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Clinical Trial Site Contracting: The Conservative, Progressive and Hybrid Models

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For the last 20 years, pharmaceutical companies have turned to a variety of clinical outsourcing solutions to reduce costs and improve timelines, enabling them to focus on their core value of research and development. In today's tightly competitive market, companies are constantly striving for ways to further cut costs and reduce study startup cycle times, while maintaining quality.

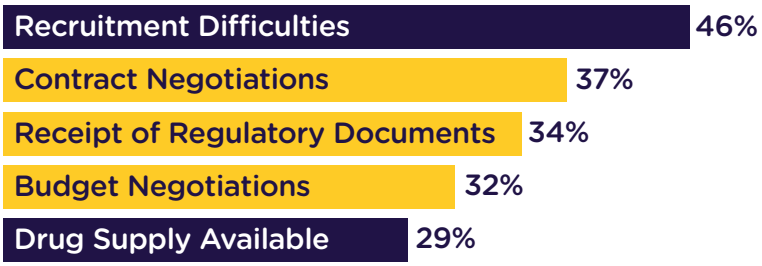
One of the key cost factors in global R&D spending, estimated at around $102 billion per Kalorama market research, is the cost of conducting clinical trials. CRO's, which account for about 30% of the total R&D spending, have risen to the challenge of the clinical, technical and administrative management of these trials. But some pharmaceutical companies question how much control to relinquish to vendor partners, especially in the legal arena, due to potential ramifications.

Legal departments that wrestle with the question of relinquishing control often find themselves overburdened with mounds of legal paperwork. Even with today's technology, many lawyers still prefer to read hard copies of contracts and make notes in red pen. Concerns and challenges in the process include managing litigation, ensuring compliance, understanding the regulatory landscape, managing vendor contracts and — the piece that brings all the company's efforts at research and development to fruition — the Clinical Trial Agreement, or CTA.

Depending on the size and culture of the pharmaceutical company, the legal department can vary in structure and culture. It can look like an Ivy League firm with numerous divisions and specialists for each segment of the business, a country storefront with one office attorney who manages everything, or something in between. In all scenarios, the payroll, time and opportunity costs are high. With or without IRB/ethics approval, the clinical trial cannot begin without an executed clinical trial agreement. Numerous studies have cited the CTA process as one of the top 3 reasons clinical trials are delayed.

Factors Contributing Most to Delays in Enrolling the First Patient

% Rate 'Often' Causes Delays



Source: CenterWatch Clinical Trials Data Library
Source: Tufts CSDD (http://csdd.tufts.edu), 2010 Survey of 3,516 Global Sites

There are many different ways to accomplish the goal of reducing costs, shortening cycle times, and activating clinical trial sites faster while maintaining quality and minimizing risk. Three site contracting models are

often considered: Conservative, Progressive and Hybrid. Companies of any size, culture, or management style can use these models to strategically manage the risks of delaying the clinical trial due to the CTA process – while cutting costs, protecting investments, mitigating risk and maintaining top quality. While one model may fit today, a company may find it can (and perhaps should) evolve into another more effective and efficient process.

Model 1: The Conservative Model

In the conservative model, you will often find companies with a very formal culture grounded in tradition. The company may have more attorney-level resources and highly detailed policies with multi-layered approval systems. The leadership may have experienced poor audit findings due to inconsistencies, non-compliance with a Corporate Integrity Agreement, or a legal challenge to a site contract. The tendency is to keep all of the CTA negotiations in-house and require that the final signature process utilize hard copy originals and wet ink signatures, often with very limited grants of authority. The position held is that the sponsor company is better able to control and manage risk.

Delays abound in this model, caused by the tremendous volume of contracts, study team reporting and meeting requirements, courier delivery times, and vacation and travel schedules, just to name a few. To manage the volume, a company may need a large administrative staff, in addition to lawyers and paralegals.

A potential improvement to this process is outsourcing the logistics — or administrative portion of routing and tracking the contracts through the process ("knocking on the doors", getting comments and rationale, maintaining site relationships and giving the study teams the transparency they require during this critical study startup time).

In such a model, a conservative company can continue to control the legal negotiation, but increase their speed and scale, while reducing the administrative burden and cost by leveraging better logistics processes and technology. Consider flexible, specialty providers to provide these types of dedicated solutions that are designed for the transparency, efficiency and scale you need.

Model 2: The Progressive Model

The Progressive Model focuses on the other end of the site contracting spectrum. In this scenario — most commonly found among smaller pharma and biomedical companies — the clinical trial sponsor completely outsources the site contract management process.

With just one or a few product lines, smaller pharma and biotech companies usually have very limited staffing and are completely focused on bringing their novel, unique or blockbuster drug, biologic or device to market as quickly as possible. As a result, they have no choice but to identify creative ways to manage their workload and stay afloat.

This fully outsourced model for site contract management allows these sponsors to focus their limited resources on research and development, including oversight of the trial. Though still concerned with risk management, these sponsors are willing to relinquish control to professionals who have the skill to independently finalize contracts and budgets with very limited oversight.

Under the Progressive Model, the boundaries within which the outsourced provider may negotiate are defined more broadly. That allows the flexibility to work with the site to establish final language and budget within those parameters. Success with the Progressive Model requires that the sponsor engage a resource with the right blend of capabilities: the legal and financial knowledge to understand and act on the company's guiding principles, along with the negotiation skills to reach consensus with all parties in order to finalize contracts and budgets without the need to regularly escalate to the sponsor for approval.

Although many law firms can support the Progressive Model, they often lack the administrative management

and technology required to provide seamless reporting and speed. A more effective solution may be a provider with specialty skilled professionals who maintain a more narrow focus in fully understanding the legal risks and site budgetary nuances of clinical trials. To maximize success with the Progressive Model, the provider should also offer strong negotiation skills, administrative contract management experience including delivery of the negotiated investigator payments, and proven processes for study start up—along with current, seamless technology built for speed, transparency and flexibility.

Model 3: The Hybrid Model

The Hybrid Model blends the Conservative and Progressive Models for site contracting. From the largest global pharma companies to highly focused pharma and biotech startups, many sponsors see the value in the Hybrid Model. This approach enables a sponsor to retain more control over risk and quality than in the Progressive Model —while avoiding the long delays and high costs typically associated with the Conservative Model.

The Hybrid Model is inherently flexible — enabling a sponsor to establish how much or little control it will relinquish to the CRO or specialty provider. In most cases, the sponsor gives the third party its clinical trial agreement (CTA) template, along with clear guidelines for fallback language. The provider is then able to drive CTAs forward within those parameters. (While many large pharma companies already have developed comprehensive manuals with templates and fallback language, others may need to create one. A specialty provider has the experience and expertise to help with that task.)

The sponsor retains tighter control over key areas — including indemnification, subject injury, intellectual property and data ownership, as well as publication and confidentiality. When a site asks for contractual changes that extend beyond the fallback language, the provider can alert the sponsor of the need to engage in-house or outside counsel. However, these needs typically arise in less than half of CTAs, and the process of creating, negotiating and finalizing most agreements tends to be much faster and less expensive than it would be with the Conservative Model.

With the Hybrid Model, a CRO or specialty provider can streamline the entire administrative function as well — passing the document back and forth, cleaning it up, formatting it and maintaining structured records of all the changes. With clear templates and fallback language, a third party can also handle the first and even second set of responses and "redlines" from sites, which is often enough to finalize the CTA.

A specialized provider, such as DrugDev, can provide another layer of value and support. Because of our vast database of site information and structured site profiling capability, we often alert a sponsor when a particular site has a long, cumbersome contract review and approval process that will jeopardize a study schedule — this becomes key when identifying new sites, particularly in rescue situations. We also maintain records of basic terms and conditions that sites may continually request — to follow a particular state's law, for example, or to make low-risk changes to payment terms. At the end of the day, if a sponsor opts for a specialty provider — one that combines contracting and payment capabilities — the process of study startup becomes even faster and more efficient. Moreover, the global contracting complexities related to VAT tax risk management can also be addressed potentially saving hundreds of thousands of dollars or more.

With the Hybrid Model, a sponsor can industrialize management of site contracting, but it can do so in a manner that aligns with its tolerance for risk, its desire for speed and its goals for cost efficiency. For many sponsors, it has proven to be the proverbial "best of both worlds." •

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About DrugDev

DrugDev's mission is to simplify life at the clinical trial site through technology. In this way DrugDev enables sponsors, CROs and investigators to do more trials together. Featuring the largest global network of active investigators, the industry's leading grant payment and site contracting system in CFS Clinical, and the award-winning TrialNetworks platform of clinical operations apps, DrugDev creates and drives standards which promote collaboration, improve quality, shorten timelines and reduce cost. In addition, DrugDev provides Hosted Data Solutions for clinical trials including hosting the Investigator Databank (www.investigatordatabank.org) for Novartis, Janssen, Merck, Lilly and Pfizer.

We're here to help

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