Optimizing Clinical Development: Saving Time & Costs

CERTARA

applied biomath
REVOLUTIONIZING DRUG INVENTION

Discover how an IO-focused biotech expedited the clinical development of novel therapeutics for patients, all while trimming expenses, by applying strategic modeling solutions.

Introduction

Our partner is a small-sized clinical-stage biotechnology company, focusing on developing oncology therapies. They have various products in their pipeline focused on activating the immune system or inhibiting key oncogenic drivers over various modalities, each with the potential to be best- or first-in-class. We have collaborated with them to develop models to support several of their programs.

> ***"Working with Applied BioMath was like working with an extension of our team – they have been our thought-partners."***
> **– VP, Preclinical and Early Development**

Overcoming Preclinical Challenges Using Expert Solutions

Challenge

For one of their projects, our partner's drug modality was a T-cell engager. Given the high bar for FDA submissions for T-cell engagers, our partner requested support for defining their safe starting dose in Phase 1.

Solution

Applied BioMath developed a semi-mechanistic model of our client's molecule to support the design of their Phase 1 studies. In lieu of developing a cross-reactive surrogate molecule and performing a dedicated tox study, the model was used to establish safety thresholds using comparator data from published studies in cynomolgus monkey. Modeling supported the rationale for their safe-starting dose, which was ultimately approved by the FDA.

Challenge

In another project, our partner wanted to model a safe dose for a molecule meant to localize a drug within the tumor to limit systemic toxic exposure.

Solution

Using mechanistic modeling that accounted for the major mechanisms of action of the drug for localization and efficacy, we successfully identified a pharmacologically active dose in the tumor which was still conservative enough for safety in the blood by projecting data from in vivo and in vitro models into humans.

> ***"We were excited to provide critical analyses for our client and grateful for the opportunity to support them in future projects. It is a privilege to accelerate innovative candidates into the clinic."***
> **– Applied BioMath Project Lead**

Maximizing Business Efficiencies

Cost and Time Savings in the Clinic

Our innovative approach to early feasibility assessment not only saved our partner valuable time in the clinic but also delivered significant cost efficiencies. They were able to make model-informed decisions that accelerated their clinical development timelines.

Harmonization of Client's Data Packages

By using models as a framework to integrate and unify our partner's interpretation of data, we built a stronger weight of evidence for the clinical plan and impacted strategy for future programs. Performing early feasibility assessments gave our partner confidence in the investment made in their programs.

Strategic Partnership

We worked as an extension of our partner's team, which allowed us to provide strategic input and scientific expertise quickly.

Responsive to Client's Timelines

The process of developing a drug can have various challenges and delays. We worked closely with our partner to deliver on time despite the unforeseen challenges they experienced with their other partners.