ORACLE®

Introduction to Oracle ClearTrial 5.7

Customer Briefing

ClearTrial Product Management
Health Sciences Global Business Unit
April, 2017

ORACLE

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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

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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

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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.

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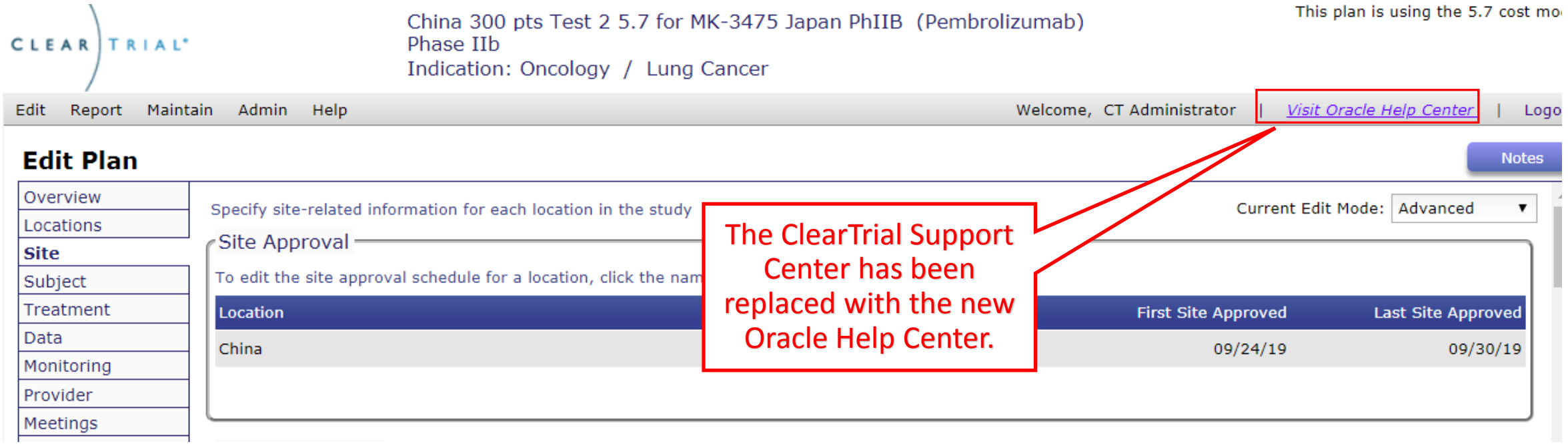
New Oracle Help Center



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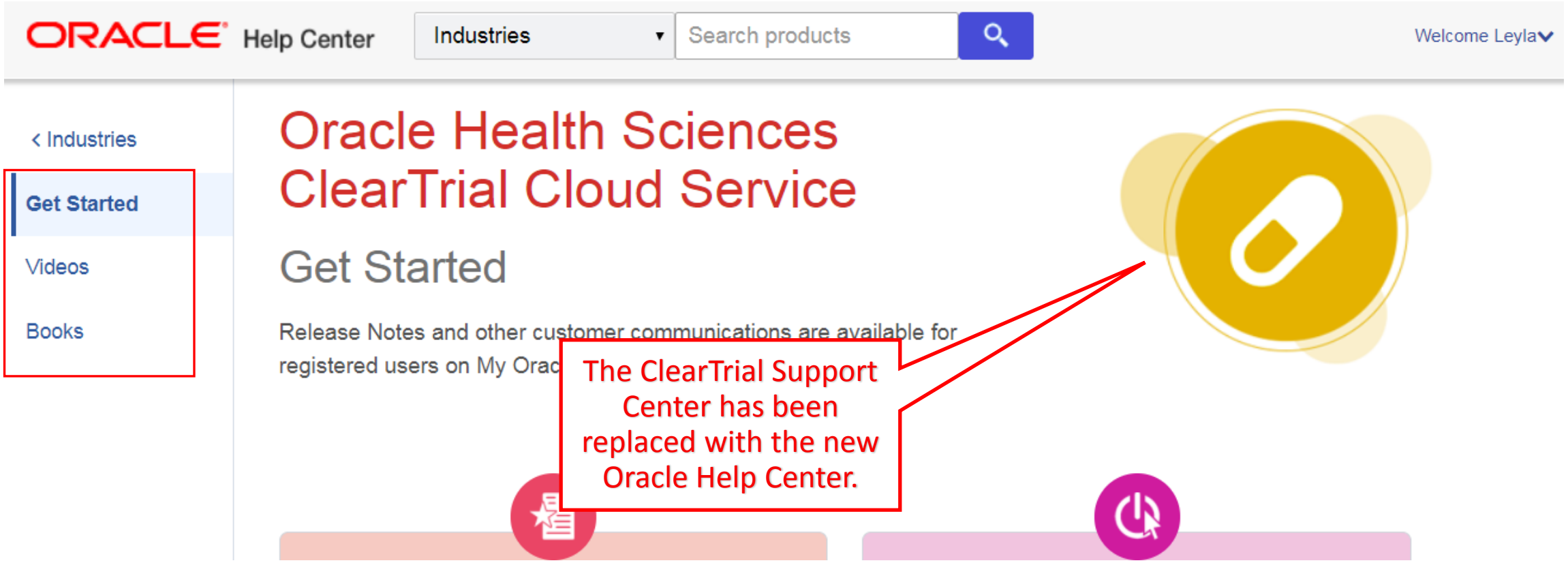
New Oracle Help Center



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New Oracle Help Center

ORACLE Help Center | Industries | Search products | Welcome Leyla

< 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.

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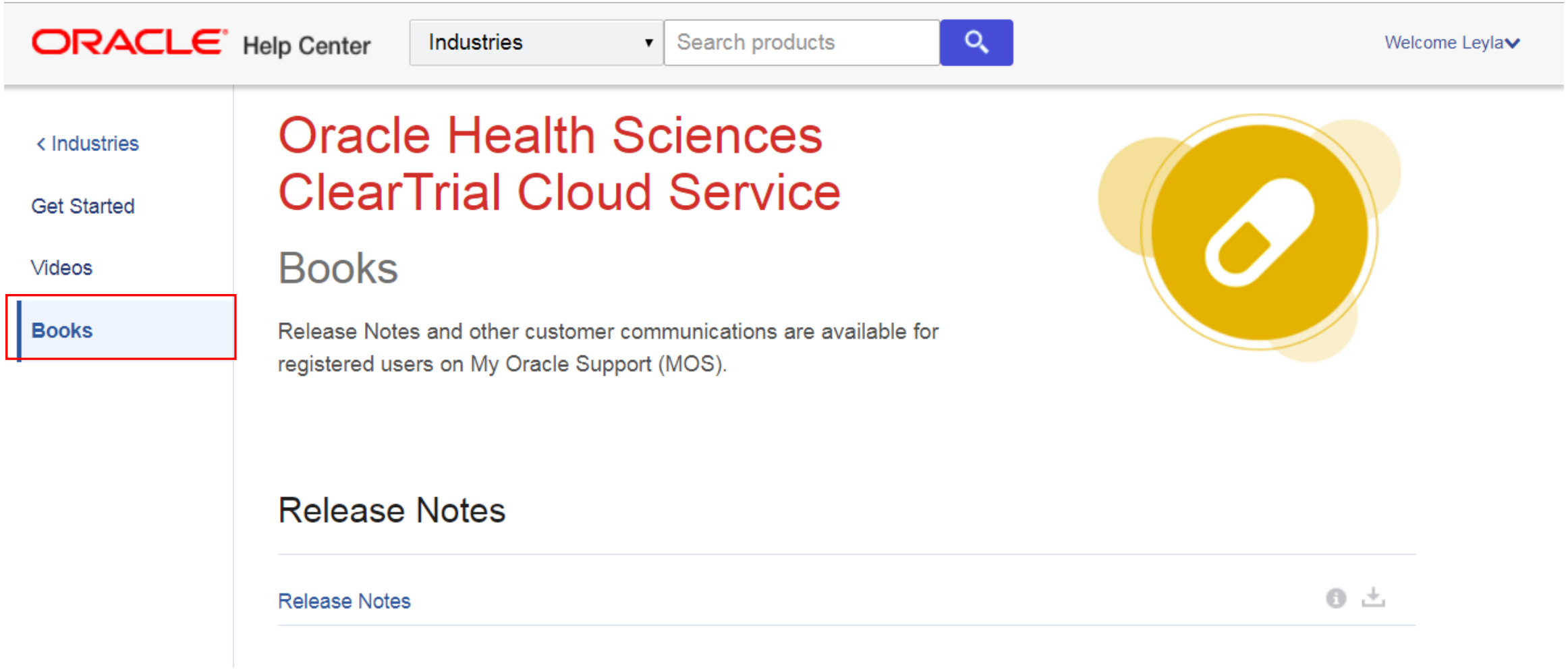
New Oracle Help Center



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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.

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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.

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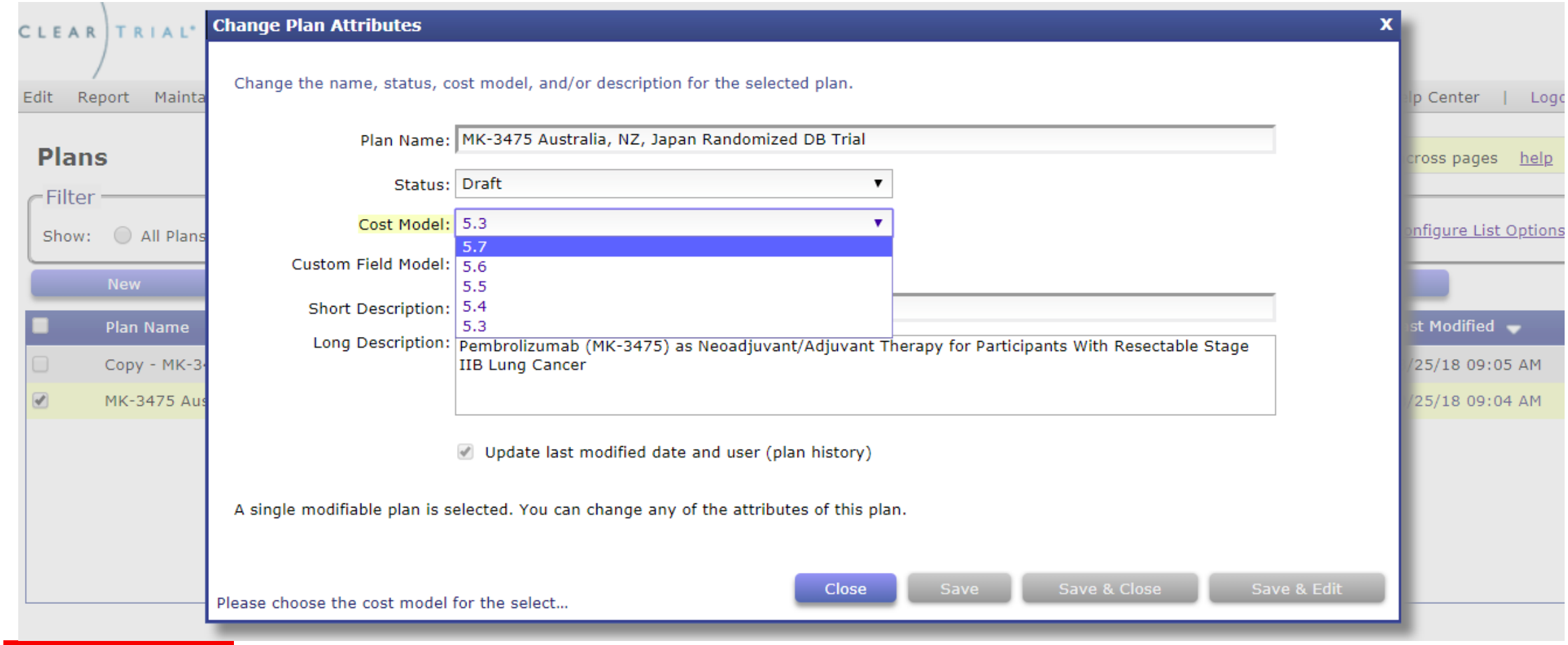
How Do I Upgrade my Plan or Template to the Latest ClearTrial Cost Model?



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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.

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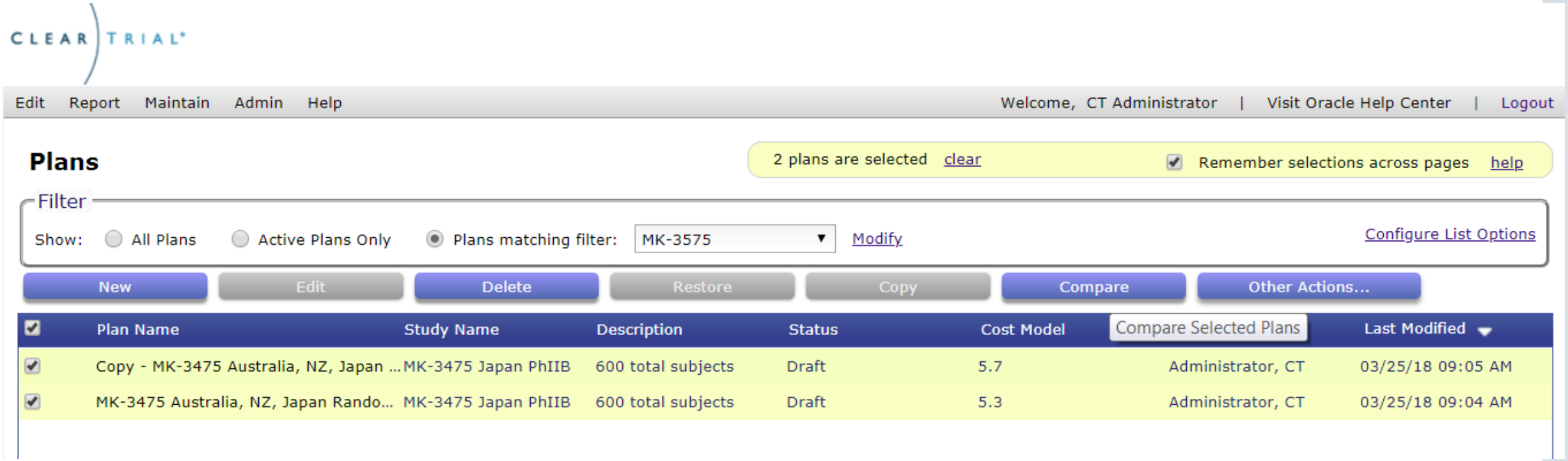
Comparing Plans to Evaluate the Impact of Upgrading to the Latest Cost Model



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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.

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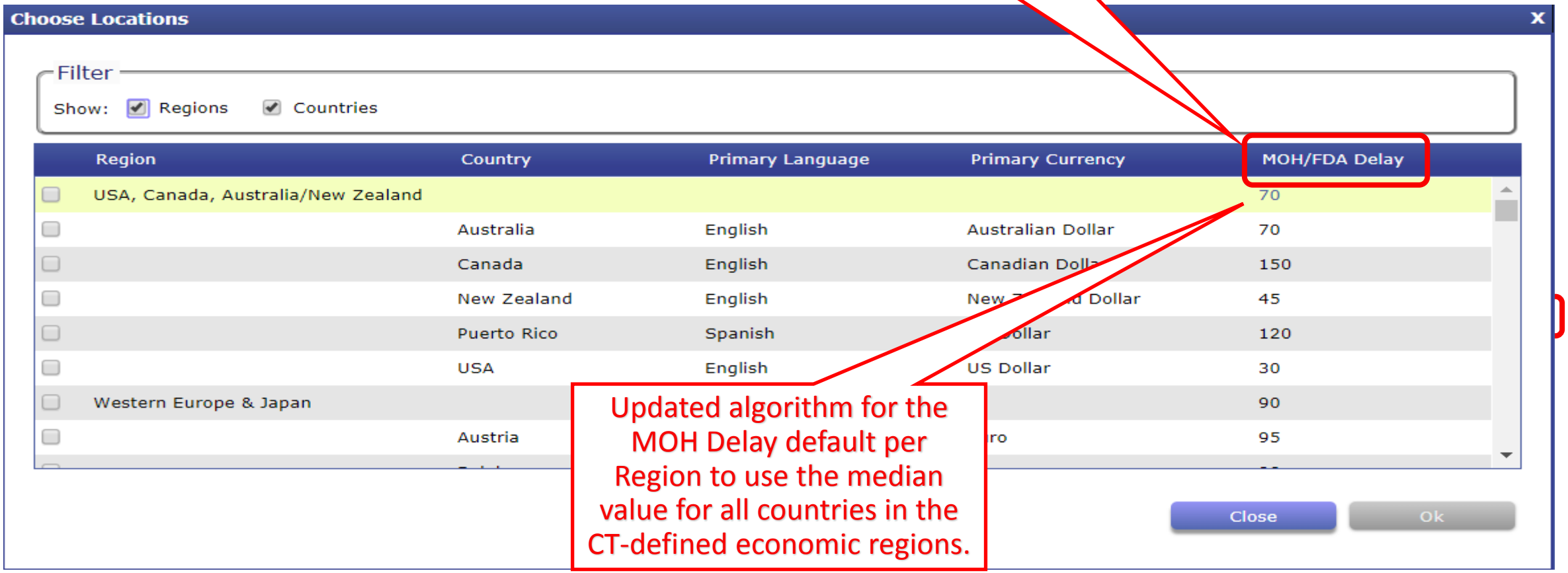
Clinical Intelligence Update

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



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

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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

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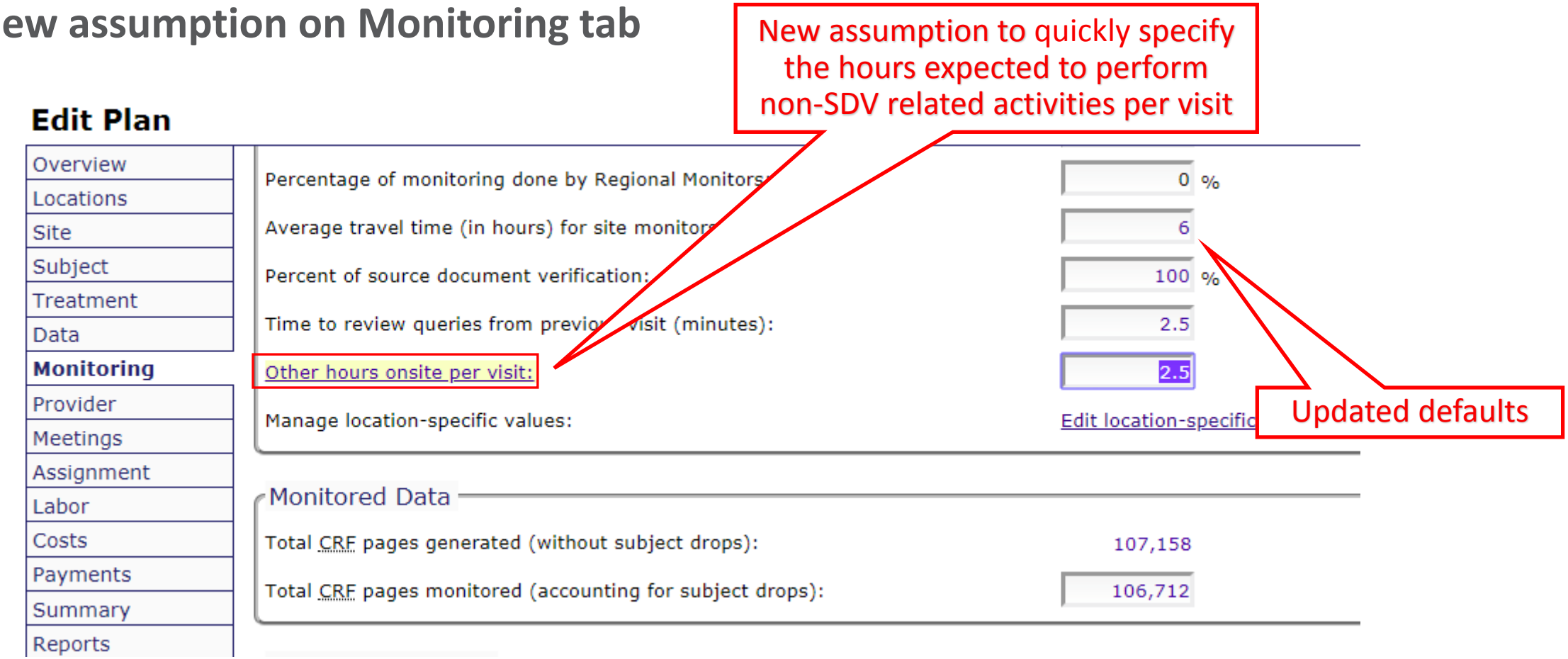
Increased Transparency into Monitoring Efforts

New assumption on Monitoring tab



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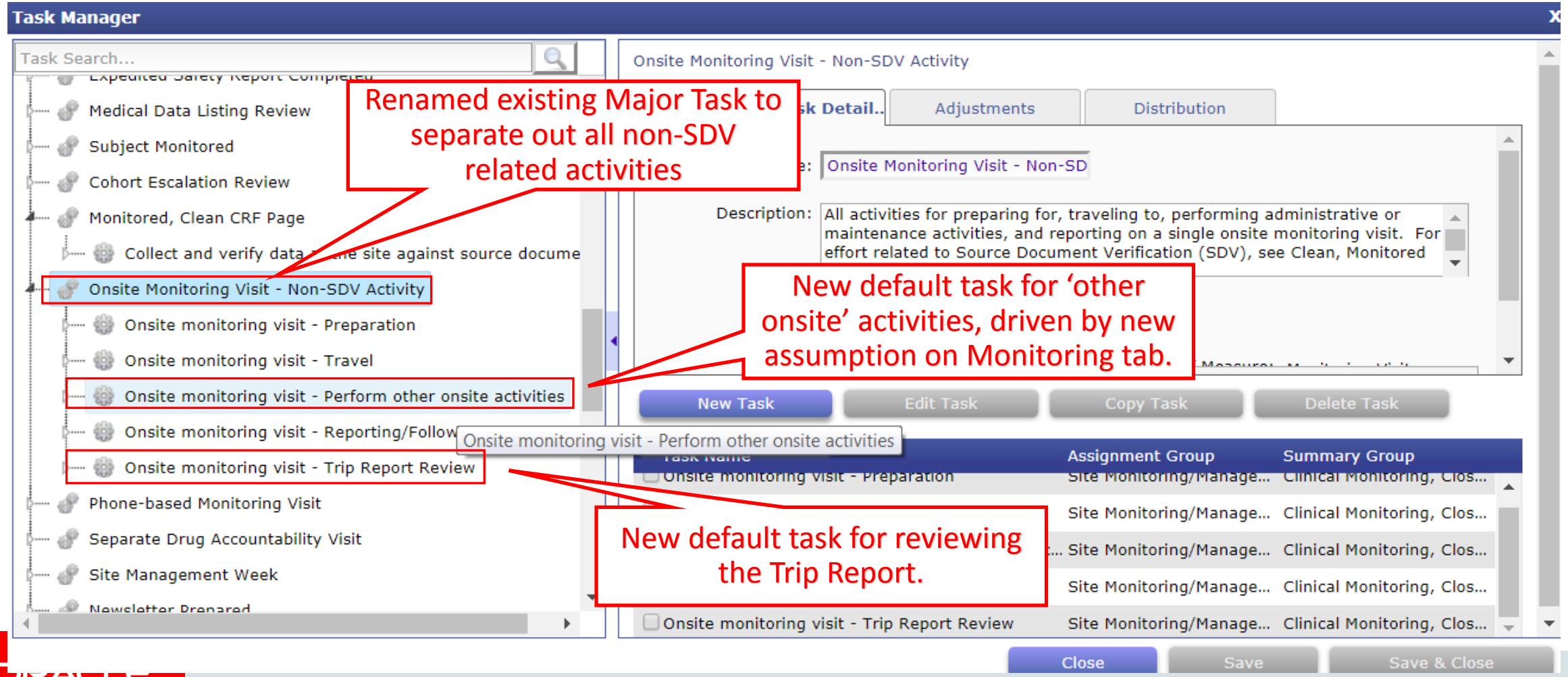
Increased Transparency into Monitoring Efforts

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



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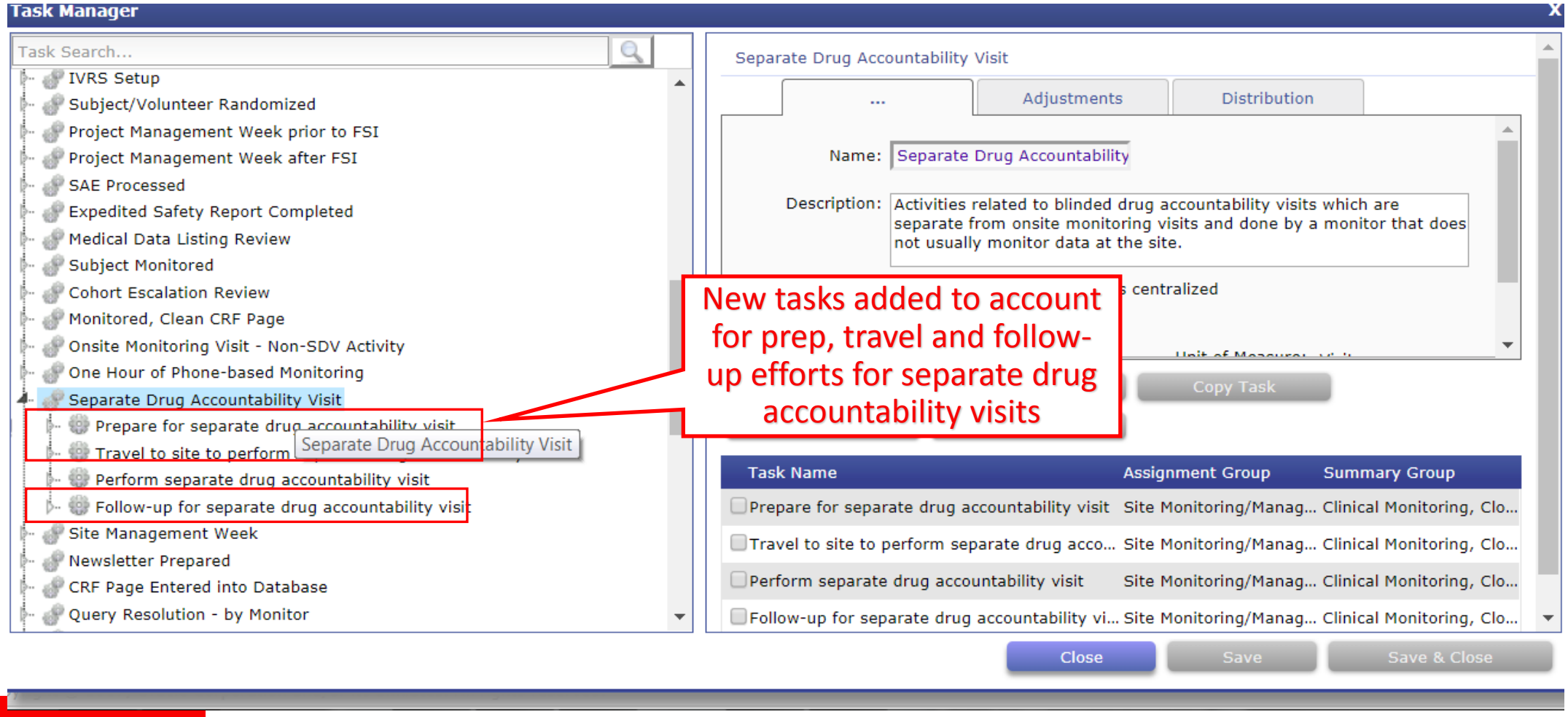
Increased Transparency into Monitoring Efforts

Additional tasks included for separate drug accountability visits



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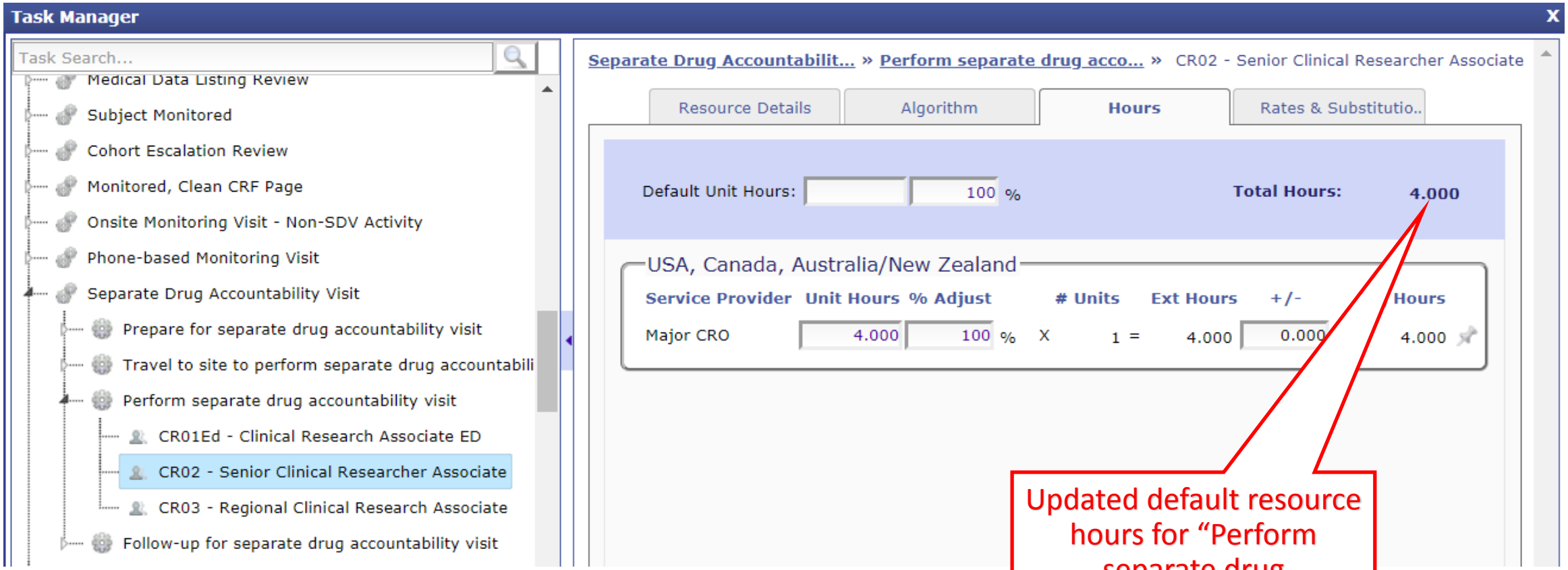
Increased Transparency into Monitoring Efforts

Updated Separate Drug Accountability Algorithm



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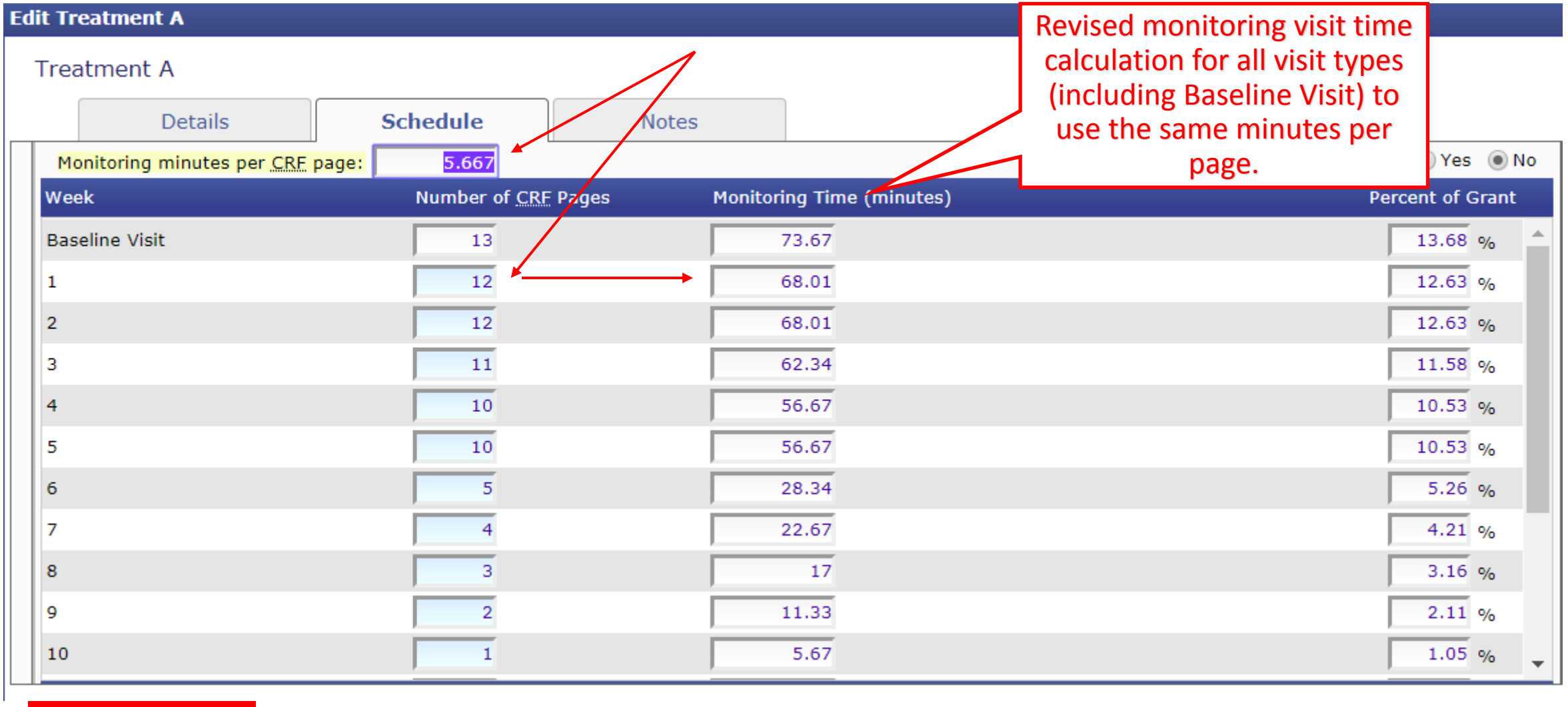
Monitoring Visit Time Calculation Update



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 %

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Reporting Enhancements

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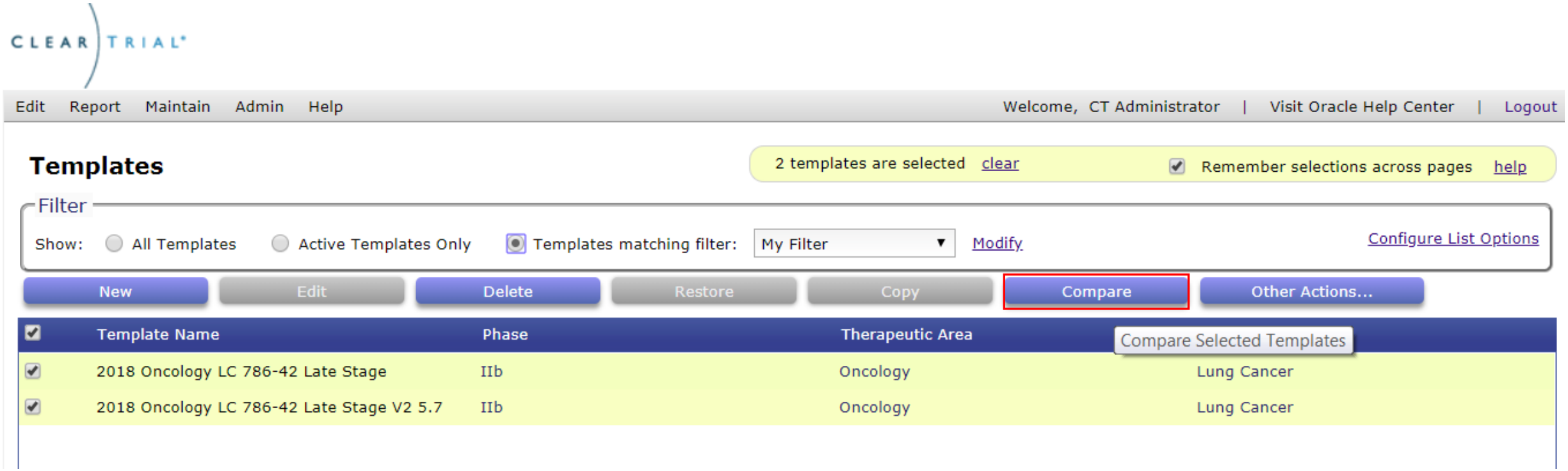
Ability to Compare Templates



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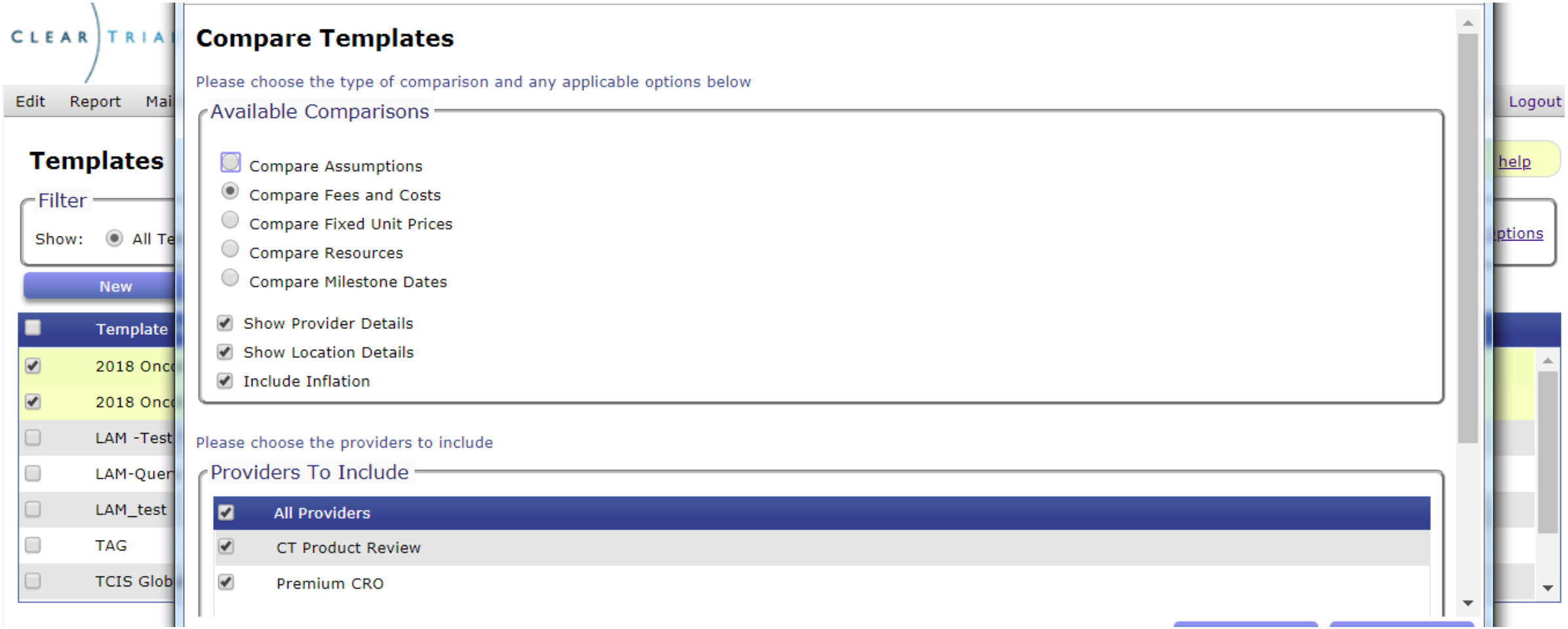
Ability to Compare Templates



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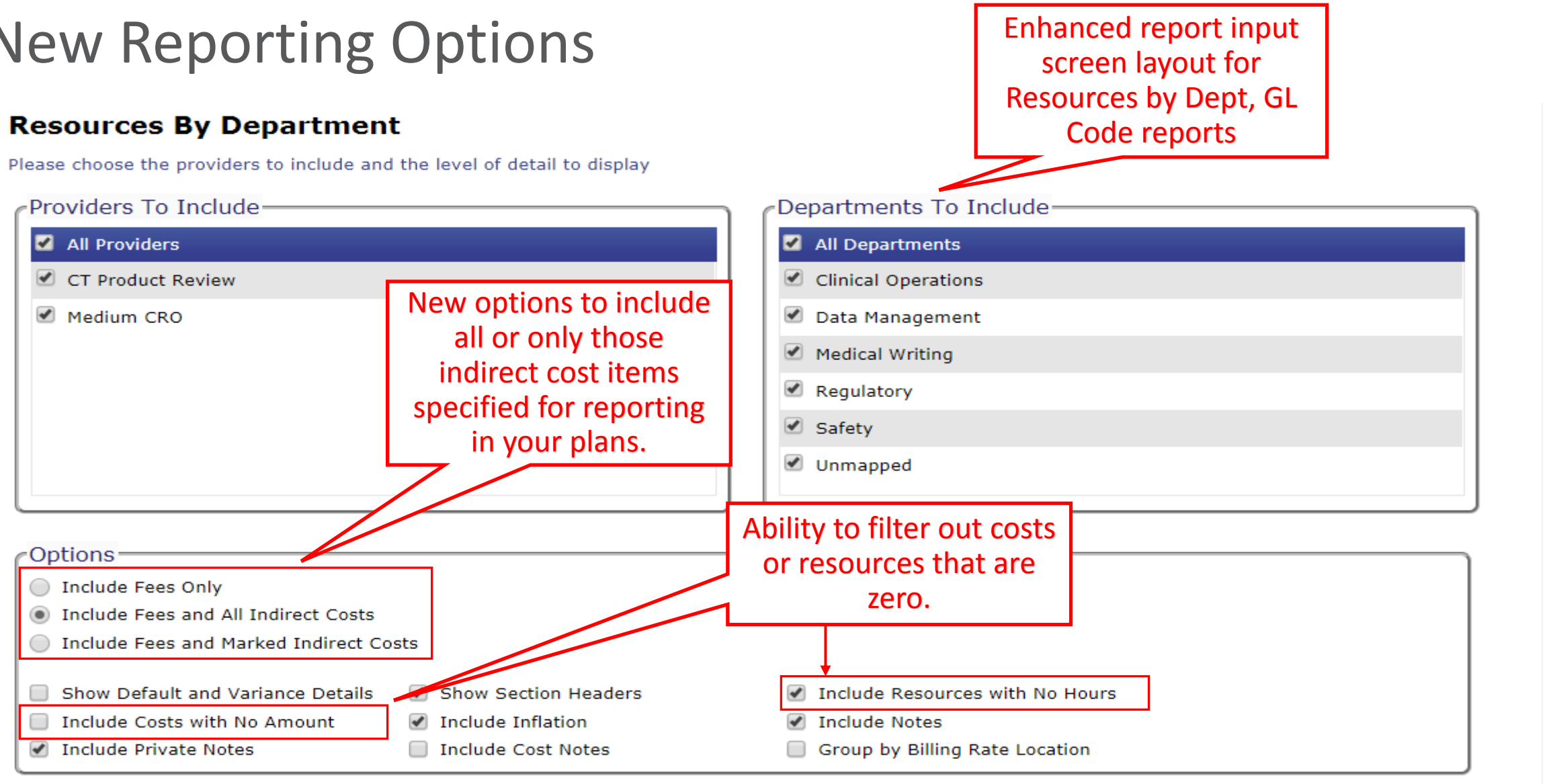
New Reporting Options



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New Reporting Options

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

User Report

Choose report options below

Options

☑ Include user roles ☑ Include deleted users

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

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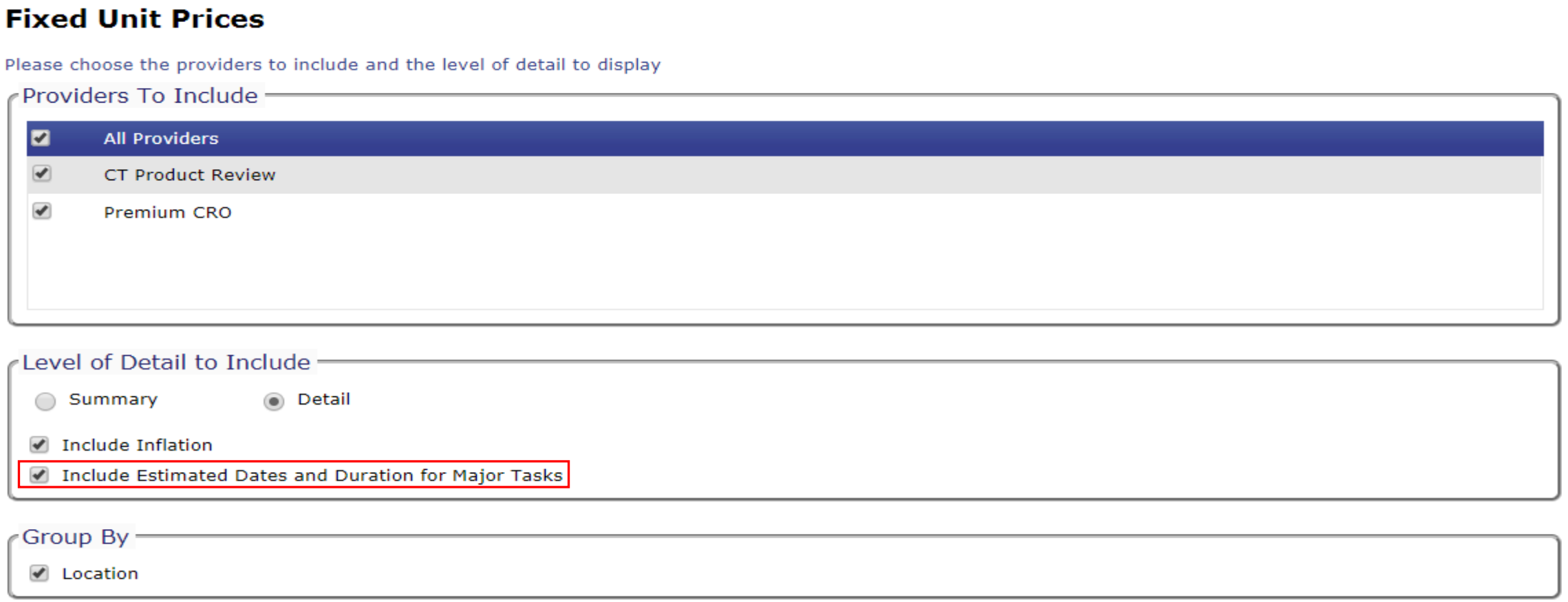
New Reporting Options



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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					
Task	**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**

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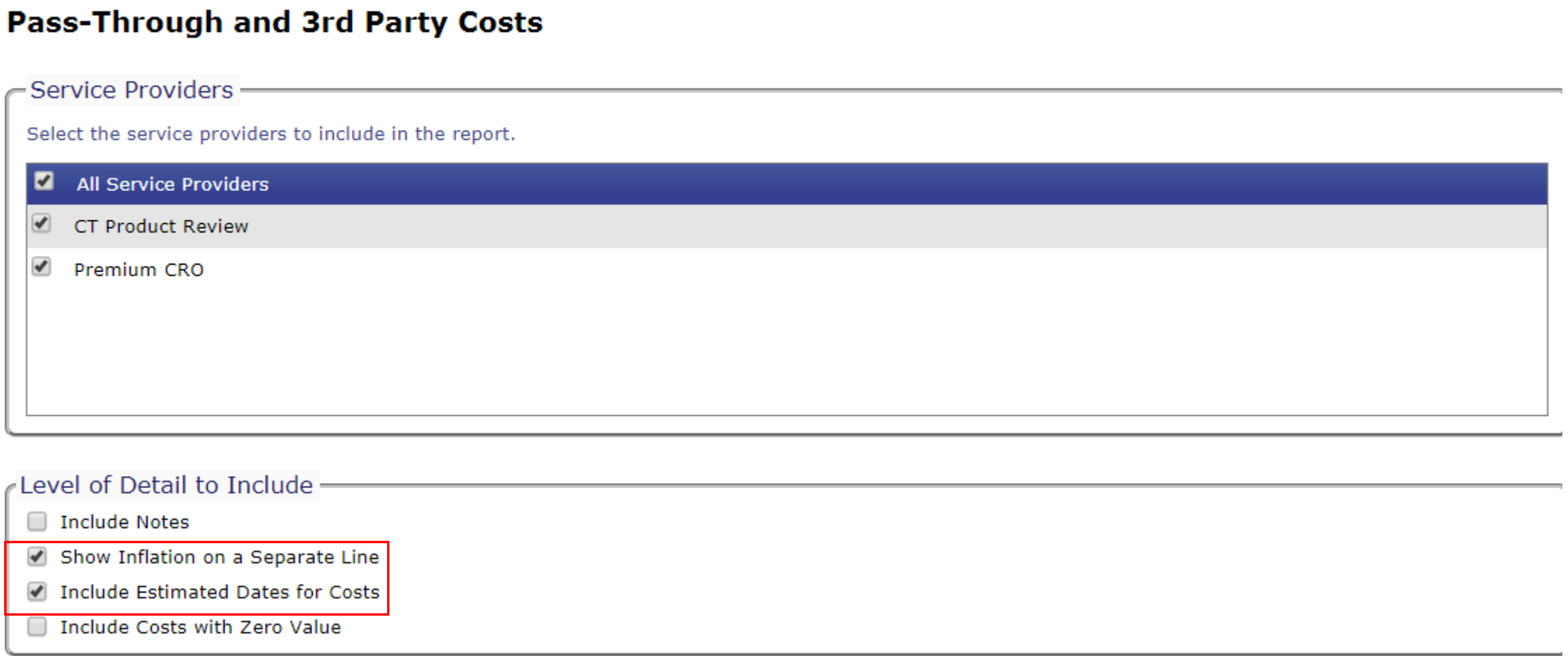
New Reporting Options



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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

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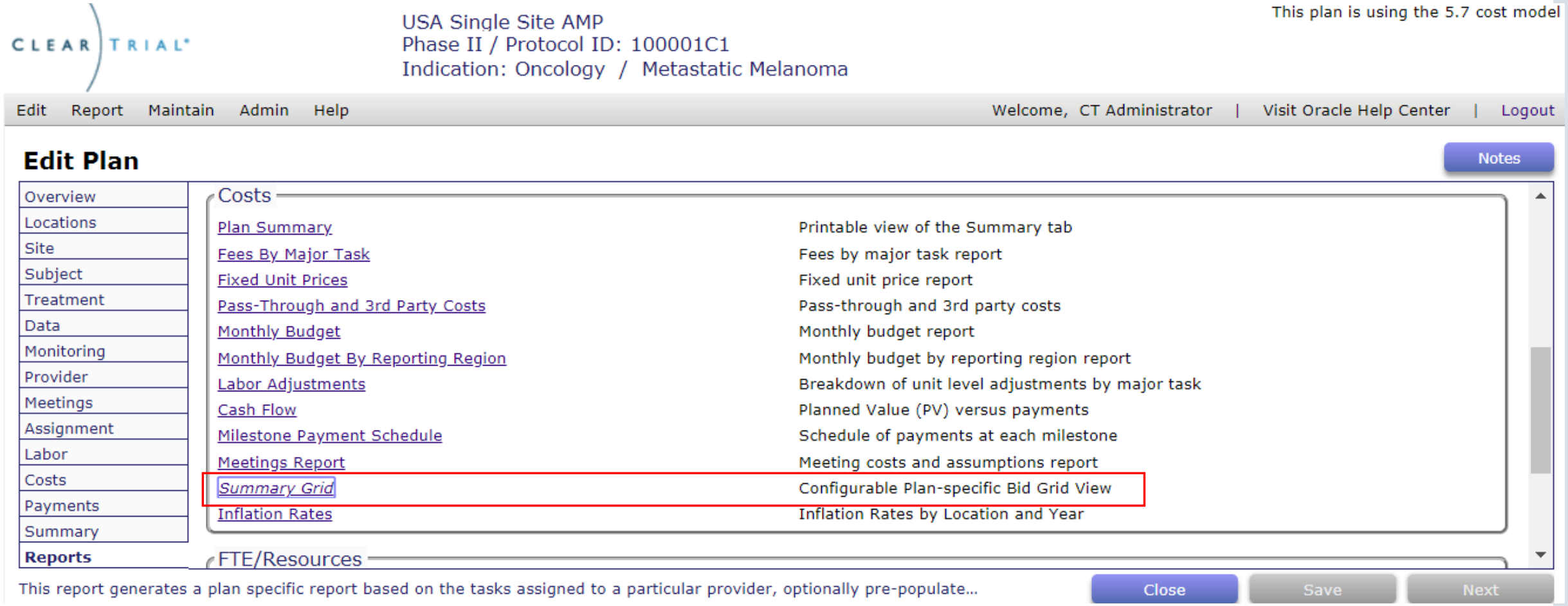
Enhanced Summary Grid Reporting

Configurable Bid Grid Views



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New Summary Grid Reporting Options

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

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

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

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

2	Plan Name:	Clarity
3	Study Name:	MK-3475 Japan PhIIB
4	Currency:	US Dollar
5	Report generated:	25-Mar-2018 05:09 PM
6		

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.

	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

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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

Study Name: MK-3475 Japan PhIIB

Report generated: 25-Mar-2018 06:29 PM

Currency: US Dollar

All monetary values are displayed in US Dollar (USD) base 18.

Note: Inflation has been added to the costs in thi

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

Cost Type	Major Task / Cost	Task	Unit Hours	Unit Cost	Extended Hours	Budget
Labor	Project Initiated [2 Studies]	Develop scope of work, timeline, work assignments	49.718	12,658	99.437	25,316
		Finalize contract (post award)	6.000	1,317	12.000	2,634

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Timestamp Added to all Reports

Fixed Unit Prices

Report generated: 29-Nov-2017 05:41 PM

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

All monetary values are displayed in US Dollar (USD) based upon exchange rates as

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 Ho
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

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Days between Each Milestone

Milestone Dates Report Update

Milestone Dates

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

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

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**	

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Usability/User Experience (UX) Enhancements*

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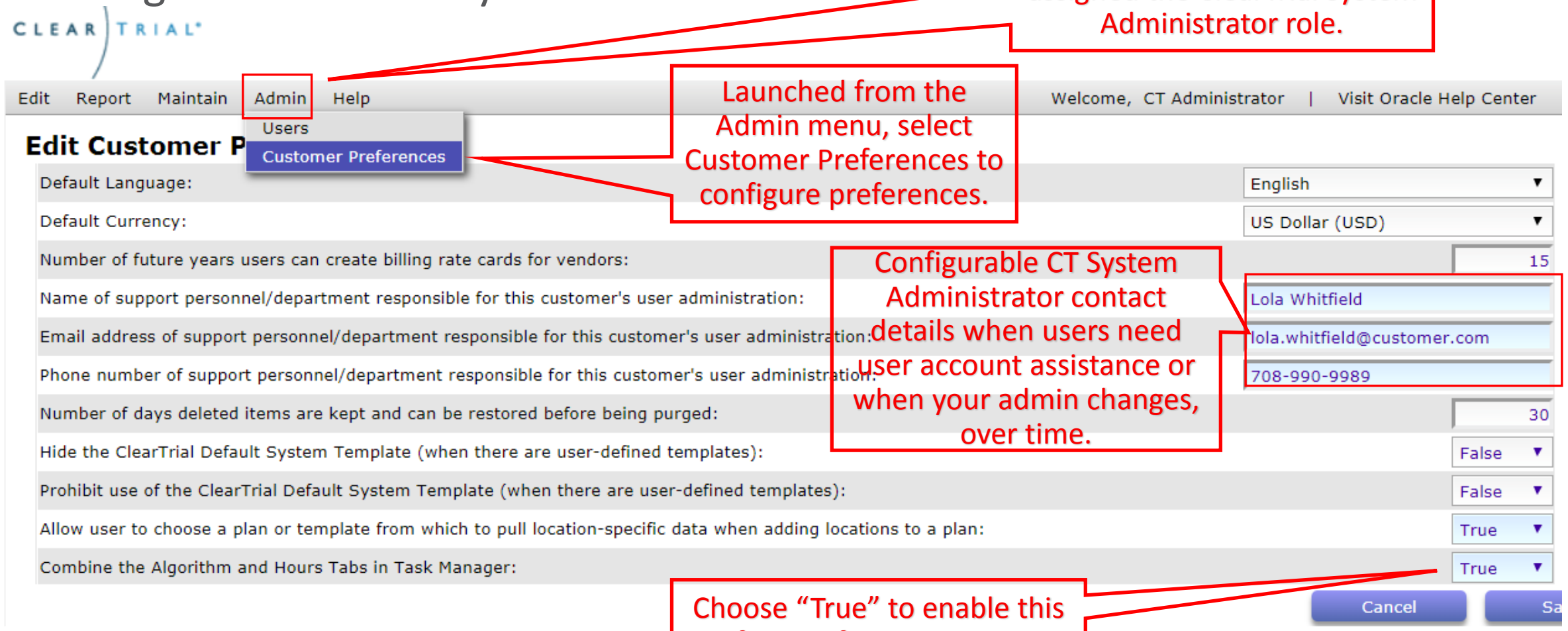
New Customer Preferences Available

for assigned ClearTrial System Administrators



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.

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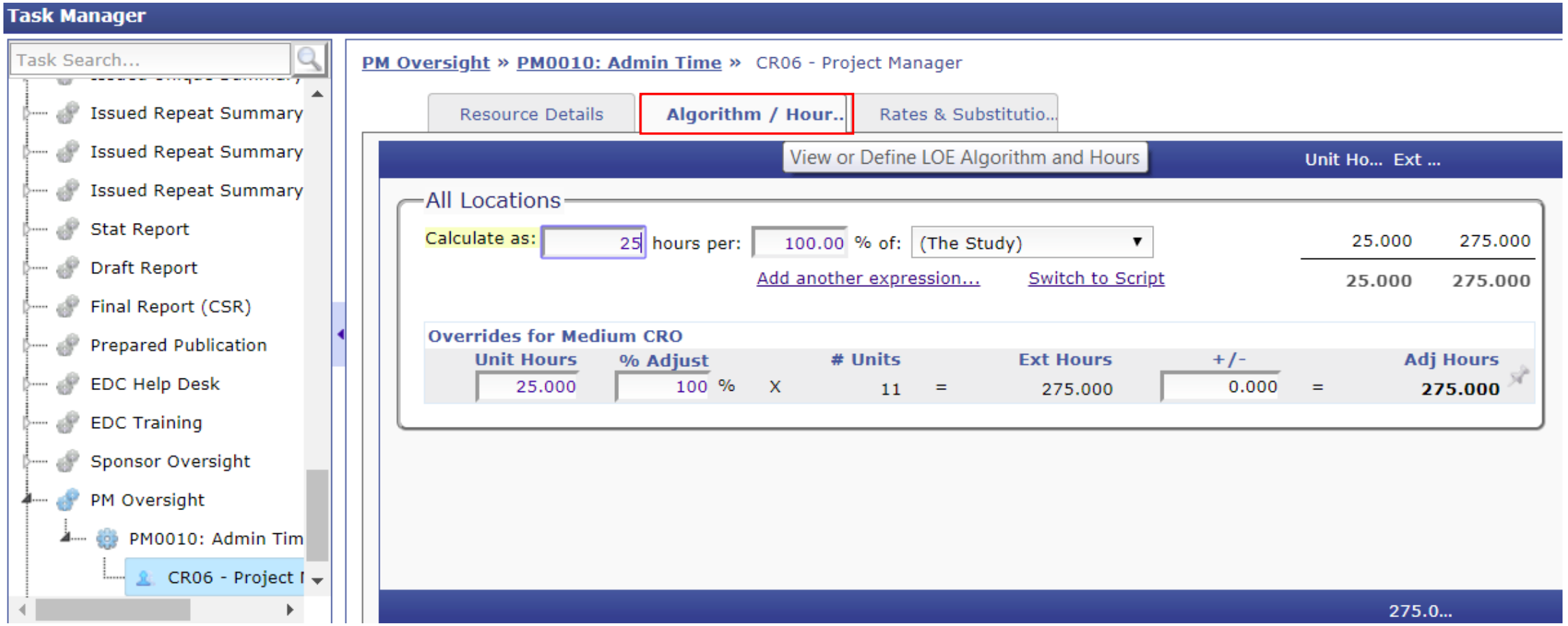
Combined Algorithm and Hours Tabs in Task Manager

Refined Task Manager user experience



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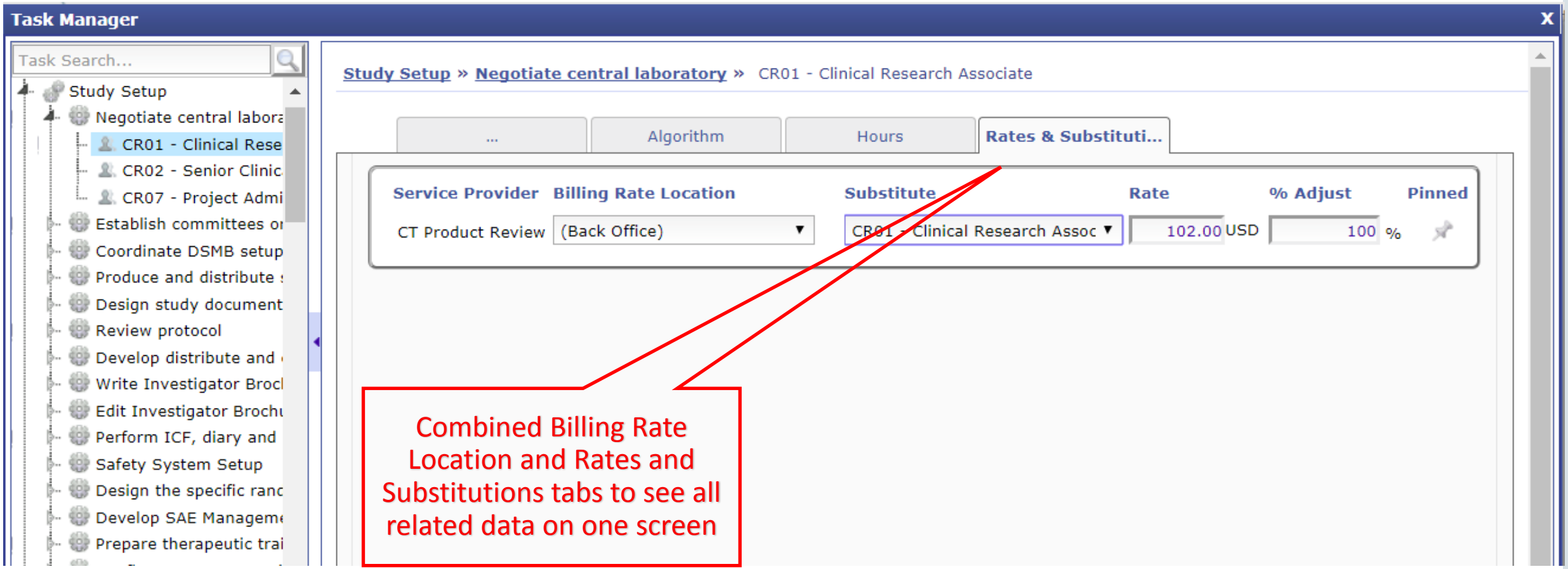
Combined Billing Location, Rates & Substitutions Tabs

Refined Task Manager user experience



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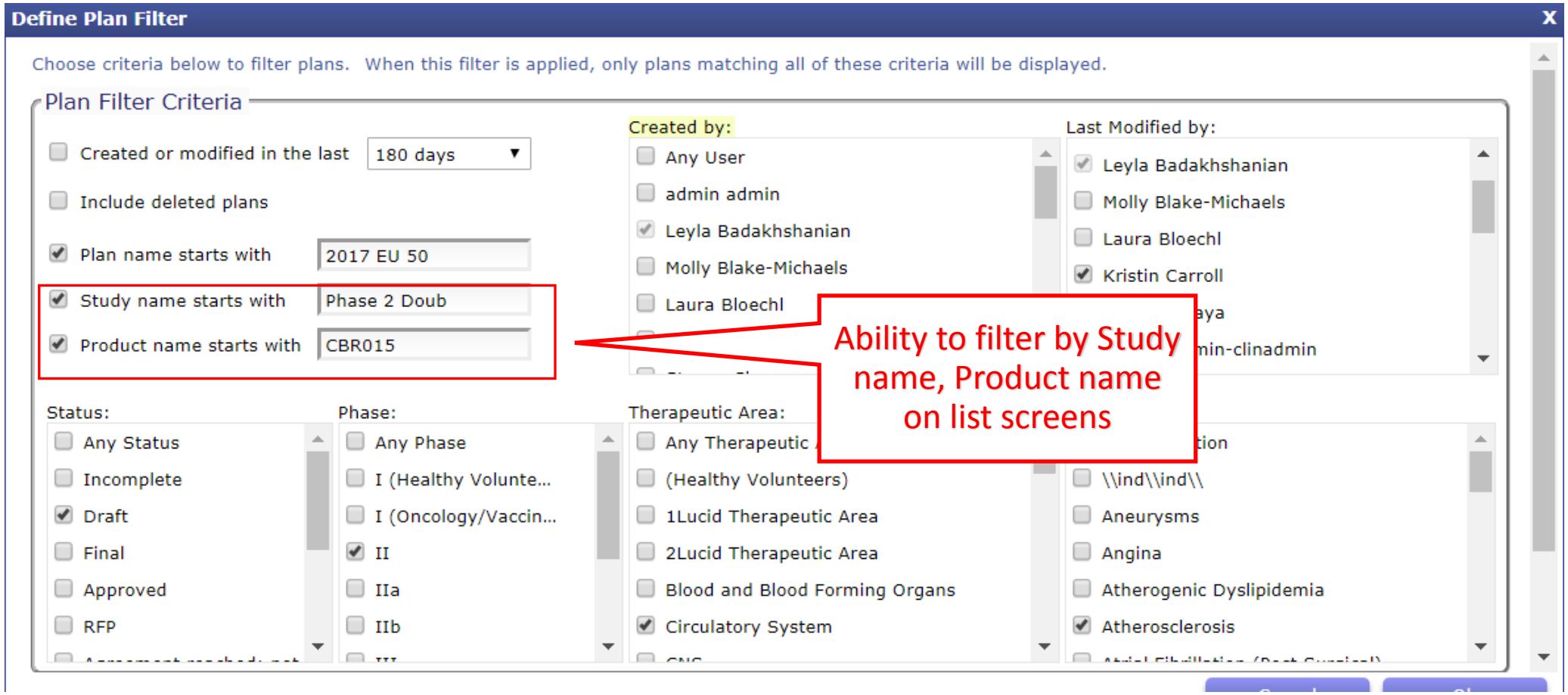
Filter Enhancements on List Screens



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Consistent Mapping Key and Codes for Grid Mappings

Assign a Code per Indirect Cost

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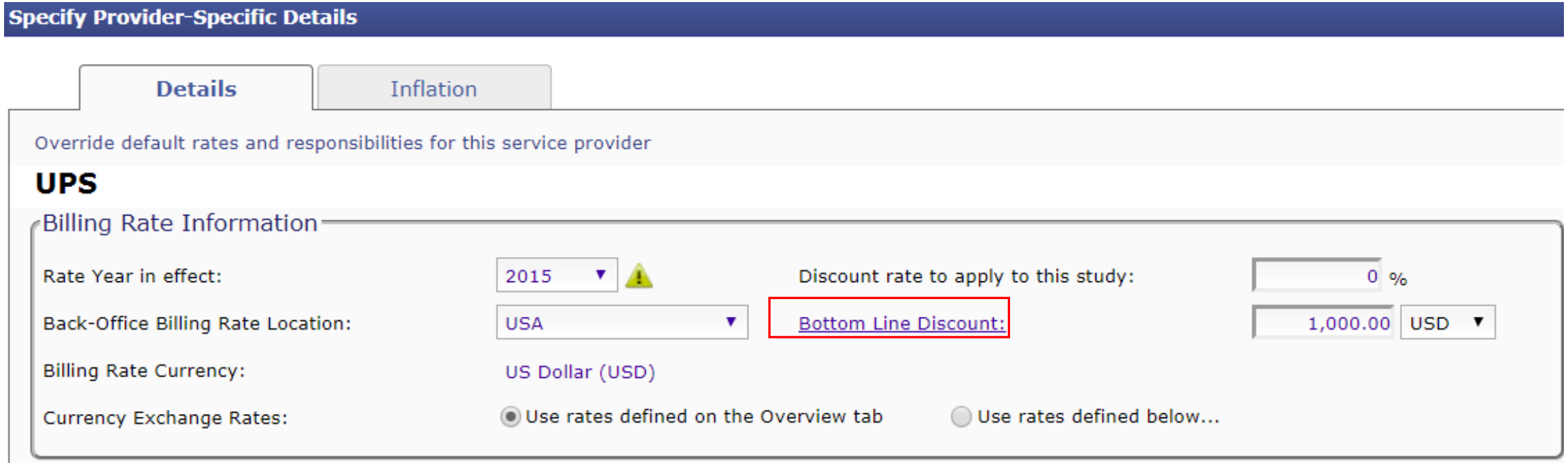
Renamed Line Item Discount to Bottom Line Discount



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Enhancements for Increased Precision and Accuracy

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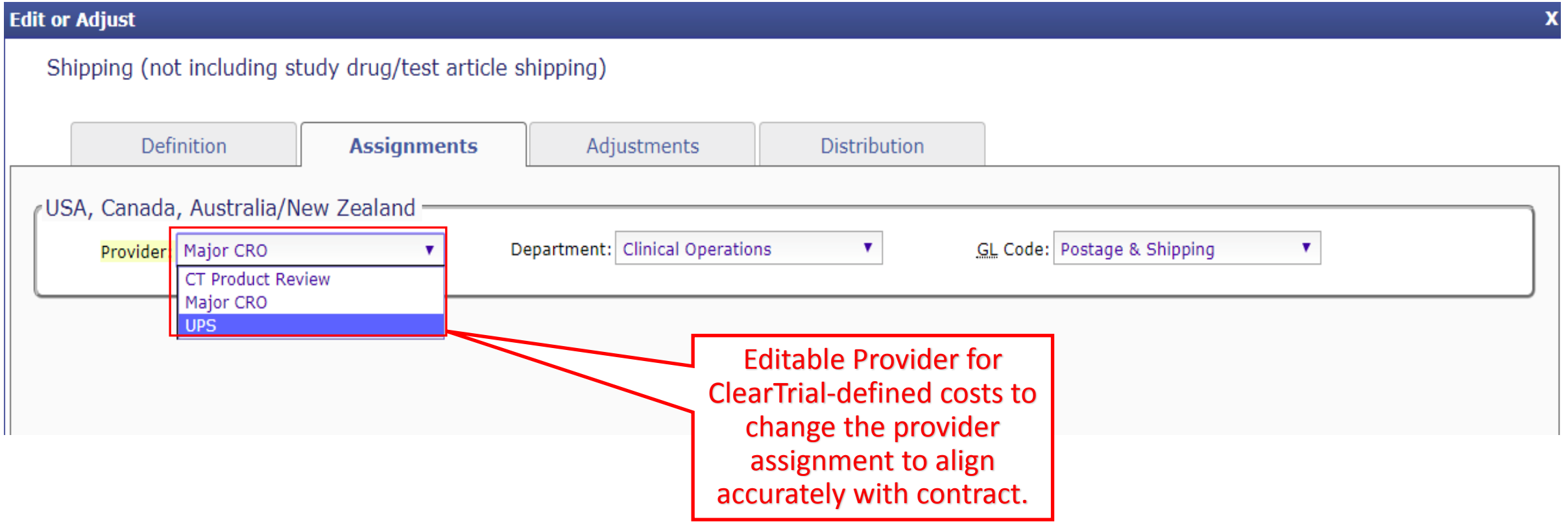
Change Provider on ClearTrial-defined Costs

Ability to edit the Provider Assignment for built-in Costs



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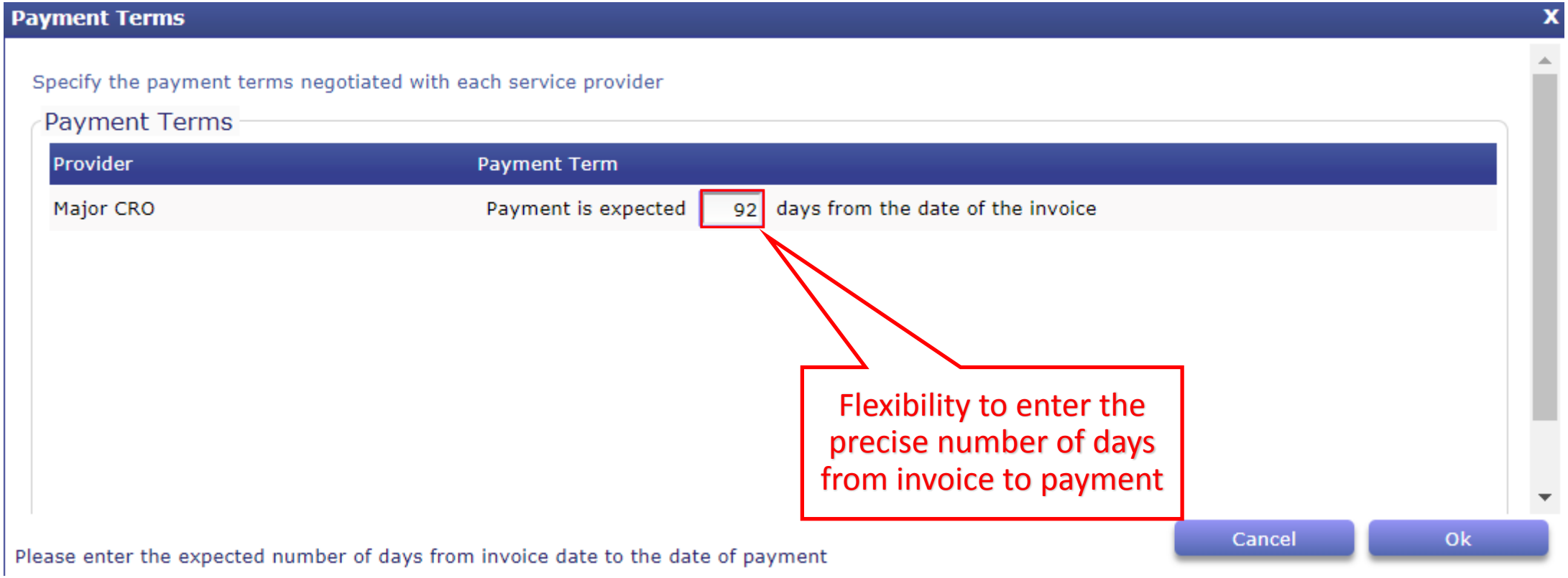
Increased Precision for Milestone Payments

Precise Payments



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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

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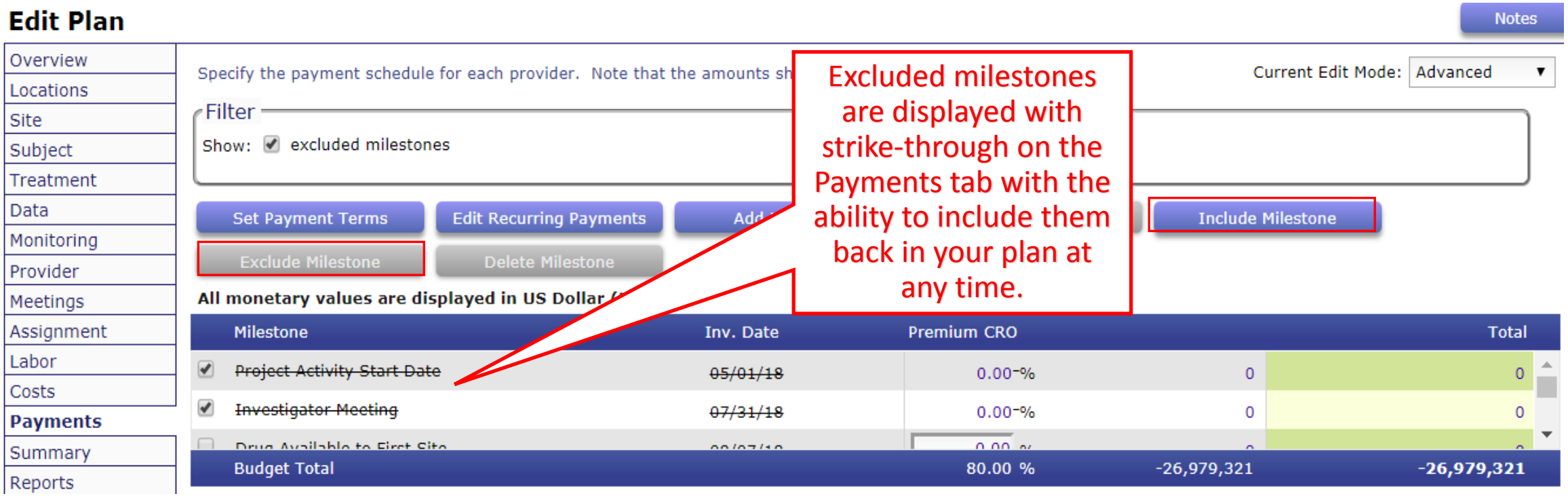
Distinguishable Excluded Milestones on Payments Tab



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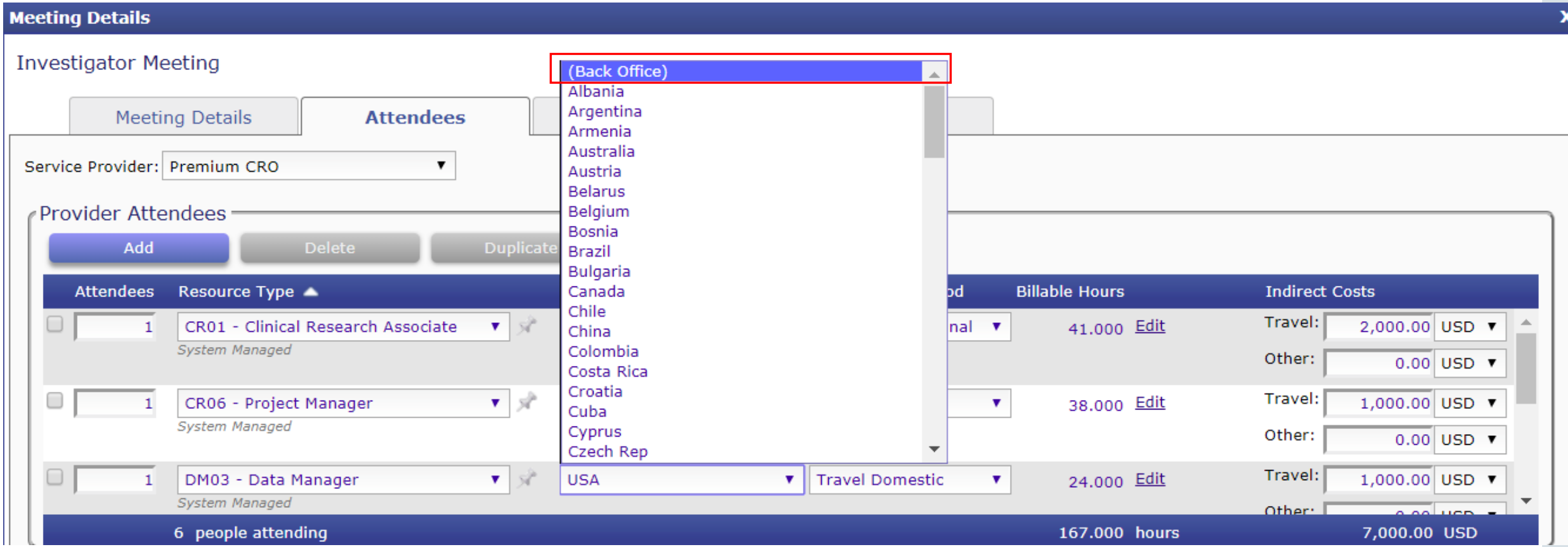
Back Office Added to Billing Rate Location for Meeting Attendees



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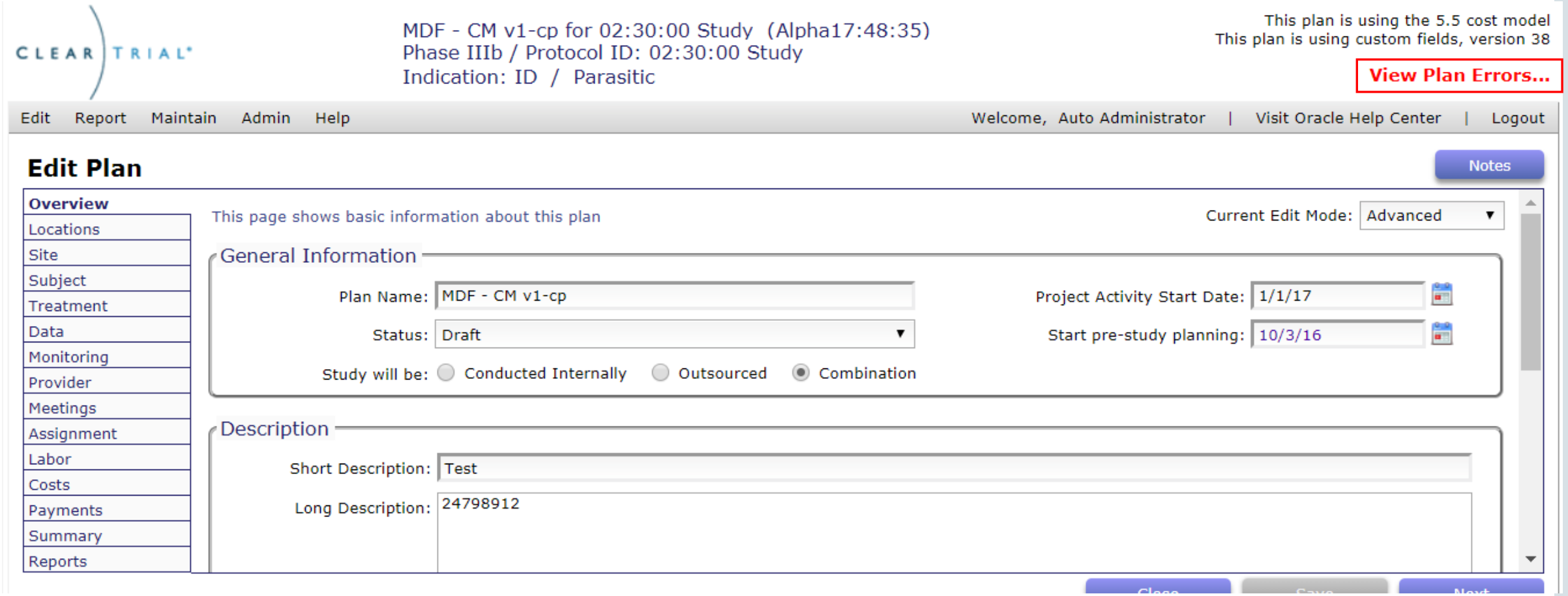
View Plan Errors

Impacts Users Assigned Custom Fields Designer/Expert Algorithm Editor Roles



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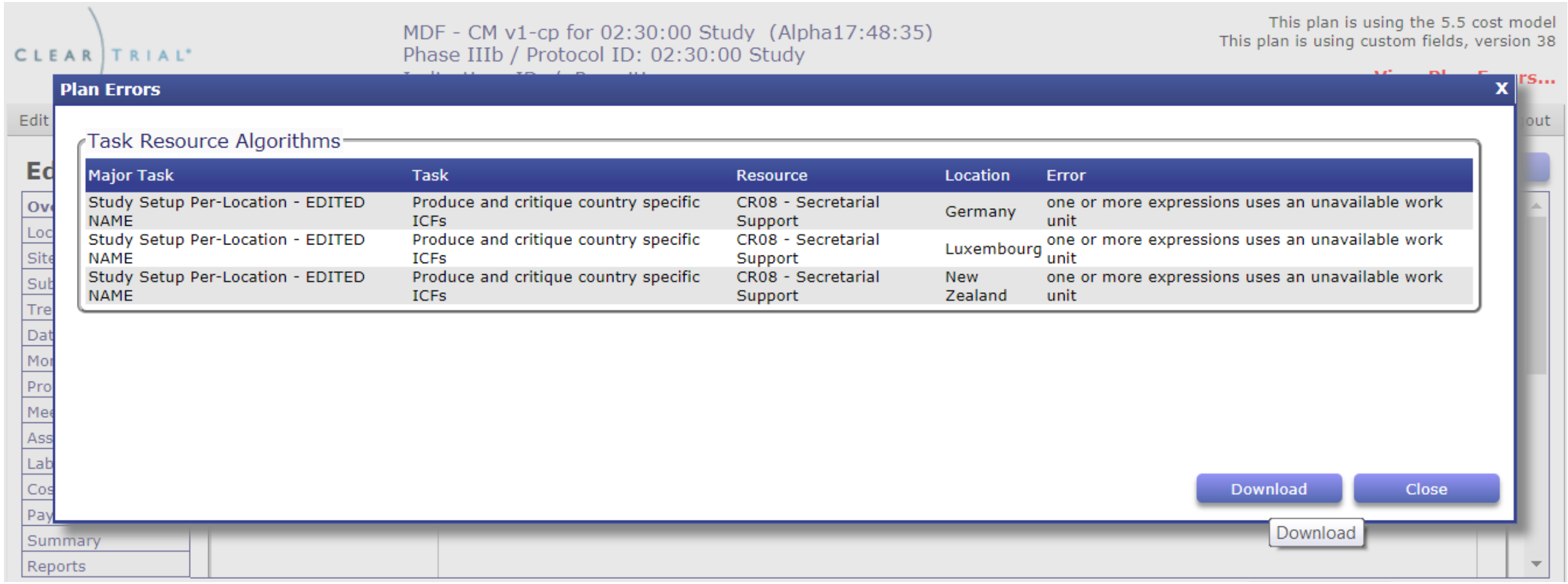
Errors in Custom Algorithms via Script



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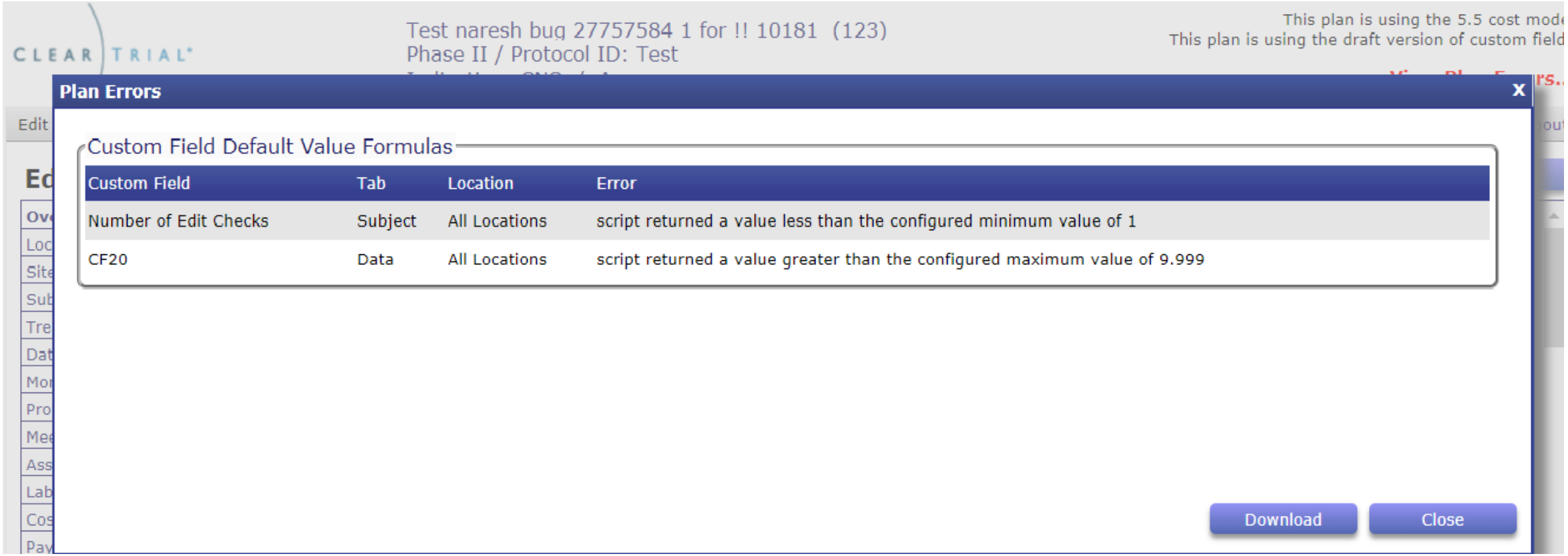
Errors in Custom Fields



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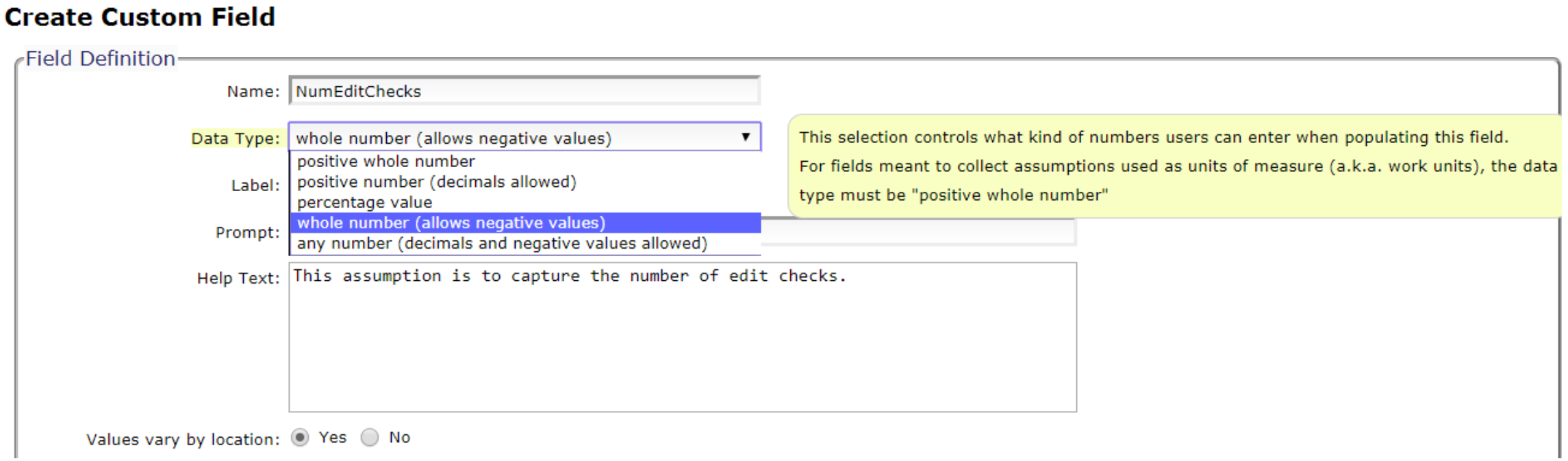
Create Negative Custom Field Value to use as Script Variable



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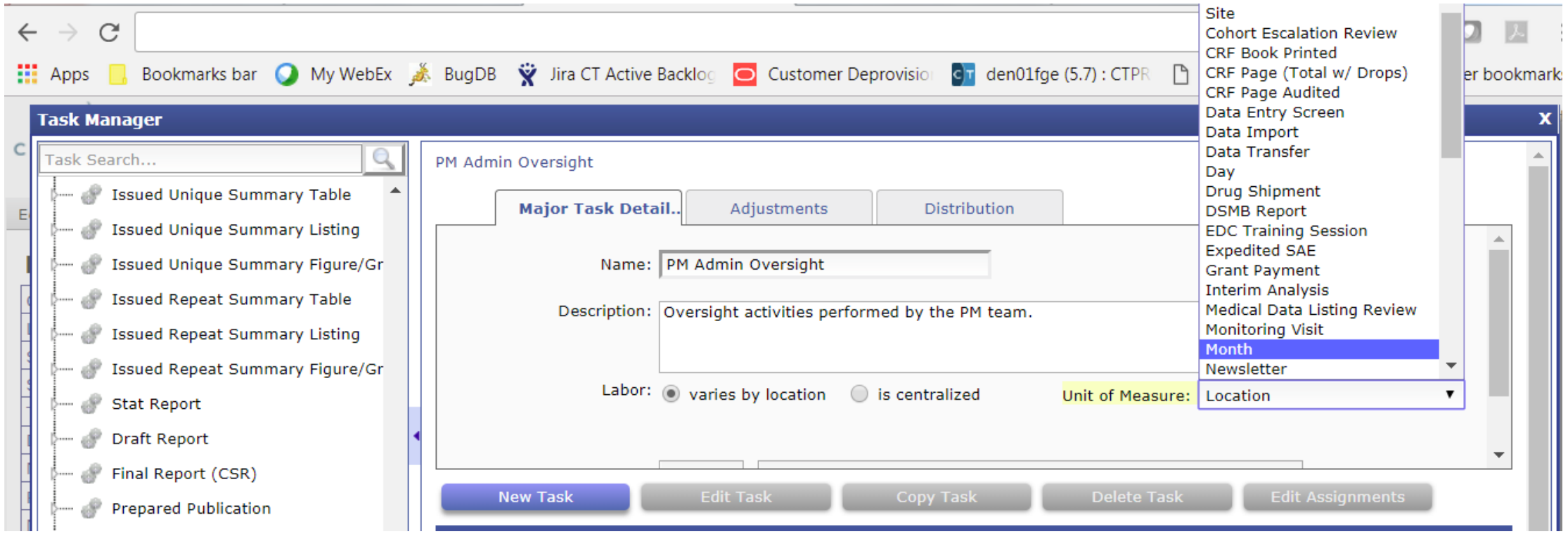
Leveraging Month as a Unit of Measure



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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

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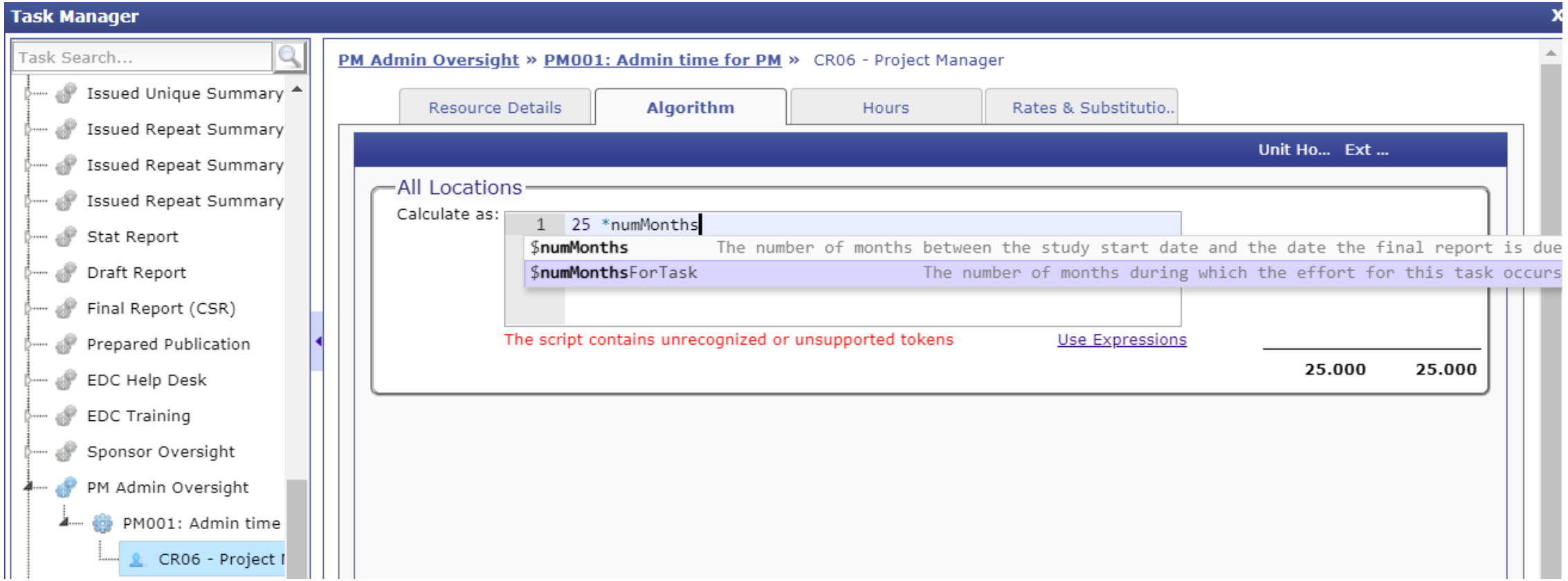
Switch to Script When Defining Custom Algorithms for Fees and Costs



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Delete ClearTrial-defined Major Tasks

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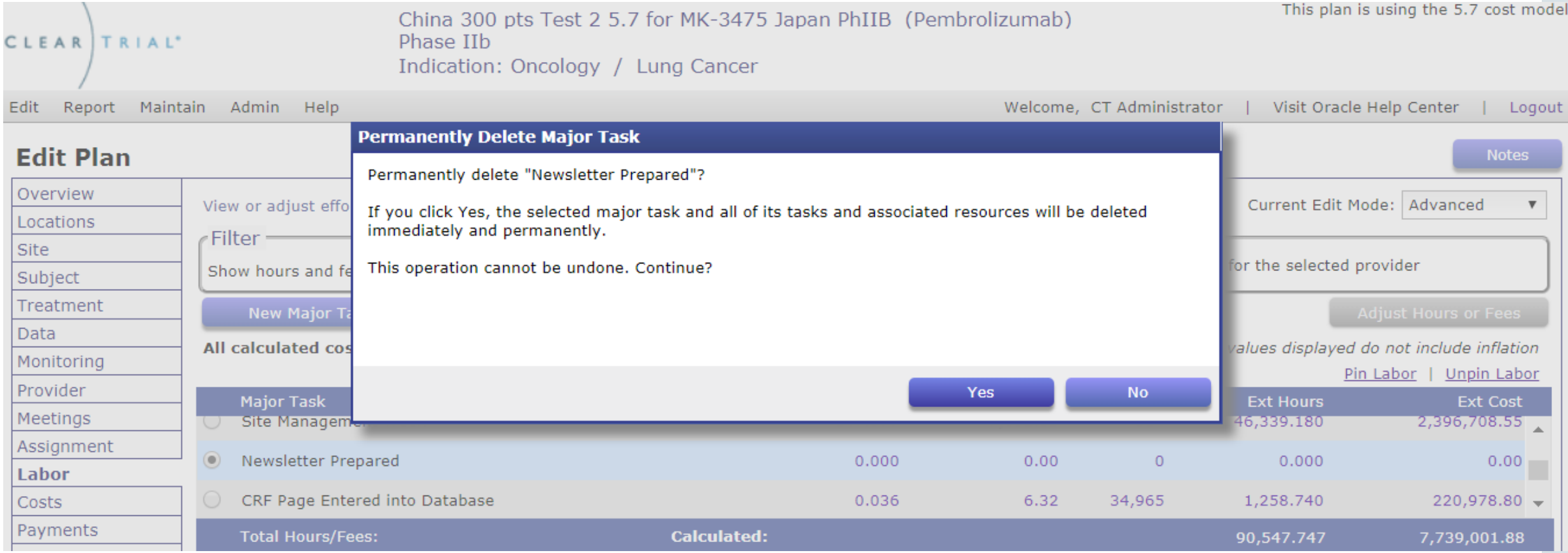
Delete ClearTrial-defined Major Tasks



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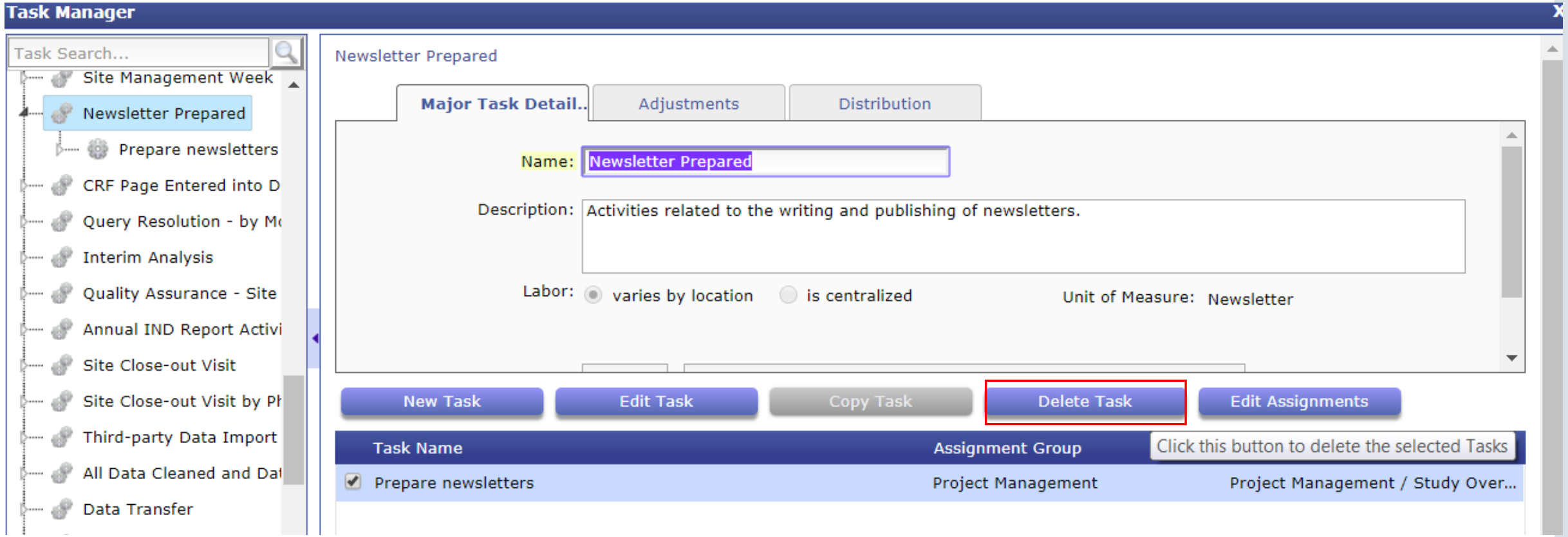
Delete ClearTrial-defined Tasks



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Improved Contract Alignment/ Change Order Support

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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

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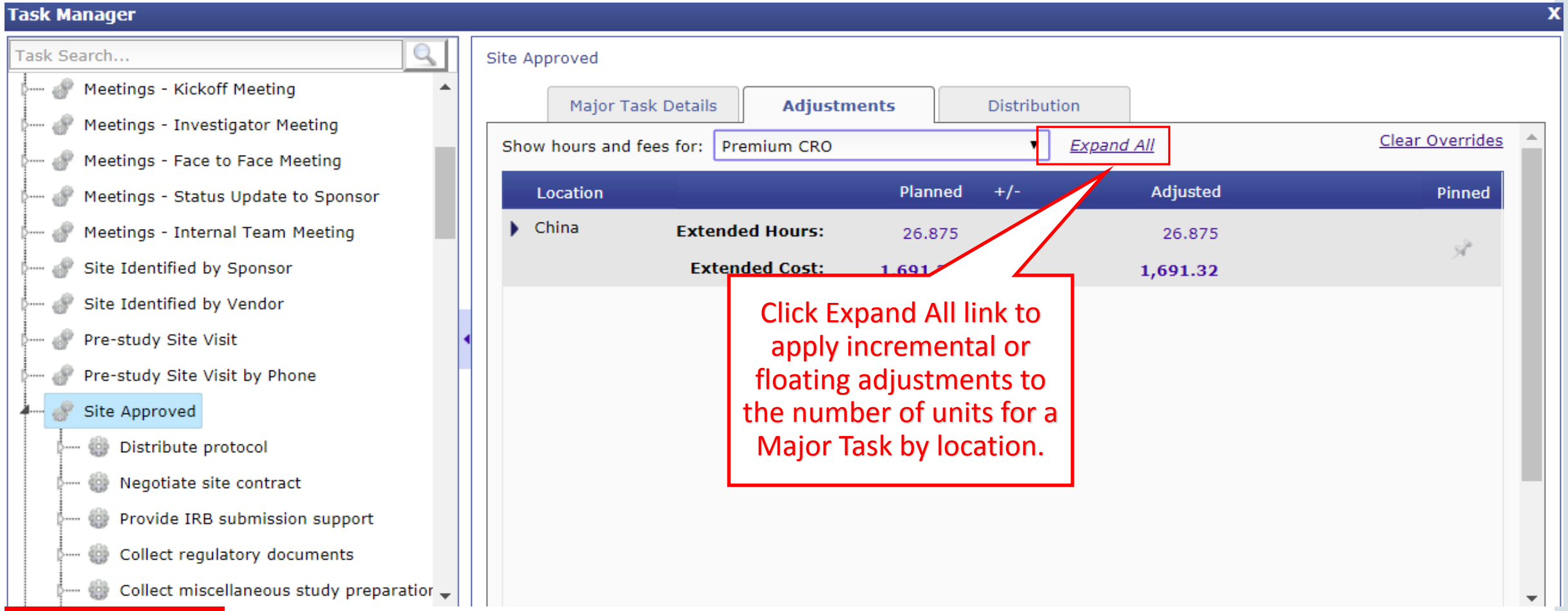
Apply Floating Adjustment to Major Task Units



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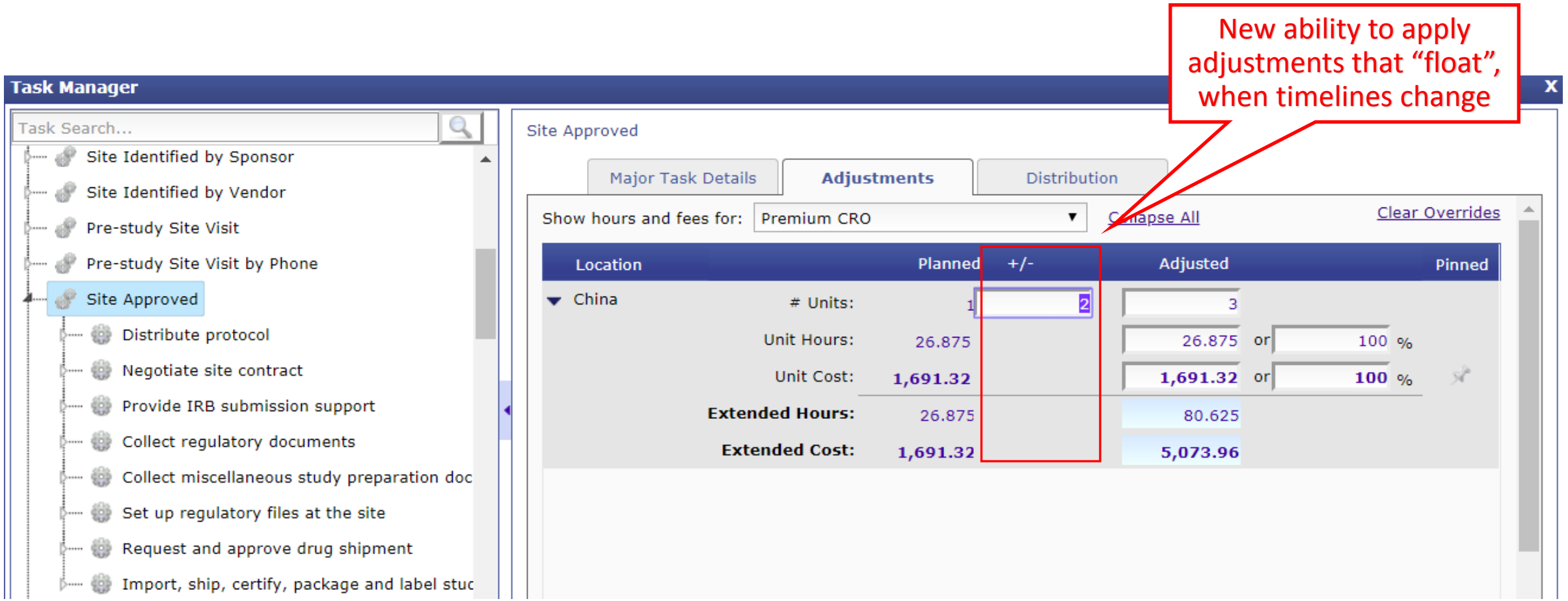
Ability to Provide a (+/-) Offset to Units



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Apply Floating Adjustment to Resource's Extended Hours

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

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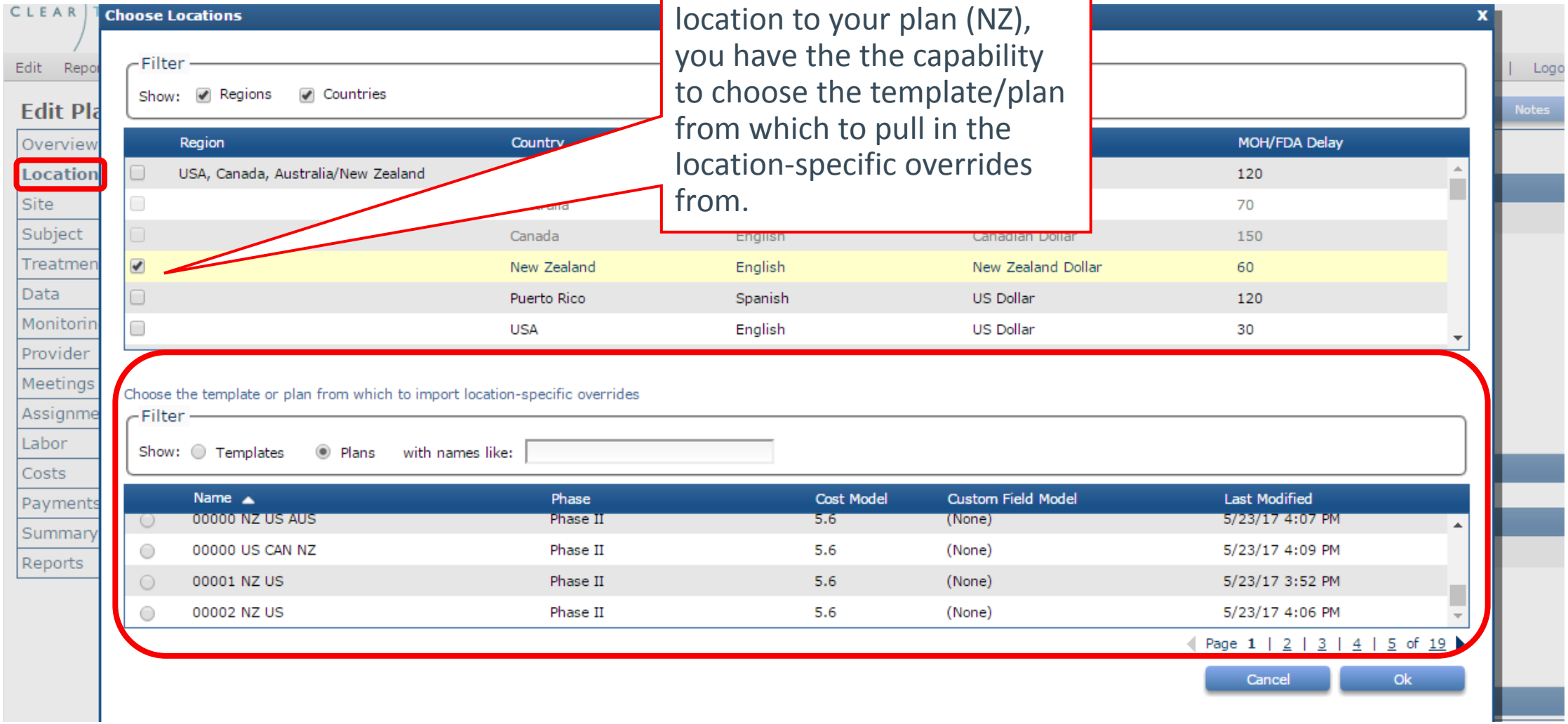
Import Additional Location-specific Overrides From a Template/Plan



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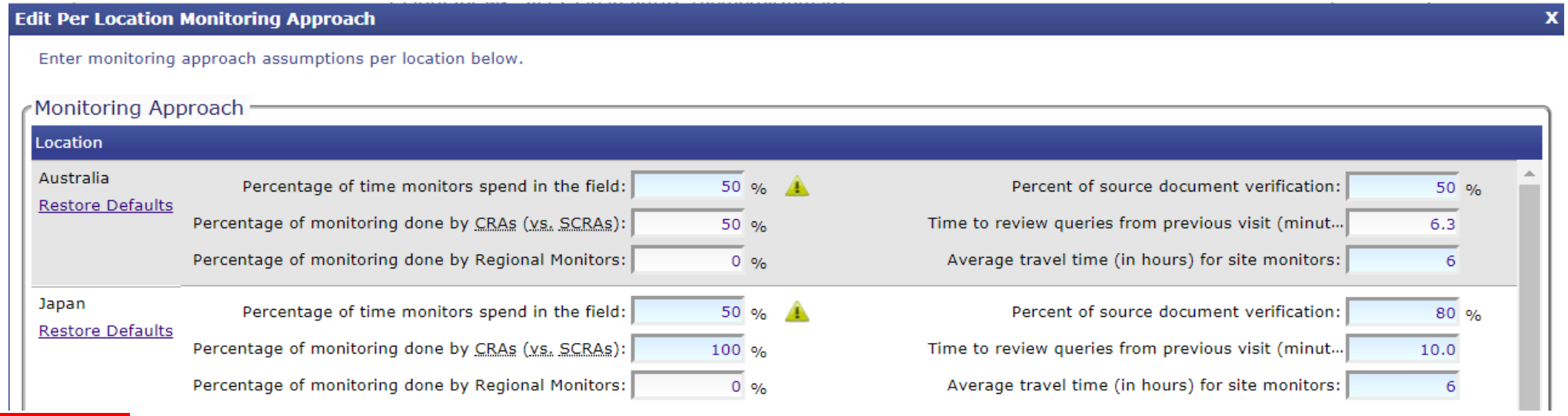
What types of overrides will be pulled into my plan?

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



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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

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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.

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Integrated Cloud

Applications & Platform Services

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