

Altasciences Preclinical Develops Procedure to Visually Evaluate Large Molecule Effects on Diffusion Rates

BACKGROUND/OVERVIEW

Large molecules administered for cancer chemotherapy via IV infusion usually require patients to spend extended periods of time in treatment centers. But what if drugs could be safely administered quickly into the subcutaneous space so that patient treatment time could be reduced? A biotechnology company focused on delivering novel cancer therapies needed to evaluate their test article's effects on the diffusion rates of a large compound in the subcutaneous space in order to determine the fastest infusion rate permissible.

To meet their objectives, the sponsor sought a preclinical contract research organization (CRO) who could provide guidance in study design, had demonstrated experience with Yucatan Swine, and had the right technology to help them visualize dispersion volume and surface area at various timepoints.

THE CHALLENGE

For over a year, the sponsor evaluated numerous CROs but could not find the right partner due to the unique scope of work and procedural challenges required for their study. They required a dedicated preclinical team with strong scientific expertise who was highly engaged, could think creatively and could proactively anticipate and overcome hurdles throughout a project.

To meet the sponsor's needs, the Altasciences' preclinical team had to address several challenges:

- Subcutaneous infusions in swine are uncommon
- Two separate subcutaneous infusions needed to be started simultaneously in the same animal
- CT scanning during the injection required staff to manually start the infusion and exit the CT room within 8 seconds in order to avoid radiation exposure
- Repeat CT scans needed to be conducted quickly and with high resolution

THE SOLUTION

The Altasciences' team initiated an effective and regular communication plan with the sponsor early on in the development phase of the program. This communication plan established trust and created the foundation for an efficient and cost-effective working relationship.

- To ensure all objectives could be achieved, the Study Director worked closely with the sponsor and designed the study to include a method development phase for the in vivo portion of the study. This carefully crafted study design supported Altasciences' commitment to the 3Rs and resulted in quality data and a reduction in animal use.

A dedicated project team consisting of Radiation, veterinary imaging and technicians throughout the organization were assigned to the project and worked collaboratively from start to finish.

- The team participated in training and mock study activities to prepare for the project which allowed them to harmonize activities and identify time constraints prior to conducting the study. This approach saved time, reduced animal use, minimized errors and maximized budget.

RESULTS

By being scientifically focused, flexible and collaborative, the Altasciences' Preclinical team provided an innovative solution to support a sponsor's unique needs. Through the creative use of CT scanning of large molecules, along with unconventional infusion techniques, a procedure was developed in order to visually evaluate a test article's effects on the diffusion rates of large molecules in the subcutaneous space of swine. By determining the fastest infusion rate permissible, the client now has valuable information on how to better administer large molecule therapies to cancer patients in the future.

Learn more about Altasciences preclinical solutions at www.altasciences.com