Biotech accounting leading practices: Accruing for outsourced R&D activities

KPMG and Condor discuss the challenges of accounting for R&D activities and offer leading practices based on their industry experience.

As life science companies strive to innovate and bring groundbreaking treatments to market, they often rely on outsourced research and development (R&D) activities. These activities enable entities to leverage external expertise and resources, reduce costs, and accelerate the development process. However, accounting for these arrangements, particularly when it comes to clinical trial accruals, can be complex.

This paper explores the intricacies of accounting for outsourced R&D activities, focusing on the nuances of clinical trial accruals. It also outlines leading practices that finance teams can embrace to help ensure adherence to the accounting standards of US Generally Accepted Accounting Principles (US GAAP), as well as provide complete and accurate information that is critical to forecasting and making important business decisions.

Complexities of accounting for outsourced R&D activities

Clinical trial accruals

To help ensure accurate financial reporting, which requires that expenses are accrued as they are incurred, it is imperative for companies to diligently record accrued liabilities for R&D activities conducted by third-party service providers (TPSPs). There can be varying degrees of complexity associated with developing complete and accurate accrual calculations, as companies generally need to estimate the extent of TPSP services that have not yet been invoiced. Often, the structure of the invoice and payment terms do not thoroughly and accurately reflect the services provided. In organizations conducting one or more ongoing clinical trials, management will find themselves working with numerous TPSPs, managing multiple arrangements with each TPSP, and overseeing arrangements with varying contract terms—a potentially complex invoicing process.

The company's estimates should be based on a thorough analysis of the progress and completion of R&D activities contained within the TPSP contracts; close monitoring of the activities, units earned, and milestones achieved; and establishment of effective internal and external communication channels with TPSPs, including regular collection and review of further data, documentation, and progress reports.

Failure to account for these liabilities completely and accurately can produce inaccurate financial statements, which may lead to restatements. Additionally, R&D accruals are commonly considered a Critical Accounting Matter for biotech companies. As such, it is essential for companies to adopt a proactive approach to capturing and recording these financial obligations.

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Primary elements underlying clinical trial accrual estimates

To account for clinical trial accruals, companies must consider several primary elements depending on the size and complexity of the trials, including:

1. **Method used:** Finance teams employ various methods to calculate for clinical trial accrual estimates. TPSP contracts, specifically contract research organizations, are usually disaggregated into three primary components with varying methods applied for each: (1) Direct Service Fees – unit- or milestone-based, (2) Investigator Fees – site and patient costs, and (3) Pass Throughs – other third-party costs passed through by the CRO or other reimbursable expenses.

   For smaller or simpler trials, such as Phase 1, commonly used methods include the milestone method, amortization based on the timeline, and the percentage-of-completion method. For larger or more complex trials, commonly used methods include activity-based drivers (patient, site, and timeline), as well as percentage-of-completion methods. The chosen method should align with the specific circumstances of the clinical trial, contract, and budget and provide the most accurate representation of the costs incurred when the services are provided.

2. **Assumptions identified:** Accurate estimation relies heavily on the assumptions made by the finance team. These assumptions may include factors such as estimated patient enrollment and site activations, trial duration, cost per patient, and any expected changes or modifications to the trial protocol. It is crucial for finance teams to exercise judgment and base their assumptions on reliable data and clinical or program management input.

3. **Data needed:** To calculate period-end expenses and accruals for clinical trials, finance teams require comprehensive and accurate data. This data encompasses various elements, including patient visits, procedures, and enrollment status, usually from Electronic Data Capture (EDC) systems; other trial-related costs; progress against milestones; units earned or other service provider activities; and any amendments or adjustments made during the reporting period. Invoices received to date are also a key data element used in calculating the necessary accrual (or prepayment in advance of services being rendered). Maintaining a robust data management system that captures life-to-date data for the duration of the trial and includes communication channels with the relevant stakeholders is vital to help ensure data integrity.

Leading practices when accounting for outsourced R&D activities

To effectively account for outsourced R&D activities, including clinical trial accruals, in accordance with US GAAP, companies can employ the following Leading practices:

1. **Establish clear accounting policies:** Develop and document clear accounting policies specific to outsourced R&D activities. These policies should outline the methodology for estimating and recording clinical trial accruals, as well as any other significant aspects of financial reporting related to the outsourced activities. Clear policies will result in accounting for similar outsourced R&D activities consistently.

2. **Clarify data requirements with service providers:** Work with your clinical operations, program management, or procurement teams to align on key deliverables and dates for financial reporting. Key data and reports are required from third-party service providers to support financial estimates. Gaining alignment internally with your teams, before setting expectations externally with third-party service providers, will mitigate confusion and delays commonly experienced.

3. **Outline key contract terms:** Help ensure that key contract terms governing outsourced R&D activities are identified and summarized. Carefully review contracts with the support of legal counsel to help ensure that the scope of services is consistent with the budget (such as timelines, and estimated patient and site enrollment), and that payment terms and milestone metrics, if applicable, are completely identified and accurately considered when developing accrual estimates. It is important to have the support of clinical operations and program management, which should also compare the detailed unit budget to the contract assumptions listed in the agreement to verify consistency and accuracy.

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4. **Establish cross-functional collaboration:** Foster collaboration between the finance team and other departments involved in the R&D process, such as clinical operations and program management. Regular communication and shared knowledge are necessary for better estimation and recording of clinical trial accruals, as well as a deeper understanding of the financial impact of the outsourced activities.
5. **Conduct regular reviews and updates of assumptions:** Periodically review and update the assumptions underlying clinical trial accrual estimates. This review should include evaluation of actual trial progress, changes in the external environment, and evolving regulatory requirements. Timely adjustments to assumptions contribute to more accurate financial reporting.
6. **Institute monitoring and control mechanisms:** Implement strong monitoring and control mechanisms to validate the accuracy and completeness of data used for clinical trial accrual estimates. Regularly reconcile trial-related expenses, units earned, milestones achieved, and patient enrollment data to help ensure consistency and reliability. Modifications are common for R&D contracts as the related studies can evolve over time. It is critical for the finance group to be made aware when modifications to existing contracts are made so that models, assumptions, and data can be updated in a timely manner and accruals remain accurately calculated.

Conclusion

Accounting for outsourced R&D activities, particularly clinical trial accruals, presents complexities in early- and late-stage biotech companies. However, by leveraging leading practices, such as developing clear accounting policies, establishing clear data requirements with service providers, summarizing key contract terms, engaging cross-functional collaboration, regularly reviewing assumptions and implementing strong monitoring and control mechanisms, companies can improve accrual accuracy for outsourced R&D activities and compliance with US GAAP. Taking a consistent and diligent approach to accounting for these items is crucial for the financial health and integrity of biotech companies.

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About Condor

Condor is building a world where finance accelerates human progress in medicine. Condor's software solution harnesses real-time clinical trial data and third-party vendor collaboration for faster, more precise accounting, accruals, and financial planning & analysis. With Condor, biotech finance teams can reduce time to close by half with automation, cash flow management, and forecasting with powerful insights and stakeholder alignment, all while trusting the integrity of Sarbanes-Oxley compliance. The technology was thoughtfully designed by biotech finance experts.

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KPMG, LLP, and Condor will participate in the *Best Practices in Accounting for Clinical Trials* panel at the Finance and Accounting for Bioscience Companies conference, September 19–20, 2023, at the Hyatt Regency Boston.

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