ORACLE

Introduction to ClearTrial 5.9

June 2021

Oracle Health Sciences. For life.

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Topics

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

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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

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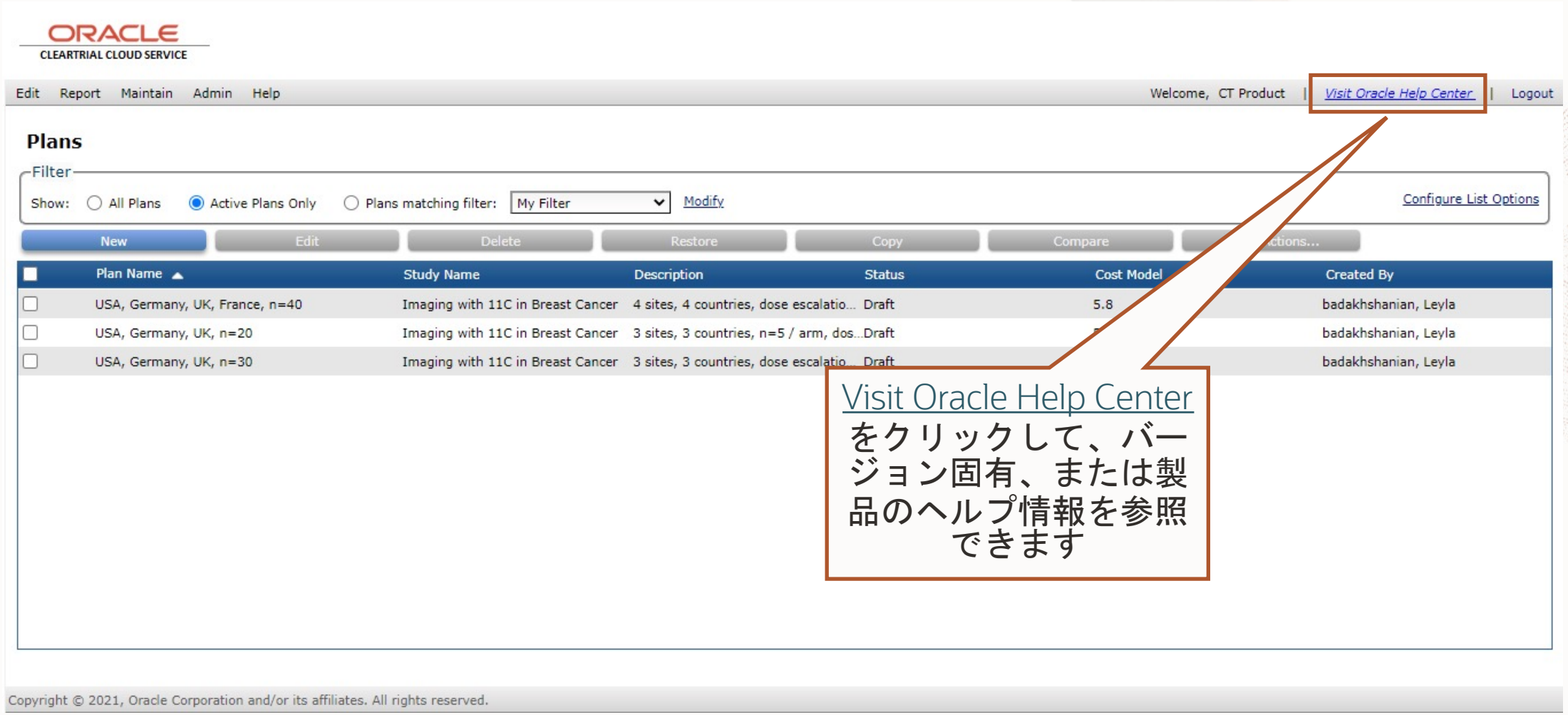
Remember to Visit the Oracle Help Center



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

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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。

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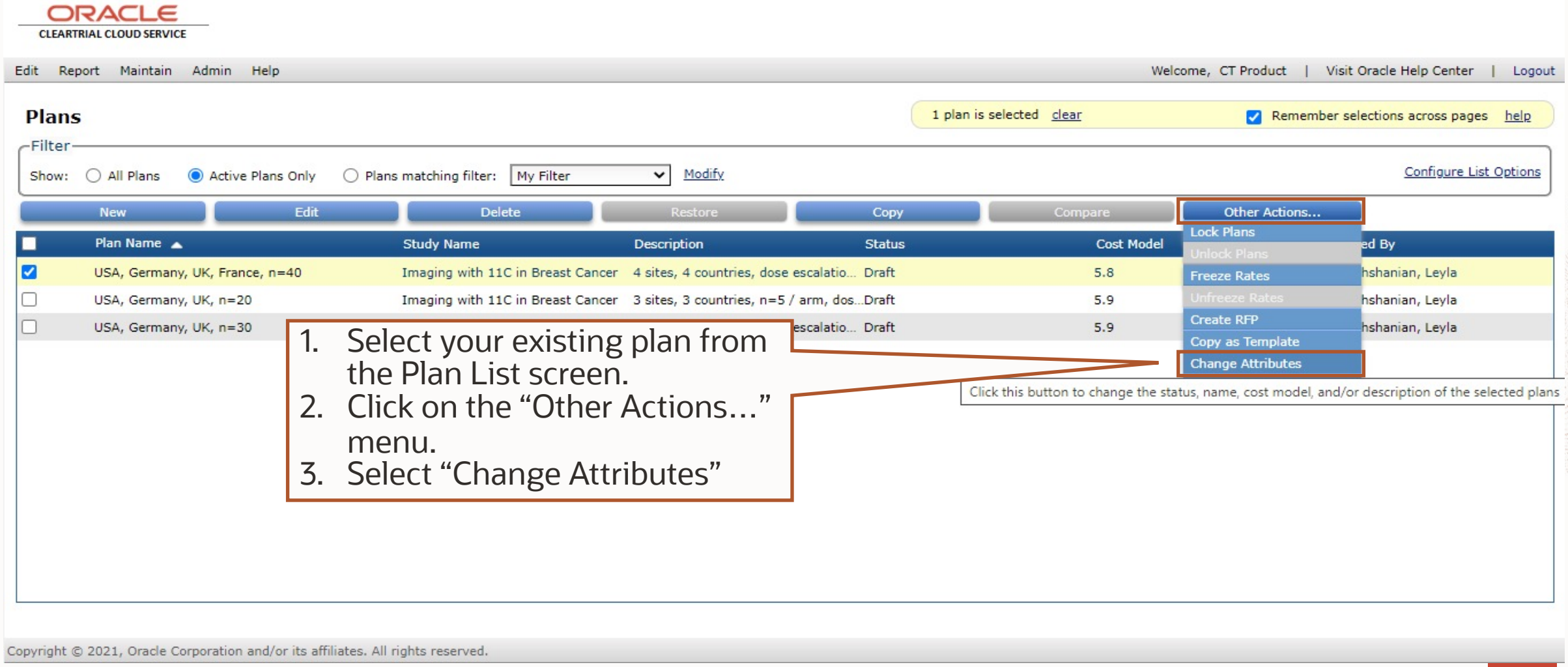
Upgrade Plans to the Latest Cost Model via Change Attributes



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

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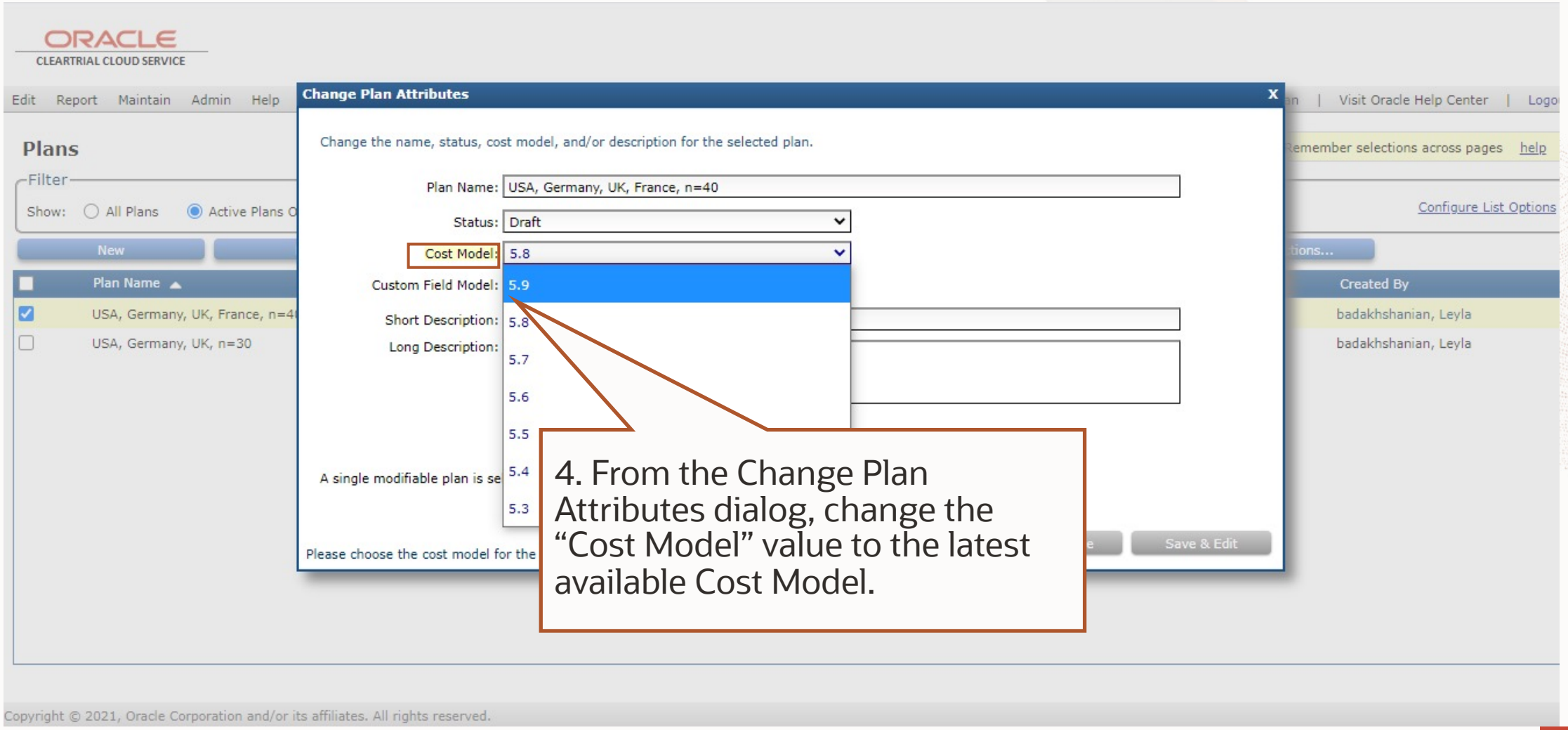
Upgrade Plans to the Latest Cost Model via Change Attributes Cont'd



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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。

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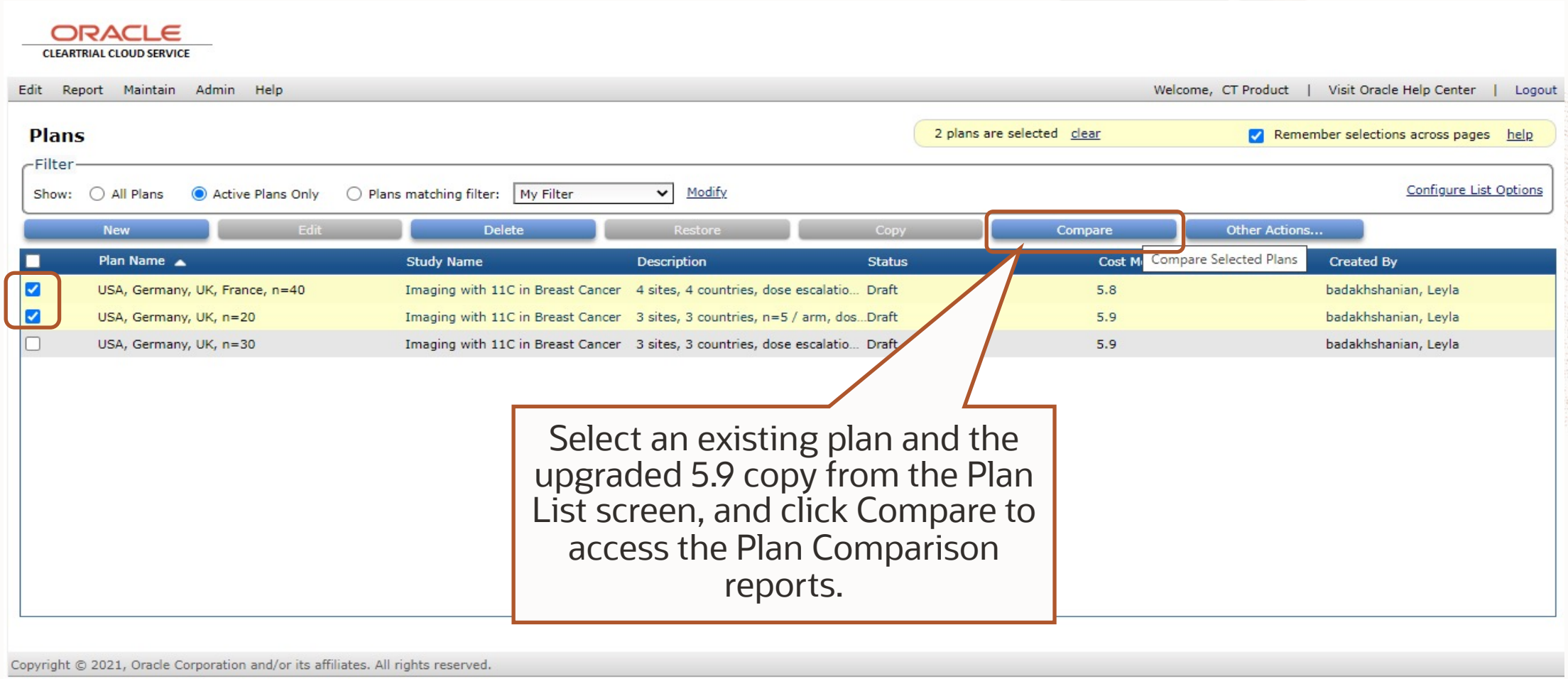
Comparing Plans with Different Cost Models



Select an existing plan and the upgraded 5.9 copy from the Plan List screen, and click Compare to access the Plan Comparison reports.

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Complex Trial Designs Support

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Support for 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

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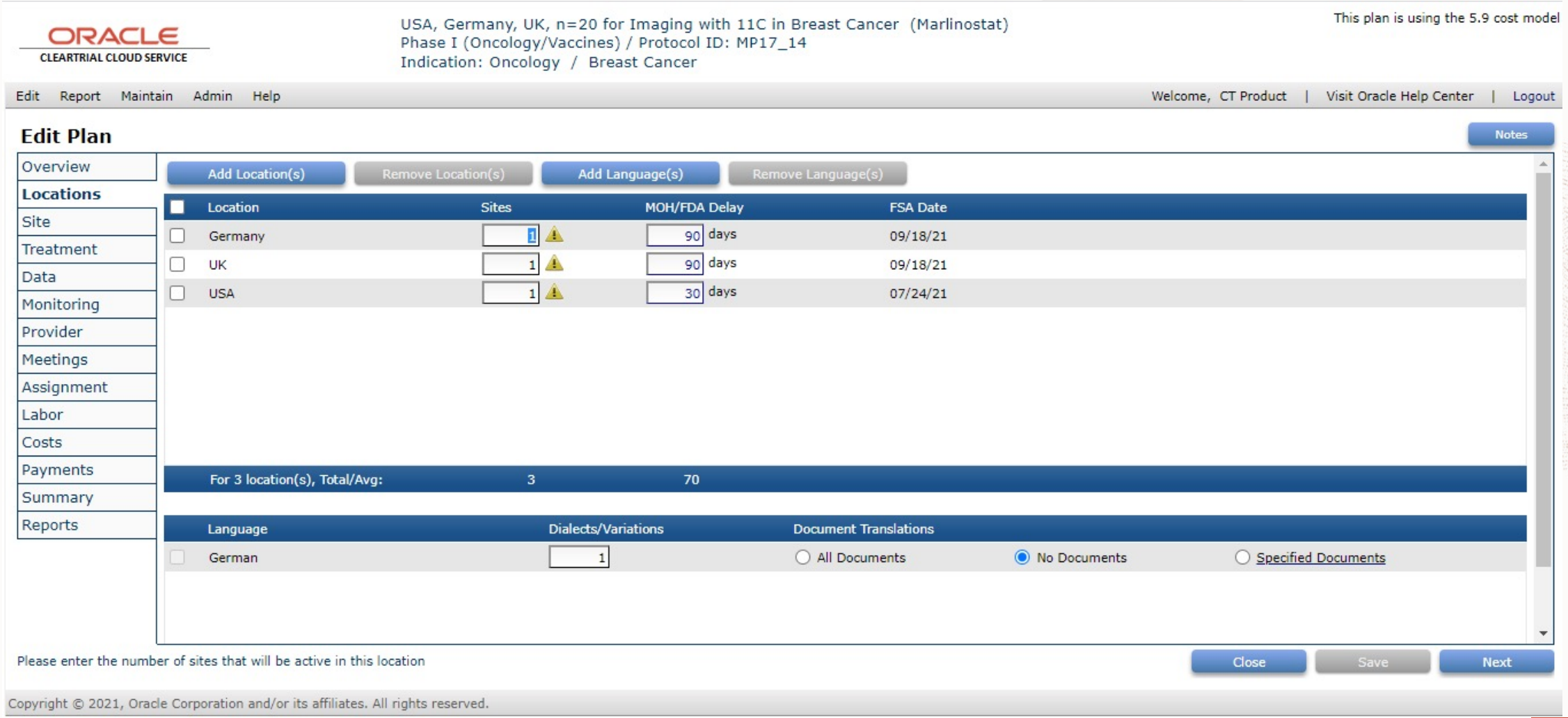
ロケーション毎の症例数、Investigator Grantを入力する項目がLocation tabからTreatment tabに移動しました



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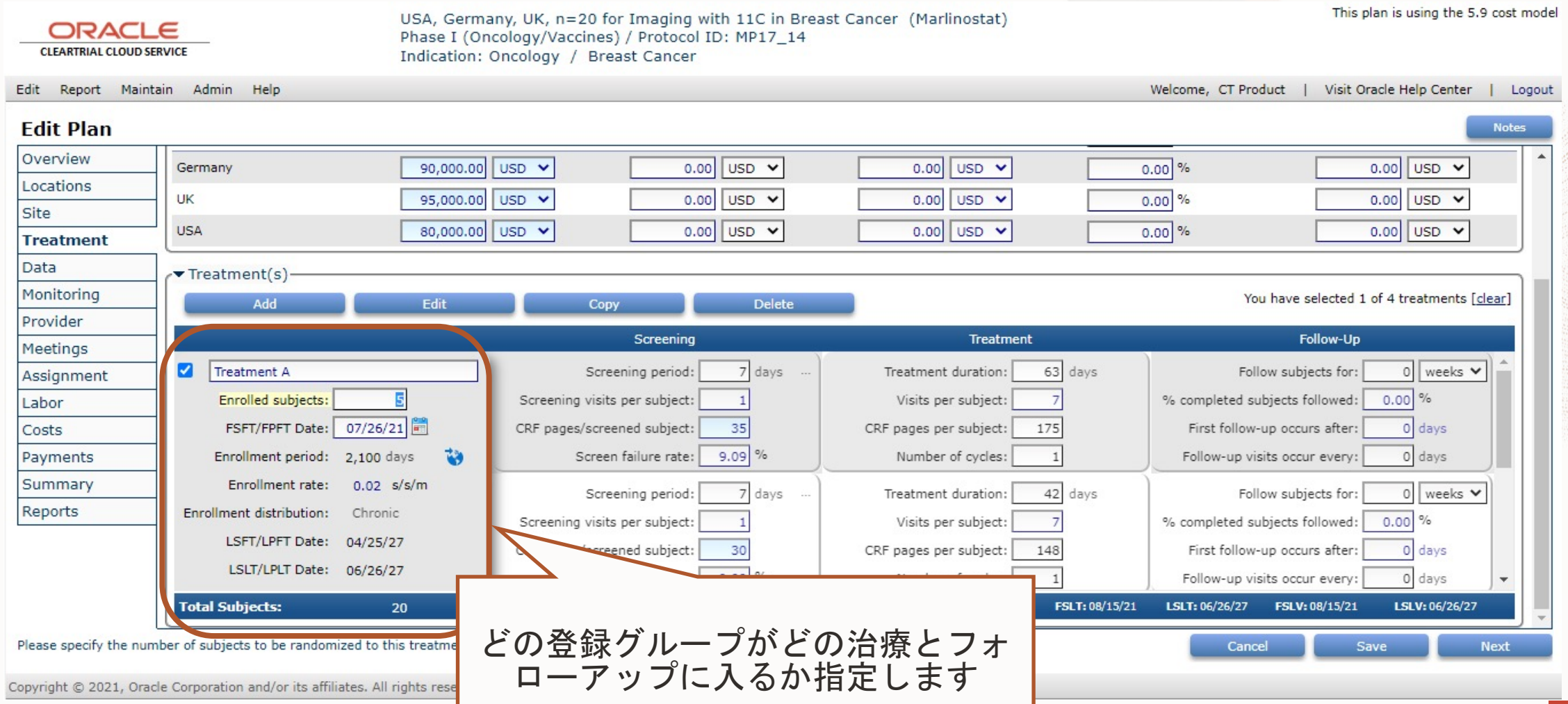
Subject Enrollment AssumptionsをTreatment tabに移動し, Subject tabが削除されました



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

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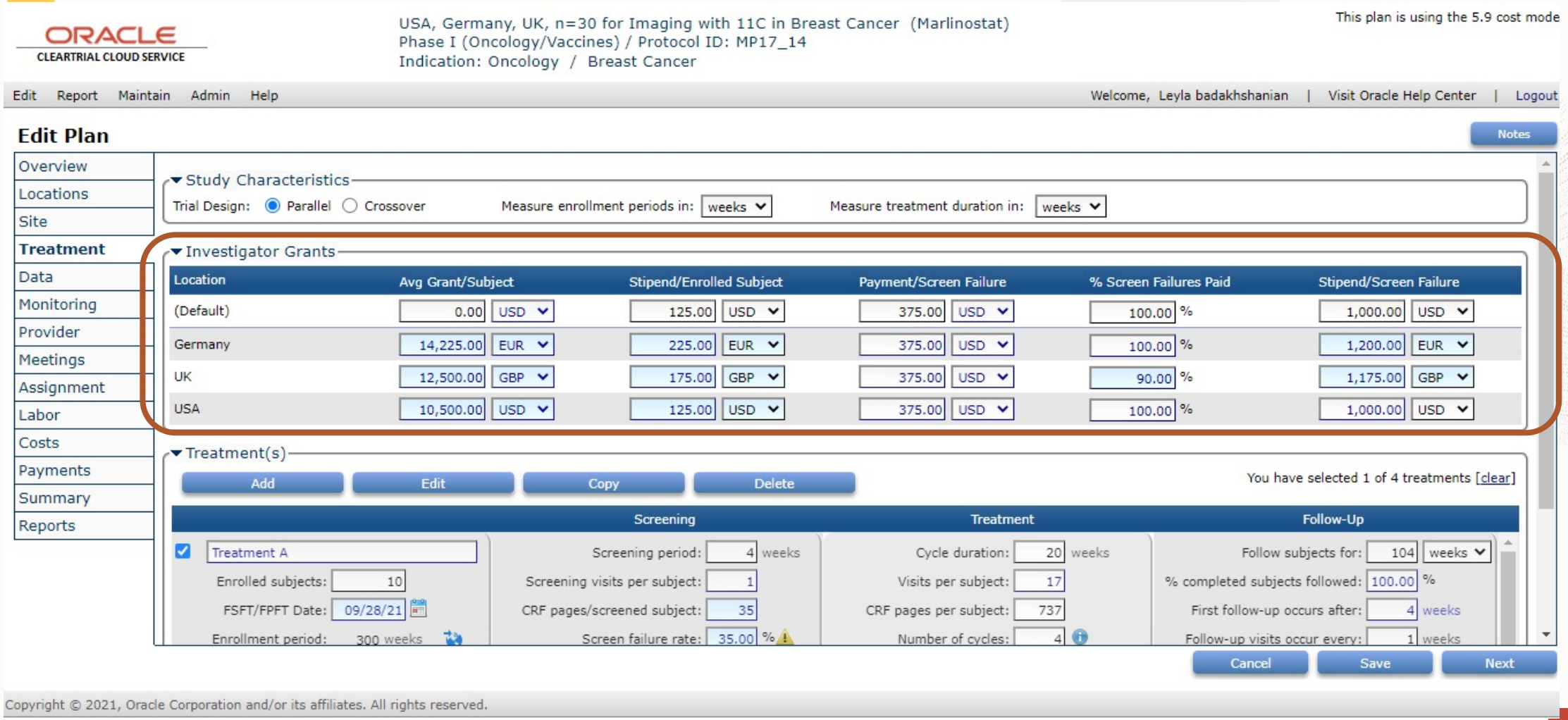
Investigator Grantsの入力項目を1画面に集約しました



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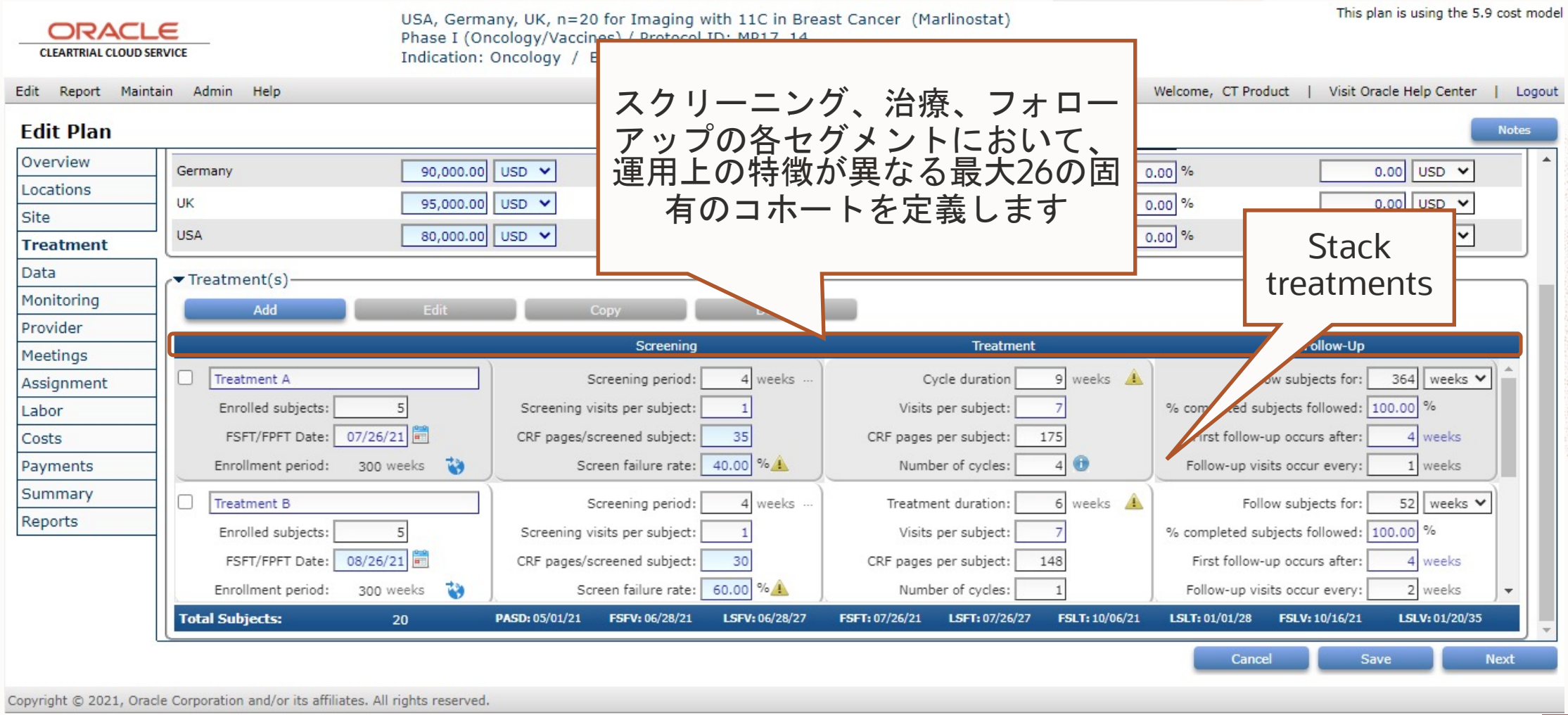
開始時期をずらした複数の症例コホート/治療法の定義ができます



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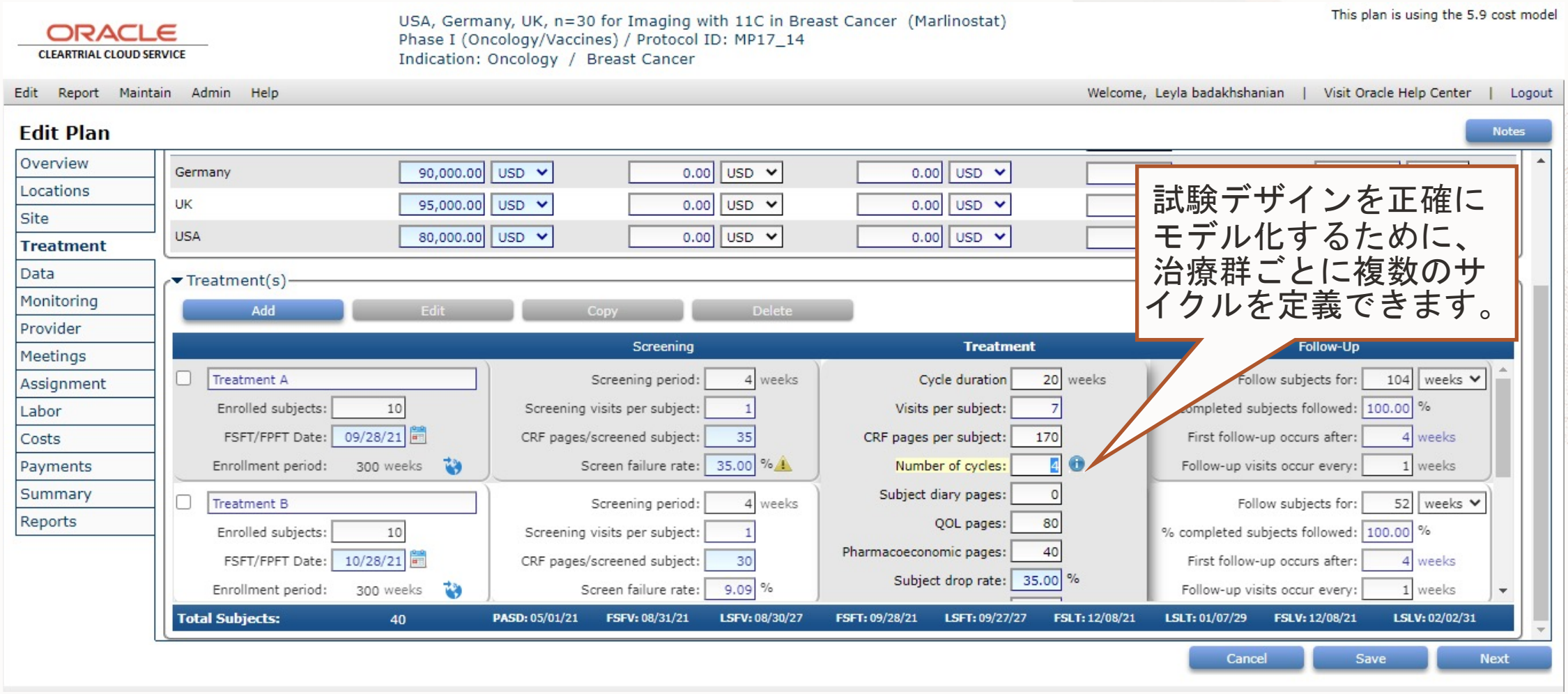
複数のトリートメントサイクルが追加できます



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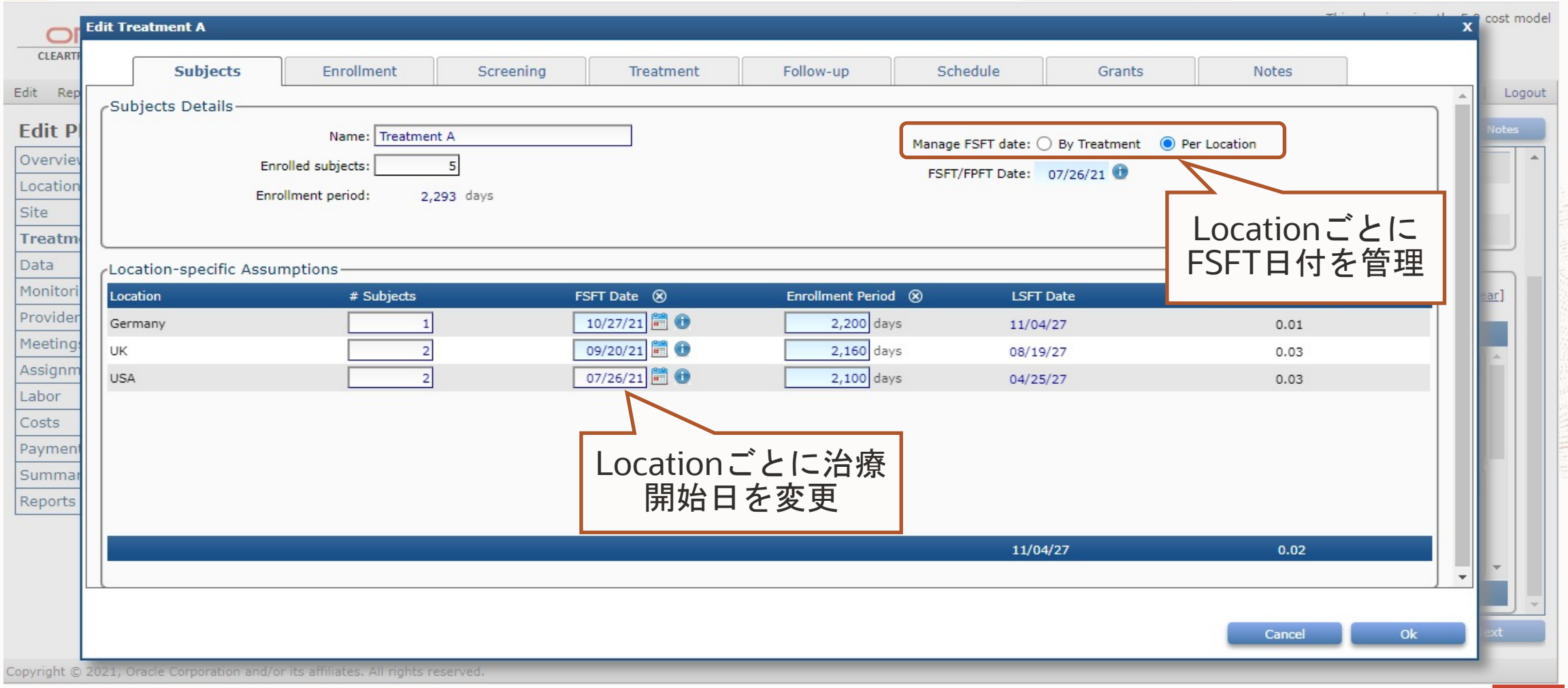
Locationごと、Treatmentごとの症例コホートの前提条件を定義します



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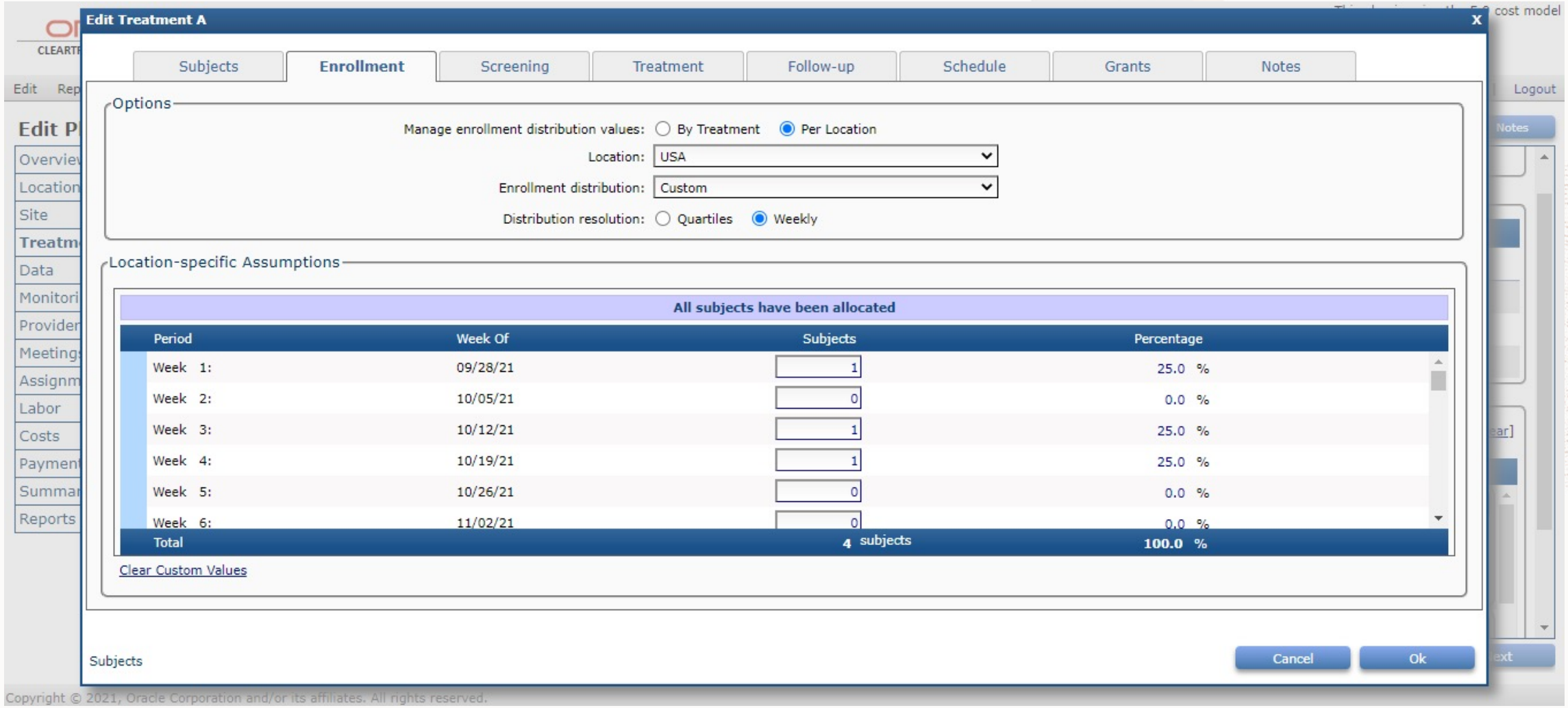
登録分布がTreatmentごと、Locationごとに移動しました



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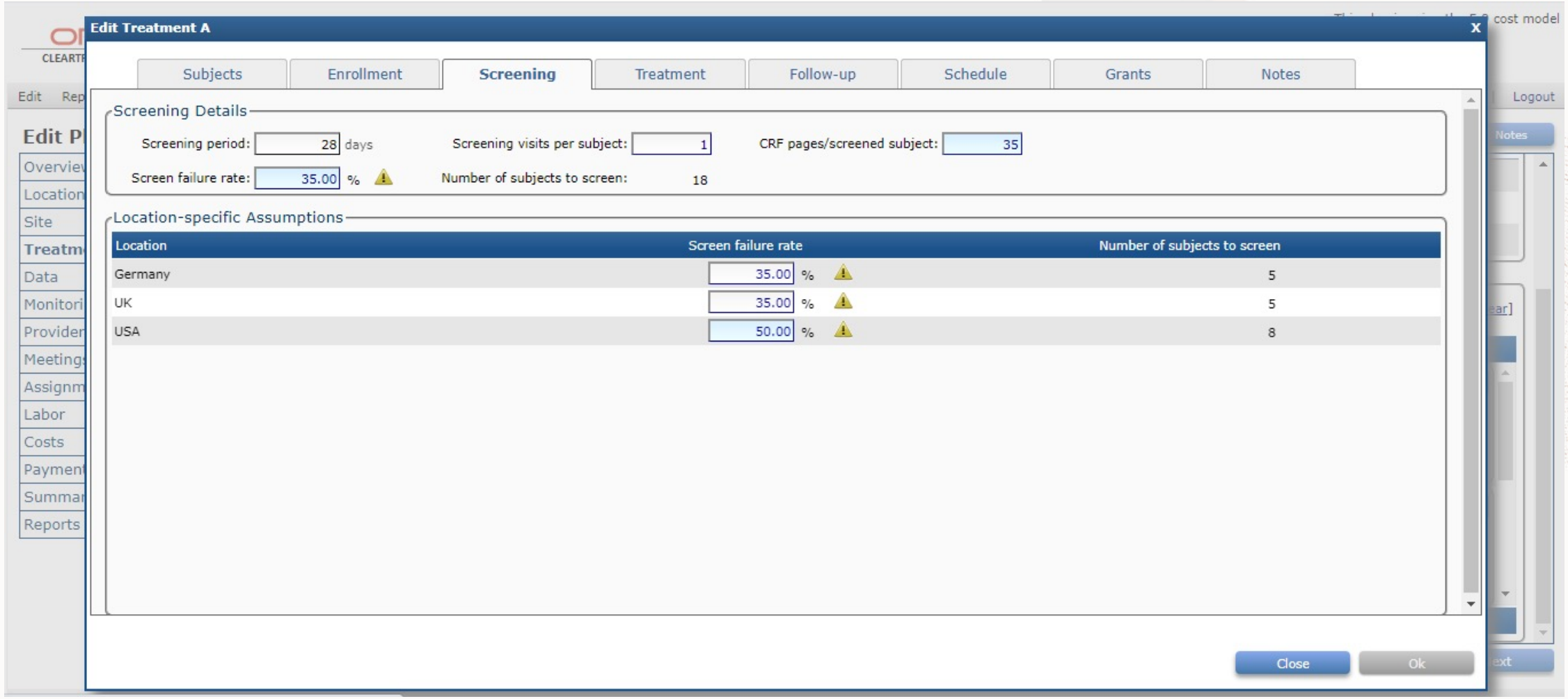
Treatmentごと、Locationごとにスクリーニングの想定を定義します



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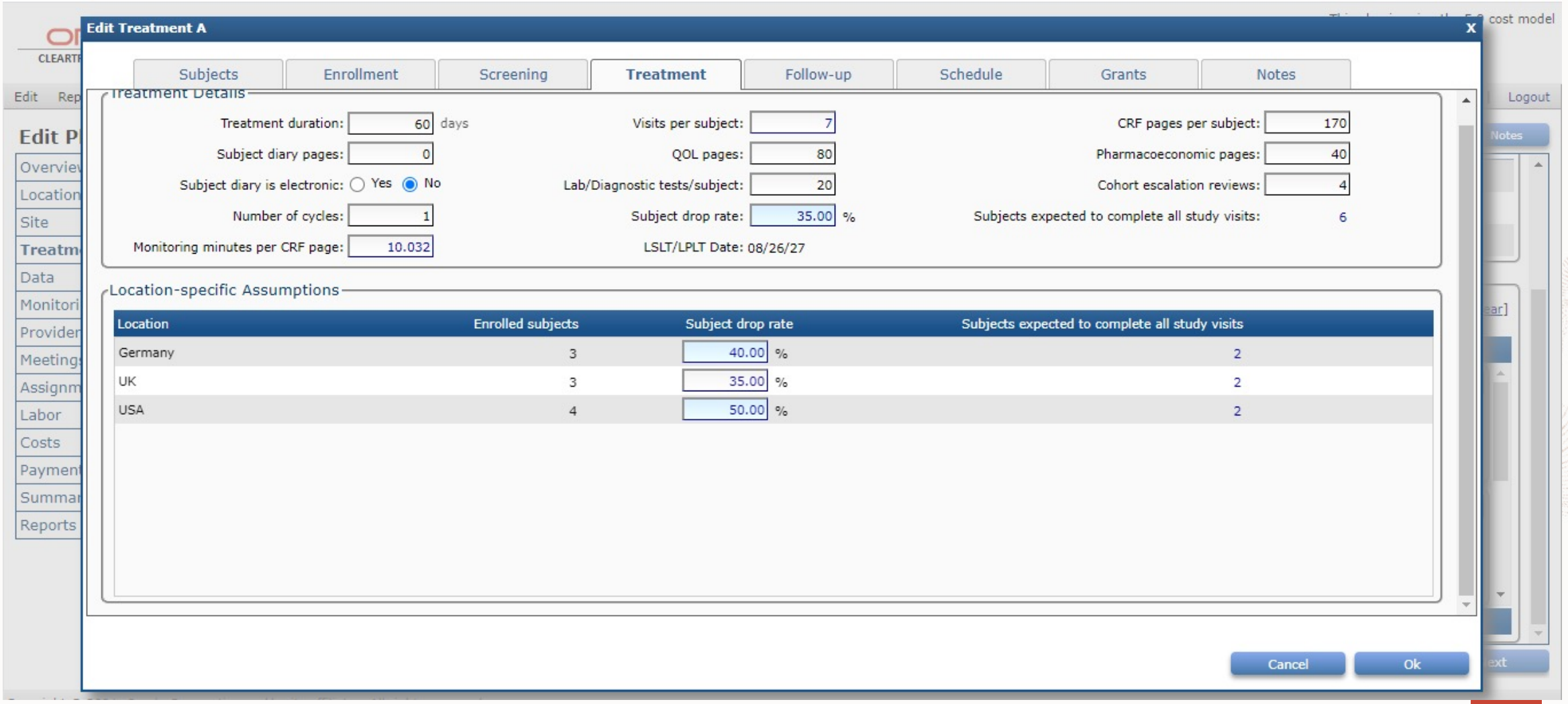
Treatmentごと、Locationごとに介入の想定を定義します



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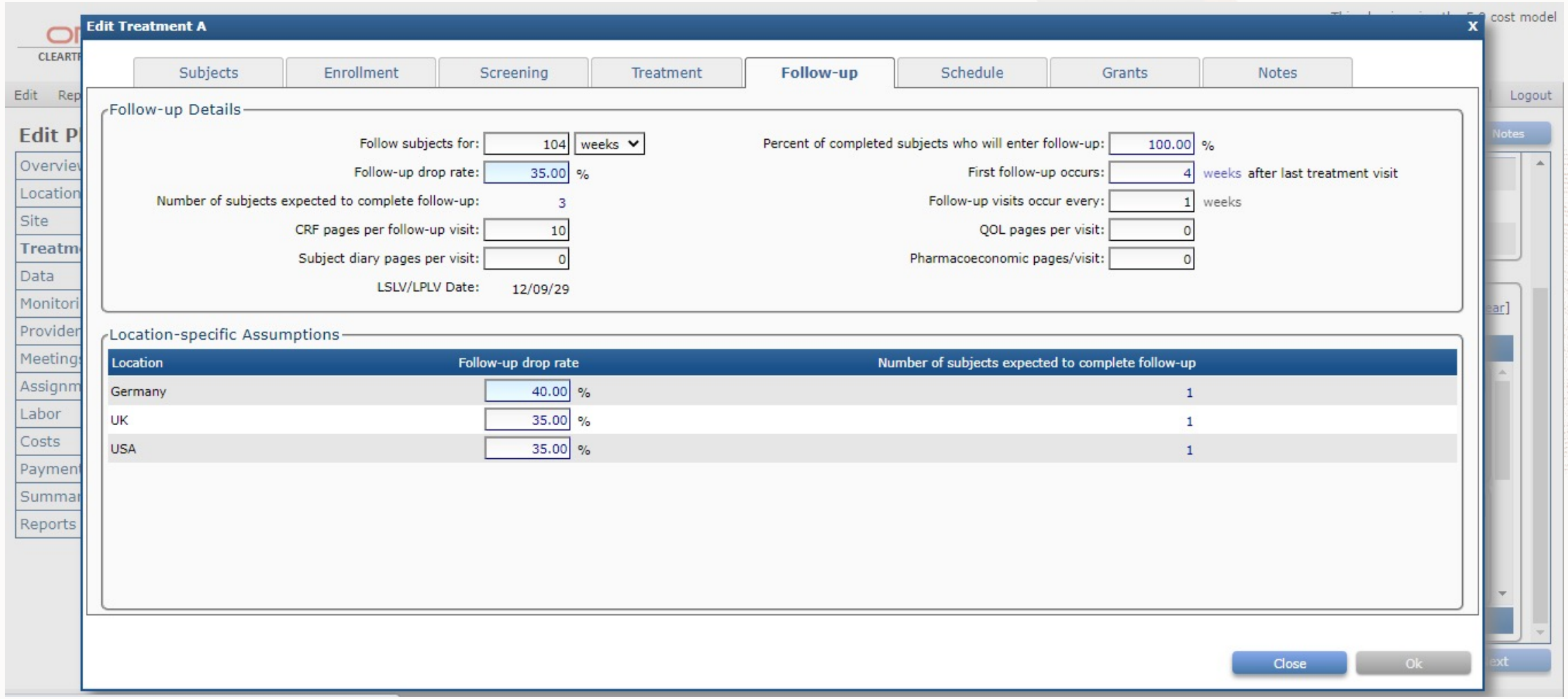
Treatmentごと、Locationごとにフォローアップの想定を定義します



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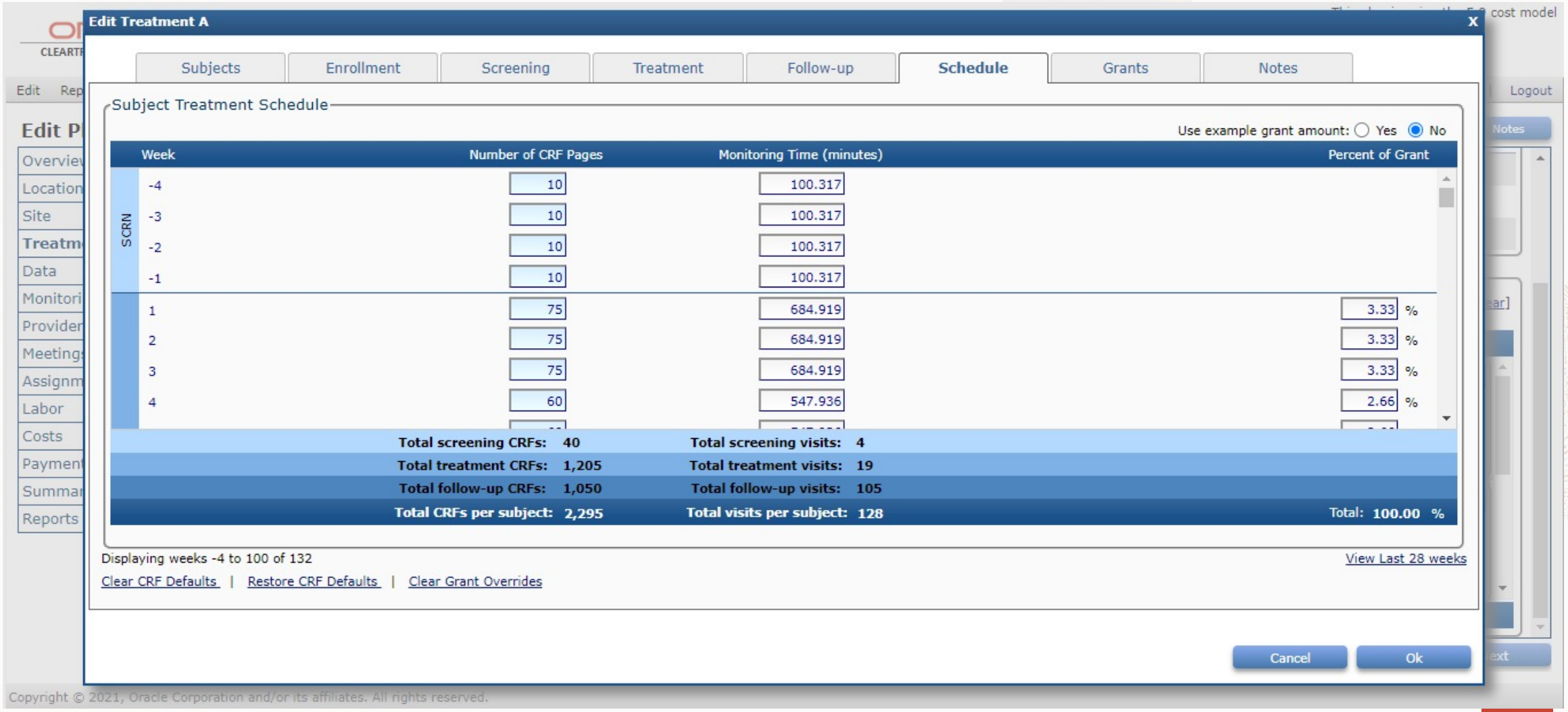
コホートごとにスクリーニング期間中のビジットスケジュール、治療、フォローアップを定義します



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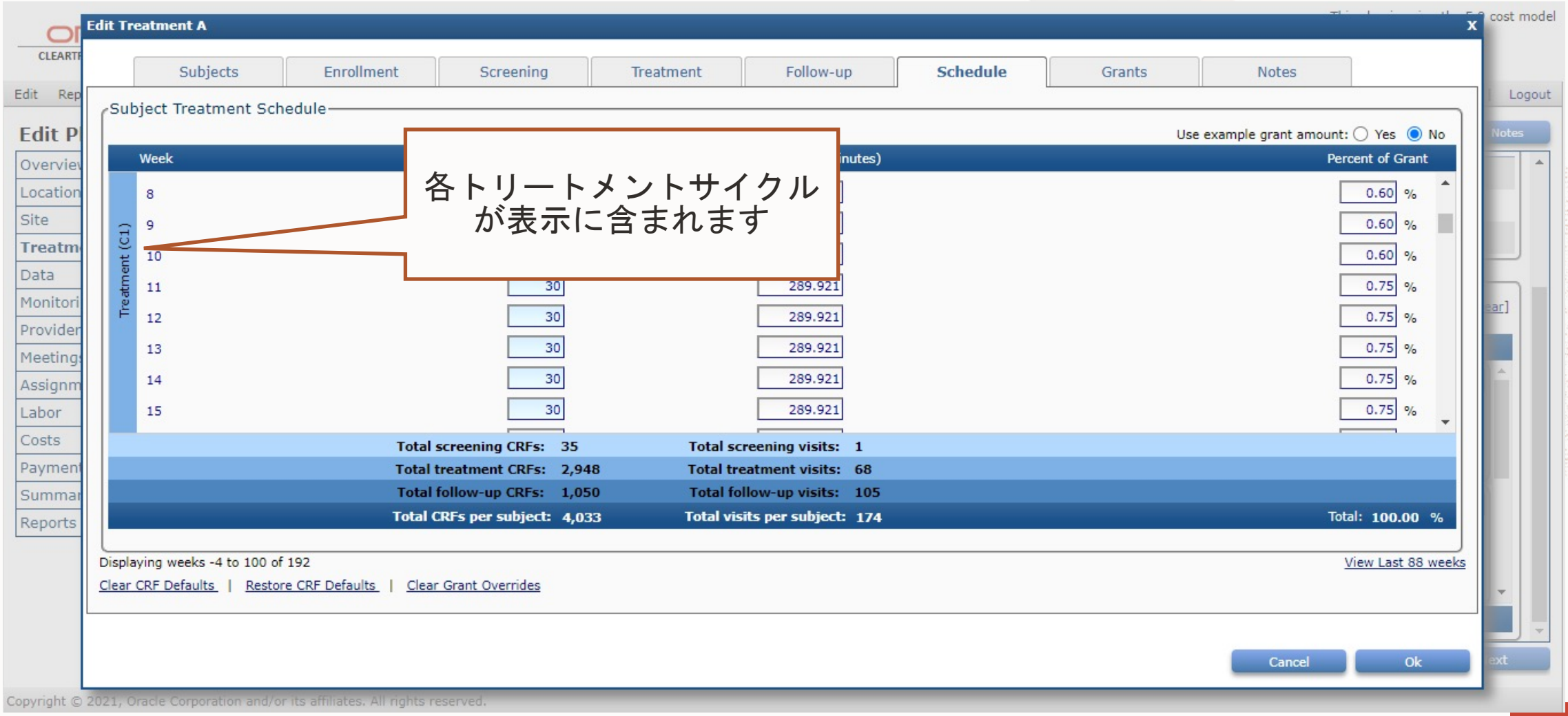
サイクル全体のビジットごとにCRF、 モニタリング時間、Grantsを定義します



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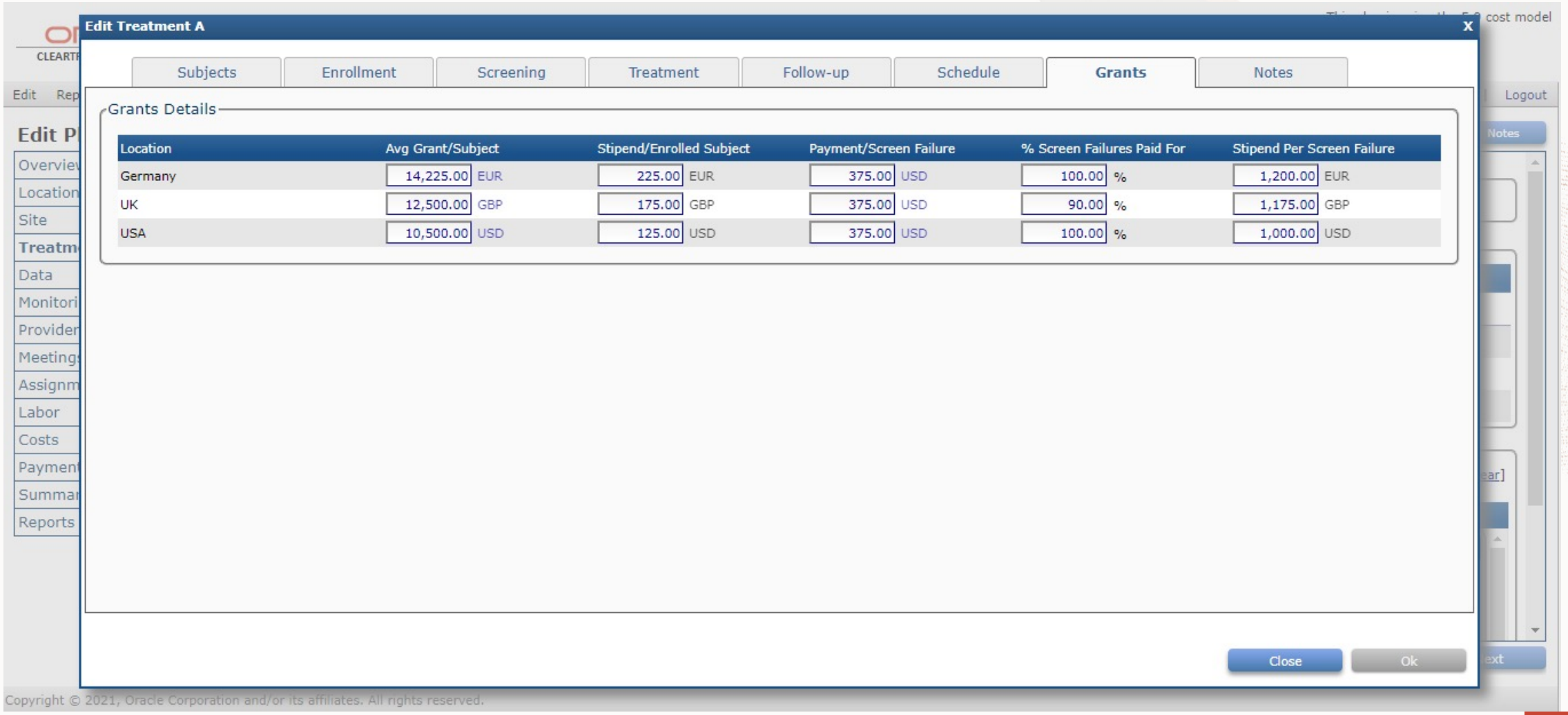
Treatmentごと、LocationごとにGrantsの想定を定義します



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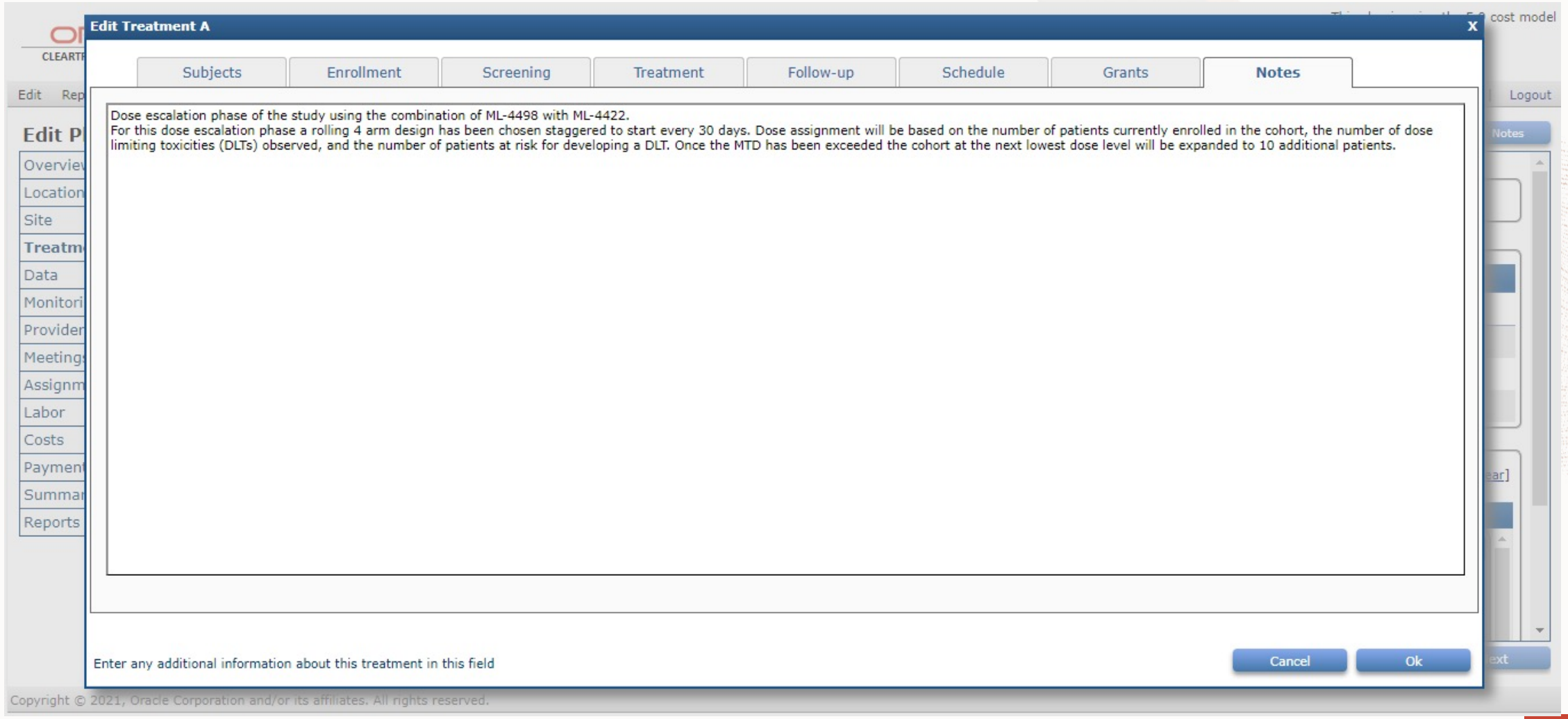
治療群ごとにStudy Design Noteを入力します



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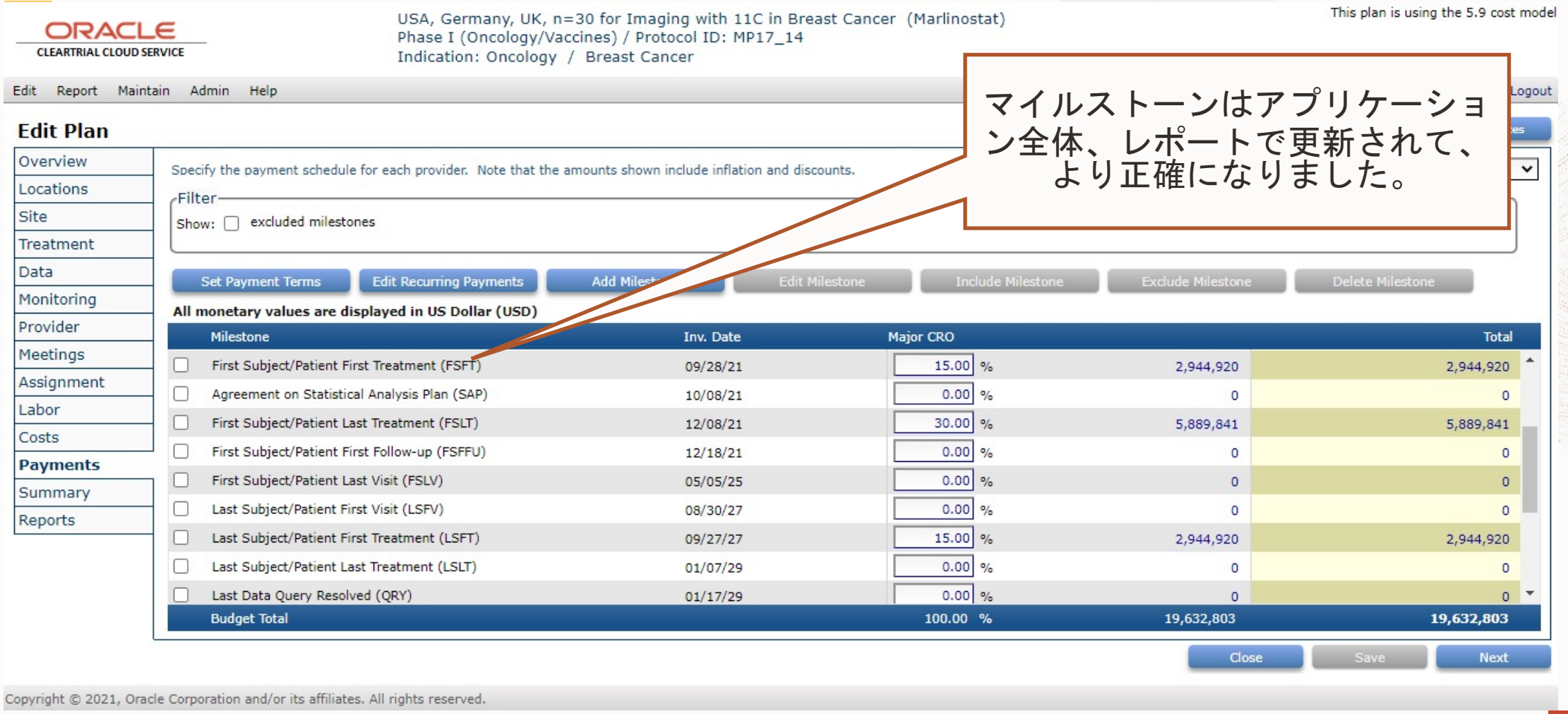
正確で明確なマイルストーン



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。

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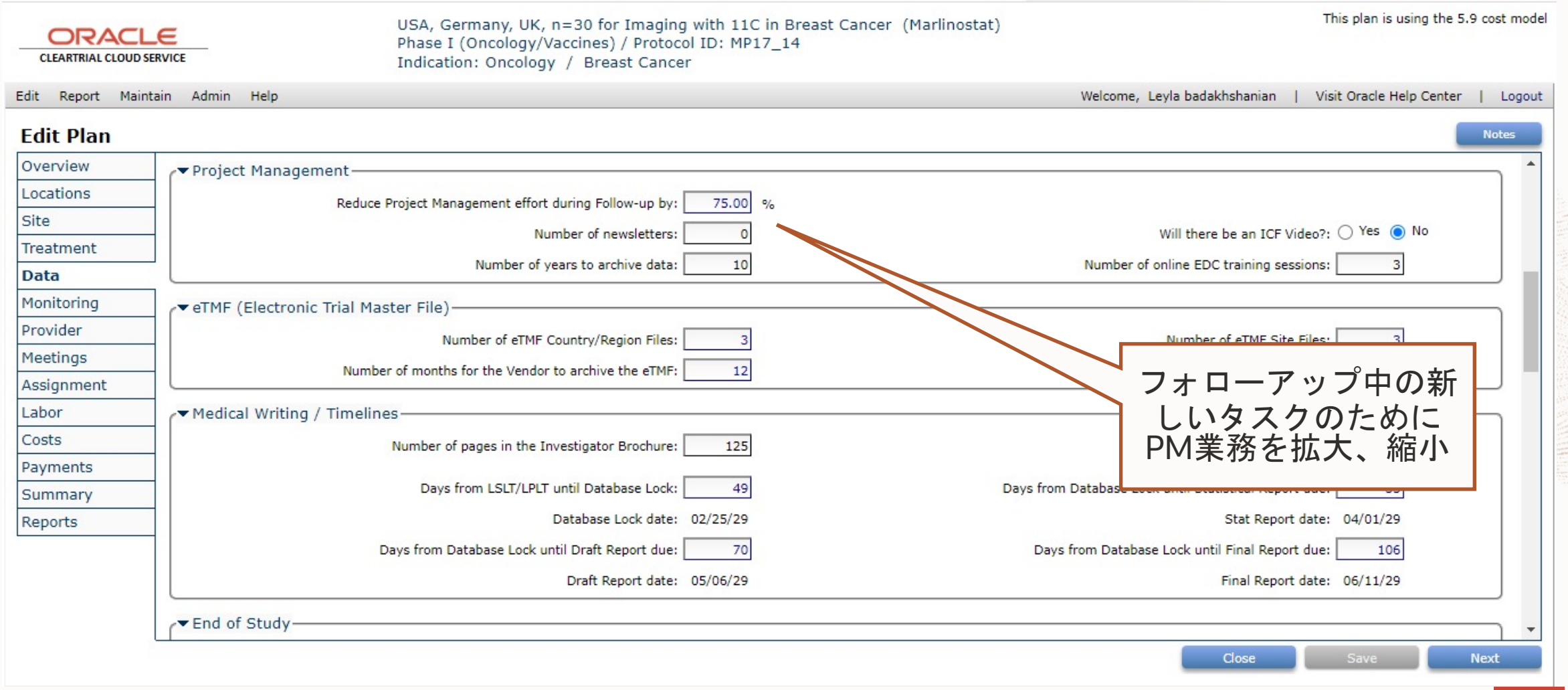
フォローアップ中のPM業務を評価するための新項目



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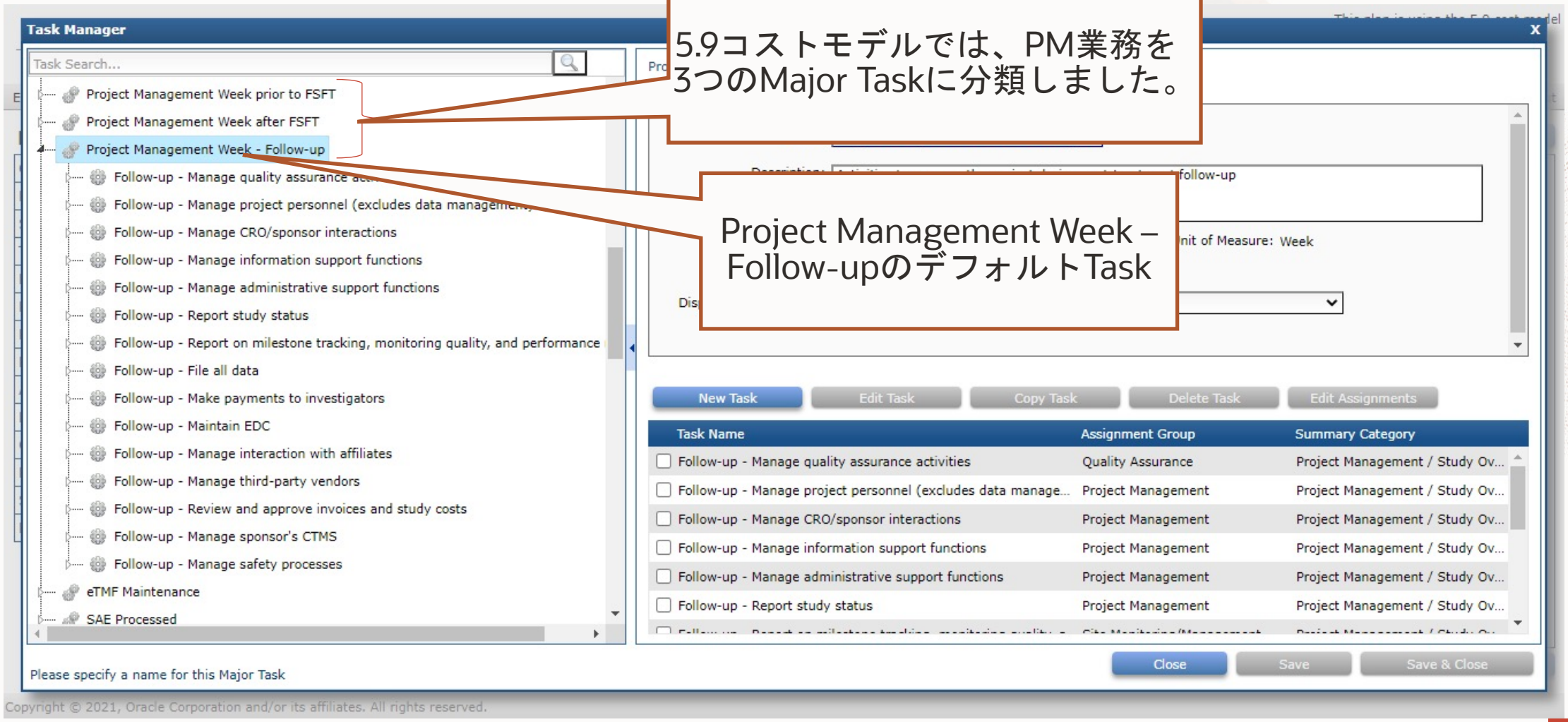
新タスク：Project Management Follow-Up Labor Fees



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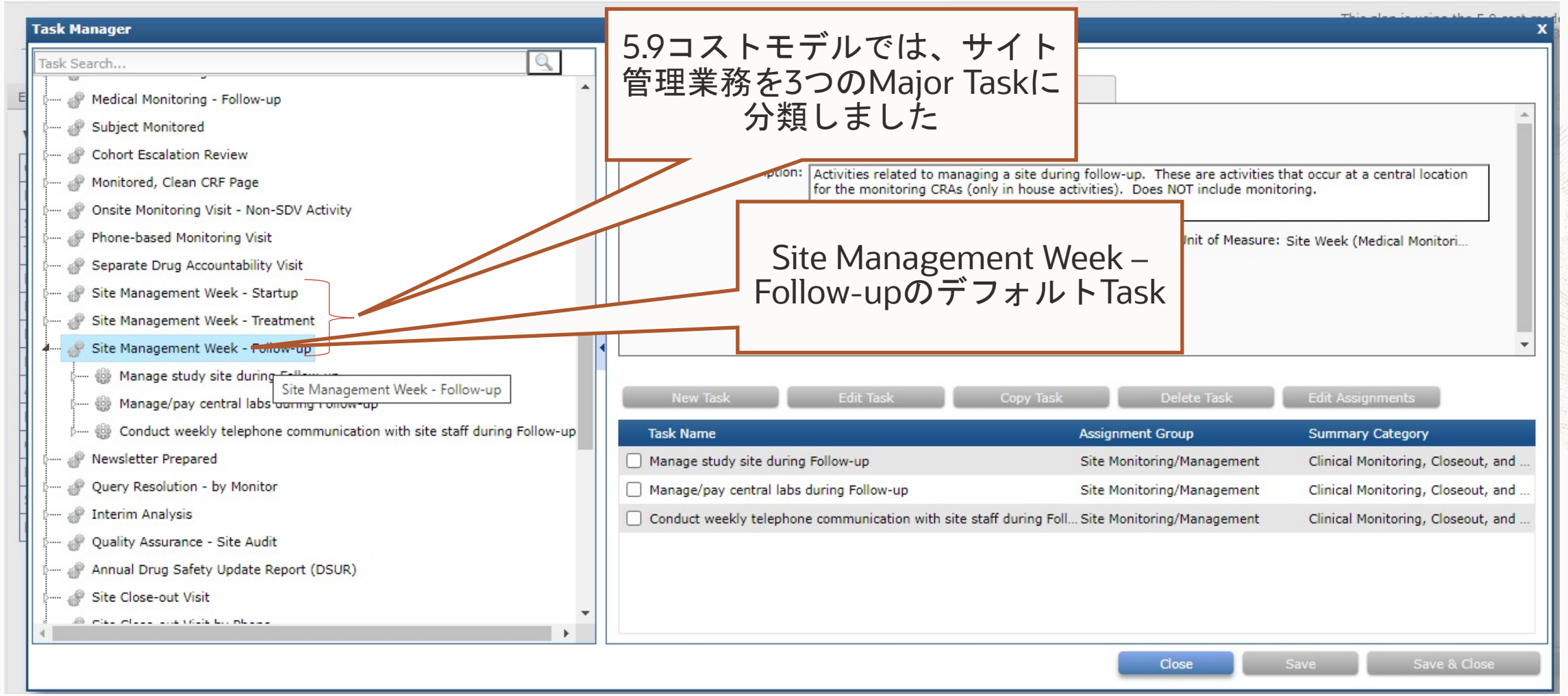
新タスク：Site Management Week Follow-up Labor Fees



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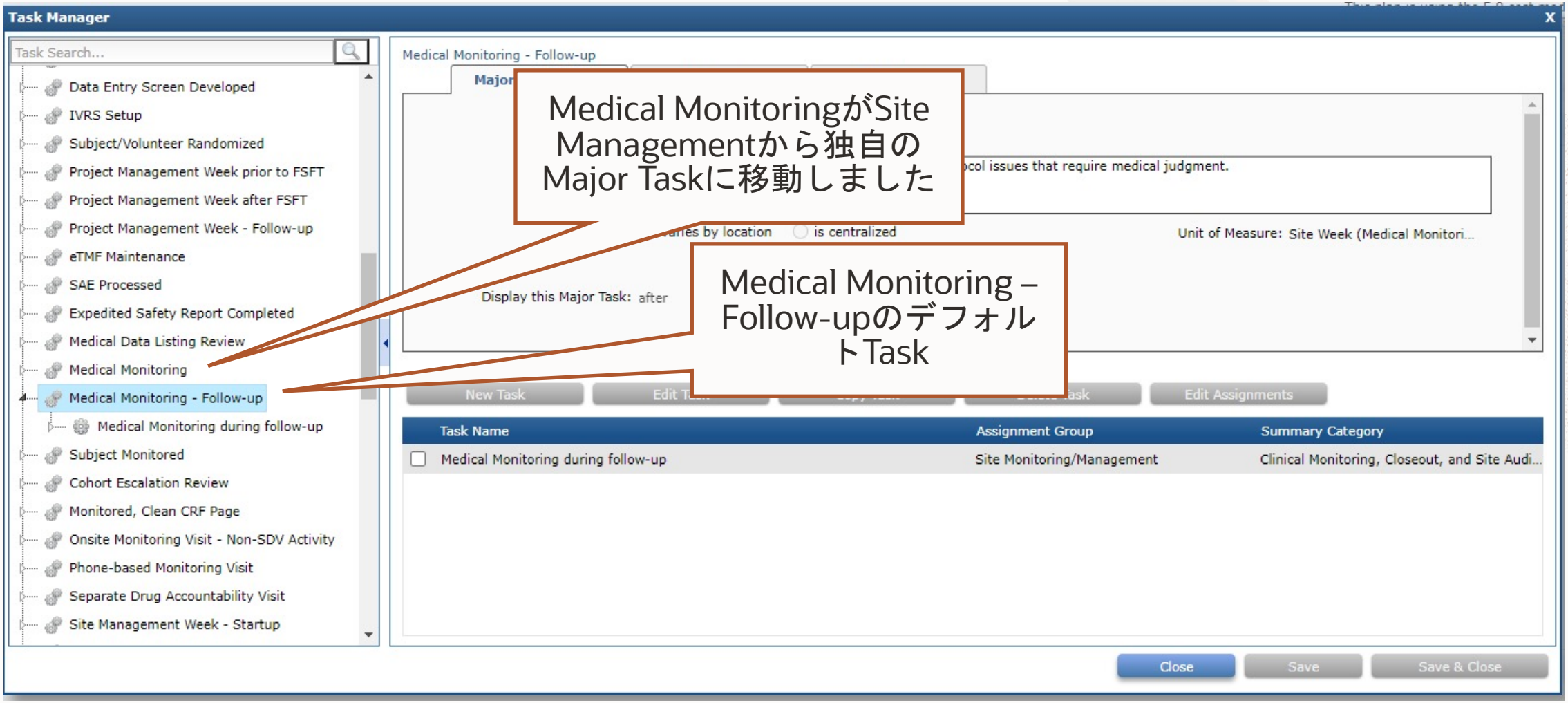
Medical Monitoring Labor Feesの更新



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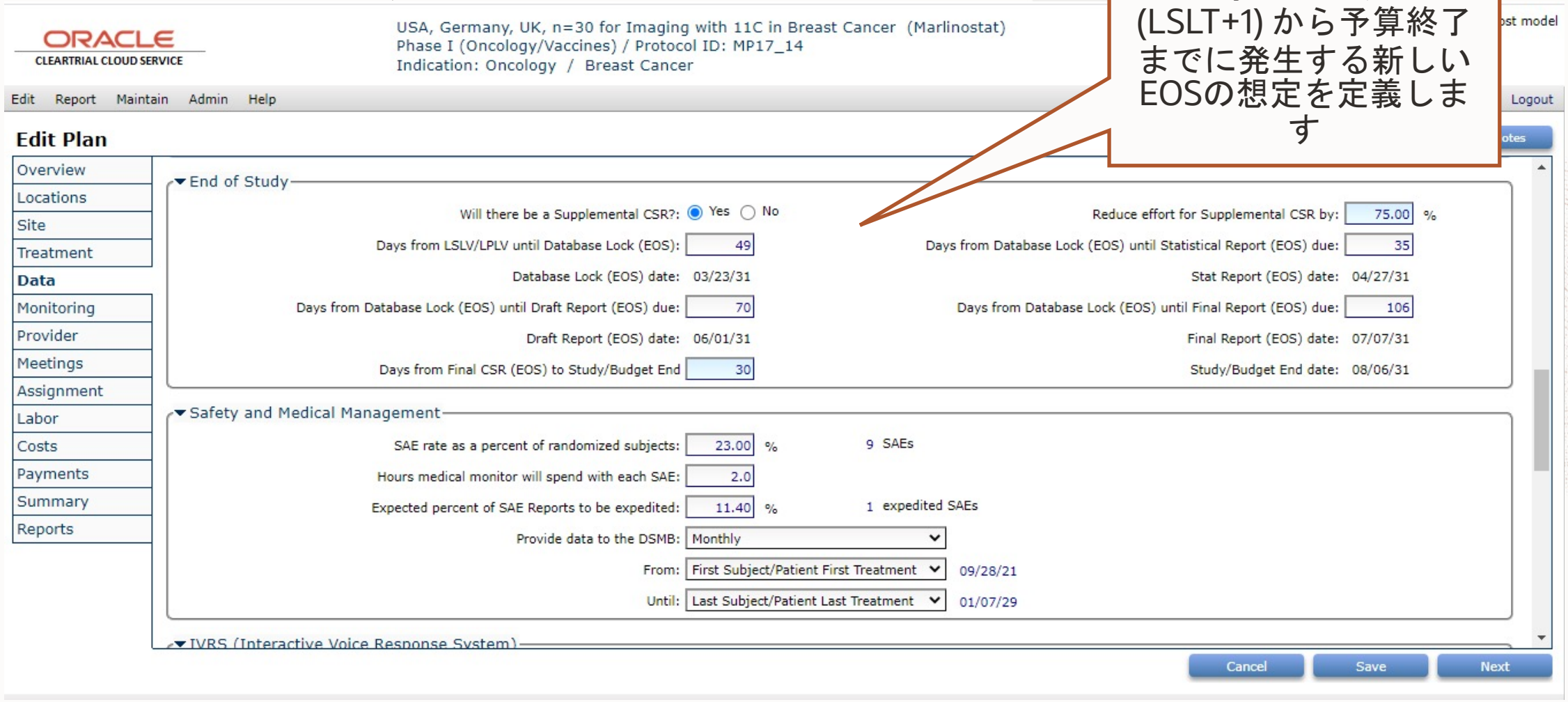
新しいEnd of Study (EOS) の想定



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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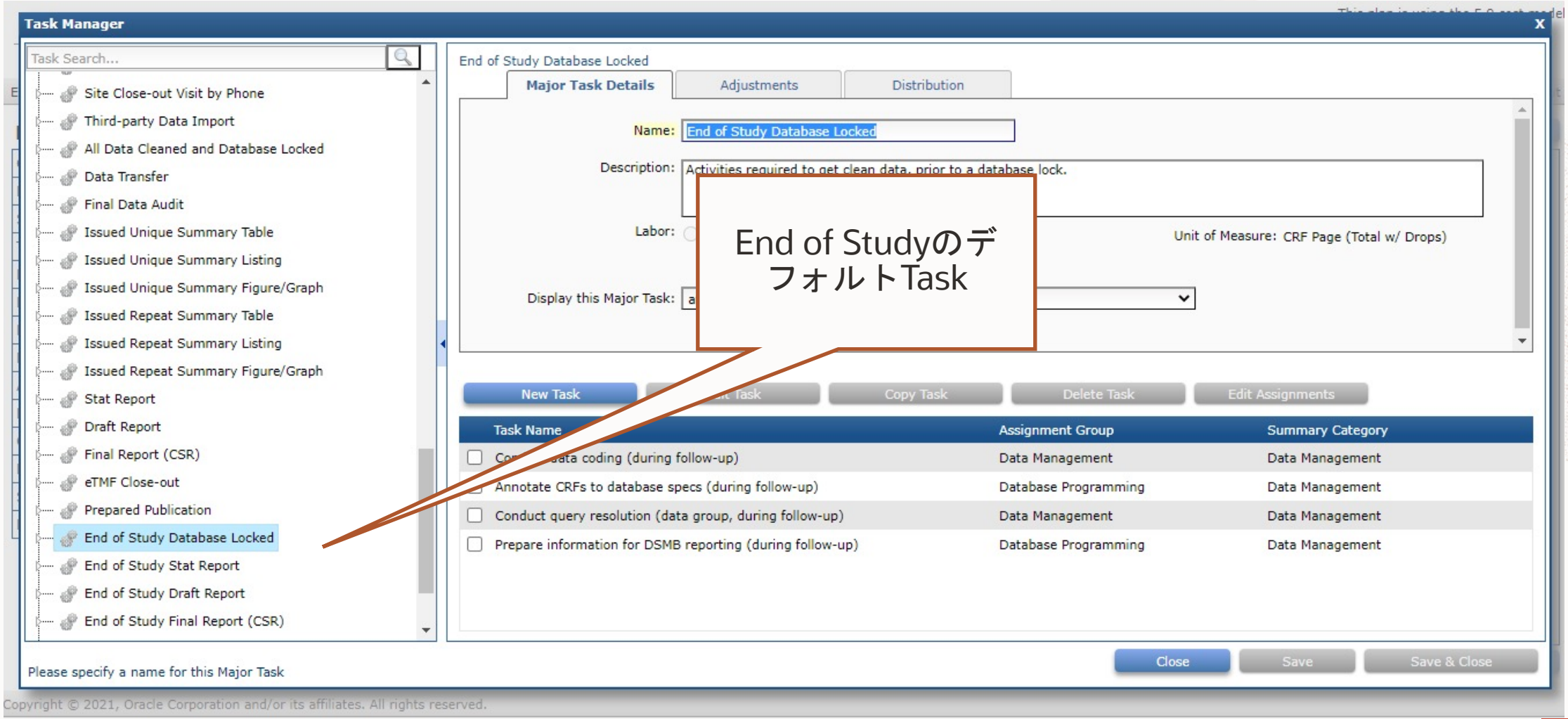
新タスク：End of Study Labor Fees



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Clinical Intelligence Update

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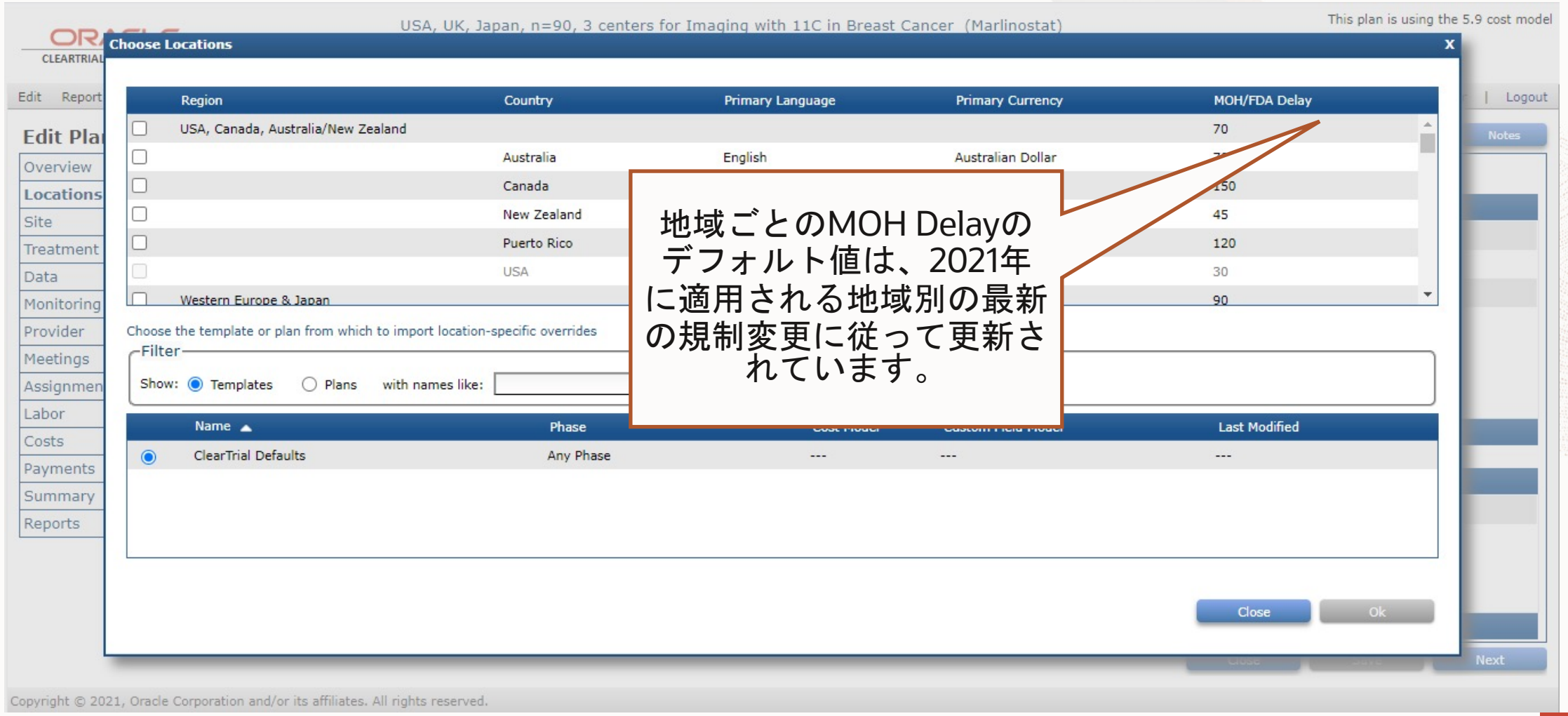
MOH/FDA Delayの更新



地域ごとのMOH Delayのデフォルト値は、2021年に適用される地域別の最新の規制変更に従って更新されています。

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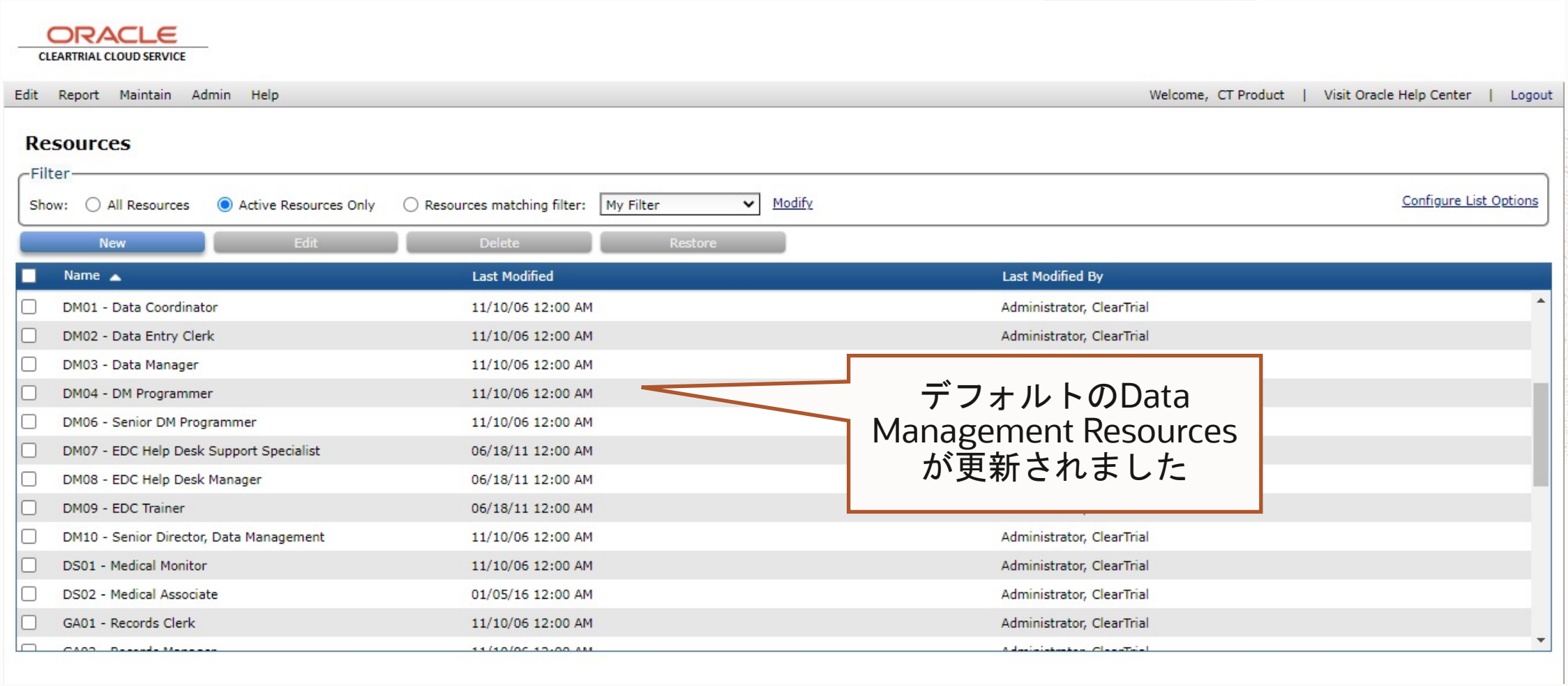
Data Management Resourceの更新



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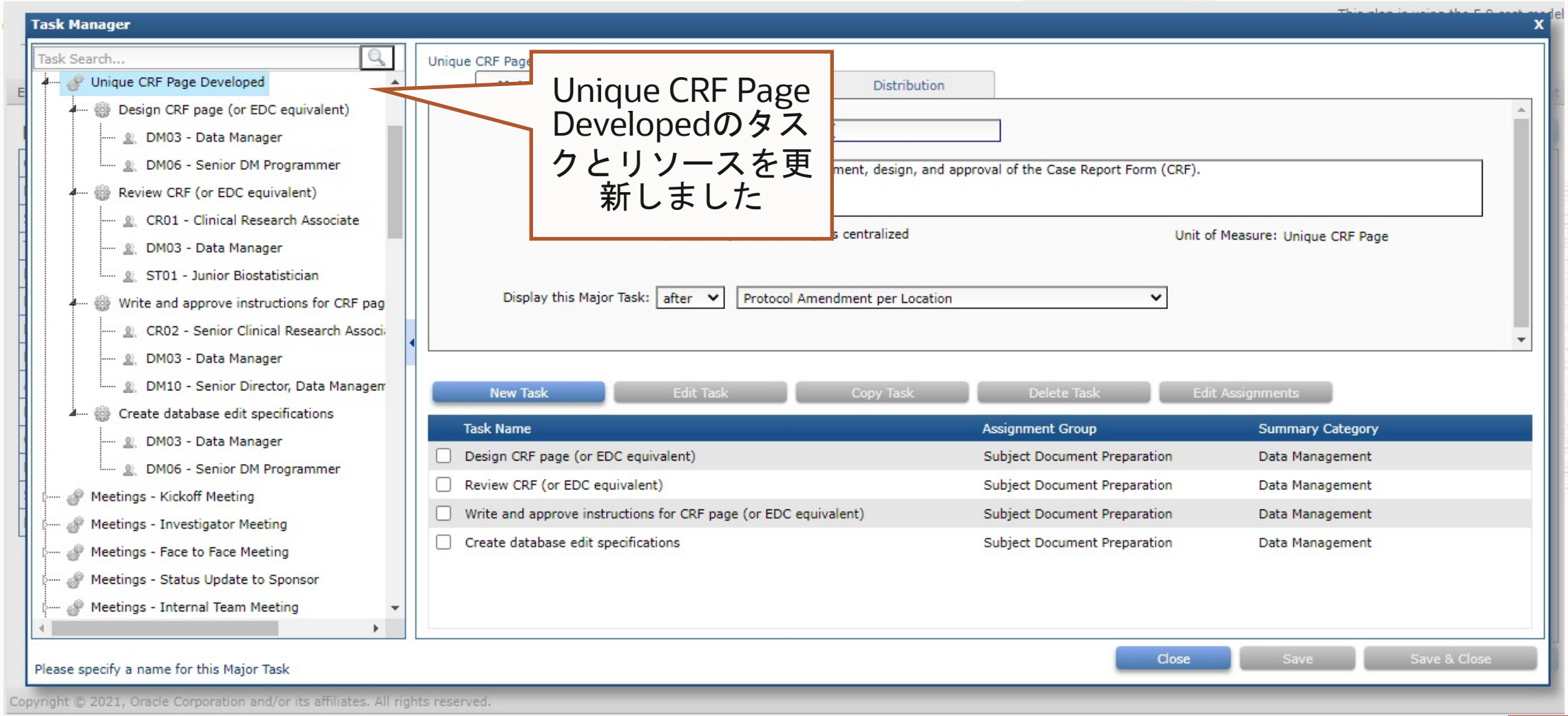
Data Management Labor Update



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

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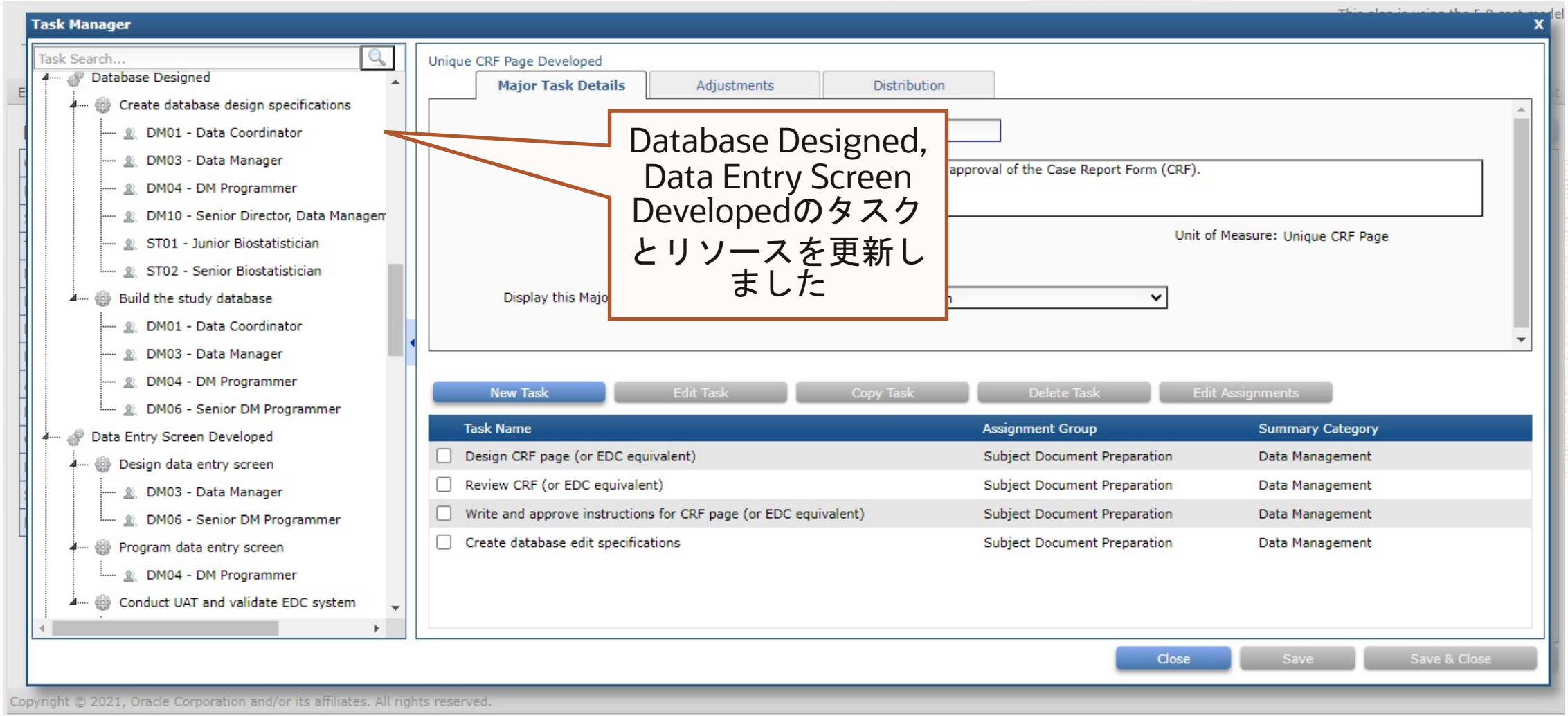
Data Management Laborの更新



Database Designed, Data Entry Screen Developedのタスクとリソースを更新しました

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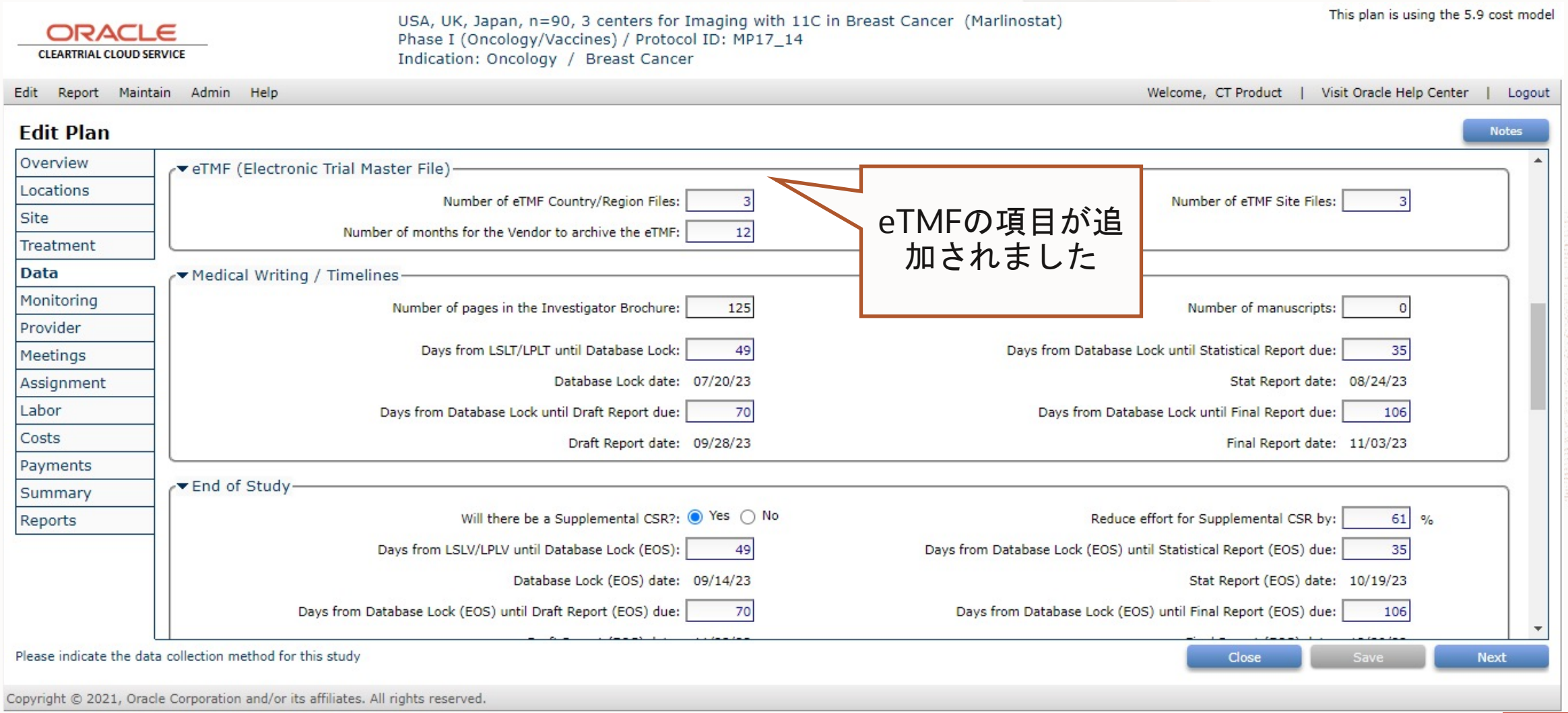
eTMFコストの更新 – 新規想定項目



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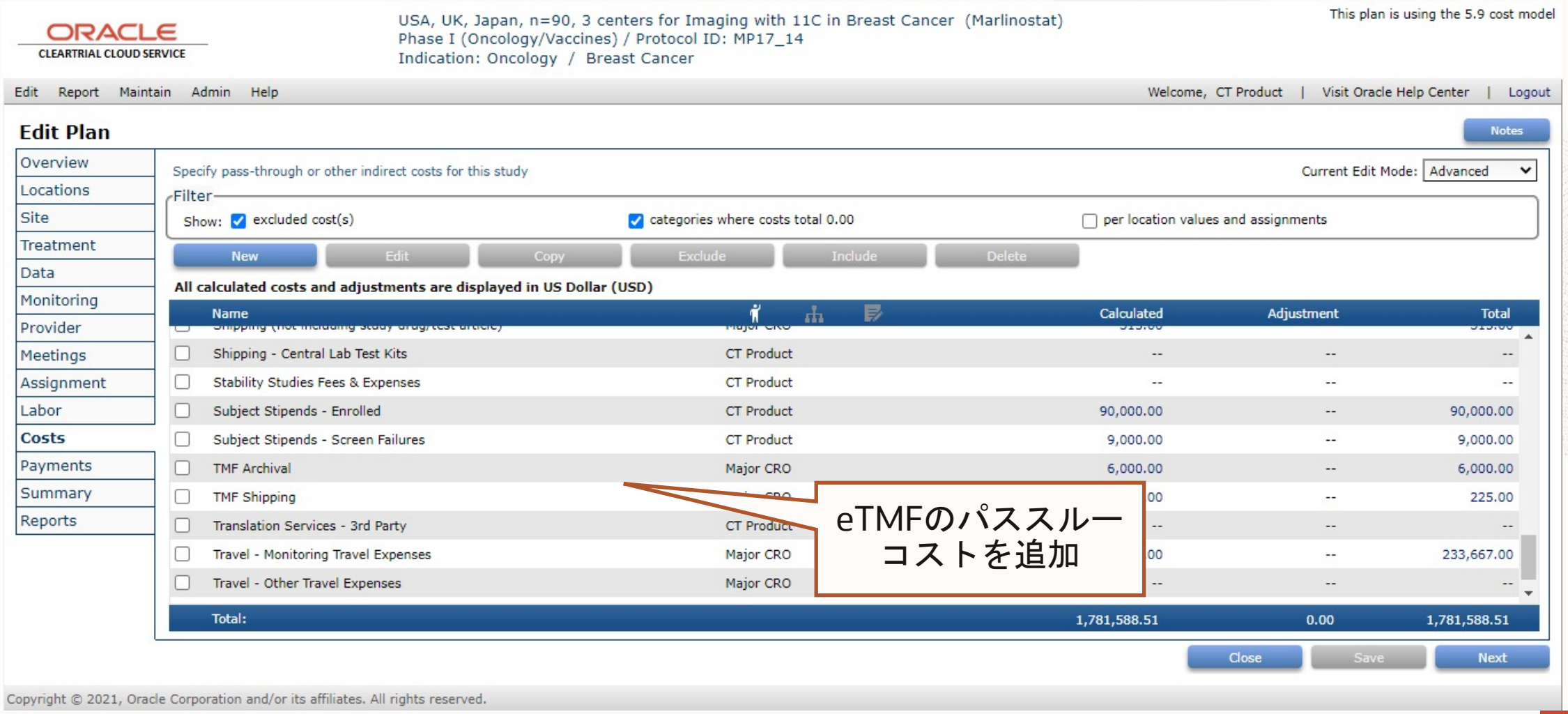
eTMFコストの更新 – 新規間接経費



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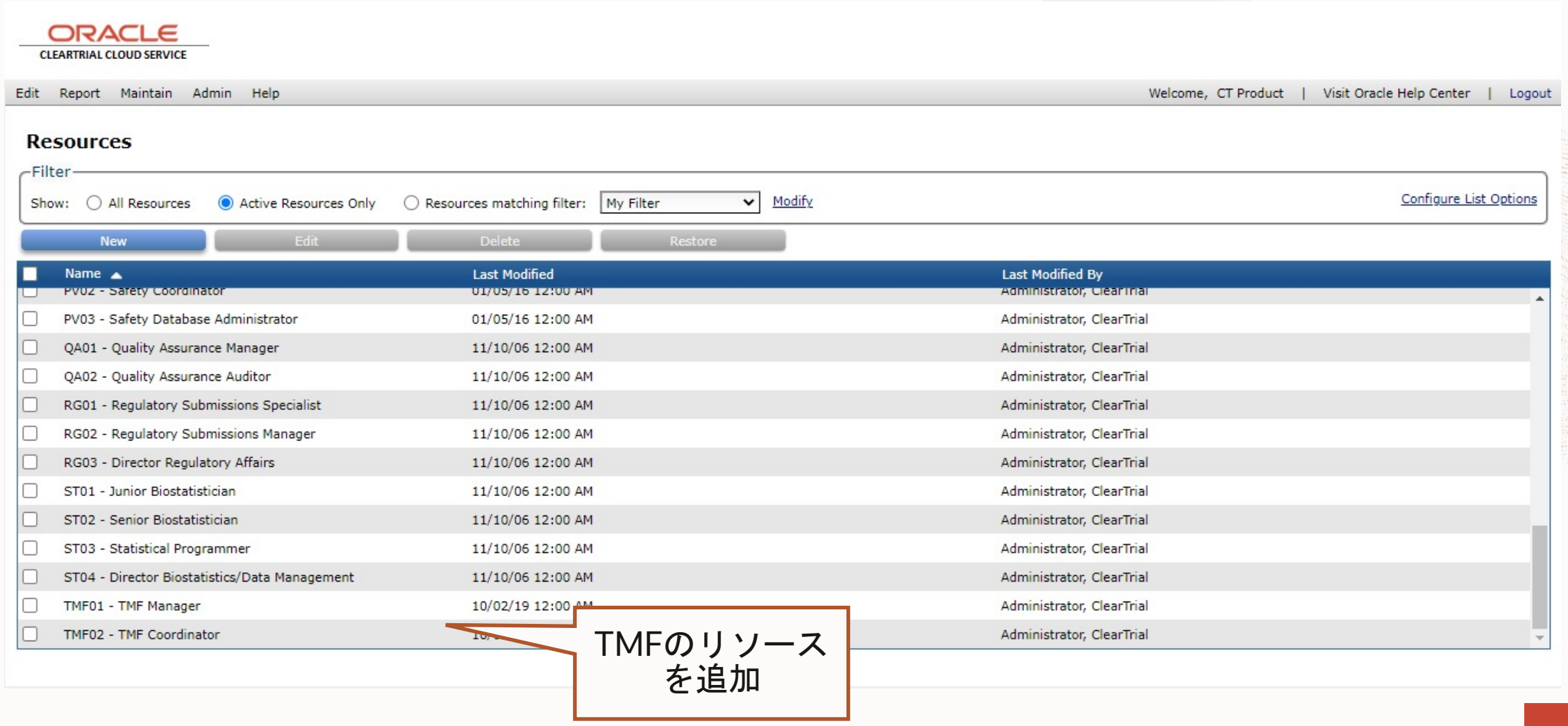
eTMFコストの更新 – 新規リソース



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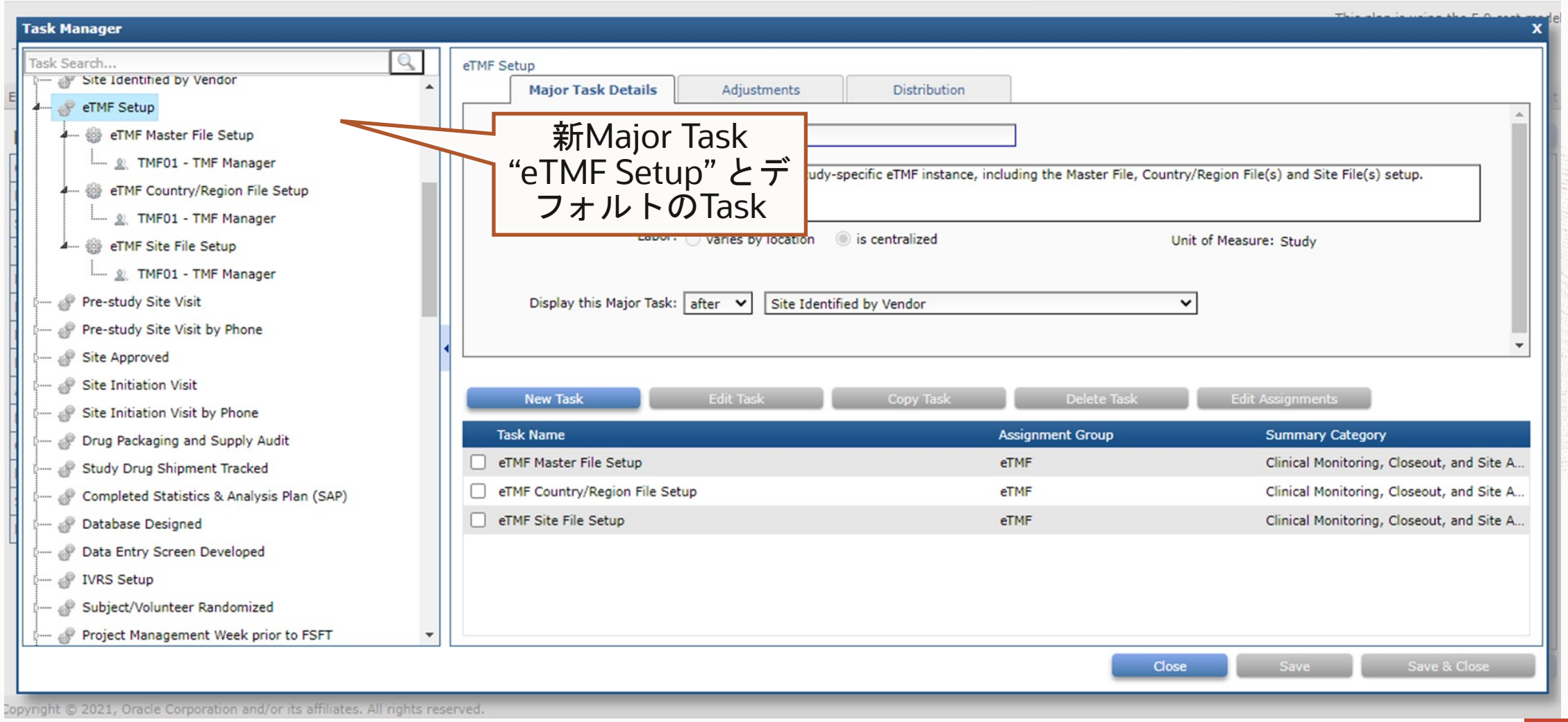
eTMFコストの更新 – 新規タスク



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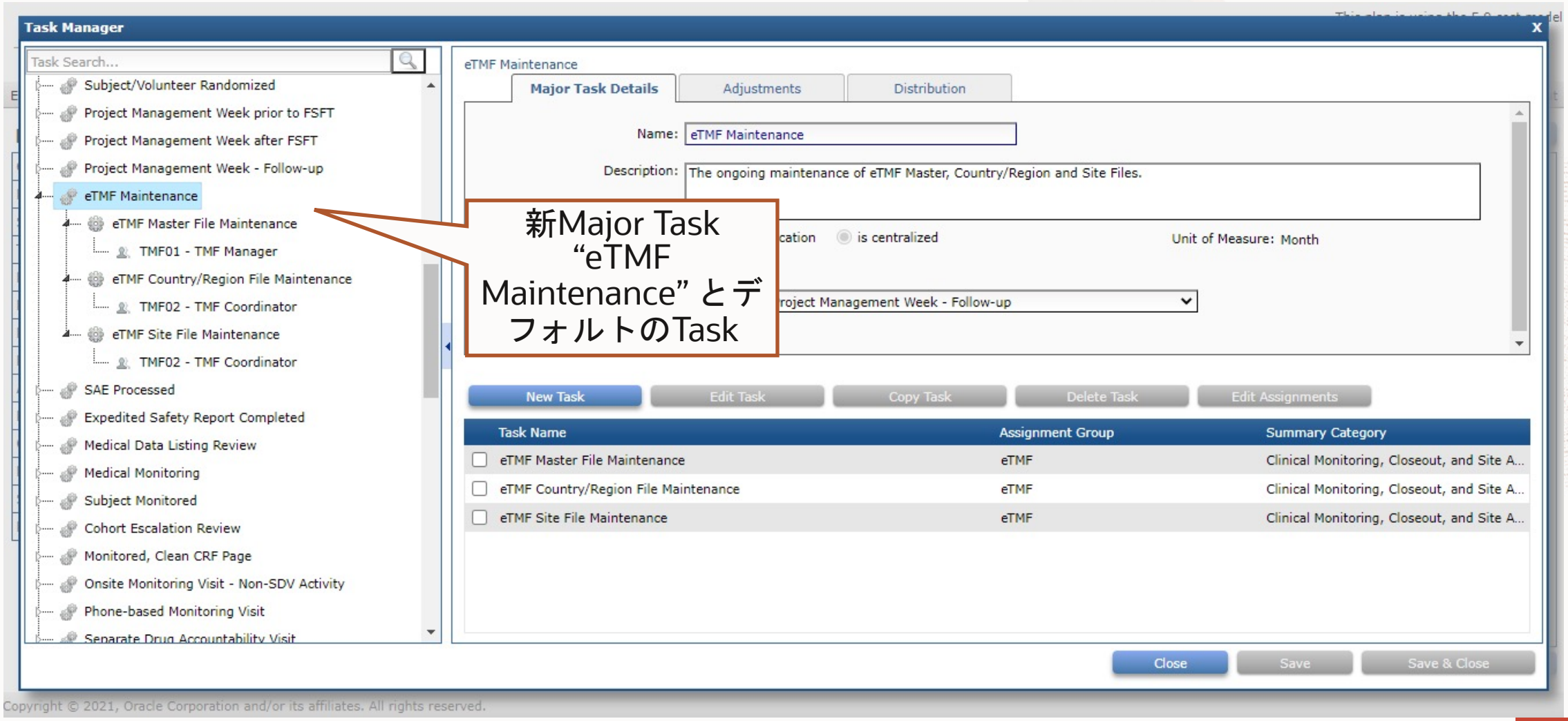
eTMFコストの更新 – 新規タスク



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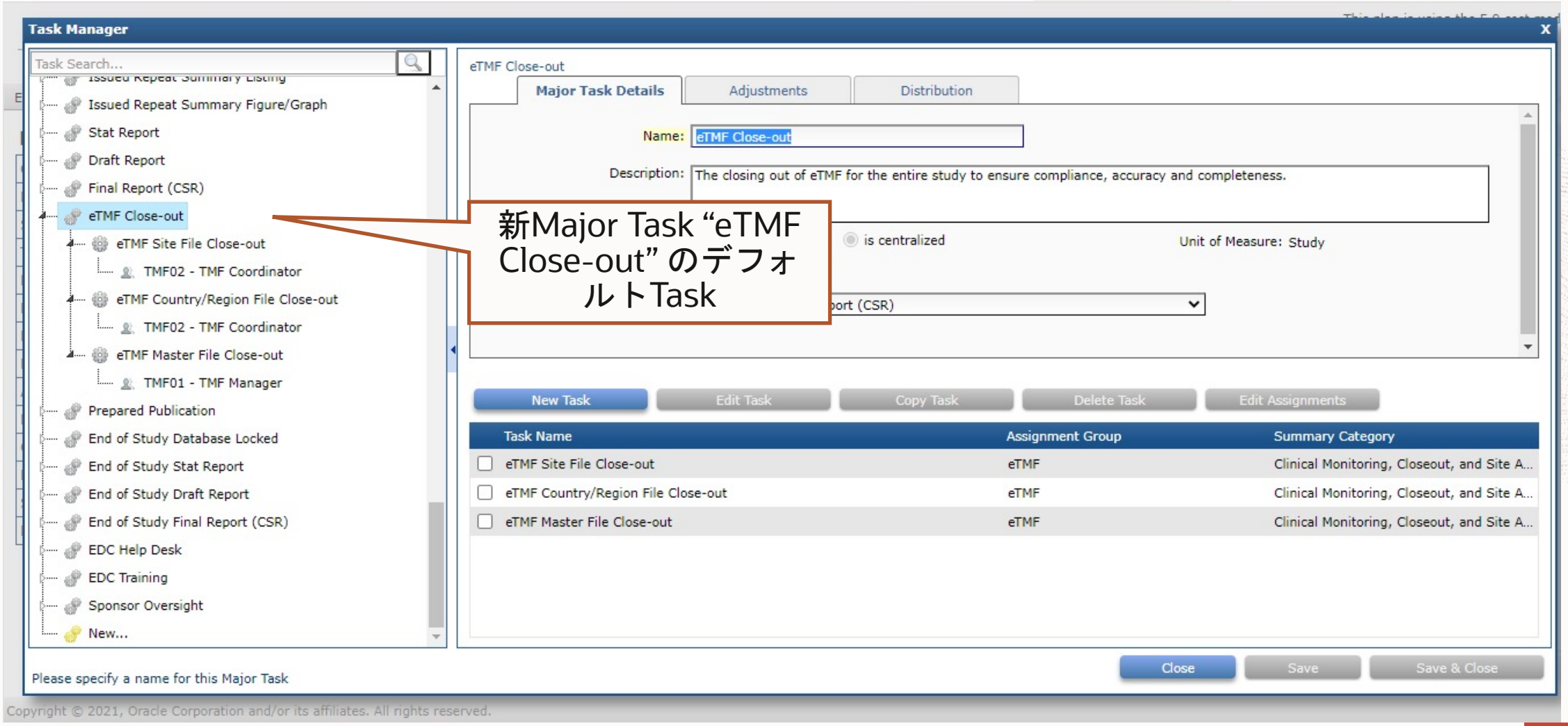
eTMFコストの更新 – 新規タスク



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Usability Enhancements

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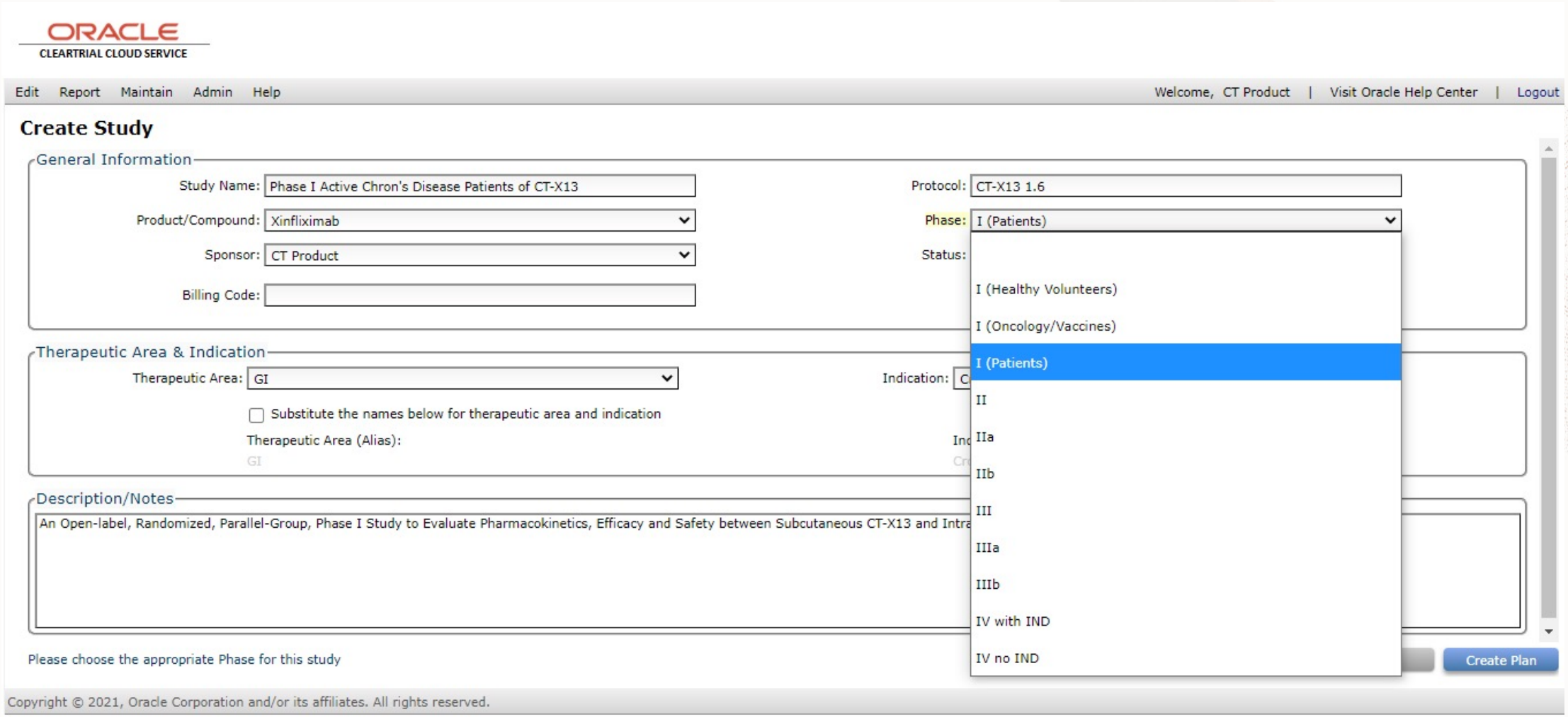
Study Phaseが追加されました：Phase I (Patients)



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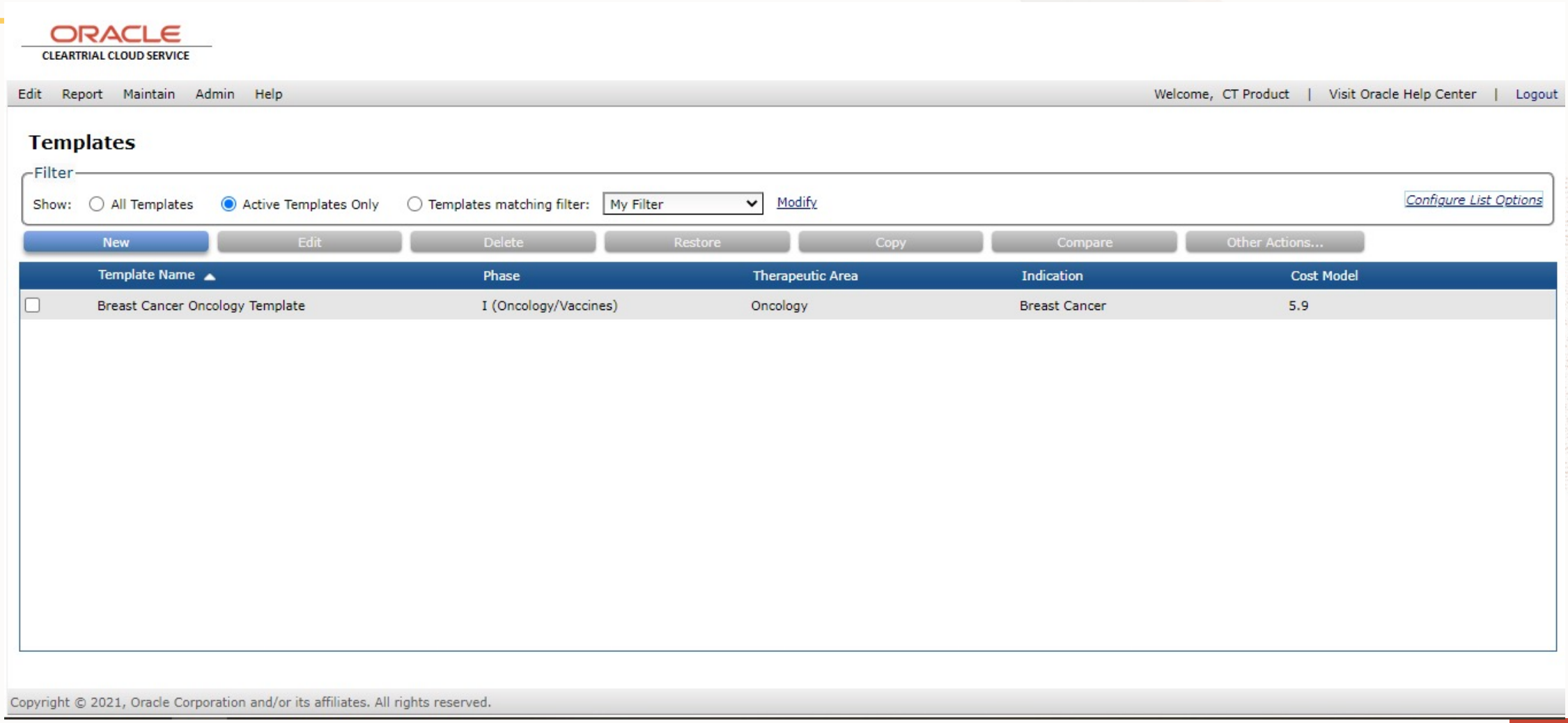
Cost ModelバージョンがTemplate List画面にデフォルトで表示されます



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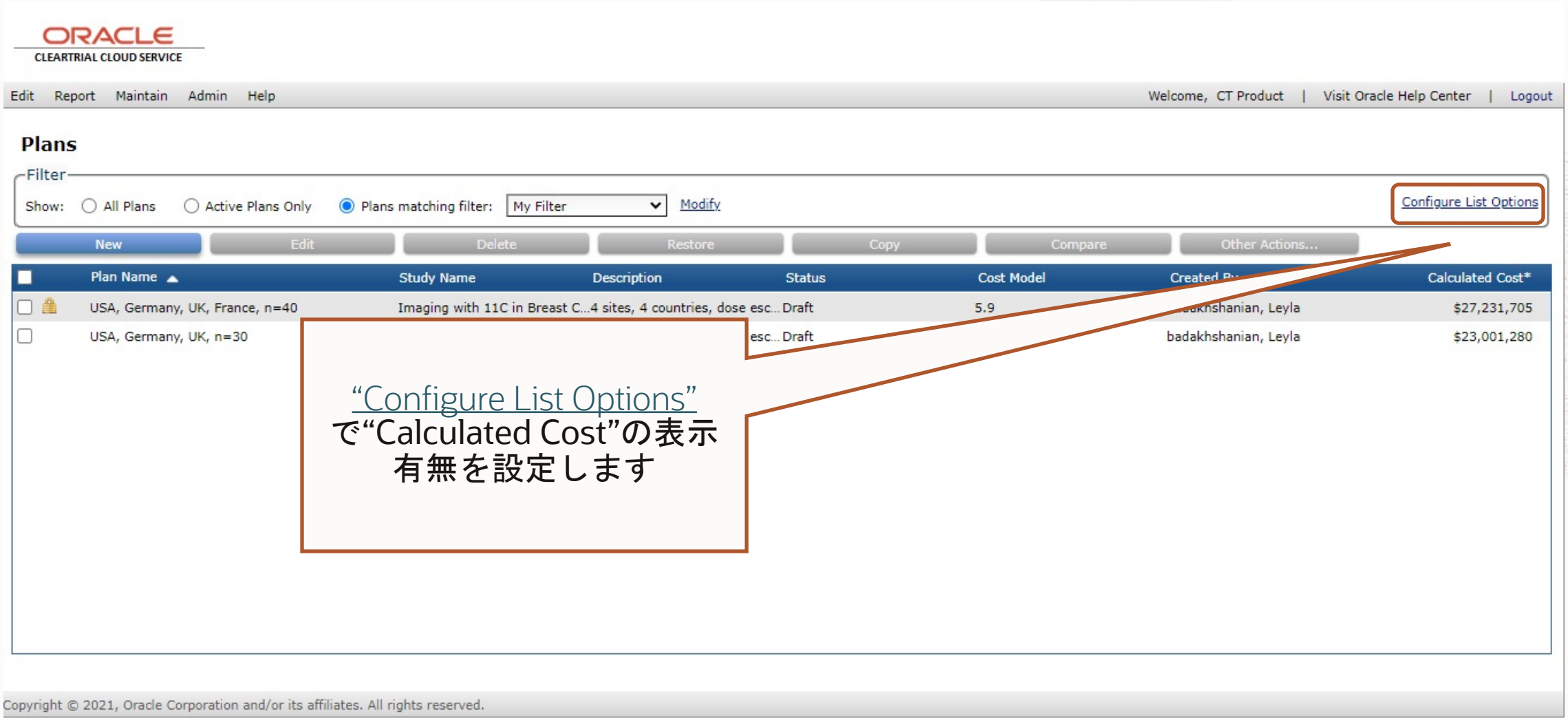
Plan List画面にCalculated Costが表示できるようになりました



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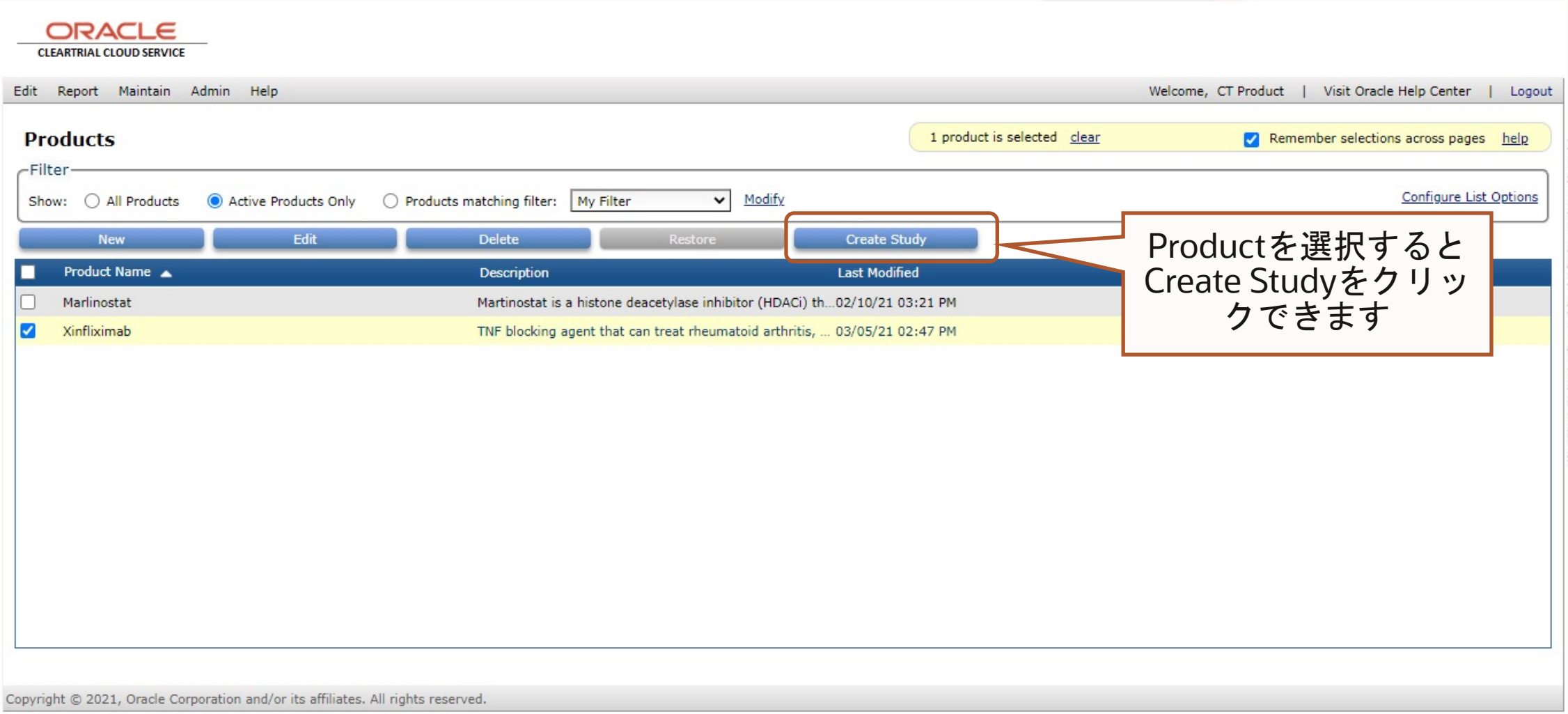
Product List画面からStudyの作成が可能になりました



Productを選択すると
Create Studyをクリックできます

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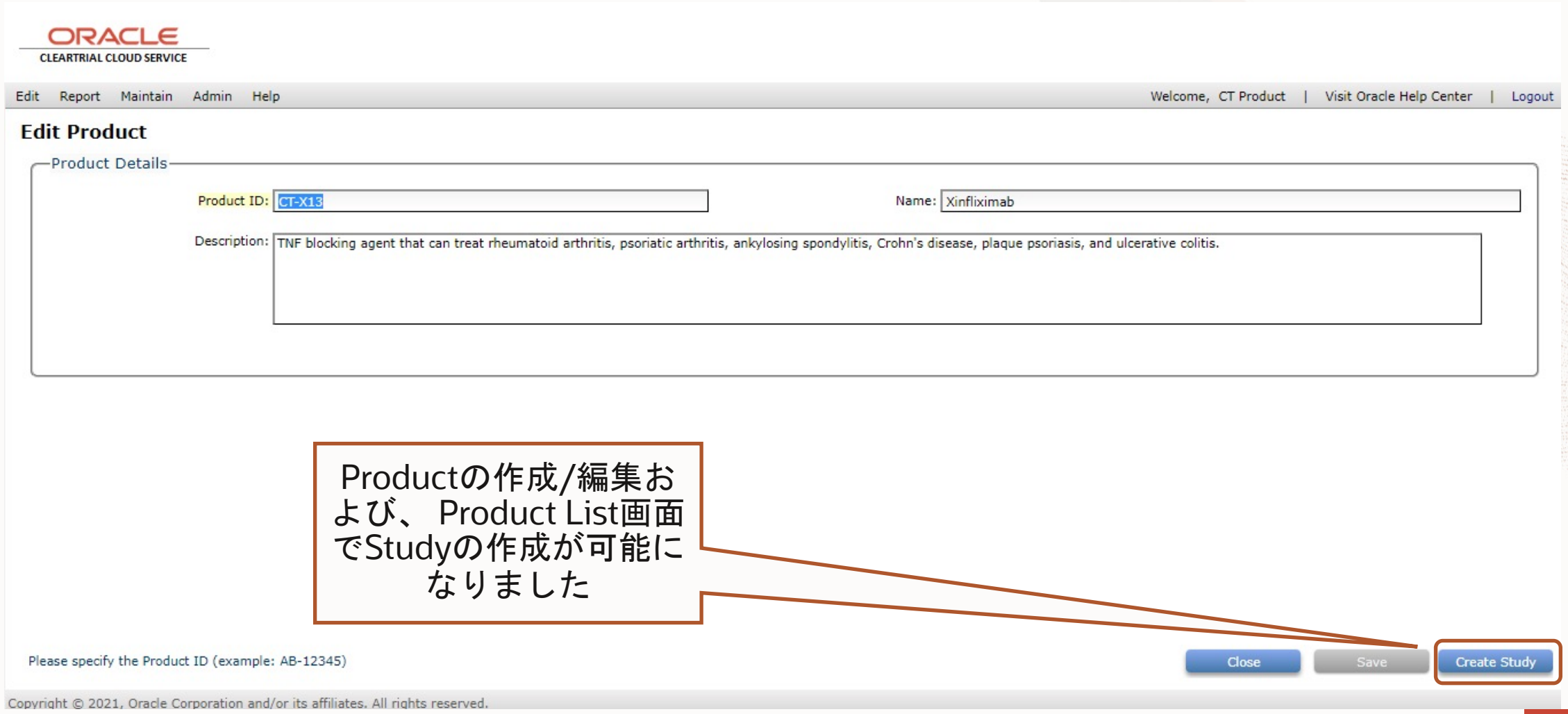
Productの作成、変更後にStudyの作成が可能になりました



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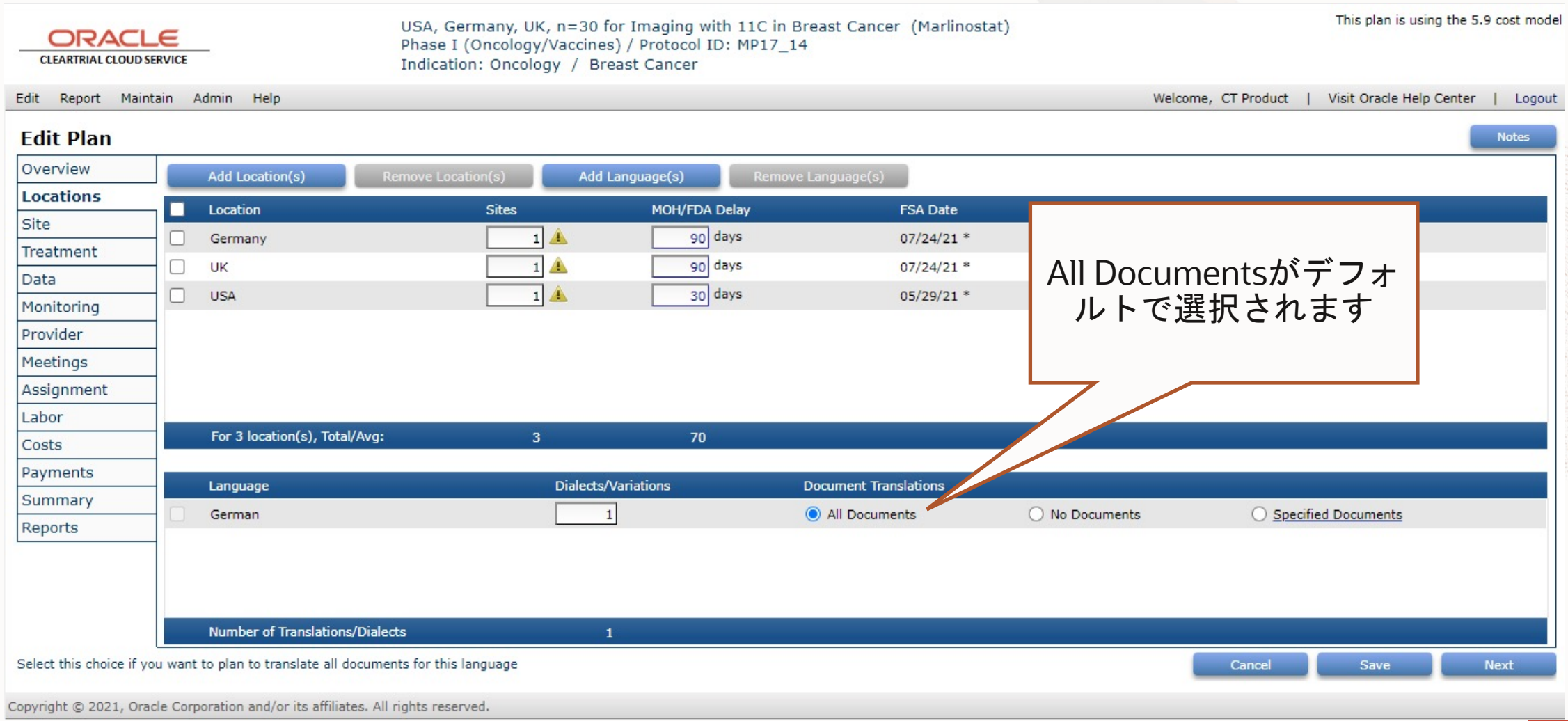
Locations画面のTranslationsでAll Documentsがデフォルトで選択されます



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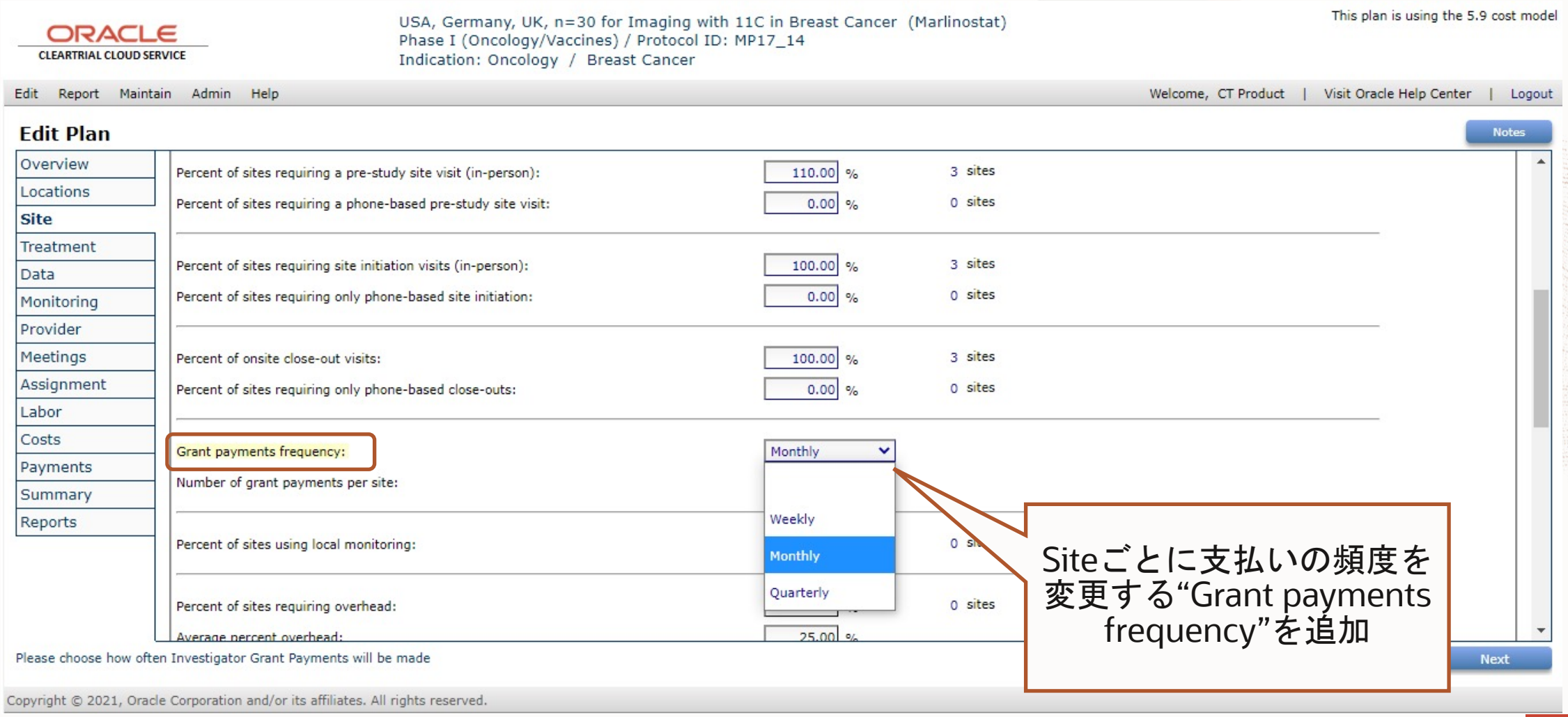
Site画面のGrant Paymentsに支払回数のオプションが追加されました



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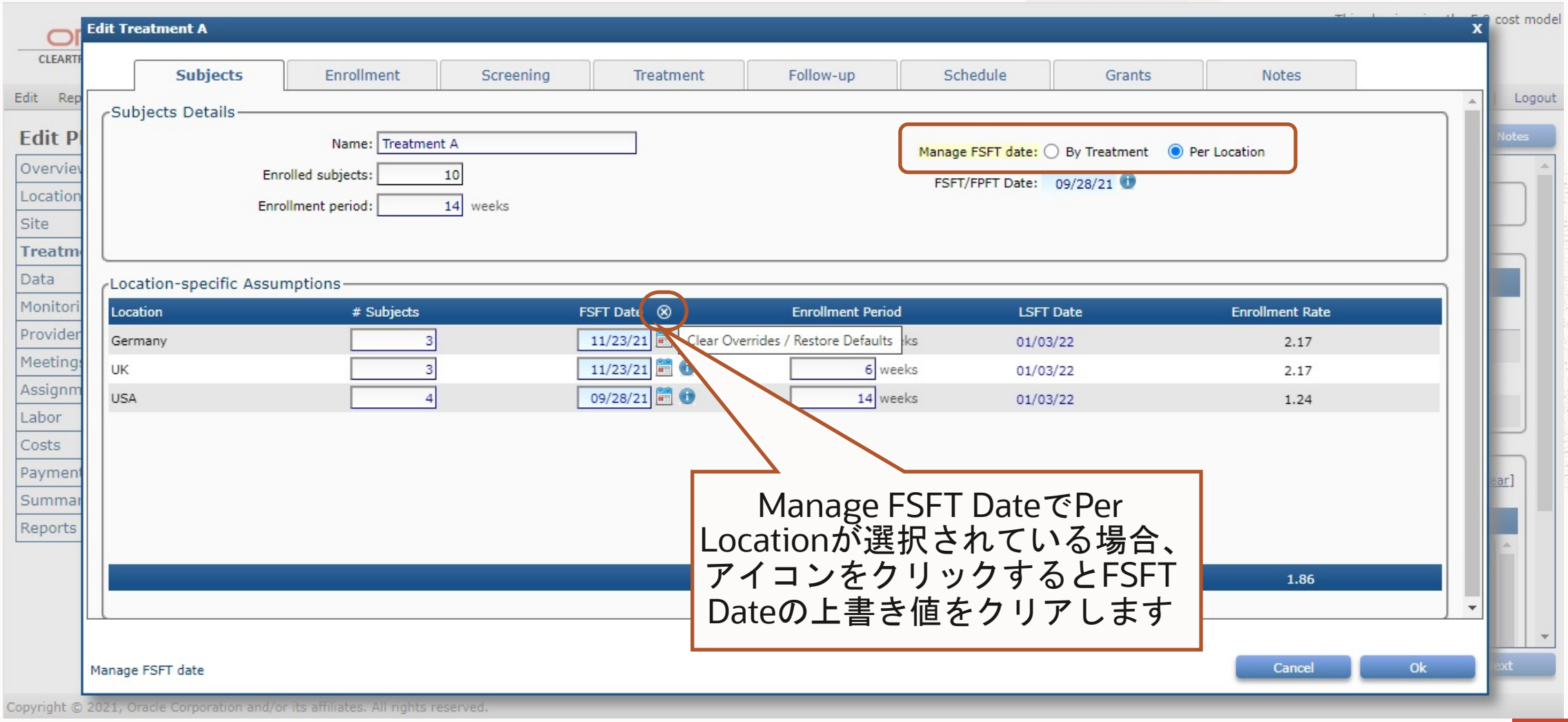
<Treatment画面>Manage FSFT DateでPer Locationを選択している際に、上書きした値をクリアしてデフォルトに戻せます



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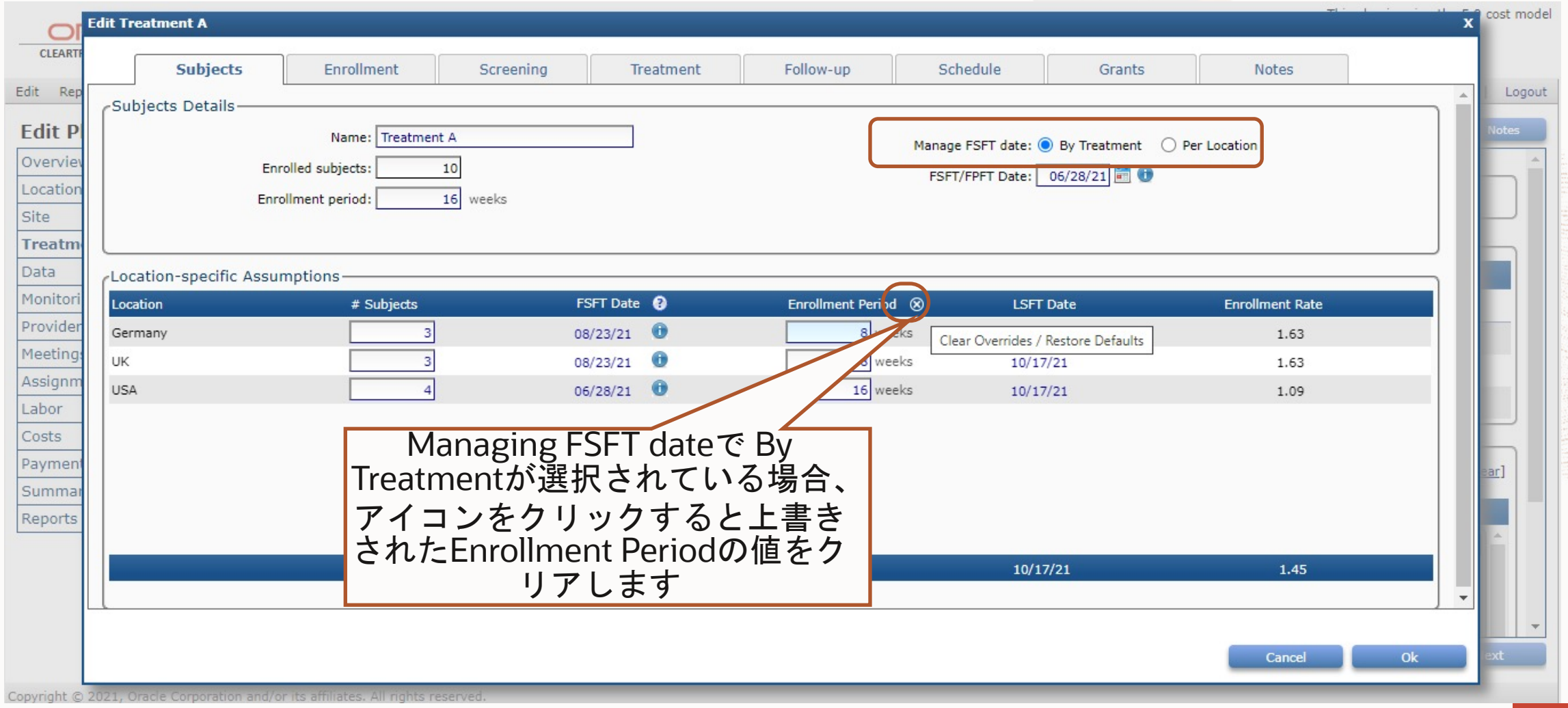
<Treatment画面>Managing FSFT Date By Treatmentを選択している際に、上書きした値をクリアしてデフォルトに戻せます



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

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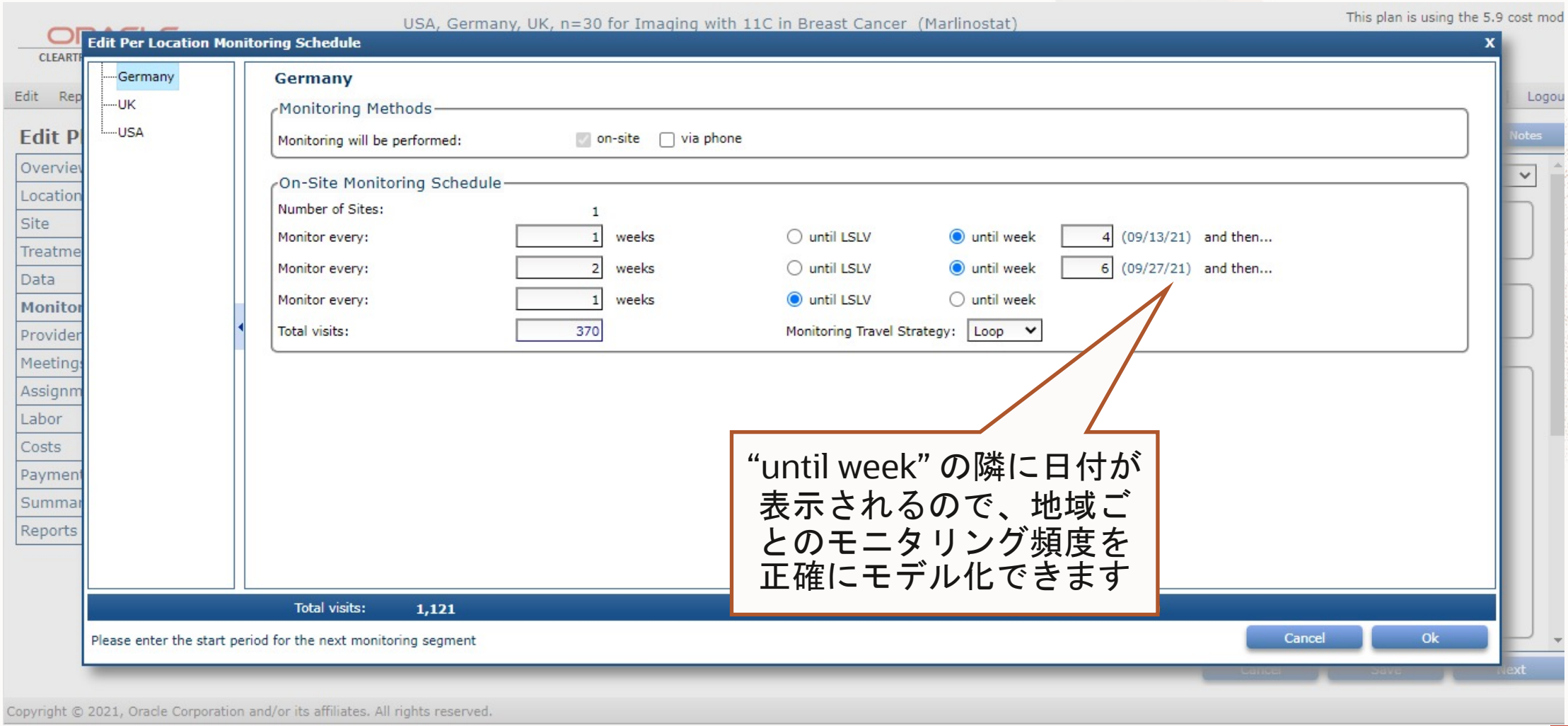
地域ごとにモニタリング頻度を調整する画面に日付が表示されます



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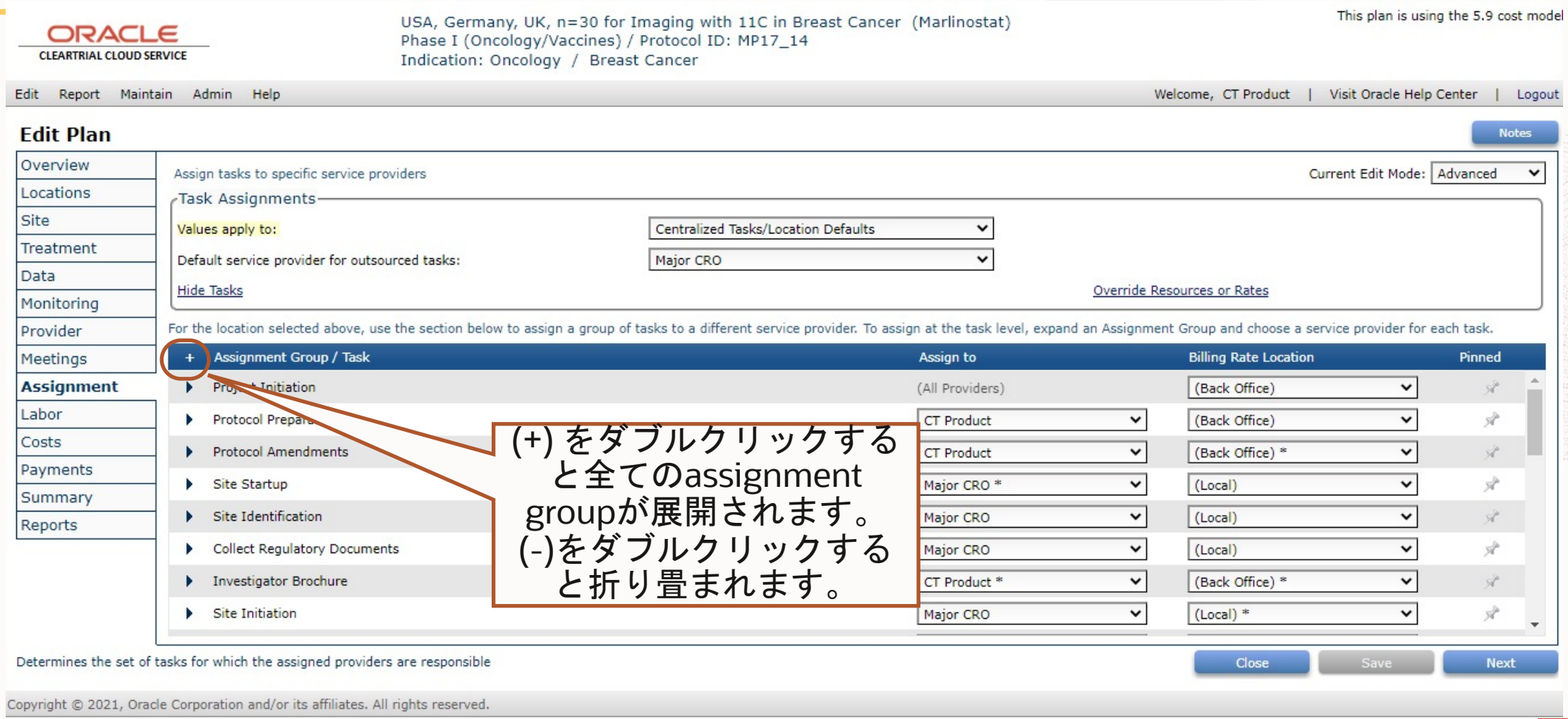
ワンクリックで全てのAssignment Groupsを展開/折り畳むことができます



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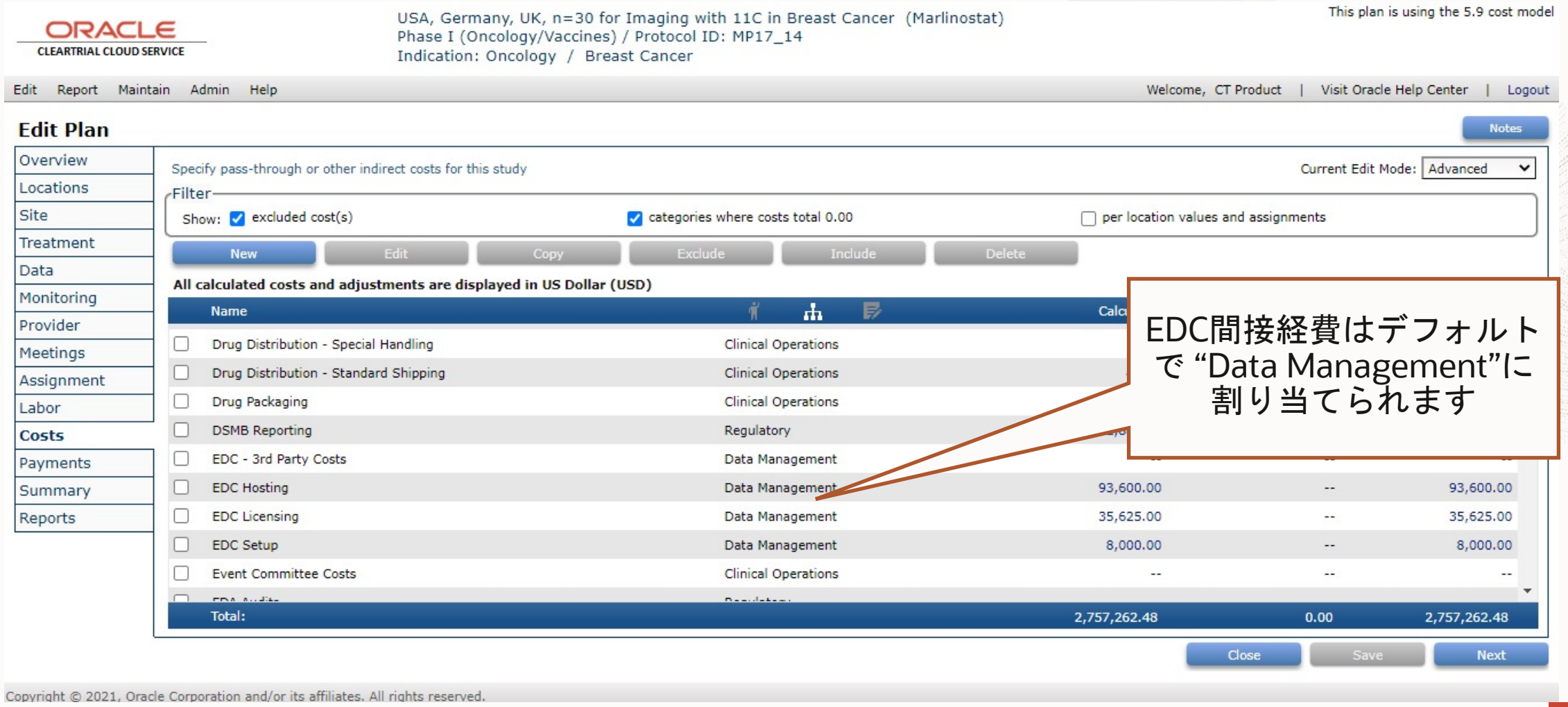
EDC間接経費：デフォルトの部門割当設定を更新



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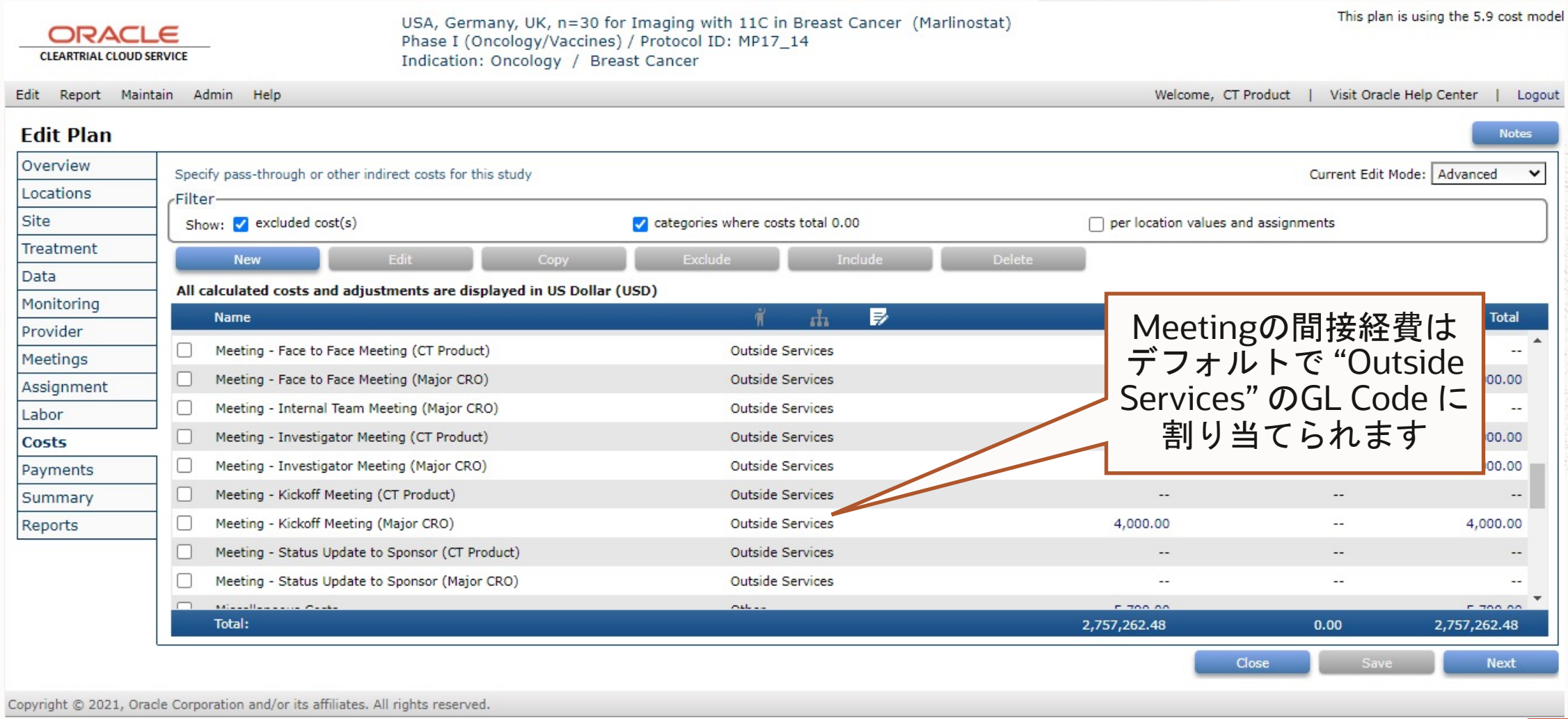
Meetings間接経費：デフォルトのGL Code割当設定を更新



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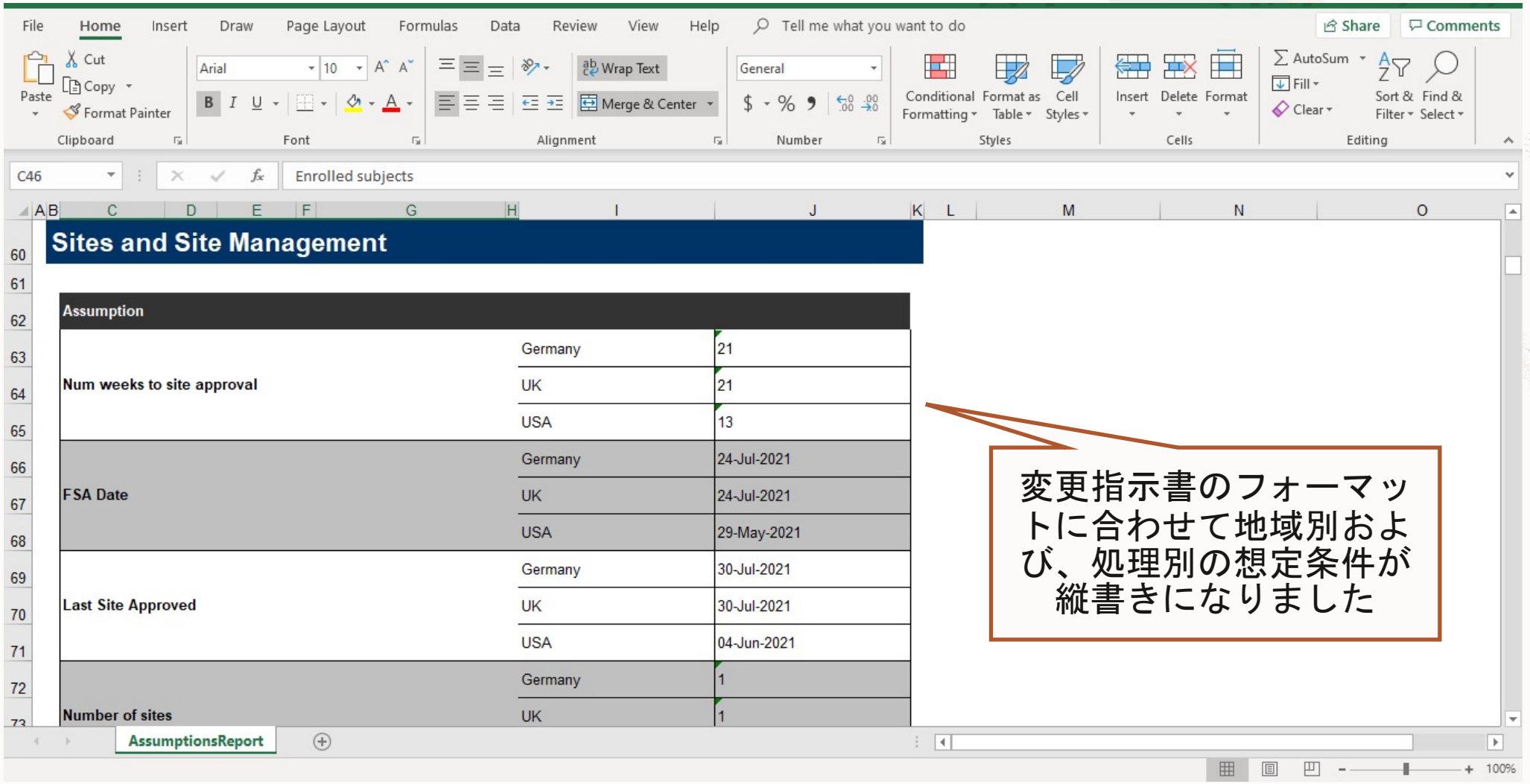
変更管理をサポートできるようにAssumptions Reportを更新しました



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

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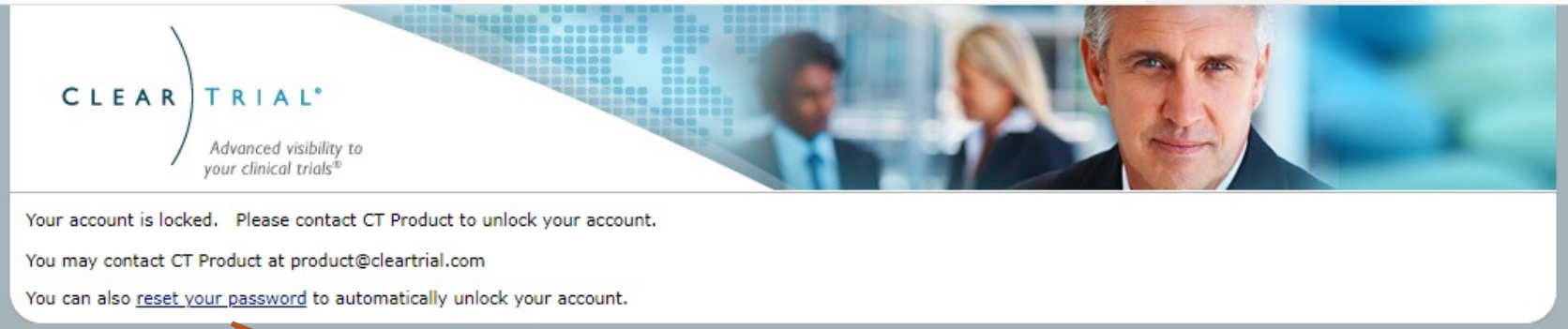
アカウントがロックされた際にパスワードリセットのリンクが表示されます



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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