

Accelerating Clinical Trial Agreement Negotiations through Effective Communications

By Erica L. McKeon and Matthew G. Drapeau

Negotiating a clinical trial agreement (CTA) requires communications between the sponsor (or CRO) and the site, and also within each party's organization. Efficient communications accelerate the negotiation process and strengthen the relationship between the parties for the upcoming challenges of the clinical study.

Good communications are also likely to yield a better agreement for both sides, since each party will more clearly understand what the other party wants and there will be more time available to address any issues.

Prepare to Communicate

Both parties should determine upfront their objectives for the negotiation, including preferred and back-up language. A master "back-up language" document can promote consistency and streamline the process.

Each party should understand its history with the other party. What were the pricing and other terms in previous contracts? Is there a master CTA in place? Were there performance issues in previous studies? For example, did the site meet its enrollment commitment? Did the sponsor monitor in a timely manner?

The parties should also identify who will serve as their point of contact and who will be the back-up to that person, if appropriate. Each party should identify the decision-maker(s) and establish the who, when, why and how of their escalation process. For example, if escalation to the legal department is required, who is the contact in that department? In what form will he or she respond? What is his or her commitment for response time?

Internally, each party should ensure that all negotiators, decision-makers and stakeholders have realistic expectations for a plan that includes goals, processes and timelines. There should be contingency plans and accountability for deviations from the plan. For example, if a sponsor finds that high-priority sites are not accepting a particular contract term, can that term be reviewed and potentially modified?

Set Expectations between the Parties

Negotiations proceed more smoothly if the parties communicate their expectations for the process between the parties. What is each party's internal process? For example, does the site want to finalize the budget before negotiating contract language? What authority does the sponsor or site's negotiator have? Do changes in certain terms need escalation? What are the expected timelines? For example, does the sponsor plan to complete negotiations with all sites by a specific date? Does either party have non-negotiable requirements? For example, sovereign immunity prevents state universities in the U.S. from indemnifying study sponsors.

Keep the Other Side Informed

Both parties in a CTA negotiation make assumptions about the timeline. They plan their businesses based on their expectations of when a study might start. If either party learns of

a potential delay or other issue, the other party is likely to want that information. For example, an approval process might change. A pending protocol amendment might affect the study budget. A surge in new studies at a site might delay its ability to respond quickly. Timely notice to minimize surprises builds trust between the parties.

While predictability is an admirable trait, surprises do happen. Flexibility minimizes the disruption. It can also speed the negotiations. For example, if a signature will be needed by someone planning a vacation, it might be possible to speed the process up a bit to meet the new deadline.

Very little of a CTA negotiation timeline is spent negotiating. Most of the time is consumed waiting for the other party to review, prepare or approve something. The other party can easily assume nothing is happening during those gaps, so it is essential for updates to continue.

Track Progress

When beginning a CTA negotiation, both parties should agree on a timeline. When delays occur, they should discuss the reasons and recover or adjust the timeline.

When sponsors and sites are simultaneously negotiating multiple CTAs — especially between the same parties — keeping track of communications is particularly important.

Recycle Previously Agreed-Upon Contract Terms

Once the parties agree on a CTA, why not extend that agreement to future studies, or at least use it as the baseline for the next negotiation? The most efficient communications are those that do not need to take place at all.

There are four common levels of CTA recycling:

1. Reuse specific terms or clauses from a recent CTA.
2. Adapt the entire previous agreement for the next study.
3. Use the agreement as the basis for an agreement covering a group of the sponsor's studies, e.g., a "program," at that site.
4. Use the agreement as the basis for master CTA covering all the sponsor's studies at that site.

Learn from the Experience

Clinical research proceeds study by study, so it is easy to forget that there will usually be a next study. By learning from each study, the parties can improve their communications over time. At the end of a negotiation and, again, at the end of a study, the parties can have a quick "lessons learned" meeting about the issues that arose, how these issues can be minimized in the future, and realistic expectations for the next negotiation.

Conclusion

Good communications accelerate CTA negotiations by minimizing the delays caused by misunderstood expectations, missed signals, and other miscommunications.

People prefer to do business with other people who are easy to do business with. Good communications are key to any successful relationship and to ensuring that business is conducted as smoothly as possible. While the parties rightly focus on the study at hand, a successful experience based on good communications will open the door to future studies.

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