Case Study: Business Benefits from Monitoring of Ongoing Studies

CASE 2

Delay in availability of Pharmacokinetic (PK) data from Bio-Analytics labs inhibits assessment of clinical pathology findings.

Challenge: Pharmacokinetic Concentration (PC) calculations of the treatment and metabolites are generated from biosamples sent to bio-analytics labs. The PK modeling and generation of PK parameters such as Cmax and Tmax, AUC (for various timepoints), and Cav, reported in PDF format or Excel is not available in standard machine-readable format. The Sponsor was losing considerable time waiting for the generation of these reports and then manually extracting and curating the data so that it could be integrated with the in-life clinical pathology data.

PointCross Solution: For PK reports provided in the PDF report, the PK parameters were extracted and un-pivoted to a machine-readable, columnar form for loading and integration into the remaining study in Xbiom. We further reduced the time and cost for the sponsor monitors by directly calculating the Pharmacokinetic parameters from the Concentration data from the assays.

Business Benefits: PK parameter calculations traditionally took the Sponsors' CRO between two weeks to a month to generate. PointCross is able to generate these within two business days, at no additional charge to Data Concierge customers. This saved the Sponsor over three weeks and thousands of dollars in modeling service charges by the CRO. This allowed the Sponsor to assess the treatment effects closer to real time, while reducing thousands of dollars in cost for obtaining the Pharmacokinetic parameters.

Applicable software and service deployed: Digital data extraction from PDF reports from DaaS service; Ability to standardize and normalize to SEND-IG CT using Terminology Harmonizer and Standards Management. Pharmacokinetic modeling and regression fits of subject data using statistical and mathematical techniques.