

Accounting for clinical trials

Accounting

Transactions

Risk

Tax

Industry insights



Introduction

The costs and risks of the clinical development of a drug are significant for life sciences companies – especially in the later stages. While some companies have built significant internal clinical-development capabilities, most look outside their organizations in search of unique talents, tools and geographic reach. Clinical-research organizations (CROs), from large multinationals to small, specialized boutiques, are serving this demand. In addition to clinical-trial monitoring and data management, CROs may also be engaged to provide a wider range of clinical-development services, including consultation on study design, investigator recruitment, study monitoring and data analysis. Life sciences companies commonly contract with various clinical investigators, consultants and laboratories to facilitate clinical activities.

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As the cost of conducting clinical trials increases, life sciences companies should give additional consideration to (1) the potential for errors in accounting for clinical-trial activities and (2) the related internal controls that may reduce the risk of error.

Typically, the challenge associated with accounting for clinical trials relates to activities performed by CROs and other external vendors. The diverse nature of services that may be provided under CRO and other arrangements, the different compensation arrangements that can exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials.

This publication includes an overview of the relevant authoritative accounting literature and analyzes industry practice in accounting for clinical-trial activities. We also summarize our observations on the common accounting issues related to clinical activities and provide examples of internal controls in use at life sciences companies that may reduce the risk of error. This publication may be useful to companies wishing to benchmark their internal controls over clinical expenses against peers, or for companies who are expecting an increase in clinical activities in the near term.

US Generally Accepted Accounting Principles (GAAP) guidance

Accruing for the cost of clinical-trial activities

There is general agreement that expenses incurred pursuant to arrangements associated with clinical activities should be recognized in the period that the services are rendered. Financial Accounting Standards Board Concepts Statement No. 6, *Elements of Financial Statements*, provides that recognition of revenues, expenses, gains and losses and the related increments or decrements in assets and liabilities – including matching of costs and revenues, allocation and amortization – is the essence of using accrual accounting to measure performance of entities. The goal of accrual accounting is to account for the effects of transactions and other events and circumstances in the periods in which they occur, to the extent that those financial effects are recognizable and measurable. As a result, we believe that life sciences companies should make reasonable efforts to estimate accruals at each reporting period for clinical activities performed during the period, including services rendered by CROs and other vendors.

Nonrefundable advance payments

Emerging Issues Task Force Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3), provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity's expectations change such that it does not expect the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense.

Supplies for clinical trials

To prepare for larger clinical trials, companies often manufacture or purchase larger supplies of the product candidate being evaluated in the trial. These clinical supplies can be expensive, as biologic product candidates are often manufactured in large batches. In our February 2007 bio*link article, "Accounting Considerations for Collaborative Arrangements and Pre-Launch Inventory" (EYG No. EJ0002), we addressed the topic of whether "inventories" of products that have yet to receive Food and Drug Administration





approval should be capitalized. Based on informal discussions, we understand that the Securities and Exchange Commission (SEC) staff believes there must be a high likelihood of regulatory approval to conclude that future economic benefit of the inventory is probable and cost capitalization is appropriate. We understand that the SEC staff would be very skeptical of any company that asserts probable future economic benefit prior to the completion of Phase III clinical trials. Accordingly, we believe that companies generally should not be capitalizing prelaunch inventory prior to the completion of Phase III clinical trials. As a result, we expect that supplies of unapproved products will generally be expensed upon their manufacture or upon the delivery from a vendor.

International Financial Reporting Standards (IFRS)

The issuance of the SEC's proposed road map to allow US issuers to file financial statements prepared on the basis of IFRS has generated dialog about whether US GAAP will ultimately be replaced. We believe that the eventual widespread use of IFRS by US issuers is likely. As such, we believe it is important for US companies to now become familiar with IFRS.

With regard to expense recognition for clinical-trial costs, we believe the IFRS guidance is in many respects consistent in principle with the US GAAP standards. However, one key difference under IFRS is that internal project-development costs are capitalized when technical and economic feasibility of a project can be demonstrated in accordance with certain criteria. The stated criteria include: demonstrating technical feasibility, intent to complete the asset, and ability to sell the asset in the future, as well as others.

Although not generally seen in practice, there could be scenarios under IFRS where certain clinical-trial costs may be capitalized. Under US GAAP, internal project-development costs, including clinical-trial costs, are expensed as incurred. In the development phase of an internal project, an entity can in some instances identify an intangible asset under IFRS and demonstrate that the asset will generate probable future economic benefits. For example, internal project-development costs related to a post-marketing clinical trial may meet the criteria for capitalization under IFRS, while these costs would be expensed under US GAAP.

Observations on industry practice

We reviewed the accounting practices of several life sciences companies with clinical activities and identified the methods most commonly used to estimate clinical-trial liabilities. One notable observation is that there is significant diversity in practice, as each company has typically developed and refined its clinical-accounting process to meet the unique needs of its business and terms of its arrangements with CROs. For example, each company reviewed had established controls to achieve differing thresholds of reporting accuracy for an individual clinical

trial, based on the magnitude of the effects of each individual trial on the company's overall financial statements. Under this implied view, the financial-reporting controls surrounding large trials would generally be more robust than the controls surrounding smaller trials.

Not surprisingly, we also observed that larger life sciences companies were more likely to automate portions of the accrual process. Automated functions include the integration of a contract database within the accrual process, the integration of clinical development data within the accrual process and the automated matching of vouchered invoices with the related clinical-trial accrual.

While we observed significant diversity in practice, we also observed many common themes in the accounting for clinical-trial liabilities. Most companies grouped the contractual or budgeted clinical expenditures into major categories for accounting purposes, such as the following:

- ▶ Directly attributable costs
- ▶ Start-up period
- ▶ Patient-treatment period
- ▶ Wrap-up period

Accounting treatment of clinical trial expenditures

Categories of clinical expenditures	Phases of clinical development:		
	Start-up period	Treatment period	Wrap-up period
Costs directly attributable to a period <ul style="list-style-type: none"> ▶ Consultants for clinical monitoring ▶ Consultants for project management ▶ "Pass through" and travel costs ▶ Costs for investigator meetings ▶ Lab costs 	Costs for direct consultants and other direct costs are frequently invoiced and/or can be reliably estimated on a monthly basis. These expenses can be uneven from period to period, but also best reflect the level of services rendered during the period.		
Costs related to start-up activities <ul style="list-style-type: none"> ▶ Investigator site selection and training ▶ Database setup and design 	Contractual costs to provide services related to clinical trial start-up activities are often recognized ratably over the estimated start-up period.		
Costs related to patient treatment <ul style="list-style-type: none"> ▶ Doctor and hospital investigator costs ▶ Patient screening and recruitment costs ▶ Enrolled patient treatment ▶ CRO clinical monitoring costs (site visits) ▶ Database maintenance 		Contractual costs to provide services related to patient treatment are often recognized based on data related to patient screening, enrollment and monitoring visits. Fixed fees not directly correlated to patient activities, such as CRO management fees or database maintenance, are often recognized ratably over the treatment period.	
Costs related to wrap-up activities <ul style="list-style-type: none"> ▶ Report writing and quality control ▶ Data cleaning 			Contractual costs to provide wrap-up activities are often recognized ratably over the estimated wrap-up period.

Source: Ernst & Young

Directly attributable costs

Inherently, the accounting for clinical trials is an estimation process. However, some types of clinical costs can be more clearly attributed to a period and do not need to be included in attribution methodologies, such as expense recognition on a straight-line basis. For example, a life sciences company may contract directly for certain services, such as consultants who are paid on an hourly basis or by lab costs. For these directly attributable clinical costs, we observed companies estimating these costs on a discrete basis, generally monthly.

Start-up phase

The start-up phase is generally the period before patients begin dosing under the clinical-trial study. Expenses such as site selection and database development are examples of costs that may be included in the start-up phase of a clinical study. These costs incurred by CROs or outsourced to other vendors by the CROs can span a few months, but the length of time varies depending on the size and design of the trial. Certain clinical programs may have only a few clinical sites, while some phase 3 studies may have numerous clinical sites around the world. We observed that most companies recognized the estimated start-up expenditures using a straight-line attribution methodology over the estimated start-up period.

Patient-treatment phase

The patient-treatment phase typically represents a majority of the clinical-study costs. While the conduct and protocols of each study may vary widely based on the indication and clinical endpoints measured, we did observe a consistent practice in that all models estimated the expenses incurred based on patient-activity data. We observed that when the treatment phase was brief, the companies expensed the full average treatment cost per patient when each patient started the treatment phase. For longer treatment phases, a more detailed analysis was used to measure patient-treatment costs, based on patient activity data such as the number of screening visits, patient enrollment, dosing and/or monitoring visits. This kind of detailed model is dependent on obtaining information from CROs or other service providers. Some companies are able to obtain this information with automated tools, such as online databases that include data from patients and doctors, in order to track the progress of patients throughout the study.

Reporting and wrap-up phase

Occurring over the last few months of a clinical study, the activities during the wrap-up phase include a statistical review of the data and the final clinical research study reporting. We generally observed that the wrap-up phase was accounted for in a manner similar to the start-up phase (expense the estimated wrap-up expenses using a straight-line attribution method over the estimated wrap-up period).

What could go wrong?

Informal amendments to CRO agreements

Most life sciences companies have an established control related to the finance department's review of all material contracts. However, the finance department may not be aware of all amendments to contracts, particularly when an amendment is informal. It is not uncommon for the terms of an agreement with a CRO to be amended during the term of a study, to provide for additional services. In many cases, these additional services are authorized by the company's clinical development staff verbally, through email communications or by other informal methods. In addition, it is also not uncommon for the parties to take some time to finalize formal change orders or amendments; meanwhile, expenses might be incurred

pursuant to the less formal agreement, which could result in an “overrun” invoice from the CRO.

To reduce the risk of material “surprises” in CRO billing due to informal amendments, companies should consider the following internal controls:

- ▶ Purchasing authority limits are clearly established regarding amendments.
- ▶ Amendments are required to be formally documented and executed.
- ▶ The finance department reviews all material clinical contracts (including amendments) and periodically evaluates the underlying clinical accrual estimation against the financial terms of the contract.
- ▶ A finance-department representative periodically meets with a clinical-development representative to validate the completeness of the agreements, including informal or “in process” agreements.
- ▶ There is quarterly communication or “confirmation” with the CROs regarding unbilled amounts.

Clerical errors in a manual process

The accounting for clinical trials is typically a very manual process. Most companies establish models in spreadsheets that require

updates each reporting period to reflect the most current trial activity and vendor invoices. These spreadsheets are often complex and include inputs from various sources, such as the contractual costs with the CRO or other vendors, known activity under the trial (such as patient enrollment) and estimates of other activities under the trial (such as reimbursable travel expenses). As with any accounting process, manual activities have a higher risk of error than automated activities. Due to the complexity of most clinical accrual spreadsheets, manual errors occasionally happen, and sometimes these are identified only after a material error has occurred.

To reduce the risk of clerical errors in the accrual process, life sciences companies should consider the following internal controls:

- ▶ Clinical-trial reconciliations and analyses are subject to a periodic detailed review. The periodic reconciliation process should include steps to ensure that prepaid clinical-trial expenses are appropriately evaluated under EITF 07-3, such that prepaid amounts are not inadvertently netted against other accrued clinical liabilities.
- ▶ Separate project expense codes are used for each clinical trial, and/or vouchered invoices are automatically matched to the related clinical-trial accrual to avoid double counting of the liability.

- ▶ A robust process to create a clinical budget is followed; the clinical expenses for each program for each period are compared to the budget, and budget variances are explained.
- ▶ The finance department reviews all material clinical contracts (including amendments) and periodically evaluates the underlying clinical accrual estimation against the financial terms of the contract.
- ▶ A finance-department representative meets with a clinical-development representative periodically to validate the significant assumptions used for accounting purposes.
- ▶ There is quarterly communication or “confirmation” with the CROs regarding unbilled amounts.

Conclusion

Clinical development can lead to significant breakthroughs for a company, but often requires years of effort and hundreds of millions of dollars. Even a small percentage error in managing this spending could be material to the expenditure trends and to investors. We encourage companies to challenge their internal controls over the accounting for clinical trials and to incorporate leading practices. ▶

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EYG No. EJ0032
0902-1025630

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