

Alters Bioscience Consulting

Preclinical Development, Due-Diligence, Scientific Writing

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Advancing the preclinical development of therapeutic agents

Expertise spans basic research through Phase I and includes IND-enabling pharmacology, efficacy and mechanistic studies using a variety of therapeutic strategies. Experience in multiple clinical areas including cancer, autoimmunity, inflammation, metabolics, hematology and pain.

Consulting Services

- Identifying client needs, developing and implementing preclinical/translational R&D strategy, compiling and adhering to project plans and budgets.
- Performing literature-based project assessments, designing and implementing study protocols and integrating study results into ongoing development plans.
- Evaluating, selecting and managing appropriate contract research organizations (CROs) and academic collaborators.
- Performing scientific and intellectual property due-diligence on new corporate ventures and product in-licensing opportunities.
- Writing relevant sections of INDs, business plans, reports, manuscripts, grants and other scientific and corporate documents.

Summary of Qualifications

Fifteen years of broad and extensive experience in the biopharmaceutical industry. Expertise spans all phases of drug development from basic research through Phase I clinical study, and multiple therapeutic areas including oncology, autoimmunity, inflammation, metabolics, hematology and pain. Experience with a wide range of therapeutics including proteins, small molecules, cell-based vaccines, nanoparticles and antibodies, and major technology areas including targeted therapeutics, immunology, drug delivery, biomarker identification and cell and gene therapy.

Excellent collaborative skills gained by serving as liaison between industry, CROs, government agencies and thought leaders in academia and industry. Proven analytical, writing and presentation skills as evidenced by reports, IND submissions, publications and presentations to external experts in the field. Extensive management experience including scientists with diverse educational backgrounds, project teams composed of cross-functional contributors and external collaborators.

Representative Consulting Projects

Preclinical development

- Designed and implemented IND-enabling preclinical strategy for oncology therapeutic now in Phase II. Evaluated and directed CROs to perform a series of *in vitro/in vivo* studies including mechanism of action, efficacy in orthotopic and metastatic xenograft models, pharmacokinetic and biodistribution studies.
- Developed and implemented preclinical strategy for a series of biologics, one of which is now in Phase I. Performed literature-based assessments of novel therapeutic agents for autoimmune disease and transplantation, followed by immunoassay development, *in vitro* mechanism of action studies and *in vivo* efficacy and biomarker experiments performed by CROs.
- Designed and implemented preclinical pharmacokinetic and pharmacodynamic studies in rodents and non human primates. Data were used to determine optimal dosage for each therapeutic in *in vivo* efficacy studies in autoimmune/inflammatory, metabolic/endocrinology and xenograft models.
- Implemented studies to document the *in vitro* activity and *in vivo* efficacy and toxicity of a targeted oncology therapeutic both as a single agent and in combination with standard cytotoxic drugs. Compound is now in Phase I.

Due-diligence

- Provided scientific evaluation of new corporate ventures. Assessed scientific and clinical data and evaluated input from thought leaders in the field. Proposed internal preclinical development strategy for chosen corporate ventures.
- Evaluated intellectual property position of a variety of therapeutic and diagnostic approaches for potential new partnership opportunities.

Writing

- Worked with team to write and submit INDs including obtaining, analyzing and graphing data from IND enabling studies and writing a series of study reports.
- Wrote business plans, Investigator Brochures, INDs, grants and manuscripts.
- Represented company at scientific meetings, presented findings and initiated collaborations with industrial, academic and government institutions.

Education

- Ph.D. Cancer Biology, Stanford University, Stanford, CA.
 - B.S. Molecular Genetics, University of Rochester, NY.
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