Danforth Advisors

Knowledge. Discipline. Perspective.

Preclinical Advisory

Strategy, guidance and oversight for life science companies on the path to IND

Engaging an experienced partner to oversee the work of outsourced preclinical development is an effective strategy for smaller biopharma companies who typically operate with lean internal teams. While capital efficiency is important, the quality and integrity of preclinical programs cannot be compromised. Danforth Advisors offers an efficient model for early-stage companies to leverage specialized knowledge and guidance in a variable way, keeping fixed costs down while advancing preclinical development with sound planning, input and oversight.

Key Considerations

Alignment on the roadmap to IND

Reaching the milestone of IND submission requires careful planning and harmonization of several disciplines in preclinical development (e.g., cell biology, pharmacology, toxicology and bioanalytical work), where each of these development steps can effectively create value for an organization. Our preclinical advisors have the experience necessary to oversee the journey from end to end.

Forward-looking approach

It is critical to ensure that the early contributions of discovery are carried forth into preclinical development, as well as intentionally integrated into clinical plans to support a deliberate transition of the drug candidate into clinical development. We provide preclinical guidance with perspective across the entire development continuum.

Integration with complementary resources

We have a team of specialists who can manage preclinical outsourcing, including vendor selection and oversight, contract structure and negotiation. We also offer Chief Medical Officer advisory across preclinical and clinical development stages.

How Danforth Can Help

We take a leadership role in selecting the right preclinical vendors, providing input and guiding critical activities in the following areas.

- **Discovery/Target Input**
  We can oversee or provide input on efforts including validation of proposed mechanism of action (MoA), target positioning and clinical indication selection, and establishment of a target product profile (TPP) as a roadmap for project planning.
- ***In Vitro***
  Expertise in the areas of In Vitro characterization (binding, activity, target selectivity/specificity), 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.
- **IND-Enabling**
  Expertise in Good Laboratory Practice (GLP) toxicology package planning, ADME/tox/safety pharmacology, and qualified/validated bioanalytical assay development.
- **Document management**
  We provide document management at all levels, including data room, vendor study report reviews, and preIND/IND/CTD section writing.

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