



## ○ Featured Article

# Avoiding Project Failure: Best Practices for Study Start-Up

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At this year's Partnerships with CROs conference, I co-presented on Developing Scope of Work where we received a tremendous positive response. In fact, we didn't get past slide 12 because the session was so interactive! The basis of our presentation is that the requirements management between a sponsor and CRO is deceptively simple, yet it remains illusive to achieve. I want to share the points from our presentation that prompted the most discussion from the audience.

To be sure, we covered some common territory in the study start-up phase – develop a clearly defined scope of work, define deliverables, quality, timeline and budgets and work collaboratively. But what energized the audience was not the list of required elements in the process, but how it should be done and who should be involved.

Our whole approach to clinical trials management at INC Research is based on the answer to the pop quiz question, "What is the number one reason for clinical trials project failure?" The answer is not surprising . . . ineffective communication leading to unfulfilled expectations. While drug development outsourcing is forecasted to continue its growth – by more than 15% annually according to the Tufts Center for the Study of Drug Development<sup>1</sup> – the sponsor/CRO relationship will only be successful if we improve communication.

## Defining Roles

A clear definition of roles is a fundamental and often overlooked step that can help enable sponsors and CROs to capitalize on the strengths of each other. A typical partnership at a Phase I-IV engagement is one where the sponsor brings knowledge and core competencies on:

- The drug compound and the science behind it
- Company goals and specific milestones
- Medical knowledge
- Prior therapeutic experience

Complementary to this skill set are the services and knowledge a CRO should provide, including:

- Project management expertise
- Therapeutic experience
- The horsepower to handle complex logistics
- Global reach if and when needed
- Comprehensive services or a specialized sub set of services

At this stage of clinical research, CROs have the proven project management techniques and expertise to operationalize clinical trials. They are able to predict and plan for the unexpected, maintain open channels of communication and ensure that sponsors meet their corporate milestones and objectives. This allows sponsors to focus on the science and not utilize their own resources on the daily tasks of managing a trial.

## Key Study Start-up Best Practices

Once roles are clearly defined, ideally during the RFP process, teams can move forward to study start-up activities. Based on our extensive experience, we have found three main start-up best practices we adhere to for every single study.

### 1) Ensure active up-front engagement of the combined team

I can't emphasize enough the importance and benefits of having key people from the CRO team and sponsor in the same room to complete all study plans. The dedicated effort and focus avoids lost time and momentum that can typically occur when stakeholders are in different locations and are most likely multitasking at their desks. Additionally, it eliminates "white space" between process steps. By white space, we mean the time it takes to route things through approvals, the time that passes with vague action lists and other non value-added spaces of time.

While the benefits of avoiding these pitfalls are important, the intangible benefits are really the most valuable at the kick-off stage. Through our QuickStart® Camps, we have witnessed the transformation that takes place between these two teams in a room over the course of several days. Like any other relationship, teams move through stages of development to earn mutual trust and respect. A well-designed and facilitated start-up workshop is critical to move through these stages quickly and effectively. Surprisingly, although outsourcing has become much more sophisticated, and start-up tasks assigned to CROs have risen dramatically, only 36% of sponsors indicate routinely using a formal kick-off meeting<sup>2</sup>.

I personally have had customers thank us for getting them out of the office and dedicating time to focus their attention at the beginning of a study. We've also had investigators comment at the end of our workshops that they couldn't tell who was from INC Research and who was from the sponsor. This is a true – and intangible – indication of a tightly aligned team.

We have found that conducting kick-off workshops requires more art than science. It takes a certain skill set to turn a potentially unplanned or floundering session into an interactive, conclusive and productive meeting. One major success factor is assigning three essential roles to the CRO team – the Leader, the Facilitator and the Subject Matter Experts.

The Leader does just that. This person leads the entire group by setting the conditions of the meeting, moving through the agenda and addressing any issues along the way. The Facilitator is able to assess the personalities in the room and understands what methods of facilitation will be most successful within the group dynamics. For example, does the group need to build consensus or have a meaningful exchange of ideas? Does the group prefer a more structured approach or does that hamper the brainstorming process? Finally the Subject Matter Experts, which we refer to as Trusted Process® Specialists, are critical in providing insights and expertise to help formulate the most effective plans based on the circumstances.

We take these roles very seriously at INC Research and require our project management staff to complete our Project Leadership Training program prior to conducting our kick-off Camps. The program instills a number of soft skills for our project directors to become competent and confident leaders.

### 2) Clearly define project governance

The culmination of clearly defined roles and upfront engagement from both teams is the project governance documents. A CRO should have well-honed templates that account for major requirements, yet are flexible to be tailored as needed. These documents include project, data and monitoring plans; CRFs, study tools and templates; and a risk management plan (RMP). Within the plans, key decisions should be reflected, such as delegation of authority, goals, constraints and reporting and communications.

Because every aspect of these plans has already been discussed and agreed on by both teams during the kick-off workshop, there is no delay, or white space, to hold up the execution phase. Final project specifications are made. The work plan is finalized for project governance documents and tools. Action item assignments are made.

### 3) Apply a consistent toolset to all studies

The toolset encompasses everything from what are you measuring to how you define success. Tools and communication methods should also be agreed upon at this early stage. These methods need to enable the teams to track metrics, apply continual evaluation, offer reporting capabilities and factor in training and continuous process improvement. Keep in mind that some studies can last five years or more, so while this type of foresight is not always easy, it is essential.

Sponsors don't like surprises during the clinical trials process. Ongoing communication with their project leads in conjunction with a robust metrics toolset allows them to evaluate each stage and compare and contrast with other benchmarks and industry standards.

The underlying advantage of this consistent toolset is the control it provides the sponsor. Sponsors feel more in control of the trial when they are tracking a series of metrics – both performance and financial. They need to have scheduled and ad hoc reviews to assess the status and dedicate time to analyze the metrics. Additionally they need the reassurance of a comprehensive RMP.

In the case of the ever-important RMP, it is considered a first among equals among the list of plans as pharmacovigilance and safety concerns are at an all time high. In fact, last month's DIA Annual Meeting featured more than a dozen sessions and tutorials dedicated to risk management topics.

In summary, sponsors and CROs need to understand that requirements management is not a nice and neat linear process. It is a highly collaborative process that evolves through mutual agreement and direct communications. Remember, amid all the technological advancements that streamline the clinical trials process, nothing can replace old fashioned face-to-face interactions to build strong and successful relationships.

<sup>1</sup> Outlook 2009, Tufts Center for the Study of Drug Development

<sup>2</sup> J. Vogel, K. Getz, "Successful Outsourcing: Tracking the Evolving Use of CROs" Applied Clinical Trials, June 2005