Introduction to Oracle ClearTrial 5.6

Customer Briefing

ClearTrial Product Management
Health Sciences Global Business Unit
June, 2017

Safe Harbor Statement

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

Agenda

1. Release Overview
2. Reminder of ClearTrial Best Practices
3. List of Primary Features by Edition
4. Walk-through of the Main Enhancements

ClearTrial 5.6 Overview

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

ClearTrial Best Practice Reminders

- Internally review the 5.6 cost model updates to determine if you want to upgrade any existing plans.
  - From the Plan List screen, copy any existing plan.
  - Select the copy and from "Other Actions…" > "Change Attributes" to update the cost model.
  - Run the Compare Plans report between the two plans with different cost models to quickly view the new cost model's impact.
- Lock plans to prevent other users from changing assumptions entered.
- Freeze rates in plans, anytime you are satisfied with your operational budget's forecast.

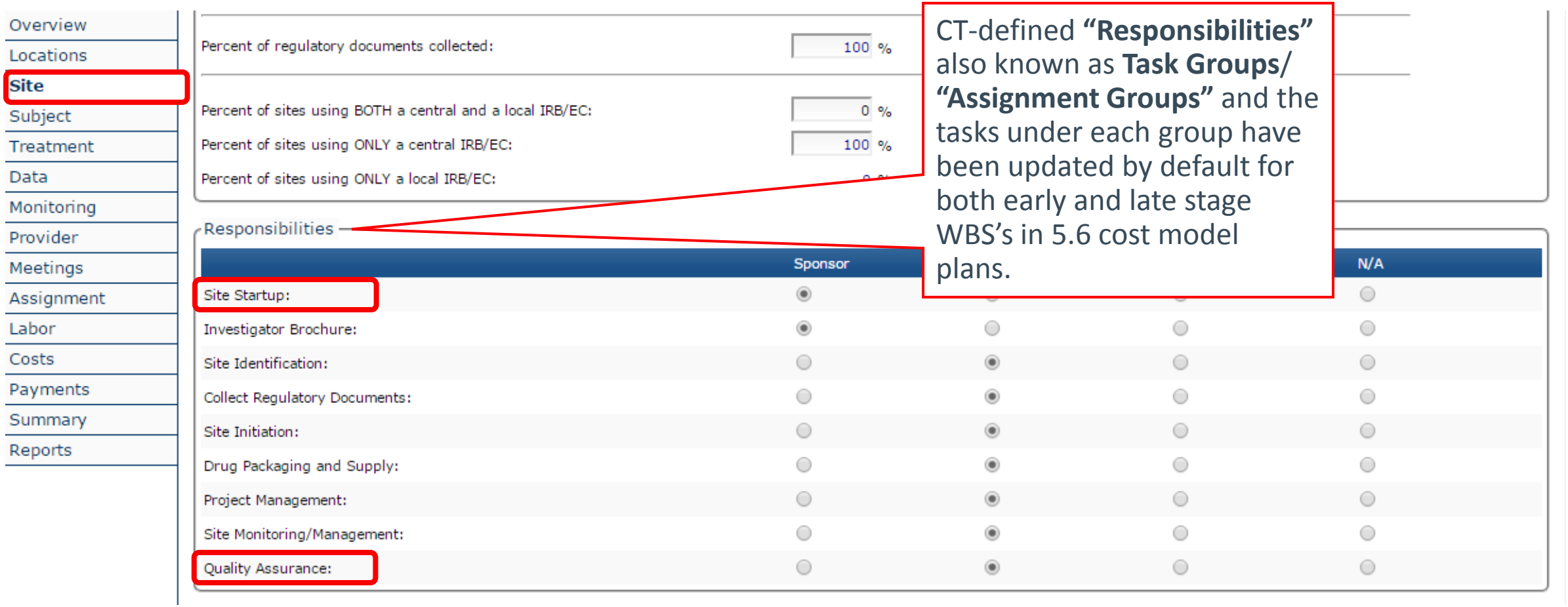
Benefits of Upgrading to the Latest ClearTrial Cost Model

- Upgrading plans/templates to the latest cost model will ensure you are working with the latest updates to fees and costs included in both ClearTrial Work Breakdown Structures and indirect (pass-through/miscellaneous) cost calculations.

5.6 Feature Edition Impact

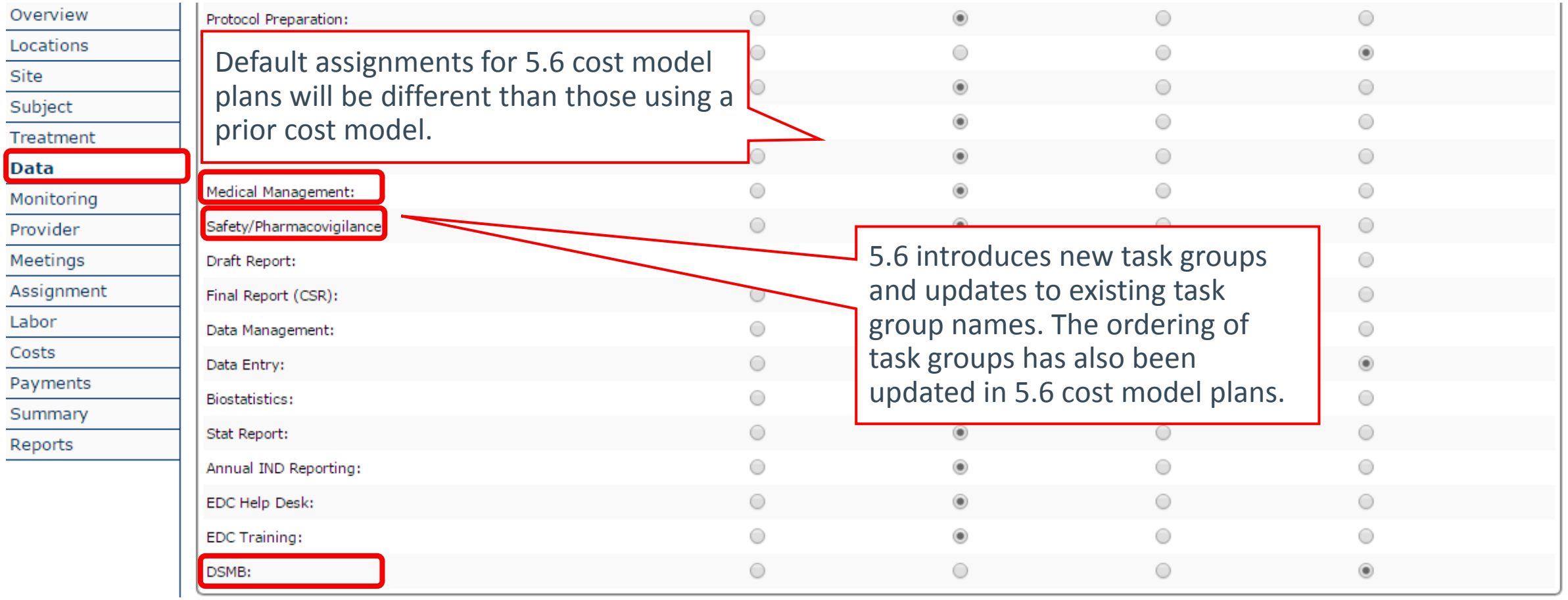
Feature	Standard Edition	Enterprise Edition
Responsibility/Task/Assignment Groups Update	X	X
Import Location-specific Data from any Plan/Template	X	X
Model Site Approval, Subject Enrollment, Tx Duration in Days	X	X
Calculated Dates Display	X	X
New Compare to Original (Template) Report	X	X
Usability/UX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

Responsibilities/Task/Assignment Groups Update



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

Responsibilities/Task/Assignment Groups Update Cont'd



Assignment Groups Update Summary

Phase I (Healthy Volunteers) WBS

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

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

Assignment Groups Update Summary

Late-Stage WBS

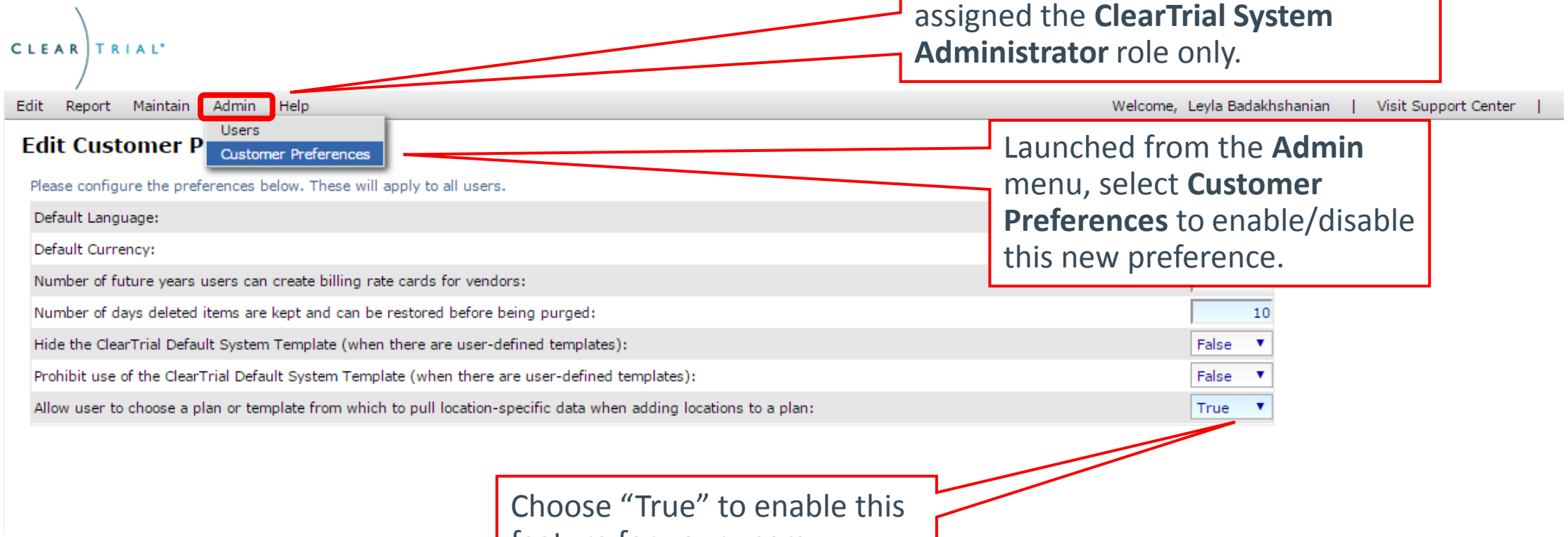
5.5 Task Group Name	5.6 Task Group Name	Details
N/A	Site Startup	New
N/A	Medical Management	New
Safety and Medical Management	Safety/Pharmacovigilance	Update
Site Auditing	Quality Assurance	Update
IVRS	IVRS/Randomization	Update
N/A	DSMB	New

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

New Customer Preference Available

for assigned ClearTrial System Administrators

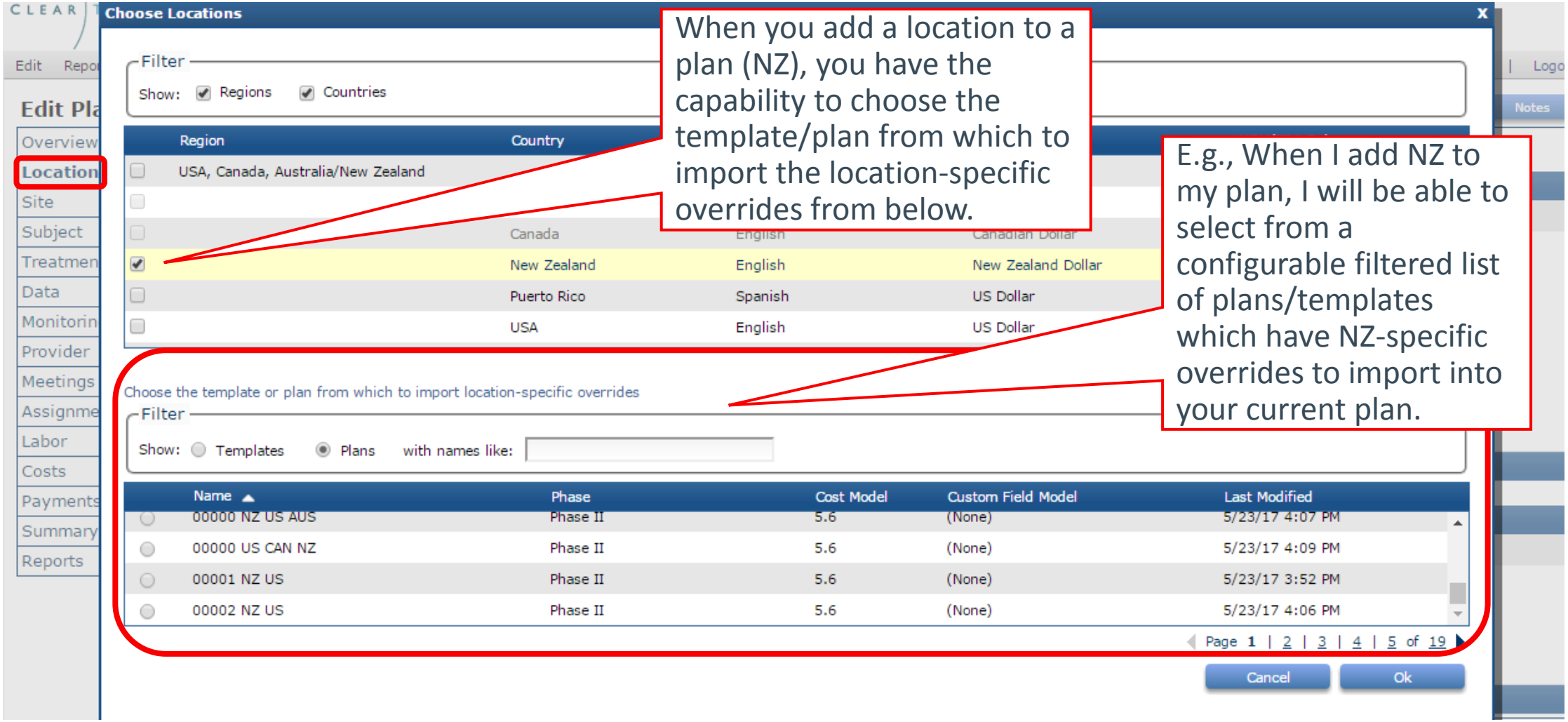
As a reminder, the Admin menu is accessible to those users who are assigned the **ClearTrial System Administrator** role only.



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

Choose “True” to enable this feature for your users.

Import Location-specific Overrides From Template/Plan



When and why would I leverage this capability?

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

What kinds of overrides will be imported/pulled in?

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

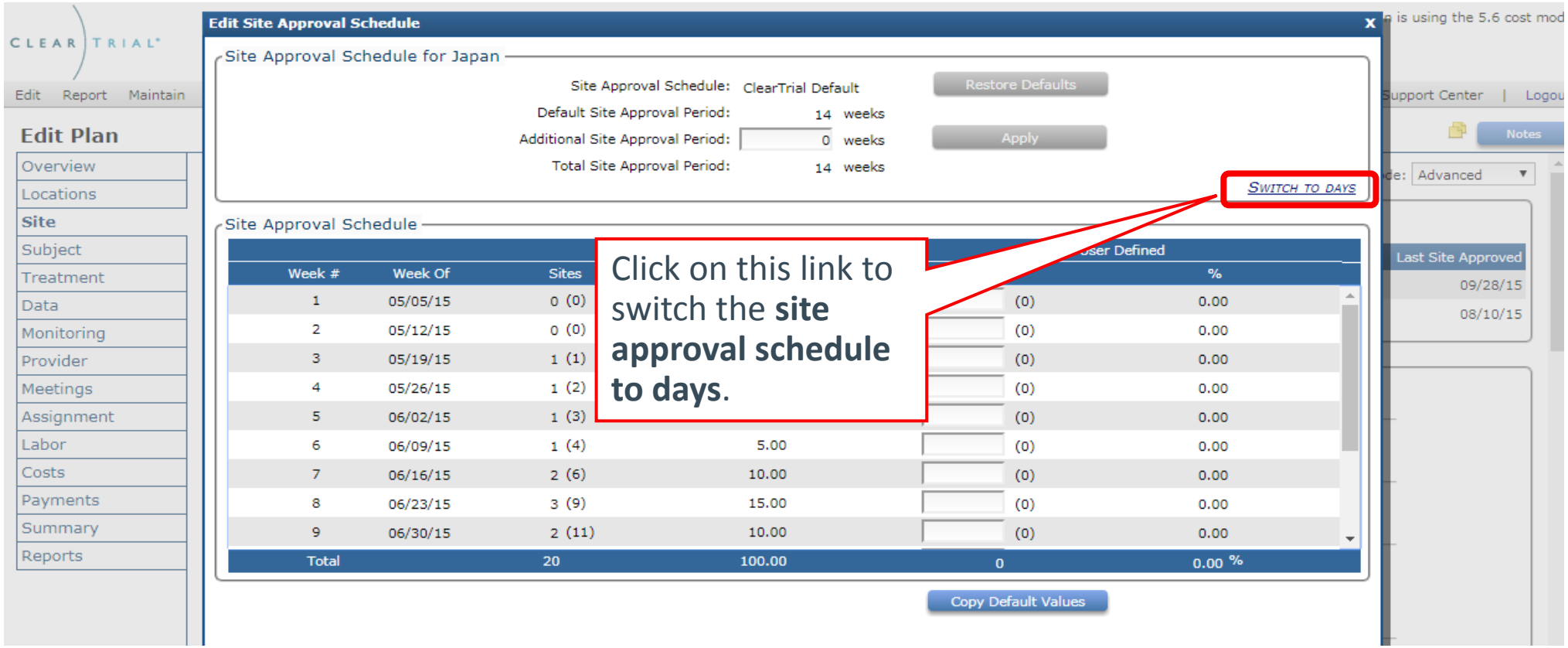
- Custom Fields
- Location data (MOH Delay, Ave Grant Amount)
- Site Information (Number of sites, …etc)
- Subject data (Screening, Drops)
- Task Assignments
- Task-Resource Department/GL Code …

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

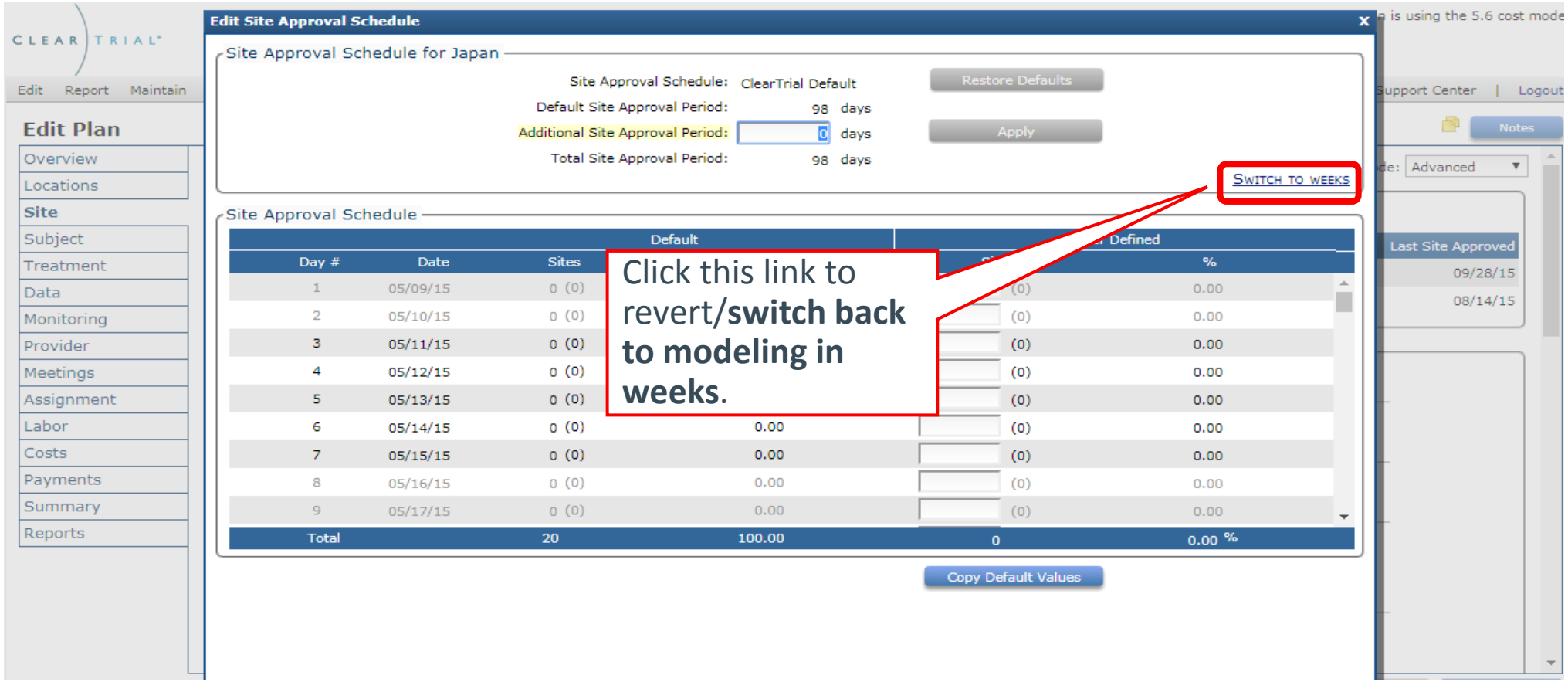
- Task-Resource Algorithms
- Task-Resource Billing Rate Location
- Task-Resource Rate Overrides
- Task-Resource Unit Hours
- Indirect Cost Assignments
- Indirect Cost Departments/GL Codes
- Indirect Cost Adjustments
- Indirect Cost Algorithms
- Meetings
- Resource Assignments (made in the Override Resources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

New Ability to Model Site Approval Period in Days

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

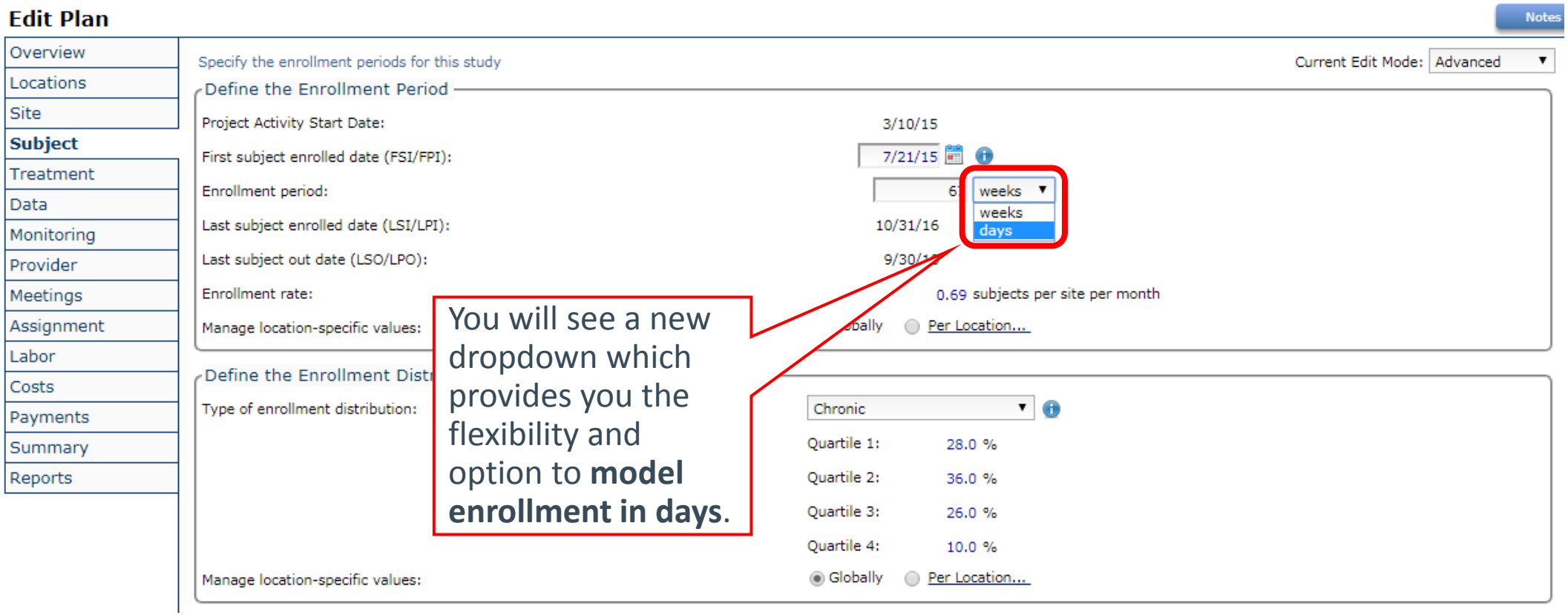


Capability to Revert Back/Switch to Weeks



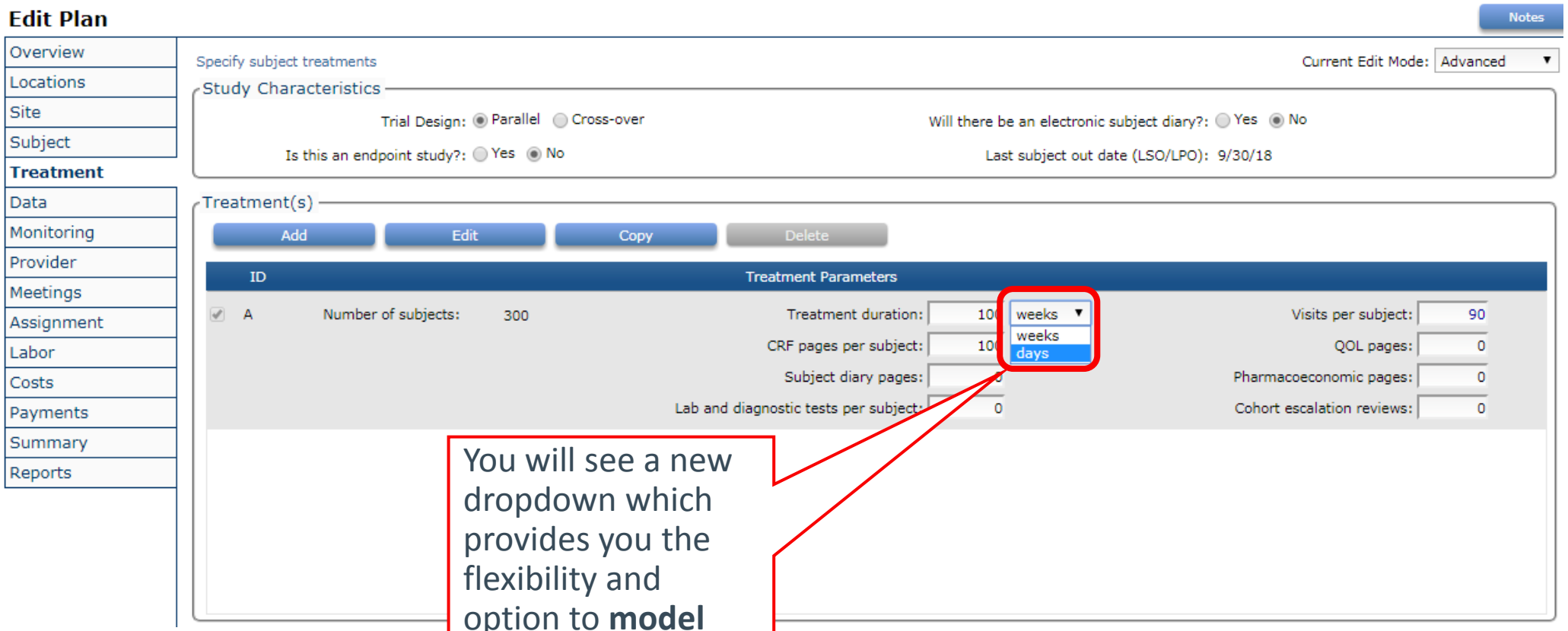
New Ability to Model Subject Enrollment in Days

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



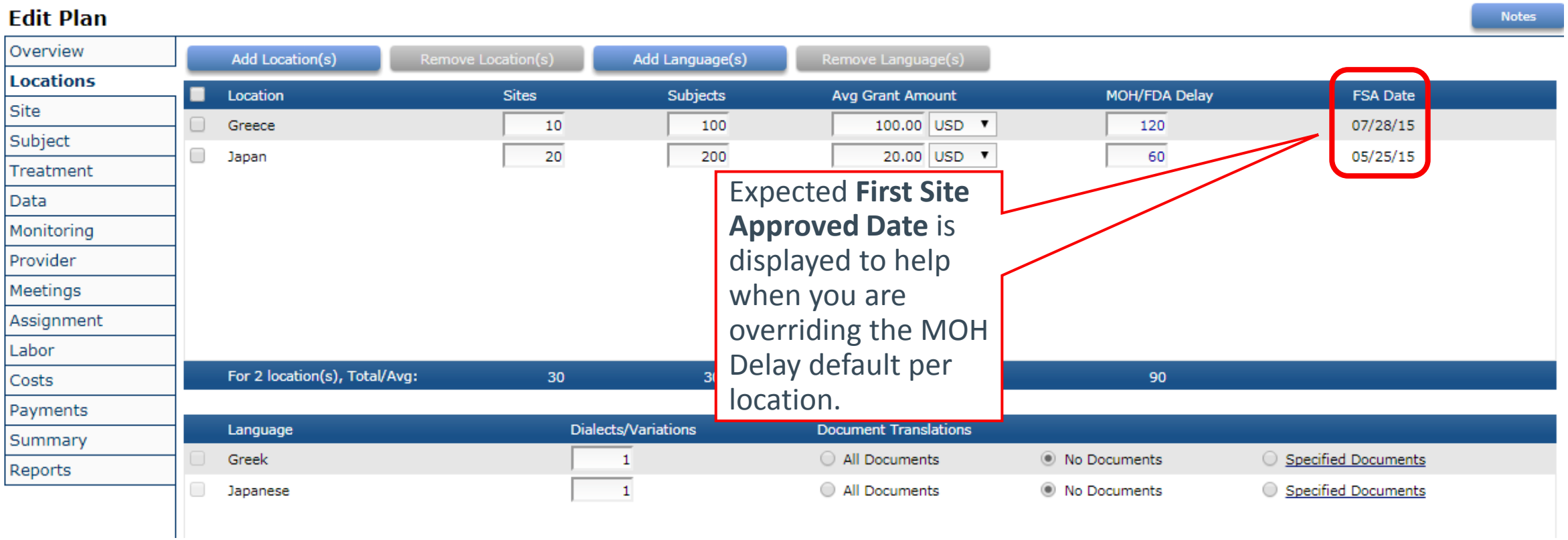
New Ability to Model Treatment Duration in Days

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

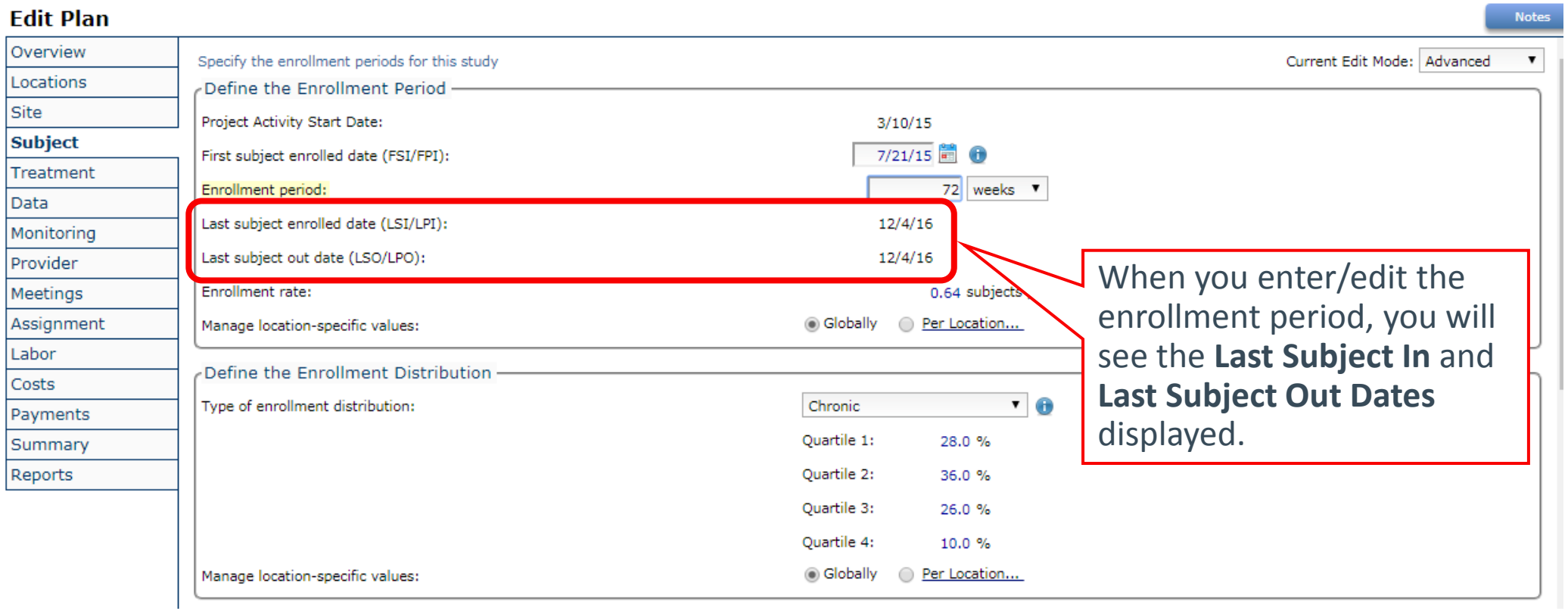


You will see a new dropdown which provides you the flexibility and option to **model Treatment duration in days**.

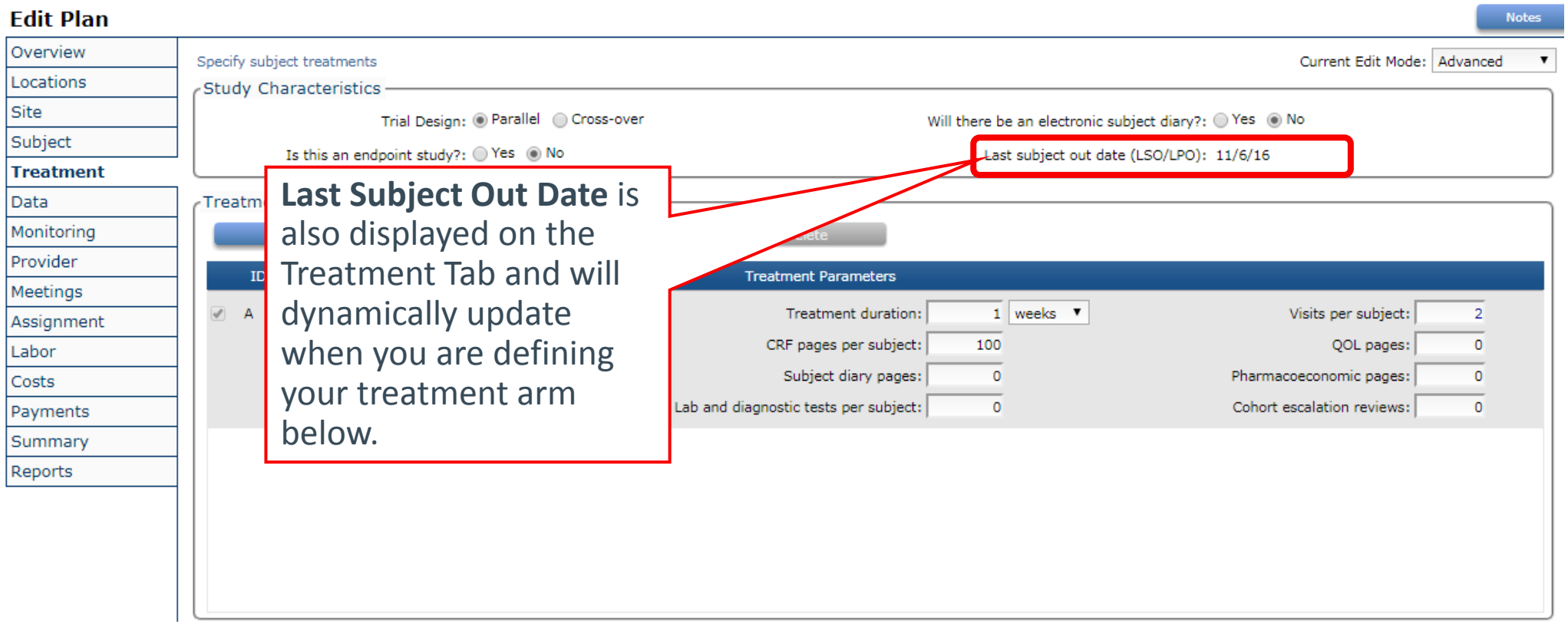
FSA Date Display on Locations Tab



LSI, LSO Dates Display on Subject Tab

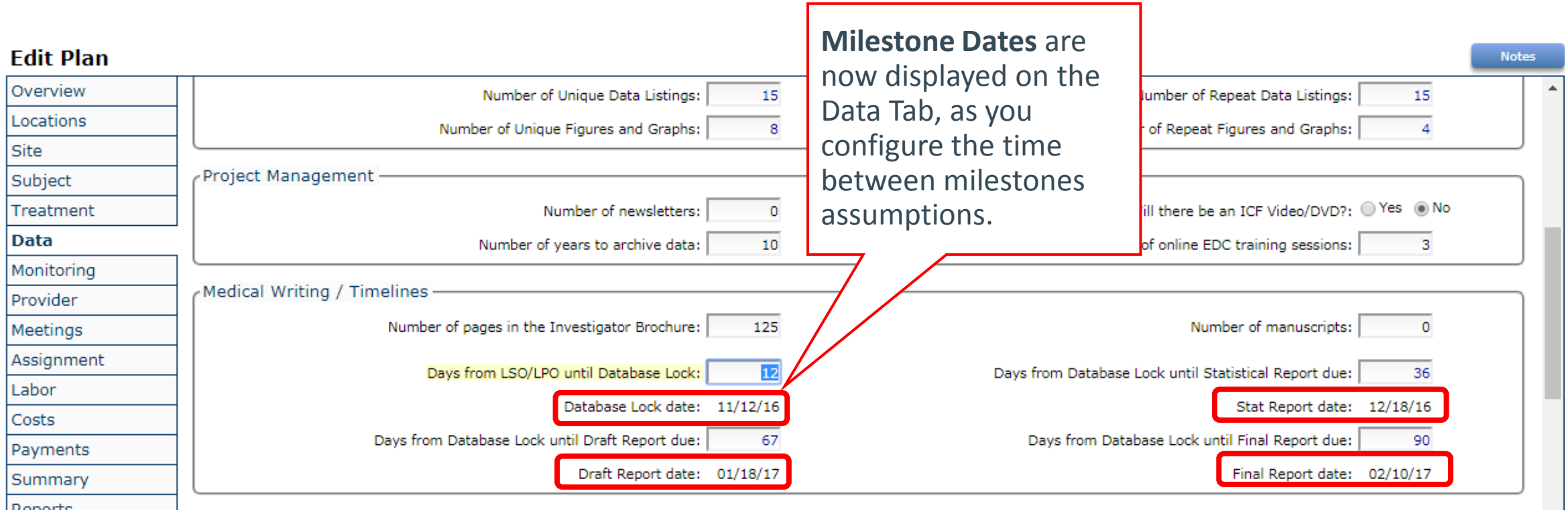


LSO Date Display



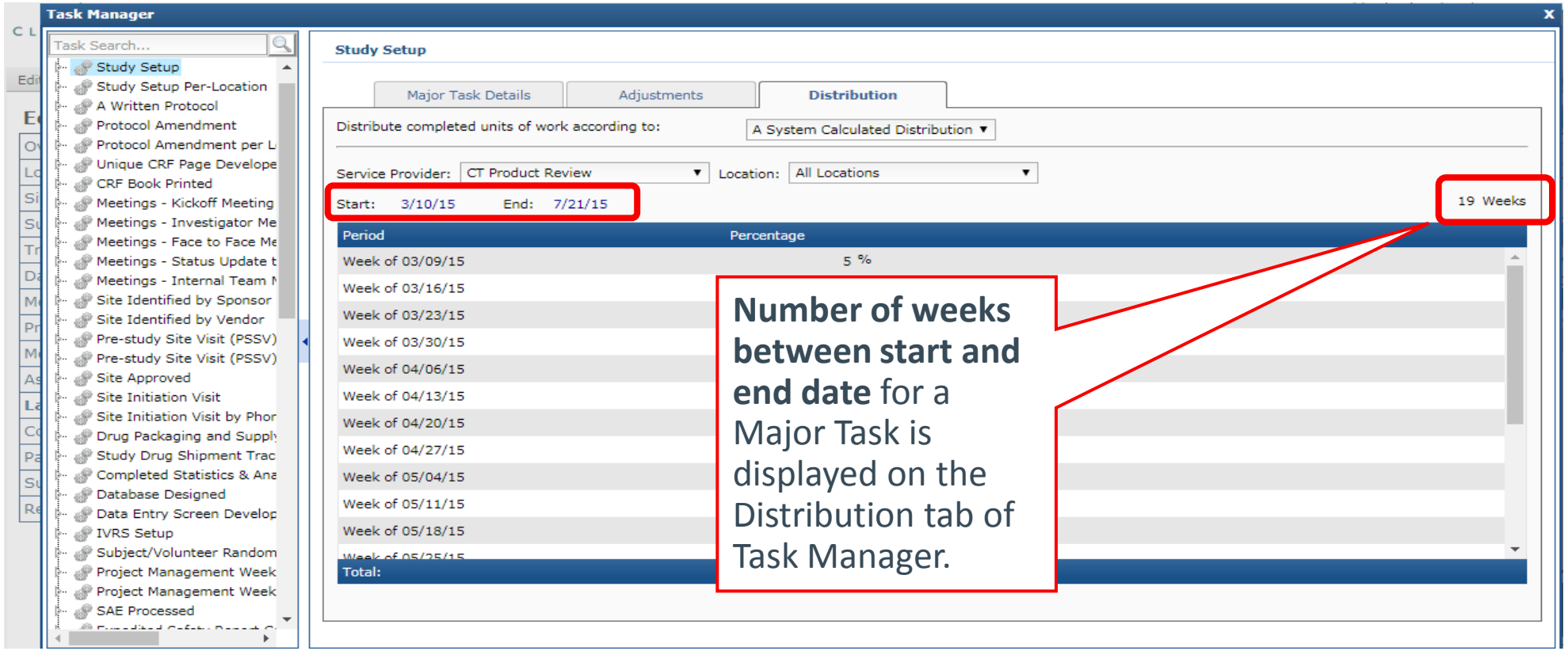
Last Subject Out Date is also displayed on the Treatment Tab and will dynamically update when you are defining your treatment arm below.

Milestone Dates Display on Data Tab

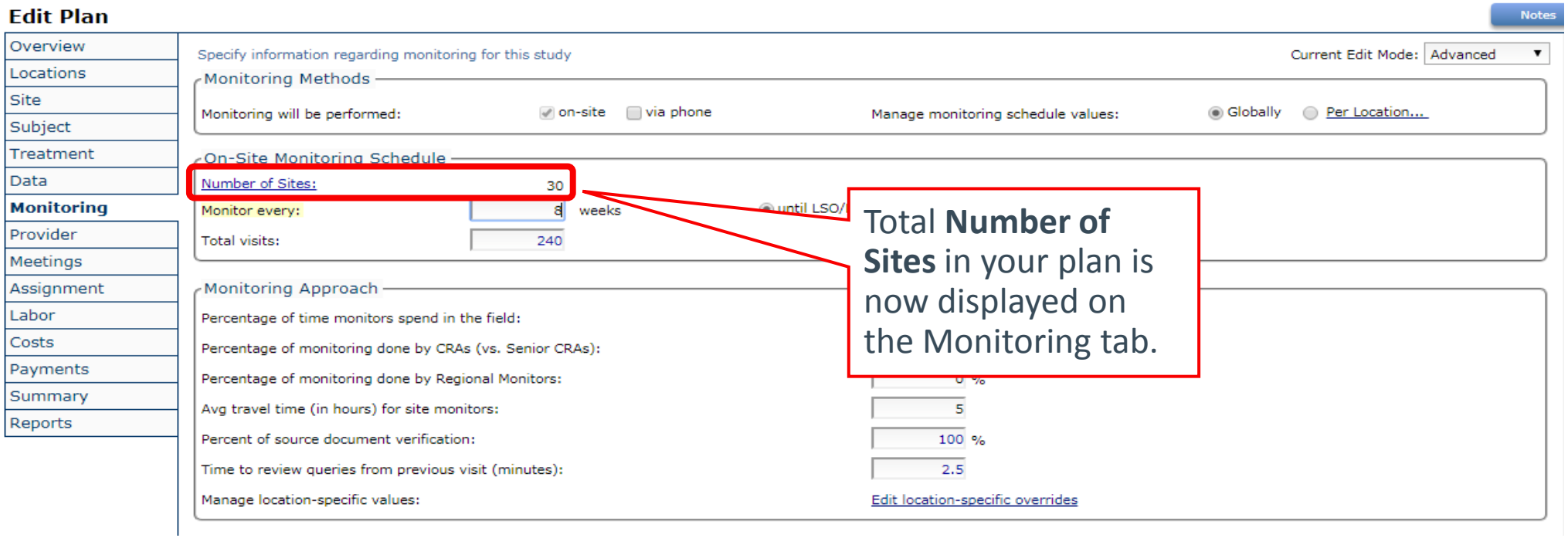


Milestone Dates are now displayed on the Data Tab, as you configure the time between milestones assumptions.

Number of Weeks Display per Major Task

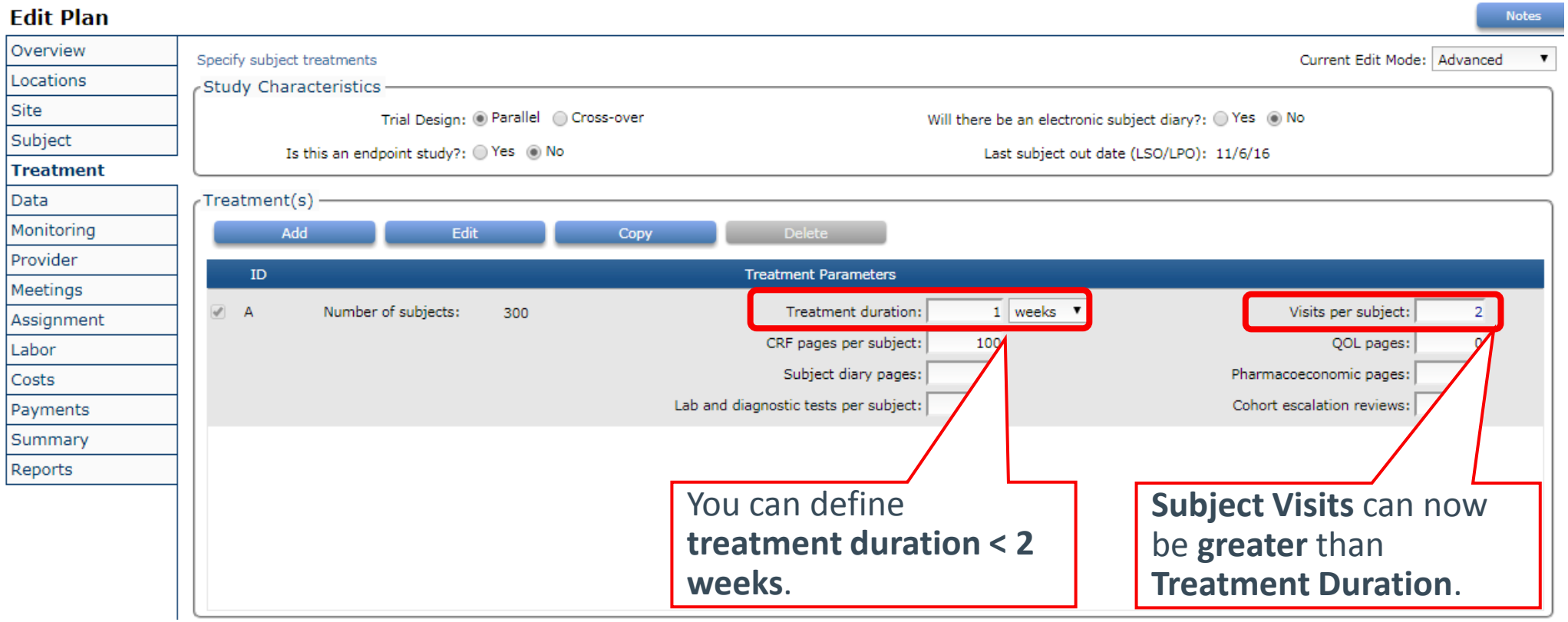


Number of Sites Display on Monitoring Tab

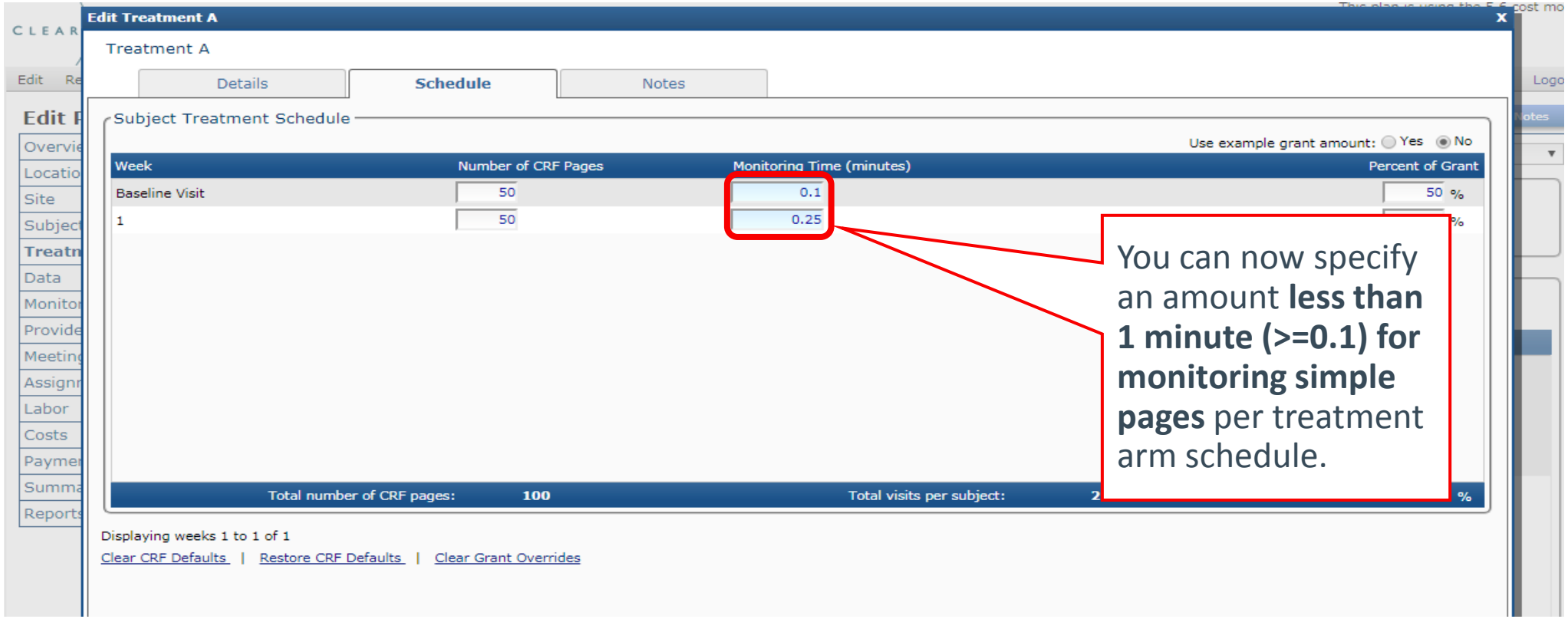


Usability Enhancements

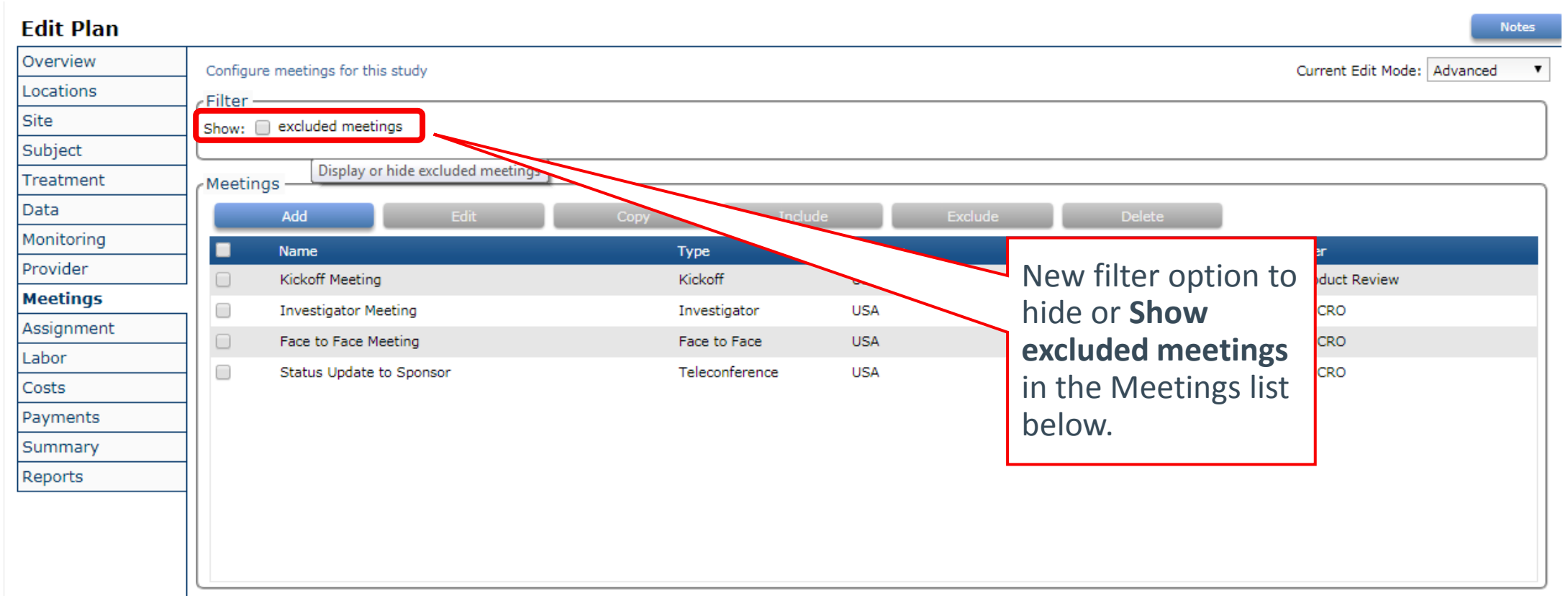
Treatment Duration < 2 Weeks, Subject Visits Can Be Greater than Treatment Duration



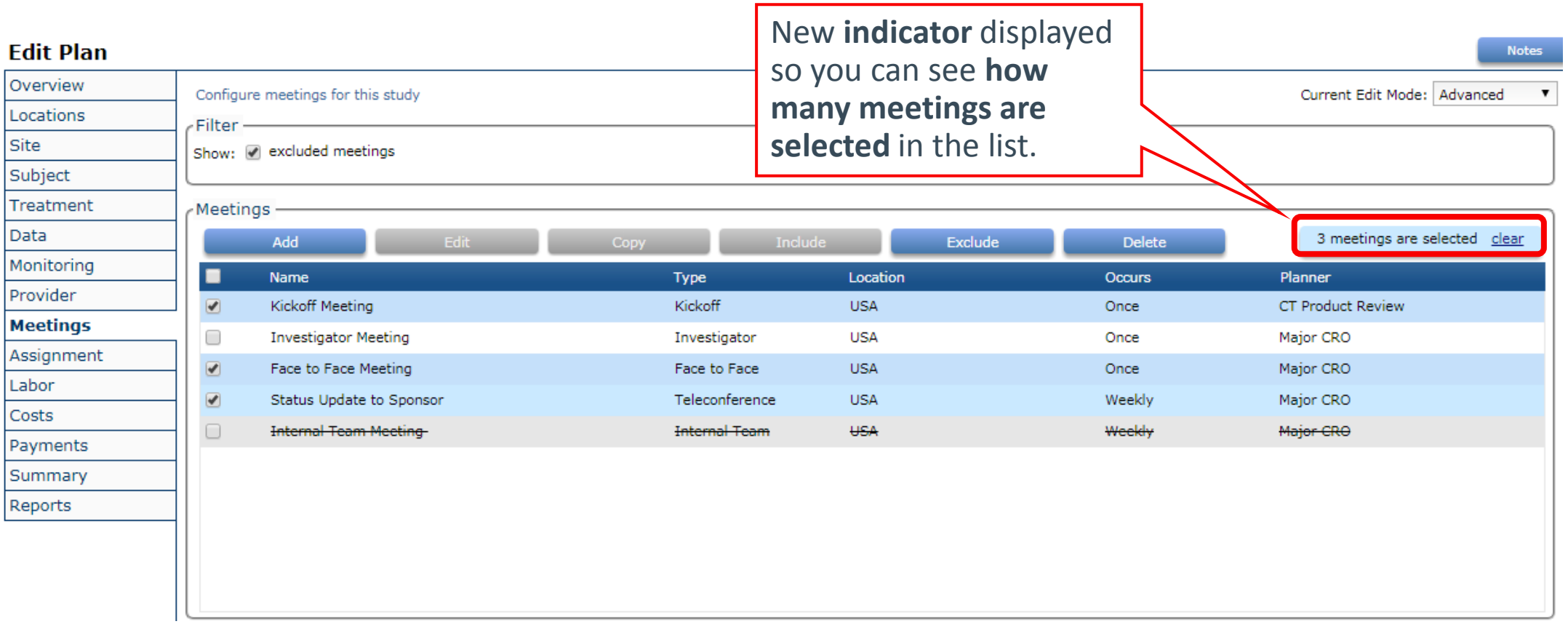
Specify Less Than 1 Minute for Monitoring Time on Treatment Schedule



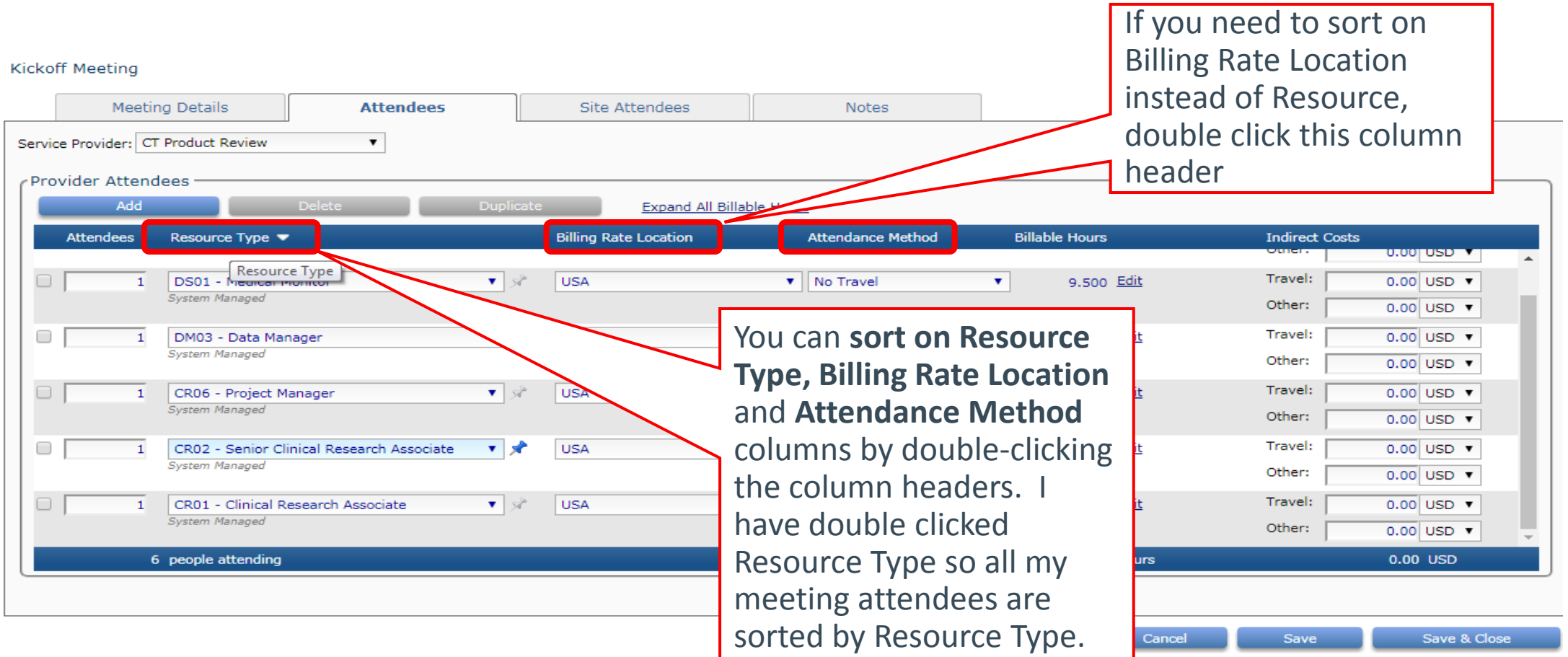
Show or Hide Excluded Meetings on Meetings Tab



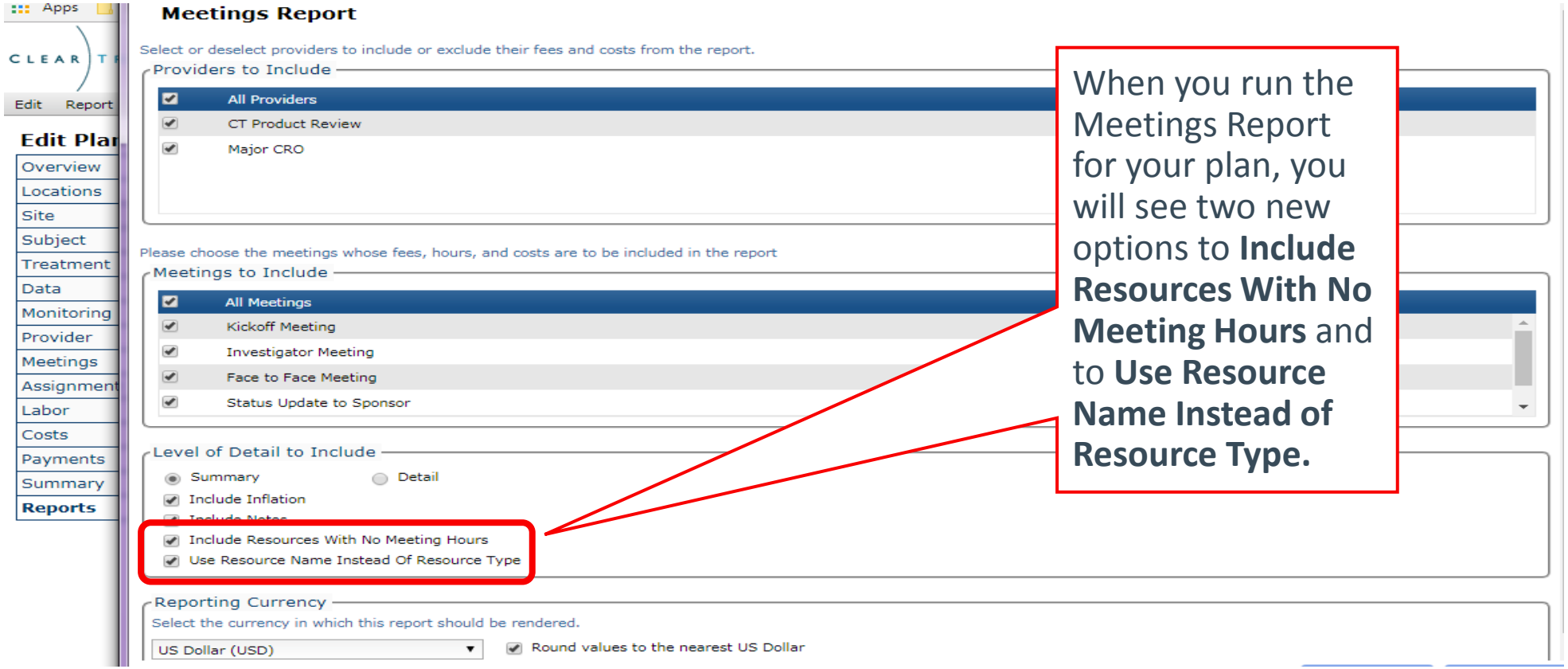
Show Number of Meetings Selected on Meetings Tab



Sort Meeting Attendees by Double-Clicking Column Headers

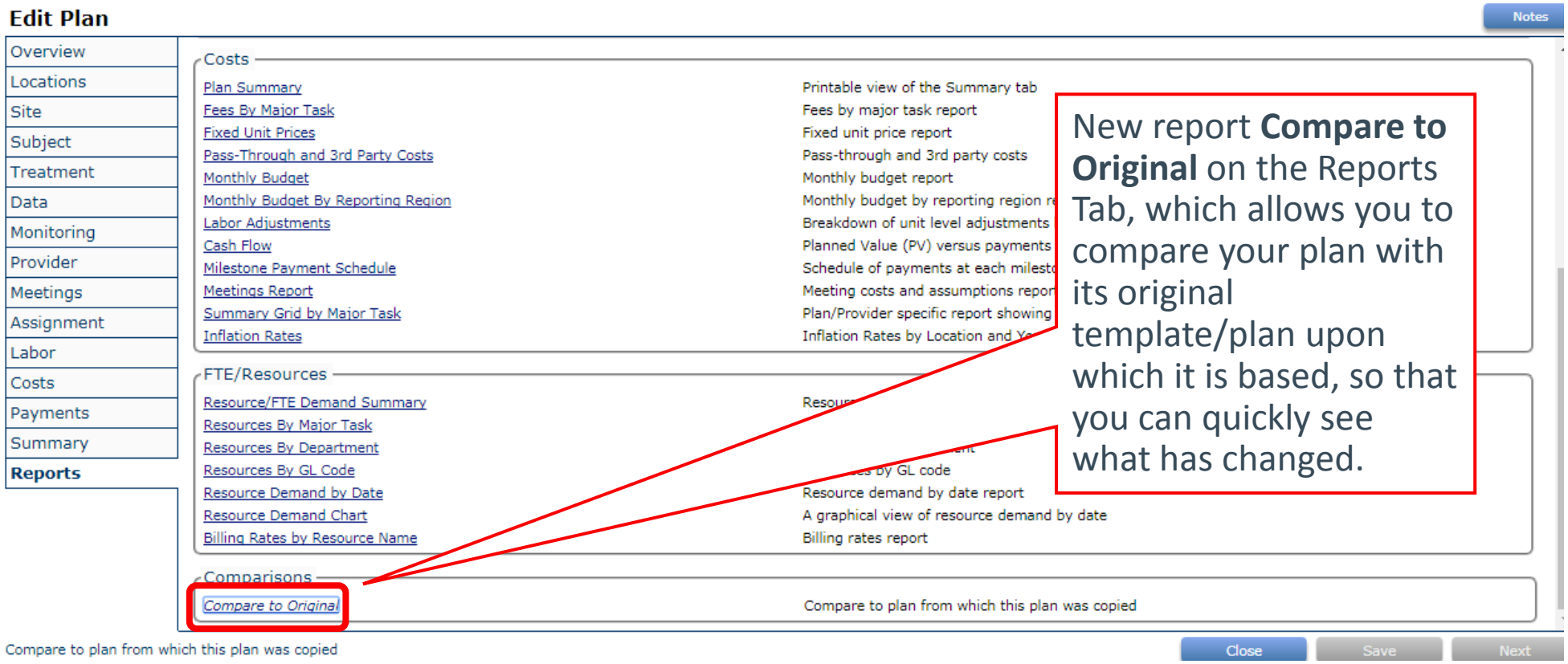


New Meetings Report Options



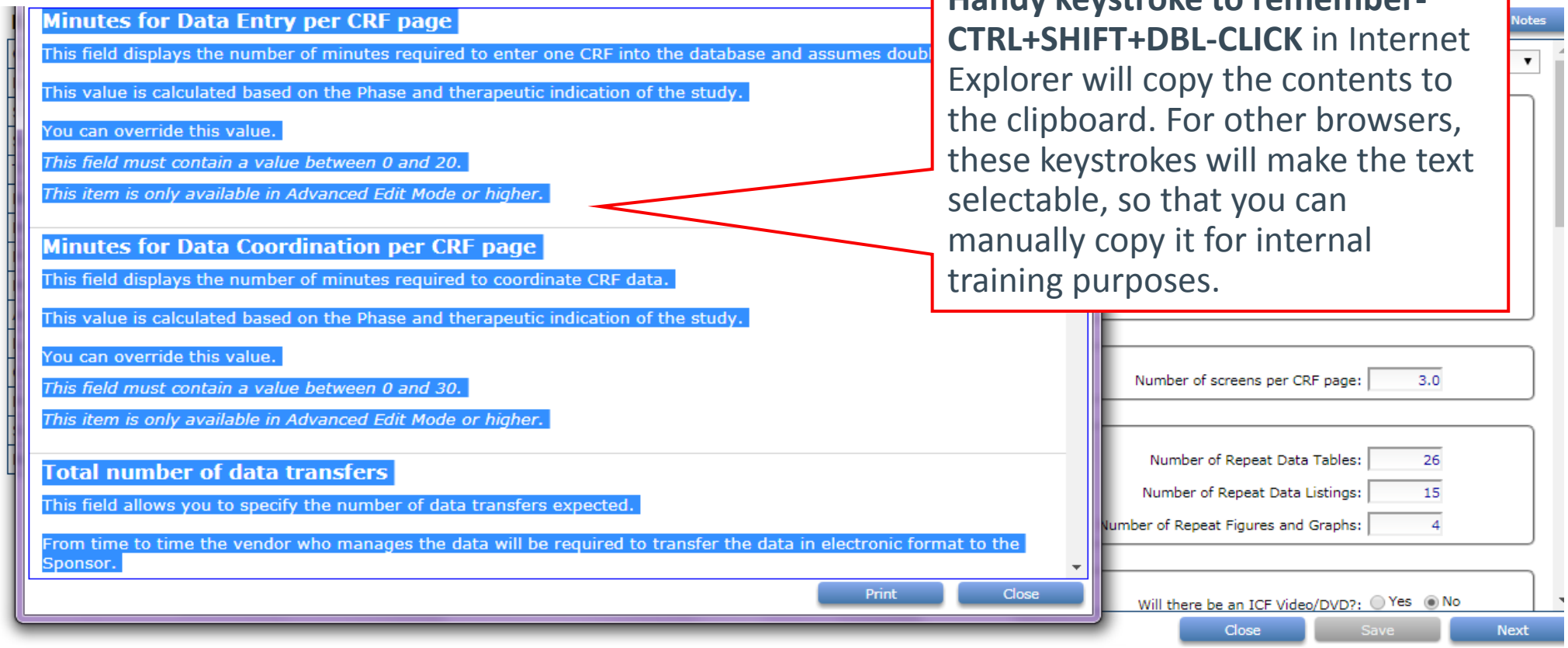
When you run the Meetings Report for your plan, you will see two new options to **Include Resources With No Meeting Hours** and to **Use Resource Name Instead of Resource Type.**

New Compare to Original Report



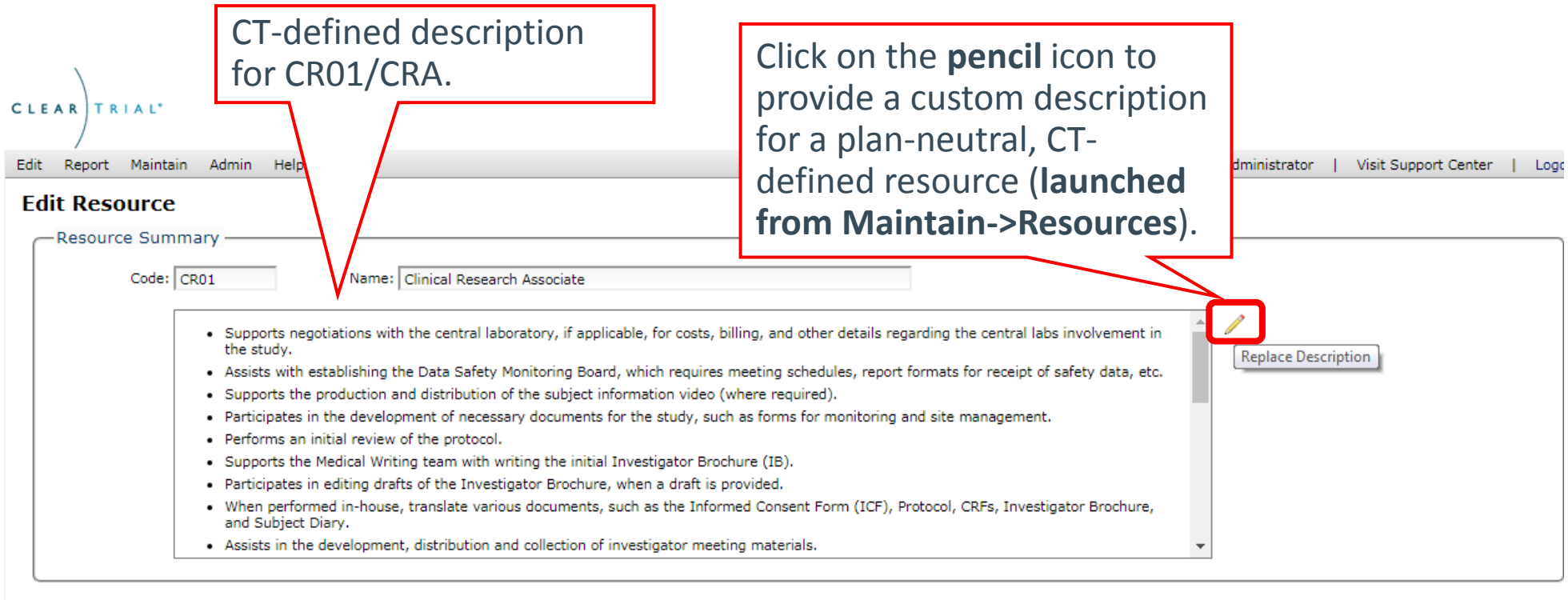
Enable Help Text Content to be Copied to Clipboard

CTRL+SHIFT+DBL-CLICK



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

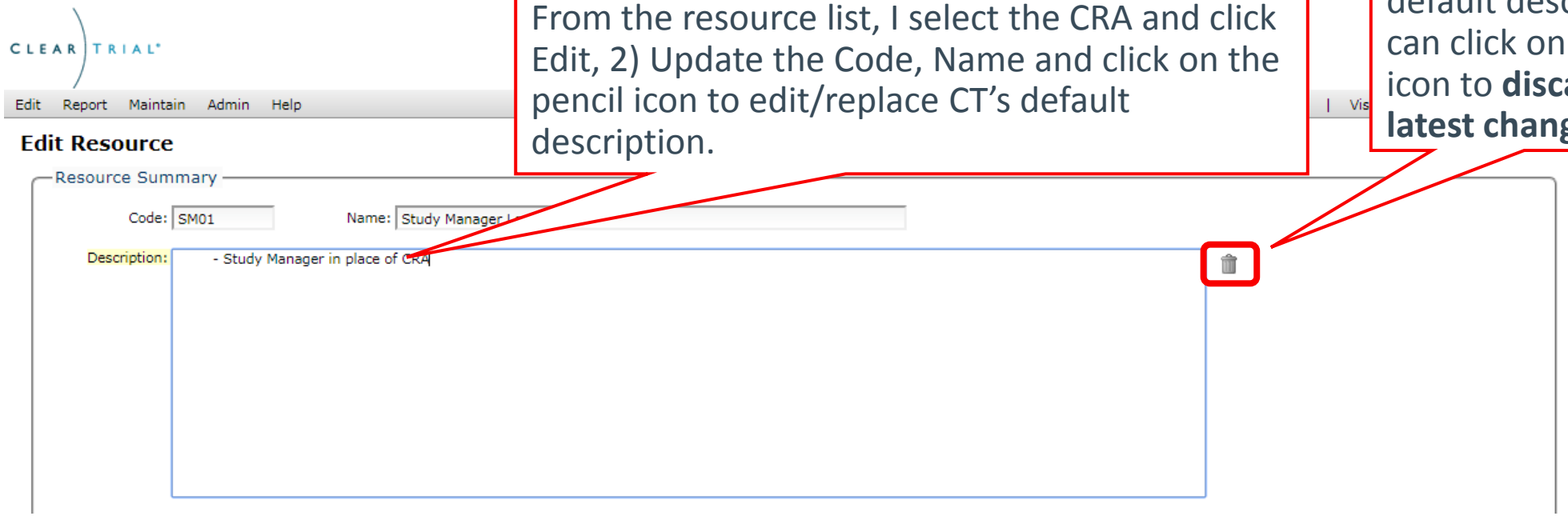
Edit/Replace CT-Defined Resource Description



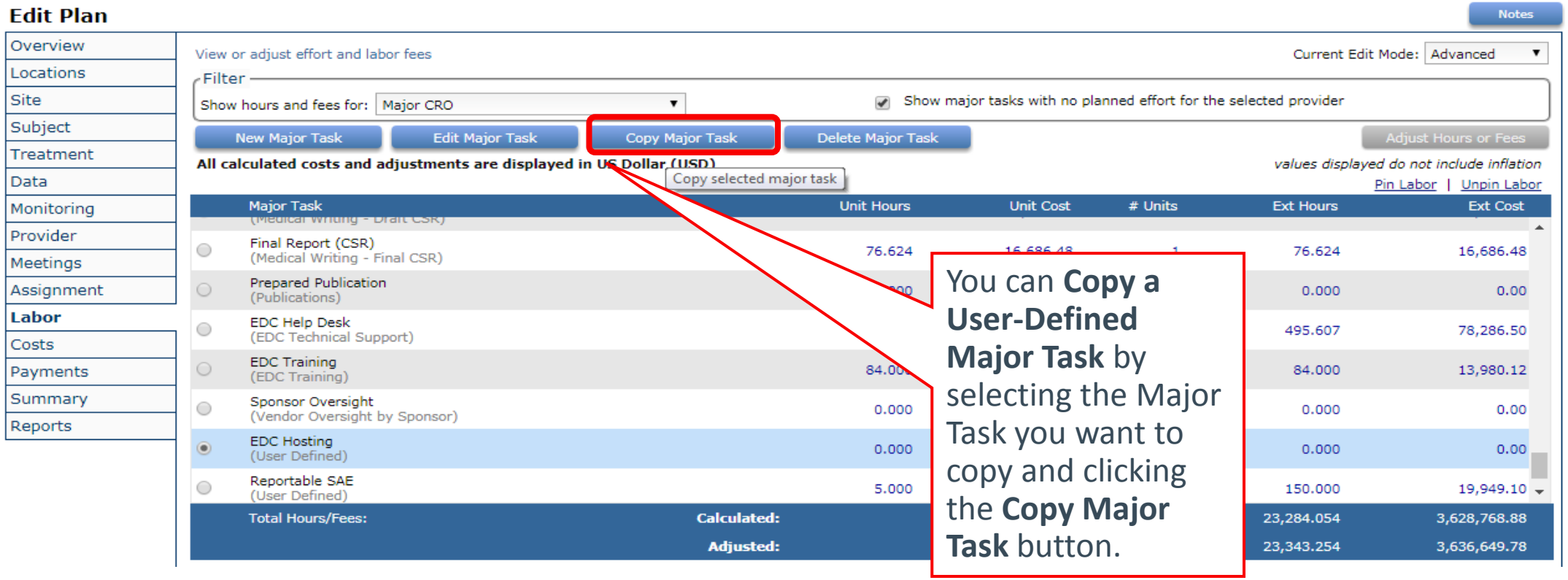
Edit/Replace CT-defined Resource Description Cont'd

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

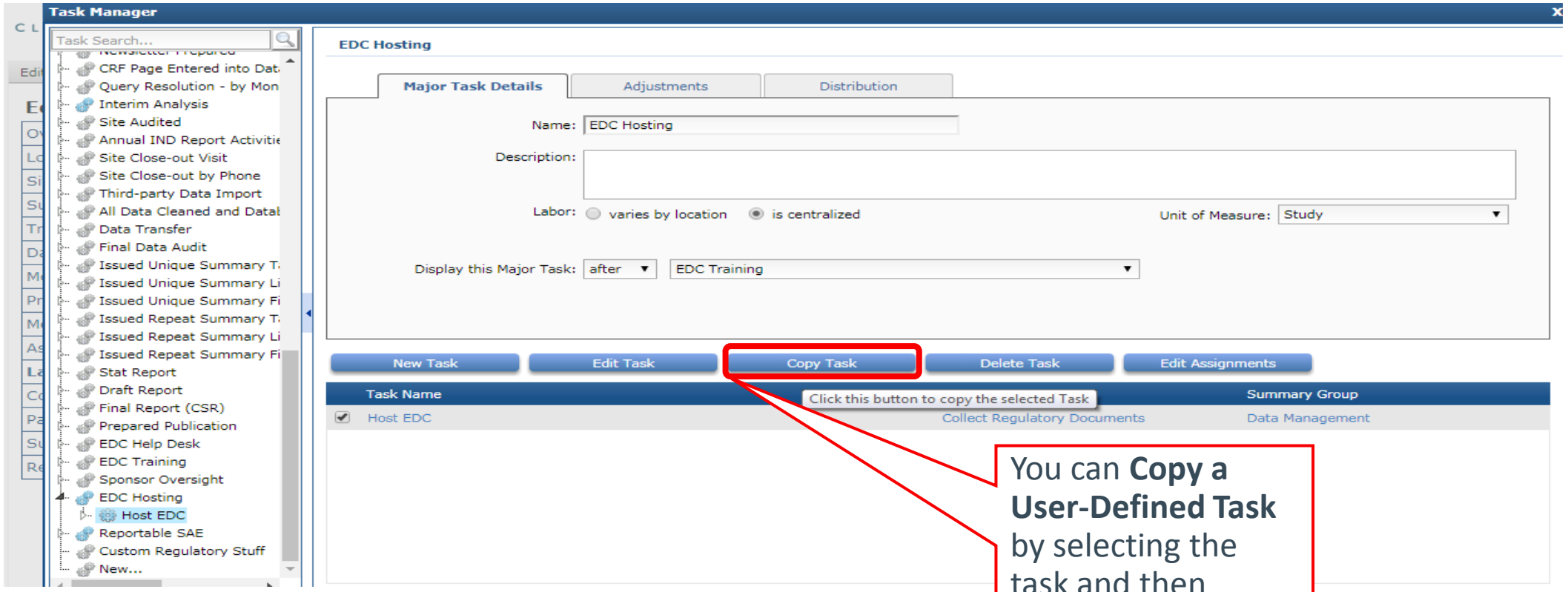
If I need to edit the description/revert back to the CT default description, I can click on the trash icon to **discard my latest change.**



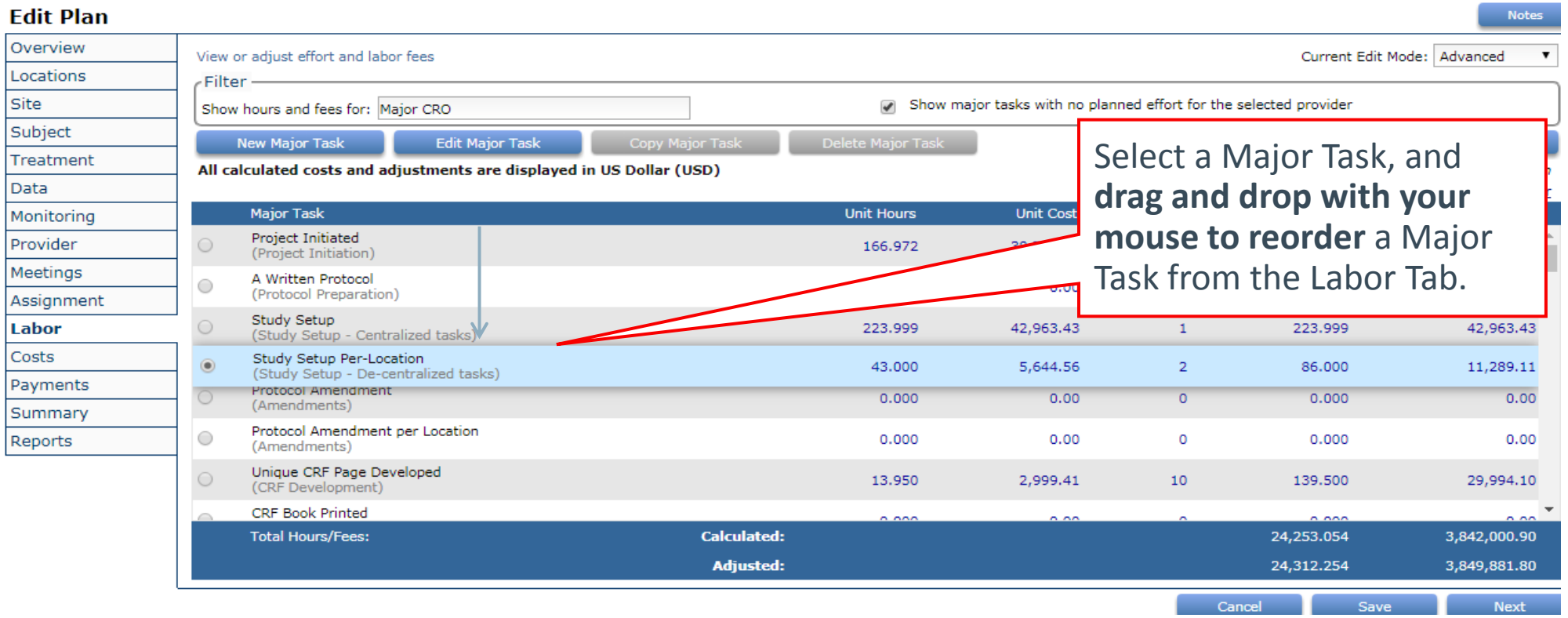
Copy User-Defined Major Task



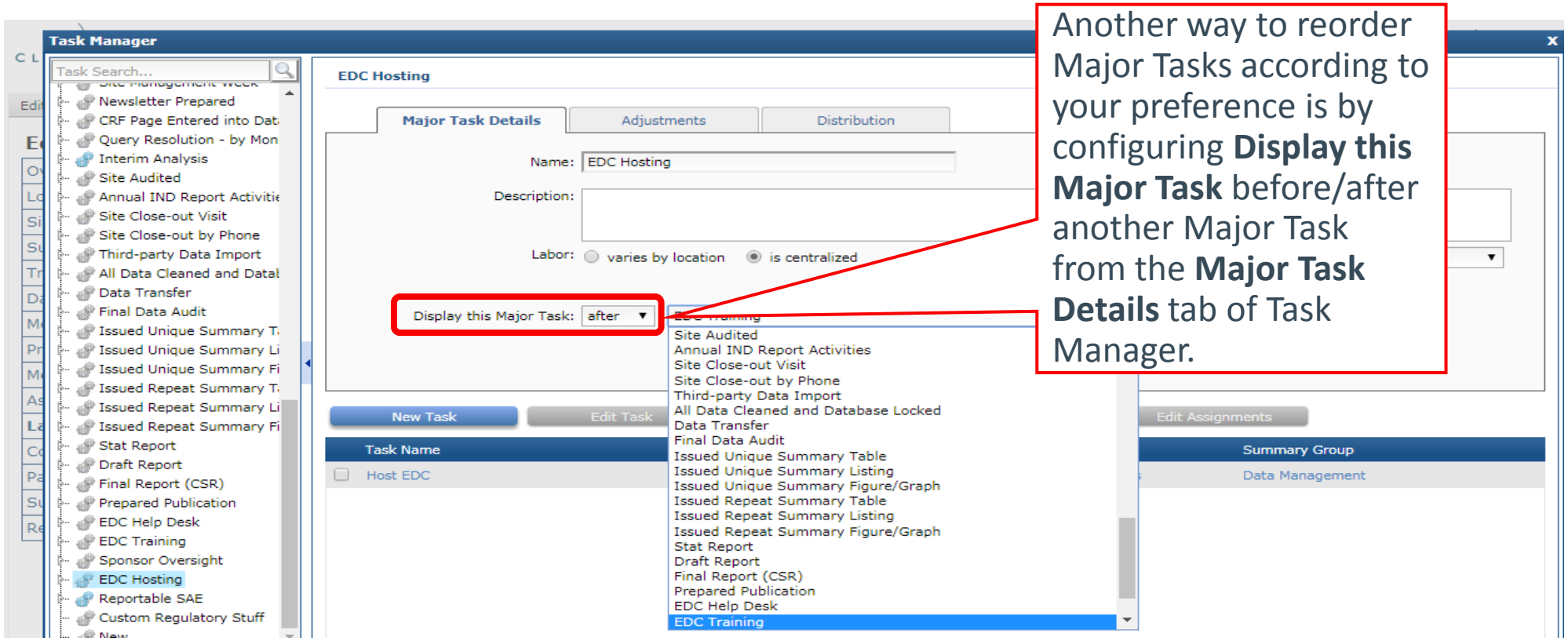
Copy User-Defined Task



Reorder Major Tasks in Your Plan from Labor Tab

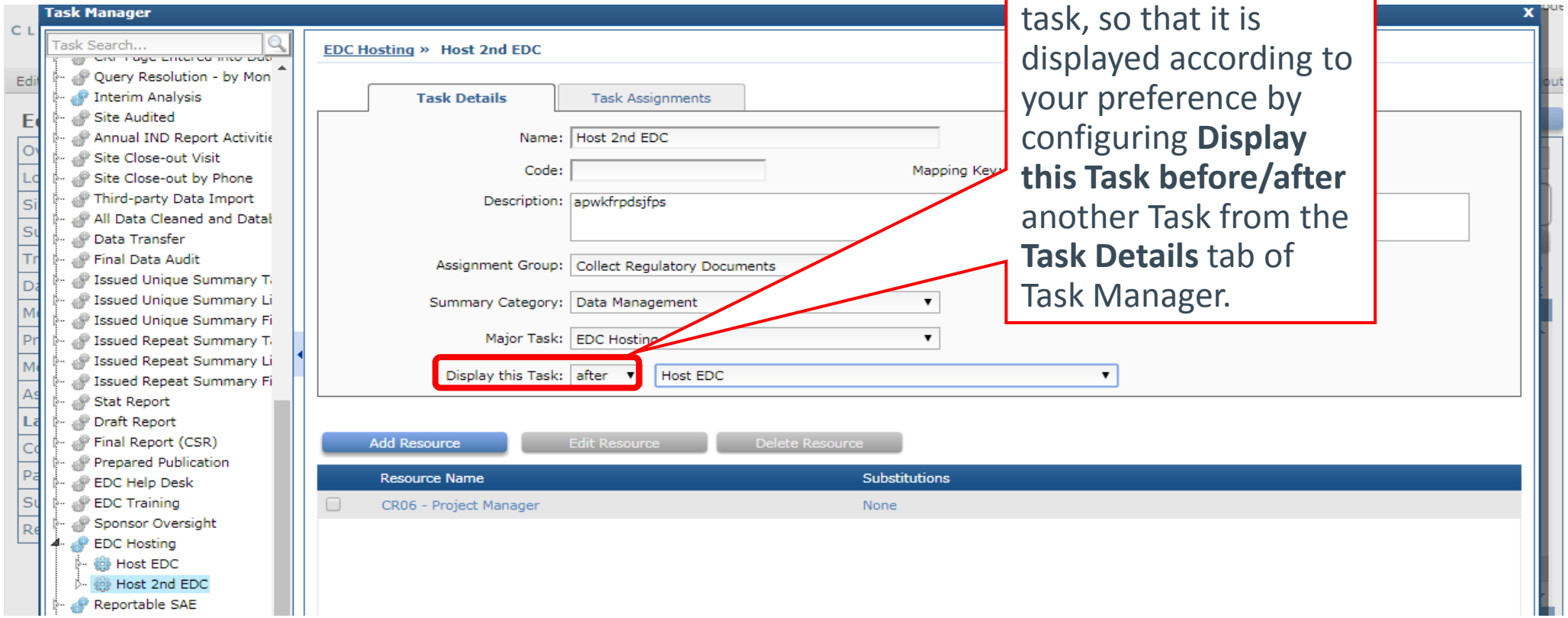


Reorder Major Tasks in Your Plan from Task Manager



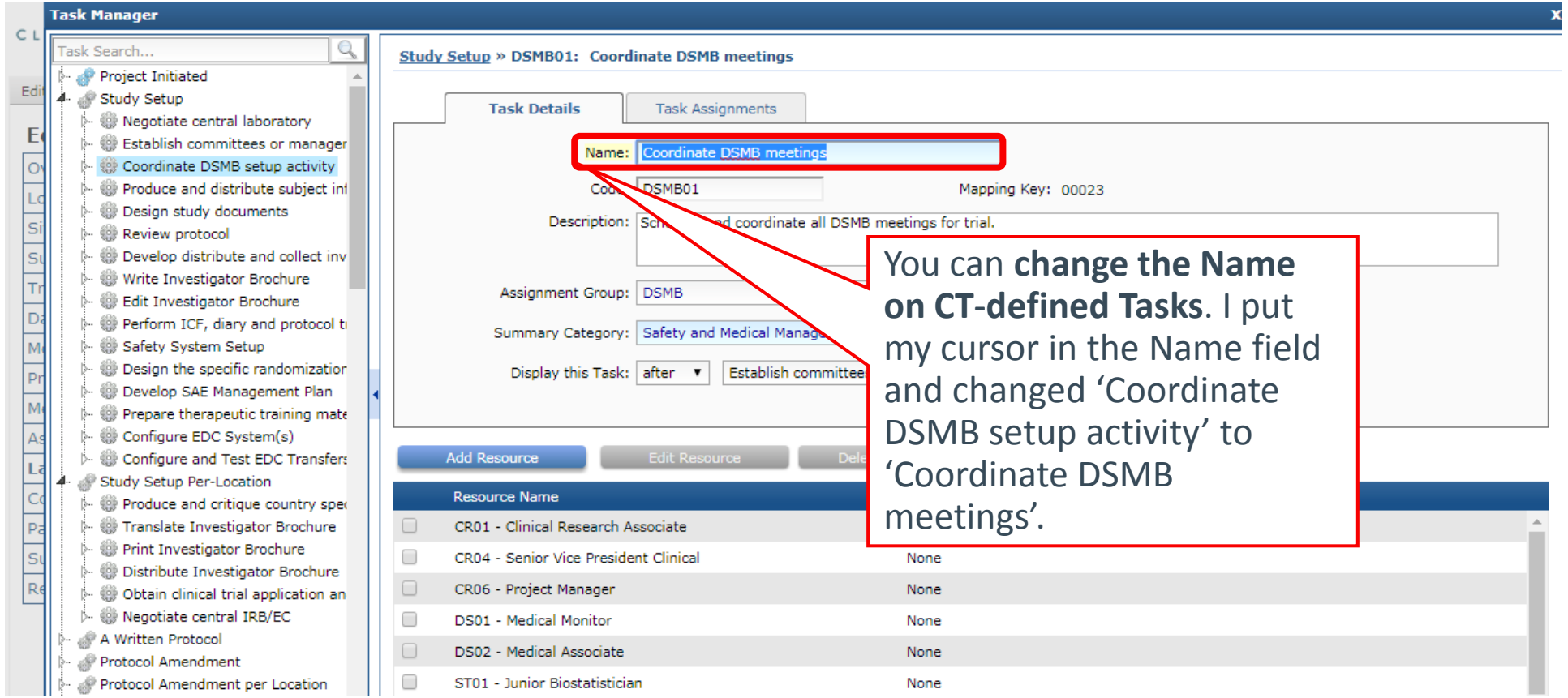
Another way to reorder Major Tasks according to your preference is by configuring **Display this Major Task** before/after another Major Task from the **Major Task Details** tab of Task Manager.

Reorder Tasks in Your Plan

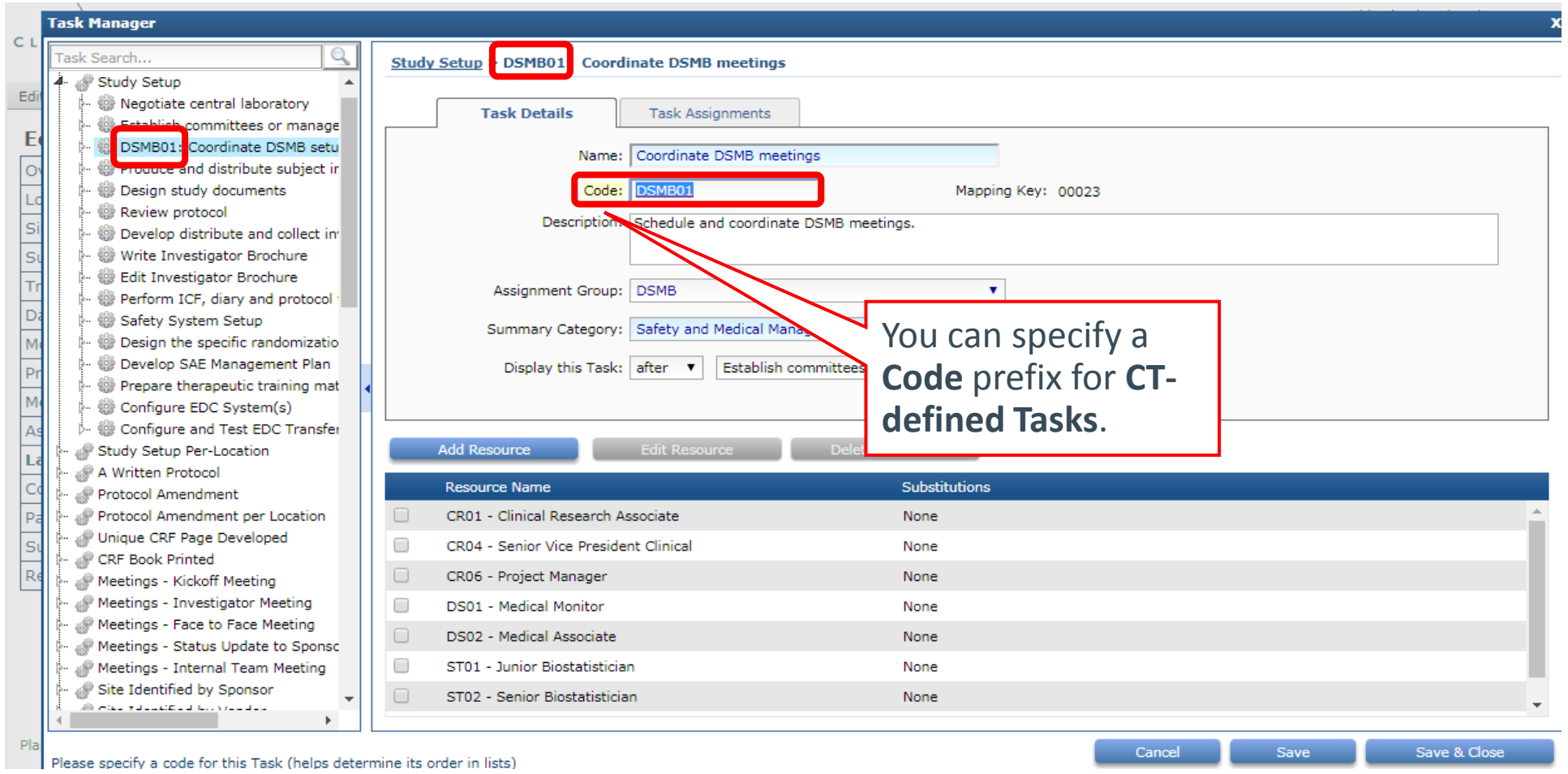


You can also reorder a task, so that it is displayed according to your preference by configuring **Display this Task before/after** another Task from the **Task Details** tab of Task Manager.

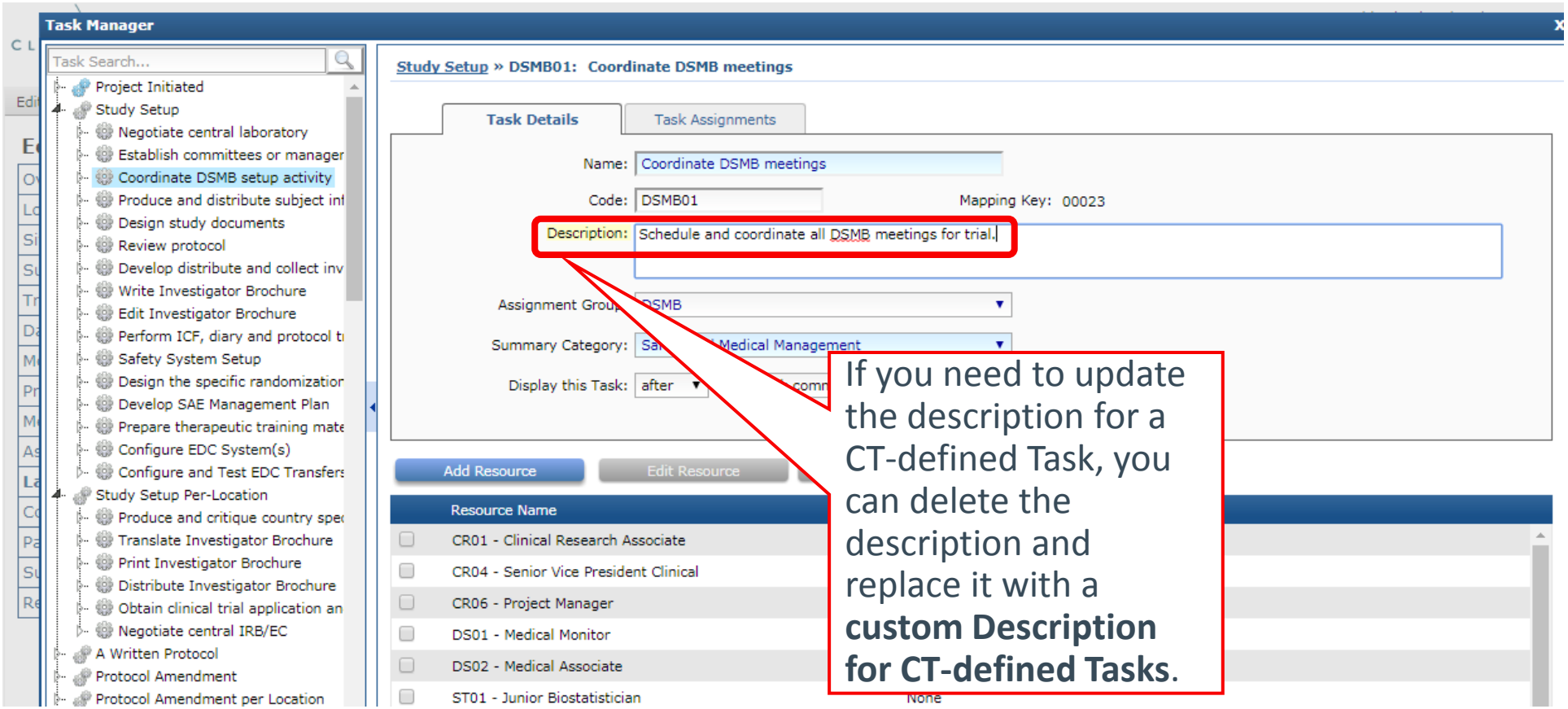
Edit Name for CT-Defined Tasks



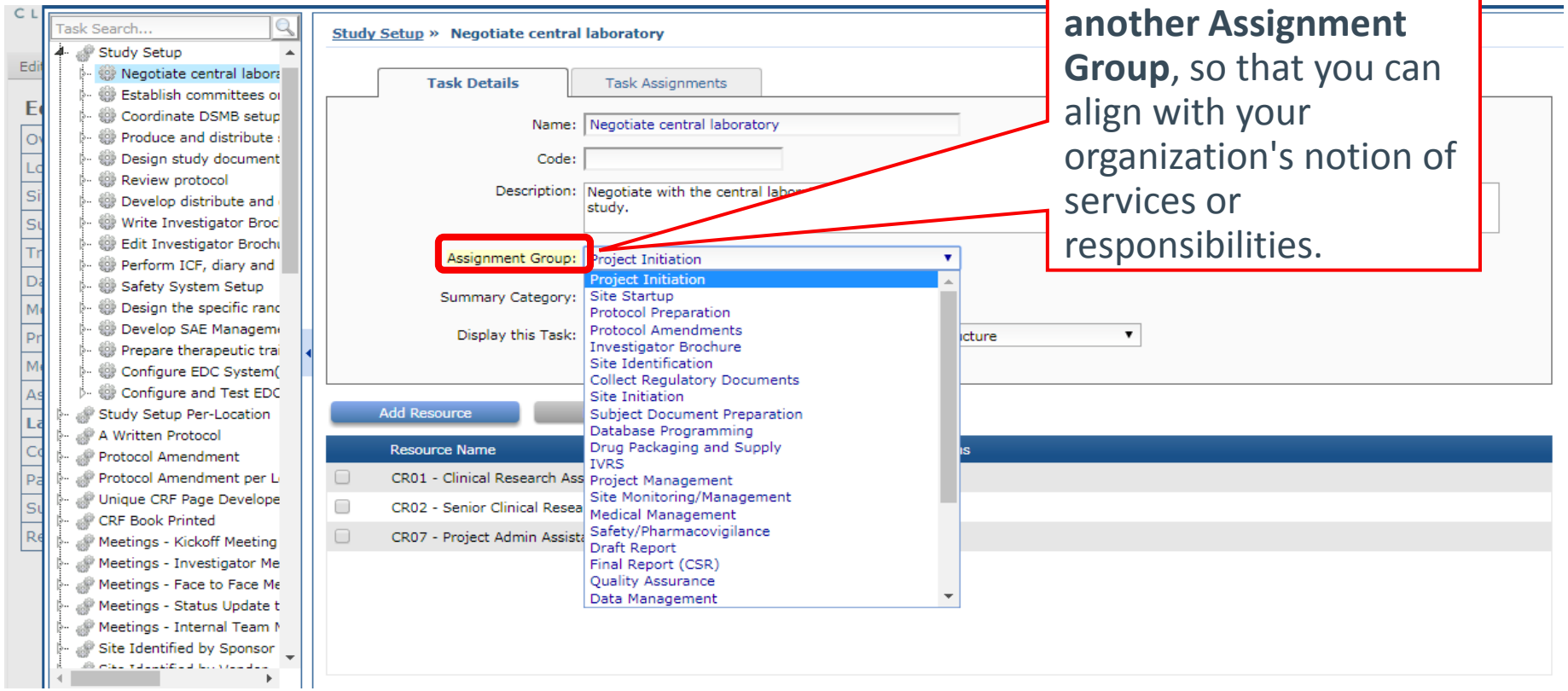
Specify Code for CT-defined Tasks



Custom Description for CT-defined Tasks

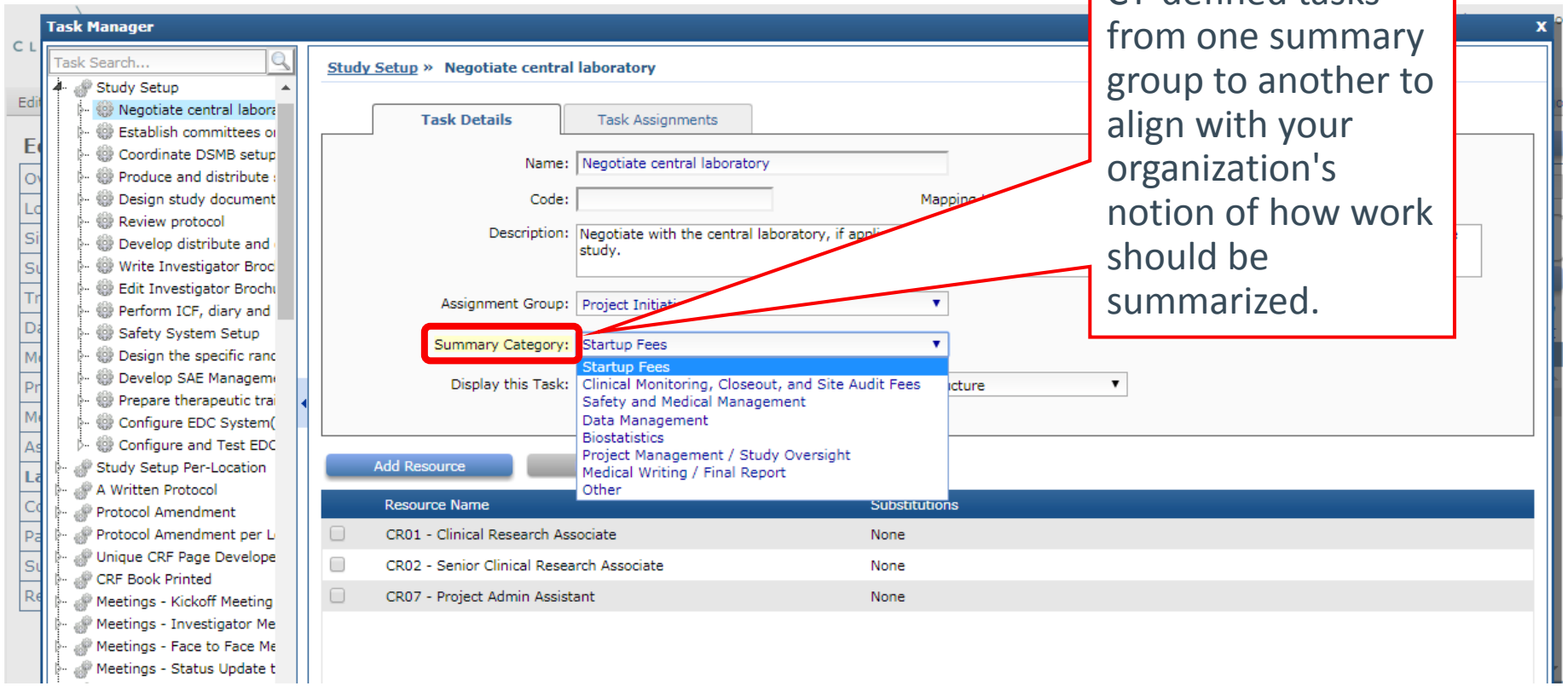


Change Assignment Group for CT-Defined Tasks



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

Change Summary Group for CT-Defined Tasks



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

Custom Fields Cap Increase

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

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

5.6 Web Services API

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

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

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