CASE STUDY

Using Modeling and Simulation to Determine FIH Dose

Background and Problem

Allucent's client requested assistance using modeling and simulation to determine the First-in-Human (FIH) dose for their program. The drug was created to prevent the toxicity of cytotoxic drugs. However, the sponsor felt that the drug could be studied in healthy volunteers in Phase 1, if given carefully and for a short period. Conducting a Phase 1 study in healthy volunteers would greatly accelerate clinical development. That is where Allucent came in — to help determine how much of the drug could be given and for how long while ensuring subject safety.

Our Solution

Allucent developed a PK/PD model based entirely on the client's Pre-clinical data. Pre-clinical data used in the model included pharmacokinetics (PK) data and precursor data from mice cell populations when dosed with the drug alone and when dosed with chemotherapy. The mouse data was used to construct a systems pharmacology model that included both the cytotoxic effects of chemotherapy and the protective effects of the drug. This model was then scaled to humans. Based on the model, Allucent was able to predict the minimum effective dose in humans and the range of the clinical dose. Importantly, Allucent also predicted that the drug infusion should occur a specific amount of time prior to cytotoxic therapy to deplete the population of precursor cells.

Outcome

The FIH study was designed based on these simulations and predictions. When the data became available, the investigator commented that the predictions for the magnitude and timing of the effects on the precursor cells, peripheral white blood cells, and the pharmacokinetics were "remarkably accurate." The drug program was approved by the FDA. As a result, the final drug label includes dosing information in line with predictions made by Allucent.

Modeling and Simulation Services

Allucent has an expert team of pharmacometricians who build models tailored to guide your drug development program's decisions. As part of these services, our team will create a custom, model-based drug development plan that will facilitate the selection of the most important model for your compound and disease area.

Contact us today to learn how Allucent's modeling and simulation services can help you gain insights that move your clinical development program forward.

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Helping bring new therapies to light

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