

A Personalized Approach

Unique strategies and data mining for small biotech companies

Visual Snapshot

Clinical Trial

Phase I, first non-human dose escalation trial

Condition

AXL-enriched tumors, including acute myeloid leukemia, ovarian, and breast cancers

Purpose

Evaluate the safety and efficacy of a first-in-class antibody

Patient-Type

Healthy volunteer patient population

Ergomed's solutions to the challenges of clinical trials

While most clinical research organizations (CROs) focus exclusively on executing clinical trials, smaller, start-up biotechnology companies need more strategic guidance from the outset. They need an expert CRO that can understand the unique challenges faced in the drug development process and work with them to develop a creative, strategic, and data-driven clinical development plan (CDP).

The Challenge

An abundance of data, and a lack of resources

The company had finished the discovery phase for its molecule in late 2016 and wanted guidance on how to develop a pathway to IND in less than 12 months or by the end of 2017. Focusing on a novel and decision-gate-filled phase I/IIa approach would be paramount to the success of their program.

The Strategy

Prioritizing what matters

Ergomed identified key opinion leaders (KOLs), internal medical, and regulatory expert team members to help validate and provide key input on the preliminary CDP. The team also performed a roleplay exercise with a mock FDA meeting to help prepare the sponsor for the upcoming pre-IND meeting.

Developing a unique approach

Ergomed's expertise and flexibility often creates the space for creative, 'out of the box', and strategic approaches to the clinical trial process. By working directly with the biotech firm to understand the distinctive qualities of the molecule at hand, Ergomed was able to develop a quicker and more effective way to get the drug into the clinic.

The Outcome

Ergomed's early involvement allowed the biotech firm to organize a high volume of complex data to reveal multiple roadmaps that presented the highest possible chances of success for their asset with acceleration. The data-mining and strategic guidance provided by Ergomed allowed the biotech firm to give their flagship program the best chances and options for success. They had experienced teams, a great asset, and an idea of where they wanted to go, but didn't have the summary analysis of key data to drive that decision. And circumstances like this aren't unique. Launching a first drug, no matter how innovative, can be tough for any small biotech. Ergomed's expertise and creative thinking helped give these companies the guidance they needed to succeed.

