



ORACLE

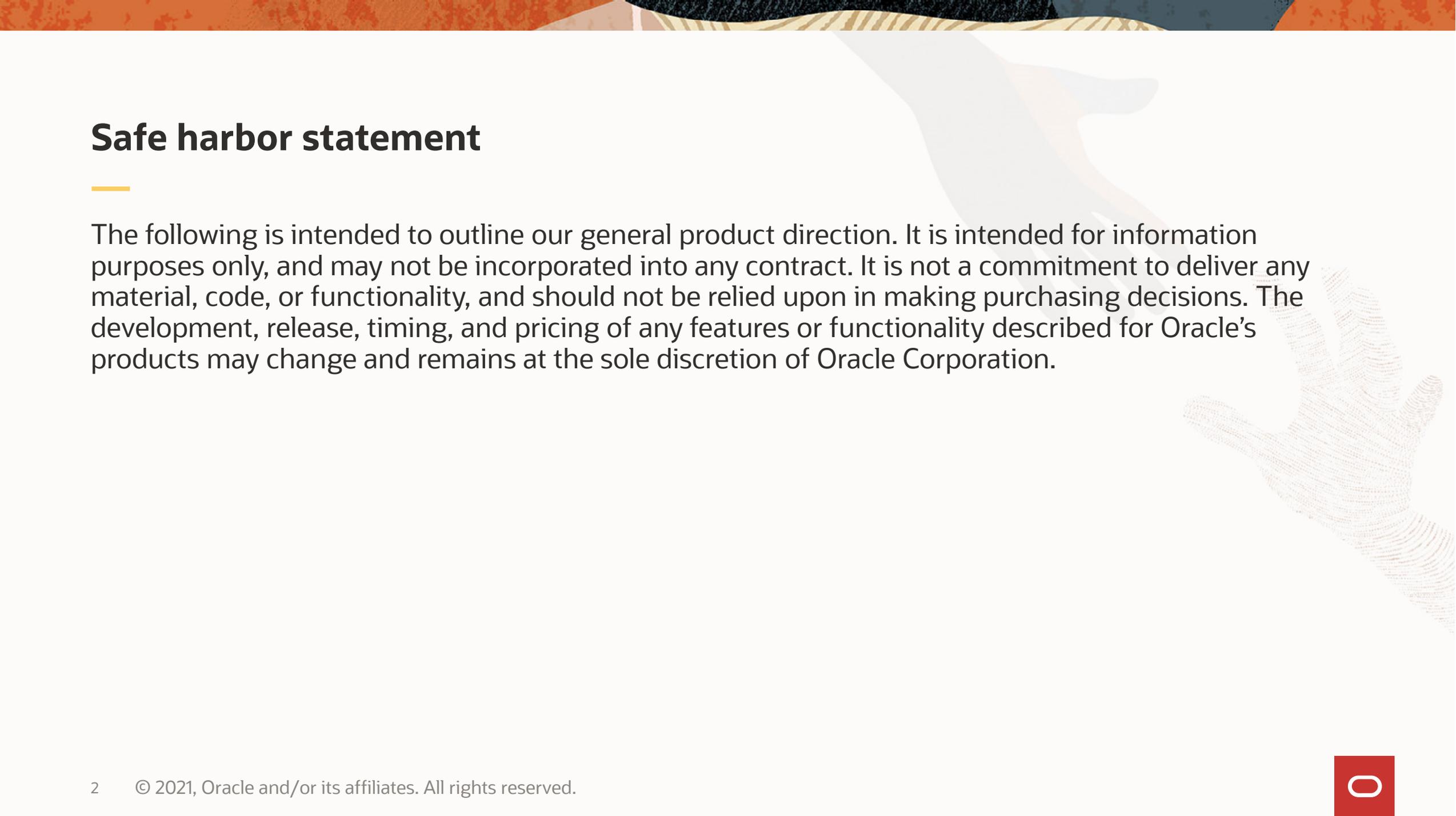
Introduction to ClearTrial 5.9

June 2021

Oracle Health Sciences. **For life.**

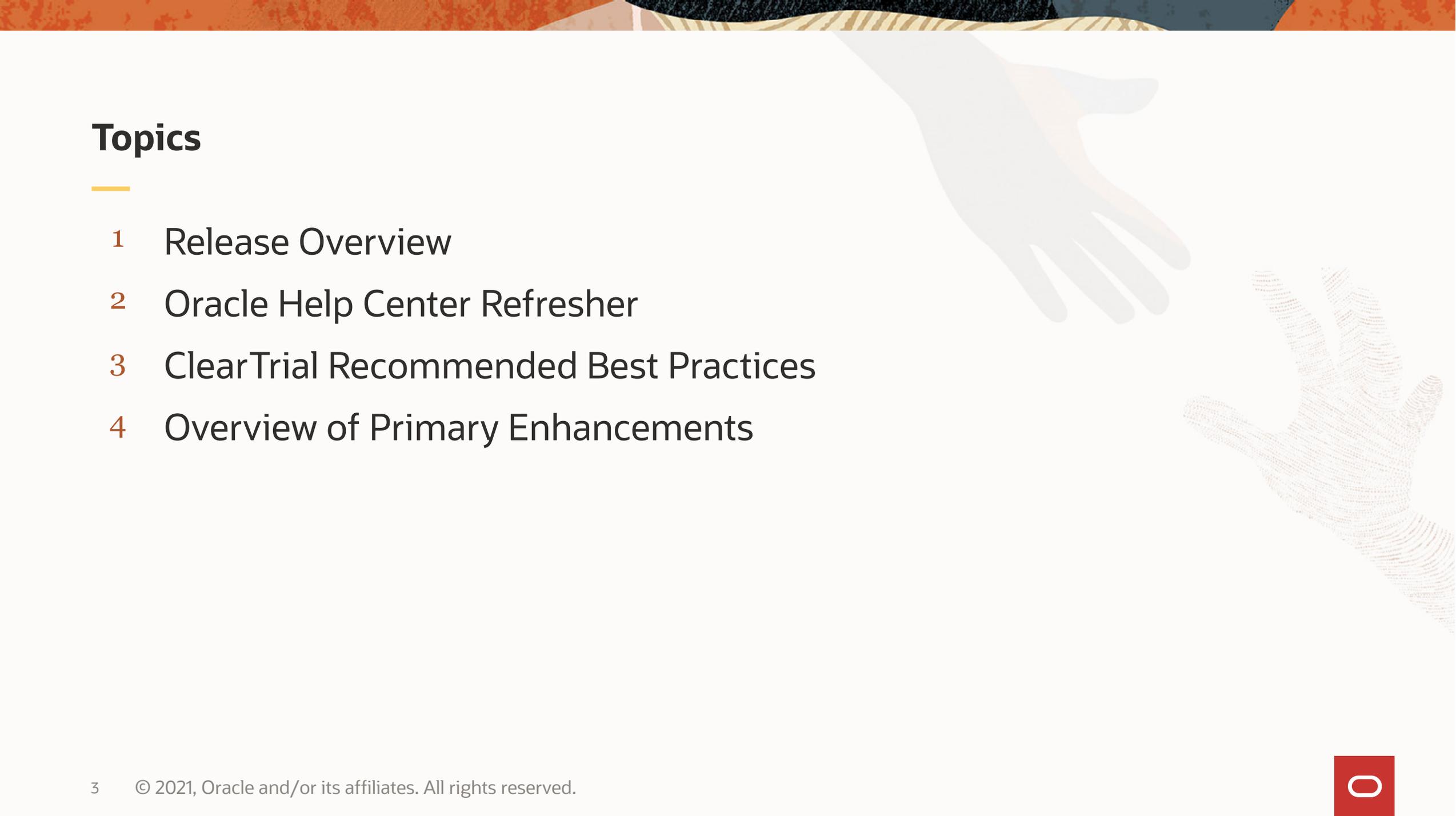


Safe harbor statement

The slide features a decorative background. At the top, there is a horizontal band with a pattern of orange, brown, and black. Below this, a large, faint, light-colored hand is shown reaching out from the top right towards the center. In the bottom right corner, there is a stylized fingerprint graphic composed of many small, overlapping lines.

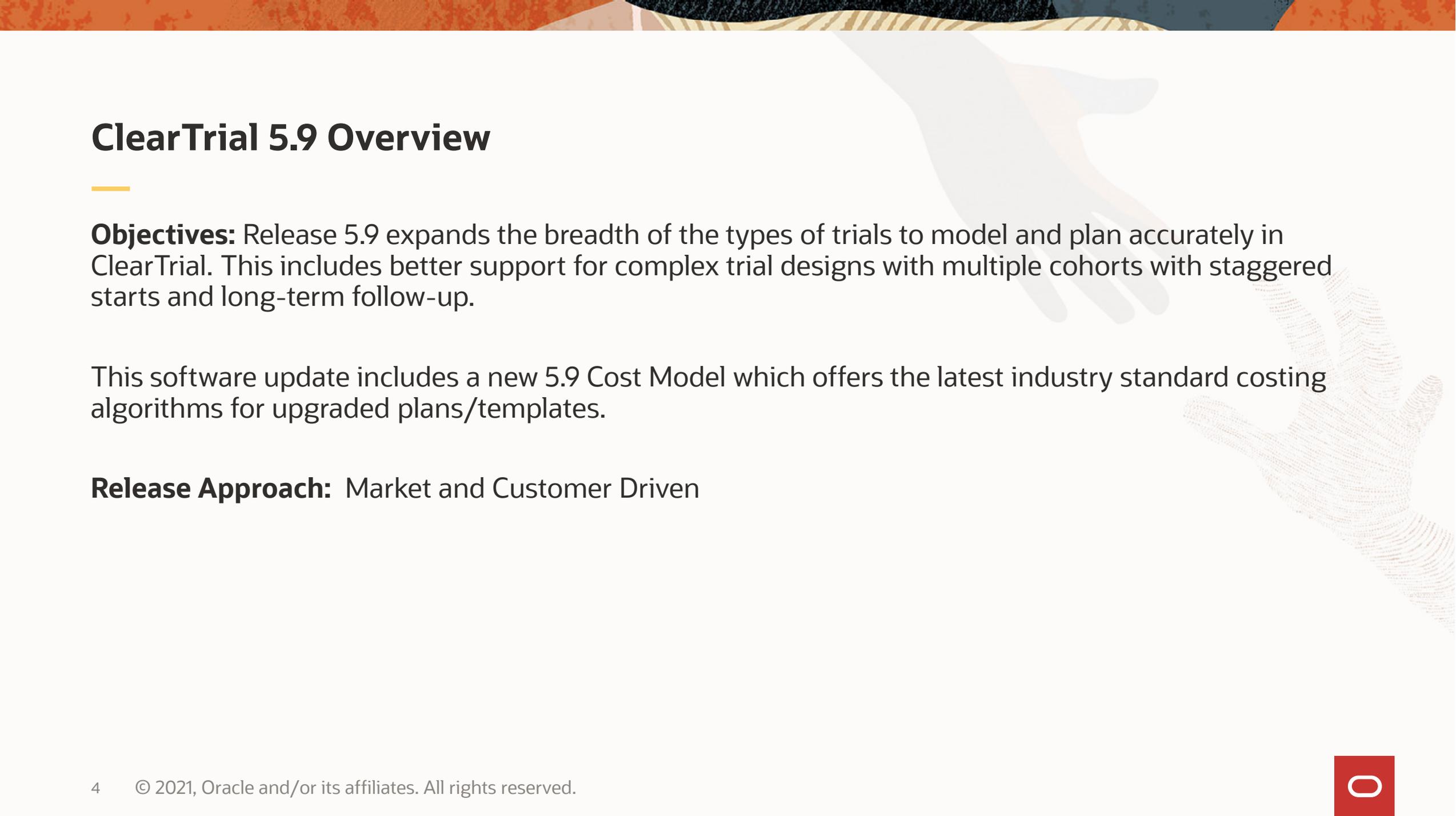
The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, timing, and pricing of any features or functionality described for Oracle's products may change and remains at the sole discretion of Oracle Corporation.

Topics

The background features a large, semi-transparent illustration of a hand reaching out from the top right. Below it, a fingerprint is shown, composed of numerous small text characters. The top of the slide has a decorative orange and brown pattern.

- 1 Release Overview
- 2 Oracle Help Center Refresher
- 3 ClearTrial Recommended Best Practices
- 4 Overview of Primary Enhancements

ClearTrial 5.9 Overview

The background features a large, faint illustration of two hands reaching towards each other. One hand is a solid light grey, while the other is a fingerprint-like pattern composed of small, repeating text characters. The top of the slide has a decorative orange and black pattern.

Objectives: Release 5.9 expands the breadth of the types of trials to model and plan accurately in ClearTrial. This includes better support for complex trial designs with multiple cohorts with staggered starts and long-term follow-up.

This software update includes a new 5.9 Cost Model which offers the latest industry standard costing algorithms for upgraded plans/templates.

Release Approach: Market and Customer Driven

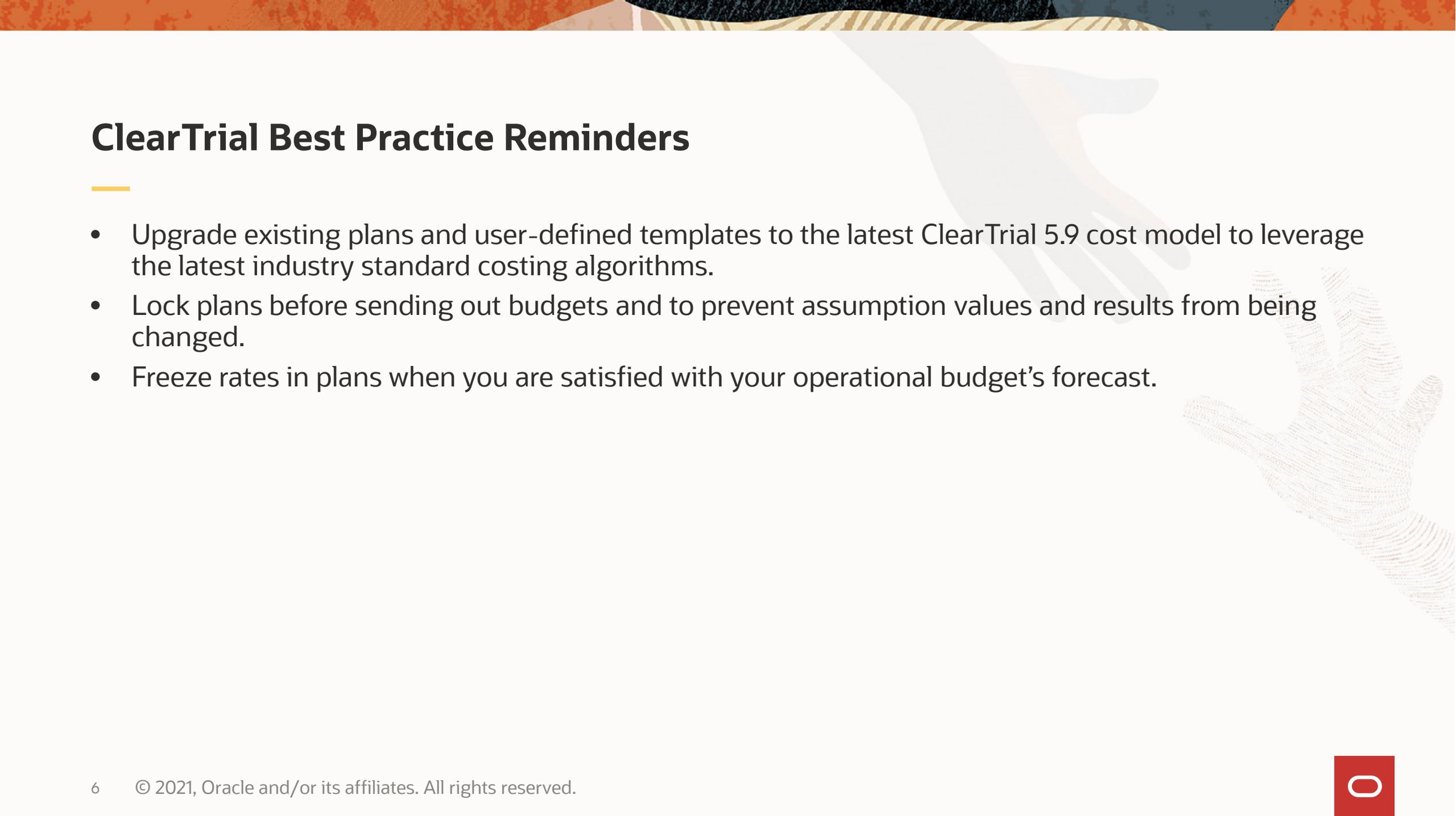
Remember to Visit the Oracle Help Center

The screenshot displays the Oracle Cleartrial Cloud Service interface. At the top left is the Oracle logo and 'CLEARTRIAL CLOUD SERVICE'. A navigation bar includes 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. On the right, it says 'Welcome, CT Product' and 'Logout', with a 'Visit Oracle Help Center' link highlighted in a red box. Below the navigation is a 'Plans' section with a filter bar. The filter bar shows 'Show: All Plans', 'Active Plans Only' (selected), and 'Plans matching filter: My Filter'. Below the filter bar are buttons for 'New', 'Edit', 'Delete', 'Restore', 'Copy', 'Compare', and 'Other Actions...'. A table of plans is shown with columns: Plan Name, Study Name, Description, Status, Cost Mo, and Created By. The table contains three rows of data. A callout box with a red border points to the 'Visit Oracle Help Center' link and contains the text: 'Click the [Visit Oracle Help Center](#) link to access application or release-specific resources'. At the bottom left, there is a copyright notice: 'Copyright © 2021, Oracle Corporation and/or its affiliates. All rights reserved.'

Plan Name	Study Name	Description	Status	Cost Mo	Created By
USA, Germany, UK, France, n=40	Imaging with 11C in Breast Cancer	4 sites, 4 countries, dose escalatio...	Draft	5.6	badakhshanian, Leyla
USA, Germany, UK, n=20	Imaging with 11C in Breast Cancer	3 sites, 3 countries, n=5 / arm, dos...Draft			badakhshanian, Leyla
USA, Germany, UK, n=30	Imaging with 11C in Breast Cancer	3 sites, 3 countries, dose escalatio	Draft		badakhshanian, Leyla

Click the [Visit Oracle Help Center](#) link to access application or release-specific resources

ClearTrial Best Practice Reminders

The slide features a decorative background at the top with a wavy pattern in shades of orange, brown, and blue. A large, semi-transparent hand is shown reaching down from the top right. On the right side, there is a stylized fingerprint graphic composed of many small, light-colored text characters.

- Upgrade existing plans and user-defined templates to the latest ClearTrial 5.9 cost model to leverage the latest industry standard costing algorithms.
- Lock plans before sending out budgets and to prevent assumption values and results from being changed.
- Freeze rates in plans when you are satisfied with your operational budget's forecast.

Upgrade Plans to the Latest Cost Model via Change Attributes

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

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

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

<input type="checkbox"/>	Plan Name ▲	Study Name	Description	Status	Cost Model	Created By
<input checked="" type="checkbox"/>	USA, Germany, UK, France, n=40	Imaging with 11C in Breast Cancer	4 sites, 4 countries, dose escalatio...	Draft	5.8	hshanian, Leyla
<input type="checkbox"/>	USA, Germany, UK, n=20	Imaging with 11C in Breast Cancer	3 sites, 3 countries, n=5 / arm, dos...Draft		5.9	hshanian, Leyla
<input type="checkbox"/>	USA, Germany, UK, n=30		escalatio... Draft		5.9	hshanian, Leyla

1. Select your existing plan from the Plan List screen.
2. Click on the "Other Actions..." menu.
3. Select "Change Attributes"

Click this button to change the status, name, cost model, and/or description of the selected plans



Upgrade Plans to the Latest Cost Model via Change Attributes Cont'd

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CLEARTRIAL CLOUD SERVICE

Edit Report Maintain Admin Help

Change Plan Attributes

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

Plan Name: USA, Germany, UK, France, n=40

Status: Draft

Cost Model: 5.8

Custom Field Model: 5.9

Short Description: 5.8

Long Description: 5.7

5.6

5.5

5.4

5.3

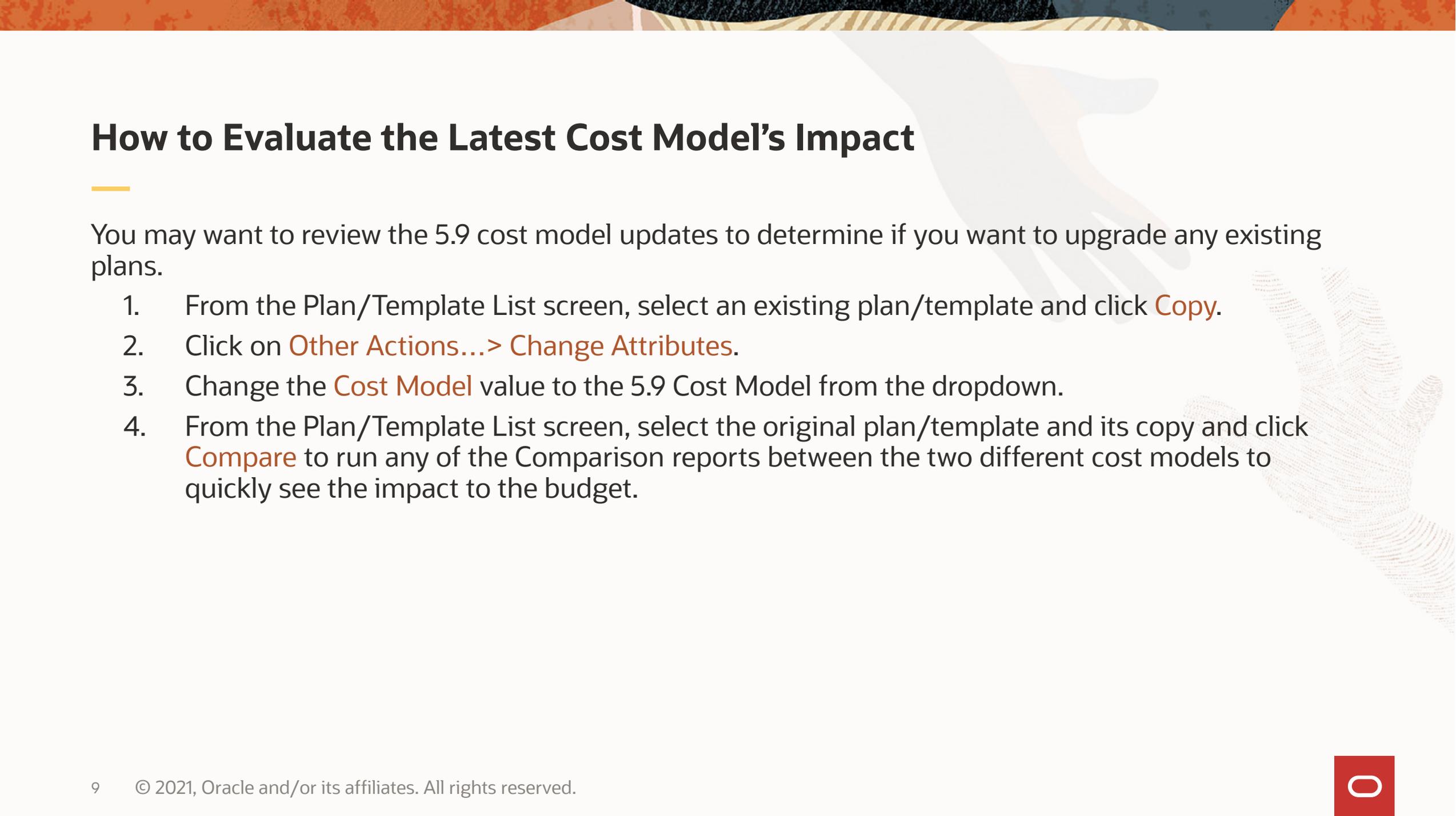
A single modifiable plan is selected.

Please choose the cost model for the selected plan.

Save & Edit

4. From the Change Plan Attributes dialog, change the "Cost Model" value to the latest available Cost Model.

How to Evaluate the Latest Cost Model's Impact



You may want to review the 5.9 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 5.9 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 with Different Cost Models

The screenshot displays the Oracle CLEARTRIAL Cloud Service interface. At the top, the Oracle logo and 'CLEARTRIAL CLOUD SERVICE' are visible. Below the logo, there are navigation tabs: Edit, Report, Maintain, Admin, and Help. On the right side, there is a user greeting 'Welcome, CT Product', a link to 'Visit Oracle Help Center', and a 'Logout' button. The main content area is titled 'Plans'. A status bar indicates '2 plans are selected' with a 'clear' link and a checked box for 'Remember selections across pages' with a 'help' link. A filter section shows 'Filter' and 'Show: All Plans Active Plans Only Plans matching filter: My Filter' with a 'Modify' link and a 'Configure List Options' link. Below the filter, there are buttons for 'New', 'Edit', 'Delete', 'Restore', 'Copy', 'Compare', and 'Other Actions...'. The 'Compare' button is highlighted with a red box. Below the buttons is a table with columns: Plan Name, Study Name, Description, Status, Cost M, and Created By. The table contains three rows, with the first two rows selected (checked boxes in the first column). The first row has a cost model of 5.8, and the second row has a cost model of 5.9. A callout box with a red border points to the 'Compare' button and contains the text: 'Select an existing plan and the upgraded 5.9 copy from the Plan List screen, and click Compare to access the Plan Comparison reports.'

Plan Name	Study Name	Description	Status	Cost M	Created By
<input checked="" type="checkbox"/> USA, Germany, UK, France, n=40	Imaging with 11C in Breast Cancer	4 sites, 4 countries, dose escalatio...	Draft	5.8	badakhshanian, Leyla
<input checked="" type="checkbox"/> USA, Germany, UK, n=20	Imaging with 11C in Breast Cancer	3 sites, 3 countries, n=5 / arm, dos...	Draft	5.9	badakhshanian, Leyla
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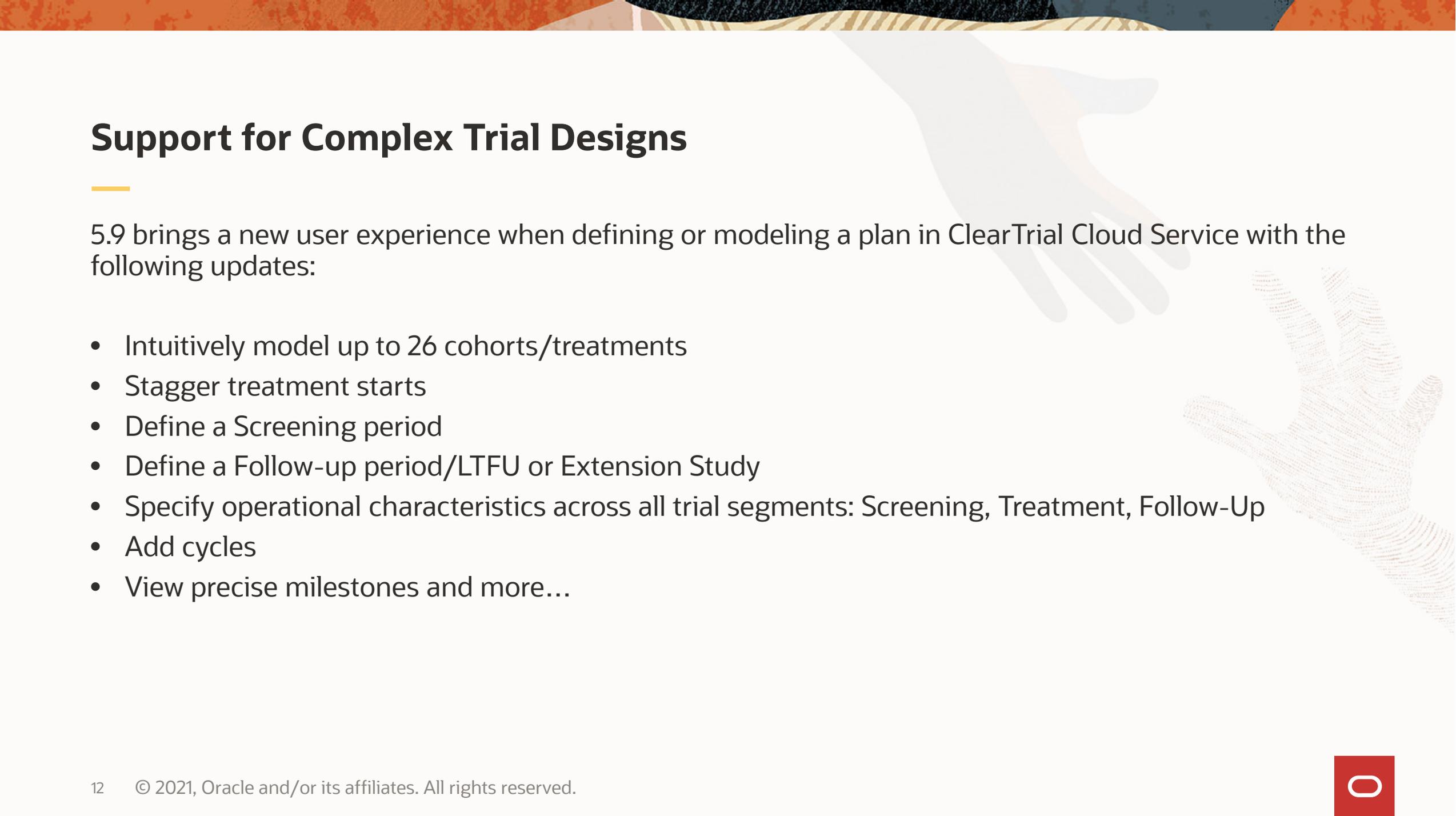
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Complex Trial Designs Support



Support for Complex Trial Designs

The background features a large, semi-transparent illustration of a hand reaching out from the top right. Below it, a fingerprint is shown, composed of many small, overlapping text characters. The overall theme is related to human interaction and digital security.

5.9 brings a new user experience when defining or modeling a plan in ClearTrial Cloud Service with the following updates:

- Intuitively model up to 26 cohorts/treatments
- Stagger treatment starts
- Define a Screening period
- Define a Follow-up period/LTFU or Extension Study
- Specify operational characteristics across all trial segments: Screening, Treatment, Follow-Up
- Add cycles
- View precise milestones and more...

Number of Subjects, Investigator Grant Amount Per Location Moved from Locations tab to Treatment tab

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CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=20 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

Notes

Add Location(s) Remove Location(s) Add Language(s) Remove Language(s)

Location	Sites	MOH/FDA Delay	FSA Date
<input type="checkbox"/> Germany	<input type="text" value="1"/> ⚠	<input type="text" value="90"/> days	09/18/21
<input type="checkbox"/> UK	<input type="text" value="1"/> ⚠	<input type="text" value="90"/> days	09/18/21
<input type="checkbox"/> USA	<input type="text" value="1"/> ⚠	<input type="text" value="30"/> days	07/24/21
For 3 location(s), Total/Avg:		3	70

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

Please enter the number of sites that will be active in this location

Close Save Next

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Subject Enrollment Assumptions Moved Per Treatment, Removing the Subject tab

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CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=20 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

Notes

Location	Enrollment	Screening	Treatment	Follow-Up
Germany	90,000.00 USD	0.00 USD	0.00 USD	0.00 %
UK	95,000.00 USD	0.00 USD	0.00 USD	0.00 %
USA	80,000.00 USD	0.00 USD	0.00 USD	0.00 %

Treatment(s)

Add Edit Copy Delete

You have selected 1 of 4 treatments [clear]

	Screening	Treatment	Follow-Up
<input checked="" type="checkbox"/> Treatment A	Screening period: 7 days Screening visits per subject: 1 CRF pages/screened subject: 35 Screen failure rate: 9.09 %	Treatment duration: 63 days Visits per subject: 7 CRF pages per subject: 175 Number of cycles: 1	Follow subjects for: 0 weeks % completed subjects followed: 0.00 % First follow-up occurs after: 0 days Follow-up visits occur every: 0 days
	Screening period: 7 days Screening visits per subject: 1 CRF pages/screened subject: 30	Treatment duration: 42 days Visits per subject: 7 CRF pages per subject: 148 Number of cycles: 1	Follow subjects for: 0 weeks % completed subjects followed: 0.00 % First follow-up occurs after: 0 days Follow-up visits occur every: 0 days

Enrollment Assumptions for Treatment A:

- Enrolled subjects: 5
- FSFT/FPFT Date: 07/26/21
- Enrollment period: 2,100 days
- Enrollment rate: 0.02 s/s/m
- Enrollment distribution: Chronic
- LSFT/LPFT Date: 04/25/27
- LSLT/LPLT Date: 06/26/27
- Total Subjects: 20

Please specify the number of subjects to be randomized to this treatment

Cancel Save Next

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Specify which enrollment group enters which treatment and

All Investigator Grants-specific Assumptions Moved to One Place

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CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost mode

Edit Report Maintain Admin Help Welcome, Leyla badakhshanian | Visit Oracle Help Center | Logout

Edit Plan Notes

Study Characteristics

Trial Design: Parallel Crossover Measure enrollment periods in: Measure treatment duration in:

Investigator Grants

Location	Avg Grant/Subject	Stipend/Enrolled Subject	Payment/Screen Failure	% Screen Failures Paid	Stipend/Screen Failure
(Default)	0.00 USD	125.00 USD	375.00 USD	100.00 %	1,000.00 USD
Germany	14,225.00 EUR	225.00 EUR	375.00 USD	100.00 %	1,200.00 EUR
UK	12,500.00 GBP	175.00 GBP	375.00 USD	90.00 %	1,175.00 GBP
USA	10,500.00 USD	125.00 USD	375.00 USD	100.00 %	1,000.00 USD

Treatment(s)

Add Edit Copy Delete You have selected 1 of 4 treatments [clear]

	Screening	Treatment	Follow-Up	
<input checked="" type="checkbox"/> Treatment A	Screening period: 4 weeks Enrolled subjects: 10 FSFT/FPFT Date: 09/28/21 Enrollment period: 300 weeks	Screening visits per subject: 1 CRF pages/screened subject: 35 Screen failure rate: 35.00 %	Cycle duration: 20 weeks Visits per subject: 17 CRF pages per subject: 737 Number of cycles: 4	Follow subjects for: 104 weeks % completed subjects followed: 100.00 % First follow-up occurs after: 4 weeks Follow-up visits occur every: 1 weeks

Cancel Save Next

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Define Multiple Subject Cohorts/Treatments with Staggered Starts

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USA, Germany, UK, n=20 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17-14
Indication: Oncology / B

This plan is using the 5.9 cost model

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

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

Location	Amount	Unit
Germany	90,000.00	USD
UK	95,000.00	USD
USA	80,000.00	USD

Treatment(s)

	Screening	Treatment	Follow-Up
<input type="checkbox"/> Treatment A	Screening period: 4 weeks Enrolled subjects: 5 FSFT/FPFT Date: 07/26/21 Enrollment period: 300 weeks	Cycle duration: 9 weeks Visits per subject: 7 CRF pages per subject: 175 Number of cycles: 4	Follow subjects for: 364 weeks % completed subjects followed: 100.00% First follow-up occurs after: 4 weeks Follow-up visits occur every: 1 weeks
<input type="checkbox"/> Treatment B	Screening period: 4 weeks Enrolled subjects: 5 FSFT/FPFT Date: 08/26/21 Enrollment period: 300 weeks	Treatment duration: 6 weeks Visits per subject: 7 CRF pages per subject: 148 Number of cycles: 1	Follow subjects for: 52 weeks % completed subjects followed: 100.00% First follow-up occurs after: 4 weeks Follow-up visits occur every: 2 weeks

Total Subjects: 20
PASD: 05/01/21 FSFV: 06/28/21 LSFV: 06/28/27 FSFT: 07/26/21 LSFT: 07/26/27 FSLT: 10/06/21 LSLT: 01/01/28 FSLV: 10/16/21 LSLV: 01/20/35

Cancel Save Next

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Define up to 26 unique cohorts with varying operational characteristics across Screening, Treatment and Follow-Up segments

Stack treatments



Add Multiple Treatment Cycles

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CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, Leyla badakhshanian | Visit Oracle Help Center | Logout

Edit Plan

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

Location	Cost	Unit	Screening	Unit	Treatment	Unit	Follow-up	Unit
Germany	90,000.00	USD	0.00	USD	0.00	USD	0.00	%
UK	95,000.00	USD	0.00	USD	0.00	USD		
USA	80,000.00	USD	0.00	USD	0.00	USD		

Treatment(s)

Add Edit Copy Delete

	Screening	Treatment	Follow-up
<input type="checkbox"/> Treatment A	Screening period: 4 weeks Enrolled subjects: 10 FSFT/FPFT Date: 09/28/21 Enrollment period: 300 weeks	Cycle duration: 20 weeks Visits per subject: 7 CRF pages per subject: 170 Number of cycles: 4 Subject diary pages: 0 QOL pages: 80 Pharmacoeconomic pages: 40 Subject drop rate: 35.00%	Follow subjects for: 104 weeks Completed subjects followed: 100.00% First follow-up occurs after: 4 weeks Follow-up visits occur every: 1 weeks
<input type="checkbox"/> Treatment B	Screening period: 4 weeks Enrolled subjects: 10 FSFT/FPFT Date: 10/28/21 Enrollment period: 300 weeks	Screening visits per subject: 1 CRF pages/screened subject: 30 Screen failure rate: 9.09%	Follow subjects for: 52 weeks % completed subjects followed: 100.00% First follow-up occurs after: 4 weeks Follow-up visits occur every: 1 weeks

Total Subjects: 40
PASD: 05/01/21 FSFV: 08/31/21 LSFV: 08/30/27 FSFT: 09/28/21 LSFT: 09/27/27 FSLT: 12/08/21 LSLT: 01/07/29 FSLV: 12/08/21 LSLV: 02/02/31

Cancel Save Next

Define multiple cycles per treatment arm to accurately model the study design



Define Subject Cohort Assumptions per Treatment per Location

Subjects Details

Name:

Enrolled subjects:

Enrollment period: 2,293 days

Manage FSFT date: By Treatment Per Location

FSFT/FPFT Date: 07/26/21

Location-specific Assumptions

Location	# Subjects	FSFT Date	Enrollment Period	LSFT Date	
Germany	<input type="text" value="1"/>	<input type="text" value="10/27/21"/>	<input type="text" value="2,200"/> days	11/04/27	0.01
UK	<input type="text" value="2"/>	<input type="text" value="09/20/21"/>	<input type="text" value="2,160"/> days	08/19/27	0.03
USA	<input type="text" value="2"/>	<input type="text" value="07/26/21"/>	<input type="text" value="2,100"/> days	04/25/27	0.03

11/04/27 0.02

Cancel Ok

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Choose Manage FSFT date Per Location

Stagger Treatment Starts Per Location



Enrollment Distribution Moved per Treatment per Location

Edit Treatment A
X

Subjects
Enrollment
Screening
Treatment
Follow-up
Schedule
Grants
Notes

Options

Manage enrollment distribution values: By Treatment Per Location

Location:

Enrollment distribution:

Distribution resolution: Quartiles Weekly

Location-specific Assumptions

All subjects have been allocated

Period	Week Of	Subjects	Percentage
Week 1:	09/28/21	<input type="text" value="1"/>	25.0 %
Week 2:	10/05/21	<input type="text" value="0"/>	0.0 %
Week 3:	10/12/21	<input type="text" value="1"/>	25.0 %
Week 4:	10/19/21	<input type="text" value="1"/>	25.0 %
Week 5:	10/26/21	<input type="text" value="0"/>	0.0 %
Week 6:	11/02/21	<input type="text" value="0"/>	0.0 %
Total		4 subjects	100.0 %

[Clear Custom Values](#)

Subjects
Cancel
Ok



Define Screening Assumptions per Treatment per Location

The screenshot shows the 'Edit Treatment A' window with the 'Screening' tab selected. The 'Screening Details' section includes the following fields:

- Screening period: 28 days
- Screening visits per subject: 1
- CRF pages/screened subject: 35
- Screen failure rate: 35.00 % (with a warning icon)
- Number of subjects to screen: 18

The 'Location-specific Assumptions' section contains a table with the following data:

Location	Screen failure rate	Number of subjects to screen
Germany	35.00 % (with a warning icon)	5
UK	35.00 % (with a warning icon)	5
USA	50.00 % (with a warning icon)	8

Buttons for 'Close' and 'Ok' are visible at the bottom right of the window.



Define Intervention Assumptions per Treatment per Location

Edit Treatment A

Subjects | Enrollment | Screening | **Treatment** | Follow-up | Schedule | Grants | Notes

Treatment Details

Treatment duration: days
 Visits per subject:
 CRF pages per subject:
 Subject diary pages:
 QOL pages:
 Pharmacoeconomic pages:
 Subject diary is electronic: Yes No
 Lab/Diagnostic tests/subject:
 Cohort escalation reviews:
 Number of cycles:
 Subject drop rate: %
 Subjects expected to complete all study visits:
 Monitoring minutes per CRF page:
 LSLT/LPLT Date: 08/26/27

Location-specific Assumptions

Location	Enrolled subjects	Subject drop rate	Subjects expected to complete all study visits
Germany	3	<input type="text" value="40.00"/> %	2
UK	3	<input type="text" value="35.00"/> %	2
USA	4	<input type="text" value="50.00"/> %	2

Cancel Ok



Define Follow-up Assumptions per Treatment per Location

The screenshot shows the 'Edit Treatment A' window with the 'Follow-up' tab selected. The interface is divided into two main sections: 'Follow-up Details' and 'Location-specific Assumptions'.

Follow-up Details:

- Follow subjects for: 104 weeks
- Follow-up drop rate: 35.00 %
- Number of subjects expected to complete follow-up: 3
- CRF pages per follow-up visit: 10
- Subject diary pages per visit: 0
- LSLV/LPLV Date: 12/09/29
- Percent of completed subjects who will enter follow-up: 100.00 %
- First follow-up occurs: 4 weeks after last treatment visit
- Follow-up visits occur every: 1 weeks
- QOL pages per visit: 0
- Pharmacoeconomic pages/visit: 0

Location-specific Assumptions:

Location	Follow-up drop rate	Number of subjects expected to complete follow-up
Germany	40.00 %	1
UK	35.00 %	1
USA	35.00 %	1

Buttons for 'Close' and 'Ok' are visible at the bottom right of the window.



Define the Subject Visit Schedule Across Screening, Treatment, Follow-up per Cohort

Edit Treatment A

Subjects | Enrollment | Screening | Treatment | Follow-up | **Schedule** | Grants | Notes

Use example grant amount: Yes No

Week	Number of CRF Pages	Monitoring Time (minutes)	Percent of Grant
SCRN	-4	10	100.317
	-3	10	100.317
	-2	10	100.317
	-1	10	100.317
1	75	684.919	3.33 %
2	75	684.919	3.33 %
3	75	684.919	3.33 %
4	60	547.936	2.66 %
Total screening CRFs: 40		Total screening visits: 4	
Total treatment CRFs: 1,205		Total treatment visits: 19	
Total follow-up CRFs: 1,050		Total follow-up visits: 105	
Total CRFs per subject: 2,295		Total visits per subject: 128	Total: 100.00 %

Displaying weeks -4 to 100 of 132 [View Last 28 weeks](#)

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

Cancel Ok

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Define CRFs, Monitoring Time and Grants per Visit Across Cycles

Subject Treatment Schedule

Use example grant amount: Yes No

Week	Treatment (C1)	Monitoring Time (minutes)	Percent of Grant
8		231.937	0.60 %
9		231.937	0.60 %
10		231.937	0.60 %
11	30	289.921	0.75 %
12	30	289.921	0.75 %
13	30	289.921	0.75 %
14	30	289.921	0.75 %
15	30	289.921	0.75 %

Summary:

Total screening CRFs:	35	Total screening visits:	1
Total treatment CRFs:	2,948	Total treatment visits:	68
Total follow-up CRFs:	1,050	Total follow-up visits:	105
Total CRFs per subject:	4,033	Total visits per subject:	174
			Total: 100.00 %

Displaying weeks -4 to 100 of 192 [View Last 88 weeks](#)

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

Buttons: Cancel, Ok



Define Grants-specific Assumptions per Treatment per Location

The screenshot shows the 'Edit Treatment A' window with the 'Grants' tab selected. The 'Grants Details' section contains a table with the following data:

Location	Avg Grant/Subject	Stipend/Enrolled Subject	Payment/Screen Failure	% Screen Failures Paid For	Stipend Per Screen Failure
Germany	14,225.00 EUR	225.00 EUR	375.00 USD	100.00 %	1,200.00 EUR
UK	12,500.00 GBP	175.00 GBP	375.00 USD	90.00 %	1,175.00 GBP
USA	10,500.00 USD	125.00 USD	375.00 USD	100.00 %	1,000.00 USD

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Enter Study Design Notes per Treatment Arm

Edit Treatment A

Subjects Enrollment Screening Treatment Follow-up Schedule Grants **Notes**

Dose escalation phase of the study using the combination of ML-4498 with ML-4422. For this dose escalation phase a rolling 4 arm design has been chosen staggered to start every 30 days. Dose assignment will be based on the number of patients currently enrolled in the cohort, the number of dose limiting toxicities (DLTs) observed, and the number of patients at risk for developing a DLT. Once the MTD has been exceeded the cohort at the next lowest dose level will be expanded to 10 additional patients.

Enter any additional information about this treatment in this field

Cancel Ok

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Precise, Unambiguous Milestones

ORACLE CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Edit Plan

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

Filter
Show: excluded milestones

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

All monetary values are displayed in US Dollar (USD)

Milestone	Inv. Date	Major CRO	Total
<input type="checkbox"/> First Subject/Patient First Treatment (FSFT)	09/28/21	15.00 %	2,944,920
<input type="checkbox"/> Agreement on Statistical Analysis Plan (SAP)	10/08/21	0.00 %	0
<input type="checkbox"/> First Subject/Patient Last Treatment (FSLT)	12/08/21	30.00 %	5,889,841
<input type="checkbox"/> First Subject/Patient First Follow-up (FSFFU)	12/18/21	0.00 %	0
<input type="checkbox"/> First Subject/Patient Last Visit (FSLV)	05/05/25	0.00 %	0
<input type="checkbox"/> Last Subject/Patient First Visit (LSFV)	08/30/27	0.00 %	0
<input type="checkbox"/> Last Subject/Patient First Treatment (LSFT)	09/27/27	15.00 %	2,944,920
<input type="checkbox"/> Last Subject/Patient Last Treatment (LSLT)	01/07/29	0.00 %	0
<input type="checkbox"/> Last Data Query Resolved (QRY)	01/17/29	0.00 %	0
Budget Total		100.00 %	19,632,803

Close Save Next

Notes

enter | Logout

Milestones have been updated throughout the application and in reporting to be more precise



New Assumption to Scale PM Effort During Follow-Up

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, Leyla badakhshanian | Visit Oracle Help Center | Logout

Edit Plan

Notes

Project Management

Reduce Project Management effort during Follow-up by: %

Number of newsletters:

Number of years to archive data:

Will there be an ICF Video?: Yes No

Number of online EDC training sessions:

eTMF (Electronic Trial Master File)

Number of eTMF Country/Region Files:

Number of months for the Vendor to archive the eTMF:

Number of eTMF Site Files:

Medical Writing / Timelines

Number of pages in the Investigator Brochure:

Days from LSLT/LPLT until Database Lock:

Days from Database Lock until Statistical Report due:

Database Lock date: 02/25/29

Stat Report date: 04/01/29

Days from Database Lock until Draft Report due:

Draft Report date: 05/06/29

Days from Database Lock until Final Report due:

Final Report date: 06/11/29

End of Study

Close Save Next

Ability to scale Project Management effort for new tasks during Follow-up



New Project Management Follow-Up Labor Fees

Project Management effort has been broken out into three Major Tasks in the 5.9 Cost Model

New default labor effort under “Project Management Week – Follow-up” Major Task

Task Manager

Task Search...

- Project Management Week prior to FSFT
- Project Management Week after FSFT
- Project Management Week - Follow-up**
 - Follow-up - Manage quality assurance activities
 - Follow-up - Manage project personnel (excludes data management)
 - Follow-up - Manage CRO/sponsor interactions
 - Follow-up - Manage information support functions
 - Follow-up - Manage administrative support functions
 - Follow-up - Report study status
 - Follow-up - Report on milestone tracking, monitoring quality, and performance
 - Follow-up - File all data
 - Follow-up - Make payments to investigators
 - Follow-up - Maintain EDC
 - Follow-up - Manage interaction with affiliates
 - Follow-up - Manage third-party vendors
 - Follow-up - Review and approve invoices and study costs
 - Follow-up - Manage sponsor's CTMS
 - Follow-up - Manage safety processes
- eTMF Maintenance
- SAE Processed

post-treatment follow-up

Unit of Measure: Week

Dis... k after FSFT

New Task Edit Task Copy Task Delete Task Edit Assignments

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Follow-up - Manage quality assurance activities	Quality Assurance	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Manage project personnel (excludes data manage...	Project Management	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Manage CRO/sponsor interactions	Project Management	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Manage information support functions	Project Management	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Manage administrative support functions	Project Management	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Report study status	Project Management	Project Management / Study Ov...
<input type="checkbox"/> Follow-up - Report on milestone tracking, monitoring quality, and performance	Site Monitoring/Management	Project Management / Study Ov...

Please specify a name for this Major Task

Close Save Save & Close

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New Site Management Week Follow-up Labor Fees

The screenshot shows the 'Task Manager' interface. On the left is a tree view of tasks. The 'Site Management Week - Follow-up' task is selected and highlighted in blue. A callout box points to this task, stating: 'Site Management effort has been broken out into three Major Tasks in the 5.9 Cost Model'. Another callout box points to the task's description, stating: 'New default labor effort under “Site Management Week – Follow-up” Major Task'. The description text reads: 'Activities related to managing a site during follow-up. These are activities that occur at a central location for the monitoring CRAs (only in house activities). Does NOT include monitoring.' Below the description, the 'Unit of Measure' is listed as 'Site Week (Medical Monitori...'. At the bottom, there is a table with three columns: 'Task Name', 'Assignment Group', and 'Summary Category'. The table lists three tasks under the 'Site Management Week - Follow-up' category.

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Manage study site during Follow-up	Site Monitoring/Management	Clinical Monitoring, Closeout, and ...
<input type="checkbox"/> Manage/pay central labs during Follow-up	Site Monitoring/Management	Clinical Monitoring, Closeout, and ...
<input type="checkbox"/> Conduct weekly telephone communication with site staff during Follow-up	Site Monitoring/Management	Clinical Monitoring, Closeout, and ...



Medical Monitoring Labor Fees Update

Medical Monitoring effort has moved from Site Management to its own Major Task.

New default labor effort under "Medical Monitoring - Follow-up" Major Task

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Medical Monitoring during follow-up	Site Monitoring/Management	Clinical Monitoring, Closeout, and Site Audi...



New End of Study (EOS) Assumptions

Define End of Study assumptions for new default effort that occurs from Follow-up (LSLT+1) until Budget End

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

Edit Report Maintain Admin Help

Edit Plan

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

End of Study

Will there be a Supplemental CSR?: Yes No

Reduce effort for Supplemental CSR by: %

Days from LSLV/LPLV until Database Lock (EOS): Days from Database Lock (EOS) until Statistical Report (EOS) due:

Database Lock (EOS) date: 03/23/31 Stat Report (EOS) date: 04/27/31

Days from Database Lock (EOS) until Draft Report (EOS) due: Days from Database Lock (EOS) until Final Report (EOS) due:

Draft Report (EOS) date: 06/01/31 Final Report (EOS) date: 07/07/31

Days from Final CSR (EOS) to Study/Budget End Study/Budget End date: 08/06/31

Safety and Medical Management

SAE rate as a percent of randomized subjects: % 9 SAEs

Hours medical monitor will spend with each SAE:

Expected percent of SAE Reports to be expedited: % 1 expedited SAEs

Provide data to the DSMB:

From: 09/28/21

Until: 01/07/29

IVRS (Interactive Voice Response System)

Cancel Save Next



New End of Study Labor Fees

Task Manager

Task Search...

- Site Close-out Visit by Phone
- Third-party Data Import
- All Data Cleaned and Database Locked
- Data Transfer
- Final Data Audit
- Issued Unique Summary Table
- Issued Unique Summary Listing
- Issued Unique Summary Figure/Graph
- Issued Repeat Summary Table
- Issued Repeat Summary Listing
- Issued Repeat Summary Figure/Graph
- Stat Report
- Draft Report
- Final Report (CSR)
- eTMF Close-out
- Prepared Publication
- End of Study Database Locked**
- End of Study Stat Report
- End of Study Draft Report
- End of Study Final Report (CSR)

End of Study Database Locked

Major Task Details | Adjustments | Distribution

Name:

Description:

Labor:

Unit of Measure: CRF Page (Total w/ Drops)

Display this Major Task:

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Complete data coding (during follow-up)	Data Management	Data Management
<input type="checkbox"/> Annotate CRFs to database specs (during follow-up)	Database Programming	Data Management
<input type="checkbox"/> Conduct query resolution (data group, during follow-up)	Data Management	Data Management
<input type="checkbox"/> Prepare information for DSMB reporting (during follow-up)	Database Programming	Data Management

Please specify a name for this Major Task

New default labor effort under new "End of Study" Major Tasks.





Clinical Intelligence Update



MOH/FDA Delay Update

USA, UK, Japan, n=90, 3 centers for Imaging with 11C in Breast Cancer (Marlinostat) This plan is using the 5.9 cost model

Choose Locations X

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

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 checked="" type="radio"/> ClearTrial Defaults	Any Phase	---	---	---

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MOH Delay default values by location have been updated to be current with the latest regulatory changes per location, effective for 2021.



Data Management Resource Update

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

Resources

Filter

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

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

<input type="checkbox"/>	Name ▲	Last Modified	Last Modified By
<input type="checkbox"/>	DM01 - Data Coordinator	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	DM02 - Data Entry Clerk	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	DM03 - Data Manager	11/10/06 12:00 AM	
<input type="checkbox"/>	DM04 - DM Programmer	11/10/06 12:00 AM	
<input type="checkbox"/>	DM06 - Senior DM Programmer	11/10/06 12:00 AM	
<input type="checkbox"/>	DM07 - EDC Help Desk Support Specialist	06/18/11 12:00 AM	
<input type="checkbox"/>	DM08 - EDC Help Desk Manager	06/18/11 12:00 AM	
<input type="checkbox"/>	DM09 - EDC Trainer	06/18/11 12:00 AM	
<input type="checkbox"/>	DM10 - Senior Director, Data Management	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	DS01 - Medical Monitor	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	DS02 - Medical Associate	01/05/16 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	GA01 - Records Clerk	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	GA02 - Records Manager	11/10/06 12:00 AM	Administrator, ClearTrial

Updated default Data Management Resources



Data Management Labor Update

The screenshot shows the Oracle Task Manager interface. On the left, a tree view lists tasks under 'Unique CRF Page Developed'. A callout box points to this task with the text: 'Updated tasks, resources for Unique CRF Page Developed'. The main panel shows details for this task, including a description, unit of measure, and display options. Below the details are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. At the bottom, there is a table of tasks and their assignments.

Task Search...

- Unique CRF Page Developed
 - Design CRF page (or EDC equivalent)
 - DM03 - Data Manager
 - DM06 - Senior DM Programmer
 - Review CRF (or EDC equivalent)
 - CR01 - Clinical Research Associate
 - DM03 - Data Manager
 - ST01 - Junior Biostatistician
 - Write and approve instructions for CRF page (or EDC equivalent)
 - CR02 - Senior Clinical Research Associate
 - DM03 - Data Manager
 - DM10 - Senior Director, Data Manager
 - Create database edit specifications
 - DM03 - Data Manager
 - DM06 - Senior DM Programmer
- Meetings - Kickoff Meeting
- Meetings - Investigator Meeting
- Meetings - Face to Face Meeting
- Meetings - Status Update to Sponsor
- Meetings - Internal Team Meeting

Unique CRF Page

Updated tasks, resources for Unique CRF Page Developed

Distribution

Unit of Measure: Unique CRF Page

Display this Major Task: after Protocol Amendment per Location

New Task Edit Task Copy Task Delete Task Edit Assignments

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Design CRF page (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Review CRF (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Write and approve instructions for CRF page (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Create database edit specifications	Subject Document Preparation	Data Management

Please specify a name for this Major Task

Close Save Save & Close

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Data Management Labor Update

The screenshot shows the Oracle Task Manager interface. On the left, a tree view lists tasks under three main categories: 'Database Designed', 'Build the study database', and 'Data Entry Screen Developed'. The 'Database Designed' category includes tasks like 'Create database design specifications' with resources DM01, DM03, DM04, DM10, ST01, and ST02. The 'Data Entry Screen Developed' category includes 'Design data entry screen' with resources DM03 and DM06, and 'Program data entry screen' with resource DM04. The main panel shows details for the task 'Unique CRF Page Developed', with tabs for 'Major Task Details', 'Adjustments', and 'Distribution'. A callout box points to the 'Database Designed' section, stating: 'Updated tasks, resources for Database Designed, Data Entry Screen Developed'. Below the callout, a table lists tasks and their assignments.

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> Design CRF page (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Review CRF (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Write and approve instructions for CRF page (or EDC equivalent)	Subject Document Preparation	Data Management
<input type="checkbox"/> Create database edit specifications	Subject Document Preparation	Data Management

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eTMF Costing Update – New Assumptions

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USA, UK, Japan, n=90, 3 centers for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

Notes

Overview
Locations
Site
Treatment

Data
Monitoring
Provider
Meetings
Assignment
Labor
Costs
Payments
Summary
Reports

▼ eTMF (Electronic Trial Master File)

Number of eTMF Country/Region Files:
Number of months for the Vendor to archive the eTMF:
Number of eTMF Site Files:

▼ Medical Writing / Timelines

Number of pages in the Investigator Brochure:
Days from LSLT/LPLT until Database Lock:
Database Lock date: 07/20/23
Days from Database Lock until Draft Report due:
Draft Report date: 09/28/23
Number of manuscripts:
Days from Database Lock until Statistical Report due:
Stat Report date: 08/24/23
Days from Database Lock until Final Report due:
Final Report date: 11/03/23

▼ End of Study

Will there be a Supplemental CSR?: Yes No
Reduce effort for Supplemental CSR by: %
Days from LSLV/LPLV until Database Lock (EOS):
Database Lock (EOS) date: 09/14/23
Days from Database Lock (EOS) until Draft Report (EOS) due:
Days from Database Lock (EOS) until Statistical Report (EOS) due:
Stat Report (EOS) date: 10/19/23
Days from Database Lock (EOS) until Final Report (EOS) due:

Please indicate the data collection method for this study

Close Save Next

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New eTMF assumptions



eTMF Costing Update – New Indirect Costs

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, UK, Japan, n=90, 3 centers for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

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

Edit Plan Notes

Specify pass-through or other indirect costs for this study Current Edit Mode: **Advanced**

Filter
 Show: excluded cost(s) categories where costs total 0.00 per location values and assignments

New Edit Copy Exclude Include Delete

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

Name		Calculated	Adjustment	Total
<input type="checkbox"/> Shipping (not including study drug/test article)	Major CRO	515.00	--	515.00
<input type="checkbox"/> Shipping - Central Lab Test Kits	CT Product	--	--	--
<input type="checkbox"/> Stability Studies Fees & Expenses	CT Product	--	--	--
<input type="checkbox"/> Subject Stipends - Enrolled	CT Product	90,000.00	--	90,000.00
<input type="checkbox"/> Subject Stipends - Screen Failures	CT Product	9,000.00	--	9,000.00
<input type="checkbox"/> TMF Archival	Major CRO	6,000.00	--	6,000.00
<input type="checkbox"/> TMF Shipping	Major CRO	225.00	--	225.00
<input type="checkbox"/> Translation Services - 3rd Party	CT Product	--	--	--
<input type="checkbox"/> Travel - Monitoring Travel Expenses	Major CRO	233,667.00	--	233,667.00
<input type="checkbox"/> Travel - Other Travel Expenses	Major CRO	--	--	--
Total:		1,781,588.51	0.00	1,781,588.51

Close **Save** **Next**

New eTMF Pass Through Costs



eTMF Costing Update – New Resources

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Resources

Filter

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

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

<input type="checkbox"/>	Name ▲	Last Modified	Last Modified By
<input type="checkbox"/>	PV02 - Safety Coordinator	01/05/16 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	PV03 - Safety Database Administrator	01/05/16 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	QA01 - Quality Assurance Manager	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	QA02 - Quality Assurance Auditor	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	RG01 - Regulatory Submissions Specialist	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	RG02 - Regulatory Submissions Manager	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	RG03 - Director Regulatory Affairs	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	ST01 - Junior Biostatistician	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	ST02 - Senior Biostatistician	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	ST03 - Statistical Programmer	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	ST04 - Director Biostatistics/Data Management	11/10/06 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	TMF01 - TMF Manager	10/02/19 12:00 AM	Administrator, ClearTrial
<input type="checkbox"/>	TMF02 - TMF Coordinator	10/02/19 12:00 AM	Administrator, ClearTrial

eTMF Costing Update – New Labor

The screenshot shows the Oracle Task Manager interface. On the left is a task search tree with 'eTMF Setup' selected. The main panel shows the configuration for the 'eTMF Setup' major task. A callout box points to the 'eTMF Setup' entry in the tree and the 'Major Task Details' tab in the main panel. The callout text reads: 'New default effort under new “eTMF Setup” Major Task'. The main panel includes tabs for 'Major Task Details', 'Adjustments', and 'Distribution'. The 'Major Task Details' tab is active, showing a description of the task, labor options (varies by location or is centralized), unit of measure, and a dropdown to display the task after another task. Below the main panel are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. At the bottom right are 'Close', 'Save', and 'Save & Close' buttons.

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> eTMF Master File Setup	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Country/Region File Setup	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Site File Setup	eTMF	Clinical Monitoring, Closeout, and Site A...

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eTMF Costing Update – New Labor

The screenshot shows the Oracle Task Manager interface. On the left is a 'Task Search...' sidebar with a tree view of tasks. The 'eTMF Maintenance' task is selected and highlighted. The main area shows the configuration for 'eTMF Maintenance' under the 'Major Task Details' tab. The 'Name' field contains 'eTMF Maintenance' and the 'Description' field contains 'The ongoing maintenance of eTMF Master, Country/Region and Site Files.' Below the description, there are radio buttons for 'is centralized' and a 'Unit of Measure: Month' dropdown. At the bottom of the configuration area, there are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. Below these buttons is a table with the following data:

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> eTMF Master File Maintenance	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Country/Region File Maintenance	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Site File Maintenance	eTMF	Clinical Monitoring, Closeout, and Site A...

A callout box with a red border and a pointer to the 'eTMF Maintenance' task in the sidebar contains the text: 'New default effort under new "eTMF Maintenance" Major Task'.

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eTMF Costing Update – New Labor

Task Manager

Task Search...

- Issued Repeat Summary Listing
- Issued Repeat Summary Figure/Graph
- Stat Report
- Draft Report
- Final Report (CSR)
- eTMF Close-out**
 - eTMF Site File Close-out
 - TMF02 - TMF Coordinator
 - eTMF Country/Region File Close-out
 - TMF02 - TMF Coordinator
 - eTMF Master File Close-out
 - TMF01 - TMF Manager
- Prepared Publication
- End of Study Database Locked
- End of Study Stat Report
- End of Study Draft Report
- End of Study Final Report (CSR)
- EDC Help Desk
- EDC Training
- Sponsor Oversight
- New...

eTMF Close-out

Major Task Details | Adjustments | Distribution

Name: eTMF Close-out

Description: The closing out of eTMF for the entire study to ensure compliance, accuracy and completeness.

is centralized Unit of Measure: Study

Report (CSR)

New Task Edit Task Copy Task Delete Task Edit Assignments

Task Name	Assignment Group	Summary Category
<input type="checkbox"/> eTMF Site File Close-out	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Country/Region File Close-out	eTMF	Clinical Monitoring, Closeout, and Site A...
<input type="checkbox"/> eTMF Master File Close-out	eTMF	Clinical Monitoring, Closeout, and Site A...

Please specify a name for this Major Task

Close Save Save & Close

New default effort under new "eTMF Close-out" Major Task

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Usability Enhancements



New Study Phase for Phase I (Patients)

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Create Study

General Information

Study Name: Protocol:

Product/Compound: Phase:

Sponsor: Status:

Billing Code:

Therapeutic Area & Indication

Therapeutic Area: Indication:

Substitute the names below for therapeutic area and indication

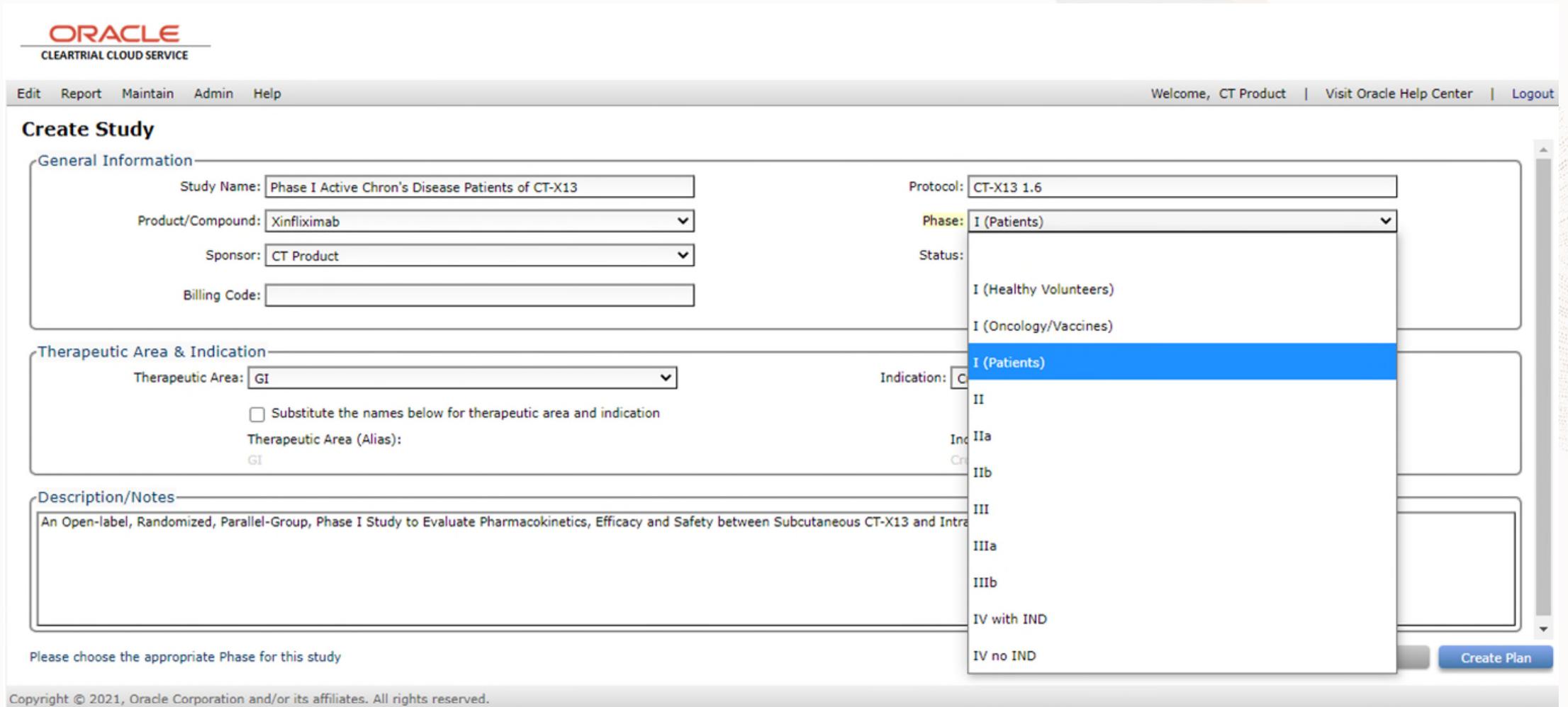
Therapeutic Area (Alias):
GI

Description/Notes

An Open-label, Randomized, Parallel-Group, Phase I Study to Evaluate Pharmacokinetics, Efficacy and Safety between Subcutaneous CT-X13 and Intra

Please choose the appropriate Phase for this study

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Cost Model Displayed by Default on Template List Screen

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Templates

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

Template Name ▲	Phase	Therapeutic Area	Indication	Cost Model
<input type="checkbox"/> Breast Cancer Oncology Template	I (Oncology/Vaccines)	Oncology	Breast Cancer	5.9

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Calculated Cost Available for Display on Plan List Screen

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CLEARTRIAL CLOUD SERVICE

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

Plans

Filter

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

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

Plan Name	Study Name	Description	Status	Cost Model	Created By	Calculated Cost*
<input type="checkbox"/> USA, Germany, UK, France, n=40	Imaging with 11C in Breast C...	4 sites, 4 countries, dose esc...	Draft	5.9	badakhshanian, Leyla	\$27,231,705
<input type="checkbox"/> USA, Germany, UK, n=30		dose esc...	Draft	5.9	badakhshanian, Leyla	\$23,001,280

View "Calculated Cost" per plan from the Plan List screen by selecting to include it from "[Configure List Options](#)"

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Create Study from Product List Screen

The screenshot shows the Oracle ClearTrial Cloud Service interface. At the top left is the Oracle logo and 'CLEARTRIAL CLOUD SERVICE'. A navigation bar contains 'Edit', 'Report', 'Maintain', 'Admin', and 'Help'. On the right, it says 'Welcome, CT Product | Visit Oracle Help Center | Logout'. Below this is a 'Products' section with a yellow status bar indicating '1 product is selected' and a 'Remember selections across pages' checkbox. A filter bar shows 'Show: Active Products Only' selected, with a 'My Filter' dropdown and a 'Modify' link. Below the filter are buttons for 'New', 'Edit', 'Delete', 'Restore', and 'Create Study'. The 'Create Study' button is highlighted with a red box and a callout bubble. Below the buttons is a table with columns 'Product Name', 'Description', and 'Last Modified'. The table contains two rows: 'Marlinostat' and 'Xinfiximab'. The 'Xinfiximab' row is selected, indicated by a checked checkbox and a yellow background. At the bottom left, there is a copyright notice: 'Copyright © 2021, Oracle Corporation and/or its affiliates. All rights reserved.'

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CLEARTRIAL CLOUD SERVICE

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

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

Filter

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

New Edit Delete Restore **Create Study**

Product Name	Description	Last Modified
<input type="checkbox"/> Marlinostat	Martinostat is a histone deacetylase inhibitor (HDACi) th...	02/10/21 03:21 PM
<input checked="" type="checkbox"/> Xinfiximab	TNF blocking agent that can treat rheumatoid arthritis, ...	03/05/21 02:47 PM

Create Study when selecting a Product

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Create Study after Creating / Editing a Product

ORACLE
CLEARTRIAL CLOUD SERVICE

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

Edit Product

Product Details

Product ID: Name:

Description:

Please specify the Product ID (example: AB-12345)

Create Study capability available from the New/Edit Product or Product List screen

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All Documents Selected by Default for Location Translations

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

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

Edit Plan Notes

Location	Sites	MOH/FDA Delay	FSA Date
<input type="checkbox"/> Germany	1	90 days	07/24/21 *
<input type="checkbox"/> UK	1	90 days	07/24/21 *
<input type="checkbox"/> USA	1	30 days	05/29/21 *

For 3 location(s), Total/Avg: 3 70

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

Number of Translations/Dialects 1

Select this choice if you want to plan to translate all documents for this language

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All Documents is selected by default for all locations with translations

New Frequency Options for Number of Grant Payments/Site

ORACLE
CLEARTRIAL CLOUD SERVICE

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Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

Notes

Overview	Percent of sites requiring a pre-study site visit (in-person):	<input type="text" value="110.00"/> %	3 sites
Locations	Percent of sites requiring a phone-based pre-study site visit:	<input type="text" value="0.00"/> %	0 sites
Site			
Treatment	Percent of sites requiring site initiation visits (in-person):	<input type="text" value="100.00"/> %	3 sites
Data	Percent of sites requiring only phone-based site initiation:	<input type="text" value="0.00"/> %	0 sites
Monitoring			
Provider	Percent of onsite close-out visits:	<input type="text" value="100.00"/> %	3 sites
Meetings	Percent of sites requiring only phone-based close-outs:	<input type="text" value="0.00"/> %	0 sites
Assignment			
Labor			
Costs	Grant payments frequency:	<input type="text" value="Monthly"/>	
Payments	Number of grant payments per site:		
Summary	Percent of sites using local monitoring:		0 sites
Reports	Percent of sites requiring overhead:		0 sites
	Average percent overhead:	<input type="text" value="25.00"/> %	

Please choose how often Investigator Grant Payments will be made

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New assumption "Grant payments frequency" to change the frequency of grant payments per site

Next



Clear Overrides/Restore Defaults when Managing FSFT Date By Location

Subjects Details

Name:

Enrolled subjects:

Enrollment period: weeks

Manage FSFT date: By Treatment Per Location

FSFT/FPFT Date: 09/28/21

Location-specific Assumptions

Location	# Subjects	FSFT Date	Enrollment Period	LSFT Date	Enrollment Rate
Germany	<input type="text" value="3"/>	11/23/21	<input type="text" value="3"/> weeks	01/03/22	2.17
UK	<input type="text" value="3"/>	11/23/21	<input type="text" value="6"/> weeks	01/03/22	2.17
USA	<input type="text" value="4"/>	09/28/21	<input type="text" value="14"/> weeks	01/03/22	1.24
					1.86

Manage FSFT date

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Click the new clear icon when managing FSFT by location to clear FSFT date overrides



Clear Overrides/Restore Defaults when Managing FSFT Date By Treatment

Subjects Details

Name:

Enrolled subjects:

Enrollment period: weeks

Manage FSFT date: By Treatment Per Location

FSFT/FPFT Date:

Location-specific Assumptions

Location	# Subjects	FSFT Date	Enrollment Period	LSFT Date	Enrollment Rate
Germany	<input type="text" value="3"/>	08/23/21	<input type="text" value="8"/> weeks		1.63
UK	<input type="text" value="3"/>	08/23/21	<input type="text" value=""/> weeks	10/17/21	1.63
USA	<input type="text" value="4"/>	06/28/21	<input type="text" value="16"/> weeks	10/17/21	1.09

Click the clear icon when managing FSFT date by treatment to clear enrollment period by location overrides

Buttons: Cancel, Ok

Click Undo to Restore FSFT Overrides by Location

Subjects Details

Name:

Enrolled subjects:

Enrollment period: weeks

Manage FSFT date: By Treatment Per Location 

FSFT/FPFT Date:  

Location-specific Assumptions

Location	# Subjects	FSFT Date	Enrollment Rate
Germany	<input type="text" value="3"/>	08/23/21	2.17
UK	<input type="text" value="3"/>	08/23/21	2.17
USA	<input type="text" value="4"/>	06/28/21	1.24
		10/03/21	1.86

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Date Displayed When Adjusting Monitoring Frequency by Location

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat) This plan is using the 5.9 cost mod

Edit Per Location Monitoring Schedule

Germany

Monitoring Methods

Monitoring will be performed: on-site via phone

On-Site Monitoring Schedule

Number of Sites: 1

Monitor every: 1 weeks until LSLV until week 4 (09/13/21) and then...

Monitor every: 2 weeks until LSLV until week 6 (09/27/21) and then...

Monitor every: 1 weeks until LSLV until week

Total visits: 370

Monitoring Travel Strategy: Loop

Total visits: 1,121

Please enter the start period for the next monitoring segment

Cancel Ok

Date is displayed next to "until week" so you can model the monitoring frequency by location accurately



Expand/Collapse All Assignment Groups in One-Click

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

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Edit Plan

Notes

Overview Assign tasks to specific service providers Current Edit Mode: **Advanced**

Locations

Site

Treatment

Data

Monitoring

Provider

Meetings

Assignment

Labor

Costs

Payments

Summary

Reports

Task Assignments

Values apply to:

Default service provider for outsourced tasks:

[Hide Tasks](#) [Override Resources or Rates](#)

For the location selected above, use the section below to assign a group of tasks to a different service provider. To assign at the task level, expand an Assignment Group and choose a service provider for each task.

+ Assignment Group / Task	Assign to	Billing Rate Location	Pinned
▶ Project Initiation	(All Providers)	(Back Office)	✕
▶ Protocol Preparation	CT Product	(Back Office)	✕
▶ Protocol Amendments	CT Product	(Back Office) *	✕
▶ Site Startup	Major CRO *	(Local)	✕
▶ Site Identification	Major CRO	(Local)	✕
▶ Collect Regulatory Documents	Major CRO	(Local)	✕
▶ Investigator Brochure	CT Product *	(Back Office) *	✕
▶ Site Initiation	Major CRO	(Local) *	✕

Determines the set of tasks for which the assigned providers are responsible

Close Save Next

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Double-click the (+) to expand all assignment groups. Double-click the (-) to collapse them.



Updated EDC Indirect Costs Default Department Assignment

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

Edit Report Maintain Admin Help

Welcome, CT Product | Visit Oracle Help Center | Logout

Edit Plan

Specify pass-through or other indirect costs for this study

Current Edit Mode: **Advanced**

Filter

Show: excluded cost(s) categories where costs total 0.00 per location values and assignments

New Edit Copy Exclude Include Delete

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

Name	Department	Calculated	Adjusted	Total
<input type="checkbox"/> Drug Distribution - Special Handling	Clinical Operations			
<input type="checkbox"/> Drug Distribution - Standard Shipping	Clinical Operations			
<input type="checkbox"/> Drug Packaging	Clinical Operations			
<input type="checkbox"/> DSMB Reporting	Regulatory			
<input type="checkbox"/> EDC - 3rd Party Costs	Data Management			
<input type="checkbox"/> EDC Hosting	Data Management	93,600.00	--	93,600.00
<input type="checkbox"/> EDC Licensing	Data Management	35,625.00	--	35,625.00
<input type="checkbox"/> EDC Setup	Data Management	8,000.00	--	8,000.00
<input type="checkbox"/> Event Committee Costs	Clinical Operations	--	--	--
<input type="checkbox"/> FDA Audit	Regulatory			
Total:		2,757,262.48	0.00	2,757,262.48

Close Save Next

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EDC indirect costs are assigned to the "Data Management" department by default



Updated Meetings Indirect Costs Default GL Code Assignment

ORACLE
CLEARTRIAL CLOUD SERVICE

USA, Germany, UK, n=30 for Imaging with 11C in Breast Cancer (Marlinostat)
Phase I (Oncology/Vaccines) / Protocol ID: MP17_14
Indication: Oncology / Breast Cancer

This plan is using the 5.9 cost model

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

Edit Plan Notes

Specify pass-through or other indirect costs for this study Current Edit Mode: **Advanced**

Filter

Show: excluded cost(s) categories where costs total 0.00 per location values and assignments

New Edit Copy Exclude Include Delete

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

Name				Total
<input type="checkbox"/> Meeting - Face to Face Meeting (CT Product)	Outside Services			--
<input type="checkbox"/> Meeting - Face to Face Meeting (Major CRO)	Outside Services			00.00
<input type="checkbox"/> Meeting - Internal Team Meeting (Major CRO)	Outside Services			--
<input type="checkbox"/> Meeting - Investigator Meeting (CT Product)	Outside Services			00.00
<input type="checkbox"/> Meeting - Investigator Meeting (Major CRO)	Outside Services			00.00
<input type="checkbox"/> Meeting - Kickoff Meeting (CT Product)	Outside Services			--
<input type="checkbox"/> Meeting - Kickoff Meeting (Major CRO)	Outside Services	4,000.00	--	4,000.00
<input type="checkbox"/> Meeting - Status Update to Sponsor (CT Product)	Outside Services			--
<input type="checkbox"/> Meeting - Status Update to Sponsor (Major CRO)	Outside Services			--
<input type="checkbox"/> Miscellaneous Costs	Other	5,700.00		5,700.00
Total:		2,757,262.48	0.00	2,757,262.48

Close **Save** **Next**

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Meetings indirect costs are assigned to the "Outside Services" GL Code by default



Updated Plan Assumptions Report to Easily Support Change Orders

The screenshot shows an Excel spreadsheet with the following data table:

Sites and Site Management		
Assumption		
Num weeks to site approval	Germany	21
	UK	21
	USA	13
FSA Date	Germany	24-Jul-2021
	UK	24-Jul-2021
	USA	29-May-2021
Last Site Approved	Germany	30-Jul-2021
	UK	30-Jul-2021
	USA	04-Jun-2021
Number of sites	Germany	1
	UK	1

A callout box points to the table with the text: "Location-specific and Treatment-specific assumptions are now vertical to align with Change Order formats".



New Reset Password Link When Locked Out



Your account is locked. Please contact CT Product to unlock your account.

You may contact CT Product at product@cleartrial.com

You can also [reset your password](#) to automatically unlock your account.

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New instructions to “[reset your password](#)” when you are locked out.



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