AMRC.org

Association for Multisite
Research Corporations

Industry Consultation
Findings:

Defining and Recognizing
Quality in Multisite Clinical
Research Corporations
(MCRCs)

Innovation. Consistency. Longevity.

Introduction

In 2025, the Association of Multisite Research Corporations (AMRC) undertook an industry consultation to better understand how quality in clinical research is currently defined, assessed, and perceived.

While multisite clinical research corporations (MCRCs) consistently deliver strong operational performance, our research shows they remain under-recognized for quality, particularly when compared with academic models. The consultation was designed to explore this gap and to understand how quality might be more clearly articulated and demonstrated on MCRCs' own terms.

The consultation gathered perspectives from leaders from MCRCs, operational and quality specialists, and industry bodies with experience spanning Sponsors, CROs, and sites. Respondents reflected a range of operating models and trial experience and roles, offering both practical insight from day-to-day trial delivery and broader views on standards, professionalism, and data integrity. While views differed in emphasis, there was a high degree of alignment on the need to move beyond narrow proxies of quality and toward more system-level, evidence-based definitions.

This paper summarises key themes from the responses and sets out how AMRC will respond. The findings will inform AMRC's advocacy priorities for 2026, including work on shared quality frameworks, benchmarking, and engagement with Sponsors, CROs, and regulators. More broadly, it is intended to support a more informed, constructive conversation about what high-quality clinical research looks like at scale, and how sites should be recognized for the outcomes they deliver.

Industry perspectives on quality in clinical trials

Across all consultation responses, key themes emerged that showed a broad consensus on how quality in clinical research should be assessed and demonstrated.

Quality is systemic

Respondents consistently described quality as something that sits at a system level, rather than something that can be inferred from the experience or reputation of any one individual.

> *While investigator experience was recognized as valuable, it was rarely seen as a sufficient or reliable proxy for quality on its own.*

While investigator experience was recognized as valuable, it was rarely seen as a sufficient or reliable proxy for quality on its own. Instead, respondents described quality as the product of the environment around the investigator: trained and stable teams, clear and usable SOPs (Standard Operating Procedures), effective oversight, strong leadership, governance, and consistent ways of working.

Several respondents noted that less experienced investigators can deliver high-quality outcomes when supported by strong infrastructure, whereas highly experienced investigators can struggle when it is absent. In this framing, quality can not be assumed. It must be deliberately designed, measured, and reproduced.

Consistency and predictability define quality

One of the clearest themes to emerge was that quality is experienced as predictability.

> *Respondents repeatedly emphasized the importance of minimizing variability in execution, data, and communication.*

Respondents repeatedly emphasized the importance of minimizing variability in execution, data, and communication. High-quality sites and networks were described as those that reduce uncertainty for Sponsors and CROs by operating in a dependable, repeatable way.

Professionalism, in this context, was not only about being personable or responsive. It was about reliability, transparency, and avoiding surprises. Consistent delivery was seen as one of the strongest signals of quality a network can offer.

Patient experience matters, but its value is contested

Patient experience and outcomes featured prominently across the consultation, but views differed on how central they should be to defining and demonstrating quality.

Some respondents argued that patient experience is a meaningful indicator of site staff quality, pointing to its direct impact on retention, adherence, and data completeness. From this perspective, positive trial experiences are not a 'soft' measure, but a leading indicator of how well a study is being run. These respondents emphasized patient satisfaction, comfort, retention rates, and willingness to participate again as evidence of mature, well-managed operations.

> *Several noted that patient outcomes are influenced by factors outside a site's control.*

Others were more cautious. While they acknowledged that poor patient experience can signal underlying operational issues, they questioned how much weight Sponsors and CROs currently place on patient experience relative to other data points. Several noted that patient outcomes are influenced by factors outside of a site's control, including the investigational product itself, and warned against conflating trial experience with clinical efficacy.

A further concern raised was the lack of standardization. Without shared instruments or agreed benchmarks, patient experience data is challenging to compare across sites and networks.

Operational performance is central to quality assessments

There was broad agreement that quality should be evidenced through observable operational performance, rather than abstract claims or reputational markers.

Across responses, similar indicators were cited as meaningful signals of quality, including:

- Protocol deviation rates and severity
- Query volume and turnaround time
- Timeliness of data entry and safety reporting
- Enrolment accuracy relative to feasibility forecast

- Retention and completion rates
- Staff stability
- Audit outcomes
- Corrective and Preventive Action (CAPA) effectiveness.

While respondents broadly agreed on the types of operational metrics that matter, they differed on how universal quality frameworks should be. Some supported shared definitions and benchmarking to improve transparency and comparability, while others were concerned that overly rigid standards could limit flexibility, mask meaningful differences between networks, or fail to reflect variation across trial types and therapeutic areas.

Critically, quality was closely associated with the ability to identify trends, intervene early, learn from issues, and continuously improve, rather than simply reporting performance after the fact.

Competence matters more than credentials

There was almost universal agreement that training completions, certifications, and years of experience are poor signals of quality when viewed in isolation.

> *Many respondents expressed frustration with attendance-based training and generic credentials*

Many respondents expressed frustration with attendance-based training and generic credentials that do not demonstrate how individuals perform in real-world trial settings. Experience was acknowledged as important, but not a guarantee of competence – particularly in environments where bad habits or shortcuts can go unchallenged.

Respondents disagreed on how competence should best be evidenced. Some respondents favored structured, competency-based assessment and independent accreditation. Others placed more emphasis on experience, internal performance data, and direct observation of how teams operate. This reflects a shared dissatisfaction with existing proxies for quality and highlights the ongoing debate about what should replace them.

Culture and leadership shape quality outcomes

Several responses highlighted the responsibility of culture, governance and leadership for quality.

Strong leadership, staff development, and a supportive environment were described as enabling better adherence to processes, greater accountability, improved oversight, and higher retention. Where teams felt trained, supported, and empowered, respondents reported stronger data quality and more consistent execution.

Quality issues were often characterized as cultural or leadership failures before they became compliance failures. This reinforces the idea that quality is not owned by a function alone but is shaped by how organizations invest in and manage their people.

Technology enables quality, but does not define it

Most respondents agreed that technology maturity is not, in and of itself, evidence of quality.

> *The real test of technology is whether it changes behavior, reduces risk, and improves outcomes, not merely its availability.*

Digital tools and artificial intelligence (AI) were generally viewed as valuable when they were validated and successfully embedded into everyday workflows. Respondents consistently emphasized that the real test of technology is whether it changes behavior, reduces risk, and improves outcomes, not merely its availability. In this framing, technology supports quality, but quality is ultimately better demonstrated through how people work and the results they deliver.

There was a varying appetite for the use of technology and AI in quality assessment itself. Some respondents highlighted the potential for these tools to identify risk and surface trends earlier, while others stressed the need for validation, governance, and human oversight, and were wary of over-reliance on emerging technologies.

AMRC's 2026 Advocacy Priorities

Our 2025 positioning paper set out a clear advocacy agenda focused on establishing the value of MCRCs and addressing structural inefficiencies in the clinical research ecosystem. That work was intentionally foundational, aimed at building understanding and credibility with Sponsors, CROs, and policymakers.

AMRC's 2026 Advocacy Priorities

In practical terms, AMRC's advocacy in 2026 will focus on:

- Establishing clearer expectations around the metrics that matter when assessing site quality
- Enabling outcome-based benchmarking that strengthens credibility and trust
- Improving how Sponsors and CROs recognise and assess quality beyond CVs

The purpose of this consultation was to ensure that our 2026 advocacy efforts reflect the needs of the wider industry and deliver for our members. The findings unequivocally showed that the industry does not need another abstract definition of quality. But what it is missing is a shared understanding of how quality should be assessed in practice, particularly by Sponsors and CROs when selecting and working with sites.

Building on AMRC's 2025 positioning work, the consultation points to three practical priorities for 2026:

1. Clarifying the metrics that matter when assessing quality

Respondents consistently called for quality to be assessed through observable, outcome-based performance, rather than individuals' experience or reputational proxies.

In response, AMRC will advocate for greater alignment around the metrics that best reflect high-quality trial delivery in multisite settings. These include, but are not limited to:

- Protocol deviation rates and severity trends
- Query volume, recurrence, and time to resolution
- Timeliness and completeness of data entry and safety reporting
- Accuracy of feasibility and predictability of enrollment
- Patient retention and completion rates
- Workforce stability and turnover
- Audit and inspection outcomes over time

AMRC's role is not to mandate thresholds, but to promote recognition of these indicators as legitimate and meaningful evidence of quality, and to encourage their consistent use in sponsor and CRO decision-making.

2. Supporting benchmarking that builds credibility

Respondents supported benchmarking where it enables learning, improvement, and transparency, but were clear that simplistic rankings risk being misleading.

In 2026, AMRC will focus on:

- Enabling voluntary, anonymized benchmarking across our members and non-
- member MCRCs if they wish to be involved
- Using benchmarking to identify ranges, trends, and patterns rather than 'good' or 'bad' thresholds
- Identifying opportunities for improving performance
- Demonstrating consistency and maturity at a sector level

This approach allows AMRC to evidence performance without undermining differentiation or innovation across member organizations.

3. Improving how quality is recognized beyond individuals and credentials

The consultation highlighted widespread dissatisfaction with existing proxies for quality, including over-reliance on investigator experience, training completions, and generic certifications.

AMRC will advocate for more balanced approaches to quality assessment that:

- Place greater emphasis on systems, governance, and repeatable execution
- Recognize workforce stability, oversight, and demonstrated competence
- Treat certifications and accreditation as supporting evidence, not substitutes for performance

This will help shift industry conversations away from individual credentials and toward organizational maturity and delivery capability.

A Systemic Approach to Quality

This consultation reinforced a clear message: quality in clinical research is systemic, shaped by stable teams, consistent processes, and effective oversight. While investigator experience matters, it is not sufficient on its own to define or demonstrate quality at scale.

AMRC's 2026 advocacy agenda responds directly to this need. By focusing on the metrics that matter, supporting meaningful benchmarking, and improving how quality is assessed beyond individual credentials, AMRC aims to help shift industry conversations toward evidence, consistency, and delivery.

Join the Conversation

The issues raised through this consultation cannot be addressed by any one part of the industry alone. In 2026, AMRC will convene a series of cross-industry working groups bringing together Sponsors, CROs, and MCRCs to develop practical approaches to shared challenges, including how quality is measured and recognized in clinical research.

We invite organizations from across the clinical research industry to participate in this work and help shape the next phase of AMRC's advocacy.

For more information on our working groups, reach out at info@amrc.org.

About AMRC

The Association of Multisite Research Corporations (AMRC) is a nonprofit organization dedicated to advancing the use of multisite clinical research corporations in the global clinical trial ecosystem. Through advocacy, collaboration, and education, AMRC aims to transform clinical trials to improve patient outcomes, data quality, and operational efficiency.

Visit amrc.org for more information.