JAVARA

The Integrated Research Organization (IRO) Framework

An Institutional Model for Integrating Clinical Research into Healthcare

A Position Paper by Javara Inc.

Authors:

Jennifer Byrne, Founder, Chief Executive Officer

Linda McCarty, JD, Co-Founder, Chief Legal Officer

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About This Position Paper

This position paper introduces the **Integrated Research Organization (IRO) Framework**, a comprehensive framework for integrating clinical research into routine healthcare delivery. It is intended to advance discussion among healthcare organizations, sponsors, contract research organizations (CROs), investigators, patient advocates, policymakers, regulators, technology providers, and other stakeholders committed to expanding equitable access to high-quality clinical research.

The IRO Framework is not intended to replace existing clinical research models. Instead, the IRO Framework addresses a different challenge: enabling **healthcare organizations** to make clinical research a sustainable component of patient care by establishing the governance, operational, legal and regulatory, financial, workforce, technology, quality, and strategic capabilities required to support research safely, consistently, and at scale.

Achieving this vision will require the clinical research enterprise to move beyond optimizing individual studies, deploying standalone technologies, or relying on fragmented operational models. It requires sustained investment in the **foundational capabilities and institutional infrastructure** that enables clinical research to become a routine care option for eligible patients wherever they receive healthcare.

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Executive Summary

Clinical research is at an inflection point. While therapies, technologies, and data capabilities have advanced, the infrastructure required to integrate clinical research into routine healthcare has not kept pace.

This paper introduces the **Integrated Research Organization (IRO) Framework**—a comprehensive institutional framework for integrating high-quality clinical research into routine healthcare delivery. An IRO is not simply a site network, technology vendor, staffing company, or CRO substitute. It provides governance, legal architecture, financial stewardship, operational infrastructure, workforce, technology ecosystem, quality systems, and strategic capabilities required to enable healthcare organizations to conduct clinical research as a sustainable organizational capability.

The IRO Framework is built around a simple premise: clinical research should not remain a parallel system accessible only to patients who happen to live near traditional clinical research centers or academic medical institutions. It should become a routine component of healthcare—embedded within the trusted relationships between patients, physicians, and healthcare organizations. Achieving that future will require more than individual studies, new technologies, or updated regulations. It will require the **institutional infrastructure** and **capabilities** necessary to integrate clinical research as a care option within routine care.

The Eight Domains of the IRO Framework

Domain	Purpose
Legal architecture and governance	Creates the legal and governance architecture that reconciles two highly regulated systems—healthcare delivery and human subjects research—enabling clinical research to be safely, ethically, and sustainably integrated into routine patient care.
Financial management and business operations	Creates the financial and business infrastructure that supports sustainable, transparent, and compliant clinical research through standardized budgeting, financial forecasting, revenue management, financial controls, resource allocation, and operational performance management.
Standardized operations	Creates a standardized operational framework that enables healthcare organizations of varying size, structure, and maturity to integrate and scale clinical research through common processes, controls, playbooks, and performance expectations.
Investigator and Workforce development	Develops the multidisciplinary workforce—including investigators, coordinators, patient navigators, regulatory professionals, quality leaders, and clinical research executives—needed to deliver safe, high-quality, patient-centered clinical research.

Domain	Purpose
Technology enablement	Provides, manages, and integrates a standardized clinical research technology stack—including EHR integration, CTMS, eSource, eRegulatory, patient identification and engagement, analytics, and digital clinical research platforms—to support efficient, compliant, and scalable clinical research operations with the underlying protections for identified access to health records and HIPAA compliance.
Quality and continuous improvement	Uses performance measurement, audits, corrective action, leadership review, and continuous learning and transparency to strengthen operational excellence, participant safety, and organizational performance.
Clinical Research Strategy and Business Development	Provides the strategic leadership and external engagement necessary to grow and sustain the clinical research enterprise by aligning organizational priorities, unmet patient needs and prioritization of the patient journey, investigator capabilities, and sponsor opportunities through portfolio strategy, business development, and clinical research partnerships.
Clinical Research ecosystem integration	Creates a coordinated clinical research ecosystem that aligns healthcare organizations, sponsors, CROs, investigators, patients, IRBs, and technology partners while preserving the unique responsibilities and expertise of each stakeholder.

The IRO Framework is more than a service model or organizational structure. It is a proposed institutional framework for integrating clinical research into healthcare delivery. Its strength lies not in any single capability, but in the deliberate integration of governance, legal architecture, financial stewardship, operations, workforce, technology, quality, and strategic leadership into a unified system capable of making clinical research a routine, trusted, and sustainable component of patient care.

1. The Infrastructure Gap

The Problem

Clinical research has made remarkable advances in study design, data collection, monitoring, and analytics. Yet the industry's greatest challenge is no longer how studies are conducted—it is where and by whom they are conducted.

Despite growing interest in expanding clinical research into community-based healthcare settings, most healthcare organizations remain unprepared to conduct clinical research as a routine part of patient care. Community hospitals, physician practices, multispecialty groups, federally qualified health centers, and other healthcare providers collectively serve most patients, yet many lack the institutional infrastructure, resources,

operational capabilities, and/or sustainable funding necessary to participate at scale and consistently in industry-sponsored or federally funded clinical research. This infrastructure gap is reflected in physician participation in clinical research. According to the Association of American Medical Colleges' 2022 National Sample Survey of Physicians, only 6% of physicians practicing outside academic medicine reported engaging in clinical research compared with 21% of physicians affiliated with academic institutions. These findings suggest that the principal barrier is not a lack of physician interest, but the absence of the institutional capabilities required to integrate clinical research into routine healthcare delivery. [1]

There is not a shortage of patients or clinical expertise. It is a shortage of clinical research infrastructure.

A healthcare organization can deliver exceptional patient care while lacking the governance, workforce, technology, financial systems, operational processes, and quality management capabilities required to conduct clinical research safely, efficiently, and at scale.

Clinical Research is a Business Within a Business

One of the most common misconceptions in clinical research is that organizations capable of delivering healthcare are inherently capable of conducting clinical research. In reality, healthcare delivery and human subjects research operate under distinct legal (federal and state), regulatory, financial, operational, demographic and population distinctions, and ethical frameworks.

Clinical research introduces obligations that extend well beyond patient care, including protocol compliance, sponsor contracting, informed consent, IRB oversight, regulatory reporting, privacy protections, financial management, data integrity, monitoring, audit readiness, and quality management.

Clinical research therefore functions as a business within a business. It requires dedicated governance, specialized expertise, financial acumen, sustainable infrastructure, and executive oversight. Without these capabilities, research remains dependent on individual champions, temporary funding, and isolated initiatives rather than becoming a durable organizational capability.

The Cost of Fragmentation

The absence of standardized clinical research infrastructure creates inefficiencies across the clinical research ecosystem.

- For sponsors, fragmentation results in inconsistent site performance, lengthy startup timelines, operational variability and delays, unpredictable enrollment, and increased costs.
- For healthcare organizations, fragmentation creates administrative burden, duplicative processes, and the need to build and maintain specialized research infrastructure that is only partially supported by

study-specific reimbursement. Consequently, many organizations struggle to sustain research operations over the long term, and clinical research is often viewed as a cost center rather than a strategic service line. [2-4]

- For physicians, it often means participating in clinical research without adequate operational support or integration into clinical workflows.
- For patients, it limits awareness of clinical trial opportunities and perpetuates unequal access to innovative therapies.

The consequence is an ecosystem in which clinical research capacity is concentrated within a relatively small number of experienced institutions while many healthcare organizations remain unable to participate despite serving large and diverse patient populations. This limits patient access to clinical trials, constrains sponsor access to representative populations, and slows the generation of evidence needed to advance new therapies.

Thus, the policy challenge is not that clinical research is inherently expensive; it is that the current model requires thousands of healthcare organizations to independently develop and maintain substantially similar research infrastructure while sponsors primarily reimburse study-specific activities rather than the underlying enterprise capabilities necessary to conduct clinical research.

The industry's response to this challenge has largely focused on technology. These innovations are essential, but they do not create clinical research-ready healthcare organizations.

2. Defining the Integrated Research Organization

An IRO is a standardized institutional framework that enables healthcare organizations to integrate high-quality clinical research into routine patient care through a combination of legal architecture, governance, standardized operations, business operations, workforce development, technology enablement, and continuous quality improvement.

The IRO is distinct from adjacent models:

Model	Primary Role	Why the IRO Is Different
CRO	Manages clinical development activities on behalf of sponsors.	The IRO is embedded with healthcare organizations and builds durable clinical research capability inside care delivery.
SMO or site network	Primarily supports individual investigators or independent research sites.	The IRO partners directly with healthcare organizations and provides an integrated institutional framework across legal, operational, workforce, technology, and quality domains, enabling the integration of clinical research with clinical care.

Model	Primary Role	Why the IRO Is Different
Technology platform	Digitizes or enables specific trial functions.	The IRO makes technology usable by connecting it to governance, workflows, trained users, and accountability.
Traditional clinical research department	Conducts clinical research within a single organization.	The IRO creates a repeatable model that can be deployed across multiple healthcare organizations while adapting to local context.

An IRO may be established within a healthcare organization or provided to a healthcare organization through a strategic partnership with an independent IRO. In either model, the purpose is the same: to provide the institutional infrastructure required to integrate high-quality clinical research into routine healthcare delivery. The framework is implementation-agnostic; what matters is that the capabilities exist, whether developed internally by the healthcare organization or accessed through partnership.

3. The Eight-Domains of the IRO Framework

The IRO Framework is organized around eight domains. Each domain addresses a different barrier to healthcare-integrated clinical research. Together, they form a complete operating model.

Domain One: Legal Architecture and Governance

Clinical research cannot be integrated into healthcare without first establishing the legal and governance architecture that reconciles two highly regulated systems: healthcare delivery and human subjects research.

A strong IRO legal architecture should address healthcare system partnerships, delegation of responsibilities, sponsor contracting, investigator obligations, HIPAA and privacy compliance, data governance, cybersecurity, IRB coordination, conflict of interest management, enterprise risk management, subject injury, indemnification, insurance, regulatory accountability, and oversight.

By creating repeatable legal and governance models, the IRO reduces ambiguity and allows healthcare organizations to participate in clinical research without reinventing core structures for every clinical trial or partnership.

Domain Two: Financial Management and Business Operations

Clinical research is not sustained by individual studies; it is sustained by disciplined business operations. This domain establishes standardized processes for budgeting, revenue cycle management, financial controls, study forecasting, resource allocation, and performance reporting. It ensures that clinical research activities are financially transparent, operationally efficient, and compliant with applicable regulatory and contractual requirements while aligning the economic interests of healthcare organizations, sponsors, investigators, and patients.

Unlike traditional clinical research programs that often manage each study as an isolated project, an IRO applies enterprise-level business practices that support long-term sustainability, scalability, and continuous investment in clinical research infrastructure. By integrating financial stewardship with operational execution, the IRO enables healthcare organizations to participate in clinical research with greater confidence, predictability, and accountability.

Domain Three: Standardized Operations

Organizations become clinical research-ready when excellence can be reproduced consistently, regardless of location, investigator, or study.

This domain includes standard operating procedures, trial activation playbooks, feasibility processes, patient identification and engagement workflows, regulatory submissions, contract and budget coordination, source documentation, visit coordination, patient navigation, issue escalation, closeout, and sponsor communication.

The purpose is not rigid uniformity. Healthcare organizations differ by geography, specialty, patient population, technology environment, staffing, and culture. The purpose is disciplined adaptability: a common operating model that can adjust to local context without sacrificing quality or accountability.

For patients, standardized operations reduce friction. They make clinical research easier to understand, easier to access, and easier to navigate. They also reduce the likelihood that participation depends on which clinic, physician, or coordinator happens to be involved.

Domain Four: Investigator and Workforce Development

People—not technology—ultimately determine whether clinical research succeeds. Healthcare organizations cannot become clinical research-ready simply by hiring coordinators. They need investigators, patient navigators, regulatory professionals, legal professionals, quality leaders, data specialists, financial analysts, and research executives who understand how clinical research and care intersect.

The IRO model treats workforce development as a strategic capability, not an administrative function.

An IRO workforce model should include:

- Competency-based role descriptions and training pathways.
- Investigator development and physician engagement programs.
- Continuing education and periodic competency assessment.
- Leadership development for clinical research executives and operational managers.
- Retention strategies that professionalize clinical research careers inside healthcare.

The patient-centered purpose is continuity and competence. Patients should not experience clinical research as a fragmented handoff among disconnected personnel. They should be supported by trained professionals who understand protocol requirements, clinical workflows, and patient needs.

Domain Five: Technology Enablement

Technology enablement provides the integrated clinical research technology ecosystem that supports the planning, conduct, oversight, and continuous improvement of clinical research. The IRO deploys, manages, and

supports a standardized technology stack—including electronic health record (EHR) integration, clinical trial management systems (CTMS), electronic source (eSource), electronic regulatory systems (e-Regulatory), patient identification and recruitment platforms, participant engagement tools, analytics, reporting, and other digital clinical research solutions—to enable consistent, compliant, and scalable clinical research operations.

Rather than implementing technology as isolated applications, the IRO integrates these platforms into standardized workflows, governance processes, and user responsibilities. Technology becomes an enterprise capability that enhances operational efficiency, data quality, regulatory compliance, and the patient and investigator experience while providing healthcare organizations with a modern, interoperable clinical research infrastructure.

Domain Six: Quality and Continuous Improvement

Quality in clinical research cannot be limited to correcting errors after they occur. It must be designed into the operating system.

The IRO Framework treats quality as both compliance and learning. Compliance ensures that participant protections, data integrity, protocol obligations, and regulatory requirements are met. Learning ensures that the organization improves over time.

This domain includes quality management systems, internal audits, monitoring support, CAPA processes, deviation tracking, inspection readiness, root-cause analysis, leadership review, and performance dashboards. It also includes patient and investigator feedback as part of the continuous improvement cycle.

A learning clinical research organization should not only conduct studies; it should become measurably better at protecting participants, reducing burden, improving access, and delivering high-quality data.

Domain Seven: Clinical Research Strategy and Business Development

Clinical research cannot become a sustainable healthcare capability without a deliberate strategy for growth, partnership, and portfolio development. Clinical research strategy and business development establish the strategic direction and external engagement necessary to sustain and expand a healthcare organization's clinical research enterprise. This domain aligns clinical research priorities with organizational goals, patient population needs, physician interests, and community health objectives while developing long-term relationships with sponsors, contract research organizations, biotechnology companies, and other clinical research partners. It encompasses strategic planning, feasibility and portfolio development, sponsor engagement, site selection readiness, marketing, and the identification of new clinical research opportunities.

Rather than viewing business development as a transactional function, the IRO treats it as a strategic capability that strengthens the long-term viability of the clinical research enterprise. By aligning scientific opportunity with clinical capabilities and patient needs, this domain enables healthcare organizations to build a diversified, sustainable portfolio of clinical research while expanding patient access to innovative therapies and advancing the organization's mission.

Domain Eight: Clinical Research Ecosystem Integration

The IRO is not designed to displace the existing clinical research ecosystem. It is designed to connect it. Clinical research has historically operated as a collection of independent organizations connected by individual studies. The IRO Framework shifts the focus from coordinating individual trials to strengthening the clinical research ecosystem itself.

Sponsors need high-performing, predictable clinical research environments. CROs need sites that can execute. Healthcare organizations need infrastructure that does not compromise care delivery. Investigators need support. IRBs need clarity. Technology vendors need workflows into which their tools can be deployed. Patients need access through trusted healthcare relationships.

The IRO aligns these roles without collapsing them into one entity. It creates a shared operating environment in which responsibilities are clear, communication is disciplined, and clinical research can function within healthcare rather than around it.

The ultimate measure of ecosystem integration is not how many entities are connected; it is whether patients can learn about, consider, and participate in appropriate clinical research opportunities without leaving the healthcare relationships they already trust.

4. Transforming Clinical Research Through Institutional Infrastructure

For Healthcare Organizations

The IRO Framework does not require every healthcare organization to independently build a comprehensive research enterprise. Healthcare organizations may develop these capabilities internally, partner with an established IRO, or adopt a hybrid approach that combines internal resources with external expertise. This flexibility allows organizations of varying size, experience, and resources to participate in clinical research without recreating complex infrastructure from the ground up.

For Sponsors and CROs

For sponsors and CROs, the greatest challenge is often not finding investigators—it is finding clinical research-ready organizations capable of delivering consistent, predictable performance. The IRO model creates standardized clinical research environments within healthcare organizations, reducing variability and increasing confidence in activation, enrollment, retention, data quality, and compliance.

It also offers access to patients who may not be connected to traditional clinical research centers.

For Physicians and Clinical Research Teams

Most physicians do not participate in clinical research because they lack interest. They do not participate because they lack the institutional infrastructure needed to integrate clinical research into clinical practice.

The IRO allows physicians to focus on science and patient care while the institutional infrastructure supports the complex legal, regulatory, financial, operational, and technological requirements of clinical research.

For Patients

Patients should not have to leave their community, navigate unfamiliar institutions, or rely on chance to learn about clinical research. They should be able to consider appropriate clinical trials through the healthcare relationships they already trust.

The IRO model supports that vision by making clinical research more accessible, better integrated with care, and supported by trained teams, consistent processes, privacy protections, and quality systems.

The ultimate purpose of the IRO is not operational efficiency. It is expanding patient access to clinical research.

5. Funding Considerations

If expanding access to clinical research is recognized as a national public health priority, investment in sustainable research infrastructure should likewise be viewed as a strategic healthcare priority.

Strengthening institutional research capabilities has the potential to expand equitable access to innovative therapies, accelerate evidence generation, improve patient outcomes and satisfaction, strengthen physician engagement, and reduce the long-term burden associated with unmet health needs. Importantly, these capabilities need not be independently developed by every healthcare organization. Organizations should have the flexibility to build IRO capabilities internally, access them through partnerships with established IROs, or adopt hybrid models that leverage both internal and external expertise.

As policymakers consider strategies to expand access to clinical research, funding models should recognize that research readiness is a foundational capability—not a study-specific expense.

Potential policy approaches may include public-private partnerships, targeted infrastructure grants or tax incentives at the federal and state level, reimbursement models that recognize research as an integral component of healthcare delivery, and shared infrastructure models that distribute costs across multiple healthcare organizations. These and other approaches warrant further evaluation in collaboration with healthcare organizations, sponsors, patients, regulators, IROs, and other stakeholders.

Regardless of the funding mechanism ultimately adopted, reducing duplicative infrastructure investment and enabling healthcare organizations to access standardized research capabilities will be essential to expanding research capacity, improving operational efficiency, and increasing equitable patient access to clinical trials.

Conclusion

If clinical research is to become a routine component of healthcare, the industry must move beyond individual studies, standalone technologies, and fragmented operational approaches. It must establish the **institutional infrastructure** necessary to integrate clinical research into routine care safely, consistently, and at scale.

The IRO Framework offers one vision for achieving that future.

The IRO Framework is not prescriptive about who owns or operates the infrastructure. It defines the institutional capabilities required for healthcare-integrated research while allowing healthcare organizations to build those capabilities internally, access them through partnership with an IRO, or combine both approaches based on their strategic objectives.

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