



Association for Multisite
Research Corporations

What Sponsors Don't See: The Systems Behind Clinical Trial Delivery

**Innovation. Consistency.
Longevity.**

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Foreword

Clinical research is not short of data – we collect more of it now than ever before, and the increasing complexity of studies has pushed many research sites to adapt.

Over the past decade, multisite clinical research corporations (MCRs) have built substantial operational infrastructure: systems that coordinate activity across sites, manage performance in near real time, and support decision-making across a portfolio. For many networks, this infrastructure is the primary mechanism through which quality and consistency are delivered at scale.

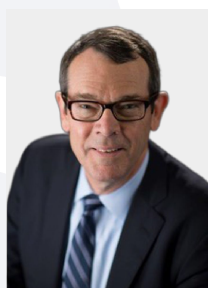
Yet, it remains largely invisible to sponsors and CROs, which typically engage with sites through study-specific systems and outputs that provide only a partial view of how delivery is managed. At the same time, sites are often required to operate sponsor-mandated technology alongside their own systems, creating parallel workflows and limiting visibility into the data and processes that underpin performance.

As a result, a significant portion of site-level capability remains unrecognized and underutilized. Data that could inform how studies are planned, executed, and evaluated already exists within site systems, but are not consistently surfaced or incorporated into decision-making. Enrolment numbers and milestone adherence tell part of the story.

The goal here is practical. AMRC is not seeking to prescribe how sponsors should work with site networks, but to contribute to a more informed conversation — one grounded in a clearer understanding of how modern MCRs operate, what data already exists within their systems, and how that data might be made more accessible to those commissioning trials.

Progress on this will require input from across the ecosystem. AMRC welcomes that engagement, from sponsors, CROs, and technology partners alike, and sees this paper as a starting point for that work.

A greater awareness of what site networks are capable of — and the data they already hold — would place Sponsors in a better position to engage more effectively, plan more accurately, and execute more consistently. That is good for sites, good for sponsors, and ultimately good for the patients that clinical trials serve.



Jim Kremidas
Executive Director, AMRC

The Infrastructure Behind Modern Trial Delivery

Sponsors currently interact with far less of the clinical research pipeline than they know. As research sites mature and specialist technologies become more readily available, the operational infrastructure that supports clinical trials is changing.

Multisite clinical research corporations (MRCs) operate integrated systems and technology stacks that support portfolio-level oversight, operational continuity, and near real-time analysis and optimization. These systems underpin how trials are planned, executed, and managed across sites, enabling coordination and consistency that extends beyond individual studies.

This level of capability requires sustained investment. Over time, many networks have developed increasingly sophisticated infrastructure, combining commercial platforms with internally developed tools designed to support trial delivery in practice.

However, much of this infrastructure sits outside of sponsor-facing systems. Sponsors and CROs typically require the use of their own technology for reporting and oversight, which often operates independently from site systems and provides limited visibility into how delivery is managed at an organizational level.

"A significant portion of site capability sits outside the systems sponsors and CROs typically see."

As a result, a large part of how trials are actually delivered remains obscure to those commissioning them. The systems that coordinate activity across studies, manage performance in real time, and support operational decision-making are not consistently visible within the tools used to evaluate performance.

Moving From Individual Performance to Systemic Assessment

This lack of visibility is reflected in how performance is assessed. Evaluation models rely heavily on investigator-level indicators and can only provide a partial view of quality. They do not reflect how delivery operates across studies, sites, and teams.

Individual performance is not scalable and, as site organizations grow, the systems and processes that support delivery become more critical. MCRCs are a good example of this, they are networks of integrated sites that can span the globe. They have developed centralized processes, governance structures, and a technological infrastructure designed specifically to support trial delivery at the site level. Most have the financial resources to invest heavily in tech, and a number now have large, dedicated teams building proprietary solutions.

"Systems — not individuals — determine whether performance can be repeated at scale."

Unlike sponsor- or CRO-imposed systems, these tech stacks are built around the realities of trial delivery at the site level. They determine how studies are executed day to day, how issues such as protocol deviations, query backlogs, or recruitment shortfalls are identified, and how performance is managed across a portfolio.

In practice, however, many site teams continue to operate sponsor-mandated systems alongside their own internal platforms. This creates parallel workflows, where the infrastructure that supports delivery is not fully visible within the systems used for oversight.

The result is a convoluted mismatch. Networks are assessed using proxy measures, while the capabilities that drive speed, quality, consistency, and patient experience remain under-recognised and underutilized.

Technology as Infrastructure

Across AMRC member networks, a remarkably consistent architecture is emerging. Clinical data sits within a range of EHR systems, while site-owned platforms manage study operations, regulatory documentation, and data capture. These are supported by recruitment and CRM tools that coordinate patient identification and engagement. Together, these systems enable activity to be planned, executed, and monitored across multiple studies and sites at once.

"Most of this data already exists at the site level but it is not consistently requested, recognized or used in sponsor decision-making."

This infrastructure is typically built around a small number of core platforms. CTMS, eSource, and regulatory systems are frequently provided by vendors such as Advarra, CRIO, and RealTime, often used in combination and configured to support the needs of each network. Recruitment and patient engagement are managed through CRM systems such as Devana or Salesforce, alongside internally developed tools that reflect the importance of recruitment as an operational function.

At the same time, site teams are required to operate Sponsor-mandated systems to support monitoring, reporting, and compliance. These include EDC, IRT, and eCOA platforms, which are typically introduced on a study-by-study basis and are not integrated with site-owned infrastructure.

The result is a dual-system environment. Site teams use one set of systems to run the study and another to report on it. Information is often entered multiple times across platforms, and operational data captured within site systems is not always visible within sponsor tools.

“Today, collaboration is often slowed by duplicate work and disconnected systems. In a more connected model, data is entered once into the systems sites already use, reducing rework, improving consistency, and streamlining workflows.

We see the industry moving toward a more connected ecosystem – one where sponsor and CRO platforms integrate directly with the systems research sites rely on, including CTMS, eISF, and eSource, such as the Advarra’s CTMSs, OnCore and Clinical Conductor, eReg, and eSource.

For sponsors and CROs, this means trials can move forward with greater speed and confidence. Ultimately, it’s about aligning around the site as the operational reality of the trial and building infrastructure that reflects how research is conducted.”

Ashley Davidson, SVP, head of product at Advarra

For Sponsors, this presents a practical opportunity. Much of the data required to improve feasibility planning, recruitment strategy, and operational oversight already exists within site systems. In many cases, it is simply not recognized or requested. Greater visibility into how sites plan and manage delivery — not just how they report it — would allow for more informed decision-making and more predictable execution.

“Clinical research networks don't struggle from a lack of data, they struggle from data that is siloed and inaccessible. Platforms like CRIO, which operate as an integrated CTMS, eSource, eConsent, and eRegulatory platform, connect the workflows that matter most to sites within a single environment. At network scale, this integration compounds in value and portfolio-level performance becomes visible in real time.

Through the CRIO Partner Program, the platform integrates with the systems sites already use, creating a connected infrastructure rather than another silo. Through the Central eSource model, CRIO partners with Sponsors and CROs to enable the adoption of site-centric systems at the protocol level. This approach leverages AI-driven eSource template development and eSource-to-EDC integrations to boost site efficiency while improving data quality.

The result is an ecosystem where site data flows where it needs to go... without duplication, workarounds, or compromise.”

Jonathan Andrus, co-CEO CRIO

Table One: The MCRC Operating System

Layer of Infrastructure	Common Vendors	Additional Data Capability Afforded
Patient Data & EHR Integration	Epic, Cerner (Oracle Health), Athena,	<ul style="list-style-type: none"> • Protocol-level feasibility based on real patient populations. • Access to longitudinal patient data. • Faster identification of eligible cohorts.
CTMS & Operational Management	CRIO, RealTime, Advarra Clinical Conductor and Oncore	<ul style="list-style-type: none"> • Portfolio-level performance tracking. • Study startup timelines across sites. • Resource allocation and capacity planning.
eSource & Clinical Data Capture	CRIO, RealTime	<ul style="list-style-type: none"> • Real-time data entry at point of care. • Reduced transcription error. • Visibility into query generation and resolution timelines.
eISF / Site Documentation	Florence, Advarra eReg, RealTime, Complion	<ul style="list-style-type: none"> • Audit readiness indicators. • Document cycle times. • Visibility into regulatory workflow efficiency.
Recruitment & Patient Engagement	Salesforce, Devana (RealTime), ObjectiveScreen, internal tools	<ul style="list-style-type: none"> • Recruitment channel performance. • Conversion rates from outreach to enrolment. • Patient engagement trends.
Informed Consent (eConsent)	Florence, CRIO, Medidata	<ul style="list-style-type: none"> • Consent completion rates. • Re-consent timelines. • Patient comprehension and drop-off points.
IRB & Regulatory Management	Advarra, WCG, RealTime, Clinical.ly	<ul style="list-style-type: none"> • Approval timelines. • Amendment turnaround. • Bottlenecks in regulatory processes.
Financial & Resource Management	NetSuite, internal systems	<ul style="list-style-type: none"> • Cost per patient. • Budget vs actual spend. • Operational cost drivers at site and study level.
Internal Tools & Integrations	DocuSign, Microsoft CoPilot, proprietary tools, Triaally (EHR interrogation)	<ul style="list-style-type: none"> • Cross-system analytics. • Workflow automation. • Operational efficiency gains across studies.

Real Metrics, Real Results

Site organizations routinely capture data that goes well beyond what is reflected in sponsor reporting. This includes cost per patient acquisition, recruitment channel performance, screen failure and dropout rates, and the operational effort required to enrol and retain participants.

These measures are used internally to manage performance across studies, allocate resources, and identify issues early. They provide a clearer view of how trials are actually delivered, not just whether milestones are met.

"Platforms like Florence capture operational and quality data embedded in day-to-day site workflows, like document timelines, signature latency, training progress, task sequencing, and audit activity. This is data that is typically not visible to sponsors, but when surfaced, highlights patterns in startup timelines, workload distribution, and process variability across sites."

Catherine Gregor, Chief Clinical Trials Officer, Florence Healthcare

However, this level of detail is rarely requested or incorporated into Sponsor evaluation models. Reporting remains focused on outputs such as enrollment numbers and timelines, with limited visibility into the underlying drivers of performance. As a result, meaningful differences in efficiency, cost, and operational risk often invisible to sponsors.

Strategic Partnership Starts with Visibility

Strategic partnerships rely on a clear understanding of how trials are actually delivered. Today, much of the infrastructure that supports delivery at the site level sits outside of sponsor-facing systems, limiting visibility into how performance is achieved.

Where system-level capability is visible and understood, site networks are able to engage differently. They can collaborate earlier on feasibility and study design, using portfolio-level data and operational insight to inform what is realistic. Budgeting can be grounded in how studies are actually delivered, rather than estimated in isolation, and studies can be run with fewer operational disruptions and greater consistency across sites.

A more consistent way of describing and evaluating system-level capability is needed to support this shift. Without it, these capabilities remain difficult to assess and are therefore underutilized.

"Today's engagement model is largely transactional and creates additional site burden: manual feasibility questionnaires, frequent status updates, and reactive issue management. Greater real-time visibility into site operations and data, via site-owned technology platforms, changes that fundamentally.

When sponsors and CROs can see verified operational readiness at feasibility, track contracting and regulatory progress during start-up, and access enrollment and source-level visit data — engagement shifts from episodic coordination to continuous, performance-based partnership.

The impact is measurable. Across high-performing site networks, real-time visibility has driven faster study execution, increased site capacity, and more predictable performance — with organizations reporting up to 59% ROI and a 75% reduction in monitoring-related costs."

Jeff Kozloff, CEO RealTime eClinical Solutions

"Greater understanding of the core uses of native site technology has the potential to transform how sponsors and CROs engage with site networks across all stages of clinical trial delivery. Site technology is centered around the clinic or hospital participating as a trial site. Sponsors want data collection centered around the study design. Both are reasonable, but they are not the same."

Accordingly, WCG's integrated site solutions bridge the gap between site-level operations and sponsor goals. By centralizing IRB submissions, streamlining workflows, and enabling real-time tracking, eReview Manager ensures that critical operational data is not only captured but also actionable. This empowers sponsors to make informed decisions during feasibility, budgeting, and execution phases, while fostering trust and transparency in sponsor-site relationships. This is one way that WCG's Site Network improves start up timelines by 29%."

Seth Halvorson, senior vice president, WCG Site Solutions

AMRC's role is to convene stakeholders across the ecosystem to support that alignment. Input from members, sponsors, CROs, and technology providers will be critical in shaping how system-level quality is defined and applied in practice.