Negotiating Clinical Trial Budgets and Contracts

Add to your practice's revenue by working closely with your local clinical research organization and sponsor.

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In today's fast-paced world of technological advances, your ophthalmic practice may need to supplement its revenue in order to keep up to date with diagnostic devices and upgrades and remain competitive. Additionally, the decline in reimbursement from health insurers, both public and private, may be driving you to look for additional resources. Participation in clinical trials within private practices, and even hospitals, is rising as physicians realize that the advantages can be both scientific and financial. This article describes the budget and contract process in clinical research, and it provides tips on streamlining the negotiating process to allow established ophthalmic practices to bring in new revenue streams.

IT IS ALL IN THE PLANNING: ASSESSING FEASIBILITY AND SELECTING A SITE

Having a solid, feasible trial is one of the foundations of any clinical research program. With increasing financial pressure on companies to deliver the most effective trial under strict timelines, feasibility can become one of the most critical aspects of moving your project forward.

Selecting a site for participation in clinical trials is a complex process that will often begin up to 1 year prior to your study's initiation. The two general streams for selection often depend on the trial phase. For phase 2 and 3 trials, the sponsor or clinical research organization (CRO) team will take the initiative in contacting centers for participation based on their previous involvement in clinical trials and the organizers' knowledge of local affiliate offices. For preregistration and postmarketing trials, the sponsor's medical affairs team will select centers based on the experience of the practice, the therapeutic area being studied, and the usage of similar devices and/or drugs. Your sales representative or CRO affiliate office can highlight your interests in clinical trials to a potential sponsor. If you are new to clinical trials, registering your interest is an important first step. Be prepared to discuss your experience and your patient population as well as your and your staff's willingness to undergo training on up-to-date clinical procedures.

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The sponsor or CRO will conduct a formal assessment of feasibility to evaluate your site against the specifics of each trial. It will look at a spectrum of information: the availability of the diagnostic equipment, the number of qualified staff members to provide valid and high-quality clinical data, the number of relevant subjects you have treated and anticipate treating, how you intend to recruit subjects, and the prevalence of competitive trials. You will also be asked to look at a synopsis of the protocol and provide feedback and should feel free to discuss any potentially major hurdles. Within the ophthalmic field, the small details of the protocol could mean the difference between success or failure, and your input can be critical. Sponsors seriously consider the feedback of the investigators, so the process can be collaborative.

Responsiveness and interest in the project are the most important assessment criteria for site selection. Although completing the documents and predicting recruitment are time-consuming tasks, they will pay dividends in the long run when your site is accepted to participate over another qualified site. One critical aspect of an assessment of feasibility is the signing of a confidential disclosure agreement (CDA). A CDA must be signed prior to the release of any confidential information to the potential investigator, site, and employees. The CDA is often a stalling point because minor issues can cause suitable clinical trial sites not to participate. To remain involved, the CDA template should be signed by the site's representative, sponsor, or CRO quickly. Of course, this action will depend on the requirements of your practice, but by offering to sign these agreements immediately, you can speed up the selection process. If comments are required, a single set of consolidated comments can be sent to your representative with a clear understanding of the requirements that are flexible and the requirements that are "dealbreakers." This distinction minimizes the back-and-forth process. If your site or institution works with a legal department, remaining in close contact during any revisions will reduce delays.

CONTRACT NEGOTIATION: STREAMLINING THE PROCESS

Once your site has been selected and has agreed to participate in a clinical trial, the more difficult aspects of the financial and contractual negotiations begin. Most sponsors and CROs have entire departments dedicated to conducting negotiations, and they will work with you to make this process flow smoothly. Hospitals and other sites with legal departments will use their legal team in negotiations with sponsors or CROs. Direct site-to-sponsor or site-to-CRO contract and budget negotiations are often done by the investigator or may be assigned to the office manager or study coordinator. If this task is delegated to another person or department, it is important that he or she be familiar with the clinical trial process and requirements and that the principal investigator review the final budget and contract before they are signed. To obtain the highest revenue and ensure the greatest integrity in following the law, it is vital to have knowledge of current reimbursement levels; local, state, and federal regulations regarding the billing of testing; and surgical procedures related to your specialty.

CROs and sponsors often use a combination of centralized and decentralized models for negotiating contracts and budgets. Centralized models use a dedicated staff based in one location that specializes in commercial contracts and manages all negotiations. Decentralized models require the cooperation of the local clinical monitoring team under the technical supervision of the centralized team. More than likely, ophthalmic practices will work under decentralized models. In this case, the local sponsor or CRO staff will feed into the central teams. The central teams are working from very stringent guidelines on contract language acceptability through highly specialized repositories and reporting mechanisms. An increasing level of contractual sophistication and legislation, both from the sites and the sponsors, has resulted in extensive requests to modify the language and negotiating time frames as they struggle to find an acceptable template.

One of the most significant delays to starting a study is site contract negotiation. This delay has led to a trend of sponsors' accepting and adapting the site's or hospital's contract to speed up timelines, which is increasingly apparent in ophthalmic trials, because sponsors and their sites have become well known to one another. Although this practice simplifies the process for legal representatives, the stringent language guidelines from the CRO or sponsor still apply to the contract revisions, no matter what template is used. There are certain terms that must be included and certain terms that cannot be accepted. If you keep this understanding in mind and consolidate your comments, the agreement timelines will be much shorter.

OPENNESS PAYS: THE CLINICAL BUDGET

The budgets allocated to each site within a study have strict limitations on what can be paid that are guided by regulations and sponsors. Approaching the negotiations with detailed breakdowns of your overhead and proposed compensation can be essential to rapid and effective negotiations. When the clinical research associate teams are able to justify to the project manager and sponsor that your requests are realistic, agreement will be more rapid.

PLANNING FOR THE FUTURE

After completing the first set of negotiations with a new CRO or sponsor, you will be able to discuss your potential to be considered for groups of ophthalmic trials based on your specialty and patient pools. In essence, there may be an opportunity to sign a master services contract with the CRO or sponsor that overarches the individual study agreements. The master contract can cover the bulk of the legal forms, and individual studies can be appended to this agreement. This approach can significantly reduce the time before contract sign-off and can allow your site to open for recruitment quickly.

Weighted payments, as approved by the ethics boards, to rapidly screen or enroll the first patient are becoming more common in an environment where time is critical to CROs and sponsors. If study recruitment opens and you are still negotiating your contract and budget, you could

miss the cut-off for the weighted payment and the potential for a rapid stream of clinical revenue. Working internally to smooth the negotiating process is crucial to increasing your revenue. Additionally, studies are being run more frequently with competitive recruitment. That is, sites can recruit as many subjects as possible, but once the target is achieved across all sites, recruitment closes. The sooner you begin recruitment, the more subjects you will be able to enroll before the target is met and recruitment closes. These "bonuses" can significantly affect your practice's income from clinical trials.

Integrity, quality, compliance with protocol, and local regulatory requirements are more important than recruitment in any clinical trial. The sponsor will always value high-quality results above everything else. You will likely be asked to provide a detailed recruitment plan that will be closely monitored by the clinical research associate to help you meet your targets and maximize your financial compensation. Adhering to this plan, enrolling the requested number of eligible subjects, and encouraging these individuals to complete the study will increase your chances of being able to participate in multiple trials. The more experience you gain, the quicker you will move through the selection and qualification processes, which allows recruitment to begin sooner. Not only does this bring revenue in more quickly, but it is also well established that sites benefit from the influx of new scientific developments by engaging their staff and being sought by new patients.

CONCLUSION

The current economic climate has caused ophthalmic practices to search for additional streams of revenue, which has increased participation in clinical trials. The keys to successful clinical trial budget and contract negotiations are internal planning, a knowledge of finances and regulations, and flexibility. Working closely with your sponsor or CRO will help streamline the negotiating process and open the door to future opportunities for participation. Taking part in clinical trials reaps rewards for a practice not only in terms of revenue, but also prestige, academic achievement, and scientific advancement. ❑

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