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Contract Delays and Legal Negotiations Become a Growing Concern in Global Site Selection

The largest pain points in global clinical site selection no longer focus just around randomization times and patient recruitment, but have broadened to include slow contract turnaround and legal negotiations.

Total spending on study startups totals over $2.7 billion, and can account for around 19 percent of a sponsor's expenditures, said Brooke Millman, WCG's vice president of consulting solutions, during her webinar *Strategies that Inform Investigator Selection and Enhance Enrollment*.

Site contracting alone accounts for more than $350 million annually, making budget considerations a much larger sticking point in negotiations.

To help speed contract turnaround and site startup, Millman recommended that sponsors employ a team of global contract negotiators and develop site-specific contracts prepopulated with a range of applicable legal terms. In addition, country-based budget templates can be used to cover non-procedural items, such as overhead costs, site start-up fees and pharmacy setup and maintenance.

Millman identified the main methods that sponsors can employ to improve contract negotiation timelines: work with teams that have international regulatory expertise to deliver a legally sound site agreement; spending time prior to negotiations to build and capitalizie on pre-existing relationships with sites; use harmonized tech solutions to track progress throughout the organization; and data-driven country selection.

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—Suzanne Caruso, WCG's vice president for clinical solutions

"When we think about the consideration of which countries would be most impactful to our enrollment, there are a couple of different factors that we take into consideration," added Suzanne Caruso, WCG's vice president for clinical solutions. "One, of course, is how many investigators in the population of that particular country are able to enroll the particular study."

Increasingly, however, sponsors are paying attention to the amount of time needed to settle on clinical trial agreement and any ancillary negotiations. "You cannot begin a study without a contract," Caruso said.

For example, if it takes 130 days on average to open a site in Poland and 75 in Spain, with both offering the same patient population, "why wouldn't you choose to go to Spain?" she asked. Other country-specific factors can affect the budget, such as requirements in Brazil that any woman of child-bearing age has to be on birth control for the duration of the study.

"Every single step we take together impacts the enrollment timeline, and impacts your time to database lock if you're the sponsor," Caruso said. "And for the site, it impacts how many patients potentially could get on a study, especially in situations that are life-threatening, where this may be a last resort for some of these particular patients."