Finding New Solutions to A Current Unsustainable Model of Clinical Trial Contracts & Budgets

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As clinical research moves into the mid-21st century, trials are becoming more sophisticated and precise. Not so for the contracting and budget functions: They remain stuck in the mid-20th century, a situation which is neither acceptable nor sustainable.

In a clinical trial, *everything* depends on contract execution and budget development; when they are not appropriately managed, progress across other study start up areas comes to a halt. Monitors cannot complete site initiation visits. Sites can't be activated. Patients are unable to enroll. Valuable time is wasted, which costs dearly.

We're not describing a worst-case scenario: This is the way it usually works—or more accurately, *doesn't* work—today. Lack of strategic planning, lack of communication and lack of transparency create avoidable errors, unnecessary delays and higher costs.

Today, roughly 57 percent of the time spent on site activation involves contract and negotiations.[1] Median site contract cycle times doubled from approximately 1.5 months in 2010-2011 to more than three months in 2014-2015,[2] and the trend shows no sign of abating.

This is a tremendous source of frustration, one the industry has been grappling with for years.

The way sponsors and CROs handle budgeting and contracting is inefficient and exhausts valuable time and resources.[3] They too often fail to align the appropriate resources to complete the contract and budget work successfully.

They want to optimize the process, but they don't know where to begin.

WCG Clintrax does: That's *all* we do, so we do it better than anyone.

The problem with the status quo

It's past time for a new approach. Fifty-six percent of sites identified budget or contract negotiations as "always" or "frequently" causing site delays, according to an ACRP/CenterWatch survey. Sixty percent of large sites identified budget negotiations "always" or "frequently" as contributing to delays. Additionally, 63 percent of large sites and 54 percent of small sites said contract negotiations "always or frequently" led to delays.[4] (See Figure 1)

Clintrax helps its clients see a 37% faster site contract execution timelines.

How do we do this? Our successful approach boils down to three factors: collaboration, strategy and expertise.

Collaboration: Understanding the client's needs

Collaboration is paramount. Before we do anything else, we make sure we understand our client's approach and priorities. Each has its own unique vision, budget negotiation expectations and contract requirements, and we respect that.

Our role is to provide data-driven insights, strategic—and sometimes educational—leadership. That demands trust. Clintrax works with clients to agree on the best path forward before the contracts ever reach the sites. Throughout the trial, we collaboratively assess key performance indicators and continual process improvement strategies to drive efficiency and promote accountability.

Clients don't need another status quo vendor. They need a partner who provides ideas and solutions. They need a partner who has the expertise to manage the process without numerous—and costly—back-and-forth negotiations over site contracts and budgets.

To provide that level of leadership, we must foster strong relationships with the sites.

Collaboration: Cultivating site relationships

The right partner has in-depth knowledge of local languages, cultural expectations, template requirements and regulations; it has cultivated relationships with the leading clinical research sites in the countries where the trial sites are located. Our extensive database of agreements from over 3,500 sites gives us the intelligence and tools we need to engage with sites in over 60 countries.

We work with 87 percent of U.S. academic medical centers. So why would we enter new negotiations with these centers every time a new study begins? We understand the centers' nuances and we know their negotiating styles. We know what they demand in their contracts and how they operate. And these sites know us *and* trust us. We speak their language, literally and figuratively.

By consistently maintaining these relationships with sites, Clintrax gives our clients an edge. The sites are going to prioritize negotiators with whom they have an existing rapport—those who won't create duplicate work that wastes their time. Sites expect fair compensation, transparency, and engaging interactions with partners in whom they have confidence.

We understand sites. We recognize they must see patients *and* conduct research. We appreciate the operational strain. Although we work for sponsors and CROs, we also serve the sites. Our goal is to relieve some of the operational burden and help sites devote their time to focus on the patient. That strengthens our rapport with sites and benefits our clients.

Strategy: Managing the process

Because we understand what the client and the sites need, we can enter the process with road-tested templates in place that minimize the back and forth and reduce escalations. No more time wasted renegotiating previously agreed-to terms.

Our database of agreements with over 3,500 sites provides insight into a site's negotiation history. Clintrax has a vast library of site agreements and budget templates, that are compliant, country-specific *and* provide fit-for-purpose solutions. We also have deep expertise in the regional nuances where budgets are split among institutions, principal investigators and sub-investigators, or how they are divided across various departments.

We proactively manage the sticking points with the sites and provide data-driven insights to our clients for informed decision making. This saves time, resources and aggravation for everyone involved.

Such an approach works only if everyone is on the same page—literally. That's why an essential component of our strategy is communication. We create communication pathways across internal and external participants. We ensure those pathways remain open between regulatory and clinical operations, between sponsors and CROs, between investigators and the payment team, etc. This ensures all these elements are aligned in the contract, the budget and the payment process. That dramatically reduces the potential of delays downstream. In particular, it reduces and streamlines the amendment process.

Global expertise

Emerging biotech and pharmaceutical companies are expanding their global footprint; this requires the unique global expertise and skill set Clintrax brings. Budget and contracting experience coupled with detailed local country knowledge promote efficient negotiations and reduce global cycle times.

Again, it gets back to collaborative relationship building. Global trials demand closer attention to establishing

clear lines of communication across cultures and languages. Each country is different. Regulations vary, of course, but so do the fair market value (FMV) benchmarks.

Aligning a budget with FMV demands measurable data that is country-, site-, phase- and indication-specific. That's another way our knowledge of the various sites proves so valuable. We provide location-specific benchmarking based on both real-time data and our historical knowledge of the site, the region and the country.

We tailor budgets at the procedure, therapeutic area and country levels to ensure global payments are at fair market value. We offer:

- Global positioning from negotiated grant information in 90+ countries;
- Access to costs associated with 4,800 procedures and 15 million industry cost data points updated quarterly to reflect the most recent 24-month period.

That gives us the ability to create accurate forecasts and detailed country-specific budgets that promote efficient negotiations and ultimately reduce cycle time.

It's *all* clinical

Neither budget development nor contracting exists in a vacuum. Anyone negotiating a site contract or budget must understand the protocol. That can be challenging:

Compared to 15 years ago, the number of endpoints and participating countries has almost doubled. During that same time, eligibility criteria soared from 31 to 50, while the number of procedures went from 97 to 163.[5, 6]

Greater complexity increases the potential for protocol errors, or inconsistencies between the protocol, the contract and the budget. Because of our clinical knowledge, we can identify and address these issues before they lead to delays.

As part of the budgeting process, we often conduct a thorough review of the protocol to get a better understanding of the trial. The problems we find are often small. Perhaps in a 120-page protocol, there are a couple inconsistent procedure descriptions. Sometimes there's a side budget that doesn't align with the contract. A complex trial may have six or seven different budgets for one site agreement. Errors can compound quickly if you don't catch them early on.

We catch them. Early on.

The WCG edge

As data becomes increasingly siloed elsewhere, we have the agility and tools to integrate data from across WCG, powering the sophisticated predictive analytics sponsors require.

For example, Clintrax has access to the proprietary WCG Knowledge Base of 3,500+ site contracts and budgets; that gives you access to 95 percent of all active protocols. We deliver a 35 percent reduction in negotiation time leading to faster site activation timelines. Our insights-driven site selection and feasibility services together with our site budgeting and contracting services solve common trouble spots in the start-up of clinical trials. As a result, we help sponsors and CROs compress their study timelines by 33 percent.[7]

If you are ready to improve your contracting and budgeting process, we can show you the way. Clintrax does one thing exceptionally well: We allow you to focus on what *you* do best: developing therapeutics, conducting trials and saving lives.

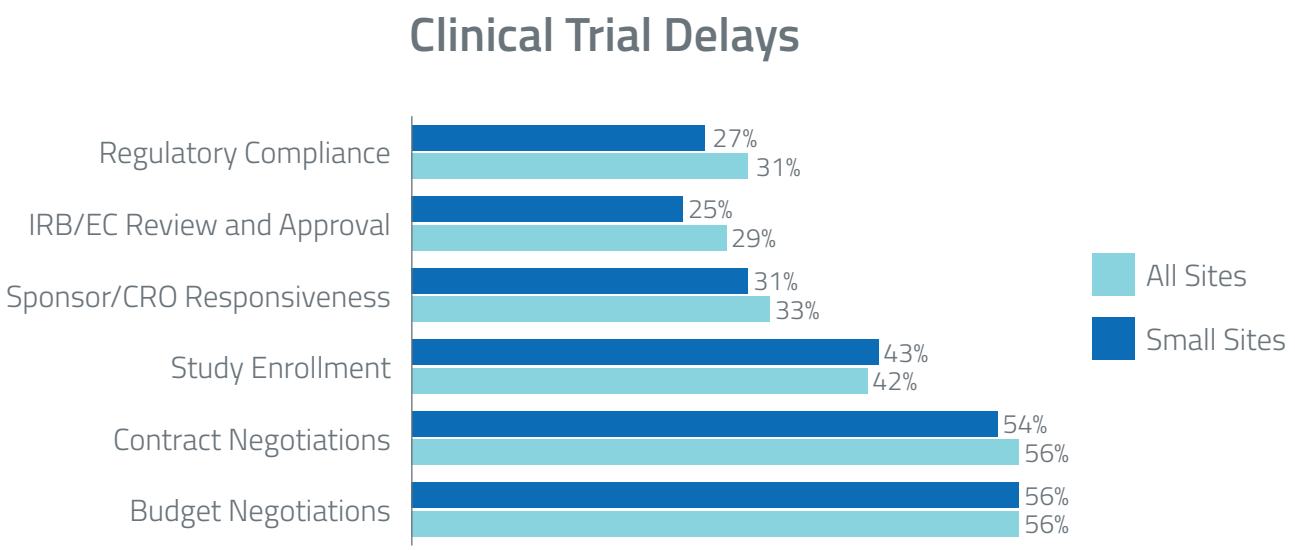

Figure 1 - Financial and operating benchmarks for investigative sites: 2016 CenterWatch-ACRP collaborative survey.

The Blight of Amendments: An Executive Perspective

Amendments, the bane of contracting, are on the rise. Fifty-seven percent of all protocols, across all phases, have at least one substantial global amendment, according to a 2016 Tufts CSDD report. Nearly half (45 percent) of protocol amendments were avoidable, up from 33 percent in 2010. Only 20 percent overall were requested by a regulatory agency.[8, 9]

Among the implications:

- Cost: The total median direct cost to implement a substantial amendment for Phase II and Phase III protocols is $141,000 and $535,000, respectively.
- Enrollment: Having even one amendment means significantly fewer patients screened and enrolled compared to protocols with none.

Keep in mind amendments typically don't come about because of glaring oversights. It's often something seemingly insignificant, such as patient travel reimbursement. Perhaps it never even gets negotiated. This happened in a trial we rescued for a client. Once enrollment began, it became apparent to the sites that the budget and the informed consent contained contradictory information about how patients would be reimbursed for patient travel. (The informed consent form clearly spelled out that patients would be; the budget did not.)

In this example, the same CRO was managing the clinical site, budget development and negotiations, so it was an easy oversight to make. Ultimately, we had to amend more than 100 contracts globally just to add that one line. Meanwhile, many of the sites had to suspend enrollment and/or study activity until the amendment was in place.

Understanding the site's need—and the country's requirements—would have avoided such a costly delay. That what we do. We design budgets that consider the full scope of a clinical study, including conditional costs, to allow for seamless performance from the negotiation process through payment.

About the Author

Russell John is the Global Director of Grants Management and Operational Excellence at Clintrax. Russ joined Clintrax in March 2014 and has a diverse background spanning over a decade in the research industry working in the laboratory, at a CRO, and in an SMO.

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