Oracle® Health Sciences ClearTrial Cloud Service

Release Notes

Release 5.9

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Oracle Health Sciences ClearTrial Cloud Service Release Notes, Release 5.9

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Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support

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.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center at: https://docs.oracle.com/en/industries/health-sciences/cleartrial/index.html

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

1

About ClearTrial 5.9 Updates

Release 5.9 brings significant enhancements that expand the breadth of the types of trials that you can model and plan accurately in ClearTrial. This includes better support for complex trial designs with multiple, staggered cohorts and long-term follow-up.

This software update includes a new 5.9 Cost Model which offers the latest industry standard costing algorithms. For information on how to upgrade plans/templates to the latest cost model, see Best Practices.

2

Support for Complex Trial Designs

This release provides a new and improved plan user experience by increasing flexibility to better support complex trial designs.

- Define up to 26 cohorts/treatment arms in a single plan/template
- Stagger starts of treatments
- Name treatments
- Define Screening
- Define Follow-up/Extension studies
- Add cycles
- Precise milestones
- New Study/Budget End assumptions
- Scaled default labor updates
- Updated reporting
- Updated scripted variables for custom algorithms

In addition, see the following:

- Redesigned user interface for the updated assumptions model
- Labor updates to reflect default scaled effort across trial segments
- Updated milestones

Redesigned user interface for the updated assumptions model

- Subject level assumptions are moved to the treatment level, by location, to increase flexibility in modeling various cohorts. As a result, the Plan Subject tab has been removed and the Treatment tab has been redesigned.
- The *Number of subjects* assumption is moved to the treatment level so you can vary the number of subjects entering per treatment and per location.
- All dialogs that were launched from the Subject tab are now displayed per treatment, per location, when you edit a treatment on the Treatment tab. The ability to manage assumptions globally/by location is available from these dialogs.
- All Investigator grant-specific assumptions per location are available from one place on the Treatment tab and when editing a treatment.
- Plan up to 26 cohorts/treatment arms with the capability to name each one to align with the protocol or be distinguished from others.
- Vary operational characteristics across screening, treatment, and follow-up segments or periods of a study.
- Define screening period characteristics per treatment.

- Define follow-up period characteristics per treatment.
- Specify a different start date per treatment or stagger treatment starts.
- Vary enrollment characteristics per treatment; for example, specify a different number of subjects enrolled and a different enrollment rate per treatment.
- New assumption for the *Number of cycles* or repetitive treatments during a treatment.
- To align with the protocol's Schedule of Assessments, each segment and cycle is displayed on the Treatment Schedule.
- New totals bar to quickly view the total subjects allocated across all treatment arms and significant milestone dates as you are defining each treatment.
- New End of Study assumptions and system-calculated dates are displayed on the Data tab to account for supplemental milestones that occur from follow-up to the end of study/budget:
  - *Will there be a Supplemental CSR?*
  - *Reduce effort for Supplemental CSR by*
  - *Days from LSLV/LPLV until Database Lock (EOS)*
  - Database Lock (EOS) date
  - *Days from Database Lock (EOS) until Statistical Report (EOS) due*
  - Stat Report (EOS) date
  - *Days from Database Lock (EOS) until Draft Report (EOS) due*
  - Draft Report (EOS) date
  - *Days from Database Lock (EOS) until Final Report (EOS) due*
  - Final Report (EOS) date
  - *Days from Final CSR (EOS) to Study/Budget End*
  - Study/Budget End date
- Updated reporting to reflect screening, treatment, and follow-up assumptions, dates, and milestones.
  - Assumptions, Compare Assumptions
  - Milestones Dates Report, Compare Milestone Dates
  - Milestones Timeline Chart
  - RFP Specifications
- Updated scripted variables for custom algorithms on the Costs tab or within Task Manager.
  - For the latest list, refer to the Scripted Variables Guide located on Oracle Help Center under **Books** then **Supporting Documentation**.

Labor updates to reflect default scaled effort across trial segments

- The Project Management default labor effort has been broken out into three Major Tasks to account for the screening, treatment, and follow-up periods.

- Project Management Week prior to FSFT
- Project Management Week after FSFT
- Project Management Week – Follow-up
  - This new Major Task effort is driven by a new assumption, “Reduce Project Management effort during Follow-up by”, located on the Data tab.
- The Site Management default labor effort has been broken out into three Major Tasks to account for the screening, treatment, and follow-up periods.
  - Site Management Week – Startup
  - Site Management Week – Treatment
  - Site Management Week – Follow-up
- New default Major Tasks for Medical Monitoring during treatment and follow-up.
  - Medical Monitoring
  - Medical Monitoring – Follow-up
- New default labor effort included for supplemental activities performed after the treatment period/from the start of follow-up to the End of Study (EOS) driven by the new assumption *Reduce effort for Supplemental CSR by*.
  - End of Study Database Locked
    - Conduct data coding (during follow-up)
    - Annotate CRFs to database specs (during follow-up)
    - Conduct query resolution (during follow-up)
    - Prepare information for DSMB reporting (during follow-up)
  - End of Study Stat Report
    - End of Study Stat Report - Prepare summary of final statistical results
    - End of Study Stat Report - Discuss summary of efficacy and safety parameters
    - End of Study Stat Report - Conduct quality control check of summary report results
    - End of Study Stat Report - Rewrite summary reports drafted
    - End of Study Stat Report - Conduct literature searches
    - End of Study Stat Report - Incorporate sponsor's comments
  - End of Study Draft Report
    - End of Study Draft Report - Prepare summary of final statistical results
    - End of Study Draft Report - Discuss summary of efficacy and safety parameters
    - End of Study Draft Report - Conduct quality control check of summary report results
    - End of Study Draft Report - Rewrite summary reports drafted
    - End of Study Draft Report - Conduct literature searches
    - End of Study Draft Report - Incorporate sponsor's comments
  - End of Study Final Report

* End of Study Final Report - Prepare summary of final statistical results
* End of Study Final Report - Discuss summary of efficacy and safety parameters
* End of Study Final Report - Conduct quality control check of summary report results
* End of Study Final Report - Rewrite summary reports drafted
* End of Study Final Report - Incorporate sponsor's comments
* End of Study Final Report - Prepare CSR (Clinical Summary Report)

Updated milestones

5.8 Milestone Name	Acronym	5.9 Milestone Name	Acronym	Description
N/A	N/A	First Subject/ Patient First Visit	FSFV/FPFV	First Subject Screened/First Screening Visit/ First data collection event
First Subject/ Patient In	FSI/FPI	First Subject/ Patient First Treatment	FSFT/FPFT	First Subject Treated/ Randomized/ Dosed/ Intervention starts
N/A	N/A	Last Subject/ Patient First Visit	LSFV/LPFV	Last Subject First Screening Visit
First Subject/ Patient Observation	FSO/LPO	First Subject/ Patient Last Treatment	FSLT/FPLT	First Subject Last Treatment Visit
Last Subject/ Patient In	LSI/LPI	Last Subject/ Patient First Treatment	LSFT/LPFT	Last Subject First Treatment Visit
N/A	N/A	First Subject/ Patient First Follow-up	FSFFU/FPFFU	First Subject First Follow-up Visit
Last Subject/ Patient Observation	FSO/LPO	Last Subject/ Patient Last Treatment	LSLT/FPLT	Last Subject Last Treatment Visit
N/A	N/A	Last Subject/ Patient First Follow-Up	LSFFU/LPFFU	Last Subject First Follow-up Visit
N/A	N/A	First Subject Last Visit	FSLV/FPLV	First Subject Last Follow-up Visit
N/A	N/A	Last Subject Last Visit	LSLV/LPLV	Last Subject Last Follow-up Visit
N/A	N/A	Study/Budget End	EOS	End of Study/ Budget or when costing is expected to end

3
Clinical Intelligence Update

This section covers the following topics:

- MOH/FDA Delay updates
- Data Management labor updates
- New electronic Trial Master File costing

MOH/FDA Delay updates

5.9 has been enhanced with updated MOH/FDA Delay Defaults effective for 2021.

ClearTrial continuously monitors the regulatory landscape to provide the latest industry observed Ethics Committee and Regulatory application processing delays. The observed changes are represented by the new MOH/FDA Delay Defaults in the application. The following supported countries and economically grouped regions have updated MOH/FDA Delay defaults in 5.9:

- Belgium
- Brazil
- Estonia
- Greece
- Israel
- Latvia
- Lithuania
- Norway
- Peru
- Poland
- Romania
- Saudi Arabia
- South Africa
- Turkey
- Ukraine
- United Kingdom

The updates to these location-specific defaults only impact new plans using the 5.9 cost model or if new locations are added to existing plans(unless you are importing the location-specific overridden MOH delay value from another plan/template).

Data Management labor updates

ClearTrial offers the latest industry standard Data Management direct labor updates. These include the following:

- New/Updated Resources (across all Cost Models)
- New/Updated Labor Fees

New/Updated Resources (across all Cost Models)

Existing Plans	New Plans
DM01 - Data Coordinator	DM01 – Data Coordinator
DM02 – Data Entry Clerk	DM02 – Data Entry Clerk
DM03 – Data Manager	DM03 – Data Manager
DM04 – Senior Programmer	DM04 – DM Programmer
DM05 – Program Analyst	Removed
DM06 – Senior Program Analyst	DM06 – Senior DM Programmer
DM07 – EDC Help Desk Support Specialist	DM07 – EDC Help Desk Support Specialist
DM08 – EDC Help Desk Manager	DM08 – EDC Help Desk Manager
DM09 – EDC Trainer	DM09 – EDC Trainer
N/A	DM10 – Senior Director, Data Management

New/Updated Labor Fees

5.8	5.9
Design CRF page (or EDC equivalent)	Design CRF page (or EDC equivalent)
Review CRF page (or EDC equivalent)	Review CRF page (or EDC equivalent)
Write and approve instructions for CRF page (or EDC equivalent)	Write and approve instructions for CRF page (or EDC equivalent)
Create database edit specifications	Create database edit specifications
Document the database design	Create database design specifications
Program the database	Build the study database
Define attributes for the database	Removed
Define the variable names for the database	Removed
Configure and test EDC transfers	Configure and test EDC transfers
Design data entry screen	Design data entry screen
N/A	Conduct UAT and validate EDC system
Conduct quality control on updated data entry screens	Conduct quality control on updated data entry screens

New electronic Trial Master File costing

New assumptions, labor fees, and indirect costs are now included by default to account for the electronic Trial Master File (eTMF).

- New Assumptions
- New Resources
- New Labor Fees
- New Indirect Costs

New Assumptions

- Number of eTMF Country/Region Files – which drives the following tasks:
  - eTMF Country/Region File Setup
  - eTMF Country/Region File Maintenance
  - eTMF Country/Region File Close-out
  - Oversee – eTMF Setup
  - Oversee – eTMF Maintenance
  - Oversee – eTMF Close-out
- Number of eTMF Site Files – which drives the following tasks and pass-through cost:
  - eTMF Site File Setup
  - eTMF Site File Maintenance
  - eTMF Site File Close-out
  - Oversee – eTMF Setup
  - Oversee – eTMF Maintenance
  - Oversee – eTMF Close-out
  - TMF Shipping (Pass-through)
- Number of months for the Vendor to archive the eTMF – which drives the following pass-through cost:
  - TMF Archival

New Resources

- TMF01 – TMF Manager
- TMF02 – TMF Coordinator

New Labor Fees

- eTMF Master File Setup
- eTMF Country/Region File Setup
- eTMF Site File Setup
- eTMF Master File Maintenance
- eTMF Country/Region File Maintenance
- eTMF Site File Maintenance
- eTMF Site File Close-out

- eTMF Country/Region File Close-out
- Oversee – eTMF Setup
- Oversee – eTMF Maintenance
- Oversee – eTMF Close-out

New Indirect Costs

- TMF Archival
- TMF Shipping

4

Increased Usability/Efficiency

- New Phase I (Patients) Study Phase for Phase I trials in patients with other indications besides oncology/vaccines or trials with Healthy Volunteers.
- Cost Model added as a default column on the Template List screen.
- Calculated Cost available from Configure List Options for the Plan List screen.
- Create Study capability is now available from the Product List screen and New/Edit Product screen.
- Click the new clear icon to clear overrides orrestore defaults when editing FSFT dates or enrollment period values by location.
- Click the new undo icon to restore existing location-specific FSFT overrides when switching to Manage FSFT dates by Treatment.
- Instructions to reset your account when locked out.
- New assumption for *Grant payment frequency* to support frequency options for *Number of grant payments per site*.
- Show expected *until week* date when adjusting monitoring frequency by location.
- Expand/Ccollapse all Assignment Groups in one click.
- Updated Plan Assumptions Report format for location and treatment-specific assumptions to easily support Change Orders.
- All documents are translated by default when locations are added to a plan.
- Updated default department of all EDC indirect costs to Data Management.
- Updated default GL Code of all Meetings indirect costs to Outside Services.

5

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** before sending out budgets to contract 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 suggested defaults.
- **Freeze billing rates** to ensure existing rates are preserved in copies of locked plans or any time you are satisfied with your operational budget forecast.
- **Upgrade** existing plans and user-defined templates to the latest available cost model.

For more information, see the following:

- Why upgrade the Cost Model?
- Upgrading existing plans and templates to the latest Cost Model
- Impact of unlocking a plan using a 5.2 or prior 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.

> **Note:**
>
> Existing plans and user-defined templates do not automatically get upgraded with each update that includes a new available cost model.

Upgrading existing plans and templates to the latest Cost Model

If you need to determine the impact of upgrading existing plans or user-defined templates to the latest cost model, do the following to quickly assess the impact to your budget:

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 dialog, select **5.9** from the **Cost Model** drop-down list.
   d. Click **Save & Close**.

2. Update the cost model of the copy.
3. From the list screen, select the original and its copy, and click **Compare** to run the comparison reports.

Impact of unlocking a plan using a 5.2 or prior Cost Model

When you unlock or copy an existing plan using a 5.2 or prior cost model, that plan defaults to the latest available cost model.