# Case Study: Business Benefits from Monitoring of Ongoing Studies

## CASE 1

**Sponsor looks to use on-going studies to make tactical and strategic decisions on planned and future studies and their design sooner, rather than wait until the final study reports are published.**

**Challenge:** Completed studies were previously not readily available to the Sponsor in a machine-readable digital form, and only PDF study reports were available in an unstructured repository in which findings were difficult to search and extract. Insights from findings must be published with substantiation and data along with the annotated insights, but searching across PDFs proved time consuming and challenging to structure.

**PointCross DaaS Solution:** The PDF reports for all the completed legacy studies of relevance were digitized by a combination of (a) Rapidly re-generating the Trial Design, (b) Extracting Study metadata that allows each of these studies to be reposed with context and provenance, (c) Extracting all the Summary Tables for all published cohorts and groups, (d) extracting all individual subject data from the tabulations and listings in the Appendices (e) Regenerating the summaries for the published summary tables -using only the extracted individual tables - and reconciling them to ensure that the data extraction is accurate and complete, and finally (f) Loading the legacy study into the Xbiom™ universal data model so they can be analyzed along with the ongoing studies.

This is done with a series of automation and machine learning tools that have aided in the processing of several thousand studies, many of which now serve as an indexed and searchable library unique to the respective Sponsor.

Toxicologists are now able to analyze the study data and visualize the data and statistics generated from the data. Figures, Tabulations, Listings and annotations about insights of interest are generated and saved as "TFL" objects for collation and publication. Sharing of the TFLs with colleagues and CRO investigators create a shared understanding of each study and their relationship with other studies – both legacy and future planned.

**Business Benefits:** Reduce time to IND filing by months, because key strategic decisions do not need to wait for a formal report to be published but rather when there is sufficient data to make a data driven decision. Sponsors see a reduced cost of conducting studies by avoiding unnecessary studies or re-designed the studies to be started.

**Applicable services and technologies:** Digital data extraction and Nonclinical Study Standardization from human readable tabulations in PDF by PointCross' Data Concierge service. Collaboration, saved TFLs with annotations, and messaging solutions in Xbiom to identify TFLs related to an insight of interest.