

The recruitment imperative: Why sites and patients determine cardiometabolic trial success



A KEY QUESTION

How can sponsors overcome increasing competition for sites and patients to keep cardiometabolic trials on track for successful recruitment and delivery?

KEYWORDS

Cardiometabolic Clinical Trials, Patient Recruitment Strategy, Site Selection and Engagement, Patient Retention, Clinical Trial Enrollment, Clinical Trial Execution

Author: James Joyce, MPH, Delivery Director, Global Project Delivery, Fortrea

Cardiometabolic drug development is advancing rapidly, with obesity, diabetes, renal, metabolic and cardiovascular (CV) disease converging into one outcomes story. As studies grow larger, more global and more complex, competition for sites and patients is intensifying.

Sponsors are also witnessing a widening gap between what today's cardiometabolic programs require scientifically and what it takes to execute them operationally, across protocols, assessments, contracts and site management. Left unaddressed, this gap tends to surface later as timeline slippage, budget overruns and delayed data.

This article shares how site strategy, patient understanding, operational flexibility and early phase engagement are shaping cardiometabolic trial success.

A widening gap: Cardiometabolic innovation is outpacing trial execution

The shared pathophysiological networks and biological trajectories of CV, renal and metabolic diseases¹ are steadily reflected in therapeutic development, with next-generation interventions such as GLP-1 receptor agonists, SGLT2 inhibitors and mineralocorticoid receptor antagonists demonstrating efficacy beyond their original disease targets.^{2,3}

These same therapies have already shifted the incidence and prevalence of major cardiovascular events, creating a pre versus post-GLP-1 split that now shapes inclusion, exclusion and feasibility assumptions for new studies.

However, the rapid development cycle of cardiometabolic therapies has drastically outpaced traditional clinical trial infrastructure. Today's cardiometabolic trial landscape often faces:

- **High demand:** Citeline Trialtrove data shows how crowded this space has become. Of 765 open or planned global studies recruiting a comparable PAD/CAD-type CV population, only 37 are active industry-sponsored trials, and just six global Phase III studies of 5,000+ patients share a comparable primary endpoint
- **Larger, more global programs:** Several cardiovascular trials aim to enroll 10,000+ patients,⁴ requiring execution across many countries and sites to recruit a meaningful patient population

- **Specific inclusion criteria and overlapping comorbidities:** Narrow inclusion criteria and comorbidities may lead to high screen failure rates as the pool of eligible subjects becomes more scarce. For example, in a Phase II severe hypertriglyceridemia trial, Fortrea found that a high triglyceride threshold (>500 mg/dL) combined with comorbidities led to an elevated screen failure rate

As cardiometabolic programs increasingly draw from the same patient population, demand for experienced sites and eligible patients is rising, affecting trial timelines and predictability.

Beyond familiar names: Building a site strategy that earns patient access

While sponsors know the science, what benefits most from a collaboration is how that science translates operationally, at both the site and the patient level. Trial readiness is often assessed through site counts, countries and timelines, all reasonable, visible metrics. What is harder to see without the right CRO is how specific protocol choices, including eligibility criteria, comorbidity restrictions and patient visit burden, will perform when tested against real-world site capability and patient epidemiology.

This shows up early. Sponsors may naturally default to selecting sites with strong historical performance and existing relationships to reduce perceived risk. Over time, however, this narrows the pool and produces ever-diminishing returns as more sponsors compete for the same limited set of experienced sites.

Successfully addressing these challenges means knowing how to:

- **Look beyond typical site metrics:** Site counts, countries and timelines confirm a study can launch, not that it can enroll. The deciding factor is whether protocol design lines up with what a specific site and patient population can actually deliver
- **Examine protocol-driven recruitment risk:** Eligibility criteria, comorbidity restrictions and patient visit burden can become operational constraints. Left unaddressed, these risks tend to resurface later, at a higher cost and lower return. This is why eligibility criteria and study design should be evaluated through both a scientific and operational lens. Is the protocol focused on what is most important from a development perspective, or can elements be streamlined to make execution easier for sites and patients without compromising study objectives?

Continuously refreshing site lists helps build a more sustainable strategy across a program's lifecycle. This involves:

- **Applying country-scoring data** that weighs competitive landscape, country experience, site performance, market saturation and start-up timelines to prioritize countries most likely to succeed
- **Applying real-world evidence** to align patient volume data to known site performance
- **Collaborating with site networks** that are actively investing in developing newer, emerging research sites
- **Balancing proven performance with future growth** by allowing for overage in the site selection process, enabling investment in new site relationships while creating opportunities for emerging sites to build experience for future studies

Ongoing site engagement, from feasibility through delivery, is equally important. This requires:

- **Investing in site engagement** to help sites prioritize the studies they're most invested in
- **Leveraging deep, longstanding relationships** to earn priority at a site, particularly for novel-mechanism compounds



For example, in a Phase IIb post-myocardial infarction imaging study across 89 sites in nine countries, Fortrea nurtured strong relationships with site investigators, limiting loss to follow-up to a single patient across the entire study, despite a multi-assessment protocol run during a global disruption. Feedback from these relationships showed that too many points of contact can overwhelm a site, so each site now works with a single, locally based Site Navigator who carries the relationship from feasibility through ongoing conduct, rather than a centralized, low-cost outreach model.

Recruitment as a discipline, not a hope

In a highly competitive cardiometabolic landscape with ongoing trials and the inherent pressure to support patient retention and engagement, these are the factors Fortrea weighs when shaping a recruitment strategy.

- **Examine the patient pathway:** How patients are diagnosed, referred and treated varies widely by clinical setting. Mapping the pathway to identify enrollment and discontinuation points helps sponsors understand the opportunities and risks
- **Proactively monitor performance:** Real-time modeling from first site activation, paired with purpose-built risk monitoring tools, can flag at-risk sites before they fall behind, triggering early, targeted support. On a 12,000+ patient global CV outcomes study across 553 sites in 36 countries, this approach delivered first-patient-in three months ahead of target and an actual screen-failure rate of 15%, against a 21% target
- **Balance speed with recruitment quality:** Faster enrollment is only valuable if it doesn't come at the cost of screen failures, protocol deviations or poor endpoint compliance, so both must be controlled together
- **Prioritize engagement:** Many cardiometabolic endpoints require 12 to 24 months or longer to capture treatment effects, so retention and long-term engagement must remain a priority. Early detection of dropout risk and ongoing site training help avoid missing a primary endpoint

The first mile determines the whole trial

In cardiometabolic trials, where competition for patients and sites keeps growing, the first experiences with a study matters most. The earlier sponsors address recruitment risk, the more control they retain and the less they spend fixing it later. Across both pillars, the throughline is the same—specificity beats scale. What actually drives outcomes is not the size of a site network or a recruitment budget, but knowing which sites, which relationships and which protocol details matter for a specific study, backed by a team that stays with it from early planning through delivery. As cardiometabolic pipelines keep expanding across CV, obesity and metabolic disease, that specificity, applied early and consistently, is what turns site strategy and recruitment from a source of risk into a sponsor's most reliable path to on-time delivery.



Want to learn more?

Get more information about our cardiometabolic experience at fortrea.com



References

1. Ndumele CE, Neeland IJ, Tuttle KR, et al. American Heart Association. A Synopsis of the evidence for the science and clinical management of cardiovascular-kidney-metabolic (CKM) syndrome: A scientific statement from the American Heart Association. *Circulation*. 2023 Nov 14;148(20):1636-1664.
2. Rroji M, Spahia N, Figurek A, Spasovski G. Targeting diabetic atherosclerosis: The role of GLP-1 receptor agonists, SGLT2 inhibitors, and nonsteroidal mineralocorticoid receptor antagonists in vascular protection and disease modulation. *Biomedicines*. 2025 Mar 17;13(3):728.
3. Liakos A, Karagiannis T, Avgerinos I, Bekiari E. SGLT-2 Inhibitors and GLP-1 receptor agonists as combination therapy in type 2 diabetes. *Curr Diab Rep*. 2026 Jan 13;26(1):1.
4. Khan MS, Jamil A, Shakoor M, et al. Patient enrollment for cardiovascular clinical trials in the United States. *JAMA Cardiol*. 2025 Mar 1;10(3):298-300.