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A woman with blonde hair is smiling and looking towards a man with glasses who is partially visible on the right. They appear to be in a meeting or collaborative work environment. In the background, another person is seated at a table.

Introduction to Oracle ClearTrial 5.8

Customer Briefing

ClearTrial Product Management
Health Sciences Global Business Unit
December, 2018

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

- 1 Release Overview
- 2 Oracle Help Center Refresher
- 3 ClearTrial Recommended Best Practices
- 4 List of Primary Enhancements by Edition
- 5 Overview of the Primary Features/Enhancements

ClearTrial 5.8 Overview

- Release Objectives: 5.8 brings new and enhanced capabilities to the Oracle Health Sciences ClearTrial Plan and Source Cloud Service providing increased flexibility, transparency and efficiency in your study planning and outsourcing.
- Includes a **NEW 5.8 Cost Model** to upgrade your plans and user-defined templates to, to leverage the latest costing algorithms.
- Release Approach: Market and Customer Driven

Remember to Visit the Oracle Help Center



Studies

Filter
Show: All Studies Active Studies Only Studies matching filter: [Modify](#) [Configure List Options](#)

[New](#) [Edit](#) [Delete](#) [Restore](#)

Study Name ▲	Product/Compound	Phase	Indication	Status
<input type="checkbox"/> MK-3475 Japan PhIIB	Pembrolizumab	I Ib	Lung Cancer	Planning

Click the [Visit Oracle Help Center](#) link to access all release and service-specific multimedia content.



Oracle Help Center Layout

ORACLE[®] Help Center Industries Search products Welcome Leyla

< Industries

Get Started

Videos

Books

Oracle Health Sciences
ClearTrial Cloud Service

Get Started

START H

About This Release

Before You Start

Be sure to visit each of the vertical tabs on the left to navigate through the different sections of the Oracle Help Center ClearTrial collateral.

Getting Started

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Oracle Health Sciences ClearTrial Cloud Service

Get Started

The Get Started tab is where you will begin to find the latest information about the release, under the About This Release section.

START HERE

About This Release

Before You Start

Oracle Help Center Videos

The screenshot shows the Oracle Help Center interface. At the top left is the Oracle logo and 'Help Center'. A navigation menu on the left includes '< Industries', 'Get Started', 'Videos' (highlighted with a red box), and 'Books'. The main content area features the title 'Oracle Health Sciences ClearTrial Cloud Service Videos' in red. Below the title is a description: 'Watch these short videos to learn how to perform the most common tasks in ClearTrial Cloud Service.' To the right is a large yellow pill icon. A red callout box points to the 'Videos' tab with the text: 'The Videos tab contains all types of short, how-to videos for additional training and education for users.' At the bottom right, there is a small thumbnail of a software interface.



Oracle Help Center Release Notes and User Guides

ORACLE[®] Help Center

Industries

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Welcome Leyla

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Get Started

Videos

Books

Oracle Health Sciences ClearTrial Cloud Service

Books



Release Notes

Release Notes

Change Log



The Books tab is where you will find the Release Notes and User Guides.

ClearTrial Best Practice Reminders



- **Upgrade existing plans and user-defined templates** to the latest ClearTrial 5.8 cost model.
- **Lock plans** before sending out budgets and to prevent assumption values from being changed.
- **Freeze rates** in plans, anytime you are satisfied with your operational budget's forecast.

Benefits of Upgrading to the Latest ClearTrial Cost Model

- Upgrading plans and user-defined templates to the latest cost model will ensure you are working with the latest costing algorithms.

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

CLEAR TRIAL

Edit Report Maintain Ac

Plans

Filter

Show: All Plans

New

Plan Name
<input checked="" type="checkbox"/> KEYDAO DB007 N=
<input type="checkbox"/> KEYDAO 2018-Oct

Change Plan Attributes

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

Plan Name: KEYDAO DB007 N=300 V1.0

Status: Draft

Cost Model: 5.6

Custom Field Model: 5.7

Short Description: 5.5

Long Description: 5.3
patients with PD-L1 positive, advanced
stage lung cancer. DB007/
2018-Oct-15

Update last modified date and user (plan history)

A single modifiable plan is selected. You can change any of the attributes of this plan.

Please choose the cost model for the sele...

Close Save Save & Close Save & Edit

Oracle Help Center |

ations across pages

[Configure List Opt](#)

Last Modified

10/19/18 02:57 PM

10/19/18 02:53 PM

How to Evaluate the Latest Cost Model's Impact

You may want to review the 5.8 cost model updates to determine if you want to upgrade any existing plans.

1. From the Plan/Template List screen, select an existing plan/template and click **Copy**.
2. Click on **Other Actions...> Change Attributes**.
3. Change the Cost Model value to the **5.8 Cost Model** from the dropdown.
4. From the Plan/Template List screen, select the original plan/template and its copy and click **Compare** to run any of the Comparison reports between the two different cost models to quickly see the impact to the budget.

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



Edit Report Maintain Admin Help

Welcome, CT Administrator | Visit Oracle Help Center | Logout

Plans

2 plans are selected [clear](#)

Remember selections across pages [help](#)

Filter

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

[Configure List Options](#)

New

Edit

Delete

Restore

Copy

Compare

Other Actions...

<input checked="" type="checkbox"/>	Plan Name	Study Name	Description	Status	Cost Model	Compare Selected Plans	Last Modified
<input checked="" type="checkbox"/>	Copy - MK-3475 Australia, NZ, Japan ...	MK-3475 Japan PhIIB	600 total subjects	Draft	5.7	Administrator, CT	03/25/18 09:05 AM
<input checked="" type="checkbox"/>	MK-3475 Australia, NZ, Japan Rando...	MK-3475 Japan PhIIB	600 total subjects	Draft	5.3	Administrator, CT	03/25/18 09:04 AM

5.8 Feature Edition Impact

Feature	Standard Edition	Enterprise Edition
Clinical Intelligence Update	X	X
Improved Plan Reporting		X
Usability Enhancements*		X
RFP and Bids Comparison Enhancements (EE Sponsors)		X

* Some of these capabilities require direct action by users with the assigned “**ClearTrial System Administrator**” role before other users can benefit from the new functionality.

Clinical Intelligence Update

MOH/FDA Delays Update

MOH Delay default values by location have been reviewed and updated to be current with the latest regulatory changes per country.

Choose Locations

Filter

Show: Regions Countries

Region	Country	Primary Language	Primary Currency	MOH/FDA Delay
<input type="checkbox"/> USA, Canada, Australia/New Zealand				70
<input type="checkbox"/>	Australia	English	Australian Dollar	70
<input type="checkbox"/>	Canada	English	Canadian Dollar	150
<input type="checkbox"/>	New Zealand	English	New Zealand Dollar	45
<input type="checkbox"/>	Puerto Rico	Spanish	US Dollar	120
<input type="checkbox"/>	USA	English	US Dollar	30
<input type="checkbox"/> Western Europe & Japan				90
<input type="checkbox"/>	Austria	German	Euro	95

Close Ok

Default Cycle Times Update

Edit Plan

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

Biostatistics

Number of Unique Data Tables:

Number of Unique Data Listings:

Number of Unique Figures and Graphs:

Project Management

Number of newsletters:

Number of years to archive data:

Will there be an ICF Video/DVD?: Yes No

Number of online EDC training sessions:

Medical Writing / Timelines

Number of pages in the Investigator Brochure:

Number of manuscripts:

Days from LSO/LPO until Database Lock:

Days from Database Lock until Statistical Report due:

Database Lock date: 06/17/20

Stat Report date: 07/15/20

Days from Database Lock until Draft Report due:

Days from Database Lock until Final Report due:

Draft Report date: 08/12/20

Final Report date: 09/09/20

5.8 cost model plans include updated default cycle times by Phase, Data Collection Method and EDC Maturity Level

Cancel Save Next

Default Data Management & Data Entry Labor Update

New Plan 7.1 copied to 5.8 for A new Study 1 (STest Co
Phase III / Protocol ID: abc
Indication: Circulatory System / Hemorrhoids

This plan is using the 5.8 cost model

Welcome, QA Administrator | Visit Oracle Help Center | Logout

Current Edit Mode: Expert

5.8 cost model plans include reorganized and updated data management & data entry tasks to better separate and distinguish tasks that are not applicable when EDC is being used.

Renamed "CRF Page Entered into Database" to "Paper CRF Entry and Processing" Major Task

Assignment Group / Task	Assign to	Billing Rate Location	Pinned
Site Audit - Report Review by Mgmt	Major CRO	(Local)	
Major CRO	Major CRO	(Back Office) *	
Not Applicable	Not Applicable	Not Applicable	
Not Applicable	Not Applicable	Not Applicable	
Not Applicable	Not Applicable	Not Applicable	
Not Applicable	Not Applicable	Not Applicable	
Major CRO	Major CRO	(Local)	
Major CRO	Major CRO	(Local)	
Major CRO	Major CRO	(Back Office)	
Major CRO	Major CRO	(Back Office)	
Major CRO	Major CRO	(Back Office)	
Major CRO	Major CRO	(Back Office)	
Major CRO	Major CRO	(Back Office)	
Not Applicable	Not Applicable	Not Applicable	
Not Applicable	Not Applicable	Not Applicable	
Major CRO	Major CRO	(Back Office) *	

Improved Plan Reporting

Existing Capability to Exclude Plan Milestones

Enterprise Edition customers

The ability to exclude milestones already exists for **Enterprise Edition** customers. In this case, I have excluded the “Last Data Query Resolved” ClearTrial-defined milestone from my plan.

Edit Plan

Specify the payment schedule for each provider. Note that the amounts shown include

Filter
Show: excluded milestones

Set Payment Terms Edit Recurring Payments Add Milestone Exclude Milestone Include Milestone Exclude Milestone Delete Milestone

All monetary values are displayed in US Dollar (USD)

Milestone	Due Date	Major CRO		Total
<input type="checkbox"/> Last Subject/Patient In (LSI/LPI)	01/30/20	20.00 %	1,552,269	1,552,269
<input type="checkbox"/> Last Subject/Patient Observation (LSO/LPO)	05/20/20	15.00 %	1,164,202	1,164,202
<input type="checkbox"/> Last Data Query Resolved	05/30/20	0.00 %	0	0
<input type="checkbox"/> Database Lock	06/24/20	10.00 %	776,135	776,135
<input type="checkbox"/> Final Report	09/30/20	5.00 %	388,067	388,067
Budget Total		100.00 %	7,761,346	7,761,346

Close Save Next

Excluded Milestones are Excluded by Default in 5.8 Report



Edit Report Main

Edit Plan

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

Milestone Dates

Please choose the milestones to include in the report

Milestones To Include

<input type="checkbox"/>	All Milestones	Date	
<input checked="" type="checkbox"/>	Project Activity Start Date	02/01/19	
<input checked="" type="checkbox"/>	Investigator Meeting	04/19/19	
<input checked="" type="checkbox"/>	Drug Available to First Site	04/26/19	
<input checked="" type="checkbox"/>	First Site Approved	04/26/19	
<input checked="" type="checkbox"/>	First Subject/Patient In (FSI/FPI)	04/26/19	
<input checked="" type="checkbox"/>	Last Site Approved	05/02/19	6
<input checked="" type="checkbox"/>	Agreement on Statistical Analysis Plan	06/21/19	50
<input checked="" type="checkbox"/>	Last Subject/Patient In (LSI/LPI)	01/30/20	223
<input checked="" type="checkbox"/>	Last Subject/Patient Observation (LSO/LPO)	05/20/20	111
<input type="checkbox"/>	Last Data Query Resolved	05/30/20	10
<input checked="" type="checkbox"/>	Database Lock	06/24/20	25
<input checked="" type="checkbox"/>	Final Report	09/23/20	91

5.8 Milestone Dates report comes with a new input screen to select which plan milestones you would like to include or exclude from the report. Excluded milestones from the Plan Payments tab will be excluded by default. "Last Data Query Resolved" is already excluded when I click on the Milestone Dates report link from the Reports tab.

Close Ok



New Options on Milestone Payment Schedule Report

Enterprise Edition customers



Edit Report

Edit Plan

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

Milestone Payment Schedule

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

Providers To Include

- All Providers
- Medium CRO

New options to include / exclude milestones with zero amount and show/hide excluded plan milestones.

Level of Detail to Include

- Include Milestones With No Payment Amount
- Show Excluded Milestones

Group By

- Provider

Reporting Currency

Select the currency in which this report should be rendered.

- US Dollar (USD) Round values to the nearest US Dollar

Cancel

Ok

Usability/User Experience (UX) Enhancements*

Existing Capability to Create Custom Fields in Custom Assumption Models for Plans

For users assigned the Custom Fields Designer additional role/capability

The screenshot shows the CLEAR TRIAL application interface. The 'Maintain' menu is open, and 'Custom Fields' is highlighted. A red box highlights the 'Maintain > Custom Fields' path, and a callout box explains that this is used for creating custom assumption models.

Maintain > Custom Fields for Custom Fields Designers to create custom assumption models to use in plans

Study ID	Description	Status	Cost Model	Created By	Last Modified
008-3475 Japan PHIB	12 wk n=30 Japan only	RFP	5.8	Administrator, CT	11/04/18 01:42 PM
008-3475 Japan PHIB	12 wk n=30 Japan only	Draft	5.8	Administrator, CT	11/02/18 02:34 PM
01-3475 TAG Late Phase	12 week Phase III lupus eval...	Draft	5.8	Administrator, CT	11/02/18 02:34 PM
MK-3475 Australia, NZ, Japan Randomized DB ...	MK-3475 Japan PHIB	Draft	5.8	Administrator, CT	11/02/18 02:30 PM

Create Custom Field as a Boolean (Yes/No)

For users assigned the Custom Fields Designer additional role/capability

Create Custom Field

Field Definition

Name:

Data Type:

Label:

Prompt:

Help Text:

Values vary by location: Yes No

Yes/No Responses

Affirmative Response:

Negative Response:

Default Value: Yes No Use Formula

New ability to create a custom field as a Boolean and specify the affirmative and negative response (up to 8 chars max). E.g., Yes and No has been specified with No as the default for this custom field which I want to apply to plans.

Cancel

Save

Last Login Added as a Column to Add to the User List Screen

For assigned ClearTrial System Administrators

New Last Login column to choose from when clicking on Configure List Options link from the User List screen.

Configure List Options

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

Configure Columns

- Last Name
- First Name
- Primary Role
- Login Name
- Email Address
- Created Date
- Created By
- Last Modified
- Last Modified By
- Last Login

Sorting and Paging

Sort By: and then: and then:

Show: users per page

Buttons: Close, Ok

france	michelle	mdf2	06/21/18 09:54 AM	06/21/18 10:02 AM
--------	----------	------	-------------------	-------------------

Last Login Added as a Column to Add to the User List Screen

For assigned ClearTrial System Administrators



Administrator | Visit Oracle Help Center | Logout

Users

Filter

Show: All Users Active Users Only Users matching filter: Filter 60 [Modify](#) [Configure List Options](#)

New Edit Delete Restore Edit Password Clear Session Reset Account

Last Name	First Name	Login Name	Last Modified	Last Login
User	Test	testuser	03/10/16 06:10 PM	06/23/17 01:12 AM
majmudar	hemal	hemal-new	01/10/18 09:36 PM	01/10/18 09:36 PM
shah	hemal	hemal1	04/05/18 05:45 PM	04/05/18 06:53 PM
user	readonly	readonly_1	10/13/14 08:54 AM	04/25/18 01:29 PM

When Last Login is selected for display on the User List screen, you will see the new column of values.

Reminder: Click "Configure List Options" link from any list screen to select which column values to display



Existing Capability to Manage Your Profile & Preferences

Click on your name in the upper right hand corner of the menu bar to manage your profile and preferences



Edit Report Maintain Help

Welcome, [Aaron Rodgers](#) | Visit Oracle Help Center | Logou

Studies Manage your Profile and Preferences

Filter

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

New View Delete Restore Create Plan

Study Name ▲	Product/Compound	Phase	Therapeutic Area	Indication	Status
<input type="checkbox"/> 1.0 Demo Study for RFP	TestProduct	I Ib	Oncology	Acute Myelogenous Leukemia (AML)	Planning

User Profile Updates

Aaron Rodgers

Login Name:

Arodgers

Email Address:

Preferred Locale:

Primary Role:

Additional Roles/Capabilities:

- [Reporting Administrator](#)
- [RFP/Bid Editor](#)
- [Advanced Editor](#)
- [Export Editor](#)
- [Manager](#)
- [Notes](#)
- [export report data](#)

Click on Edit Profile to edit your user profile settings

Edit Profile

Change Password

Click this button to edit your profile information



User Profile Updates

Edit User

Profile

Roles

Login Name: administrator

First Name: CT

Last Name: Administrator

Email Address: administrator@oracle.com

Security Question: On what street was your first job located?

Security Answer: [Click here to update your security answer](#)

Preferred Edit Mode: Advanced

Preferred Home Page: Plan List

Preferred Locale: System Default

(Controls Date and Numeric Formats)

- Receive notifications about service updates
- Participate in customer surveys to improve the service

New options to manage your notifications in real time when you edit your user profile.

Power Users Now Have Option to Create Studies

Edit User

Profile

Roles

Roles for Leyla Badakhshanian

Primary Role:

Power User

can create studies

Additional Roles/Capabilities:

- Exchange Rates Administrator
- Resources Administrator
- Reporting Regions Ad
- Depa
- RFP A
- RFP/E
- Cust
- Adva
- Expe
- Wbs
- Wbs
- Can
- Can export report data
- Can access WS-API

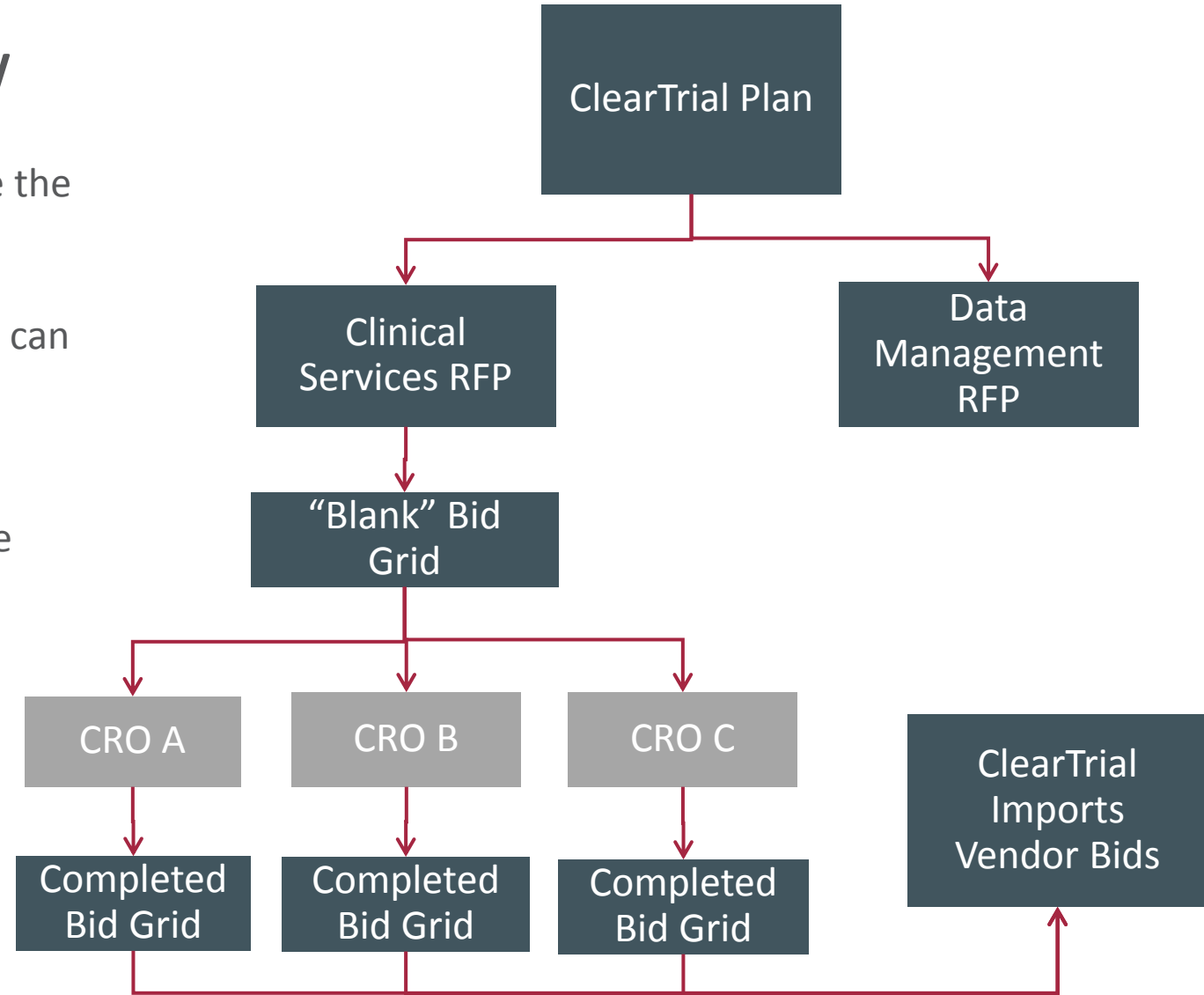
Create studies permission is now optional for Power Users. Existing users who have this role will have this capability, by default. Any new users who need the Power User role, will need to have the permission granted by their ClearTrial System Administrator.

RFP and Bids Comparison Enhancements

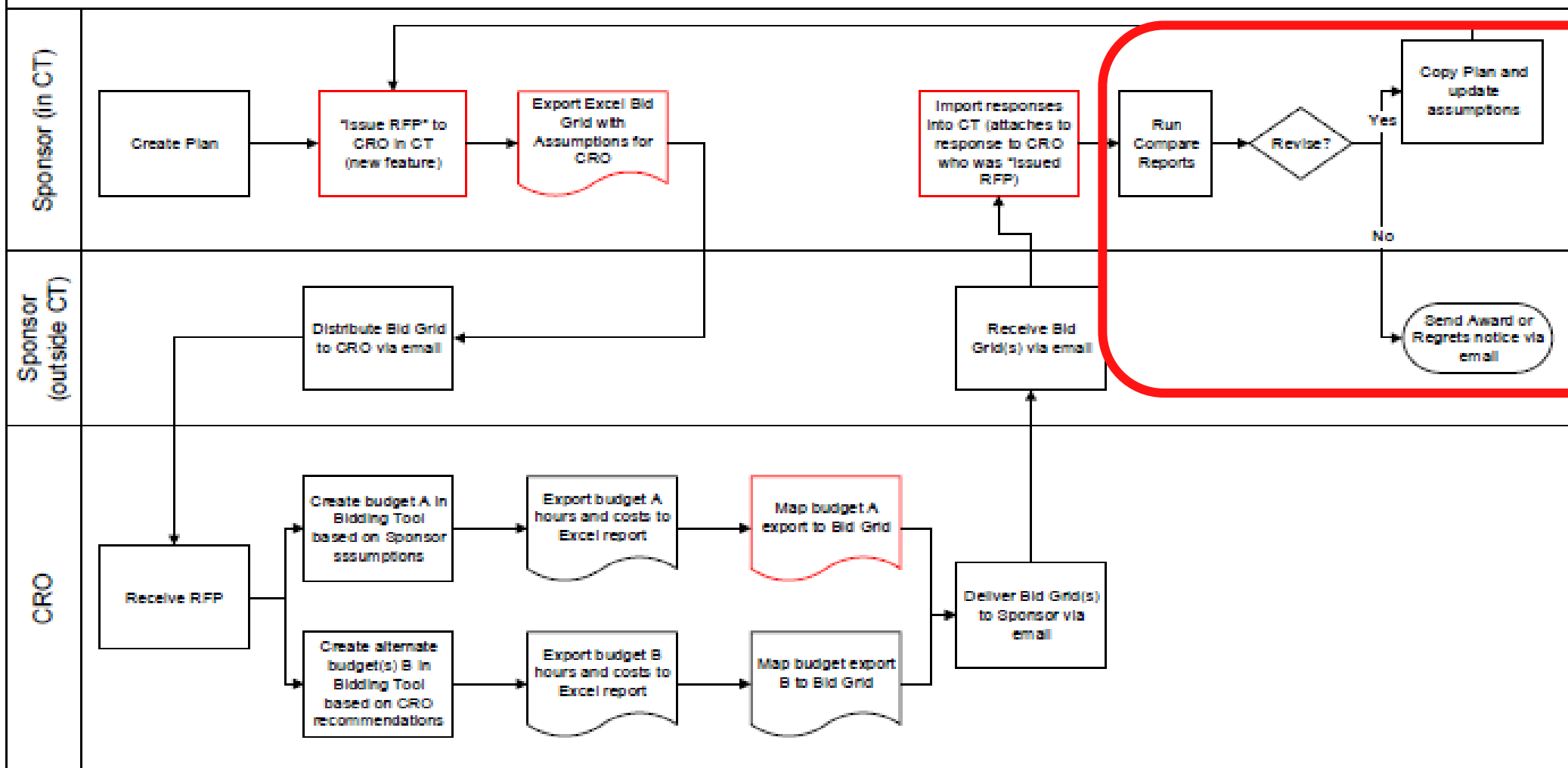
Enterprise Edition Sponsors Only

Recap of Process Overview

- 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



RFP & Revision Process using Excel Import



Required Permissions for RFPs and Bids Usage

Edit Report Maintain Admin Help

Welcome, CT Administrator | Visit Oracle Help Center

Edit User

Profile

Roles

Roles for Leyla Badakhshanian

Primary Role:

Clinical Administrator ▼

Additional Roles/Capabilities:

- Exchange Rates Administrator
- Resources Administrator
- Reporting Regions Administrator
- Departments/GL Codes Administrator
- RFP Administrator
- RFP/Bid Reader
- Custom Fields Designer
- Advanced Algorithm Editor
- Expert Algorithm Editor
- Wbs Editor
- Wbs Manager
- Can edit notes
- Can export report data
- Can access WS-API

Users granted the RFP Administrator additional role can create, edit and delete RFPs. Users granted the RFP/Bid Reader role can view RFPs and bids.

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

Select "Create RFP" option under "Other Actions..." menu on Plan List screen for a selected baseline/benchmark 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	
<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 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



Create an RFP from RFP List Screen

Oracle Application Menu: Edit, Report, Maintain, Admin, Help

Sub-menu: Plans, Studies, Products, Portfolios, **RFPs**, Bids

Page Header: Welcome, Leyla Badakhshanian | Visit Support Center | Log

Filter: ALL RFPs | Active RFPs Only | RFPs matching filter: My Filter

Buttons: 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



Choose Plan for RFP when Creating RFP on RFP List Screen

CLEAR T

Edit Report




RFPs

Filter

Show: ●

Choose Plan for RFP

Please select the plan from which you wish to generate an RFP. Click OK to Continue...

Plan Name ▲	Study Name	Phase	Indication	Status
<input type="radio"/> 01 Phase III Lupus	TAG Late Phase	III	Aneurysms	Draft
<input checked="" type="radio"/>  1.0 Demo RFP Plan v1.0	1.0 Demo Study for RFP	IIb	Acute Myelogenous Leukemia (AML)	RFP
<input checked="" type="radio"/>  1.0 Demo RFP Plan v2.0	1.0 Demo Study for RFP	IIb	Acute Myelogenous Leukemia (AML)	RFP
<input checked="" type="radio"/>  1.0 Final Plan for RFP_US Only for Sponsor Demo	TAG Late Phase	III	Aneurysms	Draft
<input type="radio"/> 1.0 Finalized RFP_US Only for Sponsor Demo	TAG Late Phase	III	Aneurysms	Draft
<input type="radio"/> 1.0 Finalized RFP_US Only for Sponsor Demo v2	TAG Late Phase	III	Aneurysms	Draft
<input type="radio"/> 5.5 AllAssumptionEnteredEDCNewplan	LAM-Test Query	III	Acne	Draft
<input type="radio"/> 5.5_PaperPlan_AllAssumptionsEntered	LAM_Cognizant demo study	III	Acne	Draft
<input type="radio"/> 5.5EDC_Defaults	LAM-Test STudy for IMS	II	Acne	Draft
<input type="radio"/> 5.5EDCPlan_AllAssum_Crossover	LAM_Cognizant demo study	III	Acne	Draft
<input type="radio"/> 5.5EDCPlan_AllAssum_Endpoint	LAM_Cognizant demo study	III	Acne	Draft
<input type="radio"/> 5.5EDCPlan_AllAssumptionsEntered	LAM_Cognizant demo study	III	Acne	Draft
<input type="radio"/> 5.5EDCPlan_AllAssumptionsEntered IVRS excluded	LAM_Cognizant demo study	III	Acne	Draft

Last Modified 11/1/18 5:16 PM By Kristin Ludwig (nca)

Page 1 | 2 | 3 of 3

Close Ok

Create RFP

Create RFP

Please choose the provider to which you assigned tasks and costs to represent the scope of work for the RFP.

Scope of Work / Assigned to Provider
Niche CRO

RFP Info

Bid Grid File Name: 2018-Nov-01 PharmaX Bid Grid

Short Description: Bid Grid for DM
(must be between 8 and 40 characters)

Comments: 2018-Nov-03 DM Bid Grid being sent to PPD, Parexel and ICON.

Bid Grid
 Download Bid Grid

Cancel Continue to download bid grid

Annotations:

- Enter in the file name for the Bid Grid, short description and comments to identify the RFP
- New option selected by default to Download Bid Grid

New Download Bid Grid Options

New dialog presented after creating RFP with set of options to choose from when generating the Bid Grid

Use the options below to control the format and contents of the bid grid you will submit to vendors.
You can choose from 3 levels of granularity for the activities to be performed and whether you want a separate sheet for each location or a single global sheet.
Additionally, you can select whether vendors will submit unit hours or total hours, unit costs or total costs, or if bidding at the lowest level of granularity, resource billing rates.

Bid Grid Detail

- Major Task / Cost
- Task
- Resource

Location Options

- Global
- Per Location

Vendor Editable Values

- Unit Hours
- Total Hours
- Unit Cost
- Total Cost
- Billing Rate

Include Additional Sheets

- Specifications
- Responsibilities Matrix
- Timelines

Launches help

Close Download

New options to generate the Bid Grid at various levels of granularity, global or by location, to indicate which values you want vendors to edit and to include default additional sheets in the Bid Grid workbook.

Generate the Default Bid Grid Workbook

Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Paste Clipboard Font Alignment Number Cells Editing

G2 [Please enter the Vendor name here]

	A	C	E	G	I
1					
2	Bid Grid			[Please enter the Vendor name here]	
3	Note: All monetary values should be entered in US Dollar (USD)				
4					
5	Labor Fees				
6		Global			0.00
7		Bottom Line Discount			0.00
8	Total Labor Fees				0.00
9					
10	Pass-through Costs				
11		Global			0.00
12					
13	Total Fees and Costs				0.00
14					
15					
16					

Instructions Specifications Responsibilities Matrix Timelines BidGrid! ...

Vendor enters their name on the Summary sheet.



Bid Grid Global Sheet

Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Clipboard Font Alignment Styles

A1

Bid Grid

Note: All monetary values should be entered in US Dollar (USD)

Cost Type	Location	Major Task / Cost	Mapping Key	Unit of Measure	# Units	Unit Hours	Total Hours	Unit Cost
Labor	Global	Project Initiated	00002	Study	1		0.000	
Labor	Global	Study Setup	00032	Study	1		0.000	
Labor	Global	Study Setup Per-Location	00031	Location(s)	3		0.000	
Labor	Global	Unique CRF Page Developed	00004	Unique CRF Pages	10			
Labor	Global	Meetings - Investigator Meeting	31712	Meetings	1			

Responsibilities Matrix | Timelines | BidGrid_Summary | **BidGrid_Global**

Editable mapping key to help vendors uniquely identify line items when mapping their internal budget values to your bid grid.

Vendor editable values specified when you generated the Bid Grid

Number of units is editable when you generate the Bid Grid by Major Task/Cost, globally or by location.

Review Default Instructions for Vendors

The screenshot shows the Microsoft Excel interface with the following elements:

- File Name:** Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel
- Menu Bar:** FILE, HOME, INSERT, PAGE LAYOUT, FORMULAS, DATA, REVIEW, VIEW
- Ribbon:** Font (Calibri, 10.5), Alignment (Wrap Text, Merge & Center), Number (General), Styles (Conditional Formatting, Format as Table), Editing.
- Formula Bar:** B3: This bid grid has been provided to you with a list of activities based on the sponsor's requirements. If you are proposing to perform
- Worksheet:** Bidder Instructions
- Text in Worksheet:**

This bid grid has been provided to you with a list of activities based on the sponsor's requirements. If you are proposing to perform activities that are not available in the grid, you c

 - a. Initiate a request to the sponsor for a grid with additional activities. (If the sponsor chooses to add the additional details to the Plan, the sponsor will provide you with a
 - b. Combine your internal budget items so they can be mapped into existing line items in this bid grid. (Use the comments column to describe any additional work that will

This Microsoft Excel workbook is password protected. Do not alter the workbook structure or format. If you alter the workbook, the sponsor might return your bid along with a lis

 - a. You may copy the worksheets into an unprotected working document to complete your bid mapping, reconciliation, and review activities, however...
 - b. You must submit your final version in this specific Excel file. This file contains hidden information that identifies it as belonging to this Plan and allows the bid to be impo

If you submit a different file or alter the structure, the sponsor cannot import and process it.

Upon import, the bid grid is validated and an error list may be generated based upon both structural and data validation criteria.

 - a. FATAL errors stop the import process and force the sponsor to return the bid grid to you for corrections prior to importing your data.
- Sheet Tabs:** Instructions (highlighted with a red box), Specifications, Responsibilities Matrix, Timelines, BidGrid_3 ...

Review default instructions included for vendors and if you would like to customize them, delete this worksheet and insert new.

Enter Your Contact Information on Specifications

The screenshot shows an Excel spreadsheet titled 'Pharma X Bid Grid 2018-Dec.xls'. The 'Specifications' section is highlighted in blue. Within this section, the 'Sponsor Contact Info' field is highlighted with a red box. A callout box points to this field with the following text:

Enter in your contact details, such as name, email, and phone, so the vendor can easily contact the key Sponsor personnel for the study, if they have any questions. If you have multiple contacts, you can enter them here also.

Assumption	Total	France	Switzerland	USA
Number of sites	150	50	50	50
Subjects to randomize	750	250	250	250
Number of sites identified by Sponsor	0	0	0	0

Specifications Display for Certain Assumptions

Total value of "--" represents certain assumptions where we are not doing a summation for its global value.

Assumption	Total	Iceland	Puerto Rico
Enrollment period	77 Weeks	77 Weeks	65 Weeks
Screen failure rate	--	9.09%	9.09%
Number of subjects to screen	366	122	244
Number of CRF pages per screen failure	0	0	0
Subject drop rate	--	1.00%	1.00%
Subjects expected to complete all study visits	330	110	220

Assumption	Total
Data Collection Method	Electronic Data Capture
Will this provider manage the CTMS?	No
Total expected data queries for all CRFs	4,378
Percent of database data to audit	10.00%

Responsibilities Matrix

Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Paste Clipboard Font Alignment Number Conditional Formatting

Quickly filter out only those assignments you are responsible for by clicking the drop down arrow

Task	Location	Sponsor Performing	Vendor Performing	Comments
12 Negotiate central laboratory	Centralized	X		
13 Design study documents	Centralized	X		
14 Review protocol	Centralized	X		
15 Write Investigator Brochure	Centralized	X		
16 Edit Investigator Brochure	Centralized	X		
17 Design the specific randomization system/schedule	Centralized			

Vendors have the flexibility to enter in any specific assumptions or comments for each assignment.

Instructions Specifications **Responsibilities Matrix** Timelines BidGrid_5 ...

Milestone Timelines

Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Paste Clipboard Font Alignment Number Editing

A1

Timelines

Milestone	Date	Days From Last	Comments
Project Activity Start Date	22-Feb-13	0	
First Site Approved	22-Mar-13	28	
Investigator Meeting	12-Apr-13	21	
Drug Available to First Site	14-Apr-13	2	
First Subject/Patient In (FSI/FPI)	19-Apr-13	5	
Last Subject/Patient Observation (LSO/LPO)	26-Jun-13	68	
Last Data Query Resolved	06-Jul-13	10	
Database Lock	07-Aug-13	32	

Instructions | Specifications | Responsibilities Matrix | **Timelines** | BidGrid_...

Timelines sheet shows the critical study milestone dates and the number of days from the last milestone.

Vendors have the flexibility to enter in any assumptions or comments for each milestone.

Vendor Completed Global Sheet

Pharma X Bid Grid 201

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Paste Clipboard Font Alignment

J6 : fx 8

A C E G I J K L

1

2 **Bid Grid** Agility Inc.

3 Note: All monetary values should be entered in US Dollar (USD)

4

5	Cost Type	Location	Major Task / Cost	Mapping Key	Unit of Measure	# Units	Unit Hours	Total Hours	Unit Cost
6	Labor	Global	Project Initiated	00002	Study	1	8.000	8.000	150.00
7	Labor	Global	Study Setup	00032	Study	1	8.000	8.000	120.00
8	Labor	Global	Study Setup Per-Location	00031	Location(s)	3	8.000	24.000	117.00
9	Labor	Global	Unique CRF Page Developed	00004	Unique CRF Pages	10	8.000	80.000	280.00
	Labor	Global	Meetings - Investigator Meeting	31712	Meetings	1	8.000	8.000	400.00

Responsibilities Matrix Timelines BidGrid_Summary **BidGrid_Global**

Vendor has provided the unit hours and unit cost and if they wanted, could also adjust the number of units per line item.

ClearTrial calculates the total hours and total cost columns when vendor enters in unit cost and unit hours.

Summary View After Vendor Enters Values Across the Sheets

Pharma X Bid Grid 2018-Dec.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Clipboard Font Alignment Number Styles

G8: =IF(ISERROR(G7+G6),G6,G7+G6)

	A	C	E	G
1				
2	Bid Grid			Agility Inc.
3	Note: All monetary values should be entered in US Dollar (USD)			
4				
5	Labor Fees			
6		Global		64,216,025.57
7		Bottom Line Discount		(5,000.00)
8	Total Labor Fees			64,211,025.57
9				
10	Pass-through Costs			
11		Global		0.00
12				
13	Total Fees and Costs			64,211,025.57
14				
15				
16				

Specifications | Responsibilities Matrix | Timelines | **BidGrid_Summary** | Bi ...

Vendor entered bottom line discount of \$-5,000.00

Import Vendor Submitted Bids into ClearTrial



Edit Report Maintain Admin Help

Home, CT Administrator | Visit Oracle Help Center | Logout

RFPs

1 RFP is selected

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

<input type="checkbox"/>	Plan Name ▲	Scope/Provider	Description	Number of Bids
<input type="checkbox"/>	1.0 Demo RFP Plan v1.0	Major CRO	RFP for Site Mgmt	2
<input type="checkbox"/>	1.0 Demo RFP Plan v2.0	Major CRO	Modified Sites/Locations and Treatments	1
<input type="checkbox"/>	1.0 Final Plan for RFP_US Only for Sponsor Demo	LAM CRO2	RFP for Protocol 12345	0
<input type="checkbox"/>	Initial DS1000 Planning	Premium CRO	DS1000 Bid	0
<input checked="" type="checkbox"/>	J08PPXY 2018-Oct V1.0	Niche CRO	Bid Grid for DM	0

With the RFP selected, click on Import Bid to import the vendor bid into ClearTrial to conduct comparison analyses.

Import Vendor Bids

Select the bid from your computer to upload. Enter in a short description, the CRO bid number and any other comments you want to capture such as CRO contact info for that specific bid.

Import a bid submitted by a vendor.

Vendor for this RFP:

Create a new version

Bid Information

Bid Grid File to Upload: Agility Bid for Pharma X.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

Plan Name	Number of Bids
1.0 Demo RFP Plan v1.0	2
1.0 Demo RFP Plan v2.0	1
1.0 Final Plan for RFP_US Only for Spon	0
Initial DS1000 Planning	0
J08PPXY 2018-Oct V1.0	0
LAM - baxter mapping	0
LAM-Region Tests for PFE	0
Plan used for RFP v2.0 (copy)	0
RFP report review	0

Compare All Bids for an RFP from the RFP List Screen

The screenshot shows the CLEAR TRIAL interface for RFPs. At the top left is the logo 'CLEAR TRIAL'. Below it is a navigation bar with 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. On the right, there is a user greeting 'Welcome, CT Administrator' and links for 'Visit Oracle Help Center' and 'Log out'. The main content area is titled 'RFPs' and includes a 'Filter' section with radio buttons for 'All RFPs', 'Active RFPs Only', and 'RFPs matching filter: My Filter'. Below the filter are buttons for 'New', 'Edit', 'Delete', 'Restore', 'Import Bid', 'Compare Bids', and 'Download Bid Grid'. The 'Compare Bids' button is highlighted with a red box. A callout box with a red border and pointer contains the text: 'To compare all bids for an RFP, select the RFP from the RFP list screen and click Compare Bids'. Below the buttons is a table with columns: 'Plan Name', 'Scope/Provider', 'Description', and 'Number of Bids'. The first row is selected and highlighted in yellow, showing '1.0 Demo RFP Plan v1.0', 'Major CRO', 'RFP for Site Mgmt', and '2'. A tooltip 'Compare Bids for the Selected RFP' is visible over the 'Compare Bids' button. A status bar at the top right indicates '1 RFP is selected' and 'Remember selections across pages'.

RFPs

Filter

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

<input type="checkbox"/>	Plan Name ▲	Scope/Provider	Description	Number of Bids
<input checked="" type="checkbox"/>	1.0 Demo RFP Plan v1.0	Major CRO	RFP for Site Mgmt	2
<input type="checkbox"/>	1.0 Demo RFP Plan v2.0	Major CRO	Modified Sites/Locations and Treatments	1

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

Compare Bids for the Selected RFP

Compare Bids from the Bid List Screen

Edit > Bids to get to the Bid List screen

To compare bids across multiple RFPs, or to compare a subset of the bids imported for an RFP, select the bids for comparison from the Bid list screen and click Compare.

The screenshot shows the Oracle Clear Trial interface. The 'Edit' menu is open, and the 'Bids' option is selected. The 'Compare' button in the action bar is highlighted. A table of bids is displayed below, with two rows selected. The table has the following columns: Plan Name, Scope, Vendor, Version, Description, Status, and Created Date.

	Plan Name	Scope	Vendor	Version	Description	Status	Created Date
<input checked="" type="checkbox"/>	1.0 Demo RFP Plan v2.0	Major CRO	CRO 1	1	CRO1's Revised Bid	Pending Review	11/02/18 01:47 PM
<input type="checkbox"/>	1.0 Demo RFP Plan v1.0	Major CRO	CRO 1	2	CRO 1 Bid	Pending Review	11/01/18 09:26 PM
<input checked="" type="checkbox"/>	1.0 Demo RFP Plan v1.0	Major CRO	CRO 2	1	CRO 2 Bid Submission	Pending Review	11/01/18 11:01 PM



Bid Comparison Options

Vendor Bid Comparison Options

Use the options below to configure the output of the report. Available options depend on the bids chosen. You can choose the level of granularity, which values to compare, and whether to highlight variances. For additional help, click any option group's heading or the help icon in the upper right corner.

Level of Comparison

- Major Task
- Task
- Resource

Location Options

- Global
- Per Location

Values to Compare

- Total Cost
- Total Hours
- Unit Cost
- Unit Hours
- Units

Variance Display

- Highlight total cost variances above %
- Highlight total hours variances above %

Baseline for Comparison

- Include Planned Values in comparison
- Use planned values as baseline
- Use selected bid as baseline

Name	
<input type="radio"/>	1.0 Demo RFP Plan v1.0 CRO 1
<input type="radio"/>	1.0 Demo RFP Plan v1.0 CRO 2

Cancel Ok

Callouts:

- Select total cost, total hours in addition to the default values selected to compare.
- Launches help
- In this example, I have chosen to compare two bids against the benchmark's planned values, where planned values is the baseline for comparison.
- Highlight total cost and hours variances above a user-defined threshold.

RfpBidCompareReport (2).xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Paste Font Alignment Number Styles Cells Editing

A1

Bid Comparison

Currency: US Dollar

Report generated: 06-Nov-2018

1.0 Demo RFP Plan v1.0 for 1.0 Demo Study for RFP

Chronic Myelogenous Leukemia (AML)

Highlighted values have total hours var

Highlighted values have total cost var

Compare the bids for a specific RFP to the ClearTrial benchmark's planned values

Included Bid mapping table to identify Bid 1 and Bid 2 by Plan Name, Vendor Name, and Bid Description

Bid Name	Plan Name	Vendor Name	Version	Bid Description
Bid 1	1.0 Demo RFP Plan v1.0	CRO 1	2	CRO 1 Bid
Bid 2	1.0 Demo RFP Plan v1.0	CRO 2	1	CRO 2 Bid Submission

Cost Type	Major Task / Cost	Unit Of Measure	Planned Values	Bid 1	Bid 2
Labor	Project Initiated	Study	Units	1	1
			Total Hours	84.391	77.000
					93.000

BidComparisonReport



RfpBidCompareReport (2).xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Normal Page Break Preview Page Layout Views Custom Views

Ruler Formula Bar Gridlines Headings

Zoom 100% Zoom to Selection

New Window Arrange All

Freeze Panes

- Split
- View Side by Side
- Synchronous Scrolling
- Reset Window Position
- Switch Windows
- Macros

Freeze Panes

- Keep rows and columns visible while the rest of the worksheet scrolls (based on current selection).
- Freeze Top Row: Keep the top row visible while scrolling through the rest of the worksheet.
- Freeze First Column: Keep the first column visible while scrolling through the rest of the worksheet.

A16

	A	B	C	D	E	F	
13		Bid 2		1.0 Demo RFP Plan v1.0		CRO 2	
14							
15			Cost Type	Major Task / Cost	Unit Of Measure		
16		Labor	Project Initiated	Study	Units	1	1
17					Total Hours	84.391	77.000
18					Total Cost	19,446.10	20,000.00
19			dy Setup	Study	Units	1	1
20					Total Hours	60.415	66.000
21						18,269.76	18,500.00
22						2	2
23						130.000	170.000
24						21,965.76	22,860.00
25						70	70

Bid 2

BidComparisonReport

Select the row after the column headers for the bids, go to (Excel) View > Window Options> Freeze panes to freeze the headers when you scroll down

Bid Comparison Options

Vendor Bid Comparison Options

Use the options below to configure the output of the report. Available options depend on the bids chosen. You can choose the level of granularity, which values to compare, and whether to highlight differences. For additional help, click any option group's heading or the help icon in the upper right corner.

Level of Comparison

- Major Task
- Task
- Resource

Location

- Global
- Per Location

Values to Compare

- Total Cost
- Total Hours
- Unit Cost
- Unit Hours
- Units

Variance Display

- Highlight total cost variances above %
- Highlight total hours variances above %

Baseline for Comparison

- Include Planned Values in comparison
- Use planned values as baseline
- Use selected bid as baseline

Name	Total	Created Date
<input type="radio"/> 1.0 Demo RFP Plan v1.0 CRO 1 Version 2 8,489,729 USD CRO 1 Bid		11/01/18 09:26 PM
<input checked="" type="radio"/> 1.0 Demo RFP Plan v1.0 CRO 2 Version 1 9,781,537 USD CRO 2 Bid Submission		11/01/18 11:01 PM

Check this box to highlight total hours variances outside the specified range

I want to drill down further and compare unit cost and unit hours in addition to the other values at the task level and I want to see cost variances highlighted outside of 25% tolerance this time.

In this example, I have chosen to compare bid v2.0 against bid v1.0, and not include the benchmark in the comparison.

RfpBidCompareReport.xls [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW

Normal Page Break Preview Workbook Views Ruler Gridlines Show Formula Bar Headings Zoom 100% Zoom to Selection New Window Arrange All Freeze Panes Unhide Split Hide Reset Window Position View Side by Side Synchronous Scrolling Switch Windows Macros

F12 : X ✓ fx CRO 2

Highlighted values have total cost variance greater than 25%

Bid Name	Plan Name	Bid Version	Bid Description
Bid 1	1.0 Demo RFP Plan v1.0	1	CRO 2 Bid Submission
Bid 2	1.0 Demo RFP Plan v1.0	2	CRO 1 Bid

I can quickly see that for the Pre-study site visit – Preparation task, Bid 2 is higher by the cost tolerance of 25% and as suspected, above the 10% hours tolerance I specified.

Cost Type	Major Task / Cost	Task	Unit Of Measure		Bid 1	Bid 2
	Pre-study Site Visit	Pre-study site visit - Preparation	Visits	Units	77	77
				Unit Hours	1,000	2,000
				Unit Cost	199.00	299.00
				Total Hours	77,000	154,000
				Total Cost	14,630.00	23,023.00
	Pre-study site visit - Travel	Visits	Units		77	77

BidComparisonReport

Edit RFP Details to Update RFP Information after Creation

Edit Report Maintain Admin Help

Edit RFP

- Details
- Labor
- Costs
- Bids

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

RFP Information

Bid Grid File Name:

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

Comments:

History

Created By:	Ludwig, Kristin	Last Modified By:	Administrator, CT
Created Date:	11/1/18 5:16 PM	Last Modified:	11/5/18 1:31 PM

[Download Bid Grid](#)

Close Save Next

Change the RFP details any time after the RFP has been created, From Edit > RFP > Details



Plans with RFPs have their status set to RFP



Edit Report Maintain Admin Help Welcome, CT Administrator | Visit Oracle Help Center | Logout

Plans

Filter

Show: All Plans Active Plans Only Plans matching filter: TAG [Modify](#) [Configure List Options](#)

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

Plan Name	Study Name	Description	Status	Cost Model	Created By	Last Modified
<input type="checkbox"/> J08PPXY 2018-Oct V1.0	MK-3475 Japan PhiIB	12 wk n=30 Japan only	RFP	5.8	Administrator, CT	11/04/18 01:42 PM
<input type="checkbox"/> J08PPXY 2018-Oct V2.0	MK-3475 Japan PhiIB	12 wk n=30 Japan only	Draft	5.8	Administrator, CT	11/02/18 02:34 PM
<input type="checkbox"/> 01 Phase III Lupus	TAG Late Phase	12 week Phase III lupus eval...	Draft	5.8	Administrator, CT	11/02/18 02:34 PM
<input type="checkbox"/> MK-3475 Australia, NZ, Japan Randomized DB ...	MK-3475 Japan PhiIB	600 total subjects	Draft		Administrator, CT	11/02/18 02:30 PM

In addition to being permanently locked, plans used to create RFPs from will have their status set to RFP so you can easily filter them out.

Benefits of using ClearTrial for your RFP/Vendor Selection Process

- Enables your vendors to be more responsive with ballpark estimates
- Enables your vendors to respond more quickly
- Provides increased transparency into the study assumptions, staffing and costs in a proposed approach
- Low impact to existing operations

Integrated Cloud

Applications & Platform Services