Is Your Study in Need of a Rescue?

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You spent months searching and interviewing CROs. You narrowed it down to a handful who received your RFP. You spent hours reviewing proposals and bringing in a select few for bid defenses. You finally chose whom you thought would be the best CRO to manage and run your study.

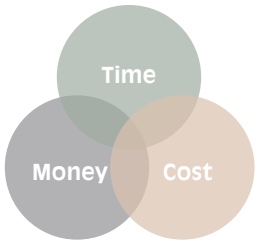
But now, a few months later:

- Patient recruitment has all but stopped, and the CRO seems focused on other things
- Budget health reflects faster than expected burn rate in a number of functional areas
- The data management plan is not as seamless as what was presented
- The assigned project manager is not being proactive or responsive
- The CRO is charging you for every request and takes forever for the change order to be drafted
- The CRO team members who started on the project have all left the company
- You are not seeing any progress in query management or external data reconciliation
- You are not being given access to data in a timely manner

If any of these issues sound familiar it may be time to reevaluate your current vendor and decide how to proceed without jeopardizing the progress of the study.

Switching CROs is not an easy decision – there are many considerations to be weighed before making the change to a new vendor. Even when a project seems like it has gone off the rails, it does not necessarily mean that it needs to be rescued – sometimes the current team you have just needs to be augmented or specific project areas need to be reassigned.

CROs experienced in rescuing studies have learned to identify contributing factors, which may include study design that does not match up with standard of care, or a study team who has lost focus due to other priorities. An experienced CRO will implement solutions to address the issues and keep the project moving forward, as well as address the impact to the project timeline and budget that may result from a change in vendor.



At the beginning of your collaboration, all parties involved agreed to contract terms that set the stage for ensuring that projected costs were reflective of the requisite time required to complete quality deliverables and keep the project on track. Ideally, these key factors were considered in developing contingency plans and mitigation strategies prior to study execution that allowed for some flexibility as the project evolved or unanticipated variables came into play. However, the reality is that projects most often at risk are so because there is not enough flexibility in one or more of the key factors. This often has a negative impact on the project, thus putting the project at risk. For example, a project in which key milestones are missed because of a delayed go-live database may in turn impact the quality of the data due to delayed data entry and on site monitoring visits. These delays in turn may require timeline adjustments which may impact the overall budget.

So, when confronted with these issues, there are some key questions you need to ask yourself, questions that will be important in determining if it makes sense to change CROs.

These questions are:

- Where are you in your overall project timeline?
- What is the financial investment thus far?
- Is making a change in vendor cost effective or prohibitive?
- Did you meet your own obligations or is it all the fault of the vendor?
- What is the root cause of the issue(s)?
- Would a team change or retraining help solve the problem?
- Are the issues confined to one functional area or are they systemic?

First things first: Important things to consider

It is vital to understand that any transition will take time to implement – processes may have to be evaluated and possibly redesigned, teams retrained, databases rebuilt, and study plans revised. Enrollment will need to be addressed to assess if it can

continue during the transition or if it will need to be put on hold temporarily. Contracts should be evaluated to assess if there is a cancellation clause. Site and team morale can be affected, as well as other collaborators, so it is important to keep everyone in the loop and communication open during the transition.

You may find that the current CRO is less inclined to provide the most current and accurate study information if they believe that you are weighing a decision to change vendors. Therefore, it is important to ensure that you have the most current study metrics, documents and plans, that you have checked the status of the database and have obtained the latest SAS datasets of the clinical data. It will be important to map out what you have and what you do not have; this will help the new vendor assess the available documents, study status, preview the quality of the data, and get a picture of how the study was managed. Cross check to see if it looks accurate and obtain copies of all your data. Know what you have and what you are passing on so efforts do not have to be duplicated any more than is absolutely necessary.

Moving Forward

Once the decision has been made to change CROs, all team members need to be involved as soon as possible. Build trust with the new CRO by having open, honest communication about what happened previously and what you expect to be different this time. Collaboratively develop a clear rescue contract agreement, including cost and scope of the project that should reflect any changes from the previous agreement based on recent experience. Both parties need to set clear expectations, develop timelines, and provide all critical study-related documents as soon as possible to get the process moving forward.

DOCUMENTS NEW CRO WILL NEED:

DOCUMENTS	COMMENTS
CLINICAL OPERATIONS	
Clinical Monitoring Plan	Critical information for monitoring team (logistics)
Study Templates & Logs (Used by sites)	Save time by not reinventing – Reuse but also revise
Study Reference Materials (Regulatory Binder, Pharmacy Binder)	Save time by not reinventing – Reuse but also revise
Current Screening & Enrollment Log	Needed to continue site payment programming
All Regulatory Documents	Avoid recollection of documents
DATA MANAGEMENT	
Data Management Plan, Database Validation Plans	Critical information for database builders, data cleaning, and study design
CRFs, annotated CRF and Edit Checks, SAS datasets	Critical information for database builders, data cleaning, and study design
Study Metrics	Provides a snapshot of how many subjects in database, queries issued, queries outstanding, missing pages, etc.
Listing of Resolved, Unresolved and Outstanding Queries	Provides details of queries resolved to prevent repeat queries issued, shows backlog of queries to be processed, and also outstanding at the site.
Listing of Missing CRF pages	Provides the back log of CRF data to be collected and processed
SAFETY SURVEILLANCE / PHARMACOVIGILANCE	
All Plans (Safety Management Plan, Medical Monitoring Plan)	Listing of previous reports (expedited/periodic)
Safety Database Specifications and Data	Historic information needed in safety database
BIOSTATISTICS	
Statistical Analysis Plan	What are the critical variables for the Electronic Data Capture system
IxRS Randomization Schema	Needed for final analyses

As soon as the new CRO is selected, hold a transition meeting with the new team. Inform the sites as soon as possible, and involve them in the transition process. Meet with sites in person and consider a mid-study investigator meeting. Be flexible and available for discussion and feedback, as well as timely review of all documents that you receive from the new CRO. Most importantly, have confidence in your new team and trust they will not make the same mistakes as the previous vendor.

Ensuring a Successful Rescue

When selecting a new CRO, find one that has an excellent track record of successfully rescuing trials. The new CRO should have established processes and systems in place for the transition process, including an inventory list, and should know what to ask for up front. Confirm that the new CRO has the ability to meet its timeline and scope of work. Be sure they have strong leadership – interview the team and project manager – and confirm everyone has experience in the field, support from senior management, and are willing to work with the previous CRO and other vendors. You are looking for a CRO that will partner with you and be part of your team.

About SynteractHCR
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SynteractHCR is a full-service contract research organization with a successful two-decade track record supporting biotechnology, medical device and pharmaceutical companies in all phases of clinical development. With its "Shared Work – Shared Vision" philosophy SynteractHCR provides customized Phase I through IV services collaboratively and cost effectively to ensure on-time delivery of quality data so clients get to decision points faster.

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