> Innovation
in Investigator Site Contracting

Clintrax Global

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In the perpetual pursuit of a more efficient clinical research process, biopharmaceutical sponsors and contract research organizations (CROs) have traditionally focused their resources on the more costly and time-consuming aspects of study start-up such as protocol development, regulatory and ethical review, and data management and analysis. Investigator site contracting and management of site payments are often overlooked as opportunities to accelerate study start-up and to reduce the expense and complications of managing study site contractual relationships. However, by targeting this smaller, yet still significant, aspect of study start-up, sponsors and CROs can expedite the process of contract negotiation, reducing both the cycle time and burden on the legal infrastructure.

Historically, it has been common practice for sponsors and CROs to adopt a standard Clinical Trial Agreement (CTA) and budget template to use during negotiations with clinical trial sites. While a standardized template might seemingly appear to streamline the negotiation process, many sponsors are finding that they are wrought with inefficiencies of their own.

As the legal landscape has evolved, the CTAs themselves have become longer and more complex in an effort to address the increasing intricacy of clinical trials and the changing legal landscape in which they reside. This has led to a more embattled negotiation process, lengthier review times, and undue scrutiny on the negotiation process itself.

In order for sponsors to truly remove these barriers and delays from the contract negotiation process, they need a partner that specializes in this area. At the most basic level, a well drafted contract provides the sponsor with the essential retention of its proprietary rights and intellectual property, as well as the unambiguous authority to fully realize the information generated by each study site for the development of the drug.

When choosing a partner to assist with the negotiation process, sponsors and CROs should look for partners who will ensure that the sponsor's rights and interests are adequately protected and the burden on the sponsor's legal department is minimized. An ideal partner will:

- Establish the proper framework for negotiations from the outset of the study – aligning competent resources with legal and budget experience.
- Have trained negotiators who understand the specific laws and institutional policies of each country in which a sponsor is conducting trials, and can utilize their local knowledge of language, site personnel, regulatory scheme, legal nuances, customs, and country budget.
- Embrace a strategy of marrying the budget development, negotiation, and payment processes to one another.

- Work with the sponsor to prioritize each facet of contract language. For example, some sponsors might place a higher value on the protection of intellectual property, while others might prioritize strict indemnification and insurance requirements.

- Handle a large enough volume of contracts yearly to establish professional relationships with sites, greatly increasing their ability to negotiate each contract with an understanding of each site's requirements and negotiation styles.

- Offer strategies for global investigator site payments and reporting that reduce operational burden on the sponsor, and ensure compliance with each country's laws and regulations.

By enlisting the support of an experienced partner who specializes in contract negotiations, sponsors are able to decrease negotiation cycle timelines and avoid additional unproductive steps in the negotiation process.

Contract negotiation is more than a function; it is an outcome-driven art. A successful negotiator should be a subject matter expert who brings best practices to the table and is allowed the freedom and flexibility to offer proactive solutions that address the other party's concerns while advancing the sponsor's position. Flexible solutions inevitably cut down on unnecessary negotiation and escalation, minimizing execution times and allowing the trial to begin and produce results.

About the Author:

Steven Jones, JD is the General Counsel and Corporate Secretary for Clintrax Global, Inc.

A seasoned corporate attorney with over 17 years of experience in legal and financial negotiation, Mr. Jones has worked inside both large pharmaceutical companies and CROs, globally implementing new legal and business engagements through effective, timeline sensitive negotiation while limiting the exposure to constantly changing regulatory and financial risks. Prior to Clintrax, Mr. Jones directed contracting and financial processes for a large, global pharmaceutical company, ushering $100+ million in outsourced, time-sensitive Phase I/II and large-scale Phase III studies from initiation to closure.

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