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# Introduction to Oracle ClearTrial 5.3

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# Safe Harbor Statement

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# Agenda

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

# ClearTrial 5.3 Release Overview

- Release Objectives:
  - Enhance Oracle ClearTrial Plan and Source to provide greater flexibility and configurability
  - 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: **Saturday, February 28<sup>th</sup> 2015 from 8am to 1pm CST**
- Lock Plans/Freeze Billing Rates:
  - ClearTrial **5.3 DOES** include changes to the software's tasks and algorithms, MOH Delay defaults, and composite billing rates



**Locking of plans and freezing billing rates is a recommended ClearTrial release best practice!**

## 5.3 Features and Functionality Edition Impact

Feature	Standard Edition	Enterprise Edition
Clinical Intelligence Update	X	X
New Assumptions/Specifications and Cost Drivers	X	X
User Configurable List Screen Views	X	X
Enhanced Meetings Labor Units Calculation	X	X
Increased Precision for Hours and Costs	X	X
Inflation Rates by Location and by Year	X	X
New Additional Roles/Capabilities		X
RFPs and Bids Data Capture, Comparisons & Reporting		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 2015 to 2028 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

Name ▲

Average All CROs

Major CRO

Medium CRO

Niche CRO

Premium CRO

Type

Contract Research Organization

Contract Research Organization

Contract Research Organization

Contract Research Organization

Contract Research Organization

Last Updated

4/4/14 2:56 PM

4/4/14 2:56 PM

4/4/14 2:56 PM

4/4/14 2:56 PM

4/4/14 2:56 PM

Updated By

ClearTrial Administrator

ClearTrial Administrator

ClearTrial Administrator

ClearTrial Administrator

ClearTrial Administrator

Close

Ok

<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

# Composite Billing Rate Updates

## Important Migration Consideration

- When rates are not frozen in existing plans, unlocked plans or copies of plans will inherit new 5.3 billing rates.



If you have added any of the ClearTrial-defined Composite Providers in any of your existing, unlocked plans, and do want those 5.2 or earlier rates to change, don't forget to **freeze your billing rates** prior to the release.

# MOH / FDA Delay Default Updates

- MOH/FDA Delay defaults by location updated to reflect the latest industry observed Clinical Trial Application and Ethics Committee expected authority review times
- A list of 5.3 values as compared to 5.2 values can be found on the Plan Locations tab when clicking on the Add Location button.

Region	Country	Primary Language	Primary Currency	MOH/FDA Delay
<input type="checkbox"/> USA, Canada, Australia/New Zealand				120
<input type="checkbox"/>	Australia	English	Australian Dollar	70
<input type="checkbox"/>	Canada	English	Canadian Dollar	120
<input type="checkbox"/>	New Zealand	English	New Zealand Dollar	60
<input type="checkbox"/>	Puerto Rico	Spanish	US Dollar	120
<input type="checkbox"/>	USA	English	US Dollar	30
<input type="checkbox"/> Western Europe & Japan				180
<input type="checkbox"/>	Austria	German	Euro	95
<input type="checkbox"/>	Belgium	Flemish	Euro	56
<input type="checkbox"/>	France	French	Euro	95
<input type="checkbox"/>	Germany	German	Euro	90

# 5.3 Updated MOH Delay Defaults By Location

Location	5.2	5.3
Middle East	200	252
Portugal	120	60
Malaysia	120	168
Saudi Arabia	200	252

# MOH / FDA Delay Default Updates

## Important Migration Considerations

- Values by location in existing plans are not affected by the upgrade and will retain the values as they were in 5.2, regardless of whether they contain “overrides” to default values
- Locations which are deleted and subsequently re-added to an existing plan will reflect the new 5.3 default value
- New locations added to an existing plan will reflect the new 5.3 default value

# New Assumptions and Algorithms

# Updated Plan Default Data Collection Method

## Create Plan

Overview
Locations
Site
Subject
Treatment
<b>Data</b>
Monitoring
Provider
Meetings
Assignment
Labor
Costs
Payments
Summary
Reports

Specify information about the data collected for this study

Current Edit Mode: **Advanced** ▼

### Data Collection

Data Collection Method: **Electronic Data Capture** ▼

EDC Maturity Level: **Stage 3: Standardization** ▼

Query Rate: **15** %

Percent of database data to audit: **10** %

Minutes for Data Entry per CRF page: **0.0**

Minutes for Data Coordination per CRF page: **1.0**

Total number of data transfers: **0**

Number of interim analyses to be performed: **0**

Number of third-party vendors/data sources: **0**

Total number of data imports from third-party vendors: **0**

### CRF Design

Number of Unique Pages: **2**

Number of screens per CRF page: **3.0**

### Biostatistics

Number of Unique Data Tables: **3**

Number of Repeat Data Tables: **6**

Number of Unique Data Listings: **3**

Number of Repeat Data Listings: **3**

Number of Unique Figures and Graphs: **2**

Number of Repeat Figures and Graphs: **1**

EDC Stage 3 is the default for all new plans



# New Configurable Assumption for Monitoring Minutes per CRF Page per Treatment Arm

Edit Treatment A

Treatment A

Details

Schedule

Notes

Subject Treatment Schedule

Monitoring minutes per CRF page: 8.994

Use example grant amount: ☐ Yes ☒ No

Week	Number of CRF Pages	Monitoring Time (minutes)	Percent of Grant
Baseline Visit		87.98	50 %
1	1	8.99	5.56 %
2	1	8.99	5.56 %
3	1	8.99	5.56 %
4	1	8.99	5.56 %
5	5		27.78 %

Total number of CRF pages: 18

Total visits per subject: 6

Total: 100 %

Displaying weeks 1 to 5 of 5

[Clear CRF Defaults](#) | [Restore CRF Defaults](#) | [Clear Grant Overrides](#)

Per Treatment Arm, 5.3 exposes the ClearTrial default value based on our clinical intelligence. This value can now be overwritten.

# New Assumptions for Number of Repeat Data TLGs

## Create Plan

Notes

Overview
Locations
Site
Subject
Treatment
<b>Data</b>
Monitoring
Provider
Meetings
Assignment
Labor
Costs
Payments
Summary
Reports

Specify information about the data collected for this study

Current Edit Mode: **Advanced** ▼

### Data Collection

Data Collection Method: **Electronic Data Capture** ▼

EDC Maturity Level: **Stage 3: Standardization** ▼

Query Rate:  %

Percent of database data to audit:  %

Minutes for Data Entry per CRF page:

Minutes for Data Coordination per CRF page:

Total number of data transfers:

Number of interim analyses to be performed:

Number of third-party vendors/data sources:

Total number of data imports from third-party vendors:

### CRF Design

Number of Unique Pages:

Number of screens per CRF page:

### Biostatistics

Number of Unique Data Tables:

Number of Repeat Data Tables:

Number of Unique Data Listings:

Number of Repeat Data Listings:

Number of Unique Figures and Graphs:

Number of Repeat Figures and Graphs:

# New Algorithms for Unique and Repeat TLGs

[Edit](#) [Report](#) [Maintain](#) [Admin](#) [Help](#)

Welcome, Auto Administrator | [Visit Support Center](#) | [Logout](#)

## Edit Plan

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

View or adjust effort and labor fees

Current Edit Mode: Advanced

**Filter**  
Show hours and fees for: Major CRO ☒ Show major tasks with no planned effort for the selected provider

[New Major Task](#) [Edit Major Task](#) [Delete Major Task](#) [Adjust Hours or Fees](#)

All calculated costs and adjustments are displayed in US Dollar (USD)  
values displayed do not include inflation  
[Pin Labor](#) | [Unpin Labor](#)

Major Task	Unit Hours	Unit Cost	# Units	Est Hours	Est Cost
<input type="radio"/> Data Transfer (Data Transfers)	0.000	0.00	0	0.000	0.00
<input type="radio"/> Final Data Audit (Data Audit)	0.017	2.32	5,393	91.681	12,511.76
<input type="radio"/> Issued Unique Summary Table (Biostatistics - Issue Tables)	14.060	1,995.95	13	182.780	25,947.35
<input type="radio"/> Issued Unique Summary Listing (Biostatistics - Issue Listings)	9.036	1,272.62	15	135.540	19,089.30
<input type="radio"/> Issued Unique Summary Figure/Graph (Biostatistics - Issue Graphs)	14.060	1,995.95	8	112.480	15,967.60
<input type="radio"/> Issued Repeat Summary Table (Issued Repeat Summary Tables)	5.018	707.62	26	130.468	18,398.12
<input type="radio"/> Issued Repeat Summary Listing (Issued Repeat Summary Listings)	3.512	490.19	15	52.680	7,352.85
<input type="radio"/> Issued Repeat Summary Figure/Graph (Issued Repeat Summary Figure/Graphs)	5.018	707.62	4	20.072	2,830.48
<input type="radio"/> Stat Report (Medical Writing - Stat Report)	50.626	7,941.15	1	50.626	7,941.15
<input type="radio"/> Draft Report (Medical Writing - Draft CSR)	244.859	40,999.92	1	244.859	40,999.92
<input type="radio"/> Final Report (CSR) (Medical Writing - Final CSR)	121.254	21,266.46	1	121.254	21,266.46
<b>Total:</b>				103,436.691	15,672,241.05

[Close](#) [Save](#) [Next](#)

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# Number of Uniques & Repeats TLGs Relationship

## Important Migration Considerations

- In 5.2,

ClearTrial calculated and provided defaults for the Number of Unique TLGs. In that algorithm/calculation, the Number of Repeats was assumed to be 2 repeats per unique.

- After migration to 5.3,

The number of unique TLGs will remain the same but the number of repeat TLGs will be based on our new default values. Both tasks will be based on updated algorithms which will most likely result in higher costs per deliverable.

- If you want to:

- preserve your prior costs, you should lock your plan.
- calculate costs based on the new algorithm but preserve your number of repeat units, you can simply overwrite the new default values for repeats with 2x the number of unique units.

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



# Enhanced Meetings Labor Representation and Units Calculation

**Create Plan**

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

Configure meetings for this study

Meetings

Add Edit Compare Import Delete

	Name	Type	Location	Occurs	Planner
<input type="checkbox"/>	Kickoff Meeting	Kickoff	USA	Once	CT Product Review
<input type="checkbox"/>	Kickoff Meeting for EU	Kickoff	Nordic Countries	Once	CT Product Review
<input type="checkbox"/>	Investigator Meeting	Investigator	USA	Once	Major CRO
<input type="checkbox"/>	Face to Face Meeting	Face to Face	USA	Once	Major CRO
<input type="checkbox"/>	Status Update to Sponsor	Teleconference	USA	Weekly	Major CRO
<input type="checkbox"/>	Internal Team Meeting	Internal Team	USA	Weekly	Major CRO

Current Edit Mode: Advanced

Notes

Created another Kickoff Meeting on Meetings tab

In version 5.2, some values from the Meetings Manager tab were averaged in order to merge multiple meetings of the same type into one Major Task.

Version 5.3 creates transparency by creating each meeting as its own Major Task and keeping the underlying assumptions from the Meetings Manager tab intact as calculations are performed in the Labor Tab and in reports.

# Enhanced Meetings Labor Representation and Units Calculation: Labor Tab

## Create Plan

Overview
Locations
Site
Subject
Treatment
Data
Monitoring
Provider
Meetings
Assignment
<b>Labor</b>
Costs
Payments
Summary

View or adjust effort and

Filter

Show hours and fees for:

New Major Task

All calculated costs and adj

5.3 will dynamically include one Major Task, per meeting type, by default.

Major Task

Current Edit Mode: Advanced

☒ Show major tasks with no planned effort for the selected provider

Adjust Hours or Fees

values displayed do not include inflation

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

Major Task	Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
<input type="radio"/> Protocol Amendment per L (Amendments)	0.000	0.00	0	0.000	0.00
<input type="radio"/> Unique CRF Page Devel (CRF Development)	14.750	3,358.59	2	29.500	6,717.18
<input type="radio"/> CRF Book Printed (CRF Printing)	0.000	0.00	0	0.000	0.00
<input type="radio"/> Meetings - Kickoff Meeting (Kickoff Meetings)	81.000	20,459.40	1	81.000	20,459.40
<input checked="" type="radio"/> Meetings - Kickoff Meeting for EU (Kickoff Meetings)	121.000	30,606.20	1	121.000	30,606.20

# Meetings Unit Calculations and Report Display

## Fixed Unit Prices

1979-CL-0422-20150211 for Protocol Amendment - Ph3  
Phase III / Protocol ID: PA1234  
Indication: Oncology / Breast Cancer

Report generated on: 18-Feb-2015

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 17-Feb-2015.

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

### Provider: CT Product Review

Major Task Name		Unit Hours	Unit Cost	# Units	Ext H	Ext Cost
Project Initiated	(Project Initiation)	131.201	13,382.49	1	131.201	13,382
Study Setup	(Study Setup - Centralized tasks)	315.998	32,231.82	1	315.998	32,232
Study Setup Per-Location	(Study Setup - De-centralized tasks)	53.749	5,482.41	1	53.749	5,482
A Written Protocol	(Protocol Preparation)	389.334	39,712.06	1	389.334	39,712
Meetings - Kickoff Meeting	(Kickoff Meetings)	49.500	5,049.00	1	49.500	5,049
Meetings - Kickoff Meeting for EU	(Kickoff Meetings)	169.500	17,289.00	1	169.500	17,289
Meetings - Investigator Meeting	(Investigator Meetings)	139.500	14,229.00	1	139.500	14,229
Meetings - Face to Face Meeting	(Face to Face Meetings)	35.500	3,621.00	1	35.500	3,621
Meetings - Status Update to Sponsor	(Teleconference Meetings)	3.500	357.00	61	213.500	21,777
Site Approved	(Site Approval)	5.667	578.03	5	28.335	2,890
Sponsor Oversight	(Vendor Oversight by Sponsor)	2330.498	237,710.72	1	2330.498	237,711
				<b>Total:</b>	<b>3856.615</b>	<b>393,375</b>

In 5.3, the units are split out for multiple meetings of the same type for those providers attending



# Usability Enhancements

# Configurable List Views

Located in Filter Section of each ClearTrial List Screen  
(Plans, Studies, Products, etc.)

## Plans

### Filter

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

[Configure List Options](#)

New


Edit

Delete

Restore

Copy

[Click here to change the columns displayed and how to sort the items in the list](#)

	Plan Name	Study Name	Description	Status	Created By
<input type="checkbox"/>	1979-CL-0422-20150211	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/> 	1979-CL-0422-20150211_FINAL	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v1	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v2	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v3	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v4	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v5	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla
<input type="checkbox"/>	1979-CL-0422-20150211_v6	Protocol Amendment - Ph3	US Study	Draft	Badakhshanian, Leyla

# Configure List Options Dialog

Ability to select the data (columns) you want displayed on a List Screen

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

☒ Plan Name

☒ Study Name

☐ Phase

☐ Therapeutic Area

☒ Indication

☒ Description

☒ Status

☐ Created Date

☒ Created By

☐ Last Modified

☐ Last Modified By

Sorting and Paging

Sort By: Plan Name and then: Plan Name and then: Plan Name

Show: 100 plans per page

Cancel

Ok

# Increased Precision for Hours and Costs

## Edit Plan

Overview
Locations
Site
Subject
Treatment
Data
Monitoring
Provider
Meetings
Assignment
<b>Labor</b>
Costs
Payments
Summary
Reports

View or add

Filter

Show hours

New

All calculated

All monetary values, such as unit cost, extended cost, and billing rates, will be rounded to the number of decimals that is standard for the relevant cost currency.

All hours will be represented to the thousandths

Major Task	Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
○ Issued Unique Summary Figure/Graph (Biostatistics - Issue Graphs)	16.125	3,853.44	2	32.250	7,706.88
○ Issued Repeat Summary Table (Issued Repeat Summary Tables)	5.638	1,333.28	6	33.828	7,999.68
○ Issued Repeat Summary Listing (Issued Repeat Summary Listings)	3.925	916.10	3	11.775	2,748.30
○ Issued Repeat Summary Figure/Graph (Issued Repeat Summary Figure/Graphs)	5.638	1,333.28	1	5.638	1,333.28
○ Stat Report (Medical Writing - Stat Report)	69.278	15,853.89	1	69.278	15,853.89
○ Draft Report (Medical Writing - Draft CSR)	340.210	76,850.36	1	340.210	76,850.36
○ Final Report (CSR) (Medical Writing - Final CSR)	155.729	34,264.84	1	155.729	34,264.84
○ Prepared Publication (Publications)	0.000	0.00	0	0.000	0.00
<b>Total:</b>				17,248.464	3,369,819.70

Notes

Current Edit Mode: Expert

☒ Show major tasks with no planned effort for the selected

Adjust Hours or Fees

values displayed do not include inflation

Pin Labor | Unpin Labor

# Increased Precision for Effective Reporting

## Fixed Unit Prices

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

### Providers To Include

- ☒ All Providers
- ☒ CT Product Review
- ☒ Major CRO

### Level of Detail to Include

- ☒ Summary ☐ Detail
- ☒ Include Inflation

### Group By

- ☐ Location

### Reporting Currency

Select the currency in which this report should be rendered

US Dollar (USD)

☒ Round values to the nearest US Dollar

New report filter option to round values to the nearest [user-selected reporting currency from dropdown]. In this example, USD is the reporting currency. Rounding of costs for reports will be selected by default.

Close

Ok

# All 5.3 reports will display the new conventions for precision

## Example: 5.3 Fixed Unit Price Report

### Fixed Unit Prices

1979-CL-0422-20150211\_v3 for Protocol Amendment - Ph3  
Phase III / Protocol ID: PA1234  
Indication: Oncology / Breast Cancer

Report generated on: 18-Feb-2015

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 17-Feb-2015.

#### Provider: CT Product Review

Major Task Name		Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
Project Initiated	(Project Initiation)	131.201	13,382.49	1	131.201	13,382.49
Study Setup	(Study Setup - Centralized tasks)	315.998	32,231.82	1	315.998	32,231.82
Study Setup Per-Location	(Study Setup - De-centralized tasks)	53.749	5,482.41	1	53.749	5,482.41
A Written Protocol	(Protocol Preparation)	389.334	39,712.06	1	389.334	39,712.06
Meetings - Kickoff Meeting	(Kickoff Meetings)	49.500	5,049.00	1	49.500	5,049.00
Meetings - Kickoff Meeting for EU	(Kickoff Meetings)	169.500	17,289.00	1	169.500	17,289.00
Meetings - Investigator Meeting	(Investigator Meetings)	139.500	14,229.00	1	139.500	14,229.00
Meetings - Face to Face Meeting	(Face to Face Meetings)	35.500	3,621.00	1	35.500	3,621.00
Meetings - Status Update to Sponsor	(Teleconference Meetings)	3.500	357.00	61	213.500	21,777.00
Site Approved	(Site Approval)	5.667	578.03	5	28.335	2,890.15
Sponsor Oversight	(Vendor Oversight by Sponsor)	2330.498	237,710.72	1	2330.498	237,710.72
				<b>Total:</b>	<b>3856.615</b>	<b>393,374.65</b>

# Inflation Profiles



# Inflation Rates Assumptions Relocation

**Specify Provider-Specific Details**

Override default rates and responsibilities for this service provider

**Average All CROs**

**Billing Rate Information**

Rate Year in effect: 2014

Discount rate to apply to this study: 0 %

Inflation rate to apply to year 2 of study: 0 %

Inflation rate to apply to subsequent years of study: 0 %

Compound inflation annually: ☒ Yes ☐ No

Back-Office Billing Rate Location: USA

Billing Rate Currency: US Dollar (USD)

Currency Exchange Rates: ☒ Use rates defined on the Overview tab

**FTE Utilization Information**

ClearTrial's suggested value for Project Management FTEs is not calculated until after you have assigned all study tasks on the Assignment tab. This suggested number of PMs will also change whenever you modify certain assumptions including the number of sites and locations. You may override the suggested value once it has been calculated. However, it is strongly recommended that you review your value if you change the

Project Manager utilization prior to FSI/FPI: 92.4 % Suggested value is pending

Project Manager utilization after FSI/FPI: 92.4 % Suggested value is pending

Resource Allocation Factor: 80 %

**Other**

Number of sponsor affiliates:

Please enter the rate year in effect for the first year of the study

Close Ok

Year 2 and Subsequent Years inflation rates were found on the Plan Provider-Specific Details screen in version 5.2.

These fields have been replaced with more robust capabilities.



# New Inflation Profiles by Location and Year

- Inflation Profiles can be created in the maintenance menu by provider and reused across multiple plans (similar to Billing Rates). We refer to those profiles as '**plan-neutral.**'
- Inflation Profiles also exist in every plan. We refer to those profiles as '**plan-specific.**'

# New Plan-Specific Inflation Rate Profiles

Details

**Inflation**

Override default rates and responsibilities for this service provider

**XYZ Provider**

**Billing Rate Information**

Rate Year in effect: 2014 ⚠

Discount rate to apply to this study:

Back-Office Billing Rate Location: USA

Billing Rate Currency: US Dollar (USD)

Currency Exchange Rates: ☒ Use rates defined on the

**FTE Utilization Information**

ClearTrial's suggested value for Project Management FTEs is not calculated until after you have as  
This suggested number of PMs will also change whenever you modify certain assumptions includi  
You may override the suggested value once it has been calculated. However, it is strongly recomm

Project Manager utilization prior to FSI/FPI: 92.4 %

Project Manager utilization after FSI/FPI: 92.4 %

Resource Allocation Factor: 80 % ⓘ

**Other**

Number of sponsor affiliates:

Type of reporting to affiliates:

Please enter the rate year in effect for the first year of the study

Details

**Inflation**

**Inflation Rates for XYZ Provider**

Compound inflation annually: ☒ Yes ☐ No

Year	USA, Canada, Australia/New Zealand	Western Europe & Japan	Eastern Europe	Nordic Countries	Latin America	Asia	Middle East	Other	Australia	Canada	New Zealand	Puerto Rico	US/ Aut
REGION:	1	2	3	4	5	6	8	7	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	US/ Aut
2015	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2016	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2017	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2018	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2019	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2020	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2021	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2022	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2023	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2024	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Clear Overrides

Set Inflation to 0%

Close

Ok

In 5.3, there is a new Inflation tab on the Plan Provider-Specific Details screen that offers you the option to model inflation rates by location, by year.



# Plan-Specific Profiles are populated by default

When you select a provider and an effective rate year (ERY) in a Plan, ClearTrial will populate the plan-specific profile based on the following....

Condition	Action	User Options
Plan-neutral profile exists for the Provider for the ERY	Plan-neutral profile is inserted in the plan	Use plan-neutral values Overwrite plan-neutral values to 0% Change selected values as needed
Plan-neutral profile does not exist for the Provider for the ERY	Plan-specific profile is 0%	Insert values as needed
ClearTrial default provider is chosen (e.g. Major CRO)	ClearTrial default inflation profile is inserted in the plan	Use ClearTrial values Overwrite plan-neutral values to 0% Change selected values as needed

# Inflation Rate Profiles

In this example, the ClearTrial default values have been overwritten in the plan.

Specify Provider-Specific Details

Details Inflation

Inflation Rates for Medium CRO

Compound inflation annually: ☒ Yes ☐ No

Year	USA, Canada, Australia/New Zealand	Western Europe & Japan	Eastern Europe	Nordic Countries	Latin America	Middle East	Other	Australia	Canada	New Zealand	Puerto Rico	USA	Austria	Belgium
REGION:	1	2	3	4	5	6	7	8	9	10	11	12	13	14
2019	2.50	1.72	3.56	2.20	6.76	3.24	5.34	6.55	2.46	2.01	2.07	1.24	2.21	1.70
2020	3.00	1.79	3.55	2.22	6.31	3.21	5.31	6.18	2.52	2.02	2.01	1.24	2.12	1.70
2021	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2022	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2023	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2024	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2025	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2026	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2027	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70
2028	3.00	1.84	3.52	2.20	5.97	3.17	5.23	6.03	2.52	2.02	2.01	1.65	1.99	1.70

Clear Overrides Set Inflation to 0%

# Inflation Rate Profiles

In this example, the ClearTrial default values have all been overwritten to 0% using the “Set Inflation to 0%” button in the plan.

Specify Provider-Specific Details

Details

Inflation

Inflation Rates for Medium CRO

Yes

No

Year	USA, Canada, Australia/New Zealand	Western Europe & Japan	Eastern Europe	Nordic Countries	Latin America	Asia	Australia	Canada	New Zealand	Puerto Rico	USA	Austria	Belgium	
REGION:	1	2	3	4	5	6	7	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	Western Europe & Japan	Western Europe & Japan
2019	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2020	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2021	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2022	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2023	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2024	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2025	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2026	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2027	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2028	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Clear Overrides

Set Inflation to 0%

# New Plan- Neutral Inflation Rate Profiles

The screenshot displays the Oracle QA Administrator web interface. The top navigation bar includes 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. The 'Maintain' menu is open, showing options like 'Templates', 'Service Providers', 'Resources', 'Billing Rates', 'Inflation Profiles', 'Departments/Functional Areas', 'GL Codes', 'Exchange Rates', 'Reporting Regions', and 'Purge Deleted'. The 'Inflation Profiles' option is highlighted with a red circle. A red arrow points from this circle to a 'New Inflation Profile' dialog box. The dialog box contains the text 'Please enter details for new inflation profile creation.' and has input fields for 'When: CRO X', 'Forms work for: ClearTrial Operations', and 'for Rate Year: 2018'. At the bottom of the dialog are 'Cancel' and 'Ok' buttons. A red-bordered text box with a red arrow pointing to the 'Inflation Profiles' menu option contains the text: 'Launched from the Maintain Menu, there is a new option to create your plan-neutral inflation profiles.'

Launched from the Maintain Menu, there is a new option to create your plan-neutral inflation profiles.

# Plan-Neutral Inflation Rate Profile

Users can choose to

- set inflation rates for a base location and allow the application to translate those rates to other locations, or
- set specific rates for each location.

### Create Inflation Profile

When: CRO X performs work for: ClearTrial Operations for Rate Year: 2018 Base Rate Location: USA

Year	Base Rate	USA, Canada, Australia/New Zealand	Western Europe & Japan	Eastern Europe	Nordic Countries	Latin America	Asia	Middle East	Other	Australia	Canada	New Zealand	Puerto Rico	USA	Austria	Belgium	France	Germany
RATE VARIANCE %:		108.10%	90.02%	174.17%	108.74%	300.40%	157.09%	259.21%	301.09%	124.15%	99.70%	99.56%	77.43%	100.00%	83.95%	64.69%	63.80%	83.95%
REGION:		1	2	3	4	5	6	8	7	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	USA, Canada, Australia/New Zealand	Western Europe & Japan	Western Europe & Japan	Western Europe & Japan	Western Europe & Japan
2019	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2020	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2021	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2022	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2023	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00





## **Question:**

“Do I have to set up inflation profiles by provider? That’s more work than I want to do.”

## **Answer:**

“You do not have to set up profiles in the maintenance section. You can continue to set your inflation preferences on a plan by plan basis.

However, there are ways to make inflation even easier by using the profiles in maintenance.”





## **Question:**

“How can I use inflation profiles in maintenance to make input of inflation rates easier?”

## **Answer 1:**

“If you have a contracted inflation rates that exist between Sponsor and Provider, you can set them up in maintenance and they will get automatically applied to all the applicable plans for the effective rate year.”

OR....



## Answer 2:

“If you have inflation rates dictated by your finance team, you can set them up for one provider in the maintenance menu and simply copy those rates for all providers. Now, your individual users will not have to enter those rates manually in each plan.”

*In both cases, the risk of using the incorrect inflation rates in a plan is much lower.*



## Question:

“I often use the default providers from ClearTrial. How do I handle inflation for those providers?”

## Answer:

“All the ClearTrial default providers now include inflation rates by location and year based on global economic data. You can:

- Use the ClearTrial inflation rates
- Override one or more of those rates in your plan
- Clear all the ClearTrial rates for plans you want to model with no inflation”



## Question:

“What do you recommend I do to prepare for inflation changes in release 5.3?”

## Answer:

We recommend the following actions:

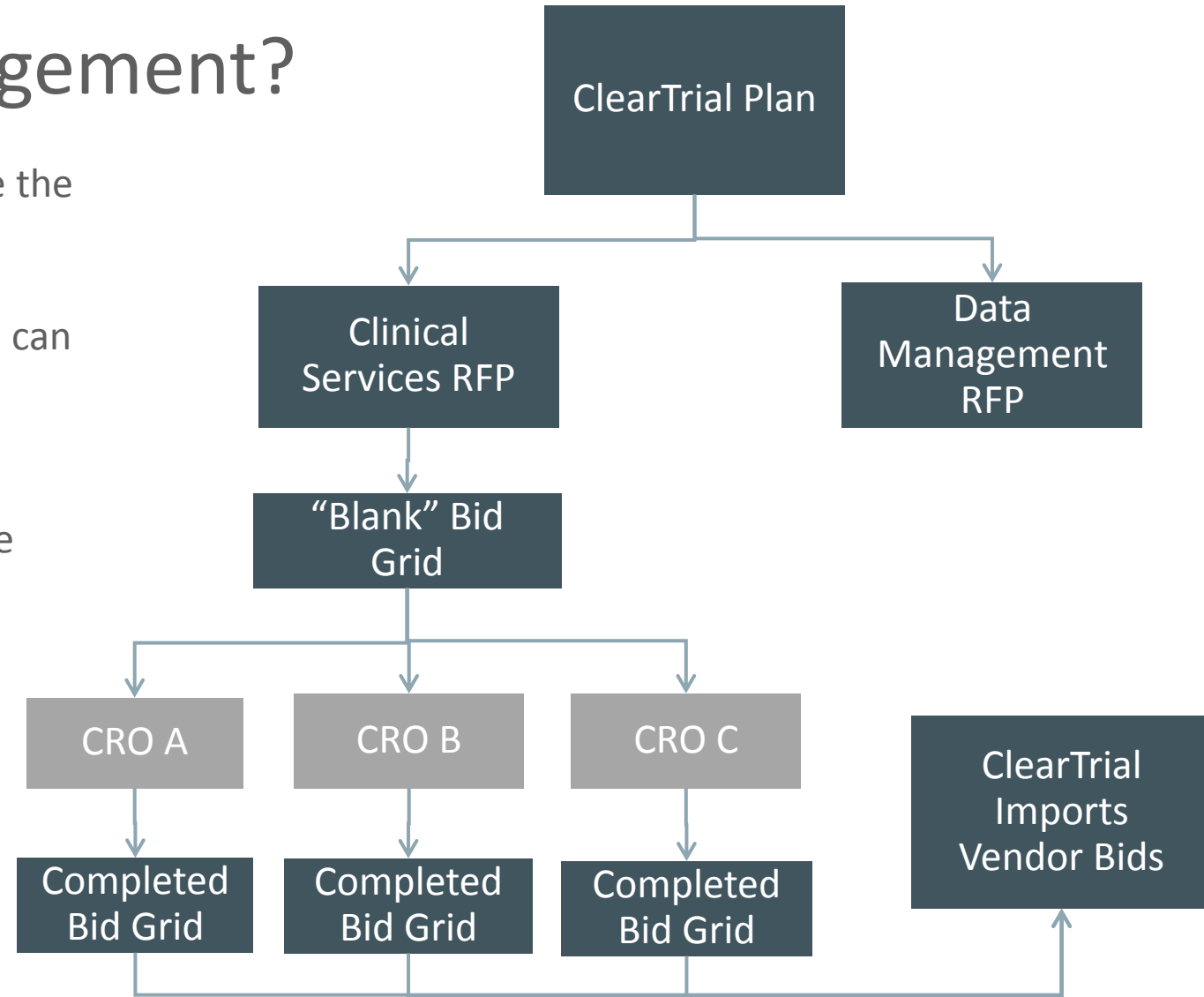
- Watch the training video or read the supplemental training material to find out more best practices on this feature.
- Ensure all ClearTrial users responsible for setting up plans have seen these slides or have watched the training video. **Don't let your users be surprised by these changes!**
- Have a conversation internally and decide if you want to continue handling inflation on a plan-by-plan basis or if you want to set up Inflation Profiles in the maintenance menu for reuse.

# RFP and Bid Management

**Enterprise Edition Only**

# What is RFP and Bid Management?

- From a Plan, you can create an RFP which can be the full scope or some subset of scope within a plan
- From the RFP, you can generate a Bid Grid which can be sent to multiple CROs as part of your RFP package
- You can import the completed Bid Grids from the CROs and store them as Bids in ClearTrial
- You can compare Bids for a specific RFP
  - to the ClearTrial benchmark values
  - to each other
- You can configure your comparison reports to highlight variances outside of a user-defined tolerance



# Create a Request for Proposal (RFP) from ClearTrial Baseline Plan

New Create RFP option under  
Other Actions...menu on Plan  
List screen for a  
selected/baseline plan

**Plans**

Filter

Show: ☐ All Plans ☒ Active Plans Only ☐ Plans matching filter: My Filter [Modify](#) [Configure List Options](#)


[New](#) [Edit](#) [Delete](#) [Restore](#) [Copy](#) [Compare](#) [Other Actions...](#)

	Plan Name	Study Name	Description	Status
<input type="checkbox"/>	1979-CL-0422-20150211	Protocol Amendment - Ph3	US Study	Draft
<input checked="" type="checkbox"/>	1979-CL-0422-20150211_FINAL	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v1	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v2	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v3	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v4	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v5	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v6	Protocol Amendment - Ph3	US Study	Draft

[Lock Plans](#)  
[Unlock Plans](#)  
[Freeze Rates](#)  
[Unfreeze Rates](#)  
[Create RFP](#)  
[Convert as Template](#)  
[Click this button to create an RFP for the selected plan](#)  
[Change Attributes](#)  
[Add to Portfolio\(s\)](#)  
[Create Reforecast](#)  
[Reforecast Exch Rates](#)  
[Set as Baseline](#)

# Plans used as the basis for an RFP are Permanently Locked

An RFP is based on the assumptions and tasks from its associated Plan. The Plan must remain static to allow import of vendor bids based on those assumptions and tasks.

<input type="checkbox"/>	Plan Name	Study Name	Description	Status
<input type="checkbox"/>	1979-CL-0422-20150211	Protocol Amendment - Ph3	US Study	Draft
<input checked="" type="checkbox"/> 	1979-CL-0422-20150211_FINAL	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v1	Protocol Amendment - Ph3	US Study	Draft
<input type="checkbox"/>	1979-CL-0422-20150211_v2	Protocol Amendment - Ph3	US Study	Draft

New (permanent) Lock icon  
for Plans with one or more  
RFPs created



# New RFPs List Screen

EditReportMaintainAdminHelp

Plans

Studies

Products

Portfolios

RFPs

Bids

From Edit Menu, select RFPs to navigate to RFPs List screen

All RFPs

Active RFPs Only

RFPs matching filter: My Filter

Modify

New

Edit

Delete

Restore

Import Bid

Compare Bids

Download Bid Grid

Configure List Options

	Plan Name	Scope/Provider	Description	Number of Bids
<input type="checkbox"/>	1979-CL-0422-20150211_FINAL	Major CRO	1979-CL-Baseline-USA	0

# RFPs List Screen Actions

RFPs

Filter

Show: ☐ All RFPs ☐ Active RFPs Only ☒ RFPs matching filter:  [Modify](#)

[Configure List Options](#)

1 RFP is selected [clear](#)

☒ Remember selections across pages [help](#)

[New](#) [Edit](#) [Delete](#) [Restore](#) [Import Bid](#) [Compare Bids](#) [Download Bid Grid](#)

Plan Name	Scope/Provider	Description	Number of Bids
<input checked="" type="checkbox"/> 1979-CL-0422-20150211_FINAL	Major CRO	1979-CL-Baseline-USA	0

Click here to download the Excel Bid Grid for this RFP

Option 1 to download new, detailed Bid Grid Report from RFPs List screen

Option 2 to download new, detailed Bid Grid Report from RFPs List screen

# Edit RFP Details

## Edit RFP

Details

Labor

Costs

Bids

View or edit the short description, bid grid title, or comments for this RFP

### RFP Information

Short Description: 1979-CL-Baseline-USA

(must be between 8 and 40 characters)

Bid Grid Title: Major CRO Bid\_v1

The contents of this field will be displayed on the exported bid grid

Comments: sallymichaels@cro.com

### History

Created By: Badakhshanian, Leyla

Last Modified By:

Leyla Badakhshanian

Created Date: 2/18/15 5:42 PM

Last Modified:

2/18/15 6:01 PM

[Download Bid Grid](#)

Option 2 to download  
new, detailed Bid Grid  
report from Edit RFP  
Details

# View/Edit RFP Labor with Option to Include Inflation

## Edit RFP

Details

Labor

Costs

Bids

These are the expected effort and fees related to the scope of work represented by this RFP

☒ Include Inflation

All monetary values are displayed in US Dollar (USD)

Major Task	Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
Project Initiated	106.678	23,355.18	1	106.678	23,355.18
Study Setup	119.642	25,810.96	1	119.642	25,810.96
Study Setup Per-Location	37.000	6,177.79	1	37.000	6,177.79
Unique CRF Page Developed	14.750	3,358.59	2	29.500	6,717.18
Meetings - Kickoff Meeting	81.000	20,459.40	1	81.000	20,459.40
Meetings - Kickoff Meeting for EU	121.000	30,606.20	1	121.000	30,606.20
Meetings - Investigator Meeting	157.000	37,703.58	1	157.000	37,703.58
Meetings - Face to Face Meeting	102.000	26,800.57	1	102.000	26,800.57
Meetings - Status Update to Sponsor	3.500	759.99	61	213.500	46,359.45
Meetings - Internal Team Meeting	7.500	1,863.76	61	457.500	113,689.39
Site Identified by Vendor	4.075	669.34	5	20.375	3,346.70
Pre-study Site Visit (PSSV)	16.800	2,751.49	6	100.800	16,508.94
Site Approved	26.875	4,519.09	5	134.375	22,595.45
<b>Total:</b>				17,248.466	3,374,592.03

Close

Save

Next

# View RFP Costs

## Edit RFP

Details	These are the expected pass-through and miscellaneous costs related to the scope of work represented by this RFP		
Labor	All monetary values are displayed in US Dollar (USD)		
Costs			
Bids			

[Close](#)[Save](#)[Next](#)

# New Detailed Level Bid Grid Report

Vendor enters their name on the Centralized sheet and it is dynamically displayed on all other tabs per plan location

ClearTrial-defined Mapping Key is displayed to help vendors uniquely identify location/task/resource line items for reuse in mapping their internal budget values to your bid grid.

*\*More on mapping keys later.*

1979-CL-0422-20150211_XYZCRO_V3 - Microsoft Excel							
Formulas Data Review View							
Wrap Text Merge & Center Alignment Number							
00001							
G							
2	Major CRO						
3	1979-CL-0422-20150211_FINAL for CT Product Review						
4	Phase III						
5	Indication: Breast Cancer						
6	Location: Centralized						
7	All monetary values should be entered in US Dollar (USD)						
8							
9	Cost Type	Location	Major Task / Cost	Task	Resource	Mapping Key	Unit of Measure
10	Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Clinical Research Associate	000-00002-00001	Study
11	Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Clinical Research Associate	000-00002-00002	Study
12	Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Vice President Clinical	000-00002-00004	Study
13	Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Director, Clinical/Therapeutic	000-00002-00005	Study

# New Detailed Level Bid Grid Report

1979-CL-0422-20150211\_XYZCRO\_V5 - Micro

Home Insert Page Layout Formulas Data Review View

Cut Copy Paste Format Painter Clipboard

Arial 9 Font

Wrap Text Merge & Center Alignment

Number

Format AutoSum Fill Clear

O10 100

Mapping Key	Unit of Measure	# Units	Resource Location	Base Billing Rate	Inflated Billing Rate	Unit Hours	Total Hours	Unit Cost	Total Cost
000-00002-00001	Study	1	Region:USA, Canada, Australia/New Zealand	100.00	105.00	8.000	8.000	840.00	840.00
000-00002-00002	Study	1	Region:USA, Canada, Australia/New Zealand	100.00	105.00	8.000	8.000	840.00	840.00
000-00002-00004	Study	1	Region:USA, Canada, Australia/New Zealand	100.00	105.00	8.000	8.000	840.00	840.00
000-00002-00005	Study	1	Region:USA, Canada, Australia/New Zealand	100.00	105.00	8.000	8.000	840.00	840.00

Vendor to input values in blue cells per line item in new Bid Grid Report

# Import Bids Against an RFP

## RFPs

1 RFP is selected [clear](#)

☒ Remember selections across pages [help](#)

### Filter

Show: ☐ All RFPs ☐ Active RFPs Only ☒ RFPs matching filter: My Filter [Modify](#)

[Configure List Options](#)

New

Edit

Delete

Restore

Import Bid

Compare Bids

Download Bid Grid

	Plan Name	Scope/Provider	Description	Number of Bids
<input checked="" type="checkbox"/>	1979-CL-0422-20150211_FINAL	Major CRO	1979-CL-Baseline-USA	0

Import a Bid from Excel

Select Import Bid to  
import the Vendor's  
completed ClearTrial Bid  
Grid



# Import Bids Dialog

Import Bid

X

Use this screen to upload a bid submitted by a vendor.

Vendor Name

☐ LAM CRO2

☐ LAM-TestP...

☒ Provider with INR Billing Rates

☐ XYZ Provider

Bid Information

Bid Grid File to Upload:

Choose File

1979-CL-0422-20150211\_Major CRO\_v1.xls

Short Description:

Major CRO Provider US Bid v1

(must be between 8 and 40 characters)

CRO Bid Number:

998766989

Comments / CRO Information:

Sally Hughes  
shughes@abccro.com  
312-333-9987  
  
Jim Macs  
jmacs@abccro.com  
312-333-9988

Please enter up to 4000 characters to capture vendor contact information or other comments

Cancel

Ok

Select the vendor who's completed bid you want to import into ClearTrial

# Import Bids Validation - Errors/Warnings Display and Issues Reporting

The following issues were encountered when importing the bid.

Severity	Message	Sheet	Row
SERIOUS	Invalid characters in billing rate. The value is treated as if 0 was entered.	BidGrid_Centraliz..	10

There were 1 issues encountered. To ... please download the file using the link below.

[Download Issues](#) Cancel Continue

Imported Bids will be validated and severe errors or warnings will be displayed to be able to correct values and retry. E.g., Vendor put in an alpha character for Billing Rate value in Bid

# Edit RFP Bids

## Edit RFP

- Details
- Labor
- Costs
- Bids**

These are the bids that have been imported for this RFP. You can compare these bids to one another and to this RFP.

Compare

Delete

Restore

Download

Update Status

<input type="checkbox"/>	Vendor	Version	Created Date	Status	Total Fees	Total PTC
<input checked="" type="checkbox"/>	XYZ Provider	1	02/18/15 06:50 AM	Pending Review	271,964,088 USD	69,830 USD
<input type="checkbox"/>	LAM-TestProvider	1	02/18/15 07:04 PM	Pending Review	210,457,512 USD	69,830 USD

From Edit RFP Bids tab,  
ability to update Bid  
status value

# Change Bid Status to Distinguish Bids During Business Process Stages

These are the bids

Compare

☐ Vendor

☒ XYZ Provider

☐ LAM-TestProv

Please specify the

**Change Bid Status** X

Choose the status to assign to the selected bid.

Status: Pending Review ▼

- Pending Review
- Proposal - Under Review
- Proposal - Pending vendor action
- Proposal - Rejected
- Proposal - Selected
- Proposal - On Hold
- Proposal - Canceled
- Contract - Under Review
- Contract - Pending vendor action
- Contract - Rejected
- Contract - Accepted Final
- Contract - Complete
- Change Order - Under Review
- Change Order - Pending vendor action
- Change Order - Rejected
- Change Order - Accepted Final
- Change Order - Complete

☒ Update Bid History

Close Save Save & Close

# New Bids List Screen

**CLEAR TRIAL**

Edit Report Maintain Admin Help

Welcome, Leyla Badakhshanian | Visit Support Center | Logo

Plans  
Studies  
Products  
Portfolios  
RFPs  
**Bids**

All Bids ☒ Active Bids Only ☐ Bids matching filter: My Filter [Modify](#) [Configure List Options](#)

New Edit Delete Restore Update Status Compare Download

	Plan Name	Scope	Vendor	Version	Description	Status	Created Date
<input type="checkbox"/>	1979-CL-0422-20150211_Final	Major CRO	XYZ Provider	1	XYZ CRO US V1	Pending Review	02/18/15 06:56 PM
<input type="checkbox"/>	1979-CL-0422-20150211_FINAL	Major CRO	LAM-TestProvider	1	LAM CRO US v1	Pending Review	02/18/15 07:04 PM

New Bids Option to select from Edit Menu which redirects you to the Bids List screen

# Edit Bids Details

## Edit Bid

### Details

Labor

Costs

Issues

View or edit the short description, cro number, status, or comments for this bid

#### Bid Information

Short Description:	XYZ CRO US V1
CRO Bid Number:	9987666
Status:	Pending Review ▼
Comments:	Sally Field SField@xyzcro.com 312-333-9988

#### History

Created By:	Badakhshanian, Leyla	Last Modified By:	Badakhshanian, Leyla
Created Date:	2/18/15 6:56 PM	Last Modified:	2/18/15 7:03 PM

[Download Imported Bid](#)

Download/regenerate the imported bid into excel (.xls) file

# View/Edit Bids Labor with Option to Include Inflation

## Edit Bid

Details

Labor

Costs

Issues

These are the proposed effort and fees supplied by this vendor

☒ Include Inflation

All monetary values are displayed in US Dollar (USD)

Major Task	Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
Project Initiated	288.000	30,240.00	1	288.000	30,240.00
Study Setup	112.000	11,760.00	1	112.000	11,760.00
Study Setup Per-Location	80.000	9,200.00	1	80.000	9,200.00
Unique CRF Page Developed	96.000	10,080.00	2	192.000	20,160.00
Meetings - Kickoff Meeting	32.000	3,360.00	1	32.000	3,360.00
Meetings - Kickoff Meeting for EU	32.000	3,360.00	1	32.000	3,360.00
Meetings - Investigator Meeting	48.000	5,040.00	1	48.000	5,040.00
Meetings - Face to Face Meeting	40.000	4,200.00	1	40.000	4,200.00
Meetings - Status Update to Sponsor	8.000	840.00	61	488.000	51,240.00
Meetings - Internal Team Meeting	32.000	3,360.00	61	1,952.000	204,960.00
Site Identified by Vendor	40.000	4,600.00	5	200.000	23,000.00
Pre-study Site Visit (PSSV)	80.000	9,200.00	6	480.000	55,200.00
Site Approved	192.000	29,640.00	5	960.000	148,200.00
Site Initiation Visit	80.000	12,800.00	5	400.000	64,000.00
Study Drug Shipment Tracked	16.000	2,560.00	5	80.000	12,800.00
<b>Total:</b>				1,874,100.800	271,964,088.01

# View/Edit Bids Costs

## Edit Bid

Details

Labor

Costs

Issues

These are the proposed pass-through and miscellaneous costs supplied by this vendor

All monetary values are displayed in US Dollar (USD)

Name	Total
EDC Hosting	1,100
EDC Licensing	2,000
EDC Setup	3,000
Investigator Grants - Grant Payments	1,500
IRB and Annual Renewal Fees	2,500
Labs - Central Lab	5,000
Meeting - Face to Face Meeting	10,000
Meeting - Investigator Meeting	5,000
Meeting - Kickoff Meeting	800
Meeting - Kickoff Meeting for EU	1,208
Miscellaneous Costs	7,000
Printing (not including CRF Printing)	1,500
Protocol Distribution	25,000
Shipping (not including study drug/test article shipping)	2,245
<b>Total:</b>	<b>69,830</b>

Close

Save

Next



# Edit Bid Issues

**Edit Bid**

Details
Labor
Costs
Issues

There were no issues encountered when importing this bid.

# New RFP and Bids Comparison Reports

## Vendor Bid Comparison Options

Please choose the type of comparison and applicable options

### Available Comparisons

- ☒ Major Task and Cost Summary
- ☐ Detailed Fees and Costs by Location, Task, Resource

Summary level comparison available to be able to identify discrepancies by function

### Compare Options

- ☒ Include RFP in comparison
- ☒ Show variances relative to RFP
- ☐ Show variances relative to a selected bid

- ☐ XYZ Provider
- ☐ LAM-TestProvider

Ver: 1

Ability to include RFP in comparison and use RFP as the baseline for comparison to bids

### Variance Analysis

- ☒ Include Variance Analysis
- ☒ Highlight total cost variances above  %
- ☒ Highlight total hours variances above  %

### Report Format

Select the format for the report.

- ☐ HTML ☐ PDF ☒ XLS (Excel) ☐ CSV

Select a report format

Cancel

Ok

# New RFP and Bids Comparison Reports Detailed Level

## Vendor Bid Comparison Options

Please choose the type of comparison and applicable options

### Available Comparisons

- ☐ Major Task and Cost Summary
- ☒ Detailed Fees and Costs by Location, Task, Resource

Detailed level comparison available to drill down into the functional areas by task-resource-location

### Compare Options

- ☒ Include RFP in comparison
- ☐ Show variances relative to RFP
- ☒ Show variances relative to a selected bid

- ☐ XYZ Provider Ver: 1
- ☐ LAM-TestProvider Ver: 1

Ability to select which bid from bids to use as your baseline for comparison

ated: 02/18/15 06:56 PM  
ated: 02/18/15 07:04 PM

### Variance Analysis

- ☒ Include Variance Analysis
- ☒ Highlight total cost variances above
- ☒ Highlight total hours variances above
- ☒ Highlight unit cost variances above
- ☒ Highlight unit hours variances above
- ☒ Highlight base billing rate variances above
- ☒ Highlight inflated billing rate variances above

25 %  
10 %  
10 %  
10 %  
10 %  
10 %

User-defined thresholds highlighted in comparison reports for variance analysis

# Highlighted Discrepancies at Task-Resource-Location levels

In this example, XYZ Provider was selected as the baseline to which another provider and the RFP were compared to

Resource	Unit of Measure	Units	Vendor	Resource Location	Base Billing Rate	Inflated Billing Rate	Hours Per Unit	Per Unit Cost	Total Hours	Total Cost
Clinical Research Associate	Study	1	XYZ Provider	USA, Canada, Australia/New Zealand	100.00	105.00	8.000	840.00	8.000	840.00
			RFP	USA	166.29	166.29	0.750	124.72	0.750	124.72
			LAM-TestProvider	USA, Canada, Australia/New Zealand	100.00	105.00	8.000	840.00	8.000	840.00
			RFP vs. XYZ Provider		66.29	61.29	(7.250)	(715.28)	(7.250)	(715.28)
			RFP vs. XYZ Provider variance %		66.29 %	58.37 %	-90.625 %	-85.15 %	-90.625 %	-85.15 %
			LAM-TestProvider vs. XYZ Provider		0.00	0.00	0.000	0.00	0.000	0.00
			LAM-TestProvider vs. XYZ Provider variance %		0.00 %	0.00 %	0.000 %	0.00 %	0.000 %	0.00 %
Senior Clinical Research Associate	Study	1	XYZ Provider	USA, Canada, Australia/New Zealand	100.00	105.00	8.000	840.00	8.000	840.00
			RFP	USA	213.03	213.03	8.000	1,704.24	8.000	1,704.24
			LAM-TestProvider	USA, Canada, Australia/New Zealand	100.00	105.00	8.000	840.00	8.000	840.00
			RFP vs. XYZ Provider		113.03	108.03	0.000	864.24	0.000	864.24

Another Provider who is bidding against this RFP

# Bid Grid Mapping Key

- A mapping key is a value assigned by ClearTrial to uniquely identify an activity by location, task, and resource.
- The mapping keys are in the format [location key]-[task key]-[resource key].
- The three elements for the mapping key are determined as follows:

## Location Keys

Location keys represent either a country or a ClearTrial-defined region.

ClearTrial region keys:

- USA, Canada, Australia/New Zealand NA01
- Western Europe & Japan WE02
- Eastern Europe EE03
- Nordic Countries NC04
- Latin America LA05
- Asia AP06
- Other ZZ07
- Middle East ME08

ClearTrial country keys:

- standard two-digit ISO codes.

## Task Keys

Task codes are uniquely assigned by ClearTrial and can be found on the Task Details screen in the Task Manager.

## Resource Keys

Resource keys are uniquely defined by ClearTrial and can be found only in the Bid Grid.

# New ClearTrial-defined Cost Mapping Key to Easily Identify Indirect Costs in RFPs and Bids

Edit or Adjust

Drug Packaging

Definition

Adjustments

Distribution

## Category Information

Name: Drug Packaging

Type: Miscellaneous

☐ Include in Payment Schedule

☒ Apply inflation over time

Mapping Key: C00003

☐ Include in Resources by Department/GL Code report

New, unique mapping key displayed per pass-through/miscellaneous cost (CT-defined)

## Notes

# New ClearTrial-defined Task Mapping Key to Easily Identify Tasks in RFPs and Bids

The screenshot displays the Oracle Task Manager interface. On the left is a 'Task Search...' sidebar with a tree view of tasks. The main area shows the 'Task Details' for 'Coordinate DSMB setup activity'. A red callout box points to the 'Mapping Key: 00023' field, with a text box stating: 'New, unique, mapping key displayed per task (CT-defined)'. Below the details are buttons for 'Add Resource', 'Edit Resource', and 'Delete Resource', followed by a table of resources.

**Task Search...**

- Project Initiated
- Study Setup
  - Negotiate central laboratory
  - Establish committees or management st
  - Coordinate DSMB setup activity**
    - CR01 - Clinical Research Associate
    - CR04 - Senior Vice President Clinical
    - CR06 - Project Manager
    - DS01 - Medical Monitor
    - ST01 - Junior Biostatistician
    - ST02 - Senior Biostatistician
    - ST04 - Director Biostatistics/Data Ma
  - Produce and distribute subject informati
  - Design study documents
  - Review protocol
  - Develop distribute and collect investigat
  - Write Investigator Brochure
  - Edit Investigator Brochure
  - Perform ICF, diary and protocol translati
  - Design the specific randomization system
  - Configure EDC System(s)
  - Configure and Test EDC Transfers
- Study Setup Per-Location
  - A Written Protocol
  - Protocol Amendment
  - Protocol Amendment per Location
  - Unique CRF Page Developed
  - CRF Book Printed
  - Meetings - Kickoff Meeting
  - Meetings - Kickoff Meeting for FU

**Study Setup » Coordinate DSMB setup activity**

**Task Details** | Task Assignments

Name: Coordinate DSMB setup activity

**Mapping Key: 00023**

Description: Establish the Data Safety Monitoring Board, which requires meeting schedules, report formats for receipt of safety data, etc.

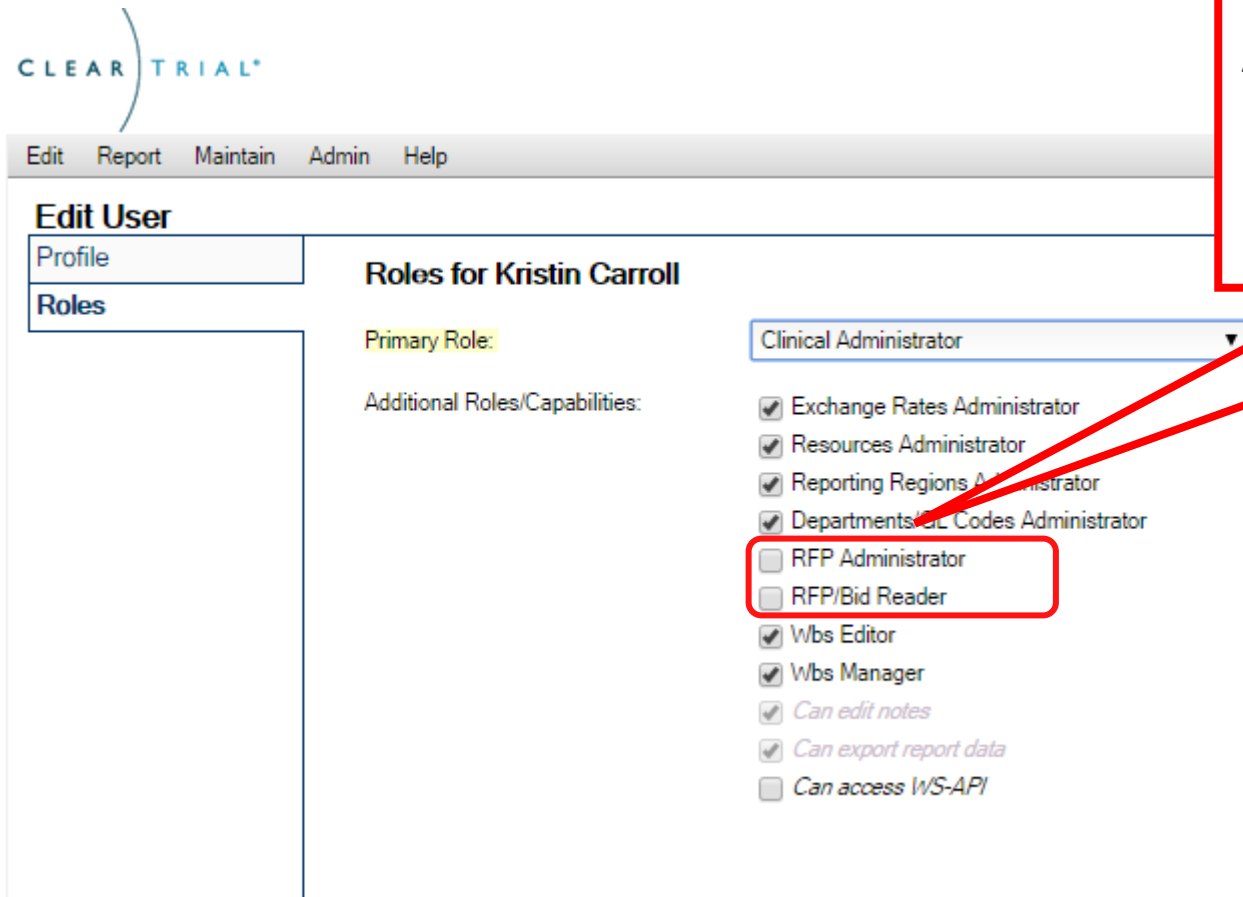
Assignment Group: Project Initiation

Summary Category: Startup Fees

**Add Resource** | **Edit Resource** | **Delete Resource**

Resource Name	Substitutions
<input type="checkbox"/> CR01 - Clinical Research Associate	None
<input type="checkbox"/> CR04 - Senior Vice President Clinical	None
<input type="checkbox"/> CR06 - Project Manager	None
<input type="checkbox"/> DS01 - Medical Monitor	None
<input type="checkbox"/> ST01 - Junior Biostatistician	None
<input type="checkbox"/> ST02 - Senior Biostatistician	None
<input type="checkbox"/> ST04 - Director Biostatistics/Data Management	None

# New Additional Roles/Capabilities for RFPs and Bids



CLEAR TRIAL

Edit Report Maintain Admin Help

**Edit User**

Profile Roles

**Roles for Kristin Carroll**

Primary Role: Clinical Administrator

Additional Roles/Capabilities:

- ☒ Exchange Rates Administrator
- ☒ Resources Administrator
- ☒ Reporting Regions Administrator
- ☒ Departments/CL Codes Administrator
- ☐ RFP Administrator
- ☐ RFP/Bid Reader
- ☒ Wbs Editor
- ☒ Wbs Manager
- ☒ Can edit notes
- ☒ Can export report data
- ☐ Can access WS-API

New Additional Roles to be Granted. RFP Administrator role can only be granted to users with Clinical Administrator role. RFP/Bid Reader role can be granted to any user role.



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