TIPS, TACTICS AND INSIGHTS FOR RESEARCH SITES

Better Budgets, Better Negotiations

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Negotiations should be a win-win in theory. In practice, sites, sponsors and CROs often fall short--typically because they don't fully understand the needs and wants of the other party. Sometimes, sites don't even understand their own budget requirements.

Jill Shilbauer, Director of Strategic Initiatives, WCG Clinical Services, took this on during a recent MAGI session, "Budget Development & Negotiation for Investigative Sites." The session, which she facilitated, focused on sites, but proved illuminating for CROs and sponsors as well as sites.

The insights provided by the session fall into three broad categories: Understanding the needs of the person at the other side of the table, knowing your own research costs, and negotiating 101.

INSIGHT AREA 1

Who Needs What? Three Perspectives

"Regardless of how we classify ourselves, we want to be able to share with each other, our experiences. We want to listen and learn from each other," she said. She asked panelists to discuss what they wanted and needed from budget negotiations; the responses provide a pre-negotiation checklist that can improve and even accelerate negotiations.

INSTITUTIONS NEED:

- A budget that covers the costs of research.
- An opportunity to show sponsors hidden or missed expenses in the protocol and budget.
- The ability to motivate the study team and support any of the ancillary departments that may be involved in the study.
- Resources that will support enrollment.
- A fair negotiation process where both sides can discuss what's required, what's necessary and what are reasonable costs for the institution.

INSTITUTIONS WANT:

- An initial budget from sponsors that is both

a reasonable starting place and respectful of the amount of work required.

- A transparent negotiation process that allows for real conversations with sponsors about anticipated costs of procedures, enrollment, etc.
- To satisfy institutional stakeholders by showing that a study is not only valuable for the institution's mission but also that it can advance the science and patient care.

INDEPENDENT SITES WANT/NEED:

- To have their voices heard and understood.
- Timely responses to requests.Acknowledge receipt and provide a timeframe for expecting a response. "Let us know when you're going to get to it," said one panelist.
- Specific feedback: Don't simply say the budget is too high; identify the issues. Have a conversation and give specific feedback. That way, the site rep can be better prepared for the next round of negotiations.
- Consistency within therapeutic areas. "If I just negotiated a COVID-19 budget two weeks ago, I would expect a very similar if not identical budget for a COVID-19 study today," explained a participant.
- Access to the sponsor when necessary. "Sometimes there's a roadblock put up, whether the CROs do it just because that's their function or the sponsors ask the CROs to do that. We do want to have a path to get to the sponsor if questions arise," said one participant.

SPONSOR AND CRO PERSPECTIVE

The sponsor and CRO perspective included many of the points made by the site representatives, as well as these:

- Keep in mind that each budget is unique. Each budget is considered individually, so what's approved for one site isn't automatically approved for the other. It's never going to be an apples-to-apples comparison.
- Understand the broader perspective. Sites forget that the investigator payments or the site payments are only one portion of the overall study budget.
- Use the sponsor/CRO template. Some sites prefer to use their own template, but that often causes longer negotiations. When the sponsor develops a project, it's working with several departments, including legal, compliance and clinical operations.

INSIGHT AREA 2

Insight Area 2: Know Your True Costs

A common theme throughout the discussion and workshop was knowing the true costs

of performing research, and panelists agreed that sites need to develop and maintain a fee schedule/policy and/or work from a research chargemaster.

Sites, regardless of the type, need a standard price list for certain pass-through costs and big-ticketed procedures. "It makes it easier from the sponsor or CRO perspective because then we know exactly what to expect when working with your site for the study," said one sponsor/CRO panelist.

Another panelist specifically advised using a list of standard procedural costs for your site. "We've created a standard list of fees, and it's very easy. And we've created a justification list to say, here's what it costs and here's why we're charging this, please consider this." Some sponsors and CROs want to use per-visit budgets. "I personally do not like that. You need to look under the hood and see what's there; you need…to break it down per procedure."

Along those same lines, some panelists cautioned against reinventing the wheel. If you recently negotiated a budget with the same sponsor or CRO, use those fees as a benchmark.

They offered several other recommendations about fully understanding a study's cost:

- **Know the protocol:** Review the protocol in detail and flag questions—then ask those questions as early in the process as possible. "One thing I would emphasize is that even with your chargemaster, you have to know what's in the protocol and what's required of you as a site in order to determine your final fee," Shilbauer said. For instance, the informed consent cost will vary widely between a COVID-19 study and a comprehensive oncology trial.
- **Know the law:** For example, in Pennsylvania, the PI must handle the informed consent process. It cannot be delegated. That will likely be more expensive than a site in a state that doesn't require the PI to complete the informed consent process. That will affect costs.
- **Include all your costs of doing business:** Be sure to factor in onetime fees. Identify procedures that must be outsourced and calculate the full cost. When you're dealing with third-party vendors, there's a cost to that, from outsourcing x-rays to sending somebody down to the Publix to get that dry ice. Do you have to reach out to vendors outside your organization or to another department that's not necessarily fully involved in the research? Find out the costs and build out your budget appropriately.
- **Create a Medicare Coverage Analysis ("MCA")**: This can become a source for not only talking through the budget with sponsor, but it also becomes a valuable tool internally in the hospital/clinic setting to assist with billing compliance and for being able to build the budget accurately into patient financial systems and clinical

trials management software. (See sidebar for more on MCA.)

- **Gather all the information you can:** Panelists emphasized the importance of gathering all the documents required to build a budget. Start with the protocol and the schedule of events, and line that up with informed consent, even if it hasn't been finalized. From there, ask for other material, including pharmacy manuals, pathology manuals and investigator brochures. Then find out the volume of eCRFs and what that will mean for your study teams. In fact, throughout the process, work with your study teams and PIs to help you better understand the clinical information in the protocol.
- This not only makes you fully prepared, said one of the panelists, but "the sponsor and the CRO will respect that you've done your due diligence and know what you are talking about."

It all comes down to building out exactly what's involved in the study.

INSIGHT AREA 3

Negotiations 101 - Making negotiations a win/win

To wrap up, Shilbauer turned to the institutional, independent site and sponsor/CRO representatives to offer some final words of advice to sites—some of which apply equally to sponsors. Many of the recommendations seem basic, but they too often go unheeded.

- **Respond to inquiries in a timely manner**—even if you don't have an answer right away.
- **Communicate, communicate, communicate.** Communicate reasonable expectations and keep the lines open. "If you're not hearing back from someone or having trouble reaching them, use the old-fashioned telephone. That's what I can't say enough about. It really does help," said one participant.
- **Go high the first round** so you have room for compromise later.
- **Time is money.** Keep the process moving forward, which means making only reasonable requests.
- **Talk about your site's value to the sponsor.** Can your site handle complex protocols? Does it have specialized laboratory facilities? Are investigators recognized leaders in their field?
- **Be respectful and professional; you'll see these people again.** Respect people as colleagues in this industry. "You don't want to win the battle and lose the war. You will cross paths with these people in the future," said one panelist.
- **Be willing to walk away.** Sites should agree

only to budgets that are adequate for the conduct of the study. It is okay to say "no" to a budget that will not cover your site's expenses. Ultimately, there may be times that as a site, you decide to accept a lower budget instead of walking away. For instance, the doctor really wants to participate in the trial to give access to the drug to patients who wouldn't otherwise have it. Or you want to get your foot in the door with a sponsor for the first time. This is certainly acceptable—as a site you just need to understand the long-term consequences of a decision of this nature.

- **Be flexible and creative**. "If sponsors tell me that they can't pay me any more money for startup, then I'll say, 'Well, where can you pay me some more money? Do you have other buckets you can put this into? Are there things that I haven't asked for that you would offer?'" Her rationale is simple: "You don't get what you deserve, you get what you ask for. So ask."

So much of budget negotiation comes down to knowing your budget in detail, understanding the sponsor's perspective and being willing to compromise, Shilbauer said. "Enter the negotiation knowing what your objectives are, and ask about those of the other party," she said. "It should be a collaborative process, not an adversarial one."