

ORACLE®

# Introduction to Oracle ClearTrial Cloud Service 5.4

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

# 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

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

# 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 11<sup>th</sup> – Saturday Dec 12<sup>th</sup>, 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!**

## 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***

# 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

# Enhancements & Features



# Clinical Intelligence Update

# 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

# Composite/CT-Defined Provider Billing Rate Updates

Choose Service Providers

<input type="checkbox"/>	Name ▲	Type	Last Updated	Updated By
<input type="checkbox"/>	Average All CROs	Contract Research Organization	4/4/14 2:56 PM	ClearTrial Administrator
<input type="checkbox"/>	Major CRO	Contract Research Organization	4/4/14 2:56 PM	ClearTrial Administrator
<input type="checkbox"/>	Medium CRO	Contract Research Organization	4/4/14 2:56 PM	ClearTrial Administrator
<input type="checkbox"/>	Niche CRO	Contract Research Organization	4/4/14 2:56 PM	ClearTrial Administrator
<input type="checkbox"/>	Premium CRO	Contract Research Organization	4/4/14 2:56 PM	ClearTrial Administrator

Close Ok



# 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

# 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.

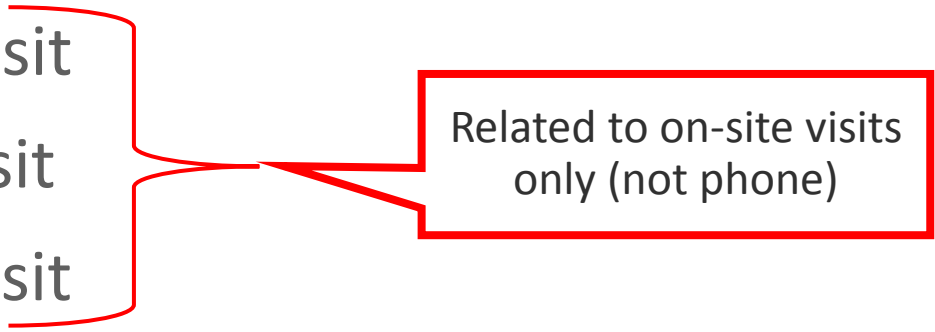
# Additional Units of Measure Available

# 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



Related to on-site visits  
only (not phone)

# Additional Work Units Available

In Task Manager and Cost Algorithm set-up screen

**Define New Category**

Travel - PSSV

Definition Algorithm Distribution

Cost Algorithm

Costs:  vary by location  are study level

Calculate as: 1,500 USD per: Study

Study-Wide Costs/Adjustments

Location	Provider	
Study-Level	ClearTrial Operations	

- Interim Analysis
- Monitoring Visit
- Newsletter
- Pre-study Site Visit
- Protocol Amendment
- Publication
- Query
- Repeat Data Listing
- Repeat Data Table
- Repeat Figure or Graph
- Serious Adverse Event
- Site Audited
- Site Close-out Visit
- Site Initiation Visit
- Site Requiring Overhead
- Subject Complete
- Subject Randomized
- Subject Screened
- Subject Visit
- Translation
- Unique CRF Page

GL Code	Costs
Unmapped	Calculate as: 1,500 USD
	Total: 1,500 USD



# Usability Enhancements

# Sort Plans by Protocol and Product/Compound

New list display options to sort by

[Configure List Options](#)

## Configure List Options



Please select the columns to display in the Plan List. You can also choose how to order the plans displayed and how many plans to display per page.

### Configure Columns

- |  |   |  |  |   |  |
|--|---|--|--|---|--|
| <input checked="" type="checkbox"/> Plan Name  | <input checked="" type="checkbox"/> Study Name  | <input checked="" type="checkbox"/> Product Name | <input checked="" type="checkbox"/> Protocol | <input checked="" type="checkbox"/> Phase   | <input checked="" type="checkbox"/> Therapeutic Area |
| <input checked="" type="checkbox"/> Indication | <input checked="" type="checkbox"/> Description | <input type="checkbox"/> Status                  | <input type="checkbox"/> Cost Model          | <input type="checkbox"/> Custom Field Model | <input type="checkbox"/> Created Date                |
| <input type="checkbox"/> Created By            | <input type="checkbox"/> Last Modified          | <input type="checkbox"/> Last Modified By        |  |   |  |

### Sorting and Paging

Sort By:  and then:  and then:

Show:  plans per page

Reminder to increase this value to show more plans / page

Sort the criteria

Cancel

Ok

# 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.

Edit Report Maintain Admin Help Welcome, Jane Doe | Visit Support

### Edit Plan

Overview	<input type="button" value="Add Location(s)"/>	<input type="button" value="Remove Location(s)"/>	<input type="button" value="Add Language(s)"/>	<input type="button" value="Remove Language(s)"/>		
<b>Locations</b>	<input checked="" type="checkbox"/>					
Site	<input checked="" type="checkbox"/>	Location	Number of Sites	Subjects to Randomize	Avg Grant Amount	MOH/FDA Delay
Subject	<input checked="" type="checkbox"/>	Armenia	10	100	8,200 USD ▼	120
Treatment	<input checked="" type="checkbox"/>	Australia	10	100	8,200 USD ▼	70
Data	<input checked="" type="checkbox"/>	Belgium	10	100	8,200 USD ▼	56
Monitoring	<input checked="" type="checkbox"/>	Canada	10	100	8,200 USD ▼	120
Provider	<input checked="" type="checkbox"/>	El Salvador	10	100	8,200 USD ▼	120

# 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.

<input checked="" type="checkbox"/>	Language	Dialects/Variations	Document Translations		
<input checked="" type="checkbox"/>	French	<input type="text" value="1"/>	<input type="radio"/> All Documents	<input type="radio"/> No Documents	<input checked="" type="radio"/> <a href="#">Specified Documents</a>
<input checked="" type="checkbox"/>	German	<input type="text" value="1"/>	<input type="radio"/> All Documents	<input type="radio"/> No Documents	<input checked="" type="radio"/> <a href="#">Specified Documents</a>
<input checked="" type="checkbox"/>	Spanish	<input type="text" value="1"/>	<input type="radio"/> All Documents	<input type="radio"/> No Documents	<input checked="" type="radio"/> <a href="#">Specified Documents</a>

# 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.

Edit Report Maintain Admin Help Welcome, Jane Doe

### Edit Plan

Overview	<input type="checkbox"/>	<a href="#">Add Provider(s)</a>	<a href="#">Remove Provider(s)</a>	<a href="#">Set as Primary Provider</a>	<a href="#">Replace Provider</a>	<a href="#">Freeze Rates</a>
Locations	<input checked="" type="checkbox"/>	<b>Provider Name</b>	<b>Provider Type</b>	<b>Rate Year in Effect</b>	<b>Back-Office Billing Rate Location</b>	
Site		<a href="#">ClearTrial Operations</a>	Sponsor	2015	USA	
Subject	<input checked="" type="checkbox"/>	<a href="#">Vendor1**</a>	Contract Research Organization	2015	USA	
Treatment	<input checked="" type="checkbox"/>	<a href="#">Vendor2</a>	Contract Research Organization	2015	USA	
Data	<input checked="" type="checkbox"/>	<a href="#">Vendor3</a>	Contract Research Organization	2015	USA	
Monitoring						
<b>Provider</b>						

# Select All Option for Meetings

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

Edit Report Maintain Admin Help Welcome, Jane Doe | Vi

### Edit Plan

Configure meetings for this study Current t

Meetings

Add Edit Copy Include Exclude Delete

<input checked="" type="checkbox"/>	Name	Type	Location	Occurs	Planner
<input checked="" type="checkbox"/>	Kickoff Meeting	Kickoff	USA	Once	ClearTrial Operations
<input checked="" type="checkbox"/>	Investigator Meeting	Investigator	USA	Once	ClearTrial Operations
<input checked="" type="checkbox"/>	Face to Face Meeting	Face to Face	USA	Once	Major CRO
<input checked="" type="checkbox"/>	Status Update to Sponsor	Teleconference	USA	Weekly	Major CRO
<input checked="" type="checkbox"/>	Internal Team Meeting	Internal Team	USA	Weekly	Major CRO

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

# Line-Item Discounts

# 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.



# Enter Line-Item Discount at the Plan Provider Level

Edit Report Maintain

## Edit Plan

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

### Specify Provider-Specific Details

Details Inflation

Override default rates and responsibilities for this service provider

#### Major CRO

##### Billing Rate Information

Rate Year in effect:	2015 ▼	Discount rate to apply to this study:	0 %
Back-Office Billing Rate Location:	USA ▼	<b>Line-Item Discount:</b>	<b>50,000.00 USD ▼</b>
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...		

# Line-Item Discount Displayed on Plan Summary Tab

Edit Report Maintain Admin Help

## Edit Plan

Overview	Included Providers <a href="#">?</a>
Locations	<input type="checkbox"/> TAG <input checked="" type="checkbox"/> Major CRO
Site	
Subject	
Treatment	
Data	
Monitoring	
Provider	
Meetings	
Assignment	
Labor	
Costs	
Payments	
<b>Summary</b>	
Reports	

**Included Providers** [?](#)

TAG  Major CRO

**Fees, Hours, and FTEs**

All fees and indirect costs are displayed in US Dollar (USD)

	Fees	Hours	FTEs
Startup Fees:	1,021,120	6222.7	4.7
Clinical Monitoring Closeout and Site Audit Fees:	7,498,064	42373.2	10.8
Data Management:	167,965	5821.6	1.3
Biostatistics:	880,775	3699.3	0.9
Project Management / Study Oversight:	1,999,538	10469.1	2.4
Medical Writing / Final Report:	140,728	682.0	0.4
Other:	0	0.0	0.0
<b>Total Fees without inflation or discount:</b>	<b>11,708,190</b>	<b>69267.9</b>	
Inflation (Fees):	268,352		
Line-Item Discounts:	(50,000)		
<b>Total Fees:</b>	<b>11,918,542</b>		
<b>Total Pass-Through Costs:</b>	<b>6,463,911</b>		
Inflation (Pass-Through Costs):	153,973		
<b>Total Study Costs: (including inflation and discount)</b>	<b>18,536,425</b>		

# Line-Item Discounts Accessible in Reports

## Metrics

### Calculation Options

Choose whether to include inflation in calculations and whether to consider any line-item discounts

Include Inflation

Consider Line-Item Discount

### Reporting Currency

Select the currency in which this report should be rendered.

US Dollar (USD) ▼

Round values to the nearest US Dollar

# Increased Transparency for Meetings Labor

# 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.

# 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.

# 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

The screenshot shows the Oracle Task Manager interface for version 5.3. On the left, a tree view lists various tasks, with 'Meetings - CRA meeting - training' selected and expanded to show sub-tasks: 'CRA meeting - training - TAG Vendor' (with a sub-task 'CR01 - Clinical Research Associate') and 'CRA meeting - training - Sponsor'. A red box highlights the 'CRA meeting - training - TAG Vendor' task. The main panel displays the 'Major Task Details' for the selected task, showing fields for Name, Description, and Labor. A red box highlights the 'CRA meeting - training - TAG Vendor' task name in the 'Task Name' list at the bottom.

In a 5.4 Plan

The screenshot shows the Oracle Task Manager interface for version 5.4. The task hierarchy on the left is similar to 5.3, but the 'CRA meeting - training - TAG Vendor' task is expanded to show two sub-tasks: 'CRA meeting - training: TAG Vendor - CR01 (US)' and 'CRA meeting - training: TAG Vendor - CR01 (GB)'. A red box highlights these two sub-tasks. The main panel displays the 'Major Task Details' for the selected task, showing fields for Name, Description, and Labor. A red box highlights the 'CRA meeting - training: TAG Vendor - CR01 (US)' task name in the 'Task Name' list at the bottom.

# 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
<b>Meetings - CRA meeting - training</b>				
CR01 - Clinical Research Associate	34.000		34.000	5,010
<b>Total:</b>	<b>34.000</b>	<b>1 Meetings</b>	<b>34.000</b>	<b>5,010</b>

## 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
<b>Meetings - CRA meeting - training</b>				
CR01 - Clinical Research Associate	22.000		22.000	3,014
<b>Total:</b>	<b>22.000</b>	<b>1 Meetings</b>	<b>22.000</b>	<b>3,014</b>

Billing Rate Location: USA

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



# Metrics Updates to Include Inflation

# 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

# 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.

## Metrics

### Calculation Options

Choose whether to include inflation in calculations and whether to consider any line-item discounts

Include Inflation

Consider Line-Item Discount

### Reporting Currency

Select the currency in which this report should be rendered.

US Dollar (USD) ▼

Round values to the nearest US Dollar

# Cost Model Versioning



# 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.

# 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.

# 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)

# 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.



## 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.

# 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

# Updated **Best Practices**

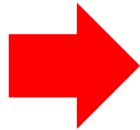
- Freeze your rates as soon as you are happy with your plan value.
  - Freezing rates for all plans upon creation will keep you from having to revisit all your plans to freeze rates before a release.
- After a ClearTrial release, review all the new changes available and decide if you want to update any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

# 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

# Change Cost Model Version for a Plan

- Other Actions...
- Lock Plans
- Unlock Plans
- Freeze Rates
- Unfreeze Rates
- Create RFP
- Copy as Template
- Change Attributes
- Add to Portfolio(s)
- Create Reforecast
- Reforecast Exch Rates
- Set as Baseline



**Change Plan Attributes** [X]

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

Plan Name: EDCPlan

Status: Draft

Cost Model: 5.4

Custom Field Model: 5.3

Short Description: EDCPlan

Long Description:

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 selected plan

Cancel Save Save & Close



# Bid Grid Versioning

**Enterprise Edition Only**

# 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.

# Bid Comparison Across RFPs

**Enterprise Edition Only**



# 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.

# Custom Assumptions

**Enterprise Edition Only**

# 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**

Calculate unit hours as

<input type="text" value="0.500"/>	x	<input type="text" value="Adverse Event*"/>
------------------------------------	---	---

Unit of Measure:

- 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.

# 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.

# Where can I find custom fields within a plan?

- Custom fields can appear on the following assumption tabs:

- Overview
- Site
- Subject
- Treatment
- Data
- Monitoring

The screenshot shows the 'Edit Plan' interface with a sidebar on the left containing tabs: Overview, Locations, Site, Subject, Treatment, Data, Monitoring, Provider, Meetings, Assignment, Labor, Costs, Payments, Summary, and Reports. The 'Subject' tab is selected. The main content area is divided into sections: 'Specify the enrollment periods for this study' (with 'Define the Enrollment Period' sub-section), 'Define the Enrollment Distribution', and 'Screening and Drops'. The 'Custom Fields' section at the bottom is highlighted with a red box and contains a field for 'Number of Adverse Events' with a value of 100.

Section	Field	Value
Specify the enrollment periods for this study	Project Activity Start Date	3/1/15
	First subject enrolled date (FSI/FP1)	9/20/15
	Enrollment period	48 weeks
	Enrollment rate	1.04 subjects per site
Define the Enrollment Distribution	Type of enrollment distribution	Custom...
	Quartile 1	15.0 %
	Quartile 2	27.0 %
	Quartile 3	28.0 %
Screening and Drops	Subjects to randomize	500
	Screen failure rate	20.63 %
	Number of subjects to screen	630
	Investigator payment per screen failure	500 USD
	Percent of screen failures paid for	0 % (0 screen failures)
	Stipend per screen failure	0 USD
	Number of CRF pages per screen failure	0
Subject drop rate	0 %	
Subjects expected to complete all study visits	500	
Custom Fields	Number of Adverse Events	100

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

# 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

The screenshot shows the 'Change Plan Attributes' dialog box. The 'Change Attributes' menu item is circled in red. The dialog box contains the following fields and options:

- Plan Name: EDCPlan
- Status: Draft
- Cost Model: 5.3
- Custom Field Model: (None)
- Short Description: DRAFT
- Long Description: 2 [updated for 3rd quarter 2015]

The Custom Field Model dropdown is also circled in red, showing a list of models including '(None)', '2 [updated for 3rd quarter 2015]', and '1 [new model]'. The dialog includes a checkbox for 'Update last modified date and user (plan history)' and buttons for 'Close', 'Save', and 'Save & Close'.

# 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.

# 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.

Edit Report Maintain Admin Help

## Edit User

Profile

Roles

### Roles for Jane Doe

Primary Role: Clinical Administrator

Additional Roles/Capabilities:

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

New additional role for Custom Fields Designer. Can be granted to users with primary role of Clinical Administrator or System Administrator.



# **Hardware and Software Engineered to Work Together**

ORACLE®