

ISSUES IN CLINICAL TRIALS MANAGEMENT

Negotiating budgets: insights from your CRO/sponsor

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In order for the relationship between pharmaceutical companies and independent sites to continue, adequate compensation must be provided to these research centers. Pharmaceutical companies understand this and are interested in providing the funds needed to conduct the highest quality research. At the same time drug companies also have a fiscal responsibility to their shareholders and potential customers. As a result it is important they retain a level of frugality and responsibility that will provide maximize return for everyone. This article discusses insights centers can use as they work with pharmaceutical companies and contract research organizations to meet their mutual objectives of fair compensation for work performed.

Key Words: Budget negotiations, contract, compensation, drug development

New compounds and medical devices are emerging at a faster rate than ever before. This is due largely to the size of today's aging population and a general public with the best prescription plans and health care coverage of any generation. Together these ingredients provide the incentive for pharmaceutical companies to contribute the \$350 to \$500 million necessary to develop each new drug.

Pharmaceutical companies rely on the objectivity of large numbers of independent research sites. The input from these centers provides the pharmaceutical companies with the confidence of knowing they are receiving unbiased insight into the effectiveness and possible side effects of new medications. This impartial information is then forwarded to the FDA as evidence of the compound's value.

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Listed below are insights centers can use as they work with pharmaceutical companies and contract research organizations (CROs) to meet their mutual objectives of fair compensation for work performed.

Remember to look at the big picture

Nikhi Fernandez, the administrator for Westlake Medical Research, explains the focus of his relationship with sponsors. "I consider each study to be a part of a long term relationship," he states. "We do not try to gain the maximum amount of money we can squeeze from each contract. Instead, we concentrate on a fair price, in a congenial manner, so we both look forward to working on future projects." Pushing for the highest amount of money possible for each aspect of a pending study might provide a good immediate return. But if it puts too much strain on the relationship with the sponsoring company, the money made on this study may be lost many times over if they do not return with future business.

Retain a reputation for reliability

When discussing a contract, consider carefully your ability to conduct the study satisfactorily. Dr. Paul Sandall of Health Research, Inc., emphasizes his site's ability to produce the desired results. He teaches his staff to look carefully, at the criterion for patient enrollment. "If we can't produce the desired patient population, we exclude ourselves from the study," he explains. "Our intent should be to reach full enrollment every time." The site that only accepts studies in which it believes it can be successful will gain a reputation for reliably in achieving its commitments and obligations. Such investigators are retained on the "A" list for future projects.

Rational pricing

Know your prices. Do your homework before you set a price. The CRO knows the price other sites are charging for services. In fact, most sponsors provide a sample budget based upon their continued exposure and experience in the cost of doing business. Sample budgets are provided as a realistic guideline by which the sponsor, CRO and site can gauge their overall cost of completing the study.

If it costs your site a little more for a given procedure, let it be known. Universities for example often have overhead costs ranging from 20% to 40% higher than independent research centers. If your site is sincerely interested in a study but needs additional funds for overhead or to acquire the services of a cardiologist, purchase a freezer or for other requirements, let your needs be known. If you have been identified as a good site the sponsor will generally work with you.

Recapture hidden costs in areas intentionally inflated

There are many hidden costs associated with conducting a study. Most of these costs can be covered under an umbrella allowance identified as overhead. Because the cost of doing business is different for each site, prices are sometimes inflated in an effort to provide an area for financial expansion. For some sites this will mean greater profitability. For others it will mean the difference between being able to participate or not.

An example of an inflated price is the stated price for completing an EKG. Payment of \$100.00 may be listed on the proposed budget with the understanding that the actual cost is much less. Most centers own the EKG machine outright and have trained staff who perform and read EKGs as a routine part of their duties. Since the time it takes to perform and read an EKG is minimal the result is a true price that is a fraction of that provided by the sponsor.

Religiously examine the fees others charge for services

It is essential to be "in the know" when it comes to the costs incurred, prices charged and mode of payment required by others. Articles in periodicals and newsletters are often useful in identifying these issues. It is also helpful to discuss fees with your colleagues. If other centers in your area are only charging \$50.00 for a routine patient visit and you are getting \$75.00, find out why. It could be they are getting additional fees for basic phlebotomy, preparation of certain laboratory work, each blood pressure taken or CRF completion that you consider a part of a routine visit. The true amount they get for each patient visit may turn out to be much greater than what you receive.

Remember, a proposed budget is just that-proposed

Don't be afraid to push the edges to see if you can get additional funds. It is important to provide solid rationale to support each increase, but do not be afraid to ask. This may be as simple as stating, "Our standard fee for each history and physical is \$200.00 not the \$100.00 proposed" or as complex as a detailed spreadsheet that provides a breakdown of all costs that are a part of your proposed increase.

The person discussing the budget with you has been given a set of guidelines with which to work. These guidelines are based on an overall project budget. Generally there are areas in which they have been given authority to increase the amount that is offered. The total of such funds seldom exceeds 10%.

Sometimes any additional money granted beyond what is listed in the proposed budget will need approval from the project manager. The project manager sees the big picture and is responsible for controlling the cost of the total project. Funds granted to you that are outside the scope of what was originally proposed may mean less money available for other sites or the need to expand the overall budget, something the company will be reluctant to do.

It may be there are not sufficient funds available to accommodate your request. If not, there are three options available. One is to decline the opportunity to participate in the study. After all, it may not be fiscally prudent to be in the study if you are losing money. A second option is to conduct the study without the increase. The third option is to explore a compromise. This could be fewer funds than requested but more than originally proposed. Another alternative might be to enroll more patients in the study than first discussed. The opportunity to increase the

number of patients will sometimes provide sufficient volume to improve the profit margin and make the project worthwhile. The selections of compromises are limited only by the imagination of the parties involved.

An administrator in the mid-Atlantic region stated that during budget negotiations he always asks, "Can you do any better than that?" Sometimes the person from the pharmaceutical company will come back with a new number, one that is sometimes more generous than expected. Other times they will let him know the price is set and he is not allowed to budge or which areas contain some elasticity.

Most budgets contain some degree of flexibility. This plasticity can only be determined if you are bold enough to ask for an increase.

Remain specific

Know up-front what is expected from you and what you can expect from others. The procedures in the protocol and budget may seem clear but there are often small items that need to be addressed. Who, for example, pays FedEx for returning unused copies of the 160page case report form (CRF) to the CRO? Who pays for shipping the weekly lab samples or for the dry ice needed to pack blood samples? If these are included in "general overhead" be sure to calibrate the expenses carefully at the beginning of the study. Hidden costs can cut into your revenue and hurt your ability to pay your staff.

Avoid being a regular nibbler

Nibblers are defined as individuals who continually seek additional funds after the budget and contract have been signed. A change in protocol or an amendment may provide reason to reexamine fees agreed upon previously. They know the sponsor has invested a great deal of money in the site and count on their willingness to pay a few dollars more to insure the site remains an enthusiastic part of the study. Such anticipation is not always warranted and must be justified. Legitimate reasons for a reexamination of cost of service performed are varied. Justified reasons for evaluations may include:

- a change in the protocol that requires additional procedures be performed
- an excessive amount of time spent by staff in conducting duties due to changes in the protocol or a poorly designed remote data entry system
- additional IRB fees accumulated due to an additional protocol and informed consent reviews
- fees for advertising
- unexpected transportation fees, cost for food or lodging related to acquiring patients
- the acquisition of equipment that must be purchased in order to conduct the study such as computers, freezers, fax machines and the installation of analogue lines for computer modems
- replacement of equipment which wears out or breaks down and must be replaced during the course of the study.
- an abnormal amount of time spent resolving queries due to changes in the CRF or as the result of poor monitoring

Nibbling is sometimes justified, but some sites are too aggressive in their desire to get another bite of the sponsor's money. For them, every small change in a procedure or unexpected expense results in a request for more funds. The site that is overly aggressive in nibbling quickly gets a reputation of being greedy. This inhibits their chance of participating in future studies.

Realistic payment schedule should be a part of every contract

Negotiate a realistic: payment schedule. Cash flow is important to most sites. Payments that are based upon the number of patients who complete the study may leave a site with financial stress as they wait for a bolus payment that may take 6 to 9 months to obtain. Delays in drug shipment, the redesign of a CRF, protocol changes or a study put on hold can also keep payments from flowing. If cash flow could be a problem ask for a change in what triggers payments. It may be more equitable to ask for payment based upon the number of visits or procedures performed. Explain your situation and set milestones reasonable to both parties. The administrator of a site in the Pacific Northwest complained bitterly about this problem. "I had to take out a loan," she explained, "just to cover payroll. Companies need to consider the sites need for cash flow when putting together their payment schedules."

Revelation of who writes the checks

Determine from the very beginning if checks are generated by the CRA, project manager or someone in the office of business development or accounting. Once you find out who this person is, talk with him or her personally. Ask the nuances of how check requests are made, what the expected timelines will be and where the money will come from.

Ideally, the CRA will generate the check based upon targets outlined in the contract; a check request is generated and money is transferred from an account in which the sponsor has placed money for this project. However, too often this is not the case. It may be that people in the data department periodically assess the number of CRFs reviewed by their department and leisurely report to the accounting department when a block of checks are due. This can create a significant lag time from when CRFs are collected and when payment is made. Sometimes the accounting department must make a request to another department or to the sponsor for funds causing still another delay.

Site personnel can protect themselves by discussing with the person who triggers payments when milestone payments are due, learning first hand the companies operational procedures and giving this person a friendly "heads up" when funds are due.

Relationships should be kept friendly throughout the study

Cordiality plays an important role in the negotiation process. Kind words and a gracious tone can be an important investment. Most negotiations are done on the telephone, not face to face. This makes it more difficult to get to know the people with whom we are negotiating. After all, body language and facial expression play an important part in communication. When talking on the telephone, the tone of voice and scope of the conversation are what must be used to convey this same information. The person who shows an interest in others and can engage in the proper amount of friendly small talk will establish a "trust factor" that is essential to healthy discussions. This can be especially important if a change in scope is necessary and the budget must be renegotiated midway through the study.

Remind yourself that you are only as good as your last study

Chances are your requests will be considered in a positive light if you are someone with whom the sponsor and CRO want to work. Conversely, the site that is difficult to work with will be the first to be dropped and the last to be to receive special treatment.

One CRA placed a site on his personal blacklist. The quality of work performed during the study was marginal and the study coordinator was curt, often refused his phone calls and needed repeated prompting to resolve outstanding data queries. When a sponsor requested the site be contacted regarding a future study the site was at an immediate disadvantage. Any request for additional funds or special consideration was denied. The CRA knew the difficult task that lay ahead in working with this site and was not interested in granting any favors. The way they ended their last study with this CRA played a part in their ability to negotiate their next budget.

The next negotiation starts now. Relationships build the climate for repeat business and terms. A site that does good work and has friendly staff will be asked to participate in more trials. Friendships and good work today go a long way to build new business and ensure realistic budgets in the future.

Research and learn all you can about the sponsor, this project and the personnel involved

There are sometimes important dynamics to a study of which most people are not aware. This information can influence how you negotiate your budget. The investigator who learns that the sponsor is having trouble acquiring sites will be at an advantage when requesting more dollars. The same site will be at a disadvantage if they learn that interest in this study is keen and other sites are being turned away. It may be worth your time to talk with the sponsor and other sites about the compound and the various protocols associated with it in an effort to gain these insights.

Other helpful information might include the total budget allocated to each aspect of the project, the amount of latitude available to expand the amount paid each site, the overall financial pressures the company is

experiencing, the time pressure the division is under, how important it is to them to have the name of your institution or principle investigator on the final report and their expectations as to the quality and quantity of work performed.

Right timing

Choose the time for special requests carefully. Timing can be critical to your negotiations. There are some points in which you are more likely to receive a positive response including the end of the deadline for enlisting investigators. This is especially important if the selection of sites has been difficult. At this point the pressure is on both parties to settle so the focus of attention can be placed on gathering critical documents and conducting the trial.

Another great time to make a request is shortly after completing a successful trial. Assuming everyone is happy with your work and is anxious to continue the relationship great effort will be given to give your site a break. Consider also that performing a pre-study visit on a new site is costly in both time and money. Such a visit is not necessary if your site has been involved in a study with this company during the past 12 months. Mentioning this savings during the course of your conversation may be helpful.

Negotiation skills

Recognize that effective negotiations take time to learn. The person who is good at achieving outstanding results has had many opportunities to practice. There are however several principles inherent to every kind of negotiation that everyone should practice, regardless of their level of experience. Once refined, these principles will lead to the most positive of results.

Remain open. Let the other person gain the feeling that you trust him or her and that you have the necessary facts. Sure, you may need to keep certain confidential items to yourself, but project a general aura of trust and cooperation. People tend to share information and needs with individuals who are first open with them.

Resist the temptation to seek an immediate agreement. Patience and time can be valued friends. Give yourself and the other party time to digest the situation. Your first response may be that you are insulted by the offer. Take time to consider the situation. It may be a day or a week but don't make an immediate response to most issues. Give yourself time to think. In many situations what might seem initially to be unacceptable may be a very workable situation or may cause a new solution may come to mind. A quick yes or no may be to your disadvantage.

Regard silent as a positive. Most Americans feel the need to keep communication open and flowing. Some people think through problems and find solutions by talking. But silence is not necessarily negative. Give yourself and the other party moments to reflect. If you have made a verbal offer to the CRA or project manager working on your budget, allow 15 to 30 seconds of silence. This will give them time to digest the offer and consider various solutions.

This may make the other person feel uncomfortable, but it will also allow both parties a chance to think. Often the silence will cause the other party to say things they might not otherwise say. They will drop hints of the underlying situation that truly concerns them. When you learn additional concerns you will know better how to respond and help them find solutions to their needs while also reaching your financial goals.

Require fair play. 'Win-win' is an overused term, but it describes well what each side should be looking for. A long-term relationship is useful both to the sponsor and the investigator. If during the course of the study unexpected expenses emerge or there is an amendment to the protocol, both sides should be ready and willing to adjust the budget.

The need of additional procedures such as an EKG or lab test should find the PI ready to comply. In the same manner, the PI should expect fair compensation for additional work performed. Taking advantage of one party or the other decreases trust. Sometimes expenses not listed in the budget are incurred and need to be addressed. It is the PIs responsibility to point these out so they can be addressed. It is in the interest of both parties to maintain an attitude of fair play.

Conclusion

Relax and enjoy the moment. See negotiations as a way to get to know the people and the company with whom you will be working. The attitudes they portray during budget negotiations reveal their general corporate culture and will tell you if they are the kind of people with whom you are interested in working. If they are congenial, help solve problems, are organized, know their facts, make decisions quickly, seek advice when necessary, and are generally helpful, they will most likely be a good partner throughout the study. What you do and learn now will set the stage for the rest of the study.

As in all aspects of life it is wise to look at the big picture when negotiating a budget or contract. Understand what it is you wish to accomplish in both the immediate and long term future. Do not get caught up in the details of winning the highest amount possible for each aspect of the contract. The site that provides good rationale for its budget, is easy to work with and does reliable research will be rewarded with an abundance of protocols. Sponsors are willing to invest the time and effort necessary to keep premier sites on their team. This reputation of being an optimal site is built upon continued relationships and trust. These are human factors that cannot be measured in dollars and cents.

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Contract/Budget Check List

Identify specific milestones of the payment schedule:

- Initial start up fees (10%)
- Fee for screen failures (number acceptable or payment acceptable)
- Fee for services performed, not just visits
- Milestones that correlate with the schedule of activities identified in the budget
- Ensure payment schedule is evenly spaced (no balloon payments)

Know the name of the person and the department to contact for payments.

Learn who will determine when milestone payments are to be made.

Understand specifically what will trigger milestone payments are to be made.

Ask for 10% more than offered in non-negotiable contracts.

Be sure all costs are included. (Check procedures in protocol and CRF with payment budget.)

Change of protocol (amendment) may mean change in payment review. Ensure new procedures are addressed which require additional costs.

Make sure the budget is attached to contract as an amendment or referred to in the contract.

Insist on a Letter of Indemnification.

Read the contract.

Know what you are responsible for.

Know what the sponsor/CRO is responsible for.

Understand the process of accountability.

List specifically where payments are to be sent.

Make sure the contract specifies to whom payment is made.
