

## A Proven Strategy for Rapid CTA Negotiations

*By Robert T. King*

Clinical Trial Agreement (CTA) negotiations are notorious for moving slowly, leaving the operational teams (and eventual patients) in limbo. Fortunately, a proven strategy is available for rapid CTA negotiations that outclasses conventional methods. In addition to speed, this inclusive approach to site negotiations yields a better contract and stronger working relationships going forward.

The key to this proven strategy is to include appropriate representatives from the operational teams in an early call to clarify the study's characteristics so the negotiators can develop a CTA that aligns with real-world medical and other issues and focuses on what matters. Participation by operational staff also generates other important benefits, as discussed below.

Begin the CTA negotiation process with preparatory research. Then follow up with an initial telephone call or internet (e.g., Zoom) meeting, one follow-up exchange and then a second call to start resolving issues. Advance research prepares you for the negotiation process. The first call sets the tone for the negotiation and the stage for the second call. The follow-up step keeps the process on track. The second call establishes the problem-solving process and builds a foundation for faster response times. These four steps smooth the way for an efficient, constructive and harmonious negotiation.

### Start with Research

Before making the first call, answer the following questions as best you can:

- **Who is your negotiation counterpart?** What authority does he or she have? What is his or her level of expertise and negotiating style? How much insight into his or her organization does he or she have and how likely is he or she to share it with you? What experience, education and professional credentials does he or she have? What are his or her personal interests? How does he or she present him or herself on LinkedIn and other social media? What previous experience has he or she had with your organization?
- **What is their organization like?** How is their team structured? What is their negotiation style and process? What is their culture? What do their financials and other resources look like? How many studies are they conducting or planning? Are they a leader in this therapeutic area? What previous experience have they had with your organization?
- **Who else on the other side may be involved in or affected by the negotiation?** Based on job titles and previous negotiations, who may have authority and influence? Who is the "customer"— the site manager or study manager who needs to get the study started ASAP? What previous experience have they had with your organization? What can you learn about them on the internet?
- **What does your side want from the negotiation?** How badly do you want the site or study? How urgent is it to reach agreement? How important is a long-term

relationship? Which contract and budget terms are essential, preferable or dispensable?

- **What does their side want from the negotiation?** How badly do they want the site or study? How urgent is it for them to reach agreement? How important is a long-term relationship to them? Which contract and budget terms are essential, preferable or dispensable to them? What does the competition from other sites or other studies look like?
- **What do you expect from the negotiation?** How do you expect the negotiation to proceed? What terms do you think the CTA will end up including? How satisfied do you expect to be with the end result? What is the minimum your organization requires to sign a CTA?

While the internet can help answer some of these questions, the best information comes from previous negotiations and other interactions, as well as information you gather during the negotiation, so keep all this information for future use.

## The First Call

Your three goals for the first call are the following:

- **Build rapport.** Start by engaging with the person with friendly small talk, not by getting down to business. Show that you respect, like, care about and empathize with your counterpart. What do you have in common? Demonstrate interest in and knowledge about his or her organization.
- **Gather intelligence.** Fill in the blanks from the questions above. What information can you share as a *quid pro quo* to build trust and create openness?
- **Obtain agreement on a second call for problem-solving.** Set its time, date, purpose and process or, at least, a firm deadline for establishing them. Make it clear that both sides will need operational representatives, including medical specialists, on the call.

If you are with the study sponsor, make the first call right before sending out the initial CTA and budget templates. If you are with a site, make the first (or next) call after you are fully prepared with the initial redline, including rationales, and before you send it back.

Start by building rapport. Then tell your counterpart you will be ready to send your document(s) after you clarify a few points. This promise will please your counterpart and open the discussion to intelligence gathering. Try to fill in the gaps from the questions above, for example:

- What are the limits of your counterpart's authority (especially if he or she is with a CRO)?
- Who is the decision-maker and how does he or she operate?
- Who else will be involved in the negotiation and approval process and what will their roles be? Who else (e.g., the principal investigator) may not be involved but would have leverage?
- Will a CTA playbook (a guide for the negotiator that typically includes backup language) be used?
- Which points are firm and where is there flexibility?
- What concessions has the other party offered in similar situations?
- What risks should you be aware of?
- Will any internal issues or politics affect the negotiation?
- What does your competition for the site or study look like?

- What has changed recently?

Thank your counterpart for their advice and, if necessary, use it to finalize your document(s).

Your document(s) are still in your hands, so use the *quid pro quo* again to help accomplish your third goal: a date for their response and an agreement that a second call will quickly follow their response to your documents.

The agenda should include a discussion of any issues your counterpart wants to raise in response to the document(s) you are about to send. Your counterpart should provide these issues in a redlined document so you can prepare for the next call, (e.g., by consulting with an attorney).

With dates for their response and a tentative second meeting two to three days later, you can time follow-up communications, set expectations within your organization and take control of the negotiation process.

If your counterpart is unable to agree on a date or other matters, obtain a date for them to deliver that information.

If your counterpart has little or no authority or expertise, (i.e., is just a message carrier), it is essential that someone with the necessary qualifications, preferably the decision-maker, attend the second call. Ideally, that person will be your counterpart moving forward. If that is not an option, communicate your positions and rationales in writing so they do not get lost in translation. Bundle issues together to get the attention of someone with authority, with the expectation that their involvement will quickly finalize negotiations.

## **Follow-Up**

Assuming your counterpart has not already responded and there is adequate time before the second call, follow up one week before your counterpart's expected response date. Send an email with the following content:

- Statement about the content and results of the meeting.
- We are very much looking forward to working together on the study.
- Please confirm we are on track for your response on [date].
- Do you need anything from me?
- Do you have any suggestions for accelerating the process and avoiding delays?
- Can I offer any assistance to help meet the deadline?

The day after sending the email, follow up with a call with the same content. While the email is a reminder of their commitment to the deadline, this call emphasizes your personal touch.

If the process is ahead of schedule, talk to your counterpart about moving up the second call.

Once you receive your counterpart's response, review any risks, issues and concerns with management and your operational team in preparation for the second call.

## **The Second Call**

Start the call with a bit of small talk, but not too much, given the number of people on the call. Follow up with introductions, the agenda and the objective to finalize the agreement. All attendees should have the relevant documents, along with the names, positions, organizations, head shots and maybe contact information for all participants. Focus on the

study's real-world issues, not on legal language, to provide context and prevent long discussions about vague, hypothetical risks. Attorneys and other negotiators often do not understand the larger context or the details of a study, so they fight over minor points that have little or no real-world significance. So, put the operational teams (i.e., the customers) front and center. They can help prevent the discussion from running off the tracks into a legal or financial thicket. In some cases, legal issues can be resolved with physical solutions (e.g., when the test article or data will be transferred to the other party and what security protections will be implemented.) In addition, the operational people will probably have more interest in relationships and little patience with protracted legal or budgetary wrangling.

In the absence of operational team members, the negotiation can run into the following problems:

- The CTA may not align with the operational realities of the study (e.g., the safety issues).
- You may offer overly generous concessions out of ignorance
- Pinning down an acceptable legal solution will require more exchanges over a longer negotiation while the negotiators work in a vacuum or wait for clinical input.

In contrast, including representatives from each side's operational team provides the following advantages:

- Operational participants can talk about likely vs. merely hypothetical risks and suggest operational instead of legal solutions.
- With the participation of an expert on the study's safety issues, legal protections can be placed in their proper context.
- The participation of "customers" places psychological pressure on the negotiators to focus on the significant issues.
- The operational staff from both sides can start forming constructive relationships with one another, exchanging information and building understanding.
- Legal issues are placed in the context of actual, not hypothetical risks; as a result drafting is accelerated.
- The negotiation can move ahead without waiting for input from the operational teams between negotiating sessions.

CTA playbooks, especially if they have multiple layers of optional language, can delay reaching an agreement. Short-circuit the process by focusing on the operational issues and the ways your counterpart has addressed them in the past.

You or a colleague should take notes, preferably the official notes for the meeting and publish them within a day or two to all participants.

When the meeting ends, there should be a solid process in place and a clear set of actions to continue progress with short turnaround times.

## **Conclusion**

It should not take months to negotiate a CTA. The four-step process described above significantly increases the effectiveness and tempo of negotiations so the study can get started earlier, a big step toward saving lives and improving health. Involving the operational teams in the second call focuses the negotiators on the real issues and helps build strong working relationships based on collaborative problem solving.

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