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HEALTH SCIENCES

Introduction to Oracle ClearTrial Cloud Service 5.4

Product Management/Strategy
Health Sciences Global Business Unit
December 08, 2015

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Agenda

- 5.4 Release Overview
- Edition Impact
- Enhancements & Features
  - Details by Enhancement or Feature

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ClearTrial 5.4 Release Overview

- Release Objectives:
  - Continue to provide greater flexibility and configurability to align plans/RFPs with vendor bids and contracts
  - Continue to enhance and refine the service to deliver greater degrees of precision and increased accuracy to your study planning and outsourcing processes
- Release Approach: Market and Customer Driven
- Go Live: **Friday Dec 11th – Saturday Dec 12th, from 9 PM - 9AM (EST)**
  - Freeze Rates: ClearTrial **5.4 DOES** include changes to composite billing rates and inflation rates.

Freezing rates is a recommended ClearTrial release best practice!

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5.4 Release Preparation Best Practice Update

- Prior to the 5.4 release, ClearTrial's best practice recommendation has been for you to lock plans prior to a release to preserve *static versions* of your plans.
- With the introduction of cost model versioning in ClearTrial 5.4, you no longer need to lock plans prior to a release in order to preserve the calculations in your plans.
- You now control when an unlocked plan will use a newer cost model.
- As billing and inflation rates are **not** preserved as part of the cost model, freezing rates is still a ClearTrial release best practice.

➢ ***Please review the Cost Model Versioning section for best practice recommendations and more information regarding this new feature***

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5.4 Features and Functionality Edition Impact

Feature	Standard Edition	Enterprise Edition
Clinical Intelligence Update	X	X
Additional Units of Measure Available	X	X
Usability Enhancements	X	X
Line-Item Discounts	X	X
Meetings Labor Update to Increase Transparency	X	X
Metrics Update to Include Inflation	X	X
Cost Model Versioning	X	X
Bid Grid Versioning		X
Bid Comparison Across RFPs		X
Custom Assumptions		X

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Enhancements & Features

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Clinical Intelligence Update

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Composite Billing Rate Updates

- Composite billing rates are reviewed and updated annually to ensure current and accurate costing based on global industry salary trends
- Rates updated for years 2016 to 2029 based on:
  - estimated inflation
  - observed provider billing rates by location
  - industry salary projections
- Rates reviewed and updated as needed for all CRO types
  - Average All CROs, Major CRO, Medium CRO, Niche CRO, Premium CRO

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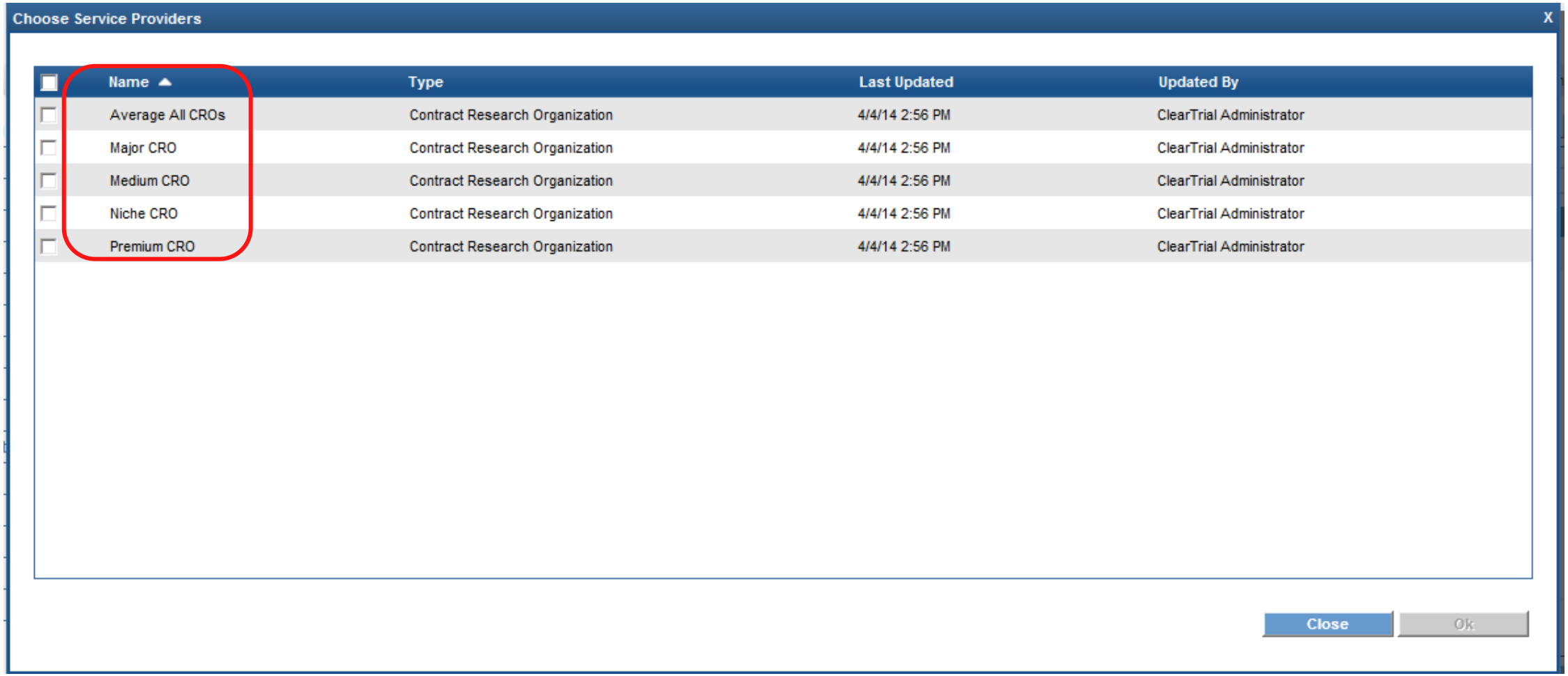
Composite/CT-Defined Provider Billing Rate Updates



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Composite Inflation Rate Updates

- Composite inflation rates are reviewed and updated annually to ensure current and accurate costing based on global economic data
- Rates updated for years 2017 to 2029 based on updated 5-year economic forecasts per location
- Rates reviewed and updated as needed for all locations impacting all composite CRO types
  - Average All CROs, Major CRO, Medium CRO, Niche CRO, Premium CRO

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Composite Billing and Inflation Rate Updates

Important Migration Consideration

- When rates are not frozen in existing plans, unlocked plans or copies of plans will inherit new 5.4 billing and inflation rates.

If you have added any of the ClearTrial-defined Composite Providers to any of your existing, unlocked plans, and do not want those 5.3 or earlier rates to change, don't forget to **freeze your rates** prior to the release.

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Additional Units of Measure Available

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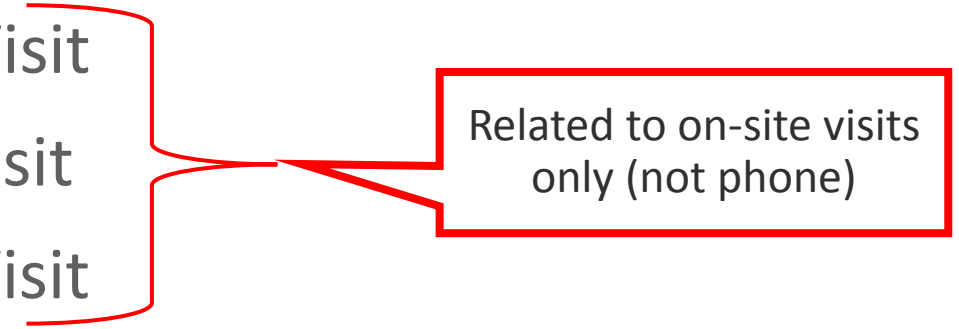
Additional Units of Measure Available

In Task Manager and Cost Algorithm set-up screen

Five new available units of measurement (UOM)

- Pre-study Site Visit
- Site Initiation Visit
- Site Close-out Visit
- Newsletter
- Publication



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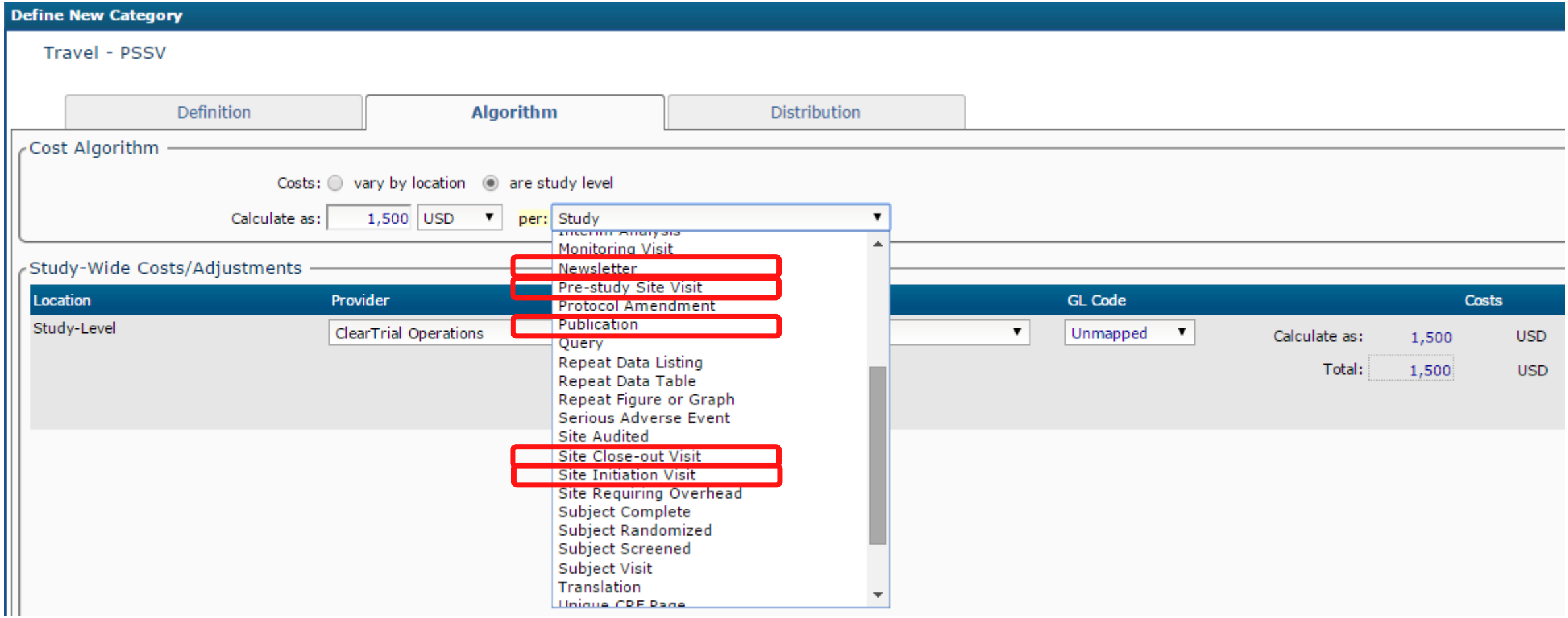
Additional Work Units Available

In Task Manager and Cost Algorithm set-up screen



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Usability Enhancements

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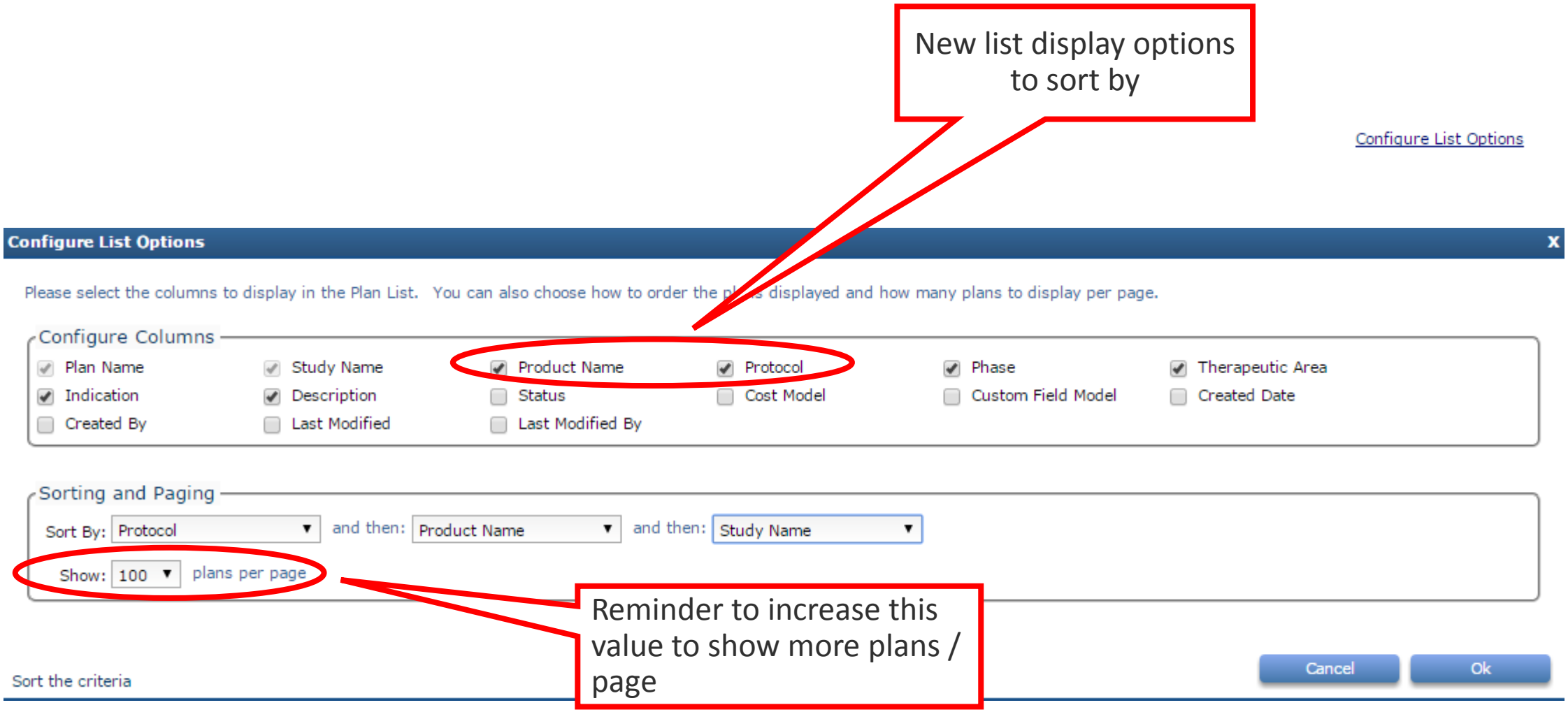
Sort Plans by Protocol and Product/Compound



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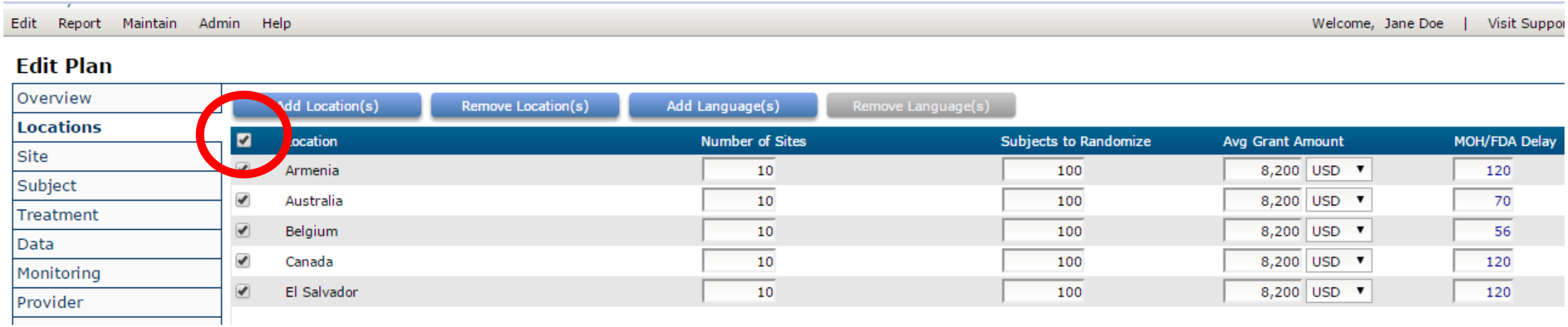
Select All Option for Locations

- Checkbox is available on the Locations tab to select or deselect all existing locations with a single click.
- The checkbox is only available if there are 2 or more existing locations.



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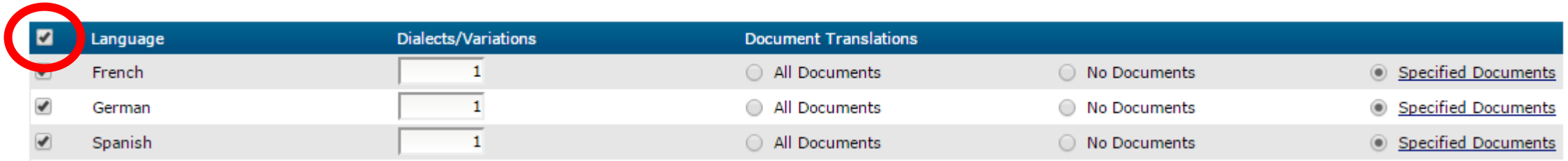
Select All Option for Languages

- Checkbox is available on the Locations tab to select or deselect all existing languages with a single click.
- The checkbox is only available if there are 2 or more existing user-specified languages. Only the user-specified languages are impacted.



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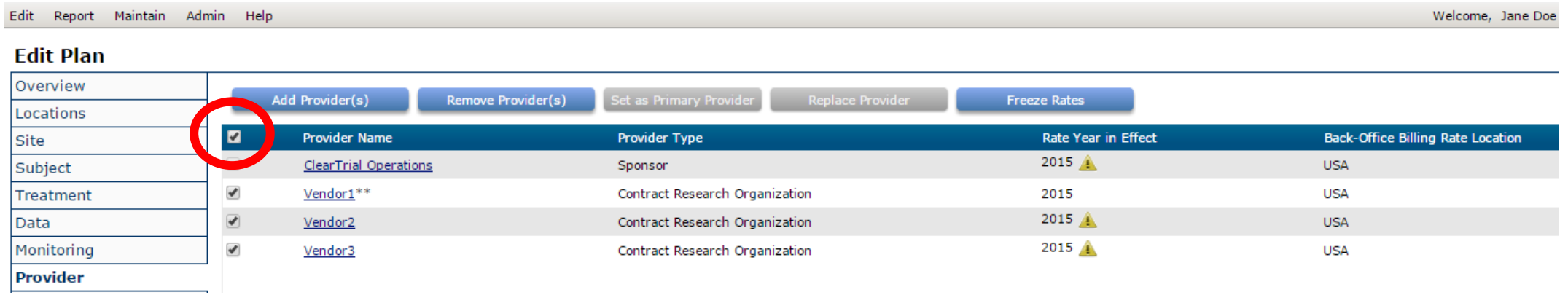
Select All Option for Providers

- Checkbox is available on the Provider tab to select or deselect all existing providers with a single click.
- The checkbox is only available if there are 2 or more existing providers. Only non-Sponsor provider types are impacted.



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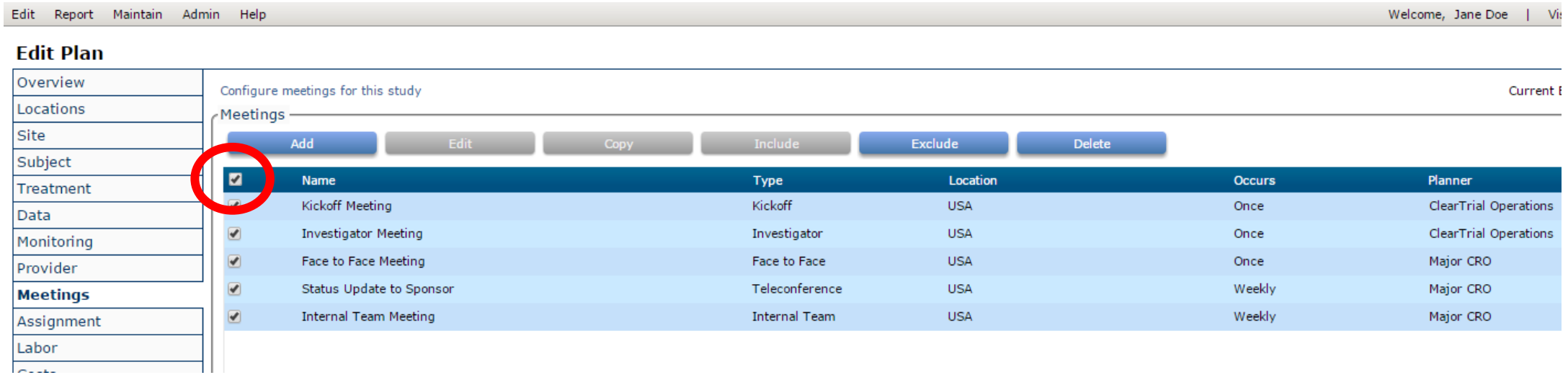
Select All Option for Meetings

- Checkbox is available on the Meetings tab to select or deselect all existing meetings with a single click.



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Line-Item Discounts

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New Line-Item Discount Assumption By Provider

- Oracle ClearTrial 5.4 provides the ability to apply line-item discounts per plan, by provider.
- Line-item discounts can be entered and will be applied to total direct labor fees in a plan.
- If you enter a line item discount for your plan, all ClearTrial-defined reports have been updated to display discount impact to total fees.
- For the Metrics Report, you can choose to include or exclude the discount from the metric calculations.

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Enter Line-Item Discount at the Plan Provider Level

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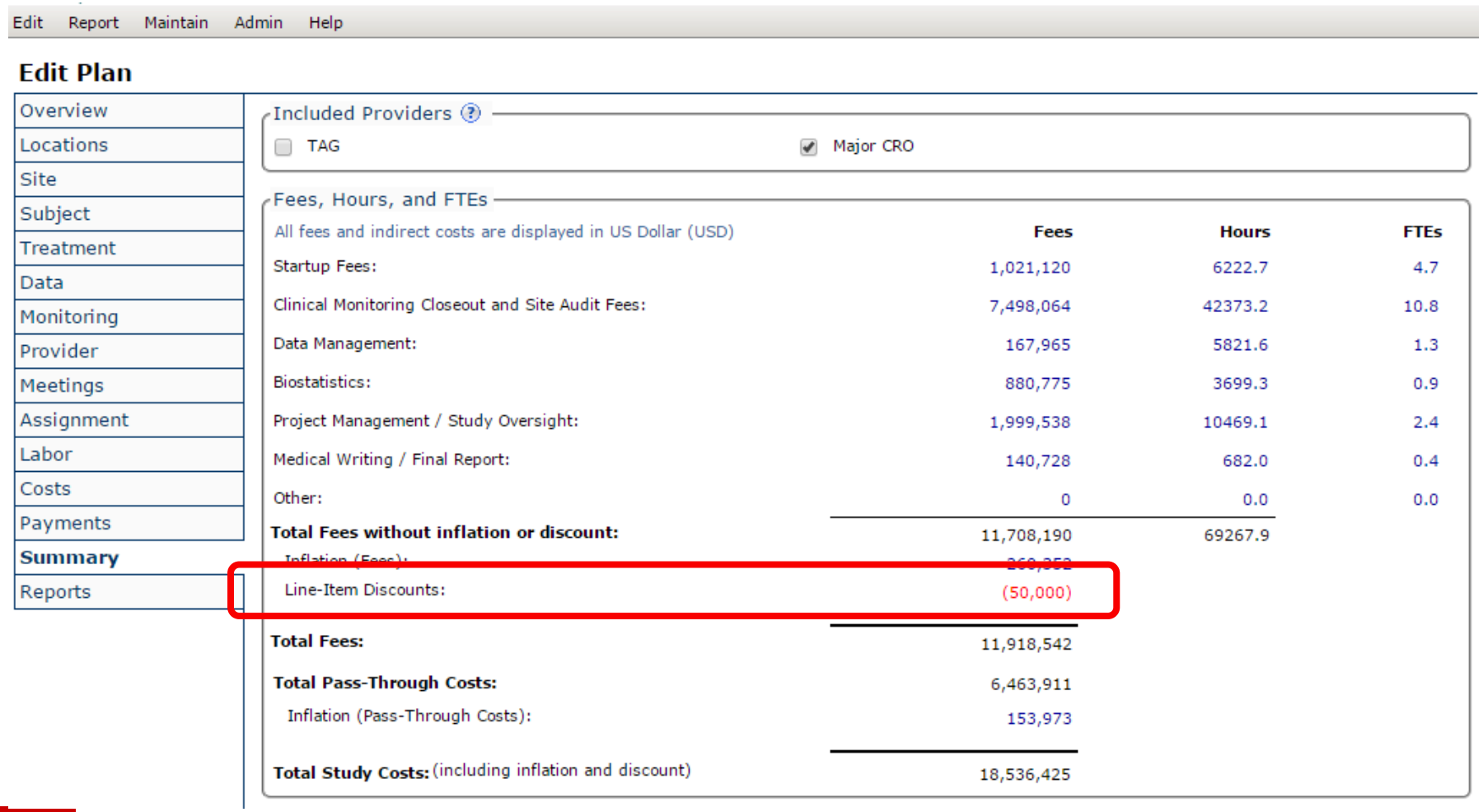
Line-Item Discount Displayed on Plan Summary Tab



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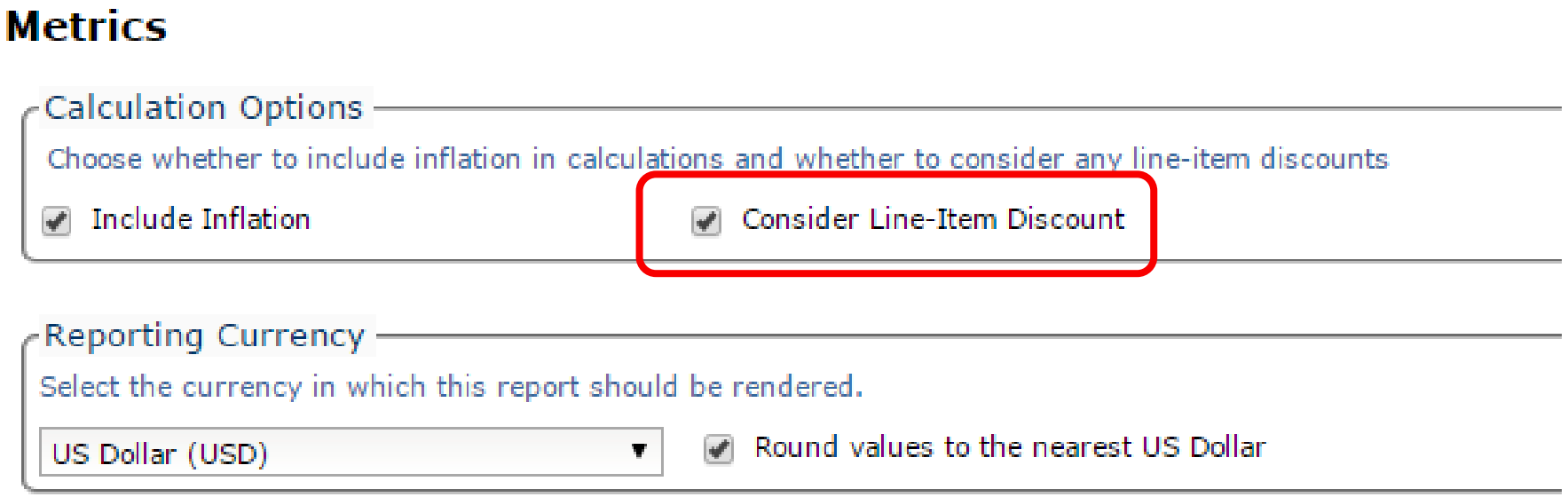
Line-Item Discounts Accessible in Reports



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Increased Transparency for Meetings Labor

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Meeting Labor In 5.3 Plans

- In 5.3 plans, meeting tasks are created for each unique provider attending the meeting.
- Regardless of billing location, multiple occurrences of the same resource for a meeting are merged together into one resource.
- The billing rates for those resources are presented as a single weighted average rate based on all relevant locations.

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Increased Transparency for Meetings Labor In 5.4 Plans

- Oracle ClearTrial 5.4 provides increased transparency for meeting labor.
- In 5.4 plans, meeting tasks will now be created for each unique provider, resource, and billing location combination.
- When fees are calculated, each line item reflects its location-specific billing rate.
- Weighted average billing rates are no longer required.

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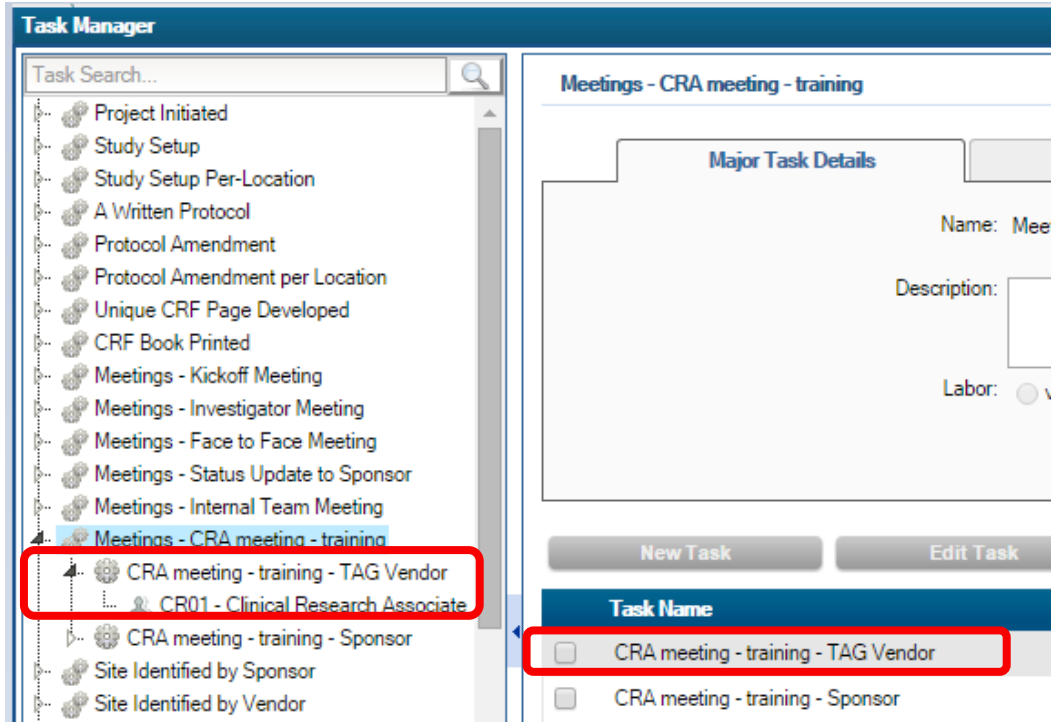
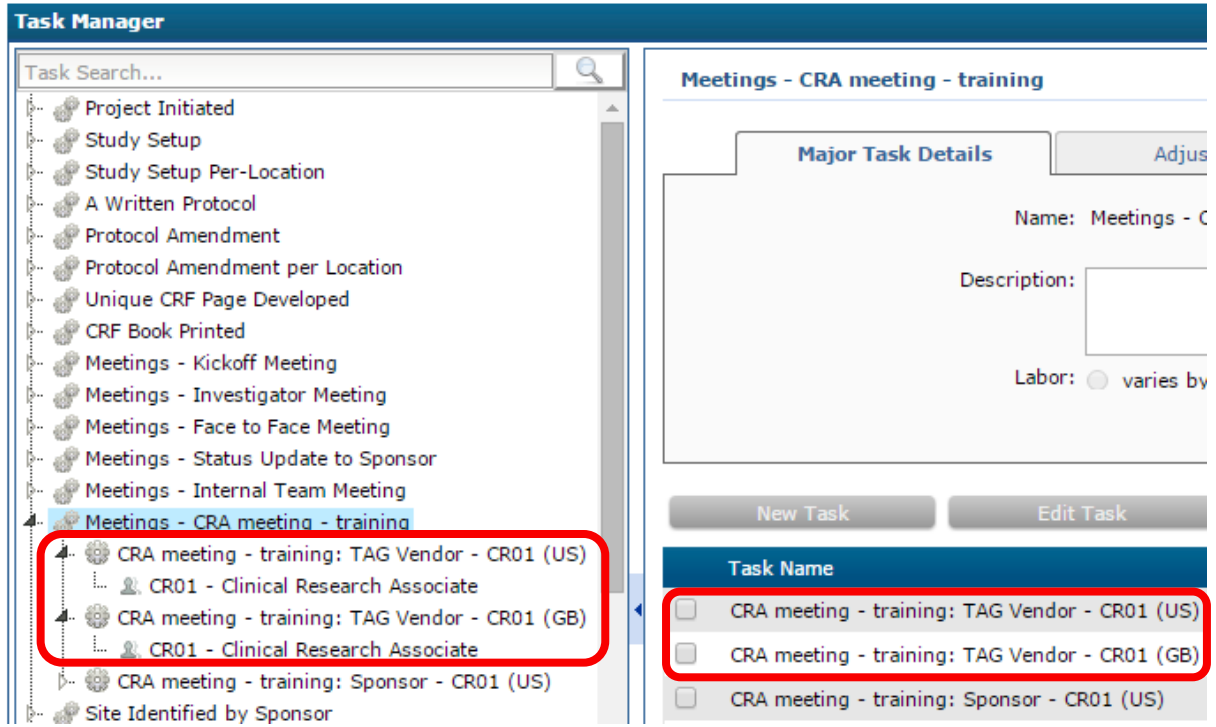
Meeting Labor in Task Manager – 5.3 vs 5.4

- For a meeting set up with 2 CRA resources with different billing locations for the same provider...

In a 5.3 Plan



In a 5.4 Plan



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Meeting Labor in Reports – 5.3 vs 5.4

- All ClearTrial-defined reports have also been updated to reflect these changes. Resources by Major Task report is shown below as an example.

Report in 5.3

Resources By Major Task

TAG 20 sites 200 subjects US and UK for TAG - PHIII
Phase III / Protocol ID: TAG123
Indication: CNS / Alzheimer's/Dementia

Report generated on: 23-Nov-2015

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 20-Nov-2015.

Provider: TAG Vendor

Billing Rate Location: USA

Major Task	Unit Hours	Units	Ext Hours	Ext Cost
Meetings - CRA meeting - training				
CR01 - Clinical Research Associate	34.000		34.000	5,010
Total:	**34.000**	**1 Meetings**	**34.000**	**5,010**

Report in 5.4

Resources By Major Task

TAG 20 sites 200 subjects US and UK for TAG - PHIII
Phase III / Protocol ID: TAG123
Indication: CNS / Alzheimer's/Dementia

Report generated on: 30-Nov-2015

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 20-Nov-2015.

Provider: TAG Vendor

Billing Rate Location: UK

Major Task	Unit Hours	Units	Ext Hours	Ext Cost
Meetings - CRA meeting - training				
CR01 - Clinical Research Associate	22.000		22.000	3,014
Total:	**22.000**	**1 Meetings**	**22.000**	**3,014**

Billing Rate Location: USA

Major Task	Unit Hours	Units	Ext Hours	Ext Cost
Meetings - CRA meeting - training				
CR01 - Clinical Research Associate	12.000		12.000	1,995
Total:	**12.000**	**1 Meetings**	**12.000**	**1,995**

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Metrics Updates to Include Inflation

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Inflation Available in Metrics Report

- You can choose to include inflation in your Metrics report calculations.
- The following metrics have been updated with the ability to include inflation on the ClearTrial-defined Metrics Report:
  - Total study cost per CRF page
  - Data management cost per CRF page
  - Total study cost per on-site monitoring day
  - Cost to monitor all sites for one additional month
  - Average cost per monitoring trip
  - Average cost for a single monitoring day
  - Cost per site per week
  - Study start-up costs per site per week
  - Cost per subject per site per week
  - Cost per completed subject
  - Direct Fees per Enrolled Subject

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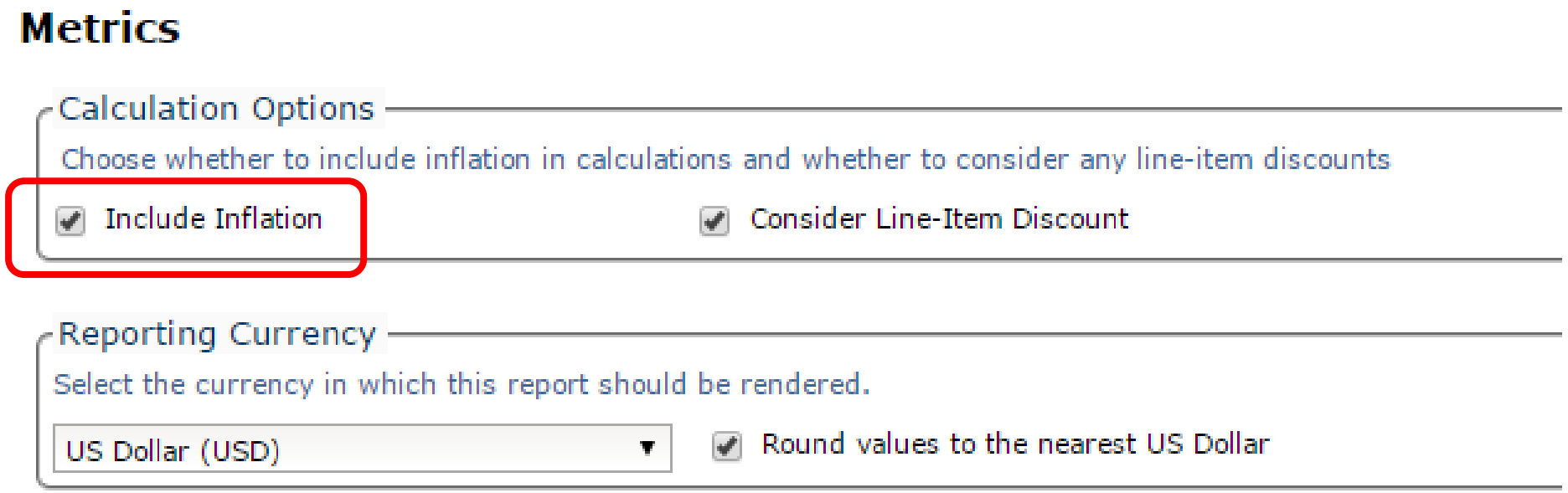
Inflation Available in Metrics Report

- Since ClearTrial-defined metric calculations are not versioned in ClearTrial-defined cost models, metrics upgraded with inflation will be displayed in 5.3 plans.



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Cost Model Versioning

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What is the ClearTrial Cost Model?

- The cost model is the combination of algorithms, default assumption values, task and cost definitions, and resources that are used to create cost and fee estimates for a plan.
- When ClearTrial releases a new version, the cost model is updated to reflect changes in the industry standards.
- The cost model does NOT include billing and inflation rates. If you want your plan to continue to use the billing and inflation rates which were used when the plan was created, you must FREEZE your rates.

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Why did we create multiple ClearTrial Cost Models?

- Our best practice recommendation has always been to lock plans prior to a release to ensure the plans you created in prior versions are not updated to reflect the newest cost model. This practice allowed you to preserve static versions of your plans.
- However, this practice did not allow you to continue to update your plans using the cost model which was in place when the plan was created. As soon as you unlocked your plan, the cost model was automatically changed to the current model and your plan values immediately and permanently reflected the most recent cost model.
- ClearTrial has created this new and valuable feature to allow you to negotiate and adjust your budgets over time without being concerned about potential impacts from a ClearTrial release.

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Cost Model Versioning

- ClearTrial's new feature, Cost Model Versioning, allows you to make changes to a plan with the assurance that all the calculations will work just as they did in the version in which the plan was created.
- For example…
  - After 5.4 is released, a plan created in ClearTrial version 5.3 will continue to calculate using the algorithms, default assumption values, task and cost definitions, and resources that were available in 5.3.
  - You can choose to update a plan from the cost model version in which it was created to a previous or subsequent version at any time. (See *Exception for Older Plans* on next slide)

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Exception for older plans

- ClearTrial cost model calculators prior to 5.3 no longer exist and plans can not be calculated or updated using these models.

Any locked plan created in version 5.2 or earlier should **NOT** be unlocked unless you are prepared to accept the changes which will occur as that plan adjusts to the oldest preserved cost model, version 5.3.

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Exception for older plans *cont'd*

- If you are considering updating a locked plan created in version 5.2 or earlier, ClearTrial's recommended best practice is to:
  - copy the locked plan
  - update the copy to version 5.3 or later (the earliest version you can select will be 5.3)
  - compare the updated copy to the original locked version.
- If you do not like the resulting changes, you can simply delete the updated copy and return to your locked version.

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Impacts of Unlocking Plans

If I unlock a plan from version….	The plan will…	I can choose to….	If I don't unlock it, the plan will….
5.2 or earlier	Automatically update to 5.3 cost model	Update the plan to a cost model version of 5.4 or later	Retain its static, existing value
5.3 or later	Remain in the cost model version in which it was created	Add/Edit assumptions and defaults with the understanding the cost model will calculate a new value based on the cost model version in which the plan was last saved OR Update the plan to a cost model version of 5.3 or later	Retain its static, existing value

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Updated Best Practices

- Freeze your rates as soon as you are happy with your plan value.
  - Freezing rates for all plans upon creation will keep you from having to revisit all your plans to freeze rates before a release.
- After a ClearTrial release, review all the new changes available and decide if you want to update any existing plans (and templates) to the new 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.

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Important Considerations for Plans Created from Templates

- New plans created from user-defined template with release version 5.3 or prior, will use 5.3 cost model
  - E.g., plan created from 5.3 custom template, will use 5.3 cost model, plan created from 5.0 custom template, will use 5.3 cost model
- New plans created from user-defined template with release version greater than 5.3, will inherit the template's cost model.
  - E.g., plan created from 5.4 custom template will use 5.4 cost model
- New plans created from ClearTrial-defined template will inherit the current release version's cost model
- Copied plans and reforecasts will use the cost model specified in dialog

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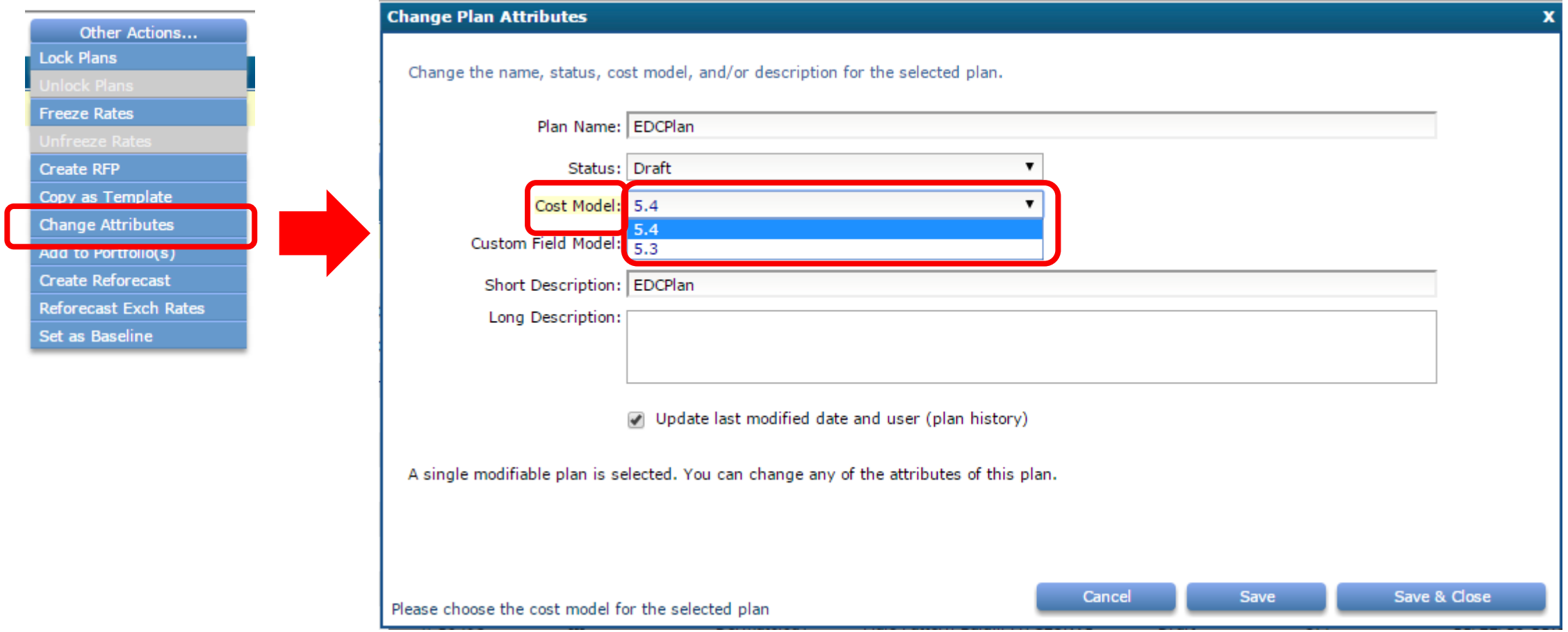
Change Cost Model Version for a Plan



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Bid Grid Versioning

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Bid Grid Versioning

- Oracle ClearTrial 5.4 introduces Bid Grid versioning which preserves the format and metadata of a Bid Grid generated from ClearTrial RFPs even if Bid Grid changes occur in the next ClearTrial release.
- This allows you to continue to produce Bid Grids for negotiations that may span multiple releases with the same format and metadata.

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Bid Comparison Across RFPs

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Bid Comparison Across RFPs

- Prior to the 5.4 release, you could only compare bids that existed within the same RFP.
- With 5.4, you can compare bids from different RFPs
- You may want to compare bids from multiple RFPs to review cost and labor changes resulting from vendor responses based on updated or alternate scenarios.

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Custom Assumptions

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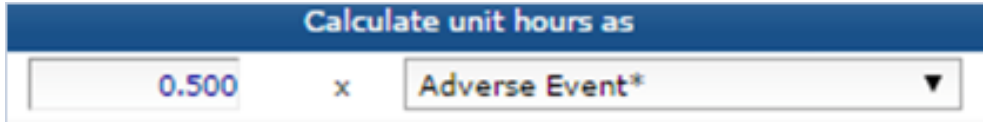
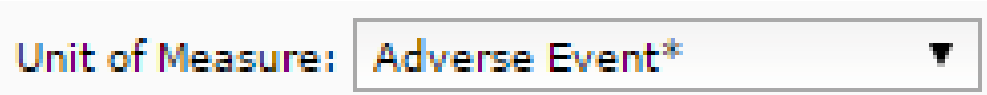
What is a Custom Assumption?

- A user-defined value that can be used in a plan as a **cost driver for a custom Task**



- Or-

- A user-defined value that can be used in a plan as a **unit of measure for a custom Major Task**



➢You can create a custom assumption if ClearTrial does not have a defined assumption that meets your need for calculating a custom task or for use as a unit of measure for billing.

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Custom Assumption Concepts

- There are two concepts related to custom assumptions.
    1. Custom Field: the data field that allows a user to enter a custom assumption value
    2. Custom Assumption: the value of the assumption
- Any user who has permission to edit the value of a ClearTrial default assumption will be able to edit the value of a custom assumption.

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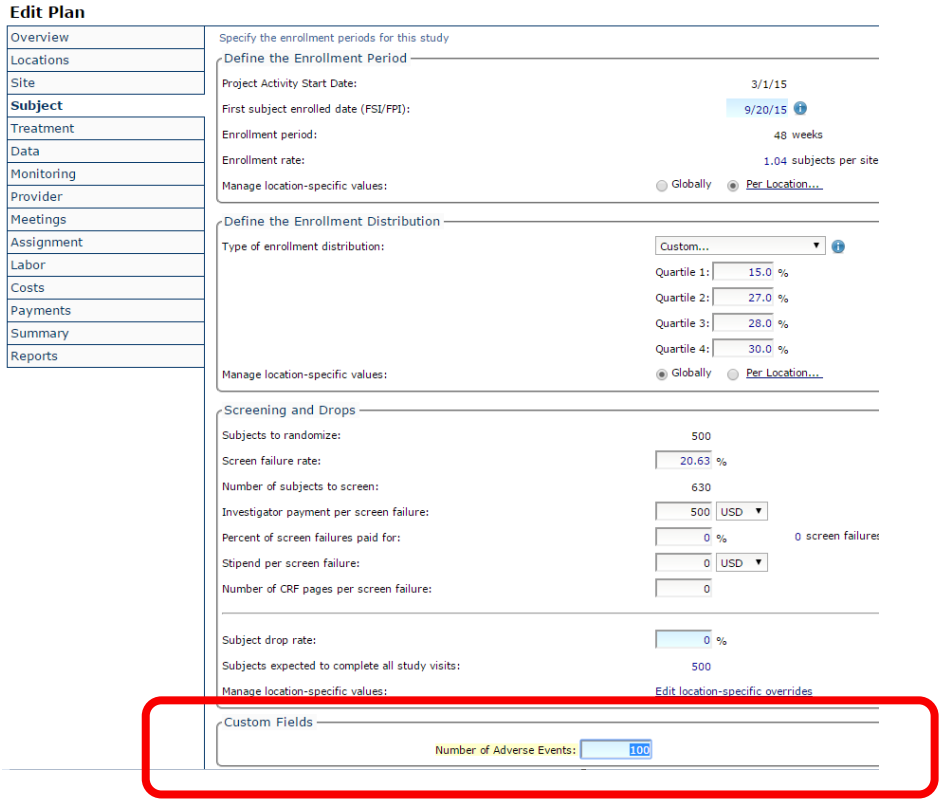
Where can I find custom fields within a plan?

- Custom fields can appear on the following assumption tabs:
  - Overview
  - Site
  - Subject
  - Treatment
  - Data
  - Monitoring



- They will appear in a separate section labeled “Custom Fields” which will appear below the ClearTrial default assumptions

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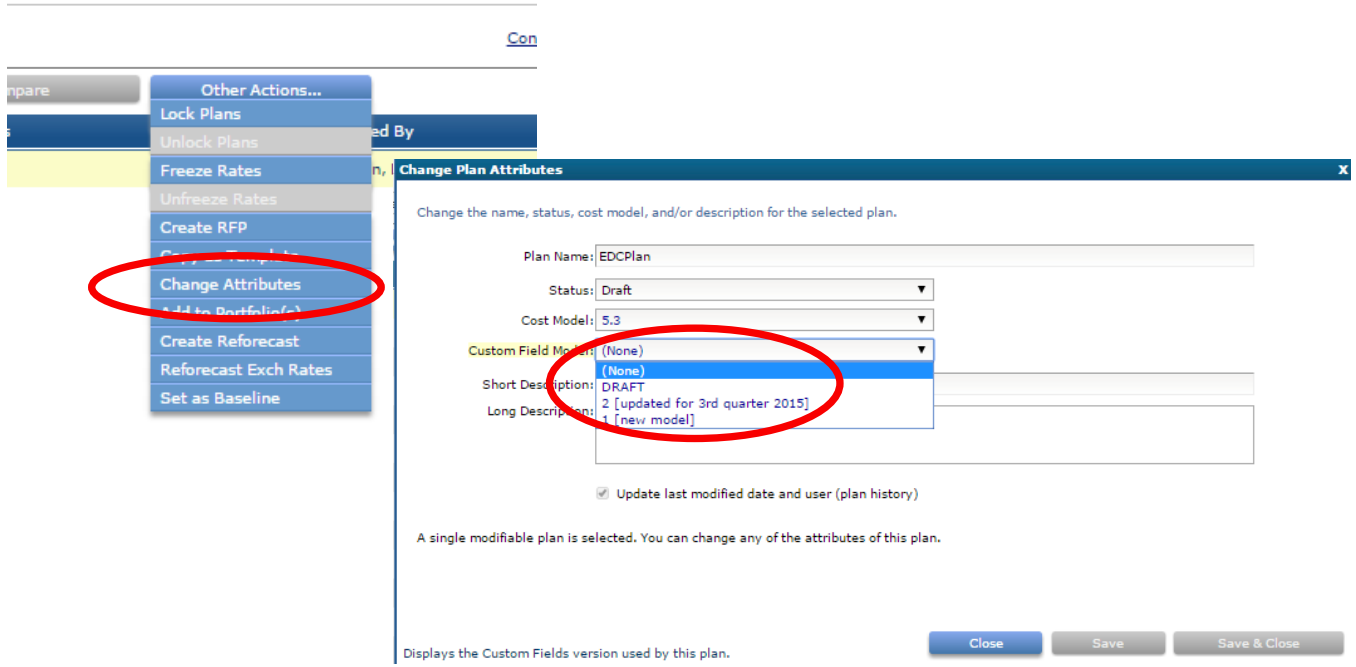
Will I see the same custom fields in every plan?

- Custom fields which are developed and published for use in plans will be grouped and versioned as a Custom Field Model. You can see all the available models for a plan by choosing:
  - Other Actions
  - Change Attributes
  - Custom Field Model



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Will I see the same custom fields in every plan? *cont'd*

- There are two reasons why fields which display in one plan do not display in another:
  - As custom field models are published over time, fields may be added or deleted in each version. For example, a plan which was assigned an older custom field model will not contain fields added in newer model versions.
  - Custom fields have criteria that determine in which type(s) of plans they will display. For example, one field may apply only to Oncology plans whereas another field may apply only to Phase IV plans. These criteria are set by the custom field designer.

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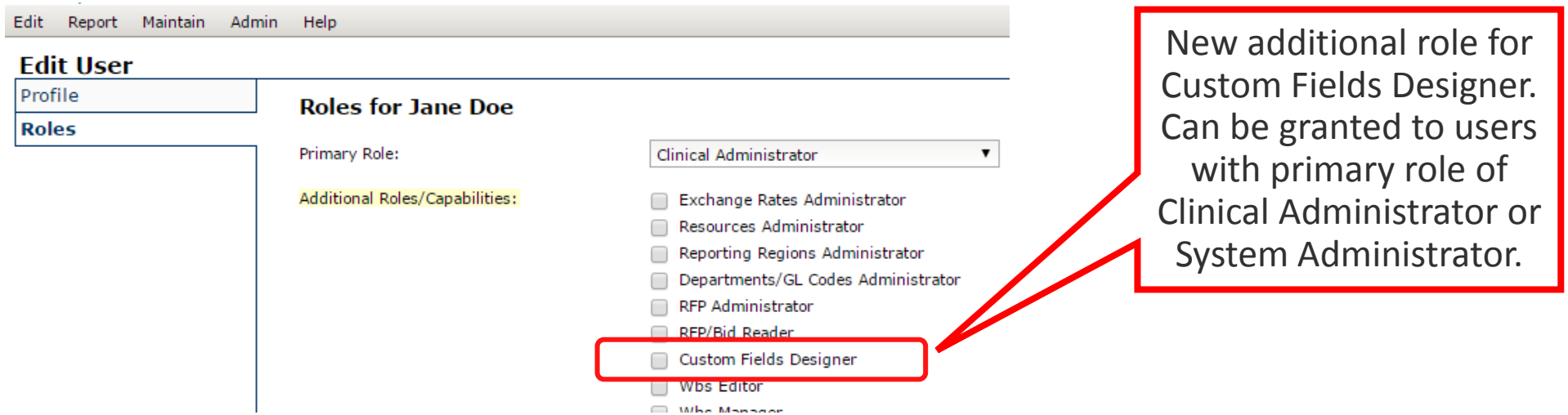
New Additional Role – Custom Field Designer

- Custom fields can only be created by users who have been assigned the role of “Custom Field Designer.” This role is only available to Clinical and System Administrators.
- A training video is available for users who will be designated as custom field designers.



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