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April 5, 2017

Fiscal Responsibility and Discipline: Budget, Negotiation, Schedules, and Terms

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Forbes Article

by Matthew Harper | Feb 10, 2012

“ During the Super Bowl, a representative of the pharmaceutical company Eli Lilly posted on the company’s corporate blog that the average cost of bringing a new drug to market is \$1.3 billion, a price that would buy 371 Super Bowl ads, 16 million official NFL footballs, two pro football stadiums, pay of almost all NFL football players, and every seat in every NFL stadium for six weeks in a row.”



One Sponsor's Perspective

Building a study budget can be complex yet maintains some simple criteria

- A study budget should compensate a site for work/services performed (e.g. protocol procedures, PI/SC personnel time)
- A study budget may also contain funds for non subject related costs (e.g. IRB related fees, administrative start up costs)
- A study budget must be within Fair Market Value

One Sponsor's Perspective

A clinical trial contract and the negotiation

- The clinical trial contract outlines the terms, conditions and performance expectations for the execution of the clinical trial
- Is a legal binding contract
- Will look different and contain different provisions from sponsor to sponsor
- Sponsor wants to finalize contract quickly to move on to start up activities

One Sponsor's Perspective

Payment to clinical sites

- Payment methods may vary from sponsor to sponsor and even from study to study from the same sponsor
- Payments should be for work performed
- Payment schedule, methodology, and amounts should be discussed upfront
- All fees to be paid to site should be explicitly listed on the executed study agreement

One Sponsor's Perspective

- Study sites should be fairly compensated for work performed
- A comprehensive review of budget/contract/payment must be completed and site/sponsor agree upfront on terms
- Clinical trials must be cost effective
- Important to build a good working relationships with investigators, study staff and the site operational team
- Without experienced and competent investigators and their respective teams, new medicines cannot be brought to patients

Mitigating budget finance pain-points

➤ **Tight budgets mentioned far more often than any other finance-related issue**

➤ **Strategies to address challenges:**

Well trained staff that:

- Reviews the protocol/schedule of assessments and can build their own cost assessment and supply “justification”
- Determines site personnel time
- Knows site’s start up costs, fee schedule, overhead costs or any non-subject related fees
- Communicates with others at site regarding fees (e.g. PI, SC, pharmacy dept, radiology dept)
- Leverages “lessons learned” from previous clinical trials
- Proactively asks any questions to Sponsor

Mitigating contracting pain-points

➤ Lengthy contract negotiations

➤ Strategies to address challenges:

Well trained staff that

- Are supportive of “Master Agreements” to shorten future contract negotiations
- Takes the time to understand the contract terms and can supply “justification”
- Identifies and/or escalates any terms that are “deal breakers” and proposes alternative language
- Communicates with stakeholders at site regarding contract terms (e.g. PI, SC, financial dept)
- Leverages “lessons learned” from previous clinical trials or contract negotiations
- Proactively asks any questions to Sponsor
- Are available and comfortable discussing contract concerns with sponsor

Mitigating payment pain-points

Delayed or outstanding payments

Strategies to address challenges:

Well trained staff that

- Are identified to help follow up on payments
- Follows a budget for the duration of the study (e.g. are there annual costs to invoice for?)
- Understands the payment methodology, schedule, and timing upfront
- Understands budget line items
- Leverages “lessons learned” from previous clinical trials
- Proactively communicates concerns with sponsor

Mitigating site “cash flow” concerns

➤ Cash flow patterns are of particular concern. Questions for the site to consider, which may serve as a significant opportunity for easing this pain-point include:

- Has the site invoiced for all the non-subject related fees so not to leave “money on the table”?
- Is there a payment trigger that they have control of that will create faster payments?
- Was the original budget negotiated still realistically covering the costs that were determined at the beginning?
- Is there extra personnel work during the course of the study that was not adequately budgeted for at the start?
- Is there a sponsor delay of payment that needs to be escalated?



Possible Misconceptions

Survey response: Perception that CROs assume a portion of the budget Sponsors allocate for studies

Key Takeaways

- **Contract negotiations and payment issues do not seem to be a primary deterrent keeping investigators from engaging in clinical research, however it's cited as an area of concern/frustration.**
- **Budgets can be a deterrent keeping experienced investigators from engaging in clinical research as they have developed the realistic knowledge/skills to understand when it's time to walk away from a trial due to finances.**
- **Investigators need to have good study support staff, who have experience in trial finances and contract negotiation and will involve the site stakeholders in key aspects of the contract/budget/payments.**
- **Sites have a responsibility to develop appropriate study budget and be able to provide “justifications.”**
- **Site staff and investigators should engage in conversations with**

THANK YOU.



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