MEDIDATA / Rave

WHITE PAPER

How sponsors and sites can achieve a harmonious and optimized site budget negotiation process

Table of Contents

Introduction

The typical site budget negotiation process is burdened by siloed data, manual activities, and a lack of trust between the sponsor, CRO, and the clinical research sites. An inadequate budget and contract process can contribute to timeline delays, poor patient enrollment, and financial instability for sites and sponsors, impacting the entire study.

As clinical trials become increasingly complex, the burden on the site and patient continues to grow, making clinical trial agreements and site budget negotiations imperative to the financial health of sites. Many factors make reaching consensus on CTAs and budgets challenging, including inflation, hidden costs, and difficulty accessing fair-market-value data. Negotiations are often handled manually through emails and spreadsheets. A lack of visibility and a central audit trail for sites, sponsors, and CROs leads to confusion, inaccurate budgets, and dissatisfied parties. Contemporary Clinical Trials Communications researched how principal investigators survive the complex process, identify coping strategies, and combat budget negotiation challenges.

Table 1: Common Coping Mechanisms Used to Address Trial-Finance Challenges[1]

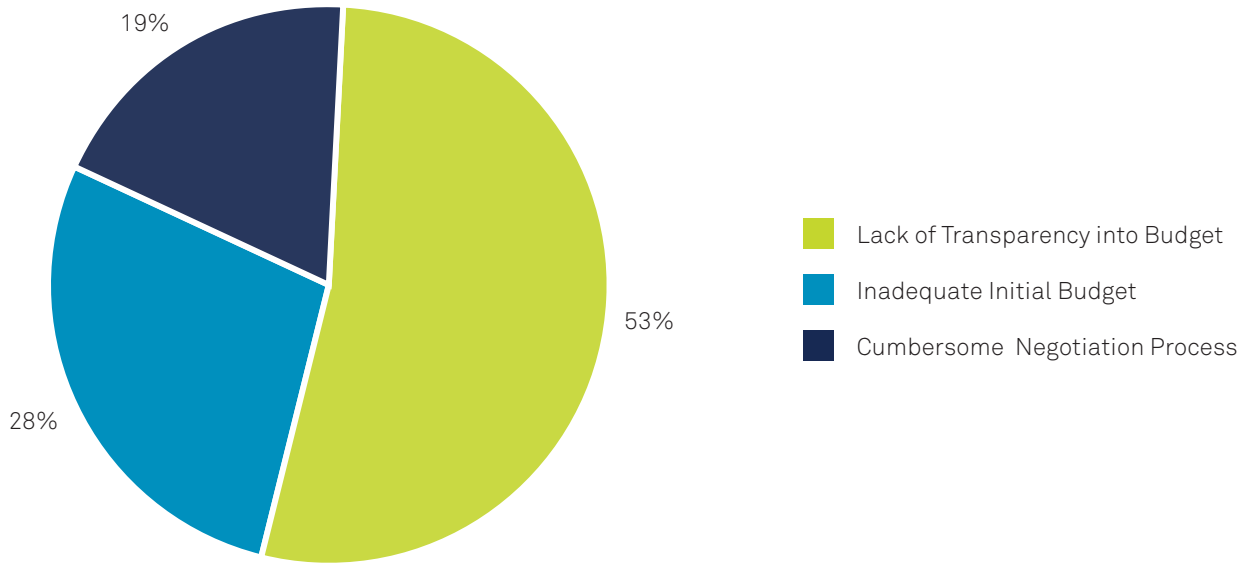
Assess: Go or no-go?	• Conduct a pre-assessment • Review the protocol carefully • Determine the feasibility of recruiting a minimum number of patients • Be selective when accepting trials • Decline trials
Reduce barriers: Know your costs and/or rely on staff to help	• Identify what is needed for operations • Know your own costs • Develop a fee schedule • Clarify fees upfront, especially start-up costs • Rely on staff to follow-up on payments not received • Understand budget line items
Communicate	• Negotiate and push back • Have an investigator decide on the payment terms and schedule • Communicate with the sponsor about cutting losses • Wait for the sponsor to return at later point to negotiate

[1]Adapted from Carrie B. Dombeck et al., "Continued investigator engagement: Reasons principal investigators conduct multiple FDA-regulated drug trials," *Contemporary Clinical Trials Communications*, March 2020. Available here: https://www.sciencedirect.com/science/article/pii/S2451865419302650#tbl2

Surveys Uncover Concerns

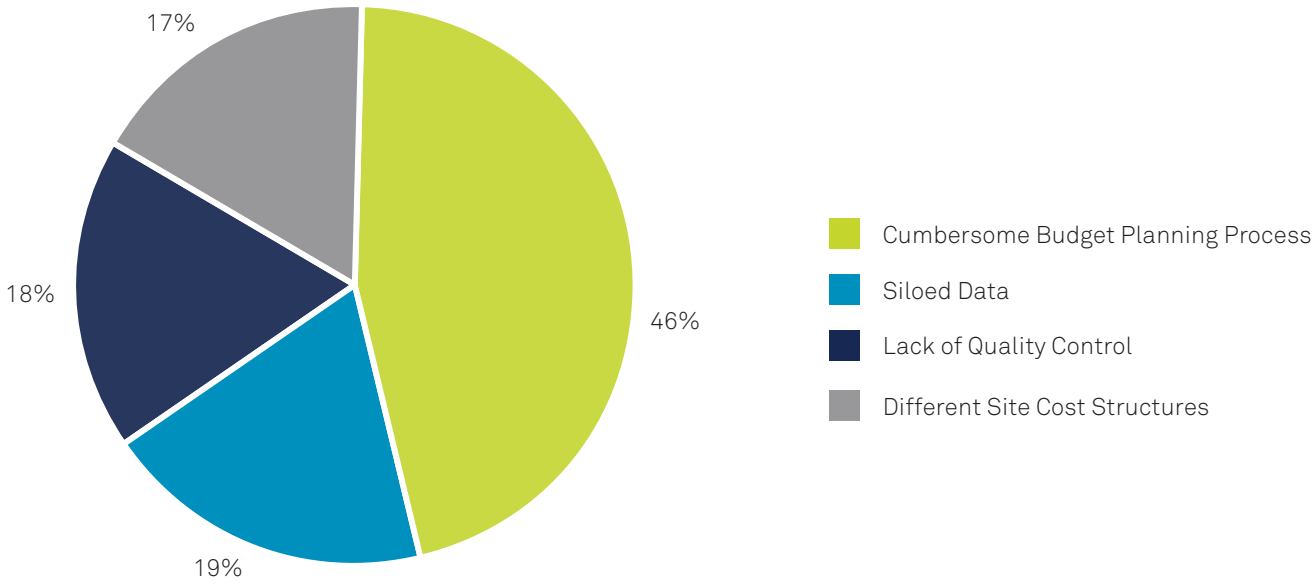
To learn the most significant pain points for sponsors, CROs, and sites, Medidata recently surveyed sites provided by the Society of Clinical Research Sites through site advocacy groups, and also surveyed its wide client base of sponsors and CROs. The survey results included data from site, sponsor and CRO representatives responsible for the study budget planning and site budget negotiation process. The sites, sponsors and CROs have all conducted clinical research within the United States, Latin America, Europe, Canada, and Australia. Fifty-three percent of site respondents said the most significant concerns involve a lack of transparency into the itemized budget and sponsors trying to make apples-to-oranges comparisons among sites. They explained that sponsors often send templated location budgets asking one site to match the per-patient rate of another without considering the specialty differences between sites, location distinctions, and possible discrepancies in health care coverage. All the sites surveyed requested budgets at the per procedure level, and CTA contracts containing the updated language used in their previous trial. Sites also responded that receiving budgets at the visit level makes the negotiation process nearly impossible and leads to mistrust and confusion.

Figure 1 Top Site Challenges: Site Budget Negotiation Process



On the sponsor side, nearly half (46 percent) of those surveyed said that budget rules and the budget planning process are significant areas of concern. Pain points include systems and data that are often siloed and disconnected from those at trial sites. Quality control and auditing are also challenging because many sites communicate manually using email and spreadsheets. Sponsors explained that negotiating this way is daunting, and said they often struggle to decipher opaque cost structures that differ from one site to the next, while trying to stay within the study budget and keep everyone happy.

Figure 2: Top Sponsor & CEO Challenges: Site Budget Negotiation Process



The Benefits of Transparency

Many of the concerns that sites, sponsors, and CROs have can be resolved by increasing the visibility of the budget negotiation process to ensure that all parties receive appropriate remuneration for their roles in advancing clinical research. Sponsors, CROs, and sites can encourage greater transparency by taking specific actions. With access to technology and site-specific cost data, sponsors and CROs would be well equipped to treat each site individually during the budget negotiation process "Being as clear as you can upfront about your pricing for a particular project helps everyone get off on the right foot," said Dawn Pittinger, research financial compliance officer at Moffitt Cancer Center in Tampa, Florida. "At least everybody knows where they stand at the beginning."

Concerned that an itemized budget can slow the negotiation process and lead to debates over details, sponsors often negotiate budgets at the visit level with intentions to help facilitate a smoother and faster negotiation. But sites say that an itemized budget makes it easier to review costs, which speeds up negotiations and provides more visibility into the process. Additionally, sites, sponsors, and CROs agree that providing negotiators with thorough training on the protocol opens the door for effective communication regarding expected trial costs. Protocol-specific training also sets the stage for a more collaborative negotiation, increasing communication and ensuring that items specific to each trial and site are considered, further enhancing the collaboration.

Practical Solutions

According to one global payments oversight manager, when negotiating the CTA,"Your legal language for a clinical trial has to tie together your strategy, tactics, and operations into a unified, well-oiled machine. But even the most thoughtful process needs oversight to track whether things are going well and provide a feedback loop for when circumstances change." To avoid disruptions and ensure the organization can pivot quickly, it's critical to remain flexible by building and documenting substantial escalation and communication plans with all parties involved, including the clinical team, sites, CROs, legal, compliance, ethics, finance, and auditors.

Eliminating manual processes like spreadsheets and email and instead using proven and compatible applications, sites, and sponsors can transform the industry's standards. Using standardized procedures and electronic audit trails helps ensure quality control and fosters trust among all parties. "The key is to show consistency and not treat one sponsor differently from another," said Pittinger. "We've put together a packet that gives sponsors up-front information on negotiation timelines and explains the formula for how we calculate costs. This sort of clarity and transparency helps set expectations. For example, staff turnover on the sponsor side can create extra costs for our staff, so we tell sponsors up front that we will have to charge a fee after a certain amount of site monitor turnover."

The upfront sponsor packet, Pittinger said, can help sites accelerate negotiation timelines. "There's less back-and-forth," she said, "which means you have the resources to work on more studies. Streamlining the process also enables you to get trials open more quickly so that patients have a chance to benefit from therapies that may represent their last glimmer of hope."

Getting to Trust and Transparency

Sponsors, CROs, and sites can start by evaluating their budgeting processes to understand the other sides' challenges and looking for ways to collaborate on mutually beneficial agreements.

Every trial is different, and each site has its own unique needs and cost structures. All parties can build trust and streamline negotiations using detailed and itemized budgets to help each side grasp and meet the other's requirements.

Medidata's surveys found that sites, sponsors, and CROs crave more budget transparency. Each side feels the other does not understand their budgeting rules and processes. To the extent that sites, sponsors, and CROs can clarify those rules and explain their budgeting processes, they may well be able to eliminate confusion, foster goodwill, and expedite negotiations for the benefit of all involved. A mutual understanding on all sides of the negotiation process is an investment in a strong and long-standing relationship that should lead to a great patient experience.

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> *Dawn Pittinger, research financial compliance officer at Moffitt Cancer Center, Tampa, Florida*