

Model-Informed Confidence in Oncology Dose Selection



Discover an oncology-focused company that gained confidence in their dose selection for an AML trial with pediatric patients and reduced their clinical development costs, by using mechanistic modeling.

Introduction

SUTRO
BIOPHARMA

Sutro is a clinical-stage company focused on the discovery and development of precisely designed cancer therapeutics. They have a large variety of potential therapeutics in their pipeline, including antibody-drug conjugates (ADC), bispecific antibodies, and cytokine-based therapeutics targeting immuno-oncology and autoimmune pathways.

“Applied BioMath was responsive, prompt, and effective. It was seamless to convene the appropriate members and skill sets to work together to problem solve for this important pediatric AML initiative.”
– Anne Borgman, CMO, Sutro Biopharma



Challenge/Solution

Our client, Sutro, wanted model-based justification for their proposed starting dose in a pediatric acute myeloid leukemia (AML) trial for their drug, an ADC that was already in clinical trials for adults with ovarian/endometrial cancer.

Challenge

Our partner wanted to justify their proposed starting dose in a pivotal trial for a rare and particularly aggressive subtype of pediatric AML.

“We were excited to make a direct impact on our client’s IND approval, and to support the clinical development of this molecule that can save the lives of young children.”
– Marissa Renardy, Principal Scientist, Modeling, Applied BioMath

Solution

Applied BioMath developed a PK/PD model calibrated to data for Sutro’s molecule from preclinical mouse studies and a clinical trial in ovarian/endometrial cancer. The model was used to predict exposure, safety, and efficacy at a range of doses and dose schedules. Modeling supported their rationale for dose selection with the FDA, which translated into an approved and open IND.



Maximizing Business Efficiencies

Cost and Time Savings in the Clinic

Our innovative approach to translational PKPD modeling 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 by reducing the need for dose escalations.



Strategic Partnership

Applied BioMath was “able to work nimbly and had the subject matter expertise” to take on any new challenges and “execute at a high level quickly.” The quality of resources used and efficiencies applied by Applied BioMath’s workflow made the project run smoothly.



Responsive to Client’s Needs

Our partner especially appreciated the speed of execution that Applied BioMath’s team was able to provide, with appropriate resources supplied and close attention to their program needs.

