

## **How to Negotiate Study Budgets**

**By Norman M. Goldfarb**

Before a study sponsor can begin conducting a clinical research study at a site, the sponsor and site must sign a clinical trial agreement (CTA), including a "budget," which states what amounts the sponsor will pay the site for what activities. Payment terms and other provisions related to the budget might be part of the budget document but are more likely to be found in the body of the clinical trial agreement. This article will focus on the budget negotiation.

While bargaining is the process of putting forth positions without any substantive rationale until the parties meet somewhere in the middle, a proper negotiation is a constructive, reasoned way for two parties to reach a sound agreement based on agreed-upon principles.

Before negotiating a study budget, the sponsor and site should understand their own objectives. One of the sponsor's primary objectives is probably to minimize the amount it pays to the site. One of the site's primary objectives is probably to maximize the amount it obtains from the sponsor. However, these straightforward objectives can be complicated by other considerations. For example, the sponsor might place a high value on a relationship with the site, perhaps because the principal investigator is a key opinion leader. Or, the site might place a high value on a relationship with the sponsor, perhaps because the sponsor is developing a breakthrough product.

The sponsor and site should also understand their own circumstances. For example, a biotechnology company developing its first product cannot offer sites a multitude of future study opportunities. Or, a site that is already overworking its study coordinators might be very picky about the next study it conducts.

Similarly, the sponsor and site should try to understand the other party's objectives and circumstances. With such information, they can develop a strategy for the negotiation that leverages their own strengths and the other party's weaknesses. The party with the better understanding of the other party can use this information to gain the upper hand in the negotiation, but it can also use the information to benefit both parties. For example, if a site just had a big study cancelled and it knows the sponsor has an urgent need to enroll study subjects, the site can offer quick enrollment at a high price. On the other hand, if the sponsor is ready to start enrolling a study and knows the site just had a big study cancelled, it can offer to quickly fill that unused capacity at a low price. Both scenarios are "win-win," but at different price points.

### **Industry Databases in Budget Negotiations**

Two industry databases — IMS Health's Grant Plan and Medidata's Grants Manager — include comprehensive information about budgets in actual clinical trial agreements. Subscribers can see what sites charge for any study procedure, broken down by geographical region, type of site, therapeutic area, etc. They can even see an historical record of what a specific site has charged for a specific procedure.

Sponsors typically use the databases to establish pricing for a study at, say, the 75<sup>th</sup> percentile, i.e., the highest price charged by the 75% lowest-priced sites. By paying more than the average price, a sponsor can reasonably believe its study budget is more than fair. However, there are some caveats: First, the data comes from all CTAs, including those with naïve sites that do not realize they can negotiate budgets and enroll zero study subjects.

Second, sponsors often set one budget for an entire country, ignoring, for example, the difference in healthcare costs between San Antonio and San Francisco. Third, the two databases, despite their large sizes, can reach different conclusions about prices.

Sites can subscribe to these databases but generally do not do so because of the cost.

### **Fair Market Value in Budget Negotiations**

It is commonly believed that sponsors must pay all sites basically the same “Fair Market Value” (FMV) prices for conducting studies, and that any significant variation invites prosecution under the Stark law, the anti-kickback law, the False Claims Act (FCA), or the Foreign Corrupt Practices Act (FCPA), if applicable under these U.S. laws. However, in fact, sponsors can pay sites any prices they wish, provided they have a sound business rationale (unrelated to prescribing volumes), apply it consistently, and keep good documentation. For example, a sponsor can pay sites higher prices if they generate high-quality data or enroll large number of subjects (with ethical subject recruiting practices). A Ferrari F12 Berlinetta and a Kia Optima both get you from point A to point B, but nobody says they should carry the same prices. The same principle applies to clinical research services, even more so since not all sites get the sponsor from point A to point B.

If one line item in a budget is above FMV and another line item is below FMV, document that the two items balance out. If multiple line items are lumped into one line item, e.g., all the costs for a study visit, document how the numbers add up.

A sponsor is well within its rights to classify sites based on its assessment of sites’ qualifications, and pay them accordingly, for example:

- **Proven sites** deserve high prices because they have successfully conducted studies for that sponsor before, so they are likely to perform well with minimal training and monitoring costs.
- **Plausible sites** deserve average prices because based on successful study experience with other sponsors, they have a good chance of performing well, with moderate training and monitoring costs.
- **Potential sites** deserve low prices because they are new to the industry. They express good intentions but are likely to incur high training and monitoring costs, with a significant risk of poor performance.
- **Problem sites**, if they are used at all, deserve the lowest prices because are likely to incur high training and monitoring costs, with a major risk of poor performance.

If the sponsor explains this policy to its sites, it will motivate the competent ones to perform and the rest to find customers that overpay them.

Figure 1 presents four pricing scenarios. On a scale of 1 (low) to 5 (high), what pricing makes sense for each scenario?

**Figure 1: Four Pricing Scenarios**

	<b>Site 1</b> is a community hospital with 16 ongoing industry-sponsored studies, mostly part-time study coordinators, and a requirement to use their local IRB.	<b>Site 2</b> operates on a stand-alone basis, with a consistent track record of being a top enroller in the study's population.
<b>Sponsor A</b> is a major pharmaceutical company with a track record of writing protocols that are relatively easy to enroll, communicating well, being respectful of the site's time, and paying sites in a timely manner.	<b>Scenario A1</b>	<b>Scenario A2</b>
<b>Sponsor B</b> is a new biotechnology company conducting its first Phase II study, is not using a CRO, has a protocol that raises numerous questions, and seems disorganized.	<b>Scenario B1</b>	<b>Scenario B2</b>

### Coverage Analysis in U.S. Budget Negotiations

By performing a coverage analysis, sites and sponsors can identify standard-of-care tests and procedures that Medicare will cover per its National Coverage Determination for Routine Costs in Clinical Trials (310.1). Medicaid and insurance companies might also cover standard-of-care costs. Eliminating the sponsor's costs for covered tests and procedures frees up sponsor funds for other purposes (including the cost of processing Medicare claims). However, using the funds to raise prices above FMV would be hard to justify legally.

### Site Hidden Costs, Overhead Costs, and Profits in Budget Negotiations

Many sites lose money on clinical research studies — often without even knowing it — because they do not understand their costs.

For some sites, only 20% of personnel time on a study is directly billable to a study.<sup>2,3,4</sup> The rest of time consists of hidden costs that must be covered by the billable hours. If a study coordinator costs a site \$30/hour, of which only 20% is billable, the site must charge \$150/hour to break even. Other hidden costs, e.g., for dry ice, must also be covered.

In addition to the unbillable costs a site incurs when conducting a study, there are overhead (indirect) costs that must be covered before a site can make a profit, e.g., rent, electricity, office and laboratory equipment, and departments like accounting and human resources. Unlike hidden costs, such items are classified as overhead because it is impractical to assign them to specific studies. Nevertheless, they are real costs that must be covered by revenue.

Even with an operating profit, sites must still cover their cost of capital, e.g., paying interest on debt and delivering a return on the equity invested in the business. Even after covering the cost of capital, sites should still include some margin to cover risks, e.g., studies that do not meet revenue expectations, for example, due to cancellation. In addition, profits fund growth, which is a goal of many, if not most, organizations.

Some non-profits price their clinical research services at cost because they are a “non-profit.” However, “non-profit” refers to an organization’s tax status, not whether revenue exceeds cost. Non-profits are free to price their clinical research services to generate “excess revenue” that supports other research, a new building, or other goals of the organization.

A study budget that covers the variable costs in a study but not its share of the site’s fixed costs, might be acceptable as a stopgap measure, but it is not a recipe for long-term financial viability. A site might be willing to lose money on clinical research to serve other objectives, such as marketing or physician retention, but it should understand the cost it is paying. It is hard for sites that want to be — or have to be — profitable to compete with sites that, knowingly or unknowingly, operate at a loss.

### **CROs in Budget Negotiations**

Study sponsors often outsource contract and budget negotiation to a contract research organization (CRO). The CRO might have responsibility for a broad range of study functions or just be responsible for the CTA and budget.

While CROs are employed by sponsors, their objective is to complete the study on time and on budget. For that, they need sites. CROs thus see themselves as facilitators who help sponsors and sites find common ground. Nevertheless, sites often find negotiating with a CRO to be frustrating. The CRO’s job is to negotiate the budget, not to escalate the negotiation to the sponsor so it can negotiate the budget. Since the sponsor typically gives the CRO a certain amount of flexibility but no more, the CRO cannot agree to the site’s request and may be unwilling or unable to escalate the issue to the sponsor. If the site has an existing relationship with the sponsor but not with the CRO, it is thus blocked from leveraging that relationship with the sponsor. On the other hand, as CROs develop strong relationships with sites, the dynamics reverse.

CROs typically bid for study contracts with sponsors. Sponsors would rather pay a low price than a high price, so CROs look for ways to reduce their costs on a study. One way to reduce the cost is to assign budget negotiation to low-level administrative personnel with minimal understanding of study budgets and very limited authority to negotiate. However, the trend is for CROs to accelerate negotiations by assigning skilled negotiators that do understand budgets, and give them more authority. Escalation to the sponsor might still be required, but it might be required even if a CRO is not involved.

It is a common belief among sites that sponsors give CROs an overall site budget, so the CRO gets to keep any savings but also absorbs any overruns. In fact, most sponsor/CRO contracts treat site payments as a “pass through” cost, with a fee-for-service charge for the negotiations. Thus, a CRO might be *more* flexible on study budgets than their sponsor-customers. On the other hand, sponsors prefer CROs that stay within the overall study budget, of which site payments are a part, so CROs are accountable in that way.

### **Negotiation Goals**

A negotiation implies the existence of goals. In the case of a clinical study, the explicit goal of both parties is for the site to conduct the study for the sponsor. Other common goals might include the following:

- Agree on a fair budget that makes economic sense
- Conduct the study quickly and smoothly
- Minimize the administrative burden of negotiating the budget
- Avoid unpleasant surprises

- Create or strengthen the relationship for future studies

In addition, the sponsor might have its own goals, such as the following:

- Pay for performance, e.g., completed study subjects
- Build relationships with key opinion leaders
- Minimize regulatory and legal risks

Sites might also have their own goals, such as the following:

- Help the subjects in the study
- Improve healthcare for the site's community
- Build the site's reputation for cutting edge healthcare
- Advance scientific knowledge
- Retain the site's relationship with the investigator

The investigator might also have personal goals, such as the following:

- Publish articles
- Build his or her professional reputation and relationships
- Satisfy intellectual curiosity
- Take a break from clinical care

Clearly, each party should understand its own goals. To the extent possible, they should also try to understand the other party's goals. However, in some cases, they should keep their goals to themselves. It is probably unwise to reveal any goal or circumstance that significantly weakens the party's strength in the negotiation. For example, if the sponsor learns that the site's chief of cardiology will leave if the site does not secure the study, the sponsor's hand in the negotiation becomes very strong.

### **Ethics in Budget Negotiations**

Clinical research ethics should extend beyond the welfare of study subjects to the business practices between organizations. Ethics becomes an issue in budget negotiation when one party unfairly takes advantage of the other party. Ethical behavior in a negotiation means treating the other party honestly and fairly. The following scenarios appear to exhibit unethical behavior (but there are often shades of gray):

- The sponsor withholds critical information about a study, e.g., a problematic exclusion criterion.
- The site assures the sponsor that it can easily enroll patients in the study, when it knows the contrary to be true.
- The sponsor falsely tells a naïve site that "everyone else is accepting the proposed budget."
- The site implies that the investigator's prescribing practices might be influenced by the budget.
- The sponsor takes advantage of its knowledge that the site desperately needs to study to survive.
- The site takes advantage of its knowledge that the sponsor desperately needs its rare patients ("price gouging").

Acting unethically often means trying to gain a short-term advantage in exchange for risking a long-term disadvantage. In the examples above, behavior that the victimized party deems unethical might damage the other party's reputation in that organization, throughout

the clinical research community, and even within the transgressor's organization, with potentially serious costs. In contrast, ethical action helps create good will, with substantial long-term benefits. Simply put, good ethics is usually good business. Sharp practices can carry a cost.

## Relationships in Negotiations

"A relationship is why you should give the other guy something specific in exchange for something abstract."

Negotiating with a friend is much easier than negotiating with a stranger, and much, much easier than negotiating with someone who has reason to question your integrity or good will. A budget negotiation is thus an opportunity to build a relationship that will smooth progress in the current negotiation, in the current study, in future negotiations, and in other business interactions. Clinical research professionals have friends, and they tend to move around, so a positive relationship with one person in one organization can propagate to multiple people in multiple organizations.

During the negotiation, think about the qualities that make for *any* good business relationship:

Reliability	or	Unreliability
Sharing	or	Withholding
Openness	or	Secrecy
Honesty	or	Deception
Flexibility	or	Rigidity
Competence	or	Incompetence
Error-free	or	Error-prone
Punctuality	or	Tardiness
Generosity	or	Me, me, me

The relationship between a sponsor and a site changes when the CTA is signed. Before the CTA is signed, the sponsor's focus is on securing sites that will perform well under terms acceptable to the sponsor. After the CTA is signed, the sponsor's focus is on ensuring that each study site performs well, even if the sponsor has to make certain accommodations for the site. The reason is that, after the CTA is signed, the sponsor becomes invested in the site, not only with time and money, but also by relying on the site as an important contributor to the study that is not easily replaced. As a result, after the CTA is signed, the sponsor becomes more accepting of a site's shortcomings. In contrast, before the CTA is signed, the site's focus is on securing the contract to conduct the study. After the CTA is signed, that pressure relaxes and the site's expectations of the sponsor increase.

The net result is that, before the CTA is signed, the site is relatively flexible, while after the CTA is signed, the sponsor is relatively flexible. This change in the relationship can create issues, but, with subsequent studies, as the sponsor and site get to know each other, the relationship should stabilize. The parties should consider this dynamic when trying to understand what is going on during a budget negotiation.

## Negotiation Tactics

A budget negotiation, like any negotiation, involves the use of tactics, i.e., how you go about conducting the negotiation. The following tactics can be used by both sponsors and sites in a budget negotiation:

- **Differentiate.** Enter into the negotiation knowing that every sponsor and every site is unique. Not only that, they might have changed since yesterday.
- **Know what you want.** Before beginning a negotiation, decide what you want to obtain. That budget should be the highest you can reasonably expect. Don't be afraid to ask for it. Set priorities. The party in a negotiation who wants more is more likely to get more.
- **Know what you need.** Before beginning a negotiation, decide what you need to obtain — the lowest budget you can accept. Be prepared to walk away if you cannot meet this objective. Employ the concept of "Best Alternative to a Negotiated Agreement" (BATNA). In other words, do not sign an agreement with one partner if it is worse than signing an agreement with a different partner.
- **Perform a coverage analysis.** Both sponsor and site should assess for themselves what costs Medicare and other third parties are likely to cover.
- **Know who you are talking to.** Find out what authority your negotiation partner has and how they fit within their organization. In their organization, who has what decision-making authority, and what is the process for obtaining decisions? Give your negotiation partner the same information about you and your organization. Learn about their expertise and experience, how much time they have for the negotiation, and how they like to negotiate. Find out what personal interests you have in common.
- **Know who needs whom.** Does the sponsor need the site more than the site needs the sponsor? Are there lots of other sites that can perform that study well? Are other good studies competing for the site's attention?
- **Understand their objectives.** If you agree on the priorities, e.g., signing an agreement quickly, you can work together to accomplish those priorities. If you care about one thing and your negotiating partner cares about something else, you can make a tradeoff. If you and your negotiating partner strongly disagree about an important objective, e.g., the total budget amount, it's better to know sooner than later that it might not be possible to reach agreement.
- **Don't make assumptions.** You cannot know with certainty why your negotiating partner is taking a particular position. For example, you might disagree on the price of a procedure because you are talking about different procedures. Articulate what appear to be assumptions so they are no longer assumptions.
- **Negotiate professionally.** Be honest, respectful, courteous, prompt, reliable, responsive, constructive, trustworthy, etc.
- **Communicate clearly.** State your questions and positions clearly to minimize misunderstandings. If you are not sure your negotiation partner understood what you meant to say, follow up appropriately. Similarly, communicate that you have or have not understood something your negotiation partner said.
- **Listen.** Listen to what your negotiation partner is saying (or not saying), and try to figure out what it means. He or she might be afraid to say something directly, so you might have to ask for clarification.
- **Just ask.** If a piece of information would be useful to know, just ask your negotiation partner. For example, the authority of the person with whom you are

negotiating probably has limits. If you know those limits, you know what you can obtain in the negotiation without involving someone with more authority (escalation).

- **Have alternatives.** Your negotiation partner likely has flexibility in some areas but not others. He or she might like doing things in one way but not another. If you have alternatives, you are more likely to find a solution that is acceptable to both parties.
- **Think relationships, not transactions.** Driving too hard a bargain can poison your relationship during the study. Achieving your negotiation objectives for one study is not as important as achieving them for many studies. You might not conduct another study with this particular site or sponsor again, but your negotiation partner might move to a different organization.
- **Say “no.”** However, leave the door open to possible solutions. Saying “no” communicates strength. Say “no,” and your negotiation partner might suddenly discover new flexibility. If you never say “no,” you will never learn the limits of your negotiating power. If you reach agreement with every negotiation partner, you probably need to ask for more.
- **Show both interest and confidence.** On the one hand, your negotiation partner will not want to invest time in a negotiation with someone who is not motivated to reach an agreement. On the other hand, showing too much interest suggests desperation driven by some hidden problem. By adding confidence to interest, you show you are highly motivated and also fully expect to obtain a satisfactory agreement.
- **Work under realistic expectations.** When beginning a negotiation, explain to your partner what he or she can realistically expect from you for the content and the process of the negotiation. Identify any areas where you have no flexibility or authority, and obtain the same information from him or her.
- **Manage negotiation as a business process.** Agree on a timeline and process and hold both parties accountable for following the process and meeting their milestones. Keep your negotiation partner informed on your progress.
- **Don’t assume ulterior motives or take things personally.** Your negotiation partner, like you, is just trying to negotiate an agreement. If he or she acts unprofessionally, it’s his or her problem, not yours.
- **Train your staff.** Ensure that anyone negotiating on behalf of your organization is competent to perform their role.
- **Standardize.** Follow a consistent process, use a standard budget template, and present prepared arguments. Then manage performance.
- **Prepare for objections.** If your initial position is not accepted, be prepared with a well-considered justification. If that justification is not acceptable, have a back-up position, if possible, that is consistent with the principles behind your initial proposal (to preserve your credibility). Consider starting with your back-up position to save everyone’s time.
- **Choose your battles.** Focus on the bottom line. However, the initial proposal might be very one-sided on the minor items, with the expectation that you will focus on the major items, so consider addressing all the minor items in one discussion.
- **Respond meaningfully.** If you do not agree on a point, explain why. If you escalate an issue, a negative response should come back with an explanation.
- **Do not make unilateral concessions.** Always look for a trade-off that is more important to you than to your negotiation partner.
- **Create a sense of urgency.** If a negotiation is moving too slowly, motivate your partner to help restart it. Creating a sense of urgency is more difficult if the budget

negotiation is not on the critical path. However, you could say, "We don't seem to be making progress, so let's set a deadline. Does September 30<sup>th</sup> work for you? If not, perhaps we should just call it a day and try again with another study."

- **Trade fixed vs. variable costs.** Increasing a variable cost (e.g., per subject) in exchange for decreasing a fixed cost (i.e., per study) works to the advantage of the site if the site exceeds expectations, and to the advantage of the sponsor if the site does not meet expectations. It is a sign of confidence when the site proposes such a trade.
- **Review previous budgets.** Compare the current budget to any that the parties have negotiated previously. If the parties agreed on a price for a procedure last time, why has it changed this time?
- **Pre-negotiate prices.** If you are negotiating a master CTA, also negotiate a standard price list.
- **Manage the queues.** Most of the calendar time in a negotiation is spent waiting for someone to respond, often because there is a queue of matters to address. Track the queues and response times, and address any problem areas.
- **Document interim steps in the negotiation.** Without documentation, an interim agreement might get lost.
- **Measure performance.** Compare your initial positions with your final agreements. Identify areas where you are always successful, sometimes successful, or never successful. Analyze the reasons and change your strategies and tactics accordingly.

## Site Negotiation Tactics

Sites can use the following additional tactics in a budget negotiation:

- **Make sure your site wants the study.** Before entering into a negotiation, make sure all the necessary decision-makers, clinical research personnel, and departments actually want to conduct the study.
- **Assume you can negotiate.** Sponsors are almost always willing to negotiate the budget for Phase I-III studies, even after they say the budget is non-negotiable. However, they might stand firm, perhaps because the study is extremely attractive to sites.
- **Read the protocol and other study documents.** Are there ambiguities? Review budgets from previous, similar studies and get input from the study coordinator, lab nurses, research pharmacy, etc., on activities that are completely missing. Are the EDC/eCRF forms available? It is not uncommon for sponsors to leave study activities out of their budget template because of an oversight or because they believe the activity should not be billable to the sponsor. Document in the CTA or an email that undisclosed, understated or new study activities will be billable.
- **Create your own budget template.** Use your own spreadsheet to analyze the study budget in a consistent manner. However, respond to the sponsor using its template. If the study budget includes only single, aggregate line item for a visit, break it down to the level of detail you need to fully understand the costs. (If you need to justify your costs by showing the details to the sponsor, keep in mind that they might view this as "nickel and diming," so keep the focus on the aggregate amount, with the details as supporting data.)
- **Provide your standard price list.** Sponsors are more likely to increase the budget if you can persuade them that you have to stick your site's standard rate schedule. Of course, it actually has to be a standard price list.

- **Justify your costs.** Sponsors are more likely to increase the budget if you can persuade them that their initial proposal will not cover your costs. Employ evidence from cost analyses, previous studies, and other sites, if available, that your prices are commercially reasonable. Provide documentation that demonstrates the diligence of your processes and the quality of your work.
- **Demonstrate value.** Sponsors are more likely to increase the budget for sites that will perform well, especially by enrolling subjects and generating high-quality data.
- **Use Invoiceables Judiciously.** Invoicing for contingent costs like advertising looks simple, but it creates a burden on the site for generating the invoices and collecting payment, as well as on the sponsor for approving and paying the invoices.
- **Talk to other sites.** Share information with other sites about how to negotiate with various sponsors and CROs. However, respect the confidentiality of information that you have agreed to keep confidential.

## Conclusion

Negotiating a budget can be a frustrating process, but is also an opportunity for a sponsor (or CRO) and a site to learn whether they can work together and how to work together. Budget negotiators thus play an important role in establishing a relationship between the parties that grows stronger over time. If the parties genuinely cannot come to terms that is fine, but it is a lost opportunity if they could have come to terms with a better negotiation.

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