AKEURA

Case Study

Cardiometabolic Diseases

# Turning Around a Stalled Phase III CVOT for a Mid-Size Biotech

A mid-size biotech's flagship Phase III cardiovascular outcomes trial was testing whether an investigational lipid-lowering therapy could reduce major adverse cardiovascular events. One year in, slow site start-up and lagging recruitment had put the timeline at serious risk, and the incumbent large CRO had missed its enrollment milestones. So the sponsor called us.

## The Study

### CONTRIBUTION
Comprehensive, multi-functional rescue delivery for a Phase III study

### DESIGN
Multinational, multicenter, randomized, double-blind, placebo-controlled study

### PATIENT POPULATION
Patients with, or at high risk for, cardiovascular disease and hypercholesterolemia who cannot tolerate statin therapy

### GEOGRAPHY
12 countries across Europe and Latin America

### SCALE
200 sites

## The Challenge

Rescues don't start with a clean slate. This was the sponsor's flagship cardiovascular outcomes trial (CVOT), and a year of slow start-up and lagging recruitment had put its timeline at serious risk. We had to work alongside the incumbent CRO, aligning on overlapping deliverables, communication, and compliance across two sets of SOPs and platforms. The study also needed more high-performing sites, and a slow first year had left existing investigators disengaged. Winning them back would take energetic, peer-to-peer site management.

The patient population raised the bar further. Participants had to be genuinely unable to tolerate statins, and screen-failure rates were already high. Finding patients who truly met that threshold across 12 countries took deep scientific fluency and protocol-specific guidance at every site. And over a three-year treatment period, every patient lost to follow-up would weaken the endpoint data.

# The Approach

A site-centric rescue model plugged into the existing trial infrastructure and got recruitment moving, fast.

### Rapid Global Activation

Our cardiometabolic network let us select and activate 200 high-performing sites quickly, clearing the bottlenecks between selection and enrollment.

### Site Re-Engagement

Experienced CRAs who speak the language of the site re-energized investigators and guided them through targeted workflows to qualify the right patients.

### Vendor Integration

Our Project Performance Analysis team unified processes and data across both CROs, delivering audit-ready data into the primary study database.

### Delivery Across Regions

One team coordinated delivery across 12 healthcare and regulatory systems, maximizing enrollment at every site.

## The Impact

- **200 sites activated across 12 countries**
- **0% lost to follow-up across all AKEURA-managed sites. Zero.**
- **35% screen-failure rate, compared to 41% across the broader study**
- **Nearly 2.5x the per-site enrollment of the rest of the study in the first full year of recruitment**

## The Difference

### Tough Gets Us Going

When a study goes sideways, sponsors call us. We stepped into a live Phase III CVOT and turned it around.

### Relationships That Deliver

CRAs who speak the language of the site won back disengaged investigators and didn't lose a single patient to follow-up.

### Built on Outcome Studies

Born at UMC Utrecht in 2008, we've run large outcome studies ever since. We know where CVOTs stumble.

## Planning a CVOT or need to turn around an underperforming study?

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