Oracle Life Sciences ClearTrial

Release Notes

Release 6.0

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Oracle Life Sciences ClearTrial Release Notes, Release 6.0

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Contents

Preface

This preface contains the following sections:

Where to Find the Product Documentation

All documentation and other supporting materials are available on the Oracle Help Center.

Click the **Visit Oracle Help Center** link next to your name on the main menu bar or on the **Start** page, open the **Help** menu and select **Visit Oracle Help Center**.

Documentation accessibility

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

Visit Oracle Life Sciences Support

For technical issues, please visit Life Sciences support in your preferred and supported browser. You can launch Oracle Life Sciences Support directly from within the ClearTrial application from the following locations:

- Start Page > Help > Report an Issue
- Main Menu bar on any other screen, Help >About…

1

About ClearTrial 6.0 Updates

ClearTrial 6.0 provides a new 6.0 Cost Model that offers the latest industry costing algorithms focused on data management and further support for the new European Union Clinical Trial Regulation requirements (EU CTR) process. Clinical intelligence updates include updated annual resource billing and inflation rates per location and refreshed oncology SAE% predictions. New alternative monitoring strategies now include optional centralized monitoring to provide flexibility in hybrid monitoring schedules and methods. Additionally, the ability to control the monitoring minutes per page during all segments of the trial has also been enabled within the user interface.

For information on how to leverage the latest cost model, see Best Practices.

2

Clinical Intelligence Updates

ClearTrial continuously monitors and aggregates changes to the economic, financial, and clinical landscapes to ensure the most current and accurate data is available.

This section covers the following topics:

Composite Billing Rate Updates

ClearTrial 6.0 updates composite billing rates for years 2024 to 2035, per location, 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.

Composite Inflation Rate Updates

ClearTrial 6.0 provides updates to composite inflation rates for years 2025 to 2035, per location, based on the latest global economic data forecasts.

Oncology-specific SAE Rate Updates

ClearTrial 6.0 refreshes the SAE% rate predictions for oncology for 6.0 cost model plans/templates based on current industry-reported SAE rates in clinical trials.

> **Note:**
>
> Any plans from a previous cost model must upgrade to get the latest SAE defaults.

3

Data Management Updates and Reorganization

The ClearTrial 6.0 Cost Model focuses on data management updates to align with the latest industry predictions and terminology. Starting with data management labor displayed in the user interface, all ClearTrial-defined data management labor is grouped together on the Labor tab and within Task Manager.

New Data Management Assumptions

ClearTrial 6.0 adds new assumptions to the Data tab of a plan/template to drive new ClearTrial-defined data management labor fees.

- Number of Adverse Event (AE) coded terms
- Number of Concomitant Medication coded terms
- Number of Medical History coded terms
- Number of Data Listings

Reorganized Data Management Assumptions

ClearTrial 6.0 reorganizes existing 5.9 CRF Design assumptions, Number of unique pages, and Number of screens per CRF page under the renamed Data Management data field set on the Data tab of a plan/template.

Collapsed Assignment Group

ClearTrial 6.0 collapses tasks assigned to the Database Programming Assignment Group into the Data Management Assignment Group on the Assignments tab of a plan/template in the 6.0 Cost Model. Existing Database Programming-assigned tasks in plans/templates with prior cost models will not be impacted.

New Data Management Labor Fees

6.0 Major Task Name	6.0 Task Name
Data Management Plan (DMP)	Develop Data Management Plan
Data Transfer Agreements (DTAs)	Develop Data Transfer Agreements

6.0 Major Task Name	6.0 Task Name
Third Party Data Source System Setup	Third Party Data Source System Setup
Data Management Oversight – Startup	Data Management Oversight – Startup
Data Management Oversight – Treatment	Data Management Oversight – Treatment
Data Management Oversight – Follow-up	Data Management Oversight – Follow-up
Coding Setup	Coding Setup
Subject Coding	Code Variables/Terms per Subject
Local Lab Reference Ranges Setup	Local Lab Reference Ranges Setup
Local Lab Reference Ranges Maintenance	Maintain Local Lab Reference Ranges
Data Listing Programming	Program Data Listings
Data Listing Reporting	Report Data Listings
Data Archival (Study Database)	Archive Data from the Study Database
Sponsor Oversight	Oversee – Data Management

Existing Data Management Labor Updates

ClearTrial 6.0 adjusts existing 5.9 resources and resource level-of-effort algorithms in the 6.0 Cost Model.

The 5.9 and 6.0 Major Task names have not been changed for the following Major Tasks and Tasks.

5.9/6.0 Major Task Name	5.9 /6.0 Task Name
Unique CRF Page Developed	Write and approve instructions for CRF Page (or EDC equivalent)
Database Designed	Create database design specifications
Database Designed	Build the study database
Data Entry Screen Developed	Design Data Entry screen
Data Entry Screen Developed	Conduct UAT and validate EDC system
Protocol Amendment	Update design of existing Data Entry screens
Protocol Amendment	Review new/modified CRF fields for protocol amendment
Protocol Amendment	Write and approve instructions for CRF page
Protocol Amendment	Update database edit specifications due to protocol amendment
SAE Processed	SAE Reconciliation
Sponsor Oversight	Oversee – Unique CRF Page Developed
Sponsor Oversight	Oversee – Database Designed
Sponsor Oversight	Oversee – Data Entry Screen Developed
Sponsor Oversight	Oversee – Data Management
Sponsor Oversight	Oversee – SAE Processed

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DSUR, Biostatistics, Sponsor Oversight, and More Updates

ClearTrial 6.0 adjusts existing 5.9 resources and resource level-of-effort algorithms for existing Drug Safety Update Reporting, Biostatistics, and Sponsor Oversight tasks in the 6.0 Cost Model.

5.9/6.0 Major Task Name	5.9/6.0 Task Name
Annual Drug Safety Update Report	Conduct summary of the status of each study in progress or completed during the previous year
Annual Drug Safety Update Report	Conduct summary of the status of the subjects planned and the number entered into the study
Annual Drug Safety Update Report	Prepare summary of any study results available
Annual Drug Safety Update Report	Prepare summary of serious adverse events (SAEs)
Annual Drug Safety Update Report	Prepare summary of deaths
Annual Drug Safety Update Report	Prepare summary of discontinued subjects
Sponsor Oversight	Oversee - Annual IND Report Activities
Issued Unique Summary Table	Complete unique summary table programming
Issued Unique Summary Listing	Complete unique summary figure/graph programming
Issued Repeat Summary Figure/Graph	Complete repeat summary figure/graph programming
Sponsor Oversight	Oversee – Issued Summary Table
Sponsor Oversight	Oversee – Issued Listing
Sponsor Oversight	Oversee – Issued Figure/Graph
Interim Analysis	Provide/review/approve interim analysis
Interim Analysis	Provide/review/approve interim SAS dataset design
Interim Analysis	Provide/review/approve interim tables
Sponsor Oversight	Oversee - A Written Protocol

Renamed/Deleted Tasks

ClearTrial 6.0 renames or deletes tasks in the 6.0 Cost Model.

5.9 Task Name	6.0 Task Name
Print Investigator Brochure	Deleted
Print protocol	Deleted
Print protocol amendment	Deleted
Develop study operating guidelines	Develop and agree on study operating guidelines
Conduct data coding (during follow-up)	Deleted
Conduct data coding (setup)	Deleted
Follow-up - Maintain EDC	Deleted
Post-FSFT - Maintain EDC	Deleted
Obtain clinical trial application and exemptions	Obtain country level regulatory approval
Obtain clinical trial application and exemptions for protocol amendment	Obtain country level regulatory approval for protocol amendment

Renamed Major Task

ClearTrial 6.0 renames existing Study Setup Per-Location Major Task to Study Setup per Location in the 6.0 Cost Model.

5.9 Major Task Name	6.0 Major Task Name
Study Setup Per-Location	Study Setup per Location

Updated Summary Groups

ClearTrial 6.0 updates existing 5.9 Summary groups in the 6.0 Cost Model. You can view the list of tasks by Summary Group if you launch the context-sensitive help on the Plan/Template Summary tab.

5.9 Summary Group Name	6.0 Summary Group Name
Startup Fees	Study Startup
Clinical Monitoring Closeout and Site Audit Fees	Clinical Operations
Safety and Medical Management	Safety/Pharmacovigilance
Safety and Medical Management	Medical Monitoring
Medical Writing/Final Report	Medical Writing
N/A	Regulatory

ClearTrial 6.0 maps ClearTrial-defined tasks under the ClearTrial-defined “Other” Summary Group to other functions in 6.0. If you have existing user-defined or CT-defined tasks mapped to “Other” in 5.9, those tasks will remain mapped to the “Other” Summary Group in 6.0 and displayed on the Summary tab.

5.9 Task Name	6.0 Summary Group
Initial CRA training for EDC	Clinical Operations
Train the EDC Trainer	Data Management
Conduct online EDC training session or refresher course	Data Management
Provide EDC Help Desk Support	Data Management

Replaced Resource

ClearTrial 6.0 replaces existing CT-defined resource, Secretarial Support with Clinical Trial Assistant across existing unlocked plans/templates.

New Work Units/Cost Drivers

ClearTrial 6.0 adds new work units/cost drivers to the list when defining resource algorithms for tasks or cost algorithms for indirect costs.

- Coded Terms
- Data Listings
- Third Party Data Sources
- Subject Months (not accounting for drops)
- Site Months
- Site Years

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Further EU CTR 536/2014 Support

EU CTR 536/2014 refers to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, which governs the conduct of clinical trials in the European Union (EU). This regulation aims to streamline and harmonize the processes for conducting clinical trials across EU member states. Overall, EU CTR aims to improve the efficiency, transparency, and safety of clinical trials conducted in the EU, facilitating the development and authorization of new medicinal products for human use.

Between January 2022 and January 2023, new trial applications could follow either the old Clinical Trial Directive (CTD) requirements or the new Clinical Trial Regulation (CTR) requirements. However, from January 31, 2023, submission according to the CTR became mandatory and by January 31, 2025, all ongoing trials approved under the legacy CTD need to transition to the new regulation. All new trials in locations in scope for EU CTR must use CTR.

ClearTrial reviews and updates the default MOH/FDA Delay timeline values per location bi-annually according to industry published summaries of expected time for the regulatory authority review of a clinical trial application (CTA) or investigational new drug application (IND) for research involving human subjects for medicinal drug products.

During 2023, the default values for the ClearTrial-supported locations in scope for EU CTR were updated to 125 calendar days from submission to approval, except Norway, which was updated to 106 calendar days from submission to approval. Additional guidance based on the type of product and type of reviews has been added to the context-sensitive help on the Locations tab. You can also click a column header on the Locations tab of a plan/template leveraging the 6.0 Cost Model to see this information.

ClearTrial Supported Locations in Scope for EU CTR

ClearTrial continuously monitors the regulatory landscape to provide the latest industry observed Ethics Committee and Regulatory application processing delays. The following supported countries and economically grouped region are in scope for EU CTR:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland

- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Nordic countries

EU CTR Impact to Labor Fees

ClearTrial 6.0 adds new logic that includes/excludes effort dynamically based on the locations that exist in a plan/template in the 6.0 Cost Model.

If a location in EU CTR scope exists in a plan/template, then new ClearTrial-defined EU CTR labor activities by regulatory resources are included while excluding “Obtain country level regulatory approval” task effort for each applicable location in the budget, thus leveraging the 6.0 Cost Model. Additionally, if a protocol amendment is defined in that plan/template, then new effort for “Modify EU CTR application for protocol amendment” will be included in the budget, while “Obtain country level approval for Protocol Amendment” task effort will be excluded for each applicable location.

Otherwise, when a location not in scope for EU CTR exists in a plan/template, then the “Obtain country level regulatory approval” task effort is included in the budget while excluding the new EU CTR activities. Additionally, if a protocol amendment is defined in that plan/template, then effort for the “Obtain country level approval for Protocol Amendment” will be included in the budget while the new “Modify EU CTR application for protocol amendment” task effort will be excluded.

New EU CTR-specific Labor

6.0 Major Task Name	6.0 Task Name
EU CTR Approval – Part I	Obtain EU CTR approval – Part I
EU CTR Approval – Part II	Obtain EU CTR approval – Part II
Protocol Amendment per Location	Modify EU CTR application for protocol amendment

6

Monitoring Enhancements

With the inclusion of centralized monitoring as a method for selection on the Monitoring tab of a plan/template, ClearTrial 6.0 introduces hybrid or alternative risk-based approaches.

Incorporating centralized monitoring as part of a risk-based monitoring approach helps reduce risk and ensure quality by detecting potential anomalies or risks more quickly.

New Monitoring Assumptions

ClearTrial 6.0 adds Monitoring Minutes per Page assumptions to the Screening and Follow-Up segments on the Treatment tab of a plan/template, providing better control over estimated effort across all study components. Additionally, the ClearTrial 6.0 Cost Model brings support for centralized monitoring to be selected as an option as part of your monitoring plan.

Centralized monitoring looks across all subject data across all sites and identifies any outliers to determine if there is an anomaly.

New Monitoring Labor

When centralized monitoring is selected as part of your risk-based monitoring strategy, ClearTrial-defined centralized monitoring activities will be included in the budget.

6.0 Major Task Name	6.0 Task Name
Centralized Monitoring Setup	Define central monitoring strategy
Centralized Monitoring Conduct	Central monitoring data review

New Monitoring Resources

ClearTrial 6.0 adds new centralized monitoring resources to the list of ClearTrial-defined resources launched from the Maintain Resources menu item as well as the list of resources to select from when defining or adjusting tasks.

These new resources work on the new centralized monitoring activities by default.

- CM01 – Central Monitor
- CM02 – Central Monitoring Analyst

Existing Monitoring Assumption Updates

ClearTrial 6.0 updates all phone-based monitoring assumptions to remote in the 6.0 Cost Model. You can continue to leverage and report on the phone-based assumptions, units/cost drivers, and variables in existing 5.9 plans.

Overridable Total Remote Visits

ClearTrial 6.0 updates the “Total Remote Visits” system-calculated field displayed globally and per location to be an editable field, allowing you to input the precise value for downstream calculations when data is available.

Existing Labor Updates

ClearTrial 6.0 updates all 5.9 ClearTrial-defined phone-based activities to being performed remotely in the 6.0 Cost Model.

5.9 Major Task Name	5.9 Task Name	6.0 Major Task Name	6.0 Task Name
Site Identified by Vendor	Approve potential sites inclusion based on telephone screening report	Site Identified by Vendor	Approve potential sites inclusion based on remote screening report
Pre-study Site Visit by Phone	Complete phone-based pre-study site visit	Remote Pre-study Site Visit	Complete remote pre-study site visit
Pre-study Site Visit by Phone	Complete phone-based pre-study site visit Trip Report Review	Remote Pre-study Site Visit	Complete remote pre-study site visit Trip Report review
Site Initiation Visit by Phone	Complete phone-based site initiation visit	Remote Site Initiation Visit	Complete remote site initiation visit
Site Initiation Visit by Phone	Complete phone-based site initiation visit Trip Report Review	Remote Site Initiation Visit	Complete remote site initiation visit Trip Report review
Phone-based Monitoring Visit	Complete phone-based interim monitoring visit	Remote Monitoring Visit	Complete remote monitoring visit
Phone-based Monitoring Visit	Complete phone-based interim monitoring visit - Trip Report Review	Remote Monitoring Visit	Complete remote monitoring visit Trip Report review
Site Management Week - Startup	Conduct weekly telephone communication with site staff - Startup	Site Management Week - Startup	Conduct weekly remote communication with site staff – Startup
Site Management Week - Treatment	Conduct weekly telephone communication with site staff	Site Management Week - Treatment	Conduct weekly remote communication with site staff – Treatment
Site Management Week – Follow-up	Conduct weekly telephone communication with site staff during Follow-up	Site Management Week – Follow-up	Conduct weekly remote communication with site staff during Follow-up

5.9 Major Task Name	5.9 Task Name	6.0 Major Task Name	6.0 Task Name
Site Close-out Visit by Phone	Conduct final site close-out visit (via phone)	Remote Site Close-out Visit	Conduct remote final site close-out visit
Site Close-out Visit by Phone	Conduct final site close-out visit (via phone) Trip Report Review	Remote Site Close-out Visit	Conduct remote final site close-out visit Trip Report review

7

New Scripted Variables

ClearTrial 6.0 updates scripted variables for user-defined algorithms at the task-resource and indirect cost levels. Please note that scripted variables apply to a specific cost model; for example, existing phone-based scripted variables are available in 5.9 and previous cost models.

For the cumulative list of scripted variables available, please refer to the *Scripted Variables Guide* located on ClearTrial 6.0 Oracle Help Center Books page in the Supporting Documentation section. New scripted variables for the 6.0 Cost Model are highlighted.

> **Note:**
>
> The variables available for use are versioned and depend on the cost model of a plan/template.

8

User Experience/Efficiency Enhancements

To enhance the efficiency of identifying or locating labor or cost items within a plan, the Define Filter section has been enhanced to include text search.

New Search Functionality

ClearTrial 6.0 adds new search functionality on the Labor tab and Costs tab of a plan/template to filter out specific cost categories or major tasks from the list.

To return back to the full list, delete the text from the Search field. This field is cost-model agnostic and available for all existing plans or new plans in 6.0.

9

Best Practices

As with every update, we are providing ClearTrial recommended best practices to ensure that you are working effectively with your usage and budgeting operations.

- **Lock your plans** when you are satisfied with your final operational budget forecast and to prevent assumption values from being changed.

  Locking a plan freezes its calculated values for expected hours effort, costs, timelines, and assumptions.
- **Freeze billing rates** to ensure existing rates are preserved in plans when you are satisfied with your operational budget forecast.
- **Upgrade** plans and templates by creating a copy of the plan or template and upgrading the copied record in order to compare the upgraded plan or template to the prior cost model version.

For more information, see the following:

- Why Upgrade the Cost Model?
- Upgrade Existing Plans and Templates to the Latest Cost Model

Why Upgrade the Cost Model?

Upgrading plans and user-defined templates to the latest cost model ensures you are working with the latest updates to fees and costs included in both the ClearTrial-defined Work Breakdown Structure (WBS) and default indirect (pass-through or miscellaneous) cost calculations. Please review existing plans and user-defined templates and make copies of these records. When copying a record, you can upgrade the copy to leverage the latest cost model updates. Compare the existing source plan/template to its upgraded copy to gain insight into the updates in the new cost model.

> **Note:**
>
> Existing plans and user-defined templates do not automatically get upgraded to the new available cost model.

Upgrade Existing Plans and Templates to the Latest Cost Model

If you need to determine the impact to your budget of upgrading existing plans or user-defined templates to the latest cost model, make a copy of the plan and template and apply the new cost model to the copy to allow comparison to the prior cost model version of the plan or template.

1. From the Plan or Template list screen, copy the existing plan/template you want to upgrade.
   a. Select the copied plan/template.

b. Click **Other Actions** and select **Change Attributes**.

c. On the **Change Plan Attributes** screen, select **6.0** from the **Cost Model** drop-down list.

d. Click **Save & Close**.

2. Update the cost model of the copy.

3. From the Plan or Template list screen, select the original and its copy, and click **Compare** to run the comparison reports.