Winning contracts

Negotiating the clinical trial agreement is an important step in sponsors and sites getting to know each other. To help the relationship start off on the right foot, **Norman Goldfarb** offers a guide to initiating fair and effective talks

The clinical trial agreement is a good way for the sponsor to communicate its respect for the site and to indicate its own competence and priorities. Active sites read numerous contracts and use them to form judgements about the authoring sponsors. An agreement that is carelessly (or craftily) drafted reflects poorly on its author. It also conveys a lack of respect and lack of interest in working with sites that know the difference between a fair, competent agreement versus those that are not.

So it is worth taking the time to negotiate the clinical trial agreement (CTA) carefully – and ethically. These negotiations are often the first point at which the sponsors' and CROs' interests are in conflict with the sites' interests. It may be tempting for companies to flex their muscles, especially with sites that are relatively inexperienced in conducting clinical trials. However, this attitude is likely to prove counter-productive in the long run. Rather, sponsors and CROs should view the negotiation process as an opportunity to demonstrate goodwill and build a solid foundation for a relationship that may continue for many years.

Unfortunately, too many companies succumb to temptation (see box). It is not surprising then, that sites rate the CTA negotiation process as the second-worst aspect of doing business with sponsors.[1] Sponsors, no doubt, also have their own frustrations.

It has been claimed that commercial real-estate lawyers can hammer out the material terms of a US$100 million transaction in 30 minutes. By contrast, it takes sponsors an average of 35 days to negotiate CTAs with community-based sites and SMOs, and 96 days with academic centres.[2] Given that these delays, in aggregate, cost the pharmaceutical company an average of US$1.3 million each day in lost revenue, something is drastically wrong with this state of affairs.

Delaying factors

Complex agreements take a lot of time and effort for sites to understand and review for 'gotchas'. This initial delay is compounded by the fact that, when questions arise, one or both parties are often slow to respond. Questions and answers absorb even more time when the terms in the agreement are complex or poorly drafted. A survey of sites revealed a clear consensus that about 75% of the time spent waiting for responses is spent waiting for the sponsor who drafted the agreement (see www.firstclinical.com/resources/).

Multiple levels of expertise and approval contribute to the delays. While it is a poor use of expensive attorney time to handle routine negotiations, it is a good use of their time to get the messengers out of the way and quickly dispose of substantive issues with competent negotiators.

Much negotiation time is spent re-inventing the wheel. If an agreement clause draws a lot of fire or requires frequent explanation, it is time to clarify or change it. If you can't change it, at least prepare a cogent FAQ. As a prime example, it seems obvious – but apparently not to everyone – that it is pointless to negotiate a master agreement if you are not going to use it.

Contract specialists and attorneys are often overloaded, sometimes having over 100 contracts on their desk. Time spent on one contract then delays 99 others. Moreover not all contract specialists and attorneys have the right expertise in this form of contracting. There are few things more frustrating than trying to negotiate with a contract specialist who has no understanding of the concept under negotiation, or negotiating with an attorney who wants to employ, for example, principles of employment law. Meanwhile, laws and regulations vary from region to region, and can be difficult to identify, much less interpret and apply to the specifics of the study.

Accelerating the process

It seems obvious, but make sure you are negotiating with competent negotiators. Agree on negotiation timelines and hold both parties accountable; terminate the negotiation on schedule, one way or another.

Companies should insist that agreements are drawn up in straightforward language. And don't make the other party hunt for the controversial terms. It is relatively easy and time-saving in the long run to repackage cogent responses to common questions and issues. Better still, rewrite the agreement to eliminate them. Use this as an opportunity to strengthen your institutional memory to avoid re-inventing the wheel.

Keep to the timetable by passing on the negotiations quickly to the appropriate level of expertise and authority. Ensure you have sufficient negotiating staff with the appropriate skills. Align expertise with responsibility; and train staff accordingly. Then set overall objectives, track performance and manage the process for improvement.

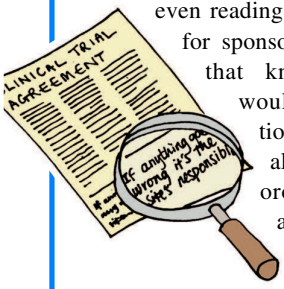
Collaborating on CTAs

There is another option. Consensus-based model agreements have been drawn up and tried by groups in the US, Canada, Germany and the UK. Model agreements address many of the above sources of delay. Their voluntary use by a sponsor or site communicates to the other party that it considers itself a good, multilateral industry citizen. Unilateralism is controversial today in the political sphere – perhaps it should also be considered controversial in the world of clinical trial agreements.

One example of this kind of collaborative approach is the Model Agreement Group Initiative (MAGI), which has attracted members from all segments of the industry both in the US and elsewhere. Employees of over 180 sponsors, sites, CROs, SMOs, and law firms are beginning to draft the agreement in about 80 sections. They are developing a flexible, 'multiple choice' model CTA, with the aim of taking months out of the drug development timeline and speeding medical products to market. The resulting model CTA with accompanying commentary is planned for publication next year (www.firstclinical.com/magi).

Such a model should cut down the delays in the negotiating process by using

Temptation 1: Writing the CTA for sites that don't read it



Around two-thirds of community-based sites are thought to sign the CTA without even reading it, so it is tempting for sponsors to include terms that knowledgeable sites would consider objectionable. Sponsors may also be less than rigorous in drafting an agreement that is comprehensible to site personnel with no legal training and little experience with contracts of any kind.

Giving in to these temptations is hazardous for the study and for the sponsor-site relationship. For example, the sponsor will find its roster filled with those sites that have signed up without carefully reading the agreement.

Sponsors will soon discover that the sites that read the contract are also the ones most likely to be competent at enrolling subjects and generating high-quality data. Unfortunately, once they read such a contract, they will want to negotiate it. The negotiation process can take weeks or months, perhaps delaying initiation, perhaps starting the relationship off on the wrong foot, or perhaps aborting – before it even starts – what otherwise would have been a successful long-term relationship.

Temptation 2: Not putting all your cards on the table

When a sponsor authorises its contract specialist to make certain concessions, it is communicating flexibility, but it is also suggesting three other messages:

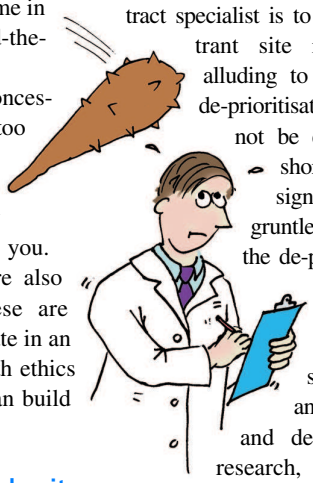
- I'm willing to waste your time in the hope of playing 'find-the-concession'.
- There are probably other concessions available, but you are too ignorant to ask for them.
- I'm willing to exploit naïve sites that don't know any better, and that includes you.

Given that investigators are also the sponsor's customers, these are bizarre messages to communicate in an industry that is so obsessed with ethics and so constrained in how it can build customer goodwill.

Temptation 3: Giving pliable sites priority

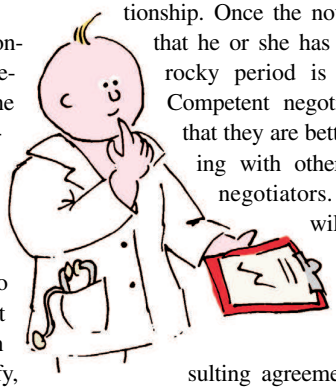
Another temptation for the sponsor's contract specialist is to de-prioritise 'troublesome' sites that dare to negotiate the agreement. If the objective is to negotiate five contracts a week, it is asking a lot of the contract specialist to devote a lot of time to challenging negotiations that may not even bear fruit. (Of course, site negotiators exist that, due to inexperience, personality or a deficient personal life, are overly aggressive in negotiations, but they are easy to identify, and do not survive for long.)

Temptation 4: Proposing I-win-you-lose contracts



A related temptation for the sponsor's contract specialist is to bludgeon the recalcitrant site into submission by alluding to the above-mentioned de-prioritisation. This gambit may not be effective even in the short term; contracts are signed every day by disgruntled parties who return the de-prioritisation favour in kind. The site will not be keen for future studies from that sponsor anyway. In an activity as complex and demanding as clinical research, the enthusiastic co-operation of all parties is essential.

Temptation 5: Exploiting the site's naiveté



Semi-experienced negotiators may enjoy having the upper hand with novices, but the resulting agreements are a minefield for a healthy long-term relationship. Once the novice realises that he or she has been had, a rocky period is guaranteed. Competent negotiators know that they are better off working with other competent negotiators. Not only will the negotiation proceed more efficiently, but the resulting agreement will also support a healthy relationship.

straightforward language as far as possible. The substance of each clause will be accompanied by an explanation of its pros and cons, so everyone knows what they are negotiating about. Of course, there will still be a negotiation, but it will focus on the substance of the clause. If one party likes one option and another party prefers another, they can still hammer out compromises and trade-offs, but the language and arguments will be transparent to both parties.

The model will also address local needs, as MAGI is compiling a list of regional laws and regulations. This will mean that the parties do not attempt to negotiate something that is illegal. Of course, there may be circumstances when the conflict between laws, regulations, and legally or self-imposed institutional restrictions make an agreement impossible, but it is better to find out sooner rather than later if the conflicts are insurmountable.

The current approach to CTA negotiation wastes time, effort and goodwill. In an era when site profitability is problematic, when sponsors are struggling with ever-tighter profit margins, and when the public is clamouring for new medical products, streamlining the CTA negotiation process is a win-win opportunity that requires no investment in technology, no research serendipity, and no regulatory authority approval. GCPj

References

1 CenterWatch. 'US investigative site survey', June, 2003.
2 A Chasse. 'Overcoming contracting challenges in clinical research', Drug Information Association Annual Meeting, 2003 (www.quintiles.com/Performance/Presentations.htm).

Norman M Goldfarb
Chairman, Model Agreement Group Initiative and President and CEO, First Clinical Research, San Francisco, CA, US
Tel: +1 415 681 4657
Fax: +1 415 681 4628
E-mail: ngoldfarb@firstclinical.com