

ORACLE®

# Introduction to Oracle ClearTrial Cloud Service 5.5

## Functional Overview

Product Management  
Health Sciences Global Business Unit  
June 13, 2016

# Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

# Agenda

- 1 ➤ ClearTrial 5.5 Release Overview
- 2 ➤ 5.5 Features and Functionality Edition Impact
- 3 ➤ 5.5 Enhancements & Features

- 1 ClearTrial 5.5 Release Overview
- 2 5.5 Features and Functionality Edition Impact
- 3 5.5 Enhancements & Features

# ClearTrial 5.5 Release Overview

- Release Objectives:
  - Continue to update and maintain the application's embedded clinical intelligence available to remain accurate and up to date with industry standards.
  - Continue to provide greater flexibility/configurability.
- Release Approach: Market and Customer Driven
- Go Live:

<b>START</b>	<b>Thu, June 16<sup>th</sup> 9PM EDT</b>
<b>END</b>	<b>Fri, June 17<sup>th</sup> 3AM EDT</b>



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*ClearTrial will not be available during the maintenance window.*

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# Best Practice Reminder

- Freeze your rates.
  - Freezing rates for all plans upon creation will keep you from having to revisit all your plans to freeze rates before a release.
- Review updates post-release and decide if you want to update any existing plans (and templates) to the latest cost model.
  - If you decide to update a plan (or template) to a new cost model version, copy the existing plan and then update the cost model on the copy.
  - You can then run a compare report on new and existing plans (or templates) to quickly view the impacts of the new cost model.

- 1 ClearTrial 5.5 Release Overview
- 2 5.5 Features and Functionality Edition Impact
- 3 5.5 Enhancements & Features



## 5.5 Features and Functionality Edition Impact

Feature	Standard Edition	Enterprise Edition
Medical Monitoring and Safety Updates	X	X
New Units of Measurement/Cost Drivers Available	X	X
Usability Enhancements	X	X
Expanded Browser Support	X	X
WS-API Updates		X
Advanced Algorithms – ‘Percentage of’ Assumption	X	X
Advanced Algorithms – Multiple Expressions		X
New Additional Role/Capability for Advanced Algorithm Editor		X

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- 3 5.5 Enhancements & Features**

# Medical Monitoring and Safety Updates

# Summary of Medical Monitoring and Safety changes

	Cost Model Impacted	Study Phase Impacted
New and removed assumptions/specifications	5.5 cost model only	All, excluding Phase I Healthy Volunteers
Algorithm updates*		
New, removed and renamed Major Tasks and tasks*		
Renamed assignment group*		
New summary category*		
New resources*	All	All

*\*Please see 5.5 Release Notes for more details*

# New Assumptions/Specifications on Treatment Tab

## Only Available in 5.5 Cost Model

### Edit Plan

Notes

- Overview
- Locations
- Site
- Subject
- Treatment**
- Data
- Monitoring
- Provider
- Meetings
- Assignment
- Labor
- Costs
- Payments
- Summary

Specify subject treatments Current Edit Mode: **Expert**

**Study Characteristics**

Trial Design:  Parallel  Cross-over Will there be an electronic subject diary?:  Yes  No

Is this an endpoint study?:  Yes  No

**Treatment(s)**

Add Edit Copy Delete

ID	Treatment Parameters		
<input checked="" type="checkbox"/> A	Number of subjects: 100	Treatment duration: <input type="text"/> weeks	Visits per subject: <input type="text"/>
	CRF pages per subject: <input type="text"/>	Subject diary pages: <input type="text"/> 0	QOL pages: <input type="text"/> 0
	Subject diary pages: <input type="text"/> 0	Pharmacoeconomic pages: <input type="text"/> 0	
	Lab and diagnostic tests per subject: <input type="text"/> 0	Cohort escalation reviews: <input type="text"/> 0	
	Monitoring minutes per CRF page: 5.667		

Displayed in Advanced and Expert edit modes and are not populated by default (0)



# New Assumptions/Specifications on Monitoring Tab

Only Available in 5.5 Cost Model

## Edit Plan

Overview	Manage location-specific values: <a href="#">Edit location-specific overrides</a>
Locations	
Site	
Subject	
Treatment	
Data	
<b>Monitoring</b>	
Provider	
Meetings	
Assignment	
Labor	

Monitored Data	
Total CRF pages generated (without subject drops):	5,000
Total CRF pages monitored (accounting for subject drops):	<input type="text" value="4,488"/>

Medical Monitoring	
24/7 coverage:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Number of medical data listing reviews:	<input type="text" value="4"/>

Separate Drug Accountability	
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Notes

Displayed in Advanced and Expert edit modes and are populated by default



# Removed Assumption/Specification from Monitoring Tab

Edit Plan		Notes
Overview	Time to review queries from previous visit (minutes):	3.4
Locations	Manage location-specific values:	<a href="#">Edit location-specific overrides</a>
Site	Monitored Data	
Subject	Total CRF pages generated (without subject drops):	5,000
Treatment	Total CRF pages monitored (accounting for subject drops):	4,488
Data	Medical Monitoring	
Monitoring	Estimated number of FTE (full-time equivalent) medical monitors:	0.01 FTEs
Provider	Separate Drug Accountability	
Meetings		
Assignment		
Labor		

Assumption still available in 5.3 and 5.4 cost models

Estimated number of FTE medical monitors not available in 5.5 cost model

Medical monitoring in 5.5 cost model is based on site weeks and patients per location and considers 24/7 coverage

Edit Plan		Notes
Overview	Manage location-specific values:	<a href="#">Edit location-specific overrides</a>
Locations	Monitored Data	
Site	Total CRF pages generated (without subject drops):	5,000
Subject	Total CRF pages monitored (accounting for subject drops):	4,488
Treatment	Medical Monitoring	
Data	24/7 coverage:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Monitoring	Number of medical data listing reviews:	4
Provider	Separate Drug Accountability	
Meetings		
Assignment		
Labor		

# Additional Units of Measure Available



# Additional Units of Measure Available

## In Task Manager and Cost Algorithm set-up screen

- Three (3) new available units of measurement (UOM)
  - Medical Data Listing Review
  - Cohort Escalation Review
  - Grant Payment

**Edit or Adjust**

New cost

Definition Assignments **Algorithm** Distribution

All Locations

Calculate as:  USD per:  % of:

[Add another expression...](#)

Total:  USD

- Studies
- Locations
- Sites
- Cohort Escalation Reviews**
- CRF Books Printed
- CRF Pages (Total w/ Drops)
- Data Entry Screens
- Data Imports
- Data Transfers
- Drug Shipments
- DSMB Reports
- EDC Training Sessions
- Expedited SAEs
- Grant Payments**
- Interim Analyses
- Medical Data Listing Reviews**
- Monitoring visits

# Usability Enhancements

# Indicator for Number of Selected Cost Items

- The Cost tab now displays the number of cost items selected.

Navigation: Edit | Report | Maintain | Admin | Help | Welcome, Jane Doe | Visit Support Center | Logout

### Edit Plan Notes

Specify pass-through or other indirect costs for this study Current Edit Mode: Expert

Filter: Show:  excluded cost(s)  categories where costs total 0.00

New Edit Exclude Include Delete

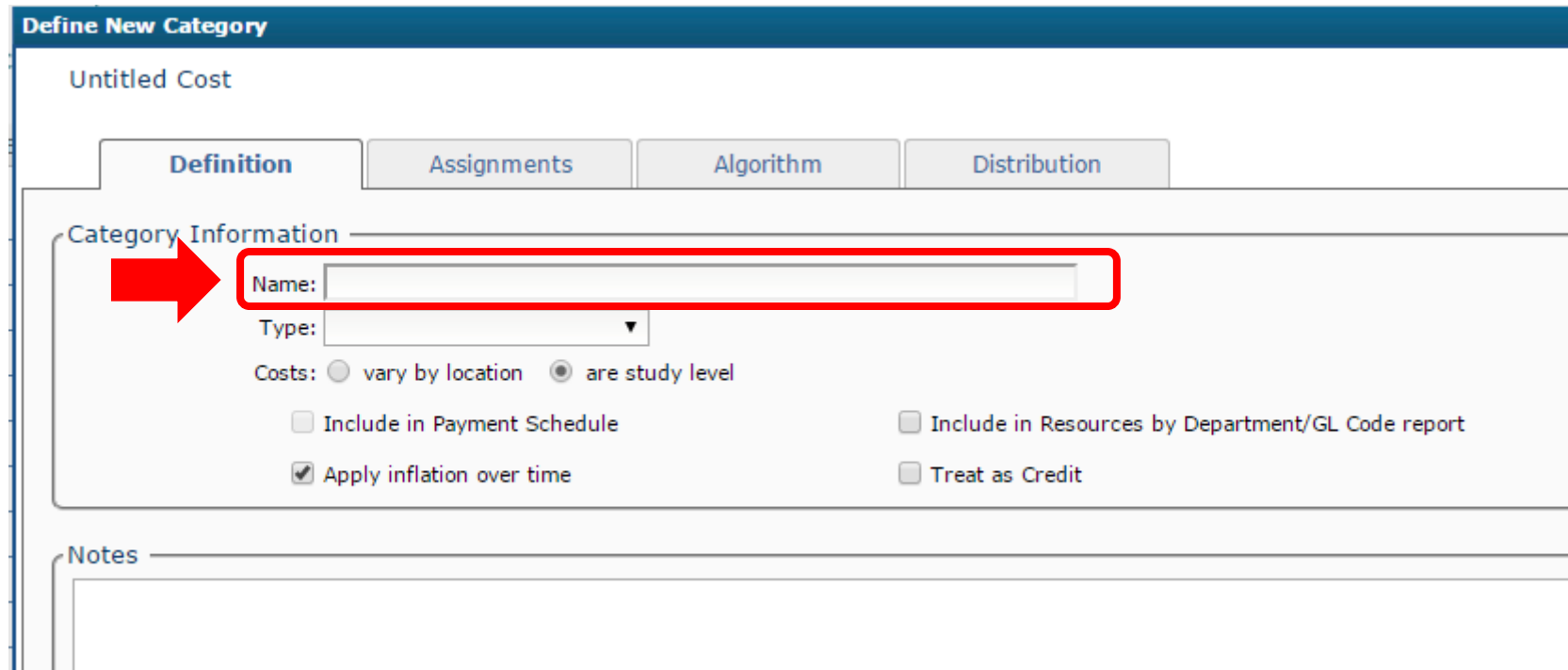
**All calculated costs and adjustments are displayed in US Dollar (USD)**

Name	Type	Calculated	Adjustment	Total
<input checked="" type="checkbox"/> Advertising (additional)	Miscellaneous	--	--	--
<input type="checkbox"/> Call Center	Miscellaneous	--	--	--
<input checked="" type="checkbox"/> Clinical Trial Insurance	Pass Through	0	0	0
<input checked="" type="checkbox"/> Consultants	Miscellaneous	--	--	--
<input type="checkbox"/> CRF Printing	Miscellaneous	0	0	0
<input type="checkbox"/> Drug Distribution - Special Handling	Miscellaneous	--	--	--

3 costs are selected [clear](#)

# Increased Number of Characters for User-Defined Cost Name

- The number of characters allowed for user-defined cost names has increased.



The screenshot shows the 'Define New Category' form for an 'Untitled Cost'. The 'Definition' tab is active. The 'Category Information' section contains the following fields and options:

- Name:** A text input field, highlighted with a red box and a red arrow pointing to it.
- Type:** A dropdown menu.
- Costs:** Radio buttons for 'vary by location' and 'are study level' (selected).
- Include in Payment Schedule
- Include in Resources by Department/GL Code report
- Apply inflation over time
- Treat as Credit

The 'Notes' section is visible at the bottom of the form.

# Expanded Browser Support

# Support for Microsoft Internet Explorer 11

- Oracle ClearTrial 5.5 now provides support for Microsoft IE11.
- The recommended configuration is Google Chrome or, if using Microsoft Internet Explorer, then IE10 or above.

# WS-API Enhancements

# WS-API Enhancements

- The Web Services API now includes the ability to filter the listing of Plans, Studies, or Compounds based on a last modified date.
- The Plan Resource and Study Resource APIs have been enhanced to include more data points.



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*As a reminder, if you are Plan Enterprise customer and your development/IT team would like more information, please refer to the Web Services API Developer User Guide accessible from the ClearTrial Support Center*

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# Advanced Algorithms

# Advanced Algorithms

- Advanced algorithms expand existing algorithm functionality for calculating the level-of-effort in hours for resources or a monetary value for costs.
- Advanced algorithms give the user more control over how fees and costs are generated by allowing the user to
  - create multiple (up to 8) expressions that can use different drivers, and
  - apply a percentage to a driver.
- As with prior releases, advanced algorithms can be used to
  - define effort for new resources added to tasks,
  - define new costs, and
  - make adjustments to ClearTrial-defined costs.

# Advanced Algorithms *cont'd*

In 5.4

**New location Major Task » New task2 » CR01 - Clinical Research Associate**

Resource Details **Algorithm** Billing Rate Location Rates & Substitutions Unit Hours

Calculate unit hours as: 12.500 x Location (per each of the Site)

Location	Calculate unit hours as	Unit Hours	# Units	Ext. Hours
Canada	12.500 x Location =	12.500	5	62.500
USA	10.000 x Location =	10.000	5	50.000

Close Save Save & Close

In 5.5

**New location Major Task » New task2 » CR01 - Clinical Research Associate**

Resource Details **Algorithm** Billing Rate Location Rates & Substitutions Unit Hours

**Default**

Calculate as: 10.000 hours per: 100.00 % of: Locations (per each of the Site)  
1.250 hours per: 50.55 % of: Subjects Complete

Restore Defaults Add another expression...

	Unit Hours	Ext Hours
<b>Canada</b>		
Calculate as: 10.000 hours per: 100.00 % of: Locations	10.000	50.000
1.250 hours per: 50.55 % of: Subjects Complete	2.528	12.638
<b>Add another expression...</b>	<b>12.528</b>	<b>62.638</b>
<b>USA</b>		
Calculate as: 5.000 hours per: 100.00 % of: Locations	5.000	25.000
2.000 hours per: 50.00 % of: Subjects Complete	4.000	20.000
2.500 hours per: 100.00 % of: Studies	2.500	12.500
<b>Use Default Algorithm Add another expression...</b>	<b>11.500</b>	<b>57.500</b>
		<b>120.138</b>

# Advanced Algorithms – Multiple Expressions

- Users are now able to create up to 8 expressions to aid in calculating the level-of-effort in hours for a task (for resources) or a monetary value (for costs).



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***Only Enterprise Edition users*** who have been assigned the *Advanced Algorithm Editor* role can add or remove expressions from an algorithm.

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# Advanced Algorithms – Multiple Expressions *cont'd*

- There are two key terms when defining advanced algorithms:
  - **Expression**: an element of an algorithm composed of various input parameters
    - Example:  $[\text{InputA} * \text{InputB} * \text{InputC}] = \text{Expression1}$
    - For resource algorithms, input parameters include hours, cost driver, and percentage to apply to the cost driver
    - For cost algorithms, input parameters include a monetary value, currency, cost driver, and percentage to apply to the cost driver
  - **Algorithm**: one or more expressions that evaluate to the level-of-effort in hours (for resources) or a monetary value in a specific currency (for costs)
    - Example:  $[\text{Expression1}] + [\text{Expression2}] = \text{Algorithm}$

# Advanced Algorithms – Multiple Expressions *cont'd*

**Task Manager**

Task Search...

**New location Major Task » New task2 » CR01 - Clinical Research Associate**

Resource Details | **Algorithm** | Billing Rate Location | Rates & Substitutions | Unit Hours

**Default**

Calculate as: 10.000 hours per: 100.00 % of: Locations (per each of the Site)  
 1.250 hours per: 50.55 % of: Subjects Complete

Restore Defaults | Add another expression...

	Unit Hours	Ext Hours
<b>Canada</b>		
Calculate as: 10.000 hours per: 100.00 % of: Locations	<b>EXPRESSION 1</b>	10.000
1.250 hours per: 50.55 % of: Subjects Complete	<b>EXPRESSION 2</b>	2.528
	<b>12.528</b>	<b>62.638</b>
<b>USA</b>		
Calculate as: 5.000 hours per: 100.00 % of: Locations	<b>EXPRESSION 1</b>	5.000
2.000 hours per: 50.00 % of: Subjects Complete	<b>EXPRESSION 2</b>	4.000
2.500 hours per: 100.00 % of: Studies	<b>EXPRESSION 3</b>	2.500
	<b>11.500</b>	<b>57.500</b>
		<b>120.138</b>

Algorithm consisting of 2 expressions equating to 62.638 hours for the resource to perform the task in this location

Algorithm consisting of 3 expressions equating to 57.500 hours for the resource to perform the task in this location

# Advanced Algorithms – Multiple Expressions *cont'd*

- If you are an EE user, but don't have the Advanced Algorithm Editor role,
  - You can continue to use the one-expression functionality that was available in 5.4; the one-expression functionality now also includes the new input parameter for percentage of cost driver.
  - You can update the input parameters for an existing multi-expression algorithm which was created by another user, but you will not be able to add new or remove existing expressions to the algorithm.



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*As a reminder, in order to use resource algorithms within the Task Manager, you are required to have permission to the Advanced or Expert edit mode.*

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# Advanced Algorithms – Percentage of Driver

- Users are now able to apply a percentage to a driver to aid in calculating the level-of-effort in hours (for resources) or a monetary value (for costs).
- The new input parameter is available to both Standard and Enterprise users who can create/edit algorithms and is also available in all supported cost models.

**Task Manager**

Task Search...

- CRF Page Entered into Data
- Query Resolution - by Mon
- Interim Analysis
- Site Audited
- Annual IND Report Activitie
- Site Close-out Visit
- Site Close-out by Phone
- Third-party Data Import
- All Data Cleaned and Datab
- Data Transfer
- Final Data Audit

**New centralized Major Task » New task » CR01 - Clinical Research Associate**

Resource Details | **Algorithm** | Billing Rate Location | Rates & Substitutions | Unit Hours

All Locations				Unit Hours	Ext Hours
Calculate as:	5.000	hours per:	100.00 % of: Studies	5.000	60.000
	2.250	hours per:	50.25 % of: Sites	11.306	135.675
<a href="#">Add another expression...</a>				<b>16.306</b>	<b>195.675</b>



# New Additional Role/Capability – Advanced Algorithm Editor

- The ability to add or remove expressions within an algorithm is only available to Enterprise Edition users who have been given the additional role/capability of “Advanced Algorithm Editor”.
- A training video is available from the ClearTrial Support Center for users who will be designated as advanced algorithm editors.

Edit Report Maintain Admin Help

### Edit User

Profile Roles

#### Roles for Jane Doe

Primary Role: Clinical Administrator

Additional Roles/Capabilities:

- Exchange Rates Administrator
- Resources Administrator
- Reporting Regions Administrator
- Departments/GL Codes Administrator
- RFP Administrator
- RFP/Bid Reader
- Custom Fields Designer
- Advanced Algorithm Editor
- Wbs Editor
- Wbs Manager

New additional role for Advanced Algorithm Editor.

Can be granted to users with primary role of Power User, Clinical Administrator or System Administrator.

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