

ORACLE®

# Introduction to Oracle ClearTrial 5.3

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February 19, 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

- 5.3 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

| <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 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:  %

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:

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** [X]

Treatment A

Details | **Schedule** | Notes

**Subject Treatment Schedule**

Monitoring minutes per CRF page:  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                   | 44.95                     | 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
- Data**
- 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 Plan

Notes

|              |
|--------------|
| Overview     |
| Locations    |
| Site         |
| Subject      |
| Treatment    |
| Data         |
| Monitoring   |
| Provider     |
| Meetings     |
| Assignment   |
| <b>Labor</b> |
| 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<br>(Data Transfers)   | 0.000      | 0.00      | 0       | 0.000       | 0.00          |
| <input type="radio"/> Final Data Audit<br>(Data Audit)  | 0.017      | 2.32      | 5,393   | 91.681      | 12,511.76     |
| <input type="radio"/> Issued Unique Summary Table<br>(Biostatistics - Issue Tables)               | 14.060     | 1,995.95  | 13      | 182.780     | 25,947.35     |
| <input type="radio"/> Issued Unique Summary Listing<br>(Biostatistics - Issue Listings)           | 9.036      | 1,272.62  | 15      | 135.540     | 19,089.30     |
| <input type="radio"/> Issued Unique Summary Figure/Graph<br>(Biostatistics - Issue Graphs)        | 14.060     | 1,995.95  | 8       | 112.480     | 15,967.60     |
| <input type="radio"/> Issued Repeat Summary Table<br>(Issued Repeat Summary Tables)               | 5.018      | 707.62    | 26      | 130.468     | 18,398.12     |
| <input type="radio"/> Issued Repeat Summary Listing<br>(Issued Repeat Summary Listings)           | 3.512      | 490.19    | 15      | 52.680      | 7,352.85      |
| <input type="radio"/> Issued Repeat Summary Figure/Graph<br>(Issued Repeat Summary Figure/Graphs) | 5.018      | 707.62    | 4       | 20.072      | 2,830.48      |
| <input type="radio"/> Stat Report<br>(Medical Writing - Stat Report)                              | 50.626     | 7,941.15  | 1       | 50.626      | 7,941.15      |
| <input type="radio"/> Draft Report<br>(Medical Writing - Draft CSR)                               | 244.859    | 40,999.92 | 1       | 244.859     | 40,999.92     |
| <input type="radio"/> Final Report (CSR)<br>(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

# 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.

# Additional Work Units Available

In Task Manager and Cost Algorithm set-up screen

Define New Category

Central Reader

Definition Algorithm Distribution

Cost Algorithm

Costs:  vary by location  are study level

Calculate as:  USD

Study Wide Costs/Adjustments

| Location    | Provider          |
|-------------|-------------------|
| Study-Level | CT Product Review |

| GL Code                               | Costs  |
|---------------------------------------|--|
| <input type="text" value="Unmapped"/> | Calculate as: 5,000 USD<br>x 0 reports<br>Total: 0 USD |

- DSMB Report
- Interim Analysis
- Monitoring Visit
- Protocol Amendment
- Serious Adverse Event
- Site Audited
- Site Requiring Overhead
- Subject Complete
- Subject Randomized
- Subject Screened
- Subject Visit
- Translation
- Unique CRF Page
- Unique Data Table
- Unique Data Listing
- Unique Figure or Graph
- Query
- Repeat Data Table**
- Repeat Data Listing
- Repeat Figure or Graph
- Week

# 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

Current Edit Mode: **Advanced**

Meetings

**Add** Edit Complete In Delete

| Name   | Type           | Location         | Occurs | Planner           |
|--|----------------|------------------|--------|-------------------|
| <input type="checkbox"/> Kickoff Meeting               | Kickoff        | USA              | Once   | CT Product Review |
| <input type="checkbox"/> <b>Kickoff Meeting for EU</b> | 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         |

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 costs for the selected provider

Current Edit Mode: Advanced

Filter

Show hours and fees for:

Show major tasks with no planned effort for the selected provider

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

All calculated costs and adjustments are shown in this table. *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 Development (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 |

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

Meetings - Kickoff Meeting (Kickoff Meetings)

1

20,459.40



# 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.

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

### 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> |





# 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](#)

| <input type="checkbox"/>   | 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** X

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 type="checkbox"/> Phase                 | <input type="checkbox"/> Therapeutic Area | <input checked="" type="checkbox"/> Indication | <input checked="" type="checkbox"/> Description |
| <input checked="" type="checkbox"/> Status    | <input type="checkbox"/> Created Date          | <input checked="" 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

Cancel Ok

# Increased Precision for Hours and Costs

## Edit Plan

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

View or ad  
Filter  
Show hour  
New  
All calculat

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 sel  
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

|                                     |                   |
|-------------------------------------|-------------------|
| <input checked="" type="checkbox"/> | All Providers     |
| <input checked="" type="checkbox"/> | CT Product Review |
| <input checked="" type="checkbox"/> | 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

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

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

Discount rate to apply to this 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 FSII/FPI: | 92.4 % | Suggested value is pending |
| Project Manager utilization after FSII/FPI:    | 92.4 % | Suggested value is pending |
| Resource Allocation Factor:                    | 80 %   | <i>i</i>                   |

#### 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

The screenshot shows the 'Specify Provider-Specific Details' window with the 'Inflation' tab selected. A red callout box points to the 'Inflation' tab and contains the following text:

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.

The 'Inflation Rates for XYZ Provider' table is shown below:

| 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                        | USA            |
|---------|------------------------------------|------------------------|----------------|------------------|---------------|------|-------------|-------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|----------------|
| 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, Australia |
| 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           |

# 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<br>Overwrite plan-neutral values to 0%<br>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<br>Overwrite plan-neutral values to 0%<br>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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |
| 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    | 1.31 |

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             |      | 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 software interface. At the top, there is a menu bar with 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. The 'Maintain' menu is open, showing options like 'Templates', 'Service Providers', 'Resources', 'Billing Rates', and 'Inflation Profiles'. The 'Inflation Profiles' option is highlighted with a red circle. A red arrow points from this circle to a dialog box titled 'New Inflation Profile'. The dialog box contains the text 'Please enter details for new inflation profile creation.' and has three input fields: 'When: CRO X', 'Forms work for: ClearTrial Operations', and 'for Rate Year: 2018'. At the bottom of the dialog box are 'Cancel' and 'Ok' buttons. A red callout box with a white background and a red border points to the 'Inflation Profiles' menu item. The callout box contains the text: '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                   | 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                   | 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                   | 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                   | 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                   | 0.00 |

Add Year Delete Year

[Export rates to Excel](#)

Cancel Save Publish





## **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:

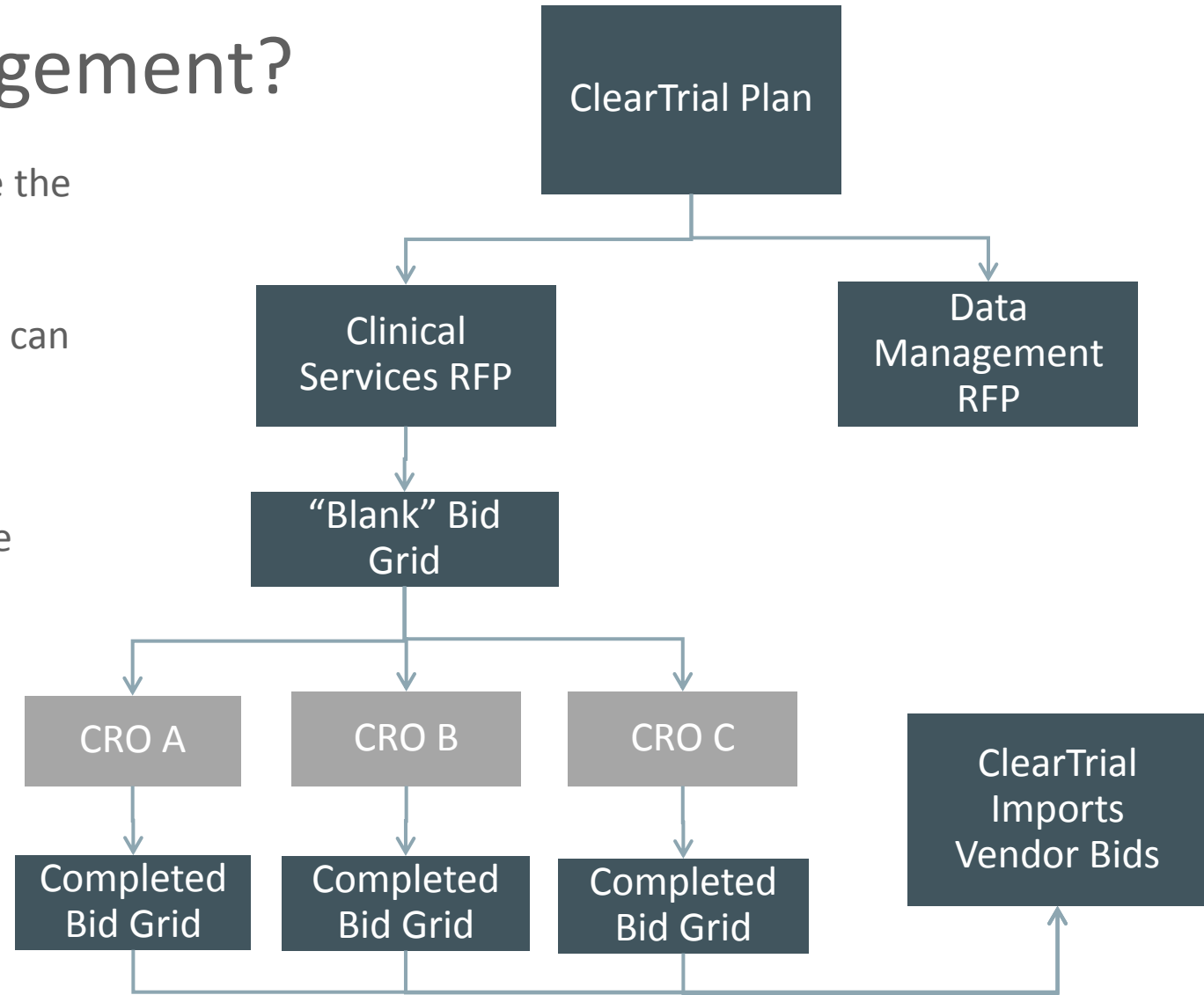
- Watch the training video or read the supplemental training material to find out more best practices on this feature.
- Ensure all ClearTrial users responsible for setting up plans have seen these slides or have watched the training video. **Don't let your users be surprised by these changes!**
- Have 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 | Owner |
|---|--------------------------|-------------|--------|-------|
| <input type="checkbox"/> 1979-CL-0422-20150211                  | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input checked="" type="checkbox"/> 1979-CL-0422-20150211_FINAL | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v1               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v2               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v3               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v4               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v5               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |
| <input type="checkbox"/> 1979-CL-0422-20150211_v6               | Protocol Amendment - Ph3 | US Study    | Draft  | eyla  |

- Lock Plans
- Unlock Plans
- Freeze Rates
- Unfreeze Rates
- Create RFP**
- Convert 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

The screenshot shows the Oracle RFPs List Screen. At the top, there is a navigation bar with the following items: Edit, Report, Maintain, Admin, Help. On the right side of the navigation bar, it says "Welcome, Leyla Badakhshanian | Visit Support Center | Log". Below the navigation bar is a sidebar menu with the following items: Plans, Studies, Products, Portfolios, RFPs (highlighted with a red box), and Bids. A red callout box with a white background and black text points to the "RFPs" menu item. The text inside the callout box reads: "From Edit Menu, select RFPs to navigate to RFPs List screen". Below the sidebar menu is a toolbar with the following items: All RFPs (selected), Active RFPs Only, RFPs matching filter: My Filter (dropdown), and Modify (link). Below the toolbar is a row of buttons: New, Edit, Delete, Restore, Import Bid, Compare Bids, and Download Bid Grid. Below the buttons is a table with the following columns: Plan Name, Scope/Provider, Description, and Number of Bids. The table contains one row with the following data: Plan Name: 1979-CL-0422-20150211\_FINAL, Scope/Provider: Major CRO, Description: 1979-CL-Baseline-USA, Number of Bids: 0.

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

Welcome, Leyla Badakhshanian | Visit Support Center | Log

Plans  
Studies  
Products  
Portfolios  
RFPs  
Bids

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 type="checkbox"/> 1979-CL-0422-20150211_FINAL | Major CRO      | 1979-CL-Baseline-USA | 0              |

# RFPs List Screen Actions

1 RFP is selected [clear](#)  Remember selections across pages [help](#)

**RFPs**

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              |

Click here to download the Excel Bid Grid for this RFP

Edit RFP will redirect you to edit or update the RFP's attributes

Option 1 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
- Labor
- Costs**
- Bids

These are the expected pass-through and miscellaneous costs related to the scope of work represented by this RFP

All monetary values are displayed in US Dollar (USD)

| Name                                  | Total            | Inflated Total   |
|---------------------------------------|------------------|------------------|
| EDC Hosting                           | 10,800           | 10,808           |
| EDC Licensing                         | 8,125            | 8,166            |
| EDC Setup                             | 8,000            | 8,000            |
| Investigator Grants - Grant Payments  | 8,662,500        | 8,662,500        |
| IRB and Annual Renewal Fees           | 7,500            | 7,500            |
| Labs - Central Lab                    | 493,050          | 493,634          |
| Meeting - Face to Face Meeting        | 5,000            | 5,000            |
| Meeting - Investigator Meeting        | 16,000           | 16,000           |
| Meeting - Kickoff Meeting             | 4,000            | 4,000            |
| Meeting - Kickoff Meeting for EU      | 8,000            | 8,000            |
| Miscellaneous Costs                   | 1,021            | 1,026            |
| Printing (not including CRF Printing) | 1,615            | 1,617            |
| Protocol Distribution                 | 70               | 70               |
| <b>Total:</b>                         | <b>9,482,099</b> | <b>9,482,764</b> |

Close

Save

Next



# New Detailed Level Bid Grid Report

The screenshot shows an Excel spreadsheet titled "1979-CL-0422-20150211\_XYZCRO\_V3 - Microsoft Excel". The spreadsheet contains a bid grid report with the following details:

- Vendor Name:** Major CRO
- Project:** 1979-CL-0422-20150211\_FINAL for CT Product Review
- Phase:** Phase III
- Indication:** Breast Cancer
- Location:** Centralized
- Note:** All monetary values should be entered in US Dollar (USD)

The bid grid table is as follows:

| Cost Type | Location    | Major Task / Cost | Task  | Resource                              | Mapping Key     | Unit of Measure |
|-----------|-------------|-------------------|---|---------------------------------------|-----------------|-----------------|
| Labor     | Centralized | Project Initiated | Develop scope of work, timeline, work assignments | Clinical Research Associate           | 000-00002-00001 | Study           |
| Labor     | Centralized | Project Initiated | Develop scope of work, timeline, work assignments | Senior Clinical Research Associate    | 000-00002-00002 | Study           |
| Labor     | Centralized | Project Initiated | Develop scope of work, timeline, work assignments | Senior Vice President Clinical        | 000-00002-00004 | Study           |
| Labor     | Centralized | Project Initiated | Develop scope of work, timeline, work assignments | Senior Director, Clinical/Therapeutic | 000-00002-00005 | Study           |

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.



# New Detailed Level Bid Grid Report

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

| 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     |



# 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:  [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:  1979-CL-0422-20150211\_Major CRO\_v1.xls

Short Description:   
(must be between 8 and 40 characters)

CRO Bid Number:

Comments / CRO Information:

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

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.

| <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-TestPro

### Change Bid Status

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

Please specify th

Close Save Save & Close



# New Bids List Screen

The screenshot displays the CLEAR TRIAL application interface. At the top left is the logo 'CLEAR TRIAL'. Below it is a navigation menu with options: Edit, Report, Maintain, Admin, Help. On the right side of the top bar, it says 'Welcome, Leyla Badakhshanian | Visit Support Center | Logo'. A dropdown menu is open on the left, listing: Plans, Studies, Products, Portfolios, RFPs, and Bids. The 'Bids' option is highlighted with a red box. Below the dropdown is a filter section with radio buttons for 'All Bids', 'Active Bids Only' (selected), and 'Bids matching filter: My Filter' (with a dropdown arrow and a 'Modify' link). To the right of this is a link 'Configure List Options'. Below the filter section is a toolbar with buttons: New, Edit, Delete, Restore, Update Status, Compare, and Download. The 'New' button is highlighted with a red box. A red arrow points from the 'New' button to a text box. Below the toolbar is a table with the following columns: Plan Name, Scope, Vendor, Version, Description, Status, and Created Date. The table contains two rows of data.

| Plan Name                   | Scope     | Vendor           | Version | Description   | Status         | Created Date      |
|-----------------------------|-----------|------------------|---------|---------------|----------------|-------------------|
| 1979-CL-0422-20150211_Final | Major CRO | XYZ Provider     | 1       | XYZ CRO US V1 | Pending Review | 02/18/15 06:56 PM |
| 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         |
| <b>Issues</b> |

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

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

dated: 02/18/15 06:56 PM  
dated: 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

Another Provider who is bidding against this RFP

| 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     |



# 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** x

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

**Notes**

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

Mapping Key: C00003



# 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 and navigation tree. The main area shows the details for the task 'Coordinate DSMB setup activity'. A red callout box points to the 'Mapping Key: 00023' field, with the text '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 Manager**

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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