BUDGET MANAGEMENT AND FORECASTING FOR CLINICAL TRIALS

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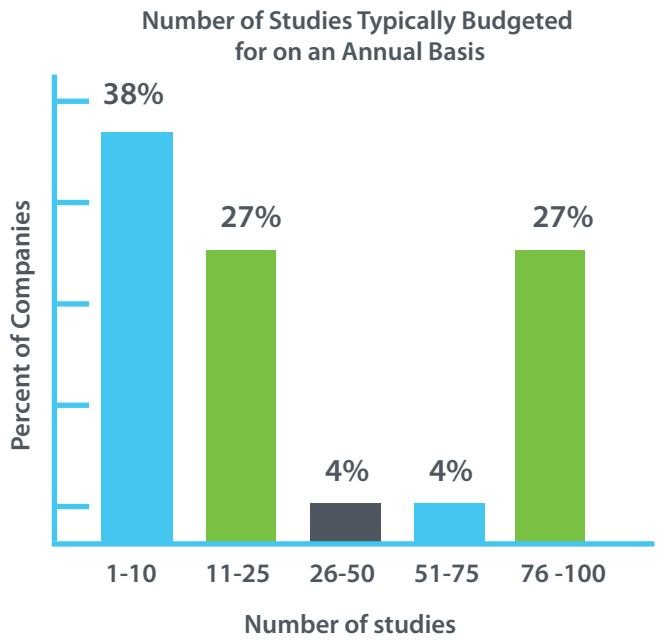
Introduction

Why are budgeting and forecasting for clinical trials so challenging today? From an industry perspective, trial costs, scope, globalization, and complexity continue to rise along with pressures for greater time and cost efficiencies to support expanded pipelines and profits. From an operations perspective, one of the biggest challenges is having more outsourced vendors than ever before contribute to the total clinical trial budget. This includes more work with contract research organizations (CROs), research sites, labs, and various other vendors. The overall trial budget is an accumulation of all these resources, creating a complex, time-consuming and multifaceted financial management rubric.

Challenges arise soon after budgets are finalized and the actual trial work begins. Almost always, there are delays in site and subject recruitment, protocol amendments that add additional clinical assessments, scope of work modifications with vendors, withdrawn investigative sites, new sites added, and a variety of other changes, including the financial and logistical challenges of subject participation in multiple geographies. All of these changes can significantly impact the original budget, leaving a gap in the ability to accurately forecast and compare against the original budget with the actual trial site activation, enrollment, and study activity expenses. As actuals replace estimates, it is difficult to get a true and real-time picture of what the reforecasted expenses will be.



The current method for collecting and accumulating study costs from the various vendor sources, reconciling them with the budget, and reforecasting expenses as the trial proceeds is inadequate at best. The necessar technology for efficient and highly accurate financial planning and management is lagging behind industry needs. Further, the life science industry is traditionally slow to adopt new methods and technology, particularly in the middle of a clinical trial when introducing change can strain already overloaded vendors and sites performing the work.

This paper reviews the challenges of clinical trial budgeting and forecasting, explores the specific concerns of sponsors and CROs, and discusses current methods of collecting actual financial data and comparing trial costs to the budget. Finally, this paper suggests the needed solution for optimum efficiency and accuracy.

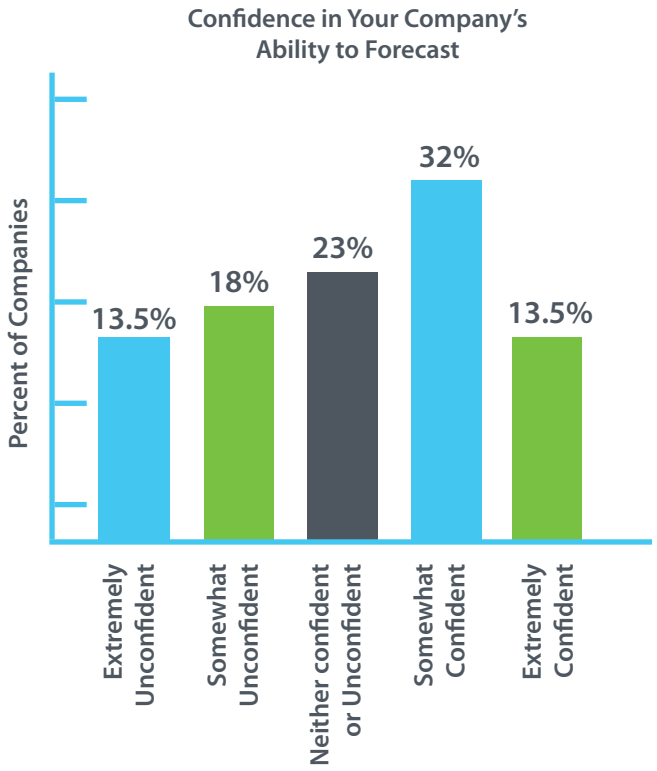
Variances: What Level of Wrong is Acceptable?

The ideal variance is no higher than 3%; however, a recent survey from Bioclinica showed that 38% of sponsors will accept an error rate of <5% and 31% of sponsors will accept a current error rate of 5-10%.[5] Yet, remarkably, the variance between forecasted and actual clinical trial costs for life science companies is a whopping 16%, according to an industry survey.[1] With pressure on earnings, financial predictability and accurate reporting, a high variance is less tolerable today as it affects revenue, future R&D budgeting, and wrong accruals can have an effect on earnings in the next reporting period.

It's also important to note that forecasting typically falls to the clinical operations team, which means the manual and labor-intensive task of forecasting is not left to an expert, but instead to a team who is already managing trial execution, data collection, site relationships, and a myriad of other service responsibilities. Now they must also be responsible for tracking, evaluating, reconciling and more accurately reforecasting future expense needs based on study information, which likely is not real time or even near it. In addition, these tasks require pulling data from multiple systems and analyzing it in cumbersome excel worksheets, which is a laborious effort that takes away critical time from trial execution.

Forecasting Challenges on a Changing Clinical Trial Landscape

The estimated average cost of bringing a drug to market in the U.S. is $1.3 – $1.7 billion, with clinical trial costs being one of the biggest expense categories for biopharmaceutical companies.[2] Due to the dynamic nature of clinical trials today, sponsors have opted to move fixed expense to variable expense, which has been accomplished by outsourcing parts of trial management to multiple vendors. A major influence on forecasting has been the increase in outsourcing clinical trials, from 20% in 2012 to 41% in 2014, according to a Nice Insight survey. Large pharmaceutical companies have the highest rate of outsourcing at 46%, and emerging pharma showed the lowest incidence at 36%.[3] The trend in outsourcing more and more trial management activities to multiple vendors has resulted in the lack of effective financial management systems required for visibility across all the vendors that play a role in the trial execution, making forecasting and budgeting extremely challenging.



Source: 2014 Bioclinica survey

In addition, more than 80% of clinical trials experience delays from one to six months, costing companies upwards of $35,000 per day, per trial. A mere 10% of trials are completed on time.[2] Time delays generate significant variability in clinical development budgets and add substantial costs. Not surprisingly, only 14% of clinical financial planners at pharmaceutical companies are highly confident in their budget forecasts.[5]

Another cause of forecasting difficulty is the expansion in number, size, length and complexity of clinical trials. In fact, as of Dec. 22, 2014, the current number of registered studies on clinicaltrials.gov is 181,107 with locations in all 50 States and in 187 countries.[4] Over the past two decades, the average length of a clinical trial increased 70%, the average number of routine procedures per trial rose 65%, and the average clinical trial staff work burden increased 67%.4 Due to the rapidly changing nature of clinical trials, forecasters may not be able to use historical data to accurately predict expenses for clinical trials being conducted in new ways.

The increased complexity and flexibility of clinical trials lead to additional forecasting issues. The trend toward adaptive trial designs, where the trial can be modified during its progress based on interim results, also makes forecasting difficult. Trials today also undergo protocol amendments, which can add new trial populations, extension arms, increased assessments, and other design modifications.

Forecasters are also challenged by unexpected events such as the impact of slower or faster site activation directly affecting enrollment activity as well as sites underperforming. When sites do not enroll enough subjects, it may be necessary to add more sites in multiple global geographical regions and to close sites that are non-performing early. Since site start-up costs are a significant study expense, these changes drastically impact the forecast and expense requirements.

In the past decade, there has been a major increase in the globalization of trials, with multiple countries using diverse financial management systems and managing expense in their own local currencies. Determining trial costs typically involves manual collection, currency translation and aggregation of financial data, often done on various spreadsheet systems.

The tools used for financial management of a study after budget completion are typically cobbled-together spreadsheets and other disparate systems and sources. As a result, the process requires frequent maintenance and updating, especially if the study trajectory changes. Since these updates and adjustments are done manually, they can create additional error and increased variance.

Sponsor Concerns

The sponsor's concern is the total trial budget, cash forecasting for both internal and vendor expenses, expense accrual in the proper period, and accurate expense forecasting for future development budget approvals. Sponsors want an accurate reflection of when total budget expenses will occur in future months, quarters, and years. Many sponsors today rely on multiple CROs and other various vendors for forecasting and must be prepared to manage the timing of cash deposits needed for these outsource partners. Typically, budgets are set annually, with approximately 35% revising them on a quarterly basis and 50% revising them on a monthly basis.[5]

Sponsors of all sizes depend on accurate budgeting and forecasting. They rely heavily on the accuracy of the trial budgets to plan and secure funding for future research and development. Public companies need reliable forecasts for shareholder reports, and venture-backed sponsors must ensure they have adequate funds to complete important development milestones in order to receive the next tranche of funding. For small sponsors, the cash flow effects of a high variance are significant, especially if they are venture capital funded, and can even compromise their survival.

When a CRO over- or under-forecasts, which can be equally problematic, the sponsor questions its partner's financial management ability and often perceives its CRO as lacking an understanding about what expenses will occur at what time or, worse, the CRO's ability to manage the overall trial execution and services.

CRO Concerns

CROs want an accurate picture of future expense needs based on trial performance in order to make more accurate fund requests from sponsors. Additionally, the CRO can minimize negative impacts of study-related changes if they can access real-time actual information to make suggestions or adjustments to the study execution strategy. CROs are motivated to proactively manage their client's expectations and site payment activity. Their focus is to effectively manage the funds required from the sponsor to ensure timely funding to sites, which can impact site satisfaction and performance.

Supported by comprehensive databases of historical costs, CROs can competently manage direct costs, but struggle with indirect costs. They need to develop a forecast for the cash requirements they will need, but the sources of this information tend to be managed within multiple systems or spreadsheets. A significant variance in the requested funds can strain the sponsor-CRO and CRO-site relationships if this causes payment delays or additional requests by the CRO for more sponsor funds to cover expenses not forecasted accurately. In addition, if the CRO's initial requested funds for site payments are short, they must request additional funds from the sponsor prior to paying the site. The delay caused by requesting additional sponsor funds can put timely payments to sites at risk. For sponsors who have a 60-day payment term, CROs must wait up to 60 days after their request to receive payment, and the site must wait even longer.

The singular concern of a CRO is providing good customer service, which means keeping site relationships strong, and focusing on trial performance and efficient execution. But sponsors frequently request that CROs provide updated forecasts and cash flow reports, so they spend a lot of time compiling this information, which takes valuable time away from the core service of trial execution.

Current Methods: What's Wrong With This Picture?

The life science industry is struggling to forecast and reforecast present and future trial expense accurately and efficiently, with spreadsheets continuing to be a predominant method. In Bioclinica's survey, a whopping 70% reported the primary tool used for budgeting and forecasting at their company was Microsoft Excel.[5] Spreadsheets are cumbersome to share and consolidate with other financial forecasting and budgeting data, do not help forecast subject and site activation, take too long to update, and are prone to error. Using this rigid, time-consuming method, it is difficult to get a clear, consolidated view across all sites and protocols.

Additionally, approximately 20% of the industry create their own systems in-house and 10% purchase off-theshelf software and try to tailor it to the dynamics of clinical trials, according to survey results.5 Clinical trial management systems (CTMS), which focus primarily on document collection generally lack a subject, site activation and financial forecasting function. In general, none of these systems works well, especially once the trial begins and changes occur.

Top Forecasting Challenges

1	Lack of software purpose-built for clinical trials
2	Subject enrollment accuracy
3	Use of actual data for accurate expense forecasting/reforecasting
4	Site activation accuracy
5	Access to actual data

Source: 2014 Bioclinica survey

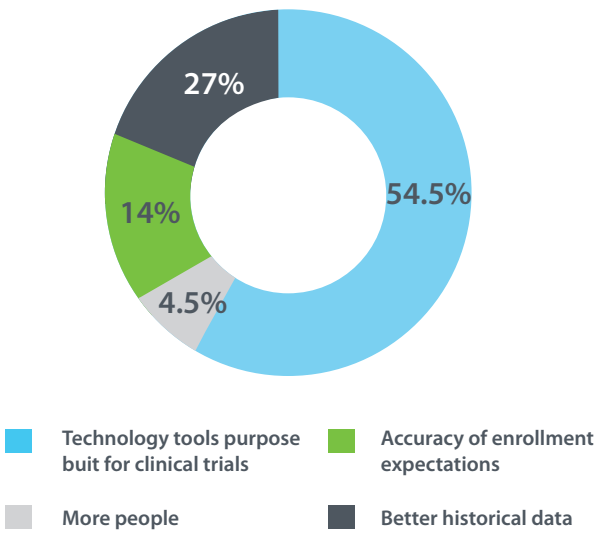
Future Outlook: The Necessary Solution

Clearly, the industry needs a better approach to forecast expenses and easily track the financial progress of a trial as compared to the original budget. The necessary solution is a robust, purpose-built, activity-based tool designed around a core site and subject forecasting engine to achieve timely, accurate forecasting.

The ideal system can be customized by both organization and trial with unique user- definable variables to forecast sites, subjects, using dynamic dates, and dynamic amounts. For example, a user should define any milestone date, which can be referenced by any user-defined activity or task to automatically reforecast the future expense date as key user-definable dates are updated. Such a system would enable financial managers to calculate expense and cash forecasts as well as timing by

changing linked key dates. Dynamic amounts change based on linked assumptions change, such as the number of monitoring visits. Further, the system can generate an expense and cash forecast and designate a primary budget to compare and report against actual results.

What is the Most Important Factor That Could Help you Forecast More Accurately?



Source: 2014 Bioclinica survey

The benefits of this system are numerous. Fully automated technology used at all trial sites will significantly reduce the time to generate a forecast, improve forecast accuracy, and easily identify delays and expense increases by trial phase, from start-up to closeout. Trial financial managers can be proactive, and the advanced technology will facilitate decision-making when study changes occur. This automation will foster collaborative, more-accurate financial reporting, reduce the variance between budgeted and actual data, and help speed valuable new drug products to market. At the same time, it will create an opportunity for sponsors and CROs to build long-lasting relationships while focusing on execution, service and delivery.

Conclusion

Changes in the clinical trial environment today have resulted in significant challenges for effective financial management of trial budgeting and forecasting. Variance from actual to budgeted trial expenses remains high. Companies face study design complexity and an increasing need to use outsourced vendors, all of which contributes to budget pressures throughout the execution of a trial. Data for financial forecasts are maintained in multiple systems with heavy use of inefficient spreadsheets.

The need to be more efficient in forecasting trials is significantly increasing and driving the need to adopt more advanced technologies for overall trial financial management. A dynamic purpose-built system, customizable by organization and trial, is necessary to achieve the required accuracy and efficiency moving forward.

To learn how Bioclinica's fully automated technology solutions can significantly reduce the time to generate a forecast, improve forecast accuracy, and easily identify delays and expense increases by trial phase, visit www.bioclinica.com or call 1.877.325.1122.

References

1. Grygiel A. The Struggle With Clinical Study Budgeting. Contract Pharma. Oct. 11, 2011. Accessible at: http://www.contractpharma.com/issues/2011-10/view_features/the-struggle-with-clinical-study-budgeting/.

1. Clinical Trials Forecasting for Finance Professionals. July 2011. Accessible at: www.healthtech.com/zctf.

2. Pharma industry: Still not budgeting accurately. CenterWatch. August 8, 2011. Accessible at: http://www.centerwatch.com/news-online/article/2039/pharma-industry-still-not-budgeting-accurately#sthash.SskmRqC3.dpbs.

3. Hammeke K. Can CROs Help Reduce the Expense of Clinical Trials? Clinical Leader. April 29, 2014. Accessible at: http://www.pharmaceuticalonline.com/doc/can-croshelp-reduce-the-expense-of-clinical-trials-0001?atc~c=771+s=773+r=001+l=a.

4. Active trials as of November 2014. Accessible at: http://clinicaltrials.gov/ct2/results?term=active+trials+2014&Search=Search http://clinicaltrials.gov/ct2/resources/trends#RegisteredStudiesOverTime.

5. Bioclinica study