



Association for Multisite
Research Corporations

Clinical Research Strategic Delivery Standards

iii) Strategic Partnership Toolkit

Innovation. Consistency. Longevity.

Clinical Research Strategic Delivery Standards

Clinical Research Strategic Delivery Standards define how sponsors and multisite clinical research corporations (MCRCs) measure quality and effectively run a strategic partnership.

It is the culmination of months of industry research and collaboration between regulators, sponsors, CROs, and MCRCs, and aims to define two things:

1. A shared standard for quality
2. A toolkit to assess whether a sponsor-MCRC relationship should be strategic, and for running it once it is.

Components:

The Strategic Delivery Standards are intended to be flexible and inclusive of different site types, CROs and Sponsors. They have been split into three core components to allow users to focus on the sections most relevant to them. All components are available as sds.amrc.org.

1. **The Network Reliability Score** measures the systems and processes MCRCs use to increase predictability and data quality across its network.
2. **The Site and Patient Standard** measures how individual sites perform for patient
3. **The Strategic Partnerships Toolkit**, to decide whether a sponsor-MCRC relationship should be strategic, and for running it once it is.

Contributors:

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Clinical Research Strategic Delivery Standards

Measurements and Metrics



Network Reliability Score



Site and Patient Standard (SPS)



Strategic Partnership Toolkit



1. Selection

Identify and align the right partner based on capability, fit and shared objectives.



2. Governance

Establish clear structures, roles and decision-making to drive accountability and alignment.



3. Joint Scorecard

Track performance against agreed metrics and drive transparent, regular reporting.



4. Structured Process Improvement

Use insights to identify opportunities, implement changes and continuously improve outcomes.

Part III: The Strategic Partnership Toolkit

The Toolkit is a set of templates for use by sponsors and MCRCs to identify truly strategic partners, govern that relationship, measure performance and deliver value to both sides.

1. Selection Framework

Defines how a sponsor and an MCRC decide whether they have the resources and alignment to commit to a strategic partnership. It aims to define the relationship each side is seeking, confirm if they meet selection criteria, and confirm that each has the capacity to run an active partnership.

A strategic partnership differs from a trusted vendor relationship in how the two sides work together. Both communicate openly, compromise when needed, and hold each other accountable, and each brings something the other cannot get elsewhere.

Part A: Relationship level

Not every working relationship should become a strategic partnership. Each side names where the relationship sits now and which level it is seeking, with a short reason.

In practice the sponsor and the MCRC collaborate early and often during protocol development: the sponsor draws on the network's PIs and KOLs, and both sides share data, insight, and operational expertise across the portfolio. Senior leaders from both sides meet on a regular basis.

Level	Definition
Emerging / Developing	Working together to develop sites
Transactional	A one-off study relationship
Targeted	A specific type of site for a specific study
Trusted	Continued use of a site based on good performance
Strategic Partner	The level this framework tests for

Both sides complete this framework on their own first. Before finalizing scores, both sides should hold a joint discussion covering how each party is approaching the partnership. Use the warning signs in the MCRC Assessment of Sponsor section below as discussion prompts: for example, whether pipeline is being discussed with real evidence behind it or used as a bargaining position, and whether feedback is sought before or after decisions are already made.

If both sides are seeking Strategic Partner, move to score Part B. If either is not, there is no need to continue.

Part B: Assessing Partners Against Selection Criteria

Below is a table for each organization to complete with seven responses that can be used to classify the current level of partnership both organizations can support.

Each criterion is scored 1 to 5 against the evidence behind it.

Score	Meaning
5	Meets this criterion in full. Strong, consistent evidence across.
4	Meets this criterion with minor gaps that do not threaten the partnership.
3	Meets this criterion in part. Gaps need discussion before proceeding.
2	Falls short on this criterion. Significant gaps to close.
1	Unable to meet this criterion. Little or no supporting evidence.

Scoring is a straight average across all seven criteria, with weighting determined by each organization, since needs and priorities will vary.

4.3 – 5.0	Strategic Partner	Clears the bar. Formalize, once any single low criterion is addressed.
3.5 – 4.2	Trusted	Strong relationship. Close specific gaps before committing to a strategic partnership.
2.5 – 3.4	Targeted / Transactional	Suited to defined, study-specific work rather than a portfolio partnership.
Below 2.5	Emerging / Developing	Material development needed before a strategic partnership is viable.

a. Sponsor Assessment of MCRC

The sponsor assessment of MCRCs should be completed by core individuals within the business, such as Operations, QA, and Site Monitoring, with results evaluated as a group.

Assessment approach:

1. Use trends rather than a single study, since one strong or one weak result should prompt investigation rather than a conclusion.
2. Normalize data by therapeutic area, study complexity, protocol burden, and patient population rather than comparing raw totals.
3. Assess fit as well as capability, since a highly capable MCRC may still be the wrong fit for a given portfolio.
4. Pair the data with direct discussion, since evidence shows what happened but not why.
5. Be explicit about uncertainty: distinguish committed pipeline from possible future work, and confirmed capacity from aspirational growth plans.

Criterion	Definition	Evidence to look for
Demonstrated Performance	Track record of delivery on past studies	Enrollment against target, data query and deviation rates, timeline adherence, audit and inspection history
Predictability	How consistent delivery is, and how open the organization is with the data that lets a partner forecast against it	Variance between forecast and actual across recent studies; consistency of startup and enrollment timelines; transparency of performance data shared without being chased
Therapeutic Area Alignment	Overlap between the sponsor's pipeline and the MCRC's strengths	Match between the sponsor's active and pipeline TAs and the MCRC's experience and site footprint in those areas
Access to Patients	The MCRC's reach into the populations the studies need	Documented patient volumes and demographics in relevant indications, referral networks, recruitment rates in comparable studies
Culture Alignment	Compatible ways of working, built on responsiveness and open communication	Speed and quality of response to queries and issues, track record of transparent issue resolution, reference conversations
Infrastructure	The systems, technology, and resources to support partnership-level work	CTMS, EDC and eSource systems in use, data governance, tech stack, sufficient resource to absorb partnership work alongside study delivery
Staff Engagement	The stability, capacity, and authority of the people running the work	Staff turnover and retention data, coordinator capacity, PI stability, whether the people assigned hold decision-making authority rather than relaying upward

b. MCRC Assessment of Sponsor

The MCRC assessment of sponsors should be completed by core individuals within the business, such as Head of BD, Head of Ops and CEO, and then compared/reviewed as a group.

Before an MCRC accepts a strategic designation, the sponsor should be able to commit to:

1. A named executive sponsor and empowered operational lead,
2. An agreed governance structure and meeting cadence,
3. Timely, candid feedback on feasibility and site-selection decisions,
4. Reasonable visibility into relevant portfolio plans,
5. Transparent performance metrics with a shared interpretation of them,
6. Fair contracting, budgeting, payment, and change-control practices;
7. Reciprocal commitments for improvement activities,
8. A respectful escalation process that protects relationships while resolving issues. A sponsor should also be willing to say openly when it cannot make a commitment.

The section rests on one member's input and needs development from the group and the sponsor validation.

Marker	What good looks like	Score (1–5)
Access to senior leadership	Reach to sponsor leaders at VP level and above	
Reach to decision-makers	Access to the upstream people who shape protocols	
Decision-making authority	The people in the room can decide, not just relay	
Willingness to pilot	Openness to testing new solutions rather than defaulting to standard process	
Responsive to feedback	Willingness to take action in response to requests	
Transparency into pipeline	Shares with strategic partner the products they have in development so they can prepare ahead of feasibility request	
Interoperability	Transparent about tech strategy and facilitates integrations with common management platforms where possible	

c. Readiness

Each side assesses its own capacity to run an active partnership before committing to one. Mark each item: In place, Partial, or Not yet for your organization.

Readiness item	Applies to	Status
Named partnership owner	Both sides	
Senior sponsorship secured	Both sides	
Willingness to share operational data	Both sides	
Sufficient scale to justify the sponsor's investment	MCRC	
Leadership bandwidth accessible for regular meetings	Both sides	

Output

A shared assessment and collaborative discussion that either confirms both sides are ready to proceed or names what each needs to change first.

2. Governance Structure

Once the Selection Framework has confirmed both sides are ready to commit, the Governance Structure dictates how a sponsor and an MCRC establish and run a strategic partnership.

Both sides agree the composition of two standing committees:

- The Governance Committee should be made up of senior leaders and owns the strategic relationship, responsible for defining the vision (long term aim) and mission (short term why) for the relationship, and communicating that throughout the business.
- The Operations Committee runs the functional partnership and owns the Joint Scorecard and Structured Process Improvement.

Without clear roles, decision rights, and escalation routes, partnerships revert to transactional behavior under pressure, the structure below is intended to guard against that.

a. Defining Common Challenges

Typical roadblocks that undermine sponsor-MCRC partnerships.

Roadblock	Impact	Addressing Challenge
Misaligned incentives	Goals and success metrics differ between sponsor and MCRC, so priorities clash.	The Governance Committee sets a joint partnership scorecard with shared KPIs and aligned incentives.
Decision latency	Cross-company decisions stall for weeks because nobody knows who holds authority.	Clear decision rights per tier and a regular meeting cadence, with ad hoc escalation for urgent issues.
Unclear roles and ownership	Both parties assume the other side is handling something; issues fall through the cracks or get duplicated.	Formal charters and a RACI matrix for each committee, plus dedicated partnership leads on both sides.
Data and communication gaps	Each side runs different systems and holds back performance data, and trust erodes.	Shared dashboards and joint performance reviews create a single source of truth.
Leadership disengagement	Senior support fades and the partnership devolves into contract management.	The Governance Committee keeps executive sponsorship and strategic oversight standing.
Cultural friction and inertia	Different organizational cultures resist change; teams fall back to working separately.	Routine joint engagement at every tier institutionalizes collaboration and builds a problem-solving culture.

b. Committee Structure

Both committees agree to joint terms of reference before the partnership goes live, covering meeting cadence, decision rights, and escalation triggers. All attendees must hold the authority to decide for their function.

Tier	Role	Membership	Cadence
Governance Committee	Owns the strategic relationship: shared mission and vision, legal structure, and removing the organizational roadblocks that stop a partnership forming or maturing. Final arbiter for escalated issues.	Sponsor: Head of Clinical Operations, Head of Supplier Relationship Management, Therapeutic Head; Head of Finance on call. MCRC: CEO, COO; CFO on call. A partnership lead on each side acts as co-chair and carries follow-ups between meetings.	Quarterly in the first year while the partnership forms. Ad hoc for critical issues.
Operations Committee	Runs the functional partnership. Owns the Joint Scorecard and the improvement agenda, decides cross-study matters, and applies lessons from individual studies across the portfolio.	Sponsor: Head of MCRC Site Management (partnership lead), Head of Site Monitoring, Head of Data Management, Head of QA, Technology lead; therapeutic heads attend on rotation by portfolio focus. MCRC: Head of Site, Head of Site Monitoring, Head of Data Management, Head of QA, Head of Technology, Head of Project Management. Regulatory or compliance input as needed. One person can cover more than one function.	Quarterly during partnership startup.
Project Teams	The existing teams managing individual studies. Their role does not change; their issues and outputs now feed the Operations Committee.	Per study, unchanged.	Weekly or bi-weekly, unchanged.

c. Decision rights and escalation

Decisions sit at the lowest tier able to make them. Predefined escalation triggers stop issues stalling between organizations, and certain scenarios are pre-designated: patient safety issues and suspected fraud escalate at once, whatever tier they surface at. A traffic-light urgency scale (green, yellow, red) marks how fast an issue moves up.

Tier	Decides	Escalates when
Project Teams	Study-specific operational decisions: recruitment strategy, site-level problem solving, protocol clarifications.	A decision reaches beyond the individual study: a significant protocol change, an MCRC-level policy issue, or a budget or scope change outside the study plan.
Operations Committee	Decisions affecting multiple studies: resource allocation across trials, partnership-wide process improvements, cross-study training or technology initiatives, corrective action plans for underperforming scorecard metrics.	A decision involves strategic direction, significant resource commitments, changes to the partnership's legal or financial terms, a pattern of serious quality or compliance issues, or an impasse between the partners.
Governance Committee	Major changes to the partnership agreement or structure, expanding or reducing scope, significant budget allocations, resolving escalated disputes, approving remediation plans.	The final tier. Only dissolution or legal action goes beyond it.

Not every partnership justifies the full three-tier structure. For a smaller MCRC or a narrow-scope partnership, merge the Governance and Operations Committees into a single Joint Steering Committee with leaner membership, splitting each agenda between strategic and operational business.

d. Getting there: the staged path

The staged model below manages the transition to strategic partnership; data transparency, joint decision-making, and cultural integration, in phases.

Function	Stage 1: Transactional	Stage 2: Initial Collaboration	Stage 3: Co-Managed Partnership	Stage 4: Strategic Partnership
Governance structure	No joint governance bodies. Sponsor project teams manage studies with ad hoc escalation.	One joint steering forum meets periodically. Partnership leads appointed on each side as points of contact.	Two-tier Operations and Governance Committees with defined membership, roles, and charters. Monthly Ops, quarterly Governance.	Full three-tier governance. Project Teams feed the Operations Committee, which reports to the Governance Committee.
Decision rights	Sponsor decides, one way. MCRC executes.	Sponsor still leads but seeks MCRC input at joint meetings. No formal joint decisions yet.	Shared tactical decisions at Ops level within agreed limits. Governance Committee co-owns major decisions.	Joint decisions at every appropriate level. Both sides hold equal say; neither dominates.
Escalation	Each side escalates internally. Slow resolution; sponsor holds veto.	Informal joint problem-solving. Hard issues still run through the sponsor's chain.	Formal bilateral escalation with clear triggers. Either party can invoke it.	Predefined urgent pathways (red flags) reach the right level at once. Escalation runs symmetrically.
Data sharing	Standard trial data only. Each side keeps its metrics private.	Selected metrics and summaries shared at joint meetings. Limited pipeline outlook from the sponsor.	Joint scorecard compiled and reviewed together. Some financial and sensitive detail stays confidential.	Open-book transparency on operational, quality, pipeline, and often financial data, through shared live dashboards.
Leadership and culture	Arms-length. Senior leaders engage only when issues occur. Client-vendor culture.	Senior sponsors appointed on both sides; sets and communicates the vision and mission for the partnership. Engagement periodic.	Executives meet in the Governance Committee. Middle managers work together in the Operations Committee. Trust building.	Senior leaders jointly define a Partnership Credo: a shared mission and vision communicated across both organizations. Staff operate as one extended team.
Joint improvement	None. Sponsor expects delivery on contract.	Ad hoc lessons-learned conversations. Improvements voluntary.	An improvement working group under the Ops Committee pilots projects on neutral ground.	Continuous improvement as core activity. MCRC input solicited during protocol development; both sides adapt their processes.

3. The Joint Scorecard

This defines what gets measured in a strategic partnership, how it gets reported, and how it gets used. Both parties are accountable to deliver on their own metrics. This is not a sponsor assessment of the MCRC. The scorecard is the standing agenda for Operations Committee meetings.

a. The Joint Scorecard

Both parties populate the scorecard ahead of each Operations Committee meeting and review it together. Each metric has a named owner on one side or the other. The sub-group ranked recruitment and enrolment as the category to watch first.

Before first use, both parties confirm a shared definition for each metric. Terms like "study startup time" or "green light" can be measured differently by each side; agreeing the definition upfront avoids reporting the same metric inconsistently.

b. Reporting cadence and format

The Operations Committee reviews the full scorecard quarterly. This gives both sides room to assess and course-correct early, without the overhead of a monthly cycle. The Governance Committee meets twice yearly; the most current metrics reviewed by the Operations Committee are brought forward as a standing agenda item at each of those meetings.

Category	Metric	Submitted by
Study startup	Study startup time	Both (for comparison)
Study startup	Green light to first screening	MCRC
Study startup	Startup milestone data across the portfolio	Sponsor
Study startup	Contracting	Both
Study startup	Protocol questions	MCRC
Study startup	Query resolution	Sponsor
Recruitment and enrollment	Recruitment rate against target	MCRC
Recruitment and enrollment	Screen failure rate	MCRC
Recruitment and enrollment	Pre-screen volume	MCRC
Recruitment and enrollment	Referral-to-consent conversion rate	MCRC
Recruitment and enrollment	Consistency between committed and delivered patient allocation. Tracks cases where a sponsor's confirmed patient number changes materially after resources have already been allocated on the strength of the original commitment.	Both

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Recruitment and enrollment	Consistency between committed and delivered patient allocation. Tracks cases where a sponsor's confirmed patient number changes materially after resources have already been allocated on the strength of the original commitment.	Both
Data quality	Query trend data across studies	Sponsor
Data quality	Protocol deviation patterns	MCRC
Operational efficiency	Document cycle times	MCRC
Operational efficiency	Technology support	MCRC
Operational efficiency	Cost per patient versus budget	MCRC
Operational efficiency	Out-of-pocket expenses incurred at sites	MCRC
Operational efficiency	Comparative site performance against other sites, US and OUS	Sponsor
Operational efficiency	Contracting turnaround, split by segment: time with site versus time with sponsor, not a single combined figure. A sponsor unable or unwilling to track its own segment is a signal worth raising at Governance Committee level.	Both
Workforce stability	Staff capacity	MCRC
Patient experience	Reported against the Site and Patient Standard, Part I.	MCRC
Relationship health	Vendor performance feedback, what works and what does not	MCRC
Relationship health	Geographic gaps in site coverage that signal expansion opportunities	Sponsor
Relationship health	Reasoning behind sponsor data requests	Sponsor
Relationship health	Governance meeting attendance and commitment of attendees.	Both
Relationship health	Periodic relationship check-in, conducted separately from the scorecard review, using a structured discussion or a simple rating exercise on both sides. Qualitative by design.	Both

c. Escalation triggers

Decisions sit at the lowest tier able to make them. A traffic-light urgency scale (green, yellow, red) marks how fast an issue is escalated.

Tier	Decides	Escalates when
Project Teams	Study-specific operational decisions: recruitment strategy, site-level problem solving, protocol clarifications.	A decision reaches beyond the individual study: a significant protocol change, an MCRC-level policy issue, or a budget or scope change outside the study plan.
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4. Structured Process Improvement Cycle

This is the clearest distinguisher of a strategic partnership from a well-managed vendor relationship. It is where MCRC operational expertise actively improves trial design and delivery, and where sponsors modify their own processes to support the efficiency of the collaborative workflow.

The section below sets out the improvement cycle, how the agenda is agreed, the protocol co-design checkpoint, and the study review structure that feeds the cycle.

a. The improvement cycle

Stage	What happens	Owner
Agree the agenda	The Operations Committee agrees one or two focused improvement areas for the cycle, with defined success metrics such as recruitment acceleration, fewer deviations, or faster startup	Sponsor and MCRC jointly
Name the owners	A responsible person on each side co-owns the improvement; an operational working group drives execution	Both sides
Run the cycle	Six months, with monthly check-ins to track progress	Working group
Evaluate	A six-month evaluation point assesses impact against the success metrics	Operations Committee
Standardize	What works is standardized and replicated across studies; what does not is documented and closed. Reported to the Governance Committee by each of the individuals responsible for the relationship (MCRC and Sponsor).	Operations Committee

b. Setting the agenda

Prioritization is joint and data-driven where possible and managed at partnership level rather than study by study.

c. Two changes to standing practice

The cycle rests on two structural changes:

- I. The MCRC names a person at Operations Committee level whose role includes proactively surfacing operational intelligence to the sponsor. This is the same operational data the Joint Scorecard depends on.
- II. The sponsor builds formal touchpoints into protocol development where MCRC partner input is solicited and recorded.

d. Study Review

The post-study review is a collaborative learning session, not a performance evaluation. It compares expectations with outcomes and identifies practical improvements for future studies.

For long studies, a structured mid-study review at 25 or 50 percent enrollment allows for improvements while the study is still running.

Review area	What it covers
Feasibility planning	Accuracy of patient population estimates, disease burden, recruitment assumptions, timelines, competitive landscape including competing trials and new product launches, budget expectations
Trial administration	Communication burden, vendor management including the case for a single portal with single sign-on, duplicate training requirements
Recruitment	Forecast versus actual enrollment and the reasons for over- or under-performance
Screen failures	Primary causes: eligibility issues, patient misunderstanding, protocol complexity
Protocol design	Procedures that created operational burden for sites or patients without adding scientific value
Study startup	Timelines, contracting, IRB approvals, vendor-related bottlenecks
Data quality	Protocol deviations and query trends
Payments	Site reimbursement timelines, sponsor payment processes, patient stipends
Patient retention	Dropout rates, timing, underlying reasons
Successes	Processes, tools, vendors, or approaches worth standardizing across future studies

Each review produces no more than five actionable recommendations, each with an assigned owner, and a commitment to apply the lessons in future studies.

e. Required Internal Changes by Sponsors

The changes sponsors need to make to their own processes, personnel, and technology to make the model work.

Area	Change
Process	Build an early co-design step into protocol development, with approval input from both academic and non-academic sites. Schedule regular improvement discussions rather than reviewing KPIs alone. Capture and reuse lessons learned after every completed study.
Personnel	Assign a dedicated partnership lead. Encourage closer collaboration between Clinical Operations, Medical, Data Management, and Quality so operational issues surface earlier.
Technology	Develop shared, standardized dashboards with transparent operational metrics, used as the platform for tracking improvement initiatives and assigned actions. Work toward standardized KPIs across the industry. Include a way to document unusual circumstances that affect study performance but that quantitative metrics miss.