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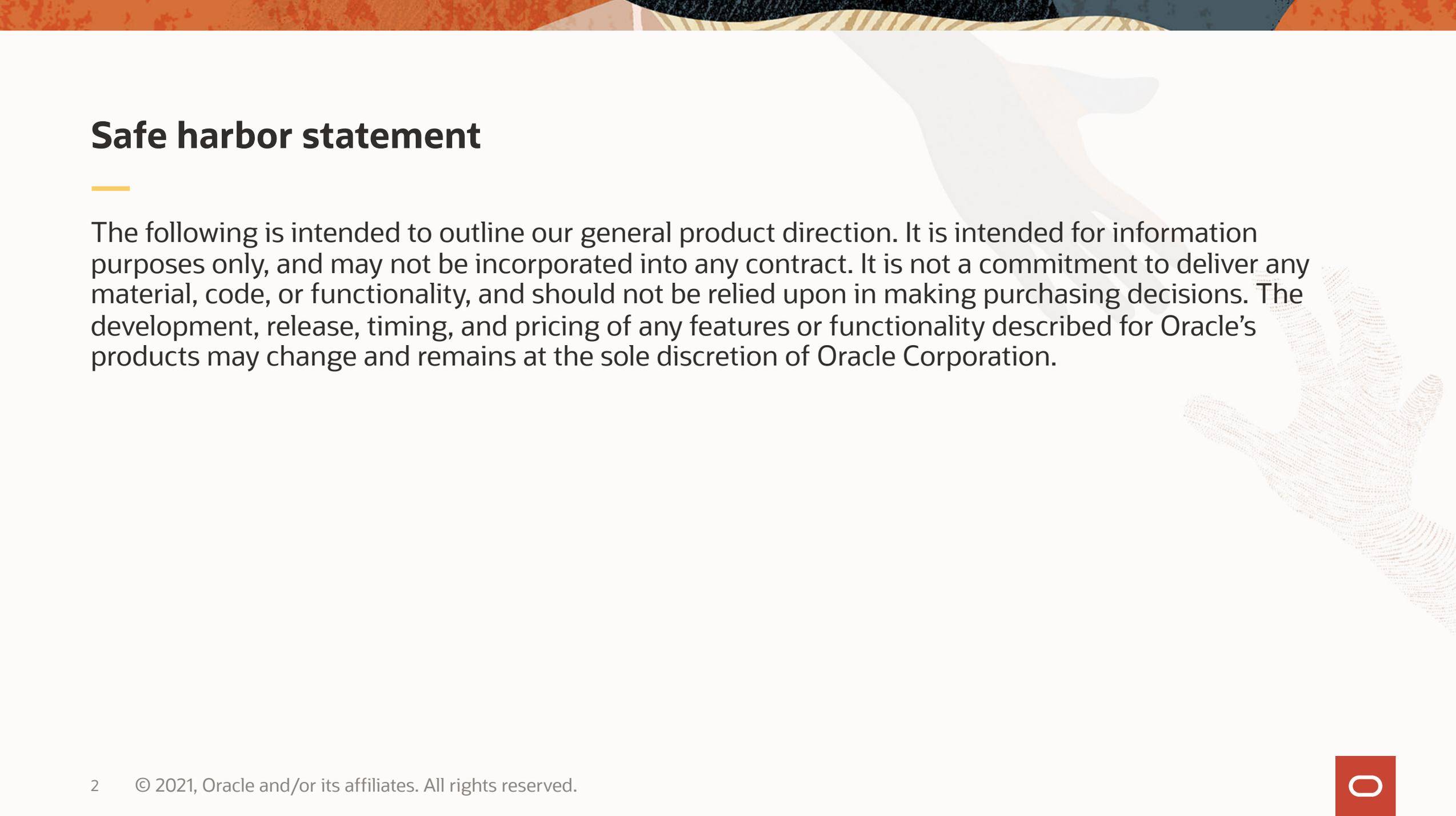
Introduction to ClearTrial 5.9

June 2021

Oracle Health Sciences. **For life.**

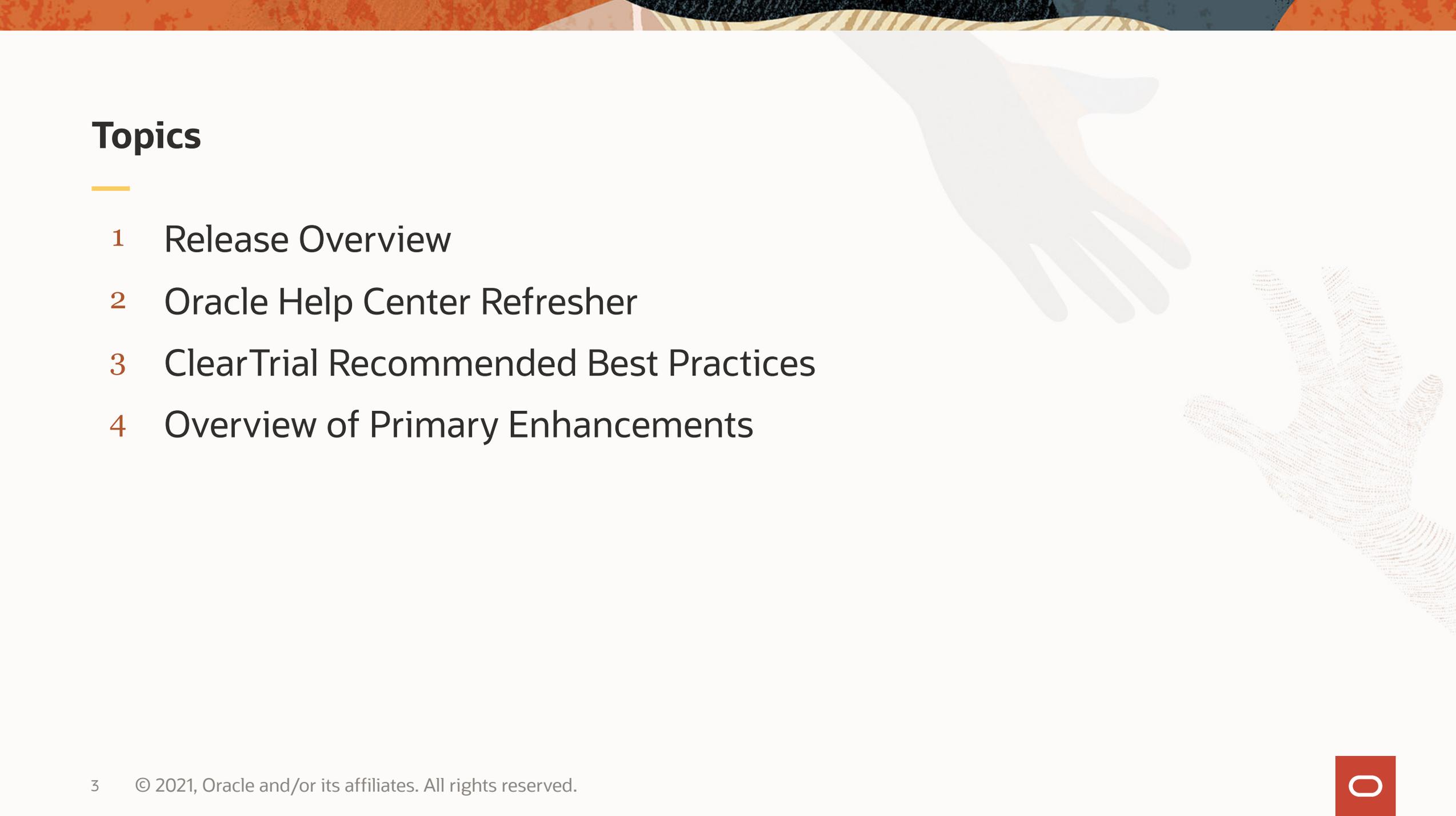


Safe harbor statement

The background of the slide features a decorative header with orange and brown tones. Below the header, there is a large, faint illustration of two hands reaching towards each other. One hand is a solid light gray, while the other is a fingerprint made of small, repeating text characters. The overall theme suggests a focus on security, trust, and digital identity.

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 hand reaching out from the top right. Below it, a fingerprint is formed by a dense collection of small, light-colored text characters, also reaching out from the right side.

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

ClearTrial 5.9 Overview



Objectives: 5.9では、ClearTrialでモデル化し、正確に計画できる試験の種類が増えました。開始時期をずらした複数のコホートや長期のフォローアップなど、複雑な試験デザインのサポートが強化されています。

このソフトウェアアップデートには、アップグレードされたプラン/テンプレートに最新の業界標準原価計算アルゴリズムを提供する新しい5.9コストモデルが含まれます。

Release Approach: Market and Customer Driven

Remember to Visit the Oracle Help Center

The screenshot shows the Oracle Cleartrial Cloud Service interface. At the top left is the Oracle logo and 'CLEARTRIAL CLOUD SERVICE'. Below it are navigation links: Edit, Report, Maintain, Admin, Help. On the right, there is a user greeting 'Welcome, CT Product' and a link 'Visit Oracle Help Center' which is highlighted with a red box. Below the navigation is a 'Plans' section with a filter bar and a table of plans. The table has columns: Plan Name, Study Name, Description, Status, Cost Model, and Created By. There are three rows of plan data. A callout box with a red border points to the 'Visit Oracle Help Center' link and contains Japanese text.

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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](#)

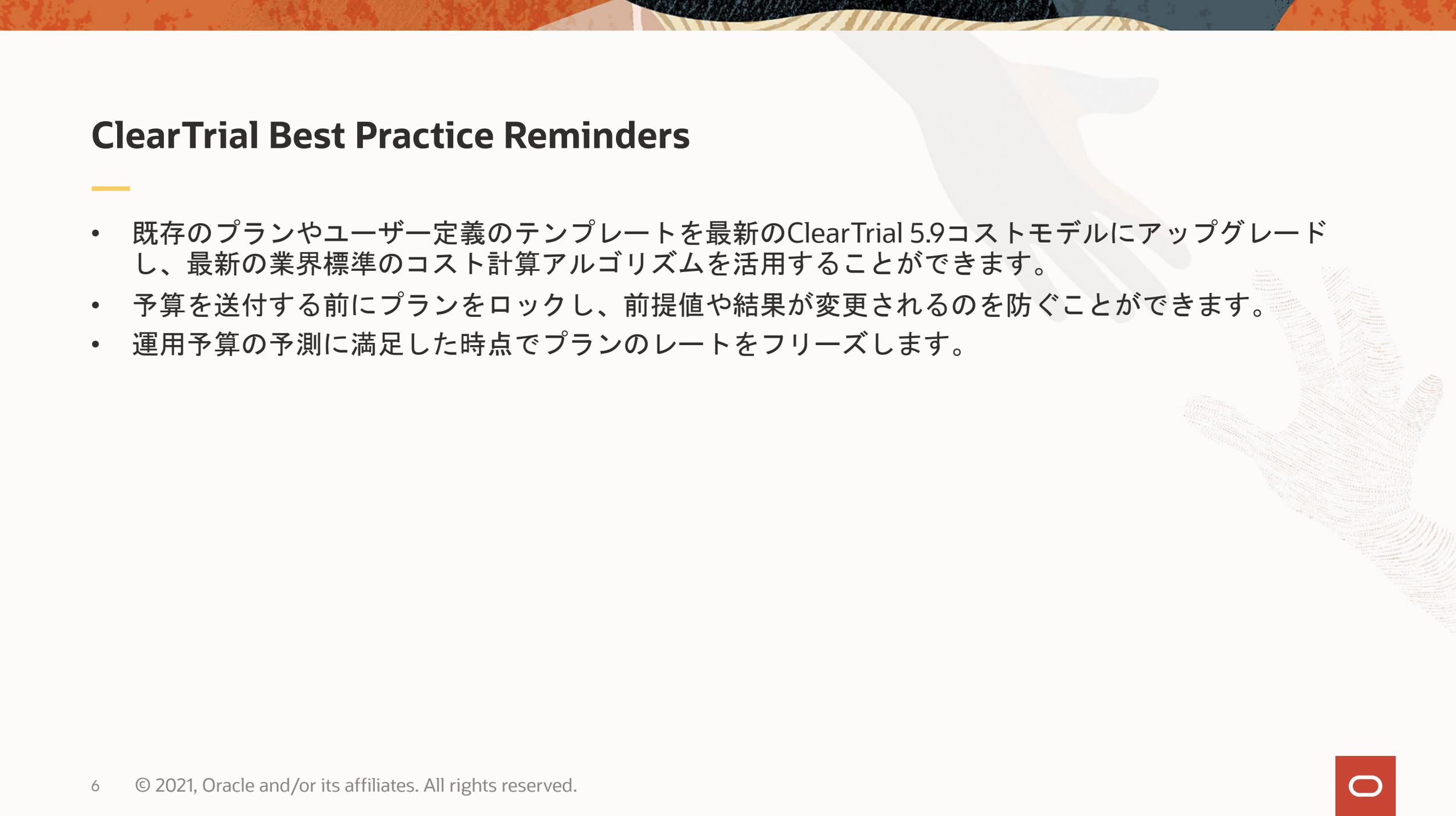
New Edit Delete Restore Copy Compare Actions...

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

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Visit Oracle Help Center
をクリックして、バージョン固有、または製品のヘルプ情報を参照できます

ClearTrial Best Practice Reminders



- 既存のプランやユーザー定義のテンプレートを最新のClearTrial 5.9コストモデルにアップグレードし、最新の業界標準のコスト計算アルゴリズムを活用することができます。
- 予算を送付する前にプランをロックし、前提値や結果が変更されるのを防ぐことができます。
- 運用予算の予測に満足した時点でプランのレートをフリーズします。

Upgrade Plans to the Latest Cost Model via Change Attributes

ORACLE
CLEARTRIAL CLOUD SERVICE

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](#)

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

<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

The screenshot displays the Oracle ClearTRIAL Cloud Service interface. On the left, a 'Plans' table lists two plans: 'USA, Germany, UK, France, n=40' (checked) and 'USA, Germany, UK, n=30'. A 'Change Plan Attributes' dialog box is open, allowing modification of the selected plan. The dialog fields include: Plan Name (USA, Germany, UK, France, n=40), Status (Draft), Cost Model (5.8), Custom Field Model (5.9), Short Description (5.8), and Long Description (5.7). The 'Cost Model' dropdown is highlighted, showing a list of options from 5.3 to 5.9. An arrow points from the '5.9' option to a callout box containing step 4 of the process.

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

最新コストモデルの影響を評価する方法

以下の手順を実施することで、既存Planのコストモデルを5.9に更新した場合の影響範囲を比較することが可能です。

1. Plan/Templateリスト画面で対象のPlan/Templateを選択して「Copy」をクリックします
2. Use Cost Model fromで5.9を選択し、「OK」をクリックします
3. オリジナルのPlan/Templateと、コピーされたPlan/Templateを選択して「Compare」をクリックして、予算の比較を実行します。

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 | Visit Oracle Help Center | Logout'.

The main section is titled 'Plans'. It includes a filter section with options: 'All Plans', 'Active Plans Only' (selected), and 'Plans matching filter: My Filter'. There is also a 'Configure List Options' link. Below the filter, there are action buttons: 'New', 'Edit', 'Delete', 'Restore', 'Copy', 'Compare', and 'Other Actions...'. The 'Compare' button is highlighted with a red box, and a tooltip 'Compare Selected Plans' is visible over it.

The table below shows a list of plans. The first two rows are highlighted in yellow, indicating they are selected. The 'Compare' button is also highlighted with a red box, and a callout box points to it with 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.'

<input type="checkbox"/>	Plan Name ▲	Study Name	Description	Status	Cost M	Compare Selected Plans	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
<input type="checkbox"/>	USA, Germany, UK, n=30	Imaging with 11C in Breast Cancer	3 sites, 3 countries, dose escalatio...	Draft	5.9		badakhshanian, Leyla

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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 user experience and complex trial designs.

バージョン5.9では以下のアップデートにより、Planを作成する際に新しいユーザーエクスペリエンスをもたらします。

- 最大26のコホート/治療法を直感的にモデル化
- 治療開始時期の分散
- スクリーニング期間の定義
- フォローアップ期間/長期フォローアップ、延長試験の定義
- すべての試験セグメントで運用特性を指定 スクリーニング、治療、フォローアップ
- サイクルの追加
- 正確なマイルストーンの表示、など

ロケーション毎の症例数、Investigator Grantを入力する項目がLocation tabからTreatment tabに移動しました

ORACLE
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をTreatment tabに移動し, Subject tabが削除されました

ORACLE 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

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

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	Follow subjects for: 0 weeks % completed subjects followed: 0.00 % First follow-up occurs after: 0 days Follow-up visits occur every: 0 days

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

FSLT: 08/15/21 LSLT: 06/26/27 FSLV: 08/15/21 LSLV: 06/26/27

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どの登録グループがどの治療とフォローアップに入るか指定します

Investigator Grantsの入力項目を1画面に集約しました

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 mode

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

Edit Plan Notes

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

▼ 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)	<input type="text" value="0.00"/> <input type="text" value="USD"/>	<input type="text" value="125.00"/> <input type="text" value="USD"/>	<input type="text" value="375.00"/> <input type="text" value="USD"/>	<input type="text" value="100.00"/> %	<input type="text" value="1,000.00"/> <input type="text" value="USD"/>
Germany	<input type="text" value="14,225.00"/> <input type="text" value="EUR"/>	<input type="text" value="225.00"/> <input type="text" value="EUR"/>	<input type="text" value="375.00"/> <input type="text" value="USD"/>	<input type="text" value="100.00"/> %	<input type="text" value="1,200.00"/> <input type="text" value="EUR"/>
UK	<input type="text" value="12,500.00"/> <input type="text" value="GBP"/>	<input type="text" value="175.00"/> <input type="text" value="GBP"/>	<input type="text" value="375.00"/> <input type="text" value="USD"/>	<input type="text" value="90.00"/> %	<input type="text" value="1,175.00"/> <input type="text" value="GBP"/>
USA	<input type="text" value="10,500.00"/> <input type="text" value="USD"/>	<input type="text" value="125.00"/> <input type="text" value="USD"/>	<input type="text" value="375.00"/> <input type="text" value="USD"/>	<input type="text" value="100.00"/> %	<input type="text" value="1,000.00"/> <input type="text" value="USD"/>

▼ Treatment(s)

You have selected 1 of 4 treatments [clear]

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

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開始時期をずらした複数の症例コホート/治療法の定義ができます

The screenshot displays the 'Edit Plan' interface for a clinical trial. The trial title is 'USA, Germany, UK, n=20 for Imaging with 11C in Breast Cancer (Marlinostat) Phase I (Oncology/Vaccines) / Protocol ID: MP17-14'. The indication is 'Oncology / B...'. The cost model is '5.9'. The interface includes a navigation menu on the left with options like Overview, Locations, Site, Treatment, Data, Monitoring, Provider, Meetings, Assignment, Labor, Costs, Payments, Summary, and Reports. The main area shows treatment definitions for Screening, Treatment, and Follow-Up phases. Two callouts are present: one pointing to the 'Treatment(s)' section with the text 'スクリーニング、治療、フォローアップの各セグメントにおいて、運用上の特徴が異なる最大26の固有のコホートを定義します' (In each segment of screening, treatment, and follow-up, you can define up to 26 unique cohorts with different operational characteristics), and another pointing to the 'Stack treatments' option. The bottom of the screen shows a summary of 'Total Subjects: 20' and various dates (PASD, FSFV, LSFV, FSFT, LSFT, FSLT, LSLT, FSLV, LSLV). Copyright © 2021, Oracle Corporation and/or its affiliates. All rights reserved.



複数のトリートメントサイクルが追加できます

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

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

Location	Cost	Unit	Screening Cost	Unit	Treatment Cost	Unit
Germany	90,000.00	USD	0.00	USD	0.00	USD
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

試験デザインを正確にモデル化するために、治療群ごとに複数のサイクルを定義できます。



Locationごと、Treatmentごとの症例コホートの前提条件を定義します

Subjects Details

Name: Treatment A
Enrolled subjects: 5
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	1	10/27/21	2,200 days	11/04/27	0.01
UK	2	09/20/21	2,160 days	08/19/27	0.03
USA	2	07/26/21	2,100 days	04/25/27	0.03

11/04/27 0.02

Cancel Ok

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Locationごとに
FSFT日付を管理

Locationごとに治療
開始日を変更



登録分布がTreatmentごと、Locationごとに移動しました

The screenshot shows the 'Edit Treatment A' window with the 'Enrollment' tab selected. The 'Options' section has 'Manage enrollment distribution values' set to 'Per Location', 'Location' set to 'USA', 'Enrollment distribution' set to 'Custom', and 'Distribution resolution' set to 'Weekly'. The 'Location-specific Assumptions' section contains a table with the following data:

All subjects have been allocated			
Period	Week Of	Subjects	Percentage
Week 1:	09/28/21	1	25.0 %
Week 2:	10/05/21	0	0.0 %
Week 3:	10/12/21	1	25.0 %
Week 4:	10/19/21	1	25.0 %
Week 5:	10/26/21	0	0.0 %
Week 6:	11/02/21	0	0.0 %
Total		4 subjects	100.0 %

Below the table is a link for 'Clear Custom Values'. At the bottom right of the window are 'Cancel' and 'Ok' buttons.



Treatmentごと、Locationごとにスクリーニングの想定を定義します

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.

Treatmentごと、Locationごとに介入の想定を定義します

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



Treatmentごと、Locationごとにフォローアップの想定を定義します

The screenshot shows the 'Edit Treatment A' window with the 'Follow-up' tab selected. The window 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

The window includes a sidebar on the left with navigation options like 'Overview', 'Location', 'Site', 'Treatment', 'Data', 'Monitoring', 'Provider', 'Meeting', 'Assignment', 'Labor', 'Costs', 'Payment', 'Summary', and 'Reports'. At the bottom right, there are 'Close' and 'Ok' buttons.

コホートごとにスクリーニング期間中のビジットスケジュール、治療、フォローアップを定義します

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	
	-3	10	
	-2	10	
	-1	10	
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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サイクル全体のビジットごとにCRF、 モニタリング時間、 Grantsを定義します

Use example grant amount: Yes No

Week	CRFs	Visits	Percent of Grant
8			0.60 %
9			0.60 %
10			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 %
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](#)

Cancel Ok



Treatmentごと、LocationごとにGrantsの想定を定義します

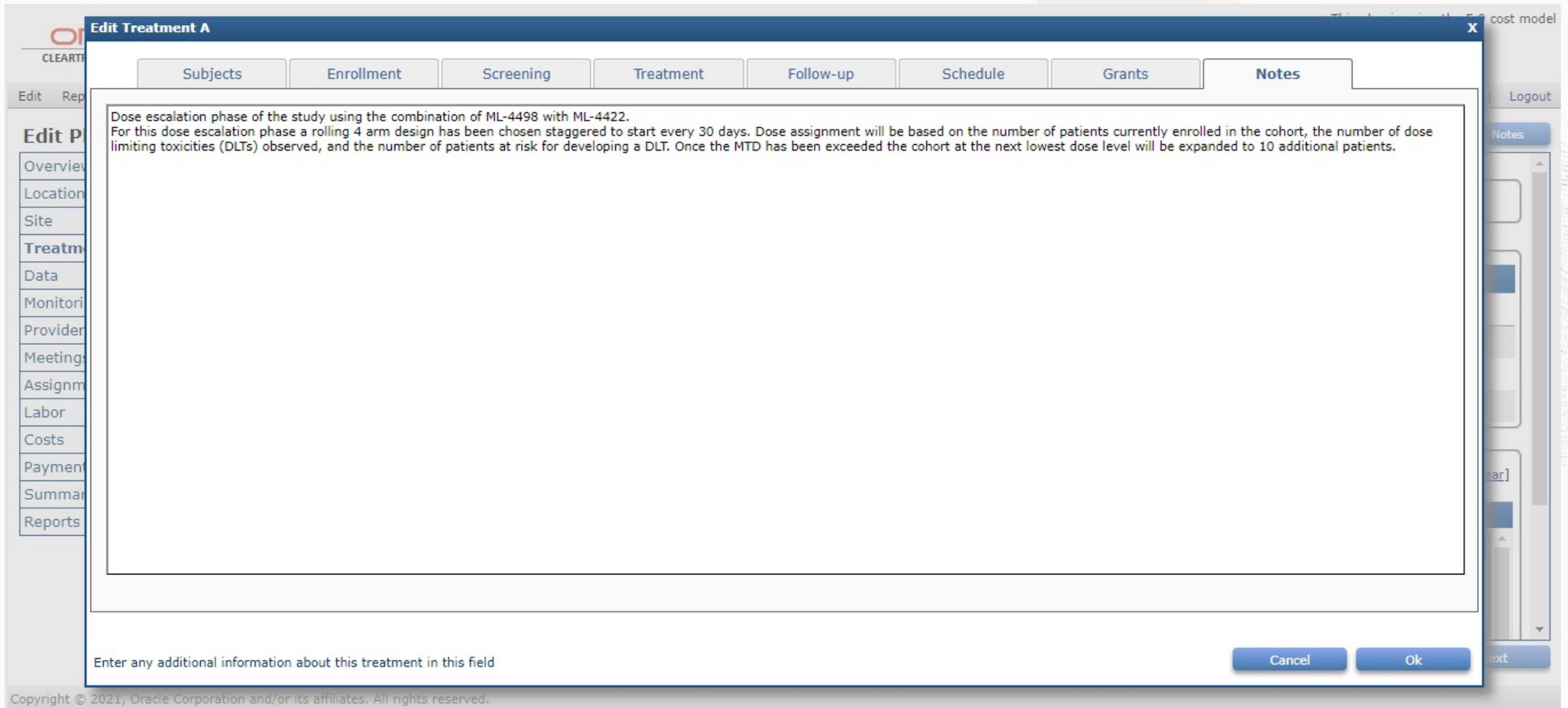
The screenshot shows the 'Edit Treatment A' window with the 'Grants' tab selected. The 'Grants Details' section contains a table with the following data:

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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治療群ごとにStudy Design Noteを入力します



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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正確で明確なマイルストーン

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: excluded milestones

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

マイルストーンはアプリケーション全体、レポートで更新されて、より正確になりました。



フォローアップ中のPM業務を評価するための新項目

ORACLE
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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 Draft Report due:

Days from Database Lock until Statistical Report due:

Days from Database Lock until Final Report due:

Database Lock date: 02/25/29

Draft Report date: 05/06/29

Stat Report date: 04/01/29

Final Report date: 06/11/29

End of Study

Close Save Next

フォローアップ中の新しいタスクのためにPM業務を拡大、縮小

新タスク : Project Management Follow-Up Labor Fees

The screenshot displays the Oracle Task Manager interface. On the left, a tree view shows a hierarchy of tasks. The 'Project Management Week - Follow-up' task is selected and highlighted in blue. A callout box points to this task with the text: '5.9コストモデルでは、PM業務を3つのMajor Taskに分類しました。' (In the 5.9 cost model, PM business is classified into 3 Major Tasks). Another callout box points to the 'Follow-up' sub-task with the text: 'Project Management Week - Follow-upのデフォルトTask' (Default Task for Project Management Week - Follow-up). The main area shows the details for the selected task, including a description, unit of measure (Week), and a table of task 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/Measurement	Project Management / Study Ov...

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新タスク : Site Management Week Follow-up Labor Fees

The screenshot displays the 'Task Manager' interface. On the left, a 'Task Search...' box is above a list of tasks. The task 'Site Management Week - Follow-up' is selected and highlighted in blue. A callout box points to this task with the text: '5.9コストモデルでは、サイト管理業務を3つのMajor Taskに分類しました'. Another callout box points to the task description in the main view, stating: 'Site Management Week - Follow-upのデフォルトTask'. The description 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 are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. A table lists tasks with checkboxes, names, assignment groups, and summary categories. At the bottom right are 'Close', 'Save', and 'Save & Close' buttons.

5.9コストモデルでは、サイト管理業務を3つのMajor Taskに分類しました

Site Management Week - Follow-upのデフォルトTask

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.

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の更新

Medical MonitoringがSite Managementから独自のMajor Taskに移動しました

Medical Monitoring - Follow-upのデフォルトTask

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



新しいEnd of Study (EOS) の想定

フォローアップ (LSLT+1) から予算終了までに発生する新しいEOSの想定を定義します

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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



新タスク : End of Study Labor Fees

The screenshot shows the Oracle Task Manager interface. On the left is a task search list with 'End of Study Database Locked' selected. The main panel shows the configuration for this task, including a name field, a description field, and a table of sub-tasks. A callout box with a red border and orange arrows points to the task name and description fields, containing the text 'End of StudyのデフォルトTask'.

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: End of Study Database Locked

Description: Activities required to get clean data, prior to a database lock.

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

Display this Major Task: a

New Task Duplicate Task Copy Task Delete Task Edit Assignments

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

Close Save Save & Close



Clinical Intelligence Update



MOH/FDA Delayの更新

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

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

Close Ok

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Data Management Resourceの更新

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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

デフォルトのData Management Resourcesが更新されました

Data Management Labor Update

The screenshot shows the 'Task Manager' application window. On the left, a tree view lists tasks under 'Unique CRF Page Developed'. The main area displays details for this task, including a description, unit of measure, and display options. A callout box highlights the task name in Japanese. At the bottom, a table lists related tasks with checkboxes.

Unique CRF Page Developedのタスクとリソースを更新しました

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



Data Management Laborの更新

The screenshot displays the Oracle Task Manager interface. On the left, a tree view shows the task hierarchy under 'Database Designed'. The main panel shows the details for the task 'Unique CRF Page Developed', including tabs for 'Major Task Details', 'Adjustments', and 'Distribution'. A callout box points to the task name in the tree view, containing the text: 'Database Designed, Data Entry Screen Developedのタスクとリソースを更新しました'. Below the task details, there are buttons for 'New Task', 'Edit Task', 'Copy Task', 'Delete Task', and 'Edit Assignments'. At the bottom, a table lists tasks with checkboxes, assignment groups, and summary categories.

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コストの更新 - 新規想定項目



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	▼ eTMF (Electronic Trial Master File)	
Locations	Number of eTMF Country/Region Files: <input type="text" value="3"/>	Number of eTMF Site Files: <input type="text" value="3"/>
Site	Number of months for the Vendor to archive the eTMF: <input type="text" value="12"/>	
Treatment	▼ Medical Writing / Timelines	
Data	Number of pages in the Investigator Brochure: <input type="text" value="125"/>	Number of manuscripts: <input type="text" value="0"/>
Monitoring	Days from LSLT/LPLT until Database Lock: <input type="text" value="49"/>	Days from Database Lock until Statistical Report due: <input type="text" value="35"/>
Provider	Database Lock date: 07/20/23	Stat Report date: 08/24/23
Meetings	Days from Database Lock until Draft Report due: <input type="text" value="70"/>	Days from Database Lock until Final Report due: <input type="text" value="106"/>
Assignment	Draft Report date: 09/28/23	Final Report date: 11/03/23
Labor	▼ End of Study	
Costs	Will there be a Supplemental CSR?: <input checked="" type="radio"/> Yes <input type="radio"/> No	Reduce effort for Supplemental CSR by: <input type="text" value="61"/> %
Payments	Days from LSLV/LPLV until Database Lock (EOS): <input type="text" value="49"/>	Days from Database Lock (EOS) until Statistical Report (EOS) due: <input type="text" value="35"/>
Summary	Database Lock (EOS) date: 09/14/23	Stat Report (EOS) date: 10/19/23
Reports	Days from Database Lock (EOS) until Draft Report (EOS) due: <input type="text" value="70"/>	Days from Database Lock (EOS) until Final Report (EOS) due: <input type="text" value="106"/>

eTMFの項目が追加されました

Please indicate the data collection method for this study

Close Save Next



eTMFコストの更新 – 新規間接経費

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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

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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	Category	Calculated	Adjustment	Total
<input type="checkbox"/> Shipping (not including study drug/test article)	Major CRO	51,000.00	--	51,000.00
<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	0.00	--	225.00
<input type="checkbox"/> Translation Services - 3rd Party	CT Product	--	--	--
<input type="checkbox"/> Travel - Monitoring Travel Expenses	Major CRO	0.00	--	233,667.00
<input type="checkbox"/> Travel - Other Travel Expenses	Major CRO	--	--	--
Total:		1,781,588.51	0.00	1,781,588.51

eTMFのパススルーコストを追加

Close Save Next

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eTMFコストの更新 – 新規リソース

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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

TMFのリソース
を追加



eTMFコストの更新 – 新規タスク

Task Search...

Site Identified by Vendor

eTMF Setup

- eTMF Master File Setup
 - TMF01 - TMF Manager
- eTMF Country/Region File Setup
 - TMF01 - TMF Manager
- eTMF Site File Setup
 - TMF01 - TMF Manager
- Pre-study Site Visit
- Pre-study Site Visit by Phone
- Site Approved
- Site Initiation Visit
- Site Initiation Visit by Phone
- Drug Packaging and Supply Audit
- Study Drug Shipment Tracked
- Completed Statistics & Analysis Plan (SAP)
- Database Designed
- Data Entry Screen Developed
- IVRS Setup
- Subject/Volunteer Randomized
- Project Management Week prior to FSFT

eTMF Setup

Major Task Details Adjustments Distribution

Study-specific eTMF instance, including the Master File, Country/Region File(s) and Site File(s) setup.

Unit of Measure: Study

Display this Major Task: after Site Identified by Vendor

New Task Edit Task Copy Task Delete Task Edit Assignments

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...

Close Save Save & Close

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eTMFコストの更新 – 新規タスク

Task Manager

Task Search...

- Subject/Volunteer Randomized
- Project Management Week prior to FSFT
- Project Management Week after FSFT
- Project Management Week - Follow-up
- eTMF Maintenance**
 - eTMF Master File Maintenance
 - TMF01 - TMF Manager
 - eTMF Country/Region File Maintenance
 - TMF02 - TMF Coordinator
 - eTMF Site File Maintenance
 - TMF02 - TMF Coordinator
- SAE Processed
- Expedited Safety Report Completed
- Medical Data Listing Review
- Medical Monitoring
- Subject Monitored
- Cohort Escalation Review
- Monitored, Clean CRF Page
- Onsite Monitoring Visit - Non-SDV Activity
- Phone-based Monitoring Visit
- Separate Drug Accountability Visit

eTMF Maintenance

Major Task Details | Adjustments | Distribution

Name: eTMF Maintenance

Description: The ongoing maintenance of eTMF Master, Country/Region and Site Files.

Unit of Measure: Month

Project Management Week - Follow-up

New Task | Edit Task | Copy Task | Delete Task | Edit Assignments

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...

Close | Save | Save & Close

新Major Task
“eTMF
Maintenance” とデ
フォルトのTask



eTMFコストの更新 – 新規タスク

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

新Major Task “eTMF Close-out” のデフォルトTask



Usability Enhancements



Study Phaseが追加されました : 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バージョンがTemplate List画面にデフォルトで表示されます

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Templates

Filter

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

New Edit Delete Restore Copy Compare Other Actions...

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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Plan List画面にCalculated Costが表示できるようになりました

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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	esc...	Draft			badakhshanian, Leyla	\$23,001,280

“Configure List Options”
で“Calculated Cost”の表示
有無を設定します

Product List画面からStudyの作成が可能になりました

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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**

<input type="checkbox"/>	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

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Productの作成、変更後にStudyの作成が可能になりました

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Edit Product

Product Details

Product ID: Name:

Description:

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

Productの作成/編集および、Product List画面でStudyの作成が可能になりました

Locations画面のTranslationsでAll Documentsがデフォルトで選択されます

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

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

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

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

Cancel Save Next

Notes

All Documentsがデフォルトで選択されます

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Site画面のGrant Paymentsに支払回数オプションが追加されました

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

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:	<input type="text" value=""/>	
Summary	Percent of sites using local monitoring:	<input type="text" value=""/>	0 sites
Reports	Percent of sites requiring overhead:	<input type="text" value=""/>	0 sites
	Average percent overhead:	<input type="text" value="25.00"/> %	

Please choose how often Investigator Grant Payments will be made

Next

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Siteごとに支払いの頻度を変更する“Grant payments frequency”を追加

<Treatment画面>Manage FSFT DateでPer Locationを選択している際に、 上書きした値をクリアしてデフォルトに戻せます

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="6"/> 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

Manage FSFT date

Cancel Ok

Manage FSFT DateでPer Locationが選択されている場合、アイコンをクリックするとFSFT Dateの上書き値をクリアします



<Treatment画面>Managing FSFT Date By Treatmentを選択している際に、 上書きした値をクリアしてデフォルトに戻せます

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="8"/> 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

Clear Overrides / Restore Defaults

10/17/21 1.45

Cancel Ok

Managing FSFT dateで By Treatmentが選択されている場合、アイコンをクリックすると上書きされたEnrollment Periodの値をクリアします



UndoアイコンでFSFT Overrides by Locationの設定を復元できます

Subjects Details

Name:

Enrolled subjects:

Enrollment period: weeks

Manage FSFT date: By Treatment Per Location

FSFT/FPFT Date:

Undo (Restore Overridden FSFT Dates)

Location-specific Assumptions

Location	# Subjects	FSFT Date
Germany	<input type="text" value="3"/>	08/23/21
UK	<input type="text" value="3"/>	08/23/21
USA	<input type="text" value="4"/>	06/28/21

Enrollment Rate
2.17
2.17
1.24

10/03/21 1.86

Cancel Ok

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地域ごとにモニタリング頻度を調整する画面に日付が表示されます

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:	<input type="text" value="1"/>	weeks	<input type="radio"/> until LSLV	<input checked="" type="radio"/> until week <input type="text" value="4"/> (09/13/21) and then...
Monitor every:	<input type="text" value="2"/>	weeks	<input type="radio"/> until LSLV	<input checked="" type="radio"/> until week <input type="text" value="6"/> (09/27/21) and then...
Monitor every:	<input type="text" value="1"/>	weeks	<input checked="" type="radio"/> until LSLV	<input type="radio"/> until week
Total visits:	<input type="text" value="370"/>		Monitoring Travel Strategy:	<input type="text" value="Loop"/>

Total visits: 1,121

Please enter the start period for the next monitoring segment

Cancel Ok

“until week” の隣に日付が表示されるので、地域ごとのモニタリング頻度を正確にモデル化できます

ワンクリックで全てのAssignment Groupsを展開/折り畳むことができます

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.

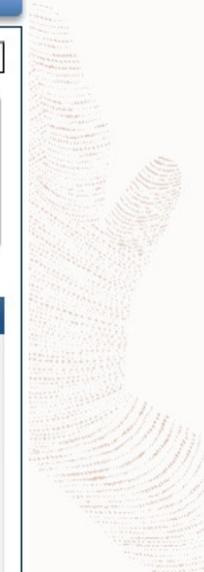
+ Assignment Group / Task	Assign to	Billing Rate Location	Pinned
▶ Project Initiation	(All Providers)	(Back Office)	✖
▶ Protocol Preparation	CT Product	(Back Office)	✖
▶ Protocol Amendments	CT Product	(Back Office) *	✖
▶ Site Startup	Major CRO *	(Local)	✖
▶ Site Identification	Major CRO	(Local)	✖
▶ Collect 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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(+) をダブルクリックすると全てのassignment groupが展開されます。
(-) をダブルクリックすると折り畳まれます。



EDC間接経費：デフォルトの部門割当設定を更新

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

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			Calcu
<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 Audits	Regulatory		
Total:		2,757,262.48	0.00 2,757,262.48

Close Save Next

EDC間接経費はデフォルトで“Data Management”に割り当てられます



Meetings間接経費：デフォルトのGL Code割当設定を更新

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

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

Meetingの間接経費はデフォルトで“Outside Services”のGL Codeに割り当てられます

Close Save Next

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変更管理をサポートできるようにAssumptions Reportを更新しました

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

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

The callout box contains the following text:

変更指示書のフォーマットに合わせて地域別および、処理別の想定条件が縦書きになりました



アカウントがロックされた際にパスワードリセットのリンクが表示されます



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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ロックされた時に表示される
パスワードリセットのリンク



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