



Optimizing Clinical Trials: Sponsor/CRO Cooperation

Working together to enroll appropriate patients

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The “Right” CRO as a Partner

› The Right CRO for each Trial depends on Many Factors

Meet with two or three CROs before Deciding: Factors to consider:

- › Does the CRO have experience in the therapeutic area?
- › Does the CRO Project Manager (PM) have experience in this area?
- › Does the CRO PM show strong oversight over the other project leaders?
- › Does the CRO use systems with latest technologies that can add efficiencies and aid in oversight of the clinical trial?
- › Will the CRO guarantee that the study leads who presented during the bid defense will be assigned to your team? Do they guarantee the “A” team or at least the B+ team? Also, inquire about staff turnover.



The Kickoff Meeting

- › The Kickoff Meeting is critical as it is often the first meeting where the CRO and other external vendors are together for the first time; it is important to establish a positive relationship with open communication. Also important:
- › Clearly identify individual roles and responsibilities; especially items that are part of study start-up (site ID, feasibility, site monitoring, recruitment strategies) and how to proceed efficiently.
- › Establish realistic timelines.
- › Communicate clearly and often: establish escalation processes.
- › Create a trusting relationship.



Patients First

› Designing the Clinical Protocol with Patients in Mind

Engage with patients ahead of study start-up to identify special needs that would simplify the protocol for them.

When designing the protocol, decide:

Is it possible to reduce the number of office visits?

Is it possible to include some virtual visits?

Can you include some extra reimbursement money for travel?



Choose Sites Wisely

- › **Site Selection involves several factors: Create a feasibility questionnaire that includes the following at a minimum:**
- › Does the site have the right population for the indication?
- › Have you chosen sites with geographically diverse locations? Is the site easily accessible to potential patients?
- › Does the site have experienced staff?
- › Does the site have the bandwidth to pay attention to your study? Is there support staff that can share the burden with the PI and the study coordinator?
- › Is the Investigator a KOL who may not have a large patient population but can contribute ideas to the protocol?



Sponsor/CRO/Site Interactions

- › **Create Concise Study Team Meeting Agendas:**
- › Meetings should be thorough but not too detailed. It is important for cross-functional teams to know what each function is doing but some agenda items should be taken off-line and discussed separately.
- › Site staff training should be offered frequently; especially when there are staff changes, protocol amendments, and eCRF updates.
- › Too many emails become ineffective; however monthly or bi-monthly newsletters can be helpful. Include tips from high enrolling sites to encourage other sites to increase enrollment.



Site Training

- › In addition to the Investigator Meeting and Site Initiation Visit; offering training for new site staff or refresher training will help to ensure they are up to date on trial procedures, regulatory requirements, and best practices in data collection and patient management. If multiple protocol deviations occur; refresher training should be mandated.
- › Optional Investigator/Study staff virtual meetings: in addition to newsletters; it can be helpful to hold ad hoc meetings where investigators and site staff can ask questions and/or share best practices with other sites.



Building a Budget Template

- › With increases in FDA regulations and technology, the costs of clinical trials has grown exponentially. The number of line items for new studies continues to grow and it is especially difficult to build a template that works for all sites.
- › Recently, we have found that sites are declining to participate because the proposed site budgets do not meet their requirements; this is especially true for academic centers with large overhead costs. To address this issue, we are now working with the sites proactively and transparently so we can meet their needs while keeping within our budget.

Tip: A phone call is worth a thousand emails!

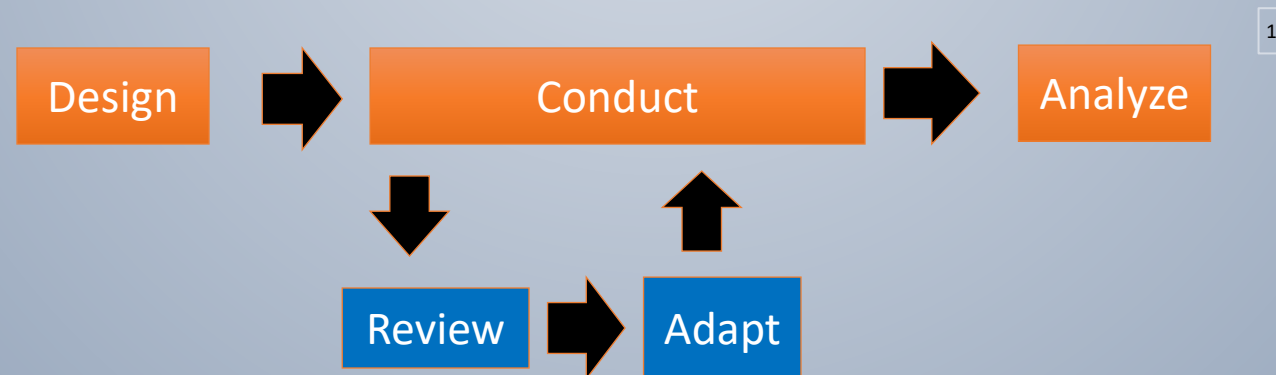


Working with Regulatory Agencies

- › Communicate with regulatory agencies early in the clinical program.
- › Monitor newly published regulatory guidances.
- › Incorporate their protocol comments during protocol development. This will reduce the number of protocol amendments and thus cut costs and save time.

Protocol Design Strategies

- › Collaborate with regulatory agencies, investigators, and patients to ensure a well-designed protocol.
- › Be open to adaptive designs; this can be done in any phase trial and can be used with double-blind studies without breaking the blind or employing an interim analysis to help identify and discontinue arms with futile doses. For pivotal studies, adaptive designs should be used with caution and the sponsor should check with the FDA to get their comments and green light.





Monitoring Trial Progress

- › Oversight of trial progress involves the entire team.
- › Monitors are essential for evaluating site performance.
- › Quick identification of issues enable timely interventions to keep the study on track.
- › Safety Monitoring and reviews of Adverse Events should be done on a regular basis.



TEAMWORK

- › Working **together** with open communication helps to ensure that the clinical trial will run smoothly and according to the protocol!