



Clinical Business Operations

A proactive strategy and program to effectively manage outsourced clinical studies

Many life science companies outsource mission-critical aspects of clinical development, entrusting their key assets to a network of external service providers. This significant investment of time and money is typically overseen by the Clinical Operations group, whose primary focus is trial planning and execution. Additional tasks related to outsourcing management – from vendor bidding and selection to performance-based negotiations and vendor management – can divert their time and effort away from the company’s most critical undertaking.

Danforth Advisors’ Clinical Business Operations (CBO) practice offers a comprehensive solution to outsourced clinical development, combining expertise in sourcing and finance management to solve the common challenge of managing vendor performance. Our CBO team is expertly qualified to manage the overall process, from strategic planning and contracting through execution, monitoring and reporting.

Key Considerations

Clinical teams are often burdened by tasks falling outside of their domain expertise: the business operations side of overseeing outsourced work to Contract Research Organizations (CROs), Contract Manufacturing Organizations (CMOs) and other vendors. The consequences can be numerous:

- Lack of strategic planning at the outset results in an inefficient outsourcing process
- Ineffective negotiation with CROs, CMOs and vendors directly leads to higher budgets
- Poor oversight of CRO, CMO and vendor activities drives unplanned contract change orders, often with inappropriate cost escalations, leading to budget overruns
- Inaccurate clinical spending forecasts result in large budget surprises
- Unreconcilable actual outsourcing spending creates accounting issues and challenges from auditors, which can cause audit findings, delay an IPO or other financing or strategic transaction
- Burden on clinical staff to manage business operations creates significant opportunity cost
- CRO, CMO and vendor compliance violations lead to FDA audit findings



How Danforth Can Help



Customized strategic outsourcing planning

We will define the clinical outsourcing strategy and plan based on your in-house capabilities and special requirements, and coordinate with Clinical Operations and Finance to forecast the outsourcing budget.



CRO/CMC/vendor bidding and selection

In conjunction with Clinical Operations, we will identify appropriate candidate vendors, prepare the Request for Information (RFI), Request for Proposal (RFP), analyze incoming proposals and facilitate bid defense meetings to make recommendations -- including a Vendor Selection Report detailing the scoring process and final decision to ensure compliance with regulatory requirements.



Contract and change order management

We will assist in the negotiation of Master Services Agreement (MSA), Statement of Work (SOW), budget proposal and payment schedule with the vendor and execute change orders as needed.



Vendor oversight

We will assist with the development, implementation and tracking of Key Performance Indicators (KPIs)/Service Level Agreements (SLAs) to measure vendor performance and document vendor oversight per compliance. We will also assist with right-sized governance to facilitate effective issue resolution.



Optimized coordination with Clinical Operations and Finance

We will ensure timely and quality information flow from Clinical Operations to Accounting, enhance forecasting and accrual accuracy and minimize surprise spending.



Integrated team approach

We will provide access to a team of professionals with highly specialized clinical business operations expertise, integrating seamlessly with your internal resources.

Clinical Business Operations Team

Our CBO practice is led by Tony Carita, who has over 35 years' experience in research and development outsourcing with expertise directing outsourced clinical operations. He previously led the global sourcing activities of a major Japanese pharmaceutical firm and worked for a top five CRO. He is supported by a group of CBO specialists who regularly work as part of an integrated Danforth team on client engagements.

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About Danforth Advisors

Danforth is the financial backbone to hundreds of life science companies, providing integrated and scalable consulting teams ranging from staff accountant through CFO. The company's services span the full breadth of a finance organization's needs, whether short or long term, including accounting and operational finance support, capital raising, financial planning and analysis, IPO preparation and post-public SEC compliance. Founded in 2011, Danforth has been a strategic and trusted thought partner to more than 400 life science companies, private and public, across all stages of the corporate life cycle. The company is headquartered in Waltham, Massachusetts with additional operations in the emerging life science clusters of metropolitan New York, Philadelphia, Pittsburgh, Colorado and Texas. Additional information is available at www.danforthadvisors.com.