Case Study: Business Benefits from Monitoring of Ongoing Studies

CASE 4

Incorporating Histopathology data of organs and tissues for terminal subjects from a draft PDF report

Challenge: Necropsy data and histopathology results were available only as a PDF report after the study's conclusion. The CRO-provided LIMS data for pathology was not available until a conversion to SEND had been done, well after the final PDF Study Report was generated. This prevented pathology findings and incidence counts from being cross-assessed against in-life and clinical pathology findings by sponsor toxicologists.

PointCross Solution: PointCross extracted the digital data for all subjects and their organs and tissues within 7 days of receipt of the draft PDF report, and loaded the digital data into the Sponsor customers' site on Xbiom's universal data model and repository. This enabled the Sponsors' pathologists and toxicologists to analyze and observe incidence counts for cohorts being assessed against the in-life data.

Business Benefits: The Sponsor was able to save 4-6 weeks by having access to the digital histopathology data, and avoided a fee of between $8,000 - $10,000 by the CRO for digital pathology data provisioning from the LIMS. Data discrepancies and tentative observations were available for disclosure to study team and report writers. The Sponsor was able to summarize incidence counts, and was able to access digital pathology data against other ongoing or concluded studies.

Applicable software and services deployed: Digital data extraction from PDF reports; Standardization and normalization to SEND-IG CT using Terminology Harmonizer and Standards Management, conversion to universal data model with Smart Transformation module for Digital Data representation and repurposing for analysis and visualization in the Xbiom platform; Automated generation of SEND data domains for submittable SEND from the UDM data in Xbiom.