



# Clinical Business Operations



Strategic advisory and execution on the business side of outsourced research, clinical development, and manufacturing

Danforth Advisors' Clinical Business Operations (CBO) practice offers a comprehensive and flexible means of improving the planning, cost efficiency, and outcomes of programs that are commonly outsourced in life sciences, including preclinical research and development, clinical studies, and manufacturing. We apply expertise in outsourcing strategy, performance-based contracting and negotiation, and study-level clinical finance to help clients better understand their clinical spend and maximize the value of relationships with research labs, Clinical Research Organizations (CROs), contract manufacturers, and other providers. Ultimately, we aim to improve our clients' ability to reach key milestones on time and on budget.

Our CBO team comprises experts in four integrated areas:

## 1 Preclinical Outsourcing Strategy and Management

Including vendor selection and negotiation.

## 2 Clinical Outsourcing Strategy and Management

Ranging from strategic planning and contracting through change order management, monitoring, and reporting across all providers engaged in the successful completion of studies. We also conduct independent investigator budget modeling and manage structure and negotiation of individual site agreements.

## 3 Clinical Finance

Bridging the gap between Finance and R&D or Clinical Operations to improve accruals, analysis, and forecasting.

## 4 CMC/Supply Chain

Advising on manufacturing and supply chain decisions in earlier clinical stages to ensure future scalability and cost efficiency.

## Key Considerations

- ✔ We understand the importance of getting it right at the outset – for example, by building accountability into master service level agreements (MSAs) and devising forward-looking strategies that anticipate clinical and CMC needs in earlier stages of development.
- ✔ Our specialists understand preclinical, CMC and clinical development processes, supply chains and timelines, and many other internal and external factors that inform outsourcing strategy in biopharma. These include the size, complexity, and capabilities of various providers in the global market, the client's ability to influence in that market, the composition of the client's in-house team and whether they need project-based support or management of the entire function – from the RFP to closing out the contract.
- ✔ Our CBO consultants regularly partner with clients' Clinical Operations teams and with other Danforth consultants in Finance and Accounting roles, ensuring efficient and timely flow of information between functions.

# How Danforth Can Help

We offer a wide range of services that are customized to meet the unique goals and requirements of each client engagement.



## Preclinical contracting and project management

We manage vendor selection and negotiation, leveraging extensive knowledge of applicable providers, and ensure adherence to project budgets and timelines.



## Clinical outsourcing planning

We 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.



## Contract and change order management

We 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 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.



## Investigator site contracts and budgets

We apply deep expertise in the nuances of site budgets and contracts, conduct independent assessments, and perform the budget modeling based on your protocol to provide an unbiased estimate of investigator fees.



## Optimized coordination between R&D/Clinical Operations and Finance

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



## Alignment between clinical study execution and drug supply management

We provide a holistic view and understanding of pharmaceutical supply chains, enabling compounded savings from clinical through commercialization.



## CRO/CMC/Vendor bidding and selection

In conjunction with Clinical Operations, we 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.

## Contact

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