

Whitepaper

The MCRC advantage: Making the case for consolidation and consistency in clinical trials

Innovation. Consistency. Longevity.

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# The MCRC advantage: making the case for consolidation and consistency in clinical trials

A note from our Executive Director

Clinical development is becoming more expensive, more complex, and more difficult to deliver at speed. Sponsors and CROs are under pressure to produce results quickly, yet the traditional models used to run trials are struggling to keep pace. Sites themselves are under strain, with trial complexity, study start-up delays, recruitment challenges, and staffing shortages consistently reported among their top concerns.

The consequence is a growing burden on investigators and coordinators. More than two-thirds of principal investigators worldwide conduct just one trial before leaving the research workforce. Smaller, independent sites are particularly exposed, reporting high staff turnover and declining capacity to take on new studies. These pressures create variability in performance, longer timelines, and rising costs -- outcomes that benefit no one.

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Multisite Clinical Research Corporations (MCRCs) offer a way forward. By operating under unified systems, protocols, and oversight models, they can reduce variability, improve efficiency, and provide the scale needed to meet today's trial demands. Yet, despite clear advantages, MCRCs are not always recognized as the preferred option.

AMRC research, detailed in this report, shows that the advantages of MCRC's are not yet universally understood by Sponsors and CROs, who routinely rank academic medical centres (AMCs) as the preferred model despite acknowledging that MCRCs operate equally well and in many areas better.

"Sponsors and CROs who build strategic partnerships with MCRCs now will be better placed to meet increasing demands on speed, quality, and consistency in the future."

Sponsors and CROs need to make efforts to understand and address these systematic biases that hold them back from engaging site networks. Independent sites are under more pressure than any other industry participant, and they lack the scale of MCRCs to address those challenges.

While this is currently a highly fragmented market, consolidation is already underway and will only gain pace as independent sites struggle with the challenges of modern clinical research. Sponsors and CROs who build strategic partnerships with MCRCs now will be better placed to meet increasing demands on speed, quality, and consistency in the future.



Jim Kremidas

AMRC Executive Director



#### **Understanding** site models

Site structure plays a significant role in determining trial performance. While the clinical research environment includes a broad range of site types, four operating models dominate large trials:

- Academic medical centres (AMCs), associated with universities or hospital systems, bring specialist expertise but often face long start-up times and competing priorities.
- Community or independent sites, typically physician-led practices, offer access to local patients but lack dedicated infrastructure and suffer from high investigator churn.
- **Dedicated research sites** focus exclusively on the delivery of clinical trials. These sites are often privately operated and include both standalone and network-affiliated models.
- Multisite clinical research corporations (MCRCs) operate multiple research sites under a unified structure, applying common systems, contracts, and quality oversight to reduce variability.

#### The MCRC model: structured consistency

Rising trial complexity, slow study start-up, and inconsistent site-level performance are now some of the most pressing challenges in clinical research. WCG found that 69% of sites say budgets and contracts as the primary drivers of study start-up delays, and 46% say operational challenges such as staffing, study complexity, and technology usability have affected their ability to take on studies<sup>1</sup>. At the same time, 14% of all sites fail to enrol a single patient in any given trial, and 33% enrol fewer than expected<sup>2</sup>.

MCRCs aim to address many of the systemic challenges facing clinical research by applying an integrated, standardized approach to site operations. Rather than functioning as a loose affiliation of independent practices, these corporations operate multiple sites under unified protocols, systems, and oversight models. Large site networks have the scale and infrastructure necessary to unburden sites from tedious administrative functions which allows for greater focus on core trial operations.

<sup>&</sup>lt;sup>2</sup> Lamberti et al., 2024. Benchmarking site activation and patient enrollment. Therapeutic Innovation and Regulatory Science.



This centralization affects nearly every aspect of trial execution:

- **Feasibility and start-up:** Central teams collect and review site capabilities, improving response time and reducing back-and-forth. MCRC-affiliated sites have been shown to speed up study start-up by two-weeks, completing feasibility assessments and site qualification visits 5.5 and 4 days faster, respectively, than the average independent site<sup>3</sup>.
- Training and staffing: By maintaining centralized training protocols and offering
  professional development across their networks, MCRCs help reduce staff
  turnover and improve retention.
- Contracting and budgeting: Standardized contracts and shared templates speed up onboarding. In 2024, 69% of sites cited budget and contract issues as the main source of study start-up delays<sup>4</sup>, highlighting the potential value of streamlining this process.
- Technology and data integrity: MCRCs often adopt common systems across sites, improving interoperability and consistency. With ICH E6(R3) placing greater emphasis on technology oversight and risk-based quality management, this alignment with regulatory expectations is increasingly important.
- Operational oversight: Centralized quality teams and standard operating
  procedures create more consistent performance across studies. While others
  have voiced concerns about losing oversight when working with centralised site
  networks, recent dialogue suggests a shift in perception. As one sponsor-side
  participant put it during a 2025 AMRC webinar: "We're not giving up control.
  We're just sharing it." This reflects a growing recognition that structured
  collaboration with MCRCs can enhance trial governance rather than dilute it.

While no model solves every challenge, the structured nature of MCRCs addresses many known inefficiencies. Their ability to standardize processes, retain trained staff, and provide sponsors with a single point of contact makes them a compelling option for trials requiring scale, speed, and reliability.

Insights from the field: Sponsor and CRO perceptions of MCRCs

The advantages offered by site networks remains largely misunderstood and untapped by many of their potential customers and partners. A 2024 investigation with Linking Leaders into perceptions of MCRCs found that the model was well understood within the industry but highlighted a hesitancy to engage with these networks, particularly among smaller organizations. The perception at the time was that consolidation added to operational complexity and increased costs<sup>6</sup>.

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 $<sup>^{\</sup>rm 3}$  Harper et al., 2025. Applied Clinical Trials, Vol 34 (1), February 2025. p 22.

<sup>&</sup>lt;sup>4</sup> WCG 2024 Clinical Research Site Challenges Report

<sup>&</sup>lt;sup>5</sup> 2024 Avoca Industry Report, p. 28

<sup>&</sup>lt;sup>6</sup> Gallagher *et al.*, 2024. The emergence of site networks in clinical trials. <u>Applied Clinical Trials</u>, October. p 22.

AMRC saw this play out more recently in our own research, conducted in July 2025 in collaboration with SBM Research. Respondents from CROs had a high familiarity with MCRCs (4.2 out of 5) and most (77%) had direct experience engaging with these site networks, yet there was a preference – particularly among oncology specialists – towards academic medical centres (AMCs).

"Across 23 operational areas and site attributes, respondents selected MCRCs as best in class 26% of the time, almost equal to AMCs at 29%."

Performance data, however, tells a different story. Across 23 operational areas and site attributes, respondents selected MCRCs as best in class 26% of the time, almost equal to AMCs at 29%. MCRCs were particularly associated with consistency, faster start-up, scalable infrastructure, and access to diverse patient populations – arguably the most important factors in site selection.

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# The perception of quality

On the dimensions Sponsors care about most, speed, consistency, and efficiency, MCRCs already match the performance of academic centres. So, why are MCRCs not yet the favored model?

The answer lies in quality, or more precisely, the perception of it. While those with direct experience of working with them rated MCRCs as 'good' (average 3.7 out of 5), none considered them 'excellent.' By contrast, AMCs were more often viewed as providing the highest quality service.

"Respondents credited MCRCs with administrative strengths such as SOP-driven operations, centralization, and document management."

Quality is subjective, but the source of this perception is clear. Respondents credited MCRCs with administrative strengths such as SOP-driven operations, centralization, and document management. These should be viewed as indicators of quality, yet they did not translate into top rankings. Investigator experience was a particular weak spot, with MCRCs rated lowest while AMCs came out on top.

<sup>&</sup>lt;sup>6</sup> Gallagher et al., 2024. Applied Clinical Trials, October. p 22.

AMRC data challenges this assumption. Across the AMRC network, PI turnover is 7.8% while turnover for CRCs is just 15.4%, compared to industry averages of 54.2% and 33% respectively. Far from lacking experience, networks provide greater stability and continuity than the industry overall.

"Across the AMRC network, PI turnover is 7.8%, while turnover for CRCs is just 15.4%, compared to industry averages of 54.2% and 33% respectively."

Sponsors recognize that MCRC's are efficient and centralized, but do not yet equate that with professionalism or quality. When asked for the best performing model, around a quarter of respondents cited 'don't know/no difference', underscoring the indifference that persists in parts of the market. Few respondents described MCRCs as the most professional site type, even when they attributed SOP adherence, consistency, and timeliness to them.

This neutrality signals an opportunity for MCRCs. They are already credited with better document management and stronger systematization than other site types, but they must reframe these operational strengths as drivers of reliable, high-quality data. By translating structural advantages into a quality narrative, MCRCs can demonstrate that operational excellence is not simply about efficiency, it is what enables better outcomes for Sponsors, CROs, and patients.

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Conclusion: a strategic imperative for Sponsors and CROs

MCRCs are no longer a peripheral model or a novelty. They are a proven, scalable solution to some of the most persistent challenges in clinical research, delivering faster start-up, more consistent operations, and stronger continuity of investigator and coordinator experience than the industry at large.

Yet, while Sponsors and CROs recognize these strengths, they often fail to see them as markers of quality. This places a responsibility on MCRCs and their advocates to demonstrate more clearly how operational consistency and stability translate into better outcomes.

With the market fragmented and consolidation inevitable as independent sites struggle, the choice is clear: Sponsors and CROs who forge strategic partnerships with MCRCs now will be best placed to deliver trials at speed, at scale, and to the highest standards of quality.







### **Appendix**

#### Survey design

Survey design was based on similar prior efforts by SBM, Dr. Howley, and AMRC representatives and was tested with several industry representatives.

The survey included a mix of question types designed to elicit perceptions of the different clinical trial site types and how they influence selection by those involved in the process.

While respondents were queried on awareness and perceived image of MCRCs, the two central questions focused on perceptions of operational performance in key operational areas and site attributes. Specifically, the areas assessed by respondents were:

#### **Operations**

- 1. Compliance History
- 2. Data Accuracy Quality
- 3. Document Management
- 4. Investigator Experience
- 5. Patient Recruitment

#### **Enrollment**

- 6. Patient Retention
- 7. Pre-Study/Study-Startup
- 8. Site Locations
- 9. Study Close-Out
- 10. Technology Compatibility

#### **Site Attributes**

- 1. Ability to Scale
- 2. Access to a Diverse

#### **Population**

- 3. Centralized Processing
- 4. Communication
- 5. Cost
- 6. Facilities
- 7. Investigator Experience
- 8. Prior Performance
- 9. Professionalism
- 10. Responsiveness
- 11. Risk-based

#### **Approaches**

- 12. Staff Experience
- 13. Therapeutic Area

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#### Sampling

Initial attempts to gather data directly from industry personnel resulted in:

- collaborating with Clinical Leader for distribution of the survey; and
- focusing and condensing the survey plan.
- Approximately 5,000 email solicitations sent twice by Clinical Leader to its pharma/CRO contacts.
- Data was collected over late July and early August 2025.
- Respondents were offered participation in a drawing for a \$200 gift card and a summary of findings.

#### **Responses:**

- 44 useable surveys
- 585 assessments of site types performance
- 89 (64% response rate) to optional open-ended text questions