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Everything You Need To Know About Budgeting For A CRO

Asking for help with your clinical trial isn't always easy, but it's often necessary. Sometimes the signs are obvious—for instance, if you have a high-risk trial or you recently received a warning letter from the FDA.

Other times, you might realize it midway through your trial, when you're already experiencing delays or your internal resources are stretched too thin to handle the daily demands of an ongoing study.

A clinical research organization (CRO) can help your trial stay on track and on budget, but you'll need to account for their services too. This whitepaper will cover everything you need to know to budget for a CRO, from getting buy-in to avoiding unexpected costs.

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WE'LL EARN YOUR APPROVAL.

GETTING BUY-IN FROM YOUR TEAM

Depending on the scope of your trial and your internal team's expertise, you may need to hire a CRO from the very beginning. The CRO can help you identify risks and develop a plan to mitigate them. They can offer support with monitoring, auditing, project management and safety management throughout your trial. They can also assist with specific needs later in your trial—or even at study close-out—if you determine you need additional help.

There are several factors you'll want to consider before hiring a CRO, so it's essential to do your homework and involve the right people in the process.

First, you'll need a well-defined study design and protocol before you can estimate costs and have an informed conversation about budgeting.

If you want to seek outside cost estimates prior to that, just be aware that they will be "ballpark" costs and another estimate will need to be provided once key study documents are finalized.

Once you have a better idea of the costs involved, it's time to bring others into the conversation. That means talking with your VP of clinical operations and clinical directors, as well as someone from your sourcing or procurement department.

YOU SHOULD BE PREPARED TO PRESENT THE FOLLOWING:

- A protocol design
- Risk analysis and risk mitigation strategies
- A general strategy plan for sourcing the study along with rationale
- An outline of the proposed scope of work

At this stage, it's helpful to have a spreadsheet outlining how you plan to delegate study responsibilities between your internal team and your CRO. You can use this as a starting point for discussion with management.

Most companies have a standard template for submitting budget requests to management. Whether you do or don't, it's important that within that request, you also provide reasonable justification.

Consider these three key questions:

1. Are there gaps in the qualification of your internal team?
2. Are internal resources constrained to the point that quality may be sacrificed?
3. Is there a good justification to involve a third party (i.e., endpoint adjudication, independent safety review, independent monitoring)?

Asking these questions will ensure you identify the right partner even before your trial begins.

HOW DO YOU KNOW IT'S TIME TO HIRE A CRO?

Keep in mind, it may not always be obvious that you need to hire a CRO from the beginning of your trial. Your needs may change, or you may identify gaps or additional risks later that require specific expertise.

Perhaps you can identify with these six common challenges:

1

YOU HAVE A HIGH-RISK TRIAL

As mentioned, this is one of the more "obvious" signs you need help. Every clinical trial comes with inherent risks, but some risks may be greater or more unique than your staff has experienced before. Perhaps you are conducting a trial on a vulnerable population, such as children or elderly patients, or perhaps your technology is very novel and you anticipate a high level of scrutiny by regulatory authorities.

2

YOU ARE EXPERIENCING HIGH STAFF TURNOVER

High turnover is an unfortunate but common challenge in clinical research. Many of the roles involve long hours and frequent travel, which is not ideal for everyone. And of course, turnover always happens at inopportune times, which means resources are either diverted to onboard replacements, or training of the replacement is inadequate (or often, both!).

3

RESEARCH COORDINATORS ARE FALLING BEHIND ON DATA ENTRY

Does it feel like your teams always have a backlog of data that needs to be entered, no matter how hard the research coordinators work? Efforts toward screening and enrolling subjects often takes priority over entering data, and of course, your study is likely not the only study the site is working on.

4

YOUR TRIAL IS EXPERIENCING DELAYS

Delays can be caused by a multitude of reasons. In fact, 80% of clinical trials experience delays of up to six months, which can cost thousands of dollars per day.

5

YOU RECENTLY RECEIVED AN FDA WARNING LETTER

The FDA regularly inspects clinical trial sites through its Bioresearch Monitoring (BIMO) program and issues warning letters for deficiencies or violations. Even if you received a Form 483 with deficiencies and it didn't lead to a warning letter, you certainly want to be sure the next trial is run with as little error as possible.

6

YOUR TRIAL HAS GONE OVER BUDGET

While you can't put a price on innovation, you still have a budget. The unforeseen costs of delays, changes in the project plan or additional resources needed can add up quickly. And with the budget limit approaching, can you minimize the added costs?

If all this sounds familiar, it's time to get help from a contract research organization. Once you've identified the need, what are your next steps?

BUDGETING FOR A CRO: WHAT TO EXPECT

You can expect that running a well-controlled clinical trial will be expensive. A good CRO will help you determine ways to control the expenses. Consider the cost variables that pertain to the scope of your trial, as well as other costs that will add to your budget.

COST VARIABLES TO CONSIDER

- Type of study (IDE?, 510(k)? Post-market? Registry?)
- Complexity of your study (Is it randomized? Global? Is there a complex patient population?)
- Number of sites and geographic distribution
- Type of sites (Are they new to this type of research?)
- Type of device (Is it the first of its kind or an iteration of an existing device?)
- Services needed (such as project management?, data management?, monitoring?, site management? and contract management?)

OTHER COSTS TO CONSIDER

- Training
- A Clinical Trial Management System
- An Electronic Data Capture (EDC) platform
- Other vendors and their scope of work (such as core labs, safety committees and consultants)
- Site costs (such as start-up costs)
- IRB fees
- Meeting costs (covering investigator meetings and general study meetings)
- Miscellaneous costs, including periodic audits, unplanned visits to secure compliance, costs of training new staff and enrollment support visits

NAVIGATING THE PROPOSAL PROCESS

Now that you have a clear picture of your clinical research budget, it's time to start the proposal process.

When seeking bids from multiple CROs, it's best to ensure that you're comparing apples to apples. Give as many details as possible to the CRO to ensure you aren't leaving it up to each CRO to figure out how to source the project. Two CROs may have different ideas of how to source a project, and this will make comparison difficult for you.

Here are a few best practices that will help you ensure a fair comparison:

DEFINE AS MANY VARIABLES AS POSSIBLE INSTEAD OF LEAVING IT OPEN-ENDED

One CRO may choose to err on the side of providing a higher estimate so that there are no "surprises" for you, while another may choose to estimate less conservatively so that they come in as the lowest bid, knowing that they can later adjust this with a change order if needed. Define timelines (first patient enrolled, duration of enrollment, length of start-up and close out) and estimated frequency of events (how many monitoring visits per site, how many safety meetings, frequency of team meetings, anticipated adverse event rates, etc.).

PROVIDE THE DETAILS OF THE BID TWO TO THREE WEEKS IN ADVANCE OF THE DEADLINE

This will allow prospective CROs to gather the right people to pull the costs together. Depending on how much you intend to utilize the CRO's services, this process can be time-consuming, taking anywhere from 20-40 hours for the CRO. Include a timeline for your review, as well as when you expect to make a decision.

DETERMINE INTERNALLY WHAT YOUR PROCESS WILL BE ONCE YOU'VE RECEIVED ALL OF THE BIDS

Usually, this involves a designated team reviewing each bid and determining strengths and weaknesses to come up with a "short list" of potential CROs.

ALTHOUGH TEMPTING, TRY NOT TO FOCUS ONLY ON THE BUDGET NUMBER

A lot of effort likely went into explaining the team, the approach and success stories. Consider all this when making your determination. Remember, the proposal is generally the start of the conversation. Upon review, you may determine you do not need certain services that were included in the proposal or you need more of others. Don't get scared by the number – it's an estimate that can be revised as additional information is shared.

IF YOU HAVEN'T WORKED WITH ANY OF THE COMPANIES BEFORE, FEEL FREE TO MEET WITH THEM IN PERSON

This will help you get to know their team, learn about their processes and understand their recommendations. This should give you a better idea of how they arrived at the numbers in their proposal.

While the proposal process can extend for months, try to target one to two months.

COMMON PITFALLS THAT CAN BUST YOUR BUDGET

By failing to prepare, you are preparing to fail.

This famous quote from Benjamin Franklin is good advice to follow when planning your clinical trial budgeting and hiring a CRO.

There are almost always unforeseen costs that emerge with any clinical trial, so it's better to account for them upfront than to be surprised later. Experienced CROs have been through this many times before, so they know what to expect and how to help you avoid the most common budget-busters. Ask CROs up front how they handle these challenges, and what costs are passed to you if they do occur.

THE 4 BIGGEST BUDGET-BUSTERS IN CLINICAL TRIALS

DELAYS

Your trial could experience enrollment delays, site start-up delays, or product availability delays, which can increase the cost of running a clinical trial. Delays might mean more IRB fees, more monitoring visits, more site selection and start-up costs, and more staff turnover. Every day of delay also means one less day that your device is not on the market bringing in revenue for your company.

SCOPE CREEP

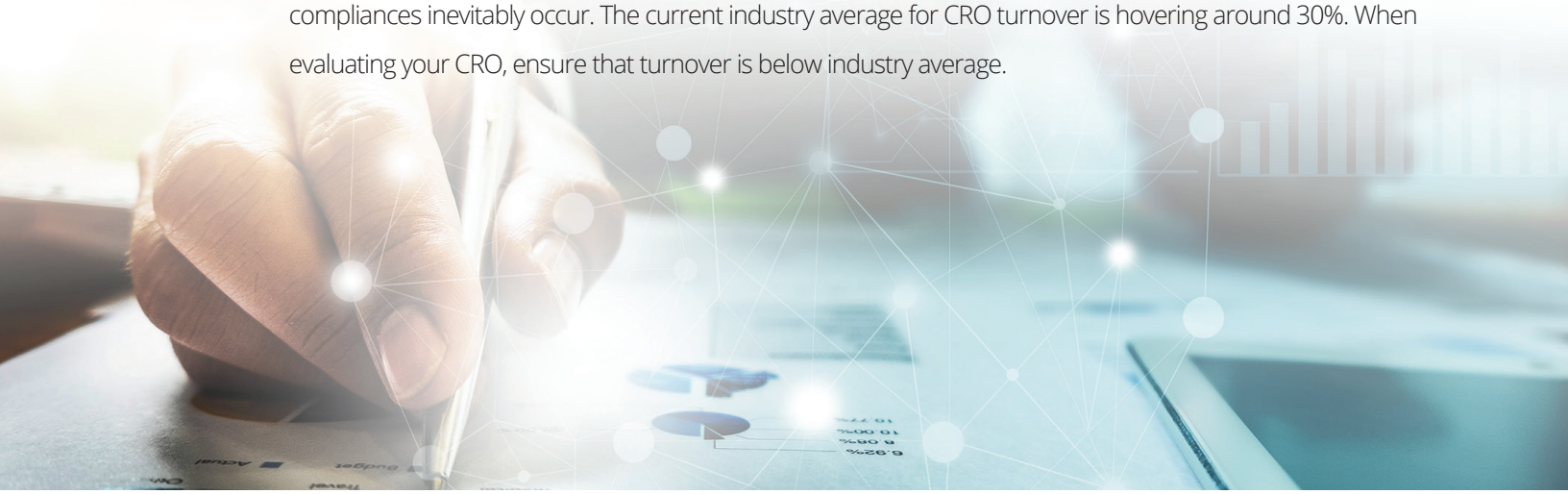
A good CRO will quickly become a seamless part of your team. They may be eager to offer to help with other areas of your trial. However, it's important to make sure you're not unintentionally adding to the scope of the project when you ask them for help with something that isn't included in the agreement.

TRAVEL

Managing clinical sites, especially in an IDE study, often involves frequent travel, which costs money. A good CRO will help you determine which study tasks can be done remotely and which are essential to do on-site. In addition, a well-trained field team will adequately prepare prior to each site visit to ensure maximum productivity.

TURNOVER

Perhaps one of the biggest hits the budget will take will be due to turnover throughout the length of the study. You could experience turnover within your internal team, turnover at your sites, and turnover with your vendors. When key study team members are replaced, additional training needs to be provided. Additional oversight may also be needed to prevent compliance issues, and other actions will need to be taken once non-compliances inevitably occur. The current industry average for CRO turnover is hovering around 30%. When evaluating your CRO, ensure that turnover is below industry average.



HOW TO CHOOSE A BUDGET-FRIENDLY CRO

A clinical trial is a marathon, not a sprint. You want to hire a contract research organization who will serve as a true partner and protect your budget over the long haul. The right CRO will treat your budget like their own. They will be proactive about identifying and mitigating added expenses that can creep up during your trial. They will be able to make adjustments as needed and communicate any additional costs to your team before simply billing you for extra charges.

To find the right one, you need to look beyond the numbers quoted in the proposal. Here are four important questions to ask as you consider your options.

WHAT IS THEIR PRICING STRUCTURE?

Do they bill hourly, or have a monthly service agreement? A fixed pricing agreement? There are pros and cons to each, depending on the project. For small projects involving just a few sites or a few months, it may make sense to have a fixed price. For longer projects, allocating hourly pricing may give you more flexibility. An audit is a great example of a fixed-priced service.

If you hire a consultant or CRO to conduct an audit in preparation for a BIMO inspection, you can expect to pay a flat fee for a one-, two- or three-day audit. If you're hiring a CRO to manage the sites for a multi-year study, their time commitment over each phase of the study would likely change. They would be busier in the start-up phase and less busy in the follow-up stage. By going with an hourly model, you pay according to the level of effort the CRO is providing.

HOW FLEXIBLE ARE THEY?

A good CRO wants to be a long-term partner with you. They're willing to adapt to your changing business goals. If, for instance, your strategic priorities shift and you have to shut down one study and allocate funds to another, they can mobilize their team to wrap everything up as quickly as possible on the first study in order to be ready to support your second study. If you anticipate a 30-site study that ends up only being a 20-site study, a good CRO will amend the budget. Likewise, if you end up needing additional sites, the CRO will be capable of resourcing it.

DO THEY OFFER REMOTE SERVICES?

Monitoring, auditing and data entry can all be done remotely to reduce travel costs. For instance, a trial master file review that involves several team members who need to spend several days on site could cost thousands of dollars. Doing this remotely can cut those costs in half.

HOW DO THEY COMMUNICATE WITH YOU?

Ask them how they communicate with your team and help you keep track of the budget. Do they report regularly on monthly key performance indicators (KPIs)? Will they call you to discuss something that may add to your costs before billing you? These are important questions—and the right CRO will have answers that give you confidence.

Budgeting is a vital element to any clinical study. It is important that the CRO you hire provides an accurate estimate and helps you contain costs throughout the study.

JOHN LEHMANN, DIRECTOR OF BUSINESS DEVELOPMENT

As the driver behind IMARC's new business efforts, getting down to business is what John Lehmann was born to do. His proven business processes, strategic sales and marketing skills, management abilities, training development and implementation talents, plus knowledge of governmental and safety market segments offer our partners a wealth of knowledge. John not only drives growth at IMARC, he also empowers our clients to grow.

Before joining IMARC, John's strong business background was leveraged in the role of Senior Business Development Manager at Tech Resources, Inc. In addition, he served as National Director of Business Development at Acxiom Corp. and Direct Connect Group, as well as Vice President of Sales and Business Development for eight years at Great Lakes Integrated.

Making an impact on our community is also a priority for John. He has done so as a former board chair and board member at Junior Achievement of Lorain County. His guidance was also effective as a respected board member for the Sales & Marketing Executives Diabetes Association of Greater Cleveland. Being a member of the Cleveland Advertising Association, and an accomplished speaker on implementing new business development processes, John is savvy to the business protocols that make or break a company. More importantly, he is happy to share them.

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At IMARC, we take pride in our ability to manage budgets and stay true to our budget estimates.

As a medium-size CRO with global partnerships and specific expertise in medical device trials, IMARC is the right size to support your clinical study support needs.

Learn more about how we can help keep your trial on track and on budget >>