

Case study

Accelerator™ Drug Development

Accelerating a complex global cardiovascular outcomes trial through coordinated execution

Early alignment across CRO, clinical supply, and central labs helped keep a large global study on track as site activation and enrollment moved ahead of plan.

Development challenge

A midsized biotech historically focused on complex therapeutics for rare diseases was expanding into larger, more prevalent indications. The cardiovascular outcomes trial was the most complex study in the company's history, requiring execution across 1,500 sites in 35 countries and enrollment of 11,000 patients.

The scale of the program created significant operational pressure across regulatory start-up, site activation, patient enrollment, investigational product supply, and lab kit readiness. The customer needed to accelerate site activation and enrollment to increase patient exposure time and improve the likelihood of reaching endpoint events sooner, while keeping clinical supply and central lab activities aligned with faster-moving timelines.

Streamlining start-up through coordinated execution

Thermo Fisher Scientific coordinated CRO, clinical supply, and central labs activities through a single delivery model, creating earlier visibility across regulatory, site activation, supply, and enrollment milestones.

The team accelerated regulatory submissions and site activation by using established CTA templates, vendor and site relationships, and process improvements to streamline start-up timelines. Experienced resources were deployed across programs to support the unprecedented scale of activity while maintaining consistency and quality.

Keeping supply aligned as activation accelerated

Faster regulatory approvals created the potential for earlier site activation, making supply readiness critical. Proactive planning and early alignment with investigational product and lab kit teams helped ensure that supply could support accelerated activation timelines rather than become a downstream constraint.

Dynamic forecasting of site activations, patient demand, and lab kit requirements enabled the supply strategy to adjust as the study progressed. This coordination also helped reduce unnecessary lab kit waste while maintaining readiness across a large global site network.

Results

- First site activated (FSA): 4 days ahead of plan and 85 days ahead of the industry benchmark
- 50% of sites activated 5 months early
- Regulatory approval achieved for 35 countries in 10 months
- First patient in (FPI): 1 month ahead of plan
- 25% of subjects enrolled 7 months early
- Following implementation of the lab kit forecasting tool, the lab kit expiry rate was 9.3%, with estimated waste avoidance of 58,411 kits valued at $1.64 million.

Development outcome

By reaching FSA and FPI ahead of schedule, the team enabled the customer to begin recruiting patients sooner and maintain momentum on a strategically important cardiovascular program. Earlier site activation and enrollment increased the number of active recruiting sites and patient exposure time, supporting the potential for earlier event accrual in an outcomes trial where event accumulation drives study duration.

The program also demonstrated that acceleration did not have to come at the expense of supply efficiency. Early coordination across clinical operations, investigational product supply, and central labs kept supply aligned with faster activation timelines while dynamic forecasting reduced unnecessary lab kit waste.

Program focus	Global Phase III cardiovascular outcomes trial across 35 countries, 1,500 sites, and 11,000 patients
Approach	Coordinated CRO, clinical supply, and central labs execution, with proactive start-up planning and dynamic forecasting of site activation, patient demand, and lab kit requirements
Operational parameters addressed	Regulatory submissions, site activation, patient enrollment, investigational product supply readiness, lab kit requirements, forecasting, and cross-functional coordination
Key technical outcome	Accelerated regulatory and site activation timelines while maintaining supply readiness; dynamic forecasting also reduced unnecessary lab kit waste
Development impact	FSA 85 days ahead of industry benchmark; 50% site activation 5 months early; FPI 1 month ahead of plan; 25% enrollment 7 months early; 35-country regulatory approval in 10 months; estimated avoidance of 58,411 wasted lab kits valued at $1.64 million



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