



CASE STUDY

## Evidence Generation Strategic Partnership for Heart Failure Studies

Development and Implementation of a Strategic Partnership to Execute a Portfolio of Heart Failure Studies to Accompany an Evidence Generation Program for a New Product Launch



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### SITUATION

UBC was selected by a major pharmaceutical company to manage a portfolio of 5 studies of patients with heart failure to generate evidence in support of a new product launch. The portfolio of studies was designed to provide insights into disease progression and treatment patterns in a real world setting as well as to assess potential novel efficacy domains that warranted deeper investigation following the pivotal studies supporting product approval. The evidence was important to support publications and potential changes to treatment guidelines and label.

The portfolio included an observational study and 4 interventional studies involving over 500 investigator sites and more than 7,000 patients. The scope and breadth of the portfolio involved diverse study designs and objectives, a range of healthcare setting types, innovative patient-generated data collection approaches, including wearable technology, biomarkers, and novel cardiac function assessment technology. A robust portfolio project plan and partnership charter were developed to drive successful execution of each project timeline within a landscape of overlapping study start-up and deliverable schedules.



### CHALLENGES

- Compressed procurement and contracting timeframe
- Rapid and overlapping study start-up timelines
- Site selection and training considerations
  - Site resourcing and equipment limitations
  - Specialized data collection technology and sample collection requirements
  - Wearable and sleep monitoring technology
  - Novel cardiac function assessment hardware and software
  - Biomarker sample handling procedures
- Patient recruitment
  - Competition for heart failure patients that meet criteria for multiple studies
- Overlapping data and biometric deliverable schedules
- High visibility initiative within sponsor organization and critical need for rapid 'on-demand' access to status reports and metrics



### SOLUTIONS

UBC implemented the following solutions to address the above challenges:

- Robust site feasibility to support an advanced analysis of staff experience, resource capacity, and equipment
- Deep exploration of patient population and critical characteristics to drive strategic site selection for multiple studies
  - Analysis of administrative claims data to identify previously unknown sites and target site selection and matching to a given protocol based on analysis of patient characteristics visible in the prescribing data



## SOLUTIONS (continued)

- Rapid site start-up and training
  - Intimate knowledge of client regulatory document requirements and systems applied across the portfolio to built in efficiencies in the study start-up workflows
  - Deep understanding of heart failure investigator population and practice dynamics shared across project teams
  - Robust multi-modal site training program:
    - Hands-on, live training sessions to introduce novel cardiac function testing hardware
    - CRA lead re-training sessions
    - Coordinated support from niche technology vendors
    - On-demand web-based recordings available for new staff and refresher training opportunities
- Heart failure “platform” patient recruitment campaign
  - Nationwide recruitment of heart failure patients funneling into UBC call center for triage to appropriate study based on inclusion / exclusion criteria
- Engagement of sponsor field team to support enriched discussions with site staff on enrollment goals and challenges
  - Field team engagement portal to provide real-time access to site level data that would enrich encounters between field team and site staff
- Efficient data capture approach and optimized EDC design that was well-received by community-based practices with limited research experience
- Deployment of investigator portal providing real-time registry data feedback loop to drive investigator engagement over life of study
- Partnership charter and governance model including single point-of-contact and senior leadership engagement
  - Alignment of purpose and mission between UBC and client project teams
  - Strategic resourcing plan
  - Implementation of knowledge-sharing ecosystem through shared workspaces and scalable project plans
  - Performance measurement infrastructure for aggregating study KPIs and portfolio financial analysis in a single web-based analytics platform
  - Implementation of customized business processes and financial templates including complexity driven / unit based budgeting tool to facilitate rapid and transparent price discovery



## RESULTS

Patient enrollment timelines and data cleaning milestones were successfully achieved ahead of schedule. Best practices for strategic partnership were applied at the outset of the engagement and drove the efficient delivery of work across the portfolio. These accomplishments facilitated the sponsor’s success in realizing their evidence-generation objectives including the output of numerous publications, acquisition of data to support a change in guideline directed therapy, and the generation of new insights that will help inform and optimize the treatment of patients with heart failure. UBC’s expertise in study design and execution, investigator and patient recruitment, and data collection and analysis led to the successful execution of this portfolio of studies.

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