

Life Science Leader

Research Development & Clinical Trials

Better Quantifying Clinical Trial Costs

By Dan Schell

A few years ago, I bet a lot of pharmaceutical companies felt they were being cost-conscious when it came to drug development. They probably thought their processes and operations were as streamlined and efficient as possible. But we all know now that this industry has changed, and with that change has come a higher set of expectations regarding expenses and efficiencies — especially when it comes to drug development.

Nowadays, you want to speed up clinical development and maintain even more stringent safety regulations all while staying within your budget. To understand more about the latter, I spoke with Tim Hoos, senior director of business operations for Astellas Pharma Global Development, a U.S.-based affiliate of Astellas Pharma Inc., Japan's second largest pharmaceutical company and ranked within the top 20 in the global market. Hoos is in charge of a finance group at Astellas that was charged with finding a standardized method of developing study budgets that could be used in a pharmaceutical environment. The group was also working with CROs on developing milestone

payment schedules that would recognize a cash-neutral position for both the sponsor and the CRO.

"As the number of studies and the complexity of the budgeting process increased, the tools that served us well in the past didn't scale as well as we had hoped," Hoos explains. "It became a burden to ensure that all of our Excel macros were working and that there were no transcription or calculation errors in the spreadsheets that we used. This 'validation' of the use of software and the possibility that someone could inadvertently cause a major miscalculation or wipe out a file was too much of a burden."



NO MORE GUESSTIMATING

The problem at Astellas was probably the same one many pharmaceutical companies still face. The solution was simple in concept, but more difficult in execution. Namely, they wanted to develop standardized costs for routine activities (e.g. study reports, NDA [new drug application] submissions) and have the functional groups focus on the activities and apply the new standardized costs to these activities. Utilizing this methodology would allow the finance group to identify causes of cost variances and would take the guesswork out of budgeting. "This was a very difficult concept to implement because the functional groups

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Monthly Budget By Major Task

1 Annual Budget 2.5 for Clarity
Phase III / Protocol ID: CLR-051-1123
Indication: Circulatory System / Lipid Metabolism

Report generated on: 12-Oct-09

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 21-Aug-2008.
Note: Inflation has been added to the costs in this report.

		2009					
		Jan	Feb	Mar	Apr	May	Jun
Major CRO	Project Initiated	31,263	29,229	31,263	30,246	31,263	30,246
	Study Setup	6,301	5,692	6,301	6,098	6,301	6,098
	Study Setup Per Location	14,447	13,049	14,447	13,981	14,447	13,981
	Unique CRF Page Developed	22,557	20,374	22,557	21,830	22,557	0
Sponsor Inc	Project Initiated	4,536	4,097	4,536	4,390	4,536	4,390
	Study Setup	2,385	2,155	2,385	2,309	2,385	2,309
	Sponsor Oversight	153,821	138,935	153,821	148,859	153,821	148,859
	Cost - Transaction Services - 3rd Party	51	47	51	50	51	50

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The ClearTrial PLAN software provides detailed monthly budget forecasts for outsourced as well as internal costs.

found it simpler to just manage a total budget number rather than the specific costs of activities that make up a study,” Hoos explains.

To articulate this problem, he gave the example of what often happens when a pharmaceutical company first contacts a CRO for an estimate on a clinical study. Typically, the pharma company provides only a high-level description of the study. Based on this limited information, the CRO provides an estimate, and the clinical person in charge of the study also develops a general estimate for extraneous other costs such as meetings, labs, etc. Thus, the functional groups manage the study within the constraints of that single, all-inclusive, and generalized budget number.

GOODBYE EXCEL SPREADSHEETS

At Astellas, Hoos and his three-person finance team knew the change management portion of this project was going to be substantial, but they first needed to find a better solution for

budgeting other than the Excel spreadsheets. Ultimately they chose the ClearTrial PLAN (Software-as-a-Service [SaaS]) application from ClearTrial, a provider of clinical trial operations (CTO) software. “ClearTrial is the only software we found that addressed the issues we were attempting to tackle alone through spreadsheets,” says Hoos.

The ClearTrial PLAN application generates multiple clinical development strategies based on clinical assumptions that are entered, allowing companies to determine the scenario that best meets the business goals of the company. The software then generates accurate forecasts for costs, resources, and timelines at the study or portfolio level. Hoos says the following were some key features that led to Astellas choosing this solution:

- Analyzes monthly cash flow, monthly man hours, and milestones
- Allows budget building from activities
- Allows for negotiated rates
- Determines internal and external costs
- Takes into account study conduct, therapeutic area, and specific country information
- Allows for the adjustment of calculated costs (with comments)

GAINING ACCEPTANCE

The finance group at Astellas acted as project managers collecting project costs and comparing them to actual costs. The group also

surveyed the contributing functions (e.g. medical writing, clinical trials materials, etc.) for activities that would result in costs that should reside within that particular budget. Two days of in-house training on the ClearTrial application consisted of teaching the finance group all of the characteristics and functions within the software. But as Hoos had anticipated, that was the easy part of this project.

“We knew the most challenging aspect of this project would be gaining acceptance from the other staff,” he says. “To do so, we performed comparisons of completed trials to what the ClearTrial system would have predicted as the total budgets. In all of these tests, the ClearTrial estimate came within 5% of our actual costs. I believe that it is so accurate because it asks you more questions than you would normally ask yourself when trying to determine a budget.”

For Astellas, the ClearTrial application is being used with clinical trials in Phases 2 through 4. In the future, Hoos would like to be able to use the application in Phase 1 trials and also take advantage of the software’s capability to consolidate budgets into projects and projects into portfolios.

Accurately budgeting for clinical trials is a tricky proposition. A myriad of problems, from unexpected toxicity issues to regulatory holdups, can delay the process, which leads to two things: medicine not getting to patients quickly and less profit for the pharmaceutical company. I’m guessing you want neither to happen. ●

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