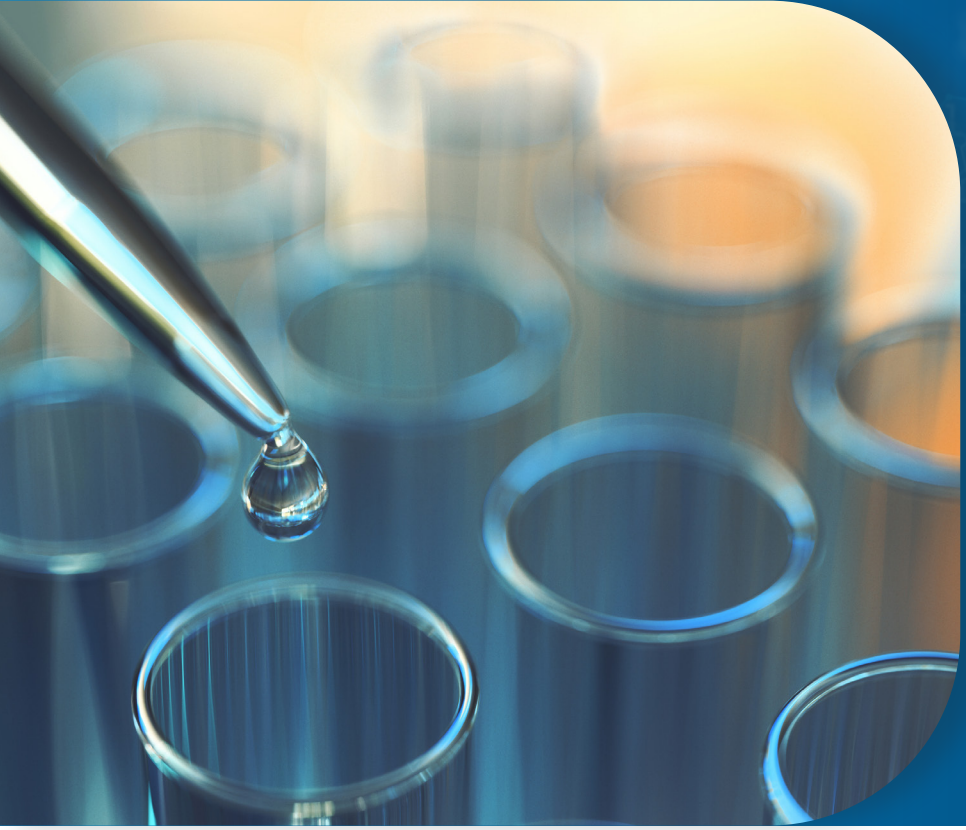

Danforth Advisors

Life Sciences, Well Run.

Development Strategy and Operations

Advisory, planning and operational oversight across all stages of development

We apply an insider's perspective to inform strategy and provide functional oversight of outsourced biopharma development, optimizing the path to proof-of-concept and, ultimately, regulatory approval.

We provide sponsor-side, stage-centric skill sets to advance development with objectivity and integrity, whether as a strategic sounding board or variable extension of your internal team.

Why Danforth

- We are deeply and exclusively rooted in life sciences. We have assembled a team of the highest caliber, performing vitally important roles for which competition in the market is intense.
- Our variable resources, engaged where and when needed, keep your fixed costs down and allow you to focus investment on de-risking the science and creating value.
- We act solely in our clients' best interests, taking an agnostic approach to selecting the right CRO or other providers.

How We Can Help

Preclinical Advisory

Strategic guidance to help early-stage companies advance development candidates to a regulatory filing that supports first in human studies. Sample capabilities:

- Advisory/input on validation of proposed mechanism of action (MoA), target positioning and clinical indication selection, and establishment of a target product profile (TPP)
- *in vitro* – Expertise in the areas of *in vitro* characterization, benchmarking against standard of care agents, and transfer of in-house assays to specialized vendors
- *in vivo* – Expertise in the areas of appropriate study design, animal model identification, efficacy modeling, bioanalytical assay development, pharmacokinetics/ pharmacodynamic modeling, dose/schedule optimization in relevant efficacy models, and biomarker co-development

Contact: Ramani Varanasi | 857-928-2302 | rvaranasi@danforthadvisors.com | **www.danforthadvisors.com**

Chief Medical Officer Advisory

Our team of highly qualified clinicians can provide expertise in distinct therapeutic areas and technologies. Sample capabilities:

- Guidance across the development continuum, including overarching clinical strategy, input toward the IND-enabling preclinical plan, and oversight of Phase 1 – Phase 4 clinical trial design and implementation
- Advisory on lead indication selection and leadership of target product profile (TPP) process
- Facilitation of alliances via extensive knowledge of the development approach endorsed by big pharma

Clinical Development Operations

Support for product development from initial application through final regulatory filing. Sample capabilities:

- Clinical project and trial management; protocol development, project team oversight, establishment of timelines and milestones, clinical monitoring
- Program management; coordination across all development functional areas, timelines, milestones, budgets, risks and resourcing
- Regulatory affairs; regulatory strategy, IND/IDE preparation, coordination of NDA/PMA/510K submissions, regulatory communication oversight
- Medical writing; protocols, Investigator Brochures, annual reports/DSUR, clinical study reports and safety narratives

Clinical Business Operations

We have specialists with deep expertise in the planning and management of outsourcing across preclinical development, clinical studies and CMC.
Sample capabilities:

- Strategic planning, vendor selection and oversight, contract structure and negotiation, independent investigator budget modeling and site agreements
- Clinical finance management; bridging the gap between Finance and Preclinical/Clinical Operations to improve forecasting and accuracy of accruals
- Advisory on manufacturing and supply chain decisions

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