Managing a Change Order

IN THIS GUIDE

This guide is intended to provide you with some quick tips and tricks to help navigate a change order negotiation and better understand the budget.

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The key issue

INTRODUCTION

Within a clinical trial, one of the most time consuming and difficult processes can be the negotiation of a CRO change order or contract amendment. These negotiations are often long in nature, and the resulting budget can be complex and difficult to interpret leading to large retrospective accounting adjustments and catch up billing. If you've ever been overwhelmed by keeping track of these change orders, don't worry — you're not alone!

ABOUT ME

I'm Jeff Jahnke, a clinical trial nerd with almost a decade of biotech finance experience. Prior to Condor, I worked at a large CRO where I managed clinical trial budgets and developed change orders for dozens of small-to-medium biotech companies. It was there that I saw firsthand how bloated bureaucracy and industry-wide lack of transparency and standards often hurt my clients' bottom lines.

Now, as Director of Customer Operations at Condor, I help our clients unlock financial superpowers and further their mission to advance medicine and cure disease.

Step 1

Sense-check the change order's downstream effects on budget line items

Every CRO budget should be tied to the overall planned scope of the trial. The agreed upon scope is used by the CRO to develop the underlying budget, and so the budget and scope should tie together.

The major variables in a typical scope are:

- The total planned number of sites and regions
- The total number of expected patients to screen, enroll, and complete
- The resulting timeline in months

If your change order adjusts in scope, then the budget should also adjust accordingly. Here are the adjustments in the budget you should look for.

1 Changes to sites / regions

As sites or regions are added or removed from the scope of the trial, you should see a corresponding or proportional increase/decrease to the line items in the budget that are impacted by the change. If line items remain unchanged or are not changing in a proportional manner without sufficient justification, the CRO should go back and revise the budget as necessary.

Some common line items that tend to correspond with site changes include:

Increase or decrease in sites or regions from the scope of the trial	→	Increase or decrease in: • Site Management • Site Recruitment and Qualification • Site Contracts & Contract Amendment • Initial Essential Document Management, including Vendor Tracking and Other Requirements to Activate Sites (PSAR) • IRB/Local Ethics Committee submissions • Initial Site Informed Consent Form (ICF) including translation coordination • Preparation of Regulatory Site Binders

2 Changes to expected patients

As expected patient enrollment is adjusted in a change order, you should see a corresponding or proportional increase/decrease to the line items in the budget that are impacted by the change. If line items remain unchanged or are not changing in a proportional manner without sufficient justification, the CRO should go back and revise the budget as necessary.

Some common line items that tend to correspond with patient changes include:

Increase or decrease in expected patient enrollment	→	Increase or decrease in: • Clinical Monitoring • Case Report Form (CRF) or Patient Data/Data Management • Investigator Grants • Medical Writing/Patient Narratives • Serious Adverse Event (SAE) Management/Reporting

3 Changes to timeline

Scope changes within the CRO change order will typically have an impact on the study's overall timeline for completion. When this is the case, the CRO should also include an overall addition or subtraction of monthly driven units from the change order budget. If the timeline in the change order is changing, but there is no resulting change to time-driven units within the budget, then the CRO should go back and revise the budget as necessary.

Typically, the Project Management (also called Project Oversight or Study Management) line items are a great place to gauge this alignment, as CRO's typically will align the number of months in these line items with the total number of months in the trial. If there is a disconnect on these line items, then it is likely that there is a pervasive issue with the budget that should be remediated by the CRO.

Change in scope	→	Change in study's overall timeline	→	Increase or decrease in monthly driven units from change order budget, typically found in Project Management (also called Project Oversight or Study Management) line items

Step 2

Prevent retrospective billing during the change order negotiation

It is common that when a CRO change order is executed the CRO will bill for previously unreported work that is contained within the newly contracted budget. This can be a frustrating surprise to biotech companies, as it is not always made clear during negotiations what, if any, historical adjustments will be made to billing.

Thankfully, this can be often mitigated during the negotiation process by keeping an eye out for unit price changes and ensuring there is no change to contract language that defines the services being provided.

1 Changes to unit price

When a CRO changes the price of a particular line item where some work has already been completed, they will typically back bill an adjustment for the difference between the new and original price.

To mitigate this, insist that the CRO break the unit into separate line items:

- The first line item should be the completed work at the original price
- The second line item should be the remaining work + additional units at the new price.

Price change example									
Original contract				Change order #1			Resulting adjustment		
Unit name	**Total months**	**Price**	**Grand total**	**Total months**	**Price**	**Grand total**	**Total months**	**Price change**	**CO adjustment**
Project management	15	$1,000	$15,000	15	$1,500	$22,500	10	$500	$5,000

Line item split example									
Original contract				Change order #1			Resulting adjustment		
Unit name	**Total months**	**Price**	**Grand total**	**Total months**	**Price**	**Grand total**	**Total months**	**Price change**	**CO adjustment**
Project management (original)	15	$1,000	$15,000	10	$1,000	$10,000	10	—	—
Project management (CO #1)	—	—	—	5	$2,500	$12,500	—	$2,500	—

Examples

Above are two different approaches to unit price changes.

In the first, the CRO is changing the unit price from $1,000 to $1,500 per month. As you can see, this causes a retrospective invoice of $5,000 for the completed months on the project.

In the second example, the unit is split into two distinct line items, which results in zero adjustment to historical expenses.

In both cases, the change to the budget in total dollars is identical — an increase of $12,500. However, by structuring the budget to show the change in two line items the CRO is not able to bill for a historical change that was previously unreported.

2 Changes to contract language

In addition to the budget, CRO contracts will often contain text which defines the work that is needed to be done in order to complete the trial. As part of this text, the CRO will define the type of work that will be performed as well as when the units are considered complete for billing.

In some cases, the CRO will bill for units using a different approach than what they've defined in the contract language. Instead of admitting the error and refunding the incorrectly billed units, they will attempt to change the definition in order to legitimize the billing. It's important to be mindful of the full text of the contract for this reason.

Examples

This often occurs with a unit such as site management. The CRO may initially define site management as valid to recognize once a Site Initiation Visit (or SIV) has occurred for that site. However, in practice, the CRO may begin to bill for units related to site management sooner, perhaps as early as when outreach is made to the site as part of the initial recruitment.

In order to remedy this issue, instead of refunding or crediting back the misbilling, the CRO may attempt to alter the language of the study contract to redefine the work. In the example outlined above, the CRO may change the language to define site management as valid to recognize once outreach is made to a site as part of site recruitment.

Because CRO change orders are often dozens of pages of legal language and scope related to the trial, and the language defining a single line item such as site management is a very small part of the grander change order, an alteration to the language may go undetected, or the impact of such an alteration may not be fully understood.

Step 3

Ask the CRO to justify all changes

Every budget change within a CRO change order budget should have explainable rationale behind it. Any questions you have on a particular line item should be able to be answered by the CRO with a clear explanation that justifies the change.

If the CRO is not able to explain why a line item is changing or how the change was determined or calculated, then that indicates that perhaps the change is not valid or in line with the revised scope of the trial.

So, when in doubt, ask the CRO for an explanation as to why a line item is changing!

Have any questions?

At Condor, we're always here to help.
You can email me at jeff@condorsoftware.com.