The Value of Specialized Expertise for Efficient Management of Clinical Supply Budgets

A financial project analyst (FPA) plays a critical role in clinical trial supply and budget management. Pharmaceutical Technology spoke with Christin Lau, financial project analyst at Catalent, about how sponsors can benefit from having this specialist on their supply partner's team.

Christin Lau
Financial Project Analyst
Catalent

There are variable elements within any clinical trial and risks that may impact a study's chances of success. An FPA assesses these factors and their potential impact on the program. By understanding the expectations and requirements of the trial, the FPA creates a forecast, assesses different scenarios, and creates a budget to help control costs, including highlighting the root causes of cost variation throughout the trial to the final closeout.

PHARMTECH: How can a financial project analyst help sponsors and their studies?
An FPA focuses on forecast and budget challenges and provides root-cause analysis to customers. They understand the details of clinical trials, including project-specific requirements and expectations; they are always striving to control costs in each phase of the study—from start-up to maintenance and closeout. An FPA appreciates the many risks and variables that can impact the study budget.

If study requirements change during clinical trials, an FPA assesses the financial impact and determines if additional funds are needed. When alternative project scenarios need to be considered, such as a change of recruitment strategy, the FPA provides a budget analysis for each scenario and the overall impact on project costs. The FPA provides clear and concise financial data to allow for informed project decisions and strategies. In addition, they work closely with operational departments to identify cost savings within projects.

All reports can be tailored to fit the customer's needs, and financial models can be built to consider the impacts of different scenarios, such as the cost of recruiting in country A versus country B. In addition, project orders are closely managed by the FPA, and issues such as invoice payments can be reduced.

PHARMTECH: How important is budget management?
Budgeting is extremely important, and the FPA helps to achieve clinical-trial operational goals within budget through forecasting and cost control.

Budget trackers are used in which the study categories are compared against initial project funds. This allows FPAs to highlight any potential budget challenges, conduct root-cause analysis, and propose corrective actions immediately. They also establish a monthly budget burn rate.

To ensure that the funds allocated for a study are sufficient for future activities, an FPA uses a forecast that outlines all planned activities and assesses the impact on the budget.

For some customers, the internal sign-off process to increase the budget can be complex and lengthy, especially if a contract research organization (CRO) is involved. The FPA can offer supporting justification for budget increases and forecast variances such as recruitment challenges, changes in the forecast, etc.

PHARMTECH: What tools do you use?

We use two main tools to track financials: forecasts and budget trackers. The **forecast** takes a long-term view and projects the finances of the trial until study completion. It also offers oversight of expected monthly, quarterly, and annual spending. The forecast contains a detailed overview of the signed contract's history to allow customers to track quote amendments of the trial.

Budget trackers compare the signed contractual spend to the actual spend and help us to advise on the remaining spending by study category. It provides a great snapshot of the remaining budget.

The assumptions for the forecast are provided by the customer, project manager, and/or clinical supply manager. Every month, the assumptions and invoices are compared. Should there be deviations between forecast and actual costs, the FPA can advise on the accrual and take corrective budget actions. This ensures an accurate accounting of all incurred and anticipated costs. Should a customer wish to receive reports in a different format than what is typically provided, the FPA should be able to accommodate this as well.

PHARMTECH: How does this role help if a CRO is involved?

If a CRO is involved in the study, it is highly recommended to take advantage of the services offered by an FPA. With the budget tracker and forecast tools, FPAs can proactively identify budget challenges and document their impact, as well as reduce funding challenges with a clear explanation of where and why an additional budget increase is required. This is based on the assumptions provided at the beginning of the study versus how the trial concluded. The driving factor(s) for a budget raise—for example, a study extension or a change in the recruitment plan—is captured on each quote amendment, which can help to secure funding faster.

PHARMTECH: You mentioned cost savings—can you give an example?

In one situation, a customer approached Catalent because they had experienced budget constraints and recruitment challenges during the COVID-19 pandemic. Stock issues led to product expirations and budget challenges due to study changes, requiring the need to create opportunities for cost savings. Catalent's FPA and clinical supply manager considered how stock locations and timeframes for stock destruction could be better managed to minimize stock expiries. The FPA developed forecasts and scenario analyses to support proactive destruction planning and cost savings. By using scenario analysis and forecasting, Catalent reduced the overall storage cost by adding a second destruction run of unneeded materials to several depots to complete the study, freeing up the budget by not spending money on unnecessary storage of an unusable product.

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PHARMTECH: How does this compare to a project manager role?

A project manager can provide some "light" financial services to support studies, which can include a budget tracker. In contrast, an FPA provides more of a "financial-plus" service that goes beyond basic budget tracking and offers financial reporting and scenario analysis to enable better decision-making. FPAs are financial experts.

PHARMTECH: What activities are taking place throughout the lifecycle of a study?

We split the lifecycle of a study into three parts: study start-up, maintenance, and closeout—each associated with different activities. At study start-up, activities are linked to cost projections and forecasting of the trial. During study maintenance, assumptions are adjusted to match the progression of the trial, cost-saving initiatives, cost investigation, data visualization, and budget control. At study closeout, final invoicing is coordinated and spend history is reviewed.