Keeping clinical trial budgets in check

Managing clinical trial budget overruns and minimising overall costs

Photography by Isy & Leigh Anderson

Introduction

As pharmaceutical and biotechnology trials become increasingly complex, it is becoming more important for clinical trial managers and procurement managers to keep their costs under control, while still ensuring quality results and regulatory compliance within required timelines.

According to a recent survey, the variances between forecasted clinical costs to actual trial costs remain high; despite the ongoing industry push for greater efficiency in clinical trials.[1] In addition, unpredictable factors such as new industry regulations, supply chain inefficiency and product security concerns (e.g. increasing issues with counterfeit products entering the market) are adding to the pressure of managing clinical trial budgets.[2]

A recent study shows variances between forecasted and actual costs remain high

In this article, we look at some of the main causes of clinical budget overruns, and how some pharmaceutical healthcare sponsors are working collaboratively with supply chain partners to reduce their overall clinical trial costs.

Top causes of clinical budget overruns

The current causes of forecasting variances and budget overruns in clinical trials tend to fall into the following four areas[3]:

- Trial delays: time delays generate significant variability in clinical development costs. For example, delays in enrolment activity mean monthly costs continue to add up. More than 80% of clinical trials experience delays that range on average from one to six months. Just 10% of trials are completed on time.[4]

- Protocol amendments: if protocol amendments are needed during the more complex stages of a trial, these amendments may require new trial populations, extension arms and other trial design modifications, each of which can dramatically increase overall costs.

- Unexpected events: unexpected events such as missed patient enrolment targets and underperforming sites can occur throughout the trial. The standard response to missed patient enrolment targets is adding new sites, which can be associated with major additional start-up, training and monitoring costs.

- Globalisation: over the past decade, there has also been a major increase in the globalisation and outsourcing of trial services. The trend in outsourcing more trial management activities to multiple vendors can make it harder for companies to keep a complete, single financial picture of their global costs.3 This is one of the reasons we recommend working with an equipment supply partner that can support your trial in all territories. We also recommend finding a partner that understands the full product lifecycle, and can help you forecast all associated costs rather than simply providing unit quotes.

Getting it right from the start

Most clinical managers primarily focus their initial budget planning on the clinical aspects of the trial, in accordance with the study protocol. These vital aspects include the trial funding, identification of the ideal patient group, selection of study sites, patient recruitment, data collection and publications planning. Factors which are not always part of clinical trials professionals' core competences, such as managing supply chain procurement and logistics, may take a back seat in budget forecasting.[5]

But recent industry changes mean that healthcare companies must now contend with the numerous trade, security, safety, and environmental regulations than are now required for each clinical trial.[2] Complying with these regulations throughout the trial is equally as important as complying with the clinical protocol. Therefore, these factors also need to be assessed at the initial trial budgeting and forecasting stage.

To help manage this complexity, many pharmaceutical sponsors and CROs choose to work with specialist equipment and logistics partners who can manage these supply, budgeting and regulatory challenges throughout the clinical trial, and help reduce overall trial costs. In this set up, an expert partner can manage equipment supply and logistics, allowing study managers to focus on the clinical aspects of the trial and protocol, where their expertise and interest lies.

Specialist partners can reduce overall costs

Working with expert procurement and equipment supply providers can enable you to increase your efficiency and reduce overall costs, without compromising supply chain quality or compliance. For example:

- Choose equipment based on long-term value: It is important that you choose the right clinical equipment to provide the best value across the length of your study, rather than basing your decision on unit costs alone. A specialist procurement partner should be able to select the appropriate equipment for your specific clinical and regulatory needs, and help optimise that choice for long term value.

- Ensure cost-effective deliveries: An ideal supply chain partner should also be able to deliver your clinical equipment in the most efficient and cost-effective way possible, which can help you to avoid potential delays in transportation and delivery – in particular, ensuring you always meet SIV dates. This efficiency can reduce the financial impact of delays on your overall budget.

- Maintain smooth global reach: Aim to work with one international supply partner that can offer you a global service for all your equipment needs, no matter where your clinical trial sites are located. A global supplier should have an in-depth knowledge of country specific regulations to keep the process smooth, even in complex or remote regions. This can also help you to avoid the time and costs involved in managing multiple suppliers in different countries, and reduce the financial threat of equipment delivery delays to these clinical sites.

Equipment should be chosen based on long term value, not just unit costs

Summary

CROs and pharmaceutical trial sponsors are recognising that working with expert supply chain partners can be the difference between a trial that meets clinical, regulatory and budget goals, and a trial that struggles under the complexity of equipment management and supply.

Improving clinical trial procurement and logistics processes can help to achieve long-term clinical trial success and meet the increasing needs of patients.

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