Shifting the Tide of Inefficient Site Contract Negotiations: Turn to an Expert

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Working in the clinical research and drug development field is exciting and inspirational. Scientists, pharmaceutical companies, doctors and patients participate because of the promise it holds for humanity.

The tasks necessary to initiate sites so investigators can test a drug are numerous. For many, one such task, site contracting, is often considered mundane. However, because of the critical role a site contract plays in a clinical trial, it should be as inspirational as any other aspect.

Contracting may sound unexciting, but it's just as important as IRB approval, patient enrollment —even the delivery of the medication to the site itself. No contract, no clinical trial.

Still, contracting should be dull—or at least uneventful. Too often, it's stressful. It should be a small part of activation process. Too often, it isn't. It shouldn't take so long or cost so much. Too often, it does.

And all of that is expensive. In fact, contracting is responsible for an outsized portion of a trial's cost. Consider:

- Study startups account for 19 percent of the sponsor's total spend, roughly $2.7 billion.
- Site-activation costs account for just over half of startup costs, roughly $1.4 billion.
- Of those site-activation costs, contracting costs $353 million.[1]

And then there are the indirect costs.

Sponsors can save $2.2 million by shaving just three months off study timelines.[2] But sponsors aren't shaving off time. If fact, timelines are growing longer. The average time from site identification to study start-up completion is 31.4 weeks; that's a month longer than 10 years ago.[3]

Contract negotiations are a main reason for study start-up delays. In a recent CenterWatch survey, 49 percent of respondents identified contract negotiations as the predominant cause of delays.[4]

Delays cost sponsors money, of course, but that's the least of the problems.

These unnecessary delays mean it takes longer for the research and development of new therapies patients urgently need.

Many potential study participants eagerly await the launch of a trial. Working on the clinical side, I've seen it first hand: Patients sitting in the waiting room, thinking the trial has started, only to discover the contract has not been executed. It's an unfortunate—and too common—of an occurrence. Investigators can't move forward. Patients can't get access to remedies.

So clearly, study delays have consequences. Sponsors want to avoid those consequences. When contracting delays occur, the sponsor CEO wants to find someone responsible.

So they will likely turn to the Office of the General Counsel (GC).

It All Lands on Legal

Ultimately, all issues with contracting end up in the GC's lap. They are the ones that have to handle the contracts escalations. And while their team may be handling the contract process, all changes are ultimately the responsibility of the GC. And that's the one the CEO turns to for answers.

Face it: The CEO hears the word "contract" and goes straight to the GC. Not the negotiators. Not the clinical operations team.

No one wants that call from the CEO demanding to know why a study is being delayed due to site-contracting issues. (For that matter, no one wants delays.)

Elements of Success

Sponsors, CROs, clinicians—they all want to begin patient enrollment as quickly as possible. But sponsors first need to negotiate site contracts that manage risk, protect intellectual property, meet regulatory requirements, foster compliance and balance business obligations with humanitarian imperatives.

It seems straightforward enough, but accomplishing that in a timely fashion is tricky. If your organization regularly deals with contracting delays, it's time to review your capabilities. At a minimum, you need the following:

- Local subject-matter expertise: Does your team have the skills to navigate each country's unique regulatory process? Do they understand, for example, which ministries of health (MoH) are slower to grant approval than others? An executed contract is useless without the appropriate—and timely—approvals. Are you aware that in some countries, the contracts must be fully negotiated and signed before the study is submitted for approval?

- Communications expertise: Can your team distill complex legal ideas into the appropriate language? Obviously, they need to literally speak the language. But that's not enough. In a negotiation, at the other side of the table may be a clinical study coordinator or a five-star legal team that really doesn't grasp the nuances of clinical trials. You need to communicate with both.

- Knowledge of what works: Do you reinvent the wheel with each site, crafting each contract from scratch? To be successful and time-efficient, it's

important to know which clauses the site has agreed to in the past. Ideally, you want a road-tested template as a starting point for each site.

Sponsors and CROs struggle with delivering site contracts on time. Everyone, including the sponsor, seems resigned to the fact that site contracting will drag out. As a result, delays have become business as usual. Excellence in this area seems unattainable.

It's time to turn the tide. Don't be stuck with business as usual anymore. There is a better way: working with a contracting expert.

Turning to an Expert

It's a long road to site activation, one filled with many roadblocks. And the more sites involved in the clinical study, the more challenges.

That's why many sponsors and CROs are turning to contract negotiations experts to help remove—or plow through—those roadblocks. These experts do nothing but negotiate and execute contracts with clinical trial sites.

We all know that getting through the contract phase is often seen as a necessary evil—a prelude to the real activity. That makes sense: study teams should be focused on the clinical trial.

Contract negotiation experts, in contrast, focus only on the contract. They get paid by the contract, not the hour.

You can improve the site-contracting process with the right partner, one who understands the pressures you face externally and internally and is attuned to the regulatory, clinical and cultural aspects of site contracts.

Experts Act as Agent of the Sponsor

This means no back and forth with the sponsor's over-worked and lean legal team. With a trusted provider, you can just hand over the site contracting process. For example, WCG Clintrax negotiates directly with sites, which limits the number of escalations. Constant back-and-forth consumes precious time and resources. Meeting deadlines requires starting with a contract that's as close to final as possible. It also requires having someone at the table empowered to make a decision—someone who doesn't have to run every change by the sponsor's legal team or GC.

Experts Know the Lay of the Land

It's frustrating to have your contract negotiated when the MoH won't look at it for three months. The right partner has in-depth knowledge of local languages, cultural norms and regulations; they have established relationships with the leading clinical research sites in those countries. Your negotiator needs to know how to prioritize—or perhaps, more accurately, triage, contracts to get things moving swiftly. For example, WCG Clintrax has attorneys across more than 60 countries. Our expertise can help save you 45 percent in your overall contracting cycle timelines, especially in the countries where most clinical trials are conducted.

Experts Understand Each Site's Requirements

Clintrax is the service provider whose sole mission is to deliver site contracts and has an impressive stockpile of successfully negotiated contracts with numerous sites, which helps shorten negotiation time. They'll also have previous contracts with study sites, so they know what each site wants or is willing to agree to. For example, WCG Clintrax has a vast technology library of clauses and contract templates that are compliant, site-specific and that have worked before. Why does that matter? Working with Clintrax results in predictable and efficient site contracting.

Experts Meet the Timeline

This should go without saying. Speed is almost as important as getting the contract right. WCG Clintrax beats the industry standard—not only in the U.S., but around the world.

Select the Right Partner

Turning the tide from unpredictable and inefficient site contracting to reliable and efficient contracting comes down to finding a partner who gets it done, and gets it done quickly the first time.

We all know the current approach to site contracting is ineffective and often times fails study start-up timelines. Delays are costly in terms of clinical resources, money and people's lives, so engage a partner who can drive excellence through collaboration.

References

[1] WCG proprietary Knowledge Base

[2] WCG proprietary Knowledge Base

[3] March/April 2018 Tufts CSDD Impact Report

[4] CenterWatch survey (2017)

About the Author

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