

Perfecting The Movement

Best Practices for Clinical Trial Budgeting and Negotiation

“Everyone can dance. The key is determining what style works for you, and the partner who will best fit that style — from there, it’s just a matter of practicing and staying on beat.”

It seems like sound advice for anyone who wants to start dancing, except that this advice is about clinical trial budgeting and negotiation.

That may be surprising, but the phrase is a simple offering that IQVIA Technologies uses to outline the most important steps for clinical trial budgeting and negotiation. As most know, clinical trial budgeting and negotiation is traditionally a difficult task, much like dancing is to most. Because modern trials are often very complex, most sponsors run the risk of miscalculating the costs involved. This causes trials to stumble, pause, and adjust, much like a poorly executed dance.

To combat this, sponsors traditionally have relied on various methods of creating budgets using spreadsheets, software, portals, or other methods. While this is always a good endeavor, anyone who has worked in budgeting and negotiation knows how dynamic and volatile the environment can be. Thus, it’s important to follow some basic guidelines when budgeting and negotiating for any clinical trial.

TO START, YOU MUST FIRST KNOW THAT YOU CAN DANCE

In 2010, section 6002 of the Affordable Care Act was enacted. Commonly known as the Physician Payments Sunshine Act, this provision is designed to increase transparency around the financial relationships between physicians, teaching hospitals and manufacturers of drugs, medical devices and biologics. This is important because it’s one of many laws that allow sponsors, sites, and other members of the clinical trial community to understand the basic Fair Market Value (FMV) costs for clinical trial services. Essentially, it’s what enables the modern era of budgeting and negotiation. Since Fair Market Value (costs) have been historically difficult to determine, it’s a sensitive subject that can quickly and easily alter your relationships with sites, investigators, and vendors.

DECIDE YOUR PREFERRED STYLE OF DANCE

This is arguably the most important step when budgeting and negotiating for a clinical trial.

Sponsors must decide what items are most important to them prior to beginning the budget. Simply put, they must decide their style.

Whether it's alone or in-tandem with others, sponsors should have a firm understanding of their budgeting plan, how they are going to track progress, the methods for holding themselves accountable, and what red flags or events will trigger a revision of the budget. Once they have a firm understanding of their plan, sponsors should begin to flesh out the protocol, research and document the costs of procedures that the protocol requires, and determine responsibility for scheduling assessments and patient events. After all this has been completed, sponsors should gain access to FMV cost information and apply it to their study budget.

CHOOSE YOUR DANCE PARTNER

With a process in hand, sponsors must now establish an FMV framework that preserves the relationships with sites and investigators while being able to withstand critical examination. How do you determine what framework is the best partner for you?

Sponsors must be able to reliably and accurately gather and compile FMV data to negotiate across countries, therapeutic areas, "prestige" providers, when certain items are covered by insurance and should not be reimbursed, and finally, when to allow exceptions. Typically, this step is where most sponsors decide if they want to "go it alone" or use portals or other software. IQVIA Technologies' GrantPlan tool, for instance, contains the necessary information to create an appropriate FMV framework. The tool allows sponsors to forecast, budget and negotiate costs electronically.

PRACTICE

With a strategy in-hand and a framework established, sponsors could create a complete and accurate investigator grant budget, as well as strategically plan for possible cost-savings or for future protocol amendments. Doing so allows organizations to better hit the ground running in a live trial setting while

being prepared for the smaller nuances that may not surface during the previous steps. For example, what will the actual budget look like? Is it by line item, or by overall cost? Is the budget created alone, in a group, or by committee? Regardless of how organizations differ, they should follow some basic steps:

- Forecasting the ongoing cost of a clinical trial forecast based on FMV
- Being ready to explain the FMV framework around a trial
- Receiving budget input from multiple persons
- Implementing any suggested changes
- Gathering team approval
- Executing the budget with sites

STAY ON BEAT

Now that the budget is complete, it's time to negotiate. Remember that budgets and negotiation are living, breathing documents. You may encounter issues, such as a revision of FMV framework or exceptions. With each of these, it's important to adjust the budget, as well as the guidelines behind your framework and return to negotiation. Updating the budget and framework based on real negotiations is critically important in ensuring your organization remains agile and up to date.

JUST DANCE

While all these steps are important to prepare, it's best to remember that a dance is a coordination of two entities and may not always be smooth sailing. While the activity gets easier over time, it's not uncommon to step on toes, stumble, or even fall. However, sponsors who know their style, pick a partner, practice, and stay on beat should find themselves navigating the dance floor just fine.