AKEURA

Case Study

Cardiometabolic Diseases

Delivering a Global Phase III Cardiovascular Outcomes Trial for a Top-10 Pharmaceutical Company

When the FDA began requiring cardiovascular outcomes data for new therapies, sponsors needed cardiovascular outcomes trials that could stand up to intense scrutiny. A global top-10 pharmaceutical company chose us to run one: a Phase III trial of an investigational therapy in patients with type 2 diabetes who had recently had an acute coronary syndrome event.

The Study

CONTRIBUTION
Full-service global delivery for a Phase III study

DESIGN
Multinational, multicenter, randomized, double-blind, placebo-controlled, event-driven study

PATIENT POPULATION
7,226 patients with type 2 diabetes and a recent ACS event

GEOGRAPHY
26 countries

SCALE
720 sites, with a planned minimum follow-up of 2.5+ years

The Challenge

Recruiting right after an acute coronary syndrome (ACS) event is hard. The window is narrow, patients aren't yet clinically stable, and many carry diabetes-related renal and cardiovascular complications. Sites were also competing for the same patients across overlapping cardiovascular and diabetes trials, in one of the most crowded investigator landscapes in clinical research. With enrollment timelines this tight, there was little room for site delays or protocol deviations, and every week lost at start-up would be felt for the rest of the study.

Scale raised the stakes. Each of the 26 countries had its own regulatory pathway, site readiness, and operational pace, and the study had to run consistently across all 720 sites for years. As an event-driven trial, its success depended on capturing every cardiovascular event accurately. Endpoint adjudication and data quality had to hold up to regulatory scrutiny from the first patient to the last visit.

The Approach

A tightly coordinated, globally scalable delivery model got sites live fast and kept quality consistent across every region.

Rapid Global Activation

Targeted feasibility drew on our cardiometabolic site expertise, getting the first patient screened within three months of initial submission.

Recruitment Strategies

We chose sites with diabetes and cardiovascular trial experience, supported patient-centric engagement, and kept back-up geographies ready to expand.

Quality & Oversight

A central compliance group, an operations committee, and regular data quality reviews kept global teams and vendors aligned.

Delivery Across Regions

One team brought cardiology and diabetes expertise together to run 700+ enrolling sites consistently across diverse regulatory and healthcare systems.

The Impact

- **First patient screened within 3 months of initial submission**
- **600+ of 720 planned sites activated in the first 10 months**
- **7,226 patients enrolled across 26 countries**
- **Controlled wind-down of all 720 sites after the DSMB recommended early termination, with adjudicated data ready for regulatory submission and publication**

The Difference

Built on Outcome Studies

Born at UMC Utrecht in 2008, we've run large outcome studies ever since, with endpoint adjudication and event-driven biostatistics in-house.

The Right Experts in the Right Roles

Cardiology and diabetes specialists, senior-led and directly reachable from day one. No layers to get through.

Speed. And Certainty.

We moved fast at start-up without cutting corners, so the data held up when it mattered most.

Planning a CVOT or complex cardiometabolic program?

Contact us at info@akeura.com to discuss how we can support your next study.