An Executive Summary

Speed, Efficiency and Accuracy in Site Contracts and Payments

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How to expedite the delivery of global clinical trial contract negotiation.

Negotiating investigator site contracts and budgets coupled with delivering global investigator payments can be challenging. By coordinating services to work together cohesively, the clinical trial process can be streamlined. Proper budget planning improves contract negotiation timelines, while providing a clear framework to expedite payment performance. Global strategies for efficient execution across all of these elements can avoid costly delays.

To make the clinical trial negotiation process more efficient and reduce timelines, it is important to focus on how services are interrelated, how delays and gaps can be avoided, and how to coordinate corollary services. An efficient collaborative startup process ensures that research investments are providing the most value in return for achieving their objectives.

No motivating factor is stronger than the opportunity to improve the lives of the patients and their families. WCG and Clintrax aim to drive efficiency by exhibiting speed and accuracy in executing contracts and payments while creating a fluid, innovative approach across the industry to expeditiously deliver effective, safe and potentially ground-breaking treatments to patients.

Challenges in Clinical Trials

The Tufts Center for Study of Drug Development recently estimated that that average cost to gain market approval and develop a new drug approaches $2.6 billion. The largest portion of that sum is attributed to clinical trials.

A separate study by KPMG suggested the R&D return on expenditures has dropped from 20% in the 1990s to 11% today. Only one out of 10 drugs that begin clinical trials currently achieve FDA approval.

Pharmaceutical and biotech companies are continuously seeking to decrease expenses. In response, they are designing new protocols to more targeted patient populations and developing smaller, more efficient clinical trials. The industry is also embracing more cloud-based solutions in innovating next-generation tools to leverage data, enhance patient and investigator identification, and to expedite clinical trial start-up.

Sponsors should also examine their clinical partners to ensure that their processes are as efficient as possible. Consistently providing and delivering high-value services will reduce administrative burdens, eliminate unexpected study costs and improve turnaround times.

Making clinical trials more efficient, however, is not a simple task as there are numerous obstacles in contracting and payments (see **Figure 1**).

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Applied Clinical Trials

Siloes and poor communication. Clinical trials encompass separate and independent services that function at overlapping intervals in different operational units. One challenge of clinical research is ensuring these operations are effective and efficient while tying together other business units and processes to move projects toward commercialization.

Clinical trial agreements (CTAs), budgets and payments often are siloed processes. Contracts are developed independently of the budgets, and then they come together in one final agreement. Payment terms are often driven by a completely different process. Although they are included in the CTAs, there may be an outside payment vendor. Ultimately, payment terms and budgets must be aligned when the contract is executed, otherwise complications may not be apparent until it is time to make payments long after the initiation of a study. Overall, coordination between groups can expedite the negotiations of contracts, budgets and payment terms. Creating clear channels of communication among outside vendors, sponsors and CROs ascertains that elements mesh to avoid delays. Reducing the high administrative burden for study teams and sites necessitates improved management of contract negotiations and budgets that are aligned to the complexity of the protocol.

Administrative burden. Inefficiencies in regulatory submissions, clinical operations, data management and contracting become a heavy burden for clinical sites. A collaborative team approach for unifying procedures in contracts, budgets and payments makes the process more efficient and less intrusive to get clinical trials up and running quickly.

One-third of amendments in clinical studies—costing an estimated $2 billion per year—could be avoided by having more careful review of CTAs, informed consents and protocols. Such factors delay patient enrollment goals, site initiation and site payments. Due to the global environment of clinical trials, it is important to have in-country experts on the ground to understand the local culture, regulations, and expectations in order to complete day-to-day operations.

Payment delays. Another challenge comes with delayed payment processing to sites and subjects. Payments must be made on the contract and budget within, that has been executed, and payment terms in the CTA must be coherent and achievable for a payment vendor or payment service. Payment management involves tying these services together, ensuring that what is negotiated in a budget is payable, aligned to the data capture system, and is enabled by a reliable payments software platform.

Technology. Technology and the data associated with it will have a continuing emphasis in the industry, demanding the best tools available. The appropriate interpretation, application, and analysis of the data provide the insight to drive operational excellence.

Factors that can be controlled include: having a consistent template, knowing the sponsor preference for specific language and understanding the sponsor's position on key sections of the contract. Gathering detailed information at the onset, being technology enabled, and having a realistic budget

Figure 1: Challenges in contracting and payments.

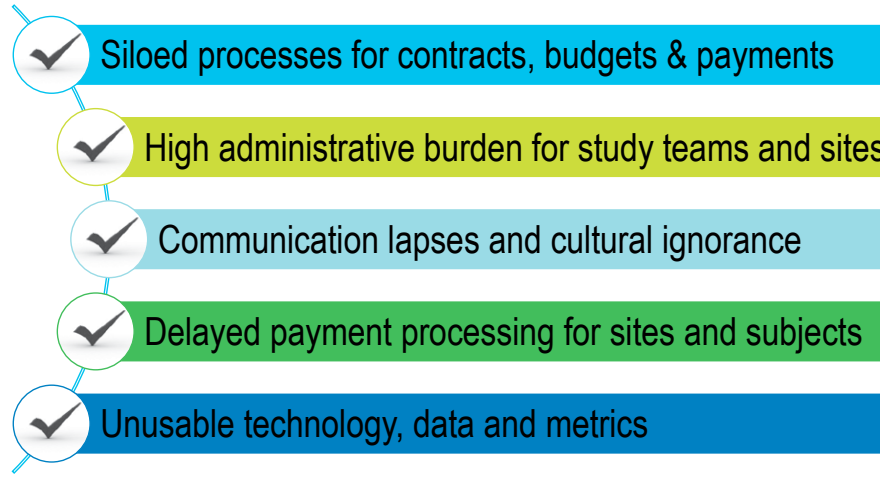

Figure 2: CTA Execution Time(s) – How do we strategize to achieve these timelines?

Sponsor	Time to Execute (Business Days)	Clintrax / Stable Sponsor Template / Masters	Playbook / Delegated Approval	PDF Execution	Budget Target Mid/ High
A	38	✓	✓	✓	✓
B	68	✗	✗	✓	✓
C	129	✗	✗	✗	✓
D	170	✗	✗	✗	✗

based on the complexity of the study can significantly improve timelines (see **Figure 2**).

Overcoming the Challenges

Contract development and negotiation. To address the increasing intricacy of CTAs and the changing legal landscape in specific countries, one must scrutinize the negotiation process to remove barriers. To establish the proper framework for negotiations at the onset of the study, knowledgeable legal resources must be in place in the appropriate countries to understand budgets, institutional policies and country-specific laws. Negotiators who leverage their knowledge of the local language, relationship with the site personnel, and their understanding of the regulatory scheme will reduce the timelines of the overall negotiation.

It is critical to work with the sponsor to prioritize each facet of contract language. By understanding the sponsor's concerns, a negotiator can be the centerpiece of communication to drive that process forward. Site relationships must be established, so that sites develop a sense of value and trust with the sponsors they are working with. By establishing the sponsor's expectations and logic, negotiators on both sides can reduce the back and forth of a negotiation to minimize the overall administrative burden.

Finally, it is important to marry the strategy of budget development, contract negotiation, and the payment process. All these processes are interrelated and must be as streamlined as possible to avoid complications later in the process.

Budget development and fair market value. As clinical protocols increase in complexity, it is important that experts understand the clinical side of the process: the therapeutic indication, how standard of care may be applied and how different site costs and conditional costs are associated with the protocol. Transparency helps the process to move faster, reduces the amount of questions and sets the expectations for the negotiation. Additionally, budgets must meet local expectations where country specific templates are required or other nuances such as split contacts exist. Design budgets that consider the full scope of a clinical study, including conditional costs, to allow for seamless performance of investigator payments.

Fair market value benchmarks are a key element of clinical trials. While vital for global compliance, fair market value is a nebulous subject without clearly defined guidelines. To control costs, it is important to analyze variations in standard of care coverage, manage administrative and ad hoc costs, justify the overall cost and make sure that it is within fair market value. Breaking costs down at the granular level provides an understanding of the time and effort to support those costs leading to a quicker negotiation process.

To control the annual increase in costs, it is necessary to document institutional policies on standard fees, understand what overhead is from year to year, and compare how an institution's costs are to similar sites and regions. Understanding the cost drivers in variance from a global perspective, while having as much transparency as possible, is vital.

With inflation and rising costs in the industry, those expenses will not be consistent for five- or 10-year periods. By assessing expenses within a 12- to 24-month time frame, it can be determined whether cost changes are justifiable, whether there is an industry wide trend and whether the cost increases fall within fair market value.

Investigator payments. Investigator payments make up the biggest pain point for site and sponsors alike. Managing payments within global research sites is very complex with associated compliance risks and tax implications.

Split and multiple payment schedules. Technology has improved, but it has lagged behind the ability to manage payments globally, especially when there are split contracts with separate budgets. There may be as many as six or more payees at a given site. From a technology standpoint, it has historically been difficult to automate payment on these budget splits. Likewise, complex protocols may result in multiple payment schedules across different treatment arms, exponentially increasing the complexity of administering payments to numerous payees on the same visit data points.

In addition to having the multiple payees, there may be different standard of care applications, withholding amounts or percentages that add complications to automating the process.

Neglecting communication before payments are needed. Another problem is developing the communication strategy. The payment process often starts several weeks or months after contracts and budgets have been negotiated. Once a study is initiated, EDC data begins to quickly grow in volume. People are often unaware of errors or gaps in the contract and budget that may delay or stop payments until a significant amount of payable data has been collected.

Without due diligence and a cross-functional strategy for payments in the project planning phase across services, it is difficult to ensure that the payment terms in the contract are viable, how the terms should be incorporated in the executed agreement, and how the budget should be interpreted to make payments to sites. Lack of coordination in services in different business units or across various vendors can lead to problems with payments on the backend of the study.

How can these problems be avoided? Communication ensures that marrying the contract, budget and payments component bridges the gaps and ensures that they are logical and consistent. Startup services, including contracts, regulatory, project management and clinical operations should closely collaborate prior to study initiation well before site payment activity commences.

It is critical to have due diligence across services and the ability to avoid compounding errors to avert a painful payments reconciliation process for database lock at the end of the study. The key for sponsors is to get the data to assess that the patients are being effectively treated and to ensure patient safety. If payments are being withheld, the overall study is adversely affected and delayed, potentially halting patient treatment and data collection.

Helpful strategies include developing compliant internal process to focus on the interrelated details of CTAs, budget development, and payment terms in order to manage negotiation expectations, strategy, and to expedite execution timelines. Establishing liaisons between functional groups working separately is imperative to bridge the gap in understanding the regulations of specific countries for making payments. Finally, enable the appropriate technology that gives both sponsors and sites a complete level of transparency and thorough detail.

Creating a strategic communication pathway. How do we tie this all together? How do we streamline and centralize contracts, budgets and payments? How can we help the sites to have a reduced administrative burden for things that sometimes fall back on people without expertise?

The answer is based on the methodology of creating communication pathways across key participants internally and externally to manage interrelated processes across numerous global teams rapidly. To streamline global services, house global teams that are in-country experts of local customs and regulations, and that also understand the components of development, negotiation, and execution.

Technology. Finally, it is important to use and enhance technology appropriately to be able to leverage data and identify efficiencies. While the technology component can streamline efficiency and drive operational excellence, individuals must have a solid understanding of how to use data, analyze data and make sure data is accurate.

Achieving Success

How does overall success look? Budget design must consider the full scope of a clinical study. It is important to include all the components to execute a contract quickly and to allow for seamless performance of investigator payments once that contract has been executed. Global expertise means understanding local customs, communicating on a global basis and understanding the regulations, components and expectations to achieve project milestones.

Whether it is a large CRO, numerous individuals and groups working together or an organization working across multiple vendors and service providers, having communication within those components is the main driver of efficiency.

Communication strategies must encompass managing the process and ascertaining that all of the global teams can work together seamlessly. It is imperative to develop realistic data-supported benchmarks, implement technology that provides useful data metrics for timelines and to identify efficiencies.

If all these pieces are in place, the overall process is expedited. Bringing together interrelated elements enables an organization to manage the negotiation, manage the overall strategy and execute with improved timelines.

Summary

Methodical, accurate CTA preparation and budget development is a key link to the execution timelines of CTAs as well the ability to perform investigator payments. Every week spent on negotiating a CTA represents a week's worth of patients potentially lost to enrollment, a week's worth of uncollected data and a huge threat to study timelines. Innovating processes and completing them accurately and efficiently across contracts, budgets and payments will result in substantial cost savings, a significantly reduced resource burden, and scalability for growth. Continually examining processes and partners is essential to achieving key performance metrics for efficiency and reliability. Delivering high-value service should be an expectation.

Coordination prevents delays; a fluid and innovative environment will help to deliver clinical trials to patients who are in need. Ultimately, new therapies improve the lives of patients and their families. Introducing effective and safe treatments to patients faster is critical. Continual improvement of processes will drive efficiency in clinical trials to get potential, quality of life improving treatments, to patients much more expeditiously.

This executive summary is based on material presented in a webcast that can be viewed on demand here.