Case Study: Business Benefits from Monitoring of Ongoing Studies

CASE 3

Sponsor conducting Xenograft studies on a tumor growth antagonist drug candidate needs to estimate the IC50 on a nonclinical study with multiple trial arms and treatment compounds.

Challenge: The study design is an involved lattice with multiple trial arms and with multiple CROs involved. Standard trial designs such as those in SEND are not sufficient. Tumor growth values are provided very frequently by multiple CROs. Sponsor-provided plasma concentration values are provided in Excel sheets. A method for estimating the inhibitory concentration for halving tumor size (IC50) is needed, each time new tumor growth and concentration data is received.

PointCross Solution: Over the course of 1 week, a trial design was developed using the study protocol. Furthermore, the biologics and data science team at PointCross developed a tumor growth model for the IC50 calculations, while the data modeling team generated automated data extraction and integration schema for incremental data provided by a constellation of CROs on daily or multiple loads per week. The Sponsor is now able to visualize the trends and analyze a number of parameters around the evolving progress of the tumor data in near real-time, and consider any protocol amendments in quasi-real time.

Business Benefits: Significantly quicker scientific and strategic decisions on the progress of the study, and the comparative performance of the tumor antagonist against other available standards of care. Normalizing and harmonizing multiple disparate data sources into a single coherent data time line for each subject.

Applicable services and technologies: Digital data extraction from human readable tabulations in Excel; Pharmacokinetic modeling and regression fits of subject data using statistical and mathematical techniques; Tumor growth modeling, end-point analysis and IC50 calculations developed using statistical and mathematics scripts.