If you have defined mappings for departments or GL codes by task or task group, you may wish to review these mappings after the upgrade.

New Customer Preference

ClearTrial 5.6 offers a new customer preference, **Allow user to choose a plan or template from which to pull location-specific data when adding locations to a plan**, for users who are assigned the ClearTrial System Administrator primary role. This new configuration allows you to turn on or off the ability to import location-specific data for any plan or template. When this configuration is turned on (set to true), you will see new prompts in the **Add Locations** dialog when you add a location to your plan/template.

This preference allows users to choose a plan or template from which to pull location-specific data when adding locations to a plan. It can be set to true or false for all users in your organization. By default, it is set to true for CROs and false for sponsors.

Import Location-specific Data from Any Plan or Template

When the new customer preference, described in the previous session, is set to true, you see a new prompt when you add a location to your plan/template in ClearTrial 5.6. On the **Choose Locations** dialog, after you have selected the location to add, a new prompt appears toward the bottom of the dialog for you to choose the location-specific overrides to import from a list of templates or plans (via a new configurable filter).

The list will contain prior/existing completed plans/templates that contain the overrides made for the specific location. Once you have selected the plan/template (source) to import the overrides from, you will see the following types of overrides pulled into your current plan/template (destination):

- Custom Fields
- Location Data (MOH Delay, Ave Grant Amount)
- Site Information (Number of sites, etc.)
- Subject Data (Screening, drops)
- Task Assignments
- Task-Resource Department/GL Code
- Task-Resource Algorithms
- Task-Resource Billing Rate Location
- Task-Resource Rate Overrides
- Task-Resource Unit Hours
- Indirect Cost Assignments
- Indirect Cost Departments/GL Codes
- Indirect Cost Adjustments
- Indirect Cost Algorithms
- Meetings
- Resource Assignments (made in the Override Resources and Rates dialog)

Model Schedules in Days

In some cases, you may want to model the site approval, enrollment, and/or treatment duration for late-stage plans in terms of days rather than weeks.

> **Tip:** If you need to model a Phase I (Healthy Volunteers) plan/template in days, you don't have to change anything.

Site Approval Schedule

ClearTrial 5.6 offers the flexibility to model the site approval schedule per location in days, for late-stage plans. You can do this by clicking the new **Switch to Days** link from within the **Edit Site Approval Schedule** dialog when editing the schedule.

If you later need to revert back or switch to model the schedule in weeks, ClearTrial 5.6 provides this capability by clicking the **Switch to Weeks** link from within the schedule.

Subject Enrollment Period

When you are defining the subject enrollment period in late-stage study plans, ClearTrial 5.6 provides the flexibility to select days from a new **Enrollment period** drop-down list to model enrollment in days instead of weeks. At any time, when editing your plan, you can switch back to weeks, if needed.

Treatment Duration

On the Treatment tab, you will see the same drop-down list to model in days when you are defining the treatment duration, per treatment arm, in ClearTrial 5.6 late-stage plans.

Calculated Dates Display

In ClearTrial 5.6, you will notice calculated read-only dates displayed on various tabs, as you are creating/overriding related assumption parameters.

- **Locations tab**—FSA Date (First Site Approved) will dynamically update when you are configuring the MOH (Ministry of Health) delay value, per location.
- **Subject tab**—Last Subject In (LSI) and Last Subject Out (LSO) Dates displayed when you enter/update the enrollment period.
- **Treatment tab**—Last Subject Out Date is displayed and will dynamically update when you are defining your treatment arm.
- **Data tab**—When you change the number of days from LSO to Db Lock, Db Lock to Stat Report, Stat Report to Draft Report, or Draft to Final, ClearTrial displays the corresponding calculated dates on the Data tab. Each date appears below the current field that captures the offset in days from a specific milestone.

Custom Descriptions for ClearTrial-defined Resources

You can make the descriptions of ClearTrial-defined resources more accurately reflect your organization's staffing and costing structures by editing or replacing ClearTrial-defined description. How do you do this?

1. From the Maintain menu, select **Resources**.
2. From the Resource list, select the CRA and click **Edit**.
3. Update the **Code** and **Name** and click the pencil icon to edit the ClearTrial default description.

   To revert to the ClearTrial default description, click the trash icon to discard the latest change.

Rename, Reorder, and Regroup Tasks

Users who have licensed the Enterprise Edition can perform the following tasks.

- **Customize Names and Descriptions**—Within your plan, you can customize the name and description of each ClearTrial-defined Major Task. To apply these customizations to future plans, create a template with these settings and any plans created from the template will inherit the configurations/settings made.
- **Resort Major Tasks**—The ClearTrial-defined Major Tasks appear in the order in which they are typically performed in a trial. You can control the order in which these Major Tasks are displayed on the Labor tab using drag and drop:

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

  You can also resort Major Tasks from within the Task Manager by configuring the new assumption on the Major Task Details tab:

  1. Select the Major Task and click **Edit Major Task**.
  2. From the **Display this Major Task** drop-down list, select **before** or **after**.

3. From the drop-down list to the right, select the Major Task before or after to display the Major Task.

- **Change the Task Sorting Order**—Within a ClearTrial-defined Major Task:

  1. On the **Labor** tab, select a Major Task and click **Edit Major Task**.
  2. Highlight the task you want to move by clicking and holding the mouse button.
  3. Drag the task to where you want it to appear in the Task list and release the mouse button then click **Save**.

- **Order of Major Tasks and Tasks Inherited in Reports**—The task ordering or major task ordering will now be inherited in ClearTrial-defined reports. When you resort the tasks, the same order is used in the ClearTrial-defined reports.
- **Move ClearTrial-defined Tasks to Another Assignment Group**—You can move ClearTrial-defined tasks to another assignment group to align the groups with your organization's notion of services or responsibilities.

  1. On the **Labor** tab, select a Major Task and click **Edit Major Task**.
  2. Select a task and click **Edit Task**.
  3. To change the Assignment Group, select a different assignment group from the drop-down list. Assignment groups are represented by radio buttons in the Responsibilities section of various tabs and as drop-down lists on the Assignment tab.
  4. Click **Save**.

- **Change the Summary Category for ClearTrial-defined Tasks**—You can change the Summary Category, from Task Details tab within Task Manager, to move ClearTrial-defined tasks from one summary group to another so that user can align the categories with your organization's notion of how work should be summarized.

  1. On the **Labor** tab, select a Major Task and click **Edit Major Task**.
  2. Select a task and click **Edit Task**.
  3. To change the Summary Category, select a different category from the drop-down list. Summary categories determine how the hours and fees are summarized (rolled up) and displayed on the Summary tab and Summary report.
  4. Reorder the tasks by specifying whether this task should appear *before* or *after* the other task you select from the drop-down list. From the **Display this Major Task** drop-down list, select **before** or **after**. From the drop-down list to the right, select the Major Task before or after to display the Major Task.
  5. Click **Save**.

Usability/User Experience Enhancements

ClearTrial 5.6 includes new capabilities to let you get more done quickly and easily, making your ClearTrial experience even more powerful.

- **Locations tab**—The footer row displays the total number of locations and updates dynamically if the number of locations changes. The footer row also shows the total number of sites, the total number of subjects, the number of

translations/dialects, the average length of MOH/FDA delays, and the weighted average of the investigator grant amounts.

- **Treatment tab**
  - Depending on the number of visits you specify, you can specify a treatment duration as short as one day or one week.
    * For a parallel trial design, you can specify one week with eight visits or one day with two visits.
    * For cross-over trial design, you can enter one week with seven visits or one day with one visit.
  - The number of subject visits can be greater than the treatment duration.
  - You can specify less than one minute of monitoring time for simple CRF pages per treatment arm schedule.
- **Monitoring tab**—In the On-Site Monitoring Schedule section, the total number of sites used in the plan is displayed.
- **Meetings tab**
  - You can show or hide excluded meetings in the Meetings list.
  - The number of meetings selected from the Meetings list is displayed at the top of the Meetings section.
  - You can sort attendees on Resource Type, Billing Rate Location, and Attendance Method by clicking the corresponding column headers. The order in which you click the column headers governs the sort. For example, Resource Type sorted by Billing Rate Location and then by Attendance Method.
- **Task Manager**
  - (Enterprise Edition only) The Distribution tab of a Major Task within Task Manager displays the number of weeks between the distribution start and end dates for each service provider/location. This allows you to quickly determine the number of weeks used for each country without having to count the individual rows of weeks.
  - You can copy a user-defined task by selecting the task and clicking the **Copy Task** button.
  - The **Code** field on the Task Details tab is now editable for ClearTrial-defined tasks. You can enter a code. You can edit it over time, when you edit the task later. You can also use it as a prefix to help order the list in which it is displayed in.
- **Labor tab**—(Enterprise Edition only) You can copy a user-defined Major Task by selecting the Major Task you want to copy and clicking the **Copy Major Task** button.
- **Reports tab**
  - When you run the Meetings Report for your plan, you will see two new options: **Include Resources With No Meeting Hours** and Use **Resource Name Instead of Resource Type**.
  - On the Plan Reports tab, a new plan-level report, **Compare to Original**, has been added to compare the current plan to its template or prior copy and quickly see differences or changes in fees and costs.

- **Context-sensitive Help**—Two capabilities have been added:
  - You can now select and copy the text from the context-sensitive help screens. When you click a field name to open the online help associated with the screen. The keystrokes depend on which browser you are using. For example, in Internet Explorer, click **CTRL+SHIFT+DBL-CLICK**. to copy the contents to the clipboard. In other browsers, these keystrokes make the text become selectable so you can copy all or part of the text.
  - The table of Major Tasks that appears in the help for the Labor tab is dynamic. It reflects tasks and Major Tasks that have been added or are unique to the current plan as well as any changes you make to the name or description.

Custom Fields Cap Increase

The total number of custom fields permitted has increased to 350. Default formulas can be applied to 75 of them.

Note: The more custom fields you add to your plans, the more you might experience slight changes to performance.

Especially for CRO Users

Several capabilities to support have been included in ClearTrial 5.6 specifically for CRO users.

- The header at the top of all screens includes Sponsor Name.
- The Overview tab includes an additional assumption which gives you the option to include/exclude Sponsor hours from your budget plan. By default, sponsor hours are excluded for CRO users.
- You can display a Sponsor column on the Plans list screen. Select the **Configure List Options** link on the Plans list screen and select **Sponsor**. You can also filter the plans list by sponsor.
- When working with meetings tasks, meeting tasks assigned to sponsors have been removed.
- When you open the Assignment ab, all tasks have been expanded by default.
- ClearTrial no longer includes sponsor oversight and sponsor-only tasks in the WBS (both WBSs) for CRO customers. On the Assignment tab, you won't see the Assignment Group for Sponsor Oversight. In the Task manager, all Sponsor Oversight Major Task and Tasks are hidden.

Web Services API Enhancements

ClearTrial 5.6 Web Services API has been updated to include additional endpoints that users can retrieve or export.

If you are a Plan Enterprise customer and your development/IT team would like additional technical information, please refer to the *Web Services API User Guide* on the Oracle Help Center.

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at
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Change Log, Release 5.7
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