

# Budget Development 101

Whether you are a seasoned expert or new to clinical trial budget development and negotiation, follow these six fundamental ideas for your next study:



**"When it comes to negotiating good budgets, GuideStar has delivered on their promise. They really know what they're doing and do it well."**

**– Clinical Research Manager,  
Hospital in Northeast**

## 1 NEGOTIATE EVERY BUDGET

Never accept the first proposed budget from a sponsor. When sponsors provide a study budget, the offered funding will most likely not cover the costs your site will incur during the course of the trial. Only the clinical research professionals at the site can understand what the costs will be.

The first step to negotiating a study budget is to conduct a detailed cost analysis of the study protocol to ensure every potential cost to the site has been identified. To justify the expense of conducting the study, the cost analysis will be a reference when the negotiation process occurs.

## 2 AGREE ON TERM DEFINITIONS

At times, the definitions your site uses for certain terms may not equate to the sponsor's definitions for those same terms. For example, what is a screen fail? Is it when a gross eligibility check has been performed on a patient's medical record, or is it when the patient has consented and is then determined to be ineligible for the trial?

While this may seem like a minor point, clarifying any ambiguous terms in the agreement will address issues and be more efficient when it's time to invoice. The easiest way to handle this situation is to develop a list of commonly used terms within your site and provide that list to the sponsor during the CTA process.

## 3 KNOW THE INTENSITY OF THE TRIAL

Understanding the resources necessary to conducting a trial at your site is critical to the negotiation of coordinator and PI fees with the sponsor. A registry trial, for example, may not be as resource-intensive as a trial conducted in the cardiac cath lab. Accurately estimate every activity the staff and PI will perform so the site is being compensated for all work conducted.

## 4 NEGOTIATE CLEAR PAYMENT TERMS

Establishing clear payment terms can mean the difference between financial success or failure. Know how much the sponsor will pay for milestones during the course of the trial, and timelines of those payments, should be clearly delineated in the agreement with the sponsor. Clarity around payments will help with allocation of revenue when checks come in, and provides legal recourse if payments are missed.

## 5 UNDERSTAND TRIAL START-UP COSTS

Underestimating the costs of study start-up or neglecting the processes for ensuring those costs are covered can have a significant impact on the site and study conduct. Sponsors will pay you for trial start-up activity, however, it is the site's responsibility to confirm the sponsor is paying for the entirety of the time it takes to complete start-up tasks, from processing regulatory documents to performing a coverage analysis. Providing clear documentation on resources is necessary to initiate the trial and will make the sponsor more likely to cover those costs.

## 6 DEMONSTRATE PROFESSIONALISM

Maintaining a professional demeanor while negotiating study budgets is critically important. Sponsors are under pressure to negotiate the best budgets within short timelines. Professionalism and clarity in communication between both parties—sponsors and sites—will help build and foster a positive relationship ultimately leading to future mutually beneficial budget agreements.