

Introduction to Oracle ClearTrial 5.6

Customer Briefing

ClearTrial Product Management
Health Sciences Global Business Unit
June, 2017

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 Reminder of ClearTrial Best Practices
- 3 List of Primary Features by Edition
- 4 Walk-through of the Main Enhancements

ClearTrial 5.6 Overview

- Release Objectives: ClearTrial 5.6 offers new and enhanced capabilities for
 - continued **precision planning and budgeting**
 - increased **configurability/flexibility**
 - increased **usability (ease-of-use)**
- **New Cost Model Available for 5.6**
- Release Approach: Market and Customer Driven

ClearTrial Best Practice Reminders

- Internally **review the 5.6 cost model updates** to determine if you want to upgrade any existing plans.
 - From the Plan List screen, **copy any existing plan**.
 - Select the copy and from “**Other Actions...**” > “**Change Attributes**” to update the cost model.
 - Run the **Compare Plans report** between the two plans with different cost models to quickly view the new cost model’s impact.
- **Lock plans** to prevent other users from changing assumptions entered.
- **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/templates to the latest cost model will ensure you are working with the latest updates to fees and costs included in both ClearTrial Work Breakdown Structures and indirect (pass-through/miscellaneous) cost calculations.

5.6 Feature Edition Impact

Feature	Standard Edition	Enterprise Edition
Responsibility/Task/Assignment Groups Update	X	X
Import Location-specific Data from any Plan/Template	X	X
Model Site Approval, Subject Enrollment, Tx Duration in Days	X	X
Calculated Dates Display	X	X
New Compare to Original (Template) Report	X	X
Usability/UX Enhancements	X	X
Rename, Reorder, and Regroup Tasks		X
Copy User-Defined Tasks		X
Web Services API Update		X

Responsibilities/Task/Assignment Groups Update

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

Percent of regulatory documents collected:	<input type="text" value="100"/>	%
Percent of sites using BOTH a central and a local IRB/EC:	<input type="text" value="0"/>	%
Percent of sites using ONLY a central IRB/EC:	<input type="text" value="100"/>	%
Percent of sites using ONLY a local IRB/EC:	<input type="text" value="0"/>	%

CT-defined “Responsibilities” also known as **Task Groups/“Assignment Groups”** and the tasks under each group have been updated by default for both early and late stage WBS’s in 5.6 cost model plans.

Responsibilities	Sponsor			N/A
Site Startup:	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Investigator Brochure:	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Site Identification:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Collect Regulatory Documents:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Site Initiation:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Drug Packaging and Supply:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Project Management:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Site Monitoring/Management:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality Assurance:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Responsibilities/Task/Assignment Groups Update Cont'd

Overview	Protocol Preparation:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Locations	Default assignments for 5.6 cost model plans will be different than those using a prior cost model.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Site		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subject		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Treatment		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data	Medical Management:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Monitoring	Safety/Pharmacovigilance	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Provider	Draft Report:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Meetings	Final Report (CSR):	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assignment	Data Management:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labor	Data Entry:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Costs	Biostatistics:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Payments	Stat Report:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Summary	Annual IND Reporting:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reports	EDC Help Desk:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	EDC Training:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	DSMB:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Assignment Groups Update Summary

Phase I (Healthy Volunteers) WBS

5.5 Task Group Name	5.6 Task Group Name	Details
N/A	Site Startup	New
N/A	Safety/Pharmacovigilance	New
Site Auditing	Quality Assurance	Update
IVRS	IVRS/Randomization	Update
N/A	DSMB	New

Tasks per Task Group have been updated in 5.6 cost model plans.

Assignment Groups Update Summary

Late-Stage WBS

5.5 Task Group Name	5.6 Task Group Name	Details
N/A	Site Startup	New
N/A	Medical Management	New
Safety and Medical Management	Safety/Pharmacovigilance	Update
Site Auditing	Quality Assurance	Update
IVRS	IVRS/Randomization	Update
N/A	DSMB	New

Tasks per Task Group have been updated for 5.6 cost model plans.

New Customer Preference Available for assigned ClearTrial System Administrators

As a reminder, the Admin menu is accessible to those users who are assigned the **ClearTrial System Administrator** role only.

The screenshot shows the ClearTrial Admin interface. The top navigation bar includes 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. The 'Admin' menu is highlighted, and a dropdown menu is open showing 'Users' and 'Customer Preferences'. The 'Customer Preferences' option is selected. The main content area is titled 'Edit Customer P' and contains the following configuration fields:

- Default Language:
- Default Currency:
- Number of future years users can create billing rate cards for vendors:
- Number of days deleted items are kept and can be restored before being purged:
- Hide the ClearTrial Default System Template (when there are user-defined templates):
- Prohibit use of the ClearTrial Default System Template (when there are user-defined templates):
- Allow user to choose a plan or template from which to pull location-specific data when adding locations to a plan:

Launched from the **Admin** menu, select **Customer Preferences** to enable/disable this new preference.

Choose "True" to enable this feature for your users.

Import Location-specific Overrides From Template/Plan

Choose Locations

Filter

Show: Regions Countries

Region	Country
<input type="checkbox"/> USA, Canada, Australia/New Zealand	
<input type="checkbox"/>	Canada
<input checked="" type="checkbox"/>	New Zealand
<input type="checkbox"/>	Puerto Rico
<input type="checkbox"/>	USA

Choose the template or plan from which to import location-specific overrides

Filter

Show: Templates Plans with names like:

Name	Phase	Cost Model	Custom Field Model	Last Modified
<input type="radio"/> 00000 NZ US AUS	Phase II	5.6	(None)	5/23/17 4:07 PM
<input type="radio"/> 00000 US CAN NZ	Phase II	5.6	(None)	5/23/17 4:09 PM
<input type="radio"/> 00001 NZ US	Phase II	5.6	(None)	5/23/17 3:52 PM
<input checked="" type="radio"/> 00002 NZ US	Phase II	5.6	(None)	5/23/17 4:06 PM

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Cancel Ok

When you add a location to a plan (NZ), you have the capability to choose the template/plan from which to import the location-specific overrides from below.

E.g., When I add NZ to my plan, I will be able to select from a configurable filtered list of plans/templates which have NZ-specific overrides to import into your current plan.

When and why would I leverage this capability?

- When you want location-specific overrides from another plan or template to be pulled into the current plan, when you add a location to your plan.
- Offers a quick and easy way to have the same location-specific overrides exist in multiple plans/templates.
- Eliminates the time required in having to redundantly re-recreate the same location-specific overrides across your plans/templates which include that location.

What kinds of overrides will be imported/pulled in?

Depending on if the source and destination plan/template matches, the following overrides will be imported into your current plan; e.g., When I add NZ to my plan, I want to pull in the overrides I made for NZ's...

- Custom Fields
- Location data (MOH Delay, Ave Grant Amount)
- Site Information (Number of sites, ...etc)
- Subject data (Screening, Drops)
- Task Assignments
- Task-Resource Department/GL Code ...

What kinds of overrides will be imported/pulled in? Cont'd

- Task-Resource Algorithms
- Task-Resource Billing Rate Location
- Task-Resource Rate Overrides
- Task-Resource Unit Hours
- Indirect Cost Assignments
- Indirect Cost Departments/GL Codes
- Indirect Cost Adjustments
- Indirect Cost Algorithms
- Meetings
- Resource Assignments (made in the Override Resources and Rates dialog)

New Ability to Model Site Approval Period in Days

For late-stage plans, as Phase I (HV) plans already use days

Edit Site Approval Schedule

Site Approval Schedule for Japan

Site Approval Schedule: ClearTrial Default

Default Site Approval Period: 14 weeks

Additional Site Approval Period: weeks

Total Site Approval Period: 14 weeks

[SWITCH TO DAYS](#)

Site Approval Schedule

Week #	Week Of	Sites		User Defined	%
1	05/05/15	0 (0)		(0)	0.00
2	05/12/15	0 (0)		(0)	0.00
3	05/19/15	1 (1)		(0)	0.00
4	05/26/15	1 (2)		(0)	0.00
5	06/02/15	1 (3)		(0)	0.00
6	06/09/15	1 (4)	5.00	(0)	0.00
7	06/16/15	2 (6)	10.00	(0)	0.00
8	06/23/15	3 (9)	15.00	(0)	0.00
9	06/30/15	2 (11)	10.00	(0)	0.00
Total		20	100.00	0	0.00 %

Capability to Revert Back/Switch to Weeks

Edit Site Approval Schedule

Site Approval Schedule for Japan

Site Approval Schedule: ClearTrial Default Restore Defaults

Default Site Approval Period: 98 days

Additional Site Approval Period: days Apply

Total Site Approval Period: 98 days

[SWITCH TO WEEKS](#)

Site Approval Schedule

Day #	Date	Sites	Default	Defined	%
1	05/09/15	0 (0)		(0)	0.00
2	05/10/15	0 (0)		(0)	0.00
3	05/11/15	0 (0)		(0)	0.00
4	05/12/15	0 (0)		(0)	0.00
5	05/13/15	0 (0)		(0)	0.00
6	05/14/15	0 (0)	0.00	(0)	0.00
7	05/15/15	0 (0)	0.00	(0)	0.00
8	05/16/15	0 (0)	0.00	(0)	0.00
9	05/17/15	0 (0)	0.00	(0)	0.00
Total		20	100.00	0	0.00 %

Copy Default Values

Click this link to revert/switch back to modeling in weeks.

New Ability to Model Subject Enrollment in Days

For late-stage plans, as Phase I (HV) plans already use days

Edit Plan

Notes

Overview
Locations
Site
Subject
Treatment
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Specify the enrollment periods for this study Current Edit Mode: Advanced ▼

Define the Enrollment Period

Project Activity Start Date: 3/10/15

First subject enrolled date (FSI/FPI): 7/21/15

Enrollment period: 6 weeks weeks days

Last subject enrolled date (LSI/LPI): 10/31/16

Last subject out date (LSO/LPO): 9/30/17

Enrollment rate: 0.69 subjects per site per month

Manage location-specific values: Globally Per Location...

Define the Enrollment Distribution

Type of enrollment distribution: Chronic

Quartile 1:	28.0 %
Quartile 2:	36.0 %
Quartile 3:	26.0 %
Quartile 4:	10.0 %

Manage location-specific values: Globally Per Location...

You will see a new dropdown which provides you the flexibility and option to **model enrollment in days.**

New Ability to Model Treatment Duration in Days

For late-stage plans, as Phase I (HV) plans already use days

Edit Plan

Notes

Overview

Locations

Site

Subject

Treatment

Data

Monitoring

Provider

Meetings

Assignment

Labor

Costs

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Reports

Specify subject treatments

Current Edit Mode: **Advanced**

Study Characteristics

Trial Design: Parallel Cross-over

Will there be an electronic subject diary?: Yes No

Is this an endpoint study?: Yes No

Last subject out date (LSO/LPO): 9/30/18

Treatment(s)

Add

Edit

Copy

Delete

ID	Treatment Parameters		
<input checked="" type="checkbox"/> A	Number of subjects: 300	Treatment duration: 10 weeks	Visits per subject: 90
	CRF pages per subject: 100	Subject diary pages: 0	QOL pages: 0
	Lab and diagnostic tests per subject: 0	Pharmacoeconomic pages: 0	Cohort escalation reviews: 0

You will see a new dropdown which provides you the flexibility and option to **model Treatment duration in days.**

FSA Date Display on Locations Tab

Edit Plan

Notes

Location	Sites	Subjects	Avg Grant Amount	MOH/FDA Delay	FSA Date
<input type="checkbox"/> Greece	<input type="text" value="10"/>	<input type="text" value="100"/>	<input type="text" value="100.00"/> USD	<input type="text" value="120"/>	07/28/15
<input type="checkbox"/> Japan	<input type="text" value="20"/>	<input type="text" value="200"/>	<input type="text" value="20.00"/> USD	<input type="text" value="60"/>	05/25/15

For 2 location(s), Total/Avg: 30 30 90

Language	Dialects/Variations	Document Translations
<input type="checkbox"/> Greek	<input type="text" value="1"/>	<input type="radio"/> All Documents <input checked="" type="radio"/> No Documents <input type="radio"/> Specified Documents
<input type="checkbox"/> Japanese	<input type="text" value="1"/>	<input type="radio"/> All Documents <input checked="" type="radio"/> No Documents <input type="radio"/> Specified Documents

Expected First Site Approved Date is displayed to help when you are overriding the MOH Delay default per location.



LSI, LSO Dates Display on Subject Tab

Edit Plan

Notes

Specify the enrollment periods for this study Current Edit Mode: **Advanced**

Define the Enrollment Period

Project Activity Start Date: 3/10/15

First subject enrolled date (FSI/FPI): 7/21/15

Enrollment period: 72 weeks

Last subject enrolled date (LSI/LPI): 12/4/16

Last subject out date (LSO/LPO): 12/4/16

Enrollment rate: 0.64 subjects

Manage location-specific values: Globally Per Location...

Define the Enrollment Distribution

Type of enrollment distribution: Chronic

Quartile 1:	28.0 %
Quartile 2:	36.0 %
Quartile 3:	26.0 %
Quartile 4:	10.0 %

Manage location-specific values: Globally Per Location...

When you enter/edit the enrollment period, you will see the **Last Subject In** and **Last Subject Out Dates** displayed.

LSO Date Display

Edit Plan

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Specify subject treatments Notes

Current Edit Mode: Advanced

Study Characteristics

Trial Design: Parallel Cross-over

Will there be an electronic subject diary?: Yes No

Is this an endpoint study?: Yes No

Last subject out date (LSO/LPO): 11/6/16

Treatment Parameters

Treatment duration:	<input type="text" value="1"/> weeks	Visits per subject:	<input type="text" value="2"/>
CRF pages per subject:	<input type="text" value="100"/>	QOL pages:	<input type="text" value="0"/>
Subject diary pages:	<input type="text" value="0"/>	Pharmacoeconomic pages:	<input type="text" value="0"/>
Lab and diagnostic tests per subject:	<input type="text" value="0"/>	Cohort escalation reviews:	<input type="text" value="0"/>

Last Subject Out Date is also displayed on the Treatment Tab and will dynamically update when you are defining your treatment arm below.



Milestone Dates Display on Data Tab

Edit Plan

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Number of Unique Data Listings: <input type="text" value="15"/>		Number of Repeat Data Listings: <input type="text" value="15"/>	
Number of Unique Figures and Graphs: <input type="text" value="8"/>		Number of Repeat Figures and Graphs: <input type="text" value="4"/>	
Project Management			
Number of newsletters: <input type="text" value="0"/>		Will there be an ICF Video/DVD?: <input type="radio"/> Yes <input checked="" type="radio"/> No	
Number of years to archive data: <input type="text" value="10"/>		Number of online EDC training sessions: <input type="text" value="3"/>	
Medical Writing / Timelines			
Number of pages in the Investigator Brochure: <input type="text" value="125"/>		Number of manuscripts: <input type="text" value="0"/>	
Days from LSO/LPO until Database Lock: <input type="text" value="12"/>		Days from Database Lock until Statistical Report due: <input type="text" value="36"/>	
Database Lock date: <input type="text" value="11/12/16"/>		Stat Report date: <input type="text" value="12/18/16"/>	
Days from Database Lock until Draft Report due: <input type="text" value="67"/>		Days from Database Lock until Final Report due: <input type="text" value="90"/>	
Draft Report date: <input type="text" value="01/18/17"/>		Final Report date: <input type="text" value="02/10/17"/>	

Milestone Dates are now displayed on the Data Tab, as you configure the time between milestones assumptions.



Number of Weeks Display per Major Task

Task Manager

Task Search...

- Study Setup
- Study Setup Per-Location
- A Written Protocol
- Protocol Amendment
- Protocol Amendment per L
- Unique CRF Page Develop
- CRF Book Printed
- Meetings - Kickoff Meeting
- Meetings - Investigator Me
- Meetings - Face to Face Me
- Meetings - Status Update t
- Meetings - Internal Team M
- Site Identified by Sponsor
- Site Identified by Vendor
- Pre-study Site Visit (PSSV)
- Pre-study Site Visit (PSSV)
- Site Approved
- Site Initiation Visit
- Site Initiation Visit by Phor
- Drug Packaging and Suppl
- Study Drug Shipment Trac
- Completed Statistics & Ana
- Database Designed
- Data Entry Screen Develop
- IVRS Setup
- Subject/Volunteer Random
- Project Management Week
- Project Management Week
- SAE Processed
- Finalized Safety Report C

Study Setup

Major Task Details | Adjustments | **Distribution**

Distribute completed units of work according to: A System Calculated Distribution ▼

Service Provider: CT Product Review | Location: All Locations

Start: 3/10/15 | End: 7/21/15 | 19 Weeks

Period	Percentage
Week of 03/09/15	5 %
Week of 03/16/15	
Week of 03/23/15	
Week of 03/30/15	
Week of 04/06/15	
Week of 04/13/15	
Week of 04/20/15	
Week of 04/27/15	
Week of 05/04/15	
Week of 05/11/15	
Week of 05/18/15	
Week of 05/25/15	
Total:	

Number of weeks between start and end date for a Major Task is displayed on the Distribution tab of Task Manager.

Number of Sites Display on Monitoring Tab

Edit Plan

Specify information regarding monitoring for this study Current Edit Mode: **Advanced**

Monitoring Methods

Monitoring will be performed: on-site via phone Manage monitoring schedule values: Globally Per Location...

On-Site Monitoring Schedule

Number of Sites: until LSO/

Monitor every: weeks

Total visits:

Monitoring Approach

Percentage of time monitors spend in the field: %

Percentage of monitoring done by CRAs (vs. Senior CRAs): %

Percentage of monitoring done by Regional Monitors: %

Avg travel time (in hours) for site monitors:

Percent of source document verification:

Time to review queries from previous visit (minutes):

Manage location-specific values: [Edit location-specific overrides](#)

Total Number of Sites in your plan is now displayed on the Monitoring tab.

Usability Enhancements

Treatment Duration < 2 Weeks, Subject Visits Can Be Greater than Treatment Duration

Edit Plan

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Specify subject treatments

Current Edit Mode: Advanced

Study Characteristics

Trial Design: Parallel Cross-over

Will there be an electronic subject diary?: Yes No

Is this an endpoint study?: Yes No

Last subject out date (LSO/LPO): 11/6/16

Treatment(s)

Add

Edit

Copy

Delete

ID	Treatment Parameters		
<input checked="" type="checkbox"/> A	Number of subjects: 300	Treatment duration: <input type="text" value="1"/> weeks	Visits per subject: <input type="text" value="2"/>
	CRF pages per subject: <input type="text" value="100"/>	Subject diary pages: <input type="text"/>	QOL pages: <input type="text" value="0"/>
	Lab and diagnostic tests per subject: <input type="text"/>	Pharmacoeconomic pages: <input type="text"/>	Cohort escalation reviews: <input type="text"/>

You can define treatment duration < 2 weeks.

Subject Visits can now be greater than Treatment Duration.

Specify Less Than 1 Minute for Monitoring Time on Treatment Schedule

The screenshot shows the 'Edit Treatment A' window with the 'Schedule' tab selected. The 'Subject Treatment Schedule' table is displayed with the following data:

Week	Number of CRF Pages	Monitoring Time (minutes)	Percent of Grant
Baseline Visit	50	0.1	50 %
1	50	0.25	%

A callout box points to the '0.1' value in the 'Monitoring Time' column for the 'Baseline Visit' row, stating: "You can now specify an amount less than 1 minute (≥ 0.1) for monitoring simple pages per treatment arm schedule."

Summary statistics at the bottom of the table:

- Total number of CRF pages: 100
- Total visits per subject: 2 %

Additional text at the bottom: "Displaying weeks 1 to 1 of 1" and links for "Clear CRF Defaults", "Restore CRF Defaults", and "Clear Grant Overrides".

Show or Hide Excluded Meetings on Meetings Tab

Edit Plan

Configure meetings for this study Current Edit Mode: **Advanced** ▼

Filter: Show: excluded meetings

Meetings Display or hide excluded meetings

Add Edit Copy Include Exclude Delete

<input type="checkbox"/>	Name	Type	
<input type="checkbox"/>	Kickoff Meeting	Kickoff	
<input type="checkbox"/>	Investigator Meeting	Investigator	USA
<input type="checkbox"/>	Face to Face Meeting	Face to Face	USA
<input type="checkbox"/>	Status Update to Sponsor	Teleconference	USA

New filter option to hide or Show excluded meetings in the Meetings list below.

Show Number of Meetings Selected on Meetings Tab

Edit Plan

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Configure meetings for this study

Filter _____

Show: excluded meetings

Notes

Current Edit Mode: Advanced

Meetings

3 meetings are selected [clear](#)

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

New **indicator** displayed so you can see **how many meetings are selected** in the list.

Sort Meeting Attendees by Double-Clicking Column Headers

Kickoff Meeting

Meeting Details | **Attendees** | Site Attendees | Notes

Service Provider: CT Product Review

Provider Attendees

Add Delete Duplicate Expand All Billable Hours

Attendees	Resource Type	Billing Rate Location	Attendance Method	Billable Hours	Indirect Costs
<input type="checkbox"/>	1 DS01 - Medical Monitor <small>System Managed</small>	USA	No Travel	9.500 Edit	Other: 0.00 USD Travel: 0.00 USD Other: 0.00 USD
<input type="checkbox"/>	1 DM03 - Data Manager <small>System Managed</small>				Travel: 0.00 USD Other: 0.00 USD
<input type="checkbox"/>	1 CR06 - Project Manager <small>System Managed</small>	USA			Travel: 0.00 USD Other: 0.00 USD
<input type="checkbox"/>	1 CR02 - Senior Clinical Research Associate <small>System Managed</small>	USA			Travel: 0.00 USD Other: 0.00 USD
<input type="checkbox"/>	1 CR01 - Clinical Research Associate <small>System Managed</small>	USA			Travel: 0.00 USD Other: 0.00 USD

6 people attending

Cancel Save Save & Close

If you need to sort on Billing Rate Location instead of Resource, double click this column header

You can sort on Resource Type, Billing Rate Location and Attendance Method columns by double-clicking the column headers. I have double clicked Resource Type so all my meeting attendees are sorted by Resource Type.

New Meetings Report Options

The screenshot shows the Oracle Meetings Report configuration page. On the left is a navigation sidebar with options like Overview, Locations, Site, Subject, Treatment, Data, Monitoring, Provider, Meetings, Assignment, Labor, Costs, Payments, Summary, and Reports. The main content area is titled "Meetings Report" and contains several sections for configuration:

- Providers to Include:** A list with checkboxes for "All Providers", "CT Product Review", and "Major CRO".
- Meetings to Include:** A list with checkboxes for "All Meetings", "Kickoff Meeting", "Investigator Meeting", "Face to Face Meeting", and "Status Update to Sponsor".
- Level of Detail to Include:** Radio buttons for "Summary" (selected) and "Detail".
- Reporting Options:** A list of checkboxes including "Include Inflation", "Include Notes", and two new options: "Include Resources With No Meeting Hours" and "Use Resource Name Instead Of Resource Type". These two new options are highlighted with a red box.
- Reporting Currency:** A dropdown menu set to "US Dollar (USD)" and a checkbox for "Round values to the nearest US Dollar".

A red callout box on the right side of the interface contains the following text:

When you run the Meetings Report for your plan, you will see two new options to **Include Resources With No Meeting Hours** and to **Use Resource Name Instead of Resource Type**.

New Compare to Original Report

The screenshot shows the 'Edit Plan' interface with a sidebar on the left containing a navigation menu. The main area displays a list of reports categorized into 'Costs', 'FTE/Resources', and 'Comparisons'. A red callout box highlights the 'Compare to Original' report in the 'Comparisons' section. The callout text reads: 'New report **Compare to Original** on the Reports Tab, which allows you to compare your plan with its original template/plan upon which it is based, so that you can quickly see what has changed.'

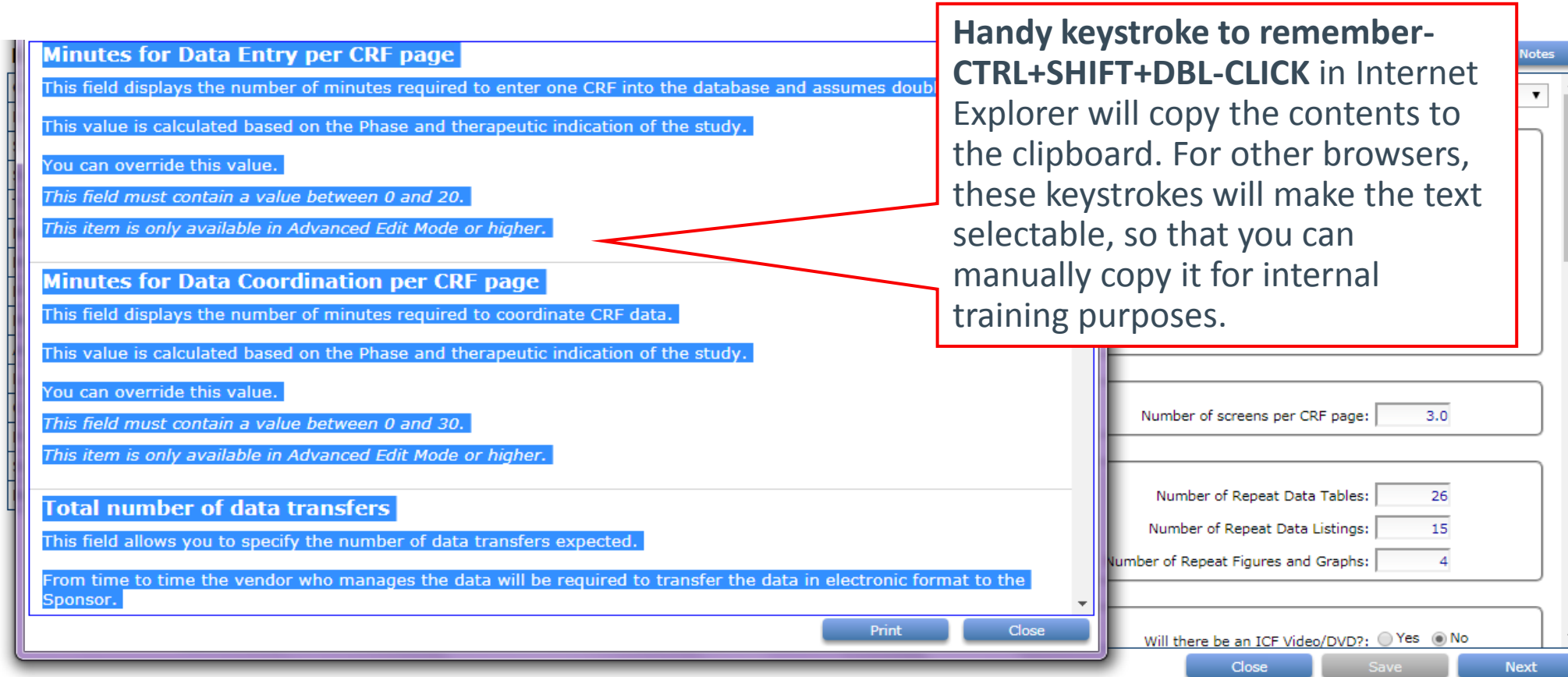
Category	Report Name	Description
Costs	Plan Summary	Printable view of the Summary tab
	Fees By Major Task	Fees by major task report
	Fixed Unit Prices	Fixed unit price report
	Pass-Through and 3rd Party Costs	Pass-through and 3rd party costs
	Monthly Budget	Monthly budget report
	Monthly Budget By Reporting Region	Monthly budget by reporting region report
	Labor Adjustments	Breakdown of unit level adjustments
	Cash Flow	Planned Value (PV) versus payments
	Milestone Payment Schedule	Schedule of payments at each milestone
	Meetings Report	Meeting costs and assumptions report
FTE/Resources	Summary Grid by Major Task	Plan/Provider specific report showing
	Inflation Rates	Inflation Rates by Location and Year
	Resource/FTE Demand Summary	Resource demand summary report
	Resources By Major Task	Resources by major task report
	Resources By Department	Resources by department report
	Resources By GL Code	Resources by GL code report
	Resource Demand by Date	Resource demand by date report
Comparisons	Resource Demand Chart	A graphical view of resource demand by date
	Billing Rates by Resource Name	Billing rates report
	Compare to Original	Compare to plan from which this plan was copied

Compare to plan from which this plan was copied

Close Save Next

Enable Help Text Content to be Copied to Clipboard

CTRL+SHIFT+DBL-CLICK



The screenshot shows a help text window with three sections: "Minutes for Data Entry per CRF page", "Minutes for Data Coordination per CRF page", and "Total number of data transfers". Each section contains descriptive text. A red callout box points to the text, containing the following information:

Handy keystroke to remember- CTRL+SHIFT+DBL-CLICK in Internet Explorer will copy the contents to the clipboard. For other browsers, these keystrokes will make the text selectable, so that you can manually copy it for internal training purposes.

The help text window includes the following sections:

- Minutes for Data Entry per CRF page**
 - This field displays the number of minutes required to enter one CRF into the database and assumes double data entry.
 - This value is calculated based on the Phase and therapeutic indication of the study.
 - You can override this value.
 - This field must contain a value between 0 and 20.
 - This item is only available in Advanced Edit Mode or higher.
- Minutes for Data Coordination per CRF page**
 - This field displays the number of minutes required to coordinate CRF data.
 - This value is calculated based on the Phase and therapeutic indication of the study.
 - You can override this value.
 - This field must contain a value between 0 and 30.
 - This item is only available in Advanced Edit Mode or higher.
- Total number of data transfers**
 - This field allows you to specify the number of data transfers expected.
 - From time to time the vendor who manages the data will be required to transfer the data in electronic format to the Sponsor.

The window also features "Print" and "Close" buttons at the bottom. The background shows a form with fields for "Number of screens per CRF page" (3.0), "Number of Repeat Data Tables" (26), "Number of Repeat Data Listings" (15), "Number of Repeat Figures and Graphs" (4), and a radio button for "Will there be an ICF Video/DVD?" (Yes/No).

Edit/Replace CT-Defined Resource Description

CLEAR TRIAL

Edit Report Maintain Admin Help

Administrator | Visit Support Center | Log

Edit Resource

Resource Summary

Code: CR01 Name: Clinical Research Associate

- Supports negotiations with the central laboratory, if applicable, for costs, billing, and other details regarding the central labs involvement in the study.
- Assists with establishing the Data Safety Monitoring Board, which requires meeting schedules, report formats for receipt of safety data, etc.
- Supports the production and distribution of the subject information video (where required).
- Participates in the development of necessary documents for the study, such as forms for monitoring and site management.
- Performs an initial review of the protocol.
- Supports the Medical Writing team with writing the initial Investigator Brochure (IB).
- Participates in editing drafts of the Investigator Brochure, when a draft is provided.
- When performed in-house, translate various documents, such as the Informed Consent Form (ICF), Protocol, CRFs, Investigator Brochure, and Subject Diary.
- Assists in the development, distribution and collection of investigator meeting materials.

Replace Description

CT-defined description for CR01/CRA.

Click on the **pencil** icon to provide a custom description for a plan-neutral, CT-defined resource (**launched from Maintain->Resources**).

Edit/Replace CT-defined Resource Description Cont'd



Edit Report Maintain Admin Help

Edit Resource

Resource Summary

Code: SM01

Name: Study Manager 1

Description: - Study Manager in place of CRA



I need to substitute the CRA on CT-defined tasks with Study Manager in all my plans. 1) From the resource list, I select the CRA and click Edit, 2) Update the Code, Name and click on the pencil icon to edit/replace CT's default description.

If I need to edit the description/revert back to the CT default description, I can click on the trash icon to **discard my latest change.**

Copy User-Defined Major Task

Edit Plan

View or adjust effort and labor fees Current Edit Mode: **Advanced**

Filter: Show major tasks with no planned effort for the selected provider

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	Ext Hours	Ext Cost
(Medical Writing - Draft CSR)					
<input type="radio"/> Final Report (CSR) (Medical Writing - Final CSR)	76.624	16,686.48	1	76.624	16,686.48
<input type="radio"/> Prepared Publication (Publications)	0.000	0.00		0.000	0.00
<input type="radio"/> EDC Help Desk (EDC Technical Support)	495.607	78,286.50		495.607	78,286.50
<input type="radio"/> EDC Training (EDC Training)	84.000	13,980.12		84.000	13,980.12
<input type="radio"/> Sponsor Oversight (Vendor Oversight by Sponsor)	0.000	0.00		0.000	0.00
<input checked="" type="radio"/> EDC Hosting (User Defined)	0.000	0.00		0.000	0.00
<input type="radio"/> Reportable SAE (User Defined)	5.000	19,949.10		150.000	19,949.10
Total Hours/Fees:		Calculated:		23,284.054	3,628,768.88
		Adjusted:		23,343.254	3,636,649.78

You can Copy a User-Defined Major Task by selecting the Major Task you want to copy and clicking the Copy Major Task button.

Copy User-Defined Task

The screenshot displays the Oracle Task Manager interface. On the left is a task list with a search bar. The main area shows the configuration for the 'EDC Hosting' task. Below the configuration are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. The 'Copy Task' button is highlighted with a red box. A callout box points to this button with the text: 'You can Copy a User-Defined Task by selecting the task and then clicking the Copy Task button.'

Task Manager

Task Search...

- Newsletter Prepared
- CRF Page Entered into Data
- Query Resolution - by Mon
- Interim Analysis
- Site Audited
- Annual IND Report Activitie
- Site Close-out Visit
- Site Close-out by Phone
- Third-party Data Import
- All Data Cleaned and Data
- Data Transfer
- Final Data Audit
- Issued Unique Summary T
- Issued Unique Summary Li
- Issued Unique Summary Fi
- Issued Repeat Summary T
- Issued Repeat Summary Li
- Issued Repeat Summary Fi
- Stat Report
- Draft Report
- Final Report (CSR)
- Prepared Publication
- EDC Help Desk
- EDC Training
- Sponsor Oversight
- EDC Hosting
- Host EDC
- Reportable SAE
- Custom Regulatory Stuff
- New...

EDC Hosting

Major Task Details | Adjustments | Distribution

Name: EDC Hosting

Description:

Labor: varies by location is centralized Unit of Measure: Study

Display this Major Task: after EDC Training

New Task Edit Task **Copy Task** Delete Task Edit Assignments

Task Name	Summary Group
<input checked="" type="checkbox"/> Host EDC	Collect Regulatory Documents Data Management

Click this button to copy the selected Task

You can Copy a User-Defined Task by selecting the task and then clicking the Copy Task button.

Reorder Major Tasks in Your Plan from Labor Tab

Edit Plan

View or adjust effort and labor fees Current Edit Mode: **Advanced**

Filter: Show major tasks with no planned effort for the selected provider

All calculated costs and adjustments are displayed in US Dollar (USD)

Major Task	Unit Hours	Unit Cost			
<input type="radio"/> Project Initiated (Project Initiation)	166.972	22,999.00			
<input type="radio"/> A Written Protocol (Protocol Preparation)		0.00			
<input type="radio"/> Study Setup (Study Setup - Centralized tasks)	223.999	42,963.43	1	223.999	42,963.43
<input checked="" type="radio"/> Study Setup Per-Location (Study Setup - De-centralized tasks)	43.000	5,644.56	2	86.000	11,289.11
<input type="radio"/> Protocol Amendment (Amendments)	0.000	0.00	0	0.000	0.00
<input type="radio"/> Protocol Amendment per Location (Amendments)	0.000	0.00	0	0.000	0.00
<input type="radio"/> Unique CRF Page Developed (CRF Development)	13.950	2,999.41	10	139.500	29,994.10
<input type="radio"/> CRF Book Printed	0.000	0.00	0	0.000	0.00
Total Hours/Fees:					
	Calculated:			24,253.054	3,842,000.90
	Adjusted:			24,312.254	3,849,881.80

Select a Major Task, and drag and drop with your mouse to reorder a Major Task from the Labor Tab.

Reorder Major Tasks in Your Plan from Task Manager

Another way to reorder Major Tasks according to your preference is by configuring **Display this Major Task** before/after another Major Task from the **Major Task Details** tab of Task Manager.

Reorder Tasks in Your Plan

The screenshot displays the Oracle Task Manager interface. On the left is a task search tree with 'Host 2nd EDC' selected. The main panel shows the configuration for this task. The 'Display this Task' dropdown is set to 'after' and is highlighted with a red box. A red callout box points to this dropdown with the following text:

You can also reorder a task, so that it is displayed according to your preference by configuring **Display this Task before/after** another Task from the **Task Details** tab of Task Manager.

Task Details for 'Host 2nd EDC':

- Name: Host 2nd EDC
- Code: [Empty]
- Description: apwkfrpdsjfps
- Assignment Group: Collect Regulatory Documents
- Summary Category: Data Management
- Major Task: EDC Hosting
- Display this Task: after

Buttons: Add Resource, Edit Resource, Delete Resource

Resource Name	Substitutions
<input type="checkbox"/> CR06 - Project Manager	None

Edit Name for CT-Defined Tasks

The screenshot shows the Oracle Task Manager interface. On the left is a task search and navigation pane. The main area displays the details for a task named 'Coordinate DSMB meetings'. A red box highlights the 'Name' field, which contains the text 'Coordinate DSMB meetings'. A callout box with a red border and pointer explains: 'You can change the Name on CT-defined Tasks. I put my cursor in the Name field and changed 'Coordinate DSMB setup activity' to 'Coordinate DSMB meetings'.' Below the task details is a table of resources.

Resource Name	
<input type="checkbox"/> CR01 - Clinical Research Associate	
<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"/> DS02 - Medical Associate	None
<input type="checkbox"/> ST01 - Junior Biostatistician	None

Specify Code for CT-defined Tasks

The screenshot displays the Oracle Task Manager interface. On the left, a tree view under 'Study Setup' has 'DSMB01: Coordinate DSMB meetings' selected and highlighted with a red box. The main window shows the 'Task Details' for 'Coordinate DSMB meetings', with the 'Code' field set to 'DSMB01' and also highlighted with a red box. A red callout box points to the 'Code' field with the text: 'You can specify a Code prefix for CT-defined Tasks.' Below the task details is a table of resources:

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"/> DS02 - Medical Associate	None
<input type="checkbox"/> ST01 - Junior Biostatistician	None
<input type="checkbox"/> ST02 - Senior Biostatistician	None

At the bottom of the window, there are buttons for 'Add Resource', 'Edit Resource', 'Delete', 'Cancel', 'Save', and 'Save & Close'. A footer note reads: 'Please specify a code for this Task (helps determine its order in lists)'.

Custom Description for CT-defined Tasks

The screenshot displays the Oracle Task Manager interface. On the left is a task search tree with 'Coordinate DSMB setup activity' selected. The main panel shows the configuration for the task 'Coordinate DSMB meetings' (Code: DSMB01, Mapping Key: 00023). The 'Description' field is highlighted with a red box and contains the text 'Schedule and coordinate all DSMB meetings for trial.'. Below this are dropdown menus for 'Assignment Group' (DSMB) and 'Summary Category' (Safety - Medical Management), and a 'Display this Task' dropdown set to 'after'. At the bottom, there is a table of resources:

Resource Name
<input type="checkbox"/> CR01 - Clinical Research Associate
<input type="checkbox"/> CR04 - Senior Vice President Clinical
<input type="checkbox"/> CR06 - Project Manager
<input type="checkbox"/> DS01 - Medical Monitor
<input type="checkbox"/> DS02 - Medical Associate
<input type="checkbox"/> ST01 - Junior Biostatistician

A red callout box points to the description field with the text: 'If you need to update the description for a CT-defined Task, you can delete the description and replace it with a custom Description for CT-defined Tasks.'

Change Assignment Group for CT-Defined Tasks

You can now move CT-defined Tasks to another Assignment Group, so that you can align with your organization's notion of services or responsibilities.

The screenshot shows the 'Study Setup' interface for a task named 'Negotiate central laboratory'. The 'Assignment Group' dropdown menu is open, showing a list of groups including 'Project Initiation', 'Site Startup', 'Protocol Preparation', 'Protocol Amendments', 'Investigator Brochure', 'Site Identification', 'Collect Regulatory Documents', 'Site Initiation', 'Subject Document Preparation', 'Database Programming', 'Drug Packaging and Supply', 'IVRS', 'Project Management', 'Site Monitoring/Management', 'Medical Management', 'Safety/Pharmacovigilance', 'Draft Report', 'Final Report (CSR)', 'Quality Assurance', and 'Data Management'. The 'Assignment Group' field is highlighted with a red box, and a callout box points to it with the text: 'You can now move CT-defined Tasks to another Assignment Group, so that you can align with your organization's notion of services or responsibilities.'

Change Summary Group for CT-Defined Tasks

Task Manager

Task Search...

Study Setup

- Negotiate central labor...
- Establish committees o...
- Coordinate DSMB setup
- Produce and distribute
- Design study document
- Review protocol
- Develop distribute and
- Write Investigator Broc
- Edit Investigator Broch
- Perform ICF, diary and
- Safety System Setup
- Design the specific ran
- Develop SAE Managem
- Prepare therapeutic tra
- Configure EDC System(
- Configure and Test EDC
- Study Setup Per-Location
- A Written Protocol
- Protocol Amendment
- Protocol Amendment per L
- Unique CRF Page Develop
- CRF Book Printed
- Meetings - Kickoff Meeting
- Meetings - Investigator Me
- Meetings - Face to Face Me
- Meetings - Status Update t

Study Setup > Negotiate central laboratory

Task Details | Task Assignments

Name: Negotiate central laboratory

Code: [] Mapping: []

Description: Negotiate with the central laboratory, if applicable, for the study.

Assignment Group: Project Initiati...

Summary Category: Startup Fees

Display this Task: Clinical Monitoring, Closeout, and Site Audit Fees

Add Resource

Resource Name	Substitutions
<input type="checkbox"/> CR01 - Clinical Research Associate	None
<input type="checkbox"/> CR02 - Senior Clinical Research Associate	None
<input type="checkbox"/> CR07 - Project Admin Assistant	None

You can now move CT-defined tasks from one summary group to another to align with your organization's notion of how work should be summarized.

Custom Fields Cap Increase

- Number of total custom fields you can have has been increased to **350**.
- **75** of them can have default formulas.

Please Note: The more custom fields you add to your plans, you will experience slight changes to performance.

5.6 Web Services API

As a reminder, ClearTrial's Web Services API is available at no cost for ClearTrial Enterprise Edition customers only.

If your development or IT group is interested in testing or calling ClearTrial's WS-API to get data exports from your plans, please send a request to Oracle Support or file an SR in My Oracle Support.

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