Five Essential Considerations for Efficient Site Contracts and Payments

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Clinical trials are a vast matrix of services functioning at overlapping intervals across numerous operational units. These services, independently, are integral to collect the data needed to advance the research, but they must be coordinated to function interdependently with one another to effectively execute a clinical trial. Often the terms of the Clinical Trial Agreements (CTA) are developed independently of the site-level budget, payment terms, and Clinical Trial Management Systems (CTMS) set-up. As these terms are negotiated and modified, the terms among these tools must also be coordinated in order to avoid startup delays, issues executing the clinical trial, or problems with making payments to sites. The coordination of information and format of these tools is imperative to the global requirements for transparency. Timely and accurate development and negotiation of the CTA, including the budget and payment terms, are often the rate-limiting factor to start-up timelines and, if not coordinated effectively, result in delays further into the study as the timelines move to executing investigator payments.

Challenges and Complications

There are many challenges involved in executing global CTAs and, in turn, performing investigator payments in clinical research, but a number of these challenges can be averted with proper planning and execution in the budget development stage. Determining fair market value (FMV) benchmarks are a vital factor to global compliance with increasing emphasis on regulations including the Physician Payments Sunshine Act, the Loi Bertrand (the French Sunshine Act), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code. Consideration must also be given to the granular details in creating budgets and how those details affect negotiation timelines, payment terms within the CTA, and subsequently, performance of investigator payments to negate a number of complications, including:

1. Delayed negotiations due to lack of transparency in relating budgets to the study protocol;

2. Unfounded benchmarking for country, phase and indication-specific costing, resulting in lack of interest in study participation;

3. Setting future precedents for unreasonable budget negotiations and increasing costs;

4. Inability to perform payments as a result of budget visits and ad hoc costs not aligned to CTMS required amendments to CTAs and further study delays; and

5. Improper payments to sites creating potential compliance issues and extensive reconciliation resulting in delayed study data collection for data base lock.

Budgets

Creating budgets that accurately reflect the complexity of a clinical trial protocol across the duration of a study, identifying potential conditional costs, assessing site costs, and analyzing potential "standard-of-care" procedures requires a thorough understanding of clinical protocols and vast therapeutic knowledge. Aligning a budget with FMV demands measurable data that is country, phase and indication specific. Managing the negotiation ensures that the budget meets compliance regulations and further sets the expectation for future endeavors between a sponsor and a site. The sponsor is relying on the clinical service organization (CSO) to represent the negotiation on their behalf with minimal escalation, due diligence, and forward thinking. Sites are expecting fair compensation to conduct the clinical trial, transparency, and to have engaging interactions with a CSO they can trust. Regional nuances where local templates exist, budgets are split between institutions, principal investigators, and sub investigators, or are divided across various departments, necessitate clear communication. Having the proper framework and an expert understanding of these local customs, budget templates, and negotiation expectations are essential in order to execute contracts with substantially reduced turnaround times leading to faster site activation timelines and patient treatment.

Payments

Investigator payments are reliant upon the interdependent components of the payment terms and budget within the CTA, as the paying agent may only pay sites as set forth in the agreement. Poorly structured budgets and payment terms in contracts may lead to the inability of the paying agent to remit payments to a site. With development and negotiation occurring in tandem during study start-up, gaps in how the budget aligns to the ability to perform investigator payments are often not fully realized until study activity commences, contracts are executed, and patients are enrolled. This becomes an exceptional constraint where communication lacks between separate teams or different vendors. These delays cause well documented site frustrations leading to strained relationships and potentially delayed enrollment activity which interferes with treatment to participants that are in need. From a sponsor perspective, there is lost time and the additional cost of executing amendments that should have been avoided at the onset of the study with appropriate planning. Often, these errors compound, requiring extensive payment reconciliation at study close-out that has lingering effects on resolving database queries and achieving database lock timelines.

Essential Considerations for Success

Partnering with a knowledgeable, global budget development expert that provides world class service to navigate these nuances and eccentricities alleviates gaps to connect critical components, and avoid these pitfalls.

Considerations for a fully-integrated process that results in high-efficiency enabled contracts and payments:

1. **Expedite CTAs** - Focus on the interrelated details of CTAs, budget development, and payment terms in order to manage negotiation expectations, strategy, and to expedite execution timelines.

2. **Seamless Integration** - Design budgets that consider the full scope of a clinical study, including conditional costs, to allow for seamless performance of investigator payments.

3. **Global Experts** - House global teams that are in-country experts of local customs and regulations and understand the components of development, negotiation, and execution.

4. **Communication Strategy** - Create communication pathways across key participants internally and externally to manage interrelated processes across numerous global teams rapidly.

5. **Data-Supported** - Develop realistic and data-supported FMV benchmarking and standard-of-care analysis for globally compliant contracts and budgets to meet evolving transparency initiatives.

Methodical and accurate budget development is a key link to the execution timelines of CTAs as well the ability to perform investigator payments. Every week lost to negotiating a CTA represents a week of participants potentially lost to enrollment, a week of data not collected, and a week that threatens the timeline of the study. Building an investigator budget upon reasonable FMV data reduces weeks lost in budget negotiations with sites. Multiplied across several hundred sites, these weeks represent substantial costs in time and resources to the study, as well as increase the risk of sites dropping participation in the research altogether. Active site participation is essential for the crucial work of screening and enrolling patients as well as accurately reporting study data in a timely fashion.

Conclusion

Prudent sponsors continuously examine their clinical partners to ensure they are getting the most efficient and reliable services. A specialized CSO that consistently delivers high-value services for reasonable fees helps to reduce sponsor administrative burden, eliminate unexpected study costs, and decreases turnaround times that prolong study start-up is in high demand. A clinical services partner that can effectively

coordinate the corollary clinical services across budgets, contracts, and payments promotes a more efficient and collaborative start-up process, and ensures that research investment provides the most return on its investment. Coordination to prevent delays creates a fluid and innovative approach that helps us deliver clinical trials to patients who are in need, and ultimately new therapies to improve the lives of patients and their families. When all is said and done, getting effective and safe treatment to patients faster is what clinical research is all about.

About the Author

Russell John is the Global Director of Grants Management with Clintrax Global. Russell has a diverse background spanning over a decade in the research industry working in the laboratory, CROs, and a SMO, developing a strong sense of the interrelatedness between the pharmaceutical, clinical site, and service provider components. Mr. John brought unique insight with this breadth of experience in the industry into the early growth of Clintrax to develop the Grants Management and Investigator Payments divisions, with a strong sense of empathy to providing improving treatments to patients more expeditiously.