

ORACLE®

Introduction to Oracle ClearTrial 5.7

Customer Briefing

ClearTrial Product Management
Health Sciences Global Business Unit
April, 2017

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 Release Overview
- 2 Technical Requirements Update
- 3 New Oracle Help Center
- 4 Reminder of ClearTrial Best Practices
- 5 List of Primary Features by Edition
- 6 Overview of the Primary Features/Enhancements

ClearTrial 5.7 Overview

- Release Objectives: ClearTrial 5.7 brings new and enhanced capabilities for
 - Increased **Accuracy, Configurability/Flexibility, Efficiency, and Transparency**
 - **Configurable, Refined Reporting**
 - Improved **Contract Alignment/Change Order Support**
- Includes a **New Cost Model Available for 5.7** to upgrade your plans and user-defined templates to take advantage of the latest costing algorithms.
- Technical Requirements Update
- New [Oracle Help Center](#)
- Release Approach: Market and Customer Driven

Technical Requirements Update

Browser Support & Screen Resolution/Size

- ClearTrial 5.7.0 will no longer operate with versions of Microsoft Internet Explorer for which Microsoft has ended support.
- Please upgrade to a currently supported version of Microsoft Internet Explorer or **as recommended, use Google Chrome** to access the service.
- Currently supported versions of Microsoft browsers are **Microsoft Edge** and **Internet Explorer 11**.
- Verify your **Screen Resolution/Size** is set to the minimum configuration **1366x768**.

New Oracle Help Center



China 300 pts Test 2 5.7 for MK-3475 Japan PhIIB (Pembrolizumab)
Phase IIb
Indication: Oncology / Lung Cancer

This plan is using the 5.7 cost mo

Edit Report Maintain Admin Help

Welcome, CT Administrator

[Visit Oracle Help Center](#)

Logo

Edit Plan

- Overview
- Locations
- Site**
- Subject
- Treatment
- Data
- Monitoring
- Provider
- Meetings

Specify site-related information for each location in the study

Site Approval
To edit the site approval schedule for a location, click the name

Location
China

The ClearTrial Support Center has been replaced with the new Oracle Help Center.

Current Edit Mode:

	First Site Approved	Last Site Approved
	09/24/19	09/30/19



New Oracle Help Center

ORACLE[®] Help Center Industries Search products Welcome Leyla

< Industries

- Get Started
- Videos
- Books

Oracle Health Sciences ClearTrial Cloud Service

Get Started

Release Notes and other customer communications are available for registered users on My Oracle Support.

The ClearTrial Support Center has been replaced with the new Oracle Help Center.

New Oracle Help Center

- < Industries
- Get Started
- Videos**

- Books

Oracle Health Sciences ClearTrial Cloud Service



Videos

Watch these short videos to learn how to perform the most common tasks in ClearTrial Cloud Service.

The videos list may take a few moments to load.



New Oracle Help Center



< Industries

Get Started

Videos

Books

Oracle Health Sciences ClearTrial Cloud Service



Books

Release Notes and other customer communications are available for registered users on My Oracle Support (MOS).

Release Notes

Release Notes



ClearTrial Best Practice Reminders

- **Upgrade existing plans and user-defined templates** to the latest cost model, ClearTrial 5.7 Cost Model.
 - Important Consideration: Plans created from user-defined templates with a previous cost model will inherit the template's cost model. Upgrade your templates to the latest cost model to ensure plans created from it are using the latest cost model.
- **Lock plans** to prevent other users from changing assumptions entered.
- **Freeze rates** in plans, anytime you are satisfied with your operational budget's forecast.

Benefits of Upgrading to the Latest ClearTrial Cost Model

- Upgrading plans and user-defined templates to the latest cost model will ensure you are working with the latest updates to fees and costs included in both ClearTrial Work Breakdown Structures and indirect (pass-through/miscellaneous) cost calculations.

How Do I Upgrade my Plan or Template to the Latest ClearTrial Cost Model?

Change Plan Attributes X

Change the name, status, cost model, and/or description for the selected plan.

Plan Name: MK-3475 Australia, NZ, Japan Randomized DB Trial

Status: Draft

Cost Model: 5.3 (selected), 5.7, 5.6, 5.5, 5.4

Custom Field Model: 5.6

Short Description: 5.4

Long Description: Pembrolizumab (MK-3475) as Neoadjuvant/Adjuvant Therapy for Participants With Resectable Stage IIB Lung Cancer

Update last modified date and user (plan history)

A single modifiable plan is selected. You can change any of the attributes of this plan.

Please choose the cost model for the select...

Close Save Save & Close Save & Edit

How to Evaluate the Latest Cost Model's Impact

You may want to internally review the 5.7 cost model updates to determine if you want to upgrade any existing plans.

1. From the Plan/Template List screen, select an existing plan/template and click **Copy**.
2. Click on **Other Actions...> Change Attributes**.
3. **Change the Cost Model** value to the 5.7 Cost Model from the dropdown.
4. From the Plan/Template List screen, select the original plan/template and its copy and click **Compare** to run any of the Comparison reports between the two different cost models to quickly see the impact to the budget.

Comparing Plans to Evaluate the Impact of Upgrading to the Latest Cost Model



Edit Report Maintain Admin Help

Welcome, CT Administrator | Visit Oracle Help Center | Logout

Plans

2 plans are selected [clear](#)

Remember selections across pages [help](#)

Filter

Show: All Plans Active Plans Only Plans matching filter: [Modify](#)

[Configure List Options](#)

New

Edit

Delete

Restore

Copy

Compare

Other Actions...

<input checked="" type="checkbox"/>	Plan Name	Study Name	Description	Status	Cost Model	Compare Selected Plans	Last Modified
<input checked="" type="checkbox"/>	Copy - MK-3475 Australia, NZ, Japan ...	MK-3475 Japan PhIIB	600 total subjects	Draft	5.7	Administrator, CT	03/25/18 09:05 AM
<input checked="" type="checkbox"/>	MK-3475 Australia, NZ, Japan Rando...	MK-3475 Japan PhIIB	600 total subjects	Draft	5.3	Administrator, CT	03/25/18 09:04 AM

5.7 Feature Edition Impact

Feature	Standard Edition	Enterprise Edition
Clinical Intelligence Update (including WBS Update)	X	X
Increased Transparency into Monitoring Efforts	X	X
Reporting Enhancements (including Enhanced Summary Grid)	X	X
Usability/User Experience (UX) Enhancements*	X	X
Enhancements for Increased Precision and Accuracy	X	X
Improved Contract Alignment/Change Order Support		X
Import Additional Location-specific Overrides from a Plan/Template*	X	X
Web Services API Update*		X

* These sets of features require direct action by users with the assigned ClearTrial System Administrator role before users can benefit from the new functionality.

Clinical Intelligence Update

Includes updates to MOH Delays by location to be current with the latest regulatory changes per country.

Choose Locations

Filter

Show: Regions Countries

Region	Country	Primary Language	Primary Currency	MOH/FDA Delay
<input type="checkbox"/> USA, Canada, Australia/New Zealand				70
<input type="checkbox"/>	Australia	English	Australian Dollar	70
<input type="checkbox"/>	Canada	English	Canadian Dollar	150
<input type="checkbox"/>	New Zealand	English	New Zealand Dollar	45
<input type="checkbox"/>	Puerto Rico	Spanish	Dollar	120
<input type="checkbox"/>	USA	English	US Dollar	30
<input type="checkbox"/> Western Europe & Japan				90
<input type="checkbox"/>	Austria		Euro	95

Close Ok

Updated algorithm for the MOH Delay default per Region to use the median value for all countries in the CT-defined economic regions.

5.7 Cost Model WBS Update Summary

- New Lead CRA resource on Site Visit tasks/activities
- Update to Major Tasks, Unit of Measure, Tasks, Resources
- Site Visit Algorithm Updates to account for Prep, Travel, Onsite, Reporting/Follow-Up and Trip Report activities (PSSV, SIV, IMV, COV)
- New units of measure/cost drivers accessible for use in custom algorithms
 - Month
 - Day
 - Phone PSSV
 - Phone SIV
 - Phone IMV
 - Phone COV

Increased Transparency into Monitoring Efforts

New assumption on Monitoring tab

Edit Plan

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

Percentage of monitoring done by Regional Monitors:	<input type="text" value="0"/>	%
Average travel time (in hours) for site monitoring:	<input type="text" value="6"/>	
Percent of source document verification:	<input type="text" value="100"/>	%
Time to review queries from previous visit (minutes):	<input type="text" value="2.5"/>	
Other hours onsite per visit:	<input type="text" value="2.5"/>	
Manage location-specific values:	Edit location-specific	

New assumption to quickly specify the hours expected to perform non-SDV related activities per visit

Updated defaults

Monitored Data	
Total CRF pages generated (without subject drops):	107,158
Total CRF pages monitored (accounting for subject drops):	<input type="text" value="106,712"/>



Increased Transparency into Monitoring Efforts

Separate, distinct tasks accessible/included for SDV-driven effort vs. non-SDV effort

Task Manager

Task Search...

Onsite Monitoring Visit - Non-SDV Activity

Task Detail... Adjustments Distribution

Name: Onsite Monitoring Visit - Non-SDV

Description: All activities for preparing for, traveling to, performing administrative or maintenance activities, and reporting on a single onsite monitoring visit. For effort related to Source Document Verification (SDV), see Clean, Monitored

Onsite Monitoring Visit - Non-SDV Activity

Onsite monitoring visit - Preparation

Onsite monitoring visit - Travel

Onsite monitoring visit - Perform other onsite activities

Onsite monitoring visit - Reporting/Follow

Onsite monitoring visit - Trip Report Review

Phone-based Monitoring Visit

Separate Drug Accountability Visit

Site Management Week

Newsletter Prepared

New Task Edit Task Copy Task Delete Task

Task Name	Assignment Group	Summary Group
Onsite monitoring visit - Preparation	Site Monitoring/Manage...	Clinical Monitoring, Clos...
Onsite monitoring visit - Travel	Site Monitoring/Manage...	Clinical Monitoring, Clos...
Onsite monitoring visit - Perform other onsite activities	Site Monitoring/Manage...	Clinical Monitoring, Clos...
Onsite monitoring visit - Reporting/Follow	Site Monitoring/Manage...	Clinical Monitoring, Clos...
Onsite monitoring visit - Trip Report Review	Site Monitoring/Manage...	Clinical Monitoring, Clos...

Close Save Save & Close

Renamed existing Major Task to separate out all non-SDV related activities

New default task for 'other onsite' activities, driven by new assumption on Monitoring tab.

New default task for reviewing the Trip Report.

Increased Transparency into Monitoring Efforts

Additional tasks included for separate drug accountability visits

The screenshot displays the Oracle Task Manager interface. On the left, a task list includes various activities such as 'IVRS Setup', 'Subject/Volunteer Randomized', and 'Separate Drug Accountability Visit'. The 'Separate Drug Accountability Visit' task is selected, and its details are shown on the right. The details include a name field with the value 'Separate Drug Accountability' and a description: 'Activities related to blinded drug accountability visits which are separate from onsite monitoring visits and done by a monitor that does not usually monitor data at the site.' A red callout box points to three new tasks in the list: 'Prepare for separate drug accountability visit', 'Travel to site to perform Separate Drug Accountability Visit', and 'Follow-up for separate drug accountability visit'. At the bottom of the task details, there is a table listing these tasks with their respective assignment and summary groups.

Task Name	Assignment Group	Summary Group
<input type="checkbox"/> Prepare for separate drug accountability visit	Site Monitoring/Manag...	Clinical Monitoring, Clo...
<input type="checkbox"/> Travel to site to perform separate drug acco...	Site Monitoring/Manag...	Clinical Monitoring, Clo...
<input type="checkbox"/> Perform separate drug accountability visit	Site Monitoring/Manag...	Clinical Monitoring, Clo...
<input type="checkbox"/> Follow-up for separate drug accountability vi...	Site Monitoring/Manag...	Clinical Monitoring, Clo...

New tasks added to account for prep, travel and follow-up efforts for separate drug accountability visits

Increased Transparency into Monitoring Efforts

Updated Separate Drug Accountability Algorithm

Task Manager

Task Search...

- Medical Data Listing Review
- Subject Monitored
- Cohort Escalation Review
- Monitored, Clean CRF Page
- Onsite Monitoring Visit - Non-SDV Activity
- Phone-based Monitoring Visit
- Separate Drug Accountability Visit
 - Prepare for separate drug accountability visit
 - Travel to site to perform separate drug accountability visit
 - Perform separate drug accountability visit
 - CR01Ed - Clinical Research Associate ED
 - CR02 - Senior Clinical Researcher Associate**
 - CR03 - Regional Clinical Research Associate
 - Follow-up for separate drug accountability visit

Separate Drug Accountabil... » **Perform separate drug acco...** » CR02 - Senior Clinical Researcher Associate

Resource Details | Algorithm | **Hours** | Rates & Substitutio..

Default Unit Hours: 100 % **Total Hours: 4.000**

USA, Canada, Australia/New Zealand

Service Provider	Unit Hours	% Adjust	# Units	Ext Hours	+/-	Hours
Major CRO	<input type="text" value="4.000"/>	<input type="text" value="100"/> %	X 1 =	4.000	<input type="text" value="0.000"/>	4.000

Updated default resource hours for "Perform separate drug accountability visit" task

Monitoring Visit Time Calculation Update

Edit Treatment A

Treatment A

Details | **Schedule** | Notes

Monitoring minutes per CRF page: Yes No

Week	Number of CRF Pages	Monitoring Time (minutes)	Percent of Grant
Baseline Visit	13	73.67	13.68 %
1	12	68.01	12.63 %
2	12	68.01	12.63 %
3	11	62.34	11.58 %
4	10	56.67	10.53 %
5	10	56.67	10.53 %
6	5	28.34	5.26 %
7	4	22.67	4.21 %
8	3	17	3.16 %
9	2	11.33	2.11 %
10	1	5.67	1.05 %

Revised monitoring visit time calculation for all visit types (including Baseline Visit) to use the same minutes per page.

Reporting Enhancements

Ability to Compare Templates



Edit Report Maintain Admin Help

Welcome, CT Administrator | Visit Oracle Help Center | Logout

Templates

2 templates are selected [clear](#)

Remember selections across pages [help](#)

Filter

Show: All Templates Active Templates Only Templates matching filter: [Modify](#)

[Configure List Options](#)

New

Edit

Delete

Restore

Copy

Compare

Other Actions...

<input checked="" type="checkbox"/>	Template Name	Phase	Therapeutic Area	Compare Selected Templates
<input checked="" type="checkbox"/>	2018 Oncology LC 786-42 Late Stage	I Ib	Oncology	Lung Cancer
<input checked="" type="checkbox"/>	2018 Oncology LC 786-42 Late Stage V2 5.7	I Ib	Oncology	Lung Cancer

Ability to Compare Templates

The screenshot shows a web application interface for comparing templates. On the left is a sidebar with a 'CLEAR TRIAL' logo, navigation links (Edit, Report, Mail), a 'Templates' section with a 'Filter' and 'Show: All Te' dropdown, a 'New' button, and a list of templates including '2018 Onc', '2018 Onc', 'LAM -Test', 'LAM-Quer', 'LAM_test', 'TAG', and 'TCIS Glob'. The main content area is titled 'Compare Templates' and contains two sections: 'Available Comparisons' and 'Providers To Include'. The 'Available Comparisons' section has a heading and a list of options: 'Compare Assumptions' (unchecked), 'Compare Fees and Costs' (selected), 'Compare Fixed Unit Prices' (unchecked), 'Compare Resources' (unchecked), 'Compare Milestone Dates' (unchecked), 'Show Provider Details' (checked), 'Show Location Details' (checked), and 'Include Inflation' (checked). Below this is the 'Providers To Include' section with a heading and a list of providers: 'All Providers' (checked), 'CT Product Review' (checked), and 'Premium CRO' (checked). On the right side of the interface, there are 'Logout', 'help', and 'ptions' buttons.

Compare Templates

Please choose the type of comparison and any applicable options below

Available Comparisons

- Compare Assumptions
- Compare Fees and Costs
- Compare Fixed Unit Prices
- Compare Resources
- Compare Milestone Dates
- Show Provider Details
- Show Location Details
- Include Inflation

Please choose the providers to include

Providers To Include

- All Providers
- CT Product Review
- Premium CRO

New Reporting Options

Resources By Department

Please choose the providers to include and the level of detail to display

Providers To Include

- All Providers
- CT Product Review
- Medium CRO

New options to include all or only those indirect cost items specified for reporting in your plans.

Departments To Include

- All Departments
- Clinical Operations
- Data Management
- Medical Writing
- Regulatory
- Safety
- Unmapped

Enhanced report input screen layout for Resources by Dept, GL Code reports

Options

- Include Fees Only
- Include Fees and All Indirect Costs
- Include Fees and Marked Indirect Costs
- Show Default and Variance Details
- Show Section Headers
- Include Costs with No Amount
- Include Inflation
- Include Private Notes
- Include Cost Notes
- Include Resources with No Hours
- Include Notes
- Group by Billing Rate Location

Ability to filter out costs or resources that are zero.

Include Resources with No Hours



New Reporting Options

User Report

Choose report options below

Options

Include user roles Include deleted users

Ability to show deleted users and when they were deleted by your ClearTrial System Administrator

Additional Roles	Created By	Created	Last Modified By	Last Modified	Locked	Deleted
Exchange Rates Administrator Resources Administrator Reporting Regions Administrator Departments/GL Codes Administrator WBS Manager Can access WS-API Can export report data Can edit notes	CT Administrator	27-Jan-14	CT Administrator	11-Sep-17	No	
Exchange Rates Administrator Resources Administrator Reporting Regions Administrator Departments/GL Codes Administrator WBS Editor WBS Manager Can export report data Can edit notes	Laura Bloechl	27-Jan-14	CT Admini		No	11-Sep-17
Exchange Rates Administrator Resources Administrator Reporting Regions Administrator Departments/GL Codes Administrator WBS Manager Can access WS-API	CT Administrator	27-Jan-14	CT Administrator	11-Sep-17	No	11-Sep-17

Exposed Created date and Deleted date per user



New Reporting Options

Fixed Unit Prices

Please choose the providers to include and the level of detail to display

Providers To Include

- All Providers
- CT Product Review
- Premium CRO

Level of Detail to Include

- Summary
- Detail
- Include Inflation
- Include Estimated Dates and Duration for Major Tasks

Group By

- Location

Formatting Updates

Fixed Unit Prices in 5.6

Meetings - Investigator Meeting		(Investigator Meetings)	Start: 17-Jan-2019	End: 17-Jan-2019	Duration: 1ed	
Task	UOM: Meetings	Unit Hours	Unit Cost	#Units	Ext Hours	Ext Cost
Investigator Meeting: Medium CRO - CR01 (US)		31.000	4,447.26	1	31.000	4,447
Investigator Meeting: Medium CRO - CR06 (US)		38.000	7,495.50	1	38.000	7,496
Investigator Meeting: Medium CRO - DM03 (US)		24.000	4,248.00	1	24.000	4,248
Investigator Meeting: Medium CRO - DS01 (US)		23.000	7,429.00	1	23.000	7,429
Investigator Meeting: Medium CRO - RG02 (US)		23.000	3,565.00	1	23.000	3,565
Investigator Meeting: Medium CRO - ST02 (US)		18.000	3,510.00	1	18.000	3,510
		157.000	30,694.76	1	157.000	30,695

Fixed Unit Prices in 5.7

Meetings - Investigator Meeting		Unit Hours	Unit Cost	Ext Hours	Ext Cost
Investigator Meeting: Medium CRO - CR01 (US)		31.000	5,248.61	31.000	5,249
Investigator Meeting: Medium CRO - CR06 (US)		38.000	8,136.94	38.000	8,137
Investigator Meeting: Medium CRO - DM03 (US)		24.000	4,479.60	24.000	4,480
Investigator Meeting: Medium CRO - DS01 (US)		23.000	10,513.76	23.000	10,514
Investigator Meeting: Medium CRO - RG02 (US)		23.000	3,833.41	23.000	3,833
Investigator Meeting: Medium CRO - ST02 (US)		18.000	5,846.76	18.000	5,847
1 Meeting		157.000	38,059.08	157.000	38,059

New Reporting Options

Pass-Through and 3rd Party Costs

Service Providers

Select the service providers to include in the report.

- All Service Providers
- CT Product Review
- Premium CRO

Level of Detail to Include

- Include Notes
- Show Inflation on a Separate Line
- Include Estimated Dates for Costs
- Include Costs with Zero Value

Additional Data Points Exposed and Easy Access

Resources by Department, GL Code Reports

Resource Name	Resource Code	Unit Hours	Default Unit Hours	Variance Unit Hours	# Units	Unit
Clinical Research Associate	CR01	10.000	10.000	0.000	1	Meetings
Senior Director, Clinical/Therapeutic	CR05	6.500	6.500	0.000	1	Meetings
Project Manager	CR06	15.000	15.000	0.000	1	Meetings
Senior Biostatistician	ST02	4.000	4.000	0.000	1	Meetings
Clinical Research Associate	CR01	9.000	9.000	0.000	1	Meetings

Resource Name and Resource Code separated into two distinct cells

#Units and Unit of Measure separated into two distinct cells for easy access

Enhanced Summary Grid Reporting

Configurable Bid Grid Views



USA Single Site AMP
Phase II / Protocol ID: 100001C1
Indication: Oncology / Metastatic Melanoma

This plan is using the 5.7 cost model

Edit Plan

Notes

Overview	Costs	
Locations	Plan Summary	Printable view of the Summary tab
Site	Fees By Major Task	Fees by major task report
Subject	Fixed Unit Prices	Fixed unit price report
Treatment	Pass-Through and 3rd Party Costs	Pass-through and 3rd party costs
Data	Monthly Budget	Monthly budget report
Monitoring	Monthly Budget By Reporting Region	Monthly budget by reporting region report
Provider	Labor Adjustments	Breakdown of unit level adjustments by major task
Meetings	Cash Flow	Planned Value (PV) versus payments
Assignment	Milestone Payment Schedule	Schedule of payments at each milestone
Labor	Meetings Report	Meeting costs and assumptions report
Costs	Summary Grid	Configurable Plan-specific Bid Grid View
Payments	Inflation Rates	Inflation Rates by Location and Year
Summary	FTE/Resources	

This report generates a plan specific report based on the tasks assigned to a particular provider, optionally pre-populate...

Close Save Next



New Summary Grid Reporting Options

Summary Grid

Please choose the providers to include and the level of detail to display

Providers To Include

- All Providers
- Niche CRO
- Premium CRO

Group By


Choose from available reporting groups in the left box. Set the order of the groups using the buttons on the right.

Available groups:

- Location
- Provider
- Resource
- Task

Groups to show:

- Major Task / Cost



Ability to include multiple providers

New available reporting groups to report by: Location, Provider, Major Task, Task and Resource

Ability to configure the sort order of the data displayed in the report output

Options

- Rollup provider level data
- Rollup location level data
- Populate values for hours/costs
- Include zero hours/costs
- Include inflation
- Include excluded tasks/costs
- Format for Excel Analysis (Creates a flat table format suitable for analysis with a pivot table in Excel)

New options to rollup across All Providers, All Locations, generate a blank or populated grid, the ability to include zero hours/costs and include tasks and costs that have been excluded from the plan

New Flat-File Format Available For Summary Grid

2	Plan Name:	Clarity
3	Study Name:	MK-3475 Japan PhIB
4	Currency:	US Dollar
5	Report generated:	25-Mar-2018 05:09 PM

Updates to report header data including Study Name, Plan Name and Time Stamp

Flexibility to include Tasks in your bid grid or for internal reporting

Report will always display Major Task/Cost regardless of format selected

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 26-Feb-2018.

Note: Inflation has been added to the costs in this report.

11	Location	Provider	Cost Type	Major Task / Cost	Task
12	All Locations	ALL PROVIDERS	Labor	Project Initiated	Develop scope of work, tin work assignments
13	All Locatio		Labor	Project Initiated	Develop scope of work, tin work assignments
14	All Locations	ALL PROVIDERS	Labor	Project Initiated	Develop scope of work, tin work assignments

New static data field before Major Task/Cost to filter data by Cost Type



Data Updates and Formats

Static columns displayed regardless of format selected

Flat file format for excel analysis to include as your Bid Grid report in your SOW

Resource Name	Unit	Number of Units	Unit Hours	Unit Cost	Extended Hours	Budget	Comments
Clinical Research Associate	Study	2	2.344	384.95	4.688	769.91	
Senior Clinical Research Associate	Study	2	4.000	841.52	8.000	1,683.04	
Senior Vice President Clinical	Study	2	4.000	1,908.80	8.000	3,817.60	

Export to XLS (Excel) format

Summary Grid		Plan Name:	Clarity
Report generated: 25-Mar-2018 06:29 PM		Study Name:	MK-3475 Japan PHIB
			US Dollar
All monetary values are displayed in US Dollar (USD) base			
Note: Inflation has been added to the costs in this			
Cost Type	Major Task / Cost	Task	Budget
Labor	Project Initiated [2 Studies]	Develop scope of work, timeline, work assignments	25,316
		Finalize contract (post award)	2,634

New static data field before Major Task/Cost to filter data by Cost Type.

Timestamp Added to all Reports

Fixed Unit Prices

Double Blind Randomized Placebo Controlled
Phase III
Indication: Dermatology / Acne

Report generated:

29-Nov-2017 05:41 PM

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 11/29/2017.

Note that for display purposes, all extended costs are rounded to the nearest US Dollar.

Distinguish between multiple reports run on the same day by the new timestamp

Provider: CT Product Review

Major Task Name		Unit Hours	Unit Cost	# Units	Ext Hd
Project Initiated	(Project Initiation)	136.534	13,382.49	1	136.
Study Setup	(Study Setup - Centralized tasks)	363.998	32,775.79	1	363.
Study Setup Per-Location	(Study Setup - De-centralized tasks)	53.749	5,482.41	1	53.
A Written Protocol	(Protocol Preparation)	389.334	39,712.06	1	389.

FixedUnitPriceByMajorTaskRepor

Days between Each Milestone

Milestone Dates Report Update

Milestone Dates

China 300 pts Test 2 5.7 for MK-3475 Japan PhIIb
Phase IIb

Indication: Oncology / Lung Cancer

Report generated: 26-Mar-2018 06:28 PM

Milestone	Date	Days From Last
Project Activity Start Date	01-May-2018	0
Investigator Meeting	31-Jul-2018	91
Drug Available to First Site	07-Aug-2018	7
First Subject/Patient In (FSI/FPI)	07-Aug-2018	0
Agreement on Statistical Analysis Plan	21-Sep-2018	45
First Site Approved	24-Sep-2019	368
Last Site Approved	30-Sep-2019	6
Last Subject/Patient In (LSI/LPI)	06-May-2024	1680
Last Subject/Patient Observation (LSO/LPO)	04-Aug-2024	90
Last Data Query Resolved	14-Aug-2024	10
Database Lock	16-Aug-2024	2
Final Report	14-Nov-2024	90
Study Duration (approx months)	78.3	

Usability/User Experience (UX) Enhancements*

New Customer Preferences Available for assigned ClearTrial System Administrators



Edit Report Maintain **Admin** Help

Welcome, CT Administrator | Visit Oracle Help Center

Edit Customer P

- Users
- Customer Preferences**

Default Language: English

Default Currency: US Dollar (USD)

Number of future years users can create billing rate cards for vendors: 15

Name of support personnel/department responsible for this customer's user administration: Lola Whitfield

Email address of support personnel/department responsible for this customer's user administration: lola.whitfield@customer.com

Phone number of support personnel/department responsible for this customer's user administration: 708-990-9989

Number of days deleted items are kept and can be restored before being purged: 30

Hide the ClearTrial Default System Template (when there are user-defined templates): False

Prohibit use of the ClearTrial Default System Template (when there are user-defined templates): False

Allow user to choose a plan or template from which to pull location-specific data when adding locations to a plan: True

Combine the Algorithm and Hours Tabs in Task Manager: True

Cancel Save

The Admin menu is accessible to those users who are assigned the ClearTrial System Administrator role.

Launched from the Admin menu, select Customer Preferences to configure preferences.

Configurable CT System Administrator contact details when users need user account assistance or when your admin changes, over time.

Choose "True" to enable this feature for your users.



Combined Algorithm and Hours Tabs in Task Manager

Refined Task Manager user experience

Task Manager

Task Search...

- Issued Repeat Summary
- Issued Repeat Summary
- Issued Repeat Summary
- Stat Report
- Draft Report
- Final Report (CSR)
- Prepared Publication
- EDC Help Desk
- EDC Training
- Sponsor Oversight
- PM Oversight
 - PM0010: Admin Tim
 - CR06 - Project I

PM Oversight » PM0010: Admin Time » CR06 - Project Manager

Resource Details | **Algorithm / Hour..** | Rates & Substitutio..

View or Define LOE Algorithm and Hours

All Locations

Calculate as: hours per: % of: (The Study)

[Add another expression...](#) [Switch to Script](#)

Overrides for Medium CRO

Unit Hours	% Adjust	# Units	Ext Hours	+/-	Adj Hours
<input type="text" value="25.000"/>	<input type="text" value="100"/> %	X 11	= 275.000	<input type="text" value="0.000"/>	= 275.000

275.0...

Combined Billing Location, Rates & Substitutions Tabs

Refined Task Manager user experience

The screenshot displays the Oracle Task Manager interface. On the left is a navigation tree under 'Study Setup' with 'Negotiate central laboratory' selected, showing sub-items CR01, CR02, and CR07. The main content area shows a breadcrumb path: 'Study Setup » Negotiate central laboratory » CR01 - Clinical Research Associate'. Below this are tabs for '...', 'Algorithm', 'Hours', and 'Rates & Substituti...'. The 'Rates & Substituti...' tab is active and contains a table with the following data:

Service Provider	Billing Rate Location	Substitute	Rate	% Adjust	Pinned
CT Product Review	(Back Office)	CR01 - Clinical Research Assoc	102.00 USD	100 %	

A red callout box with a pointer to the 'Rates & Substituti...' tab contains the text: 'Combined Billing Rate Location and Rates and Substitutions tabs to see all related data on one screen'.

Filter Enhancements on List Screens

Define Plan Filter

Choose criteria below to filter plans. When this filter is applied, only plans matching all of these criteria will be displayed.

Plan Filter Criteria

- Created or modified in the last
- Include deleted plans
- Plan name starts with
- Study name starts with
- Product name starts with

Created by:

- Any User
- admin admin
- Leyla Badakhshanian
- Molly Blake-Michaels
- Laura Bloechl

Last Modified by:

- Leyla Badakhshanian
- Molly Blake-Michaels
- Laura Bloechl
- Kristin Carroll

Status:

- Any Status
- Incomplete
- Draft
- Final
- Approved
- RFP

Phase:

- Any Phase
- I (Healthy Volunte...
- I (Oncology/Vaccin...
- II
- IIa
- IIb

Therapeutic Area:

- Any Therapeutic...
- (Healthy Volunteers)
- 1Lucid Therapeutic Area
- 2Lucid Therapeutic Area
- Blood and Blood Forming Organs
- Circulatory System

Ability to filter by Study name, Product name on list screens

Consistent Mapping Key and Codes for Grid Mappings

Assign a Code per Indirect Cost

Edit or Adjust

Shipping (not including study drug/test article shipping)

Definition

Assignments

Adjustments

Distribution

Category Information

Name: Shipping (not including study drug/test article shipping)

Type:

Code:

Costs and Adjustments: vary by location are study level

Mapping Key: C00018

Include in Payment Schedule

Include in Resources by Department/GL Code report

Apply inflation over time

Renamed Line Item Discount to Bottom Line Discount

Specify Provider-Specific Details

Details

Inflation

Override default rates and responsibilities for this service provider

UPS

Billing Rate Information

Rate Year in effect:	<input type="text" value="2015"/> ▼ 	Discount rate to apply to this study:	<input type="text" value="0"/> %
Back-Office Billing Rate Location:	<input type="text" value="USA"/> ▼	Bottom Line Discount:	<input type="text" value="1,000.00"/> <input type="text" value="USD"/> ▼
Billing Rate Currency:	US Dollar (USD)		
Currency Exchange Rates:	<input checked="" type="radio"/> Use rates defined on the Overview tab <input type="radio"/> Use rates defined below...		

Enhancements for Increased Precision and Accuracy

Change Provider on ClearTrial-defined Costs

Ability to edit the Provider Assignment for built-in Costs

Edit or Adjust X

Shipping (not including study drug/test article shipping)

Definition Assignments Adjustments Distribution

USA, Canada, Australia/New Zealand

Provider: Major CRO
CT Product Review
Major CRO
UPS

Department: Clinical Operations

GL Code: Postage & Shipping

Editable Provider for ClearTrial-defined costs to change the provider assignment to align accurately with contract.

Increased Precision for Milestone Payments

Precise Payments

Payment Terms [X]

Specify the payment terms negotiated with each service provider

Payment Terms

Provider	Payment Term
Major CRO	Payment is expected <input type="text" value="92"/> days from the date of the invoice

Please enter the expected number of days from invoice date to the date of payment

Cancel Ok

Flexibility to enter the precise number of days from invoice to payment

Exclude ClearTrial-defined Milestones

Configurable Payments

New filter to show excluded milestones on the Payments tab.

Flexibility to exclude selected ClearTrial-defined milestones from the list

Edit Plan

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

Specify the payment schedule for each provider. Note that the amounts

Filter

Show: excluded milestones

Current Edit Mode: Advanced

Set Payment Terms Edit Recurring Payments Add Milestone Edit Milestone Include Milestone

Exclude Milestone Delete Milestone

All monetary values are displayed in US Dollar (USD)

Milestone	Inv. Date	Premium CRO	Total
<input checked="" type="checkbox"/> Project Activity Start Date	05/01/18	0.00 %	0
<input checked="" type="checkbox"/> Investigator Meeting	07/31/18	0.00 %	0
<input type="checkbox"/> Drug Available to First Site	08/07/18	0.00 %	0
Budget Total		80.00 %	-26,979,321



Distinguishable Excluded Milestones on Payments Tab

Edit Plan

Notes

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

Specify the payment schedule for each provider. Note that the amounts shown are estimates.

Current Edit Mode: Advanced

Filter

Show: excluded milestones

Excluded milestones are displayed with strike-through on the Payments tab with the ability to include them back in your plan at any time.

All monetary values are displayed in US Dollar (\$) unless otherwise noted.

Milestone	Inv. Date	Premium CRO	Total
<input checked="" type="checkbox"/> Project Activity Start Date	05/01/18	0.00-%	0
<input checked="" type="checkbox"/> Investigator Meeting	07/31/18	0.00-%	0
<input type="checkbox"/> Drug Available to First Site	08/07/18	0.00-%	0
Budget Total		80.00 %	-26,979,321



Back Office Added to Billing Rate Location for Meeting Attendees

Meeting Details

Investigator Meeting

Meeting Details Attendees

Service Provider: Premium CRO

Provider Attendees

Add Delete Duplicate

Attendees	Resource Type	Country	Travel	Billable Hours	Indirect Costs
<input type="checkbox"/>	1 CR01 - Clinical Research Associate <i>System Managed</i>	(Back Office)			
<input type="checkbox"/>	1 CR06 - Project Manager <i>System Managed</i>			41.000 Edit	Travel: 2,000.00 USD Other: 0.00 USD
<input type="checkbox"/>	1 DM03 - Data Manager <i>System Managed</i>	USA	Travel Domestic	38.000 Edit	Travel: 1,000.00 USD Other: 0.00 USD
<input type="checkbox"/>	1			24.000 Edit	Travel: 1,000.00 USD Other: 0.00 USD

6 people attending 167.000 hours 7,000.00 USD

View Plan Errors

Impacts Users Assigned Custom Fields Designer/Expert Algorithm Editor Roles



MDF - CM v1-cp for 02:30:00 Study (Alpha17:48:35)
Phase IIIb / Protocol ID: 02:30:00 Study
Indication: ID / Parasitic

This plan is using the 5.5 cost model
This plan is using custom fields, version 38

[View Plan Errors...](#)

Edit Report Maintain Admin Help

Welcome, Auto Administrator | Visit Oracle Help Center | Logout

Edit Plan

Notes

Overview

Locations
Site
Subject
Treatment
Data
Monitoring
Provider
Meetings
Assignment
Labor
Costs
Payments
Summary
Reports

This page shows basic information about this plan

Current Edit Mode: Advanced

General Information

Plan Name:

Status: Draft

Study will be: Conducted Internally Outsourced Combination

Project Activity Start Date:

Start pre-study planning:

Description

Short Description:

Long Description:

Close Save Next

Errors in Custom Algorithms via Script

MDF - CM v1-cp for 02:30:00 Study (Alpha17:48:35)
Phase IIIb / Protocol ID: 02:30:00 Study

This plan is using the 5.5 cost model
This plan is using custom fields, version 38

Plan Errors

Task Resource Algorithms

Major Task	Task	Resource	Location	Error
Study Setup Per-Location - EDITED NAME	Produce and critique country specific ICFs	CR08 - Secretarial Support	Germany	one or more expressions uses an unavailable work unit
Study Setup Per-Location - EDITED NAME	Produce and critique country specific ICFs	CR08 - Secretarial Support	Luxembourg	one or more expressions uses an unavailable work unit
Study Setup Per-Location - EDITED NAME	Produce and critique country specific ICFs	CR08 - Secretarial Support	New Zealand	one or more expressions uses an unavailable work unit

Download Close

Download



Errors in Custom Fields

CLEAR TRIAL* Test naresh bug 27757584 1 for !! 10181 (123) Phase II / Protocol ID: Test This plan is using the 5.5 cost mode This plan is using the draft version of custom field

Plan Errors

Custom Field Default Value Formulas

Custom Field	Tab	Location	Error
Number of Edit Checks	Subject	All Locations	script returned a value less than the configured minimum value of 1
CF20	Data	All Locations	script returned a value greater than the configured maximum value of 9.999

Download Close

Create Negative Custom Field Value to use as Script Variable

Create Custom Field

Field Definition

Name:	<input type="text" value="NumEditChecks"/>
Data Type:	<input type="text" value="whole number (allows negative values)"/> ▼
Label:	<input type="text" value="positive whole number"/> <input type="text" value="positive number (decimals allowed)"/> <input type="text" value="percentage value"/>
Prompt:	<input type="text" value="whole number (allows negative values)"/> <input type="text" value="any number (decimals and negative values allowed)"/>
Help Text:	<input type="text" value="This assumption is to capture the number of edit checks."/>

Values vary by location: Yes No

This selection controls what kind of numbers users can enter when populating this field. For fields meant to collect assumptions used as units of measure (a.k.a. work units), the data type must be "positive whole number"

Leveraging Month as a Unit of Measure

The screenshot displays the Oracle Task Manager interface. On the left, a sidebar lists various task types such as 'Issued Unique Summary Table', 'Stat Report', and 'Draft Report'. The main area shows the configuration for a task named 'PM Admin Oversight'. The 'Name' field contains 'PM Admin Oversight' and the 'Description' field contains 'Oversight activities performed by the PM team.'. The 'Labor' section has two radio buttons: 'varies by location' (selected) and 'is centralized'. The 'Unit of Measure' dropdown menu is open, showing a list of options including 'Site', 'Cohort Escalation Review', 'CRF Book Printed', 'CRF Page (Total w/ Drops)', 'CRF Page Audited', 'Data Entry Screen', 'Data Import', 'Data Transfer', 'Day', 'Drug Shipment', 'DSMB Report', 'EDC Training Session', 'Expedited SAE', 'Grant Payment', 'Interim Analysis', 'Medical Data Listing Review', 'Monitoring Visit', 'Month' (highlighted), 'Newsletter', and 'Location'. At the bottom, there are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'.

New Duration-based Scripted Variables

Leverage when Defining Algorithms via Script

6 new duration-based scripted variables to choose from for using month as a variable depending on how you want it to calculate.

- numMonths: Number of months between the PASD and Final CSR
- numMonthsForCost: Number of months during which this cost occurs
- numMonthsForTask: Number of months during which the effort occurs for a task.
- numDays: Number of days between the PASD and Final CSR
- numDaysForCost: Number of days during which this cost occurs
- numDaysForTask: Number of days during which the effort occurs for a task

Switch to Script When Defining Custom Algorithms for Fees and Costs

The screenshot shows the Oracle Primavera P6 Task Manager interface. On the left is a 'Task Manager' sidebar with a search bar and a tree view of tasks. The main window displays the 'Algorithm' tab for a task named 'PM001: Admin time for PM' under 'CR06 - Project Manager'. The algorithm is defined as '1 25 *numMonths'. A tooltip explains that '\$numMonths' is 'The number of months between the study start date and the date the final report is due' and '\$numMonthsForTask' is 'The number of months during which the effort for this task occurs'. A red error message states 'The script contains unrecognized or unsupported tokens' with a 'Use Expressions' link. A table at the bottom right shows a unit cost of 25.000 and an extended cost of 25.000.

Unit Ho...	Ext ...
25.000	25.000

Delete ClearTrial-defined Major Tasks



China 300 pts Test 2 5.7 for MK-3475 Japan PhIIB (Pembrolizumab)
Phase IIb
Indication: Oncology / Lung Cancer

This plan is using the 5.7 cost mod

Edit Report Maintain Admin Help

Welcome, CT Administrator | Visit Oracle Help Center | Logou

Edit Plan

Notes

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

View or adjust effort and labor fees

Current Edit Mode: Advanced

Filter

Show hours and fees for: Premium CRO

Show major tasks with no planned effort for the selected provider

New Major Task
Edit Major Task
Copy Major Task
Delete Major Task
Adjust Hours or Fees

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

Delete selected major task.

values displayed do not include inflation

[Pin Labor](#) | [Unpin Labor](#)

Major Task	Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
<input type="radio"/> Site Management Week	147.577	7,632.83	314	46,339.180	2,396,708.55
<input checked="" type="radio"/> Newsletter Prepared	0.000	0.00	0	0.000	0.00
<input type="radio"/> CRF Page Entered into Database	0.036	6.32	34,965	1,258.740	220,978.80
Total Hours/Fees:	Calculated:			90,547.747	7,739,001.88

Delete ClearTrial-defined Major Tasks

CLEAR TRIAL[®] China 300 pts Test 2 5.7 for MK-3475 Japan PhIIB (Pembrolizumab) Phase IIb Indication: Oncology / Lung Cancer This plan is using the 5.7 cost model

Edit Report Maintain Admin Help Welcome, CT Administrator | Visit Oracle Help Center | Logout

Edit Plan

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

View or adjust effort

Filter

Show hours and fees

[New Major Task](#)

All calculated costs

Major Task	Hours	Rate	Cost	Ext Hours	Ext Cost
<input type="radio"/> Site Management				46,339.180	2,396,708.55
<input checked="" type="radio"/> Newsletter Prepared	0.000	0.00	0	0.000	0.00
<input type="radio"/> CRF Page Entered into Database	0.036	6.32	34,965	1,258.740	220,978.80
Total Hours/Fees:	Calculated:			90,547.747	7,739,001.88

Permanently Delete Major Task

Permanently delete "Newsletter Prepared"?

If you click Yes, the selected major task and all of its tasks and associated resources will be deleted immediately and permanently.

This operation cannot be undone. Continue?

[Notes](#)

Current Edit Mode: Advanced

for the selected provider

[Adjust Hours or Fees](#)

values displayed do not include inflation

[Pin Labor](#) | [Unpin Labor](#)



Delete ClearTrial-defined Tasks

The screenshot displays the Oracle Task Manager interface. On the left, a task search sidebar lists various tasks, with 'Newsletter Prepared' selected. The main panel shows the details for this task, including its name, description, labor type, and unit of measure. Below the details, a row of buttons includes 'New Task', 'Edit Task', 'Copy Task', 'Delete Task' (highlighted with a red box), and 'Edit Assignments'. At the bottom, a table lists tasks with checkboxes, and a tooltip for the 'Delete Task' button reads: 'Click this button to delete the selected Tasks'.

Task Manager

Task Search...

- Site Management Week
- Newsletter Prepared**
- Prepare newsletters
- CRF Page Entered into D
- Query Resolution - by M
- Interim Analysis
- Quality Assurance - Site
- Annual IND Report Activi
- Site Close-out Visit
- Site Close-out Visit by PH
- Third-party Data Import
- All Data Cleaned and Da
- Data Transfer

Newsletter Prepared

Major Task Detail.. Adjustments Distribution

Name: Newsletter Prepared

Description: Activities related to the writing and publishing of newsletters.

Labor: varies by location is centralized Unit of Measure: Newsletter

New Task Edit Task Copy Task **Delete Task** Edit Assignments

Task Name	Assignment Group	
<input checked="" type="checkbox"/> Prepare newsletters	Project Management	Project Management / Study Over...

Click this button to delete the selected Tasks

Improved Contract Alignment/ Change Order Support

Apply Floating Adjustments for Contract Alignment

Scenario 1: You have a change to your contract and there is an increase in the # of Sites Approved line item in your SOW. You don't want to change the number of calculated units, in case the timelines change from the plan.

- Ability to apply a (+/-) offset/**floating adjustment** to the **Number of Units** per Major Task (on the Adjustment Tab within Task Manager)

Scenario 2: Your Provider informs you that specific pieces of a task were performed in addition to those planned in the SOW.

- Ability to apply a (+/-) offset to the **extended hours** for a resource working on a task (on the Hours tab within Task Manager)
- Impacted reports will inherit the final adjusted values

Apply Floating Adjustment to Major Task Units

Task Manager

Task Search...

- Meetings - Kickoff Meeting
- Meetings - Investigator Meeting
- Meetings - Face to Face Meeting
- Meetings - Status Update to Sponsor
- Meetings - Internal Team Meeting
- Site Identified by Sponsor
- Site Identified by Vendor
- Pre-study Site Visit
- Pre-study Site Visit by Phone
- Site Approved**
 - Distribute protocol
 - Negotiate site contract
 - Provide IRB submission support
 - Collect regulatory documents
 - Collect miscellaneous study preparator

Site Approved

Major Task Details | **Adjustments** | Distribution

Show hours and fees for: Premium CRO [Expand All](#) [Clear Overrides](#)

Location	Planned	+/-	Adjusted	Pinned
▶ China	Extended Hours:	26.875	26.875	
	Extended Cost:	1,691.32	1,691.32	

Click Expand All link to apply incremental or floating adjustments to the number of units for a Major Task by location.

Ability to Provide a (+/-) Offset to Units

Task Manager

Task Search...

- Site Identified by Sponsor
- Site Identified by Vendor
- Pre-study Site Visit
- Pre-study Site Visit by Phone
- Site Approved**
 - Distribute protocol
 - Negotiate site contract
 - Provide IRB submission support
 - Collect regulatory documents
 - Collect miscellaneous study preparation doc
 - Set up regulatory files at the site
 - Request and approve drug shipment
 - Import, ship, certify, package and label stuc

Site Approved

Major Task Details | **Adjustments** | Distribution

Show hours and fees for: Premium CRO [Collapse All](#) [Clear Overrides](#)

Location	Planned	+/-	Adjusted	Pinned
▼ China				
# Units:	1	<input type="text" value="2"/>	<input type="text" value="3"/>	
Unit Hours:	26.875		<input type="text" value="26.875"/> or <input type="text" value="100"/> %	
Unit Cost:	1,691.32		<input type="text" value="1,691.32"/> or <input type="text" value="100"/> %	
Extended Hours:	26.875		80.625	
Extended Cost:	1,691.32		5,073.96	

New ability to apply adjustments that "float", when timelines change

Apply Floating Adjustment to Resource's Extended Hours

Task Manager

Task Search...

- Site Identified by Sponsor
- Site Identified by Vendor
- Pre-study Site Visit
- Pre-study Site Visit by Phone
- Site Approved
 - Distribute protocol
 - CR01 - Clinical Research Associate
 - CR02 - Senior Clinical Research Associa

Site Approved » [Distribute protocol](#) » CR01 - Clinical Research Associate

Resource Details | Algorithm | **Hours** | Rates & Substitutio..

Default Unit Hours: % Total Hours: 100.000

China

Service Provider	Unit Hours	% Adjust	# Units	Ext Hours	+/-	Adj Hours
Premium CRO	<input type="text" value="30.000"/>	<input type="text" value="12,000"/> %	X 3 =	90.000	<input type="text" value="10"/>	= 100.000

Import Additional Location-specific Overrides from a Plan/Template*

Import Additional Location-specific Overrides From a Template/Plan

Currently, when you add a location to your plan (NZ), you have the capability to choose the template/plan from which to pull in the location-specific overrides from.

The screenshot displays two overlapping dialog boxes in the Oracle software interface. The top dialog, titled "Choose Locations", features a "Filter" section with "Show: Regions Countries". Below this is a table with columns for "Region", "Country", "Language", "Currency", and "MOH/FDA Delay". The "New Zealand" row is highlighted in yellow and has a checkmark in the first column. The bottom dialog, titled "Choose the template or plan from which to import location-specific overrides", has a "Filter" section with "Show: Templates Plans" and a "with names like:" input field. It contains a table with columns for "Name", "Phase", "Cost Model", "Custom Field Model", and "Last Modified". The "00002 NZ US" row is selected. A red box highlights the "Location" menu item in the left sidebar and the "New Zealand" row in the top dialog. Another red box highlights the "Choose the template or plan..." dialog.

Region	Country	Language	Currency	MOH/FDA Delay
<input type="checkbox"/>	USA, Canada, Australia/New Zealand			120
<input type="checkbox"/>	Canada	English	Canadian Dollar	70
<input checked="" type="checkbox"/>	New Zealand	English	New Zealand Dollar	150
<input type="checkbox"/>	Puerto Rico	Spanish	US Dollar	60
<input type="checkbox"/>	USA	English	US Dollar	120
<input type="checkbox"/>				30

Name	Phase	Cost Model	Custom Field Model	Last Modified
<input type="radio"/> 00000 NZ US AUS	Phase II	5.6	(None)	5/23/17 4:07 PM
<input type="radio"/> 00000 US CAN NZ	Phase II	5.6	(None)	5/23/17 4:09 PM
<input type="radio"/> 00001 NZ US	Phase II	5.6	(None)	5/23/17 3:52 PM
<input checked="" type="radio"/> 00002 NZ US	Phase II	5.6	(None)	5/23/17 4:06 PM

What types of overrides will be pulled into my plan?



5.7 adds to the existing list of location-specific overrides you can pull into your plans/templates, including:

- Grant amount by treatment arm
- Monitoring Approach data (see below)
- Plan-level provider assignments

Edit Per Location Monitoring Approach X

Enter monitoring approach assumptions per location below.

Monitoring Approach

Location				
Australia Restore Defaults	Percentage of time monitors spend in the field:	<input type="text" value="50"/>	% 	Percent of source document verification:
	Percentage of monitoring done by CRAs (vs. SCRA s):	<input type="text" value="50"/>	%	Time to review queries from previous visit (minut...):
	Percentage of monitoring done by Regional Monitors:	<input type="text" value="0"/>	%	Average travel time (in hours) for site monitors:
				<input type="text" value="6"/>
Japan Restore Defaults	Percentage of time monitors spend in the field:	<input type="text" value="50"/>	% 	Percent of source document verification:
	Percentage of monitoring done by CRAs (vs. SCRA s):	<input type="text" value="100"/>	%	Time to review queries from previous visit (minut...):
	Percentage of monitoring done by Regional Monitors:	<input type="text" value="0"/>	%	Average travel time (in hours) for site monitors:
				<input type="text" value="6"/>

Existing Types of Overrides you can Pull into Plans as of 5.6

- Custom Fields
- MOH Delay
- Ave Grant Amount
- Site Information (Number of sites)
- 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
- Resource Assignments
- Indirect Cost Assignments
- Indirect Cost Departments/GL Codes
- Indirect Cost Adjustments
- Indirect Cost Algorithms
- Meetings

5.7 Web Services API Update

- As a reminder, ClearTrial's Web Services API is available at no charge for Enterprise Edition customers only.
- If your development or IT group is interested in leveraging ClearTrial's Web Services API to get data exports, please contact Oracle Support / file an SR in [My Oracle Support](#) (MOS).
- For more technical details, please leverage the *Web Services API Developer User Guide* from the Books tab of [Oracle Help Center](#).

Integrated Cloud

Applications & Platform Services