CATALYST
CLINICAL RESEARCH

Case Study

PROSTATE CANCER CLINICAL UTILITY STUDY

SITUATION

A multinational healthcare company and a front runner in epigenetic research has developed a non-invasive urine test ("liquid biopsy") that measures the expression of two mRNA cancer-related biomarkers (HOXC6 and DLX1) to help Physicians determine at what level a patient is at risk for prostate cancer, potentially avoiding intrusive biopsies for some. With approximately 1 million men receiving an inconclusive biopsy result each year in the US, this diagnostic solution would address a significant unmet medical need for timely, actionable information that can aid in the reduction of unnecessary repeat biopsies.

To further enhance their prostate cancer test, the company needed to compare its product against biopsied tissues. But the logistics of identifying 2,000 patients and collecting tissues at 21 US urology centers within 6 months was daunting.

SOLUTION

Our client reached out to Catalyst to build and deploy a competent team quickly. The team consisted of a study coordinator and a CRA for each of the 21 urology sites and a Project Manager for study oversight and logistics. The teams were located across 20 US states and local to their sites. Within 1 month of award the team met in Denver for study training before deployment to their assigned study centers, to begin collections.

OUTCOME

2,000 patients were identified across all sites and tissues shipped to Client for analysis within 3 months. The study was successfully completed in 6 months. Because of the quick response by Catalyst and the geographic alignment of the team, the study was completed under budget and our customer was able to produce a publication based on study results for publication.

> *I worked with this Sponsor as a consultant to design and implement a clinical utility study with their prostate cancer detection assay. My experience with Catalyst was first-rate and I would work with them again.*