

EXECUTIVE VIEWPOINT

CROs in the Age of AI

How do people-driven businesses adapt to the impact of artificial intelligence (AI)?

That's the top-of-mind question for leaders across many service sectors. Compared to prior emerging technologies, AI is somewhat unique: in addition to its exceptionally high velocity and broad applications, the disruption is felt heavily among skilled knowledge workers. Whereas technology innovations often empower and amplify this workforce, AI also commoditizes the delivery of knowledge work products and processes. In life sciences, contract research organizations (CROs) are one of the leading intersections of this workforce / AI transformation.

The modern CRO industry has evolved over the past 40 years to become a diverse \$100B ecosystem of service providers responsible for >70% of all clinical research conducted in the world. But the fundamental value propositions historically offered by CROs – operational efficiencies, scalable resource models, cost arbitrage, shared IT investment, and access to scientific expertise – are being re-characterized by the rapid infusion of AI. As these economics shift, CROs face an imperative to adapt both their business models and operations to remain competitive and valuable business partners.

Pathways to Smarter Clinical Research

Though a full-scale disruption of the CRO industry is unlikely, a transition in service delivery approaches and associated value creation – from labor-oriented models towards diversification into AI-enabled products and services – is already underway. Market viability of AI solutions has already been proven in areas such as:

- Site selection and start-up
- Patient recruitment and retention
- Adaptive trial designs & synthetic control arms
- Clinical / RWE data management and quality
- Adverse event detection and management
- Imaging, wearables, and devices
- Clinical monitoring and protocol deviation detection
- Document automation solutions
- Programming and TLF automation
- Real world evidence analyses and NLP

To date, the AI investment strategy of CROs in these areas has been stratified by market tier.

- **Large CROs** are building proprietary platforms, making notable investments alongside global technology players and partners to deploy large-scale data assets and extensible agent platforms. These complex systems require sizable capital investments and expertise, and while they offer compelling capabilities, they will also require sustained engineering as the underlying technologies continue to evolve.
- **Small-to-medium CROs**, lacking the capital of their larger peers, are pursuing 3rd party vendors to provision off-the-shelf AI capabilities, though such tactics introduce a wide array of risks (e.g., vendor dependency, parity with competitors, operational misalignment, cost duplication, data proliferation) that can potentially undermine long-term value creation.

For most of the CRO industry, a balanced approach to build-vs.-buy is likely the best path forward. The introduction of value-creating AI solutions does not need to be capital intensive – on the contrary, most technical capabilities can be provisioned at commodity price points. By blending affordable off-the-shelf software with tailored configurations of

supportable AI, CROs can unlock the transformative value of AI without the need for lengthy, complex system engineering projects and high operating expenses.

Business Model and Market Dynamics Implications

Given the capabilities that AI offers, performance expectations for both sponsors and CROs will change. Though geographic reach, operational scale, and clinical expertise will still matter, sponsors will evaluate CROs on their ability to deliver AI-derived advantages such as faster performance (e.g., recruitment, data review, database lock), more efficient operations (e.g., study monitoring, programming), higher quality (e.g., lower error rates, automated compliance and quality monitoring), and more precise results (e.g., modeling, targeting, diagnostics, segmentation). As such, leadership teams and their boards need to be prepared to proactively address strategic questions such as:

- **Business model:** Every CRO needs a strongly aligned strategy between their relationship model (FSO, FSP, hybrid), their differentiated capabilities (therapeutic expertise, accessible network, data, technology, etc.), and their AI-driven value delivery capabilities (speed, quality, cost, risk, precision, etc.).

What makes your CRO a truly unique value creation driver in an AI-enabled market, and how will you best enable and monetize it?

- **Investor attractiveness:** In an sector historically characterized by high investor appetites, CROs that do not demonstrate strong AI and data competencies may be seen as less competitive and garner lower valuations.

How will you align to investor interests to maximize future capitalization cycles?

- **Margins:** Some CROs may require an increase in highly skilled labor (e.g., scientific / technical expertise delivering novel research designs involving synthetic control arms, digital twins, and trial simulations).

How will you protect and improve margins with higher labor costs, especially if lower-cost resources are displaced?

- **Continuous learning and change:** For the foreseeable future, the rate of AI-driven advancements and change will remain high, presenting the CRO industry with a continuous stream of opportunities.

How will you stay agile and embrace new AI opportunities effectively while avoiding unnecessary expenses and technical debt?

- **Consolidation:** Given the market velocity, both CROs and AI companies seeking to accelerate their growth will see inorganic options as a competitive imperative. Consolidations will change both CRO competitive dynamics and vendor technology strategies.

How will you monitor and adapt to these landscape changes, and which ones would trigger adjustments to your strategy?

Practical Considerations for AI Enablement of CROs

When considering internal investments, “AI everywhere” will not create high performance. Every CRO needs an AI strategy that prioritizes the fewest, most important operational and competitive capabilities that will drive the highest value creation. The AI strategy should be deeply connected to the corporate strategy, focusing on performance metrics tied to explicit organizational goals. Examples include margin expansion, utilization improvement, avoiding unnecessary human capital growth, study enrollment optimization measures, improved turnaround times, improved quality, and higher win rates. For most CROs, that strategy will need to address the follow 7 areas.

1. **Service line transformation.** Existing service lines will evolve – and new service lines will emerge – to accommodate opportunities that AI introduces. Existing service lines will unlock efficiencies in core business processes such as recruitment, data review, scientific writing, biostatistical programming, and billing. Newer services reflect growing demand for bespoke client-driven AI applications – novel study modeling, disease modeling, and RWE data curation such as patient registries, for example. One key to unlocking the strategic value of service line transformation is laser-like clarity around a firm’s most compelling business, scientific, and technical differentiators that can be translated into AI assets.
2. **Relationship models.** Sponsor relationships with CROs can take the form of any combination of T&M projects, Full-Service Outsourcing (FSO), and Functional Service Provider (FSP) agreements. Hybrid approaches and FSP relationships tend to be more cost effective for clients, though smaller organizations such as some biotechs may require FSO providers’ infrastructure. Though AI can amplify CRO margins of all three options, it also places downward pricing pressure on labor-based contracting even under milestone-based payment models. Outcomes- or performance-based contracting can provide margin relief by leveraging AI to drive value creation provided adopting organizations ensure strong management of the contract terms.
3. **Data sharing readiness.** Ensuring that client agreements provide data reusability terms to support the CRO’s AI-enablement goals is now vital. For some, changing contract terms will seem commercially risky. But the alternative is much riskier – an organization based heavily on manual labor competing in an industry at least partially automated by AI. Numerous precedents exist for safely sharing anonymized data to support research advancements. And not all data is equally sensitive; operational, quality, and performance related data offer a wealth of innovation opportunities without introducing scientific IP, patent, or patient data risks. Accommodations may be needed for individual customers that may be unwilling, though offering clear incentives for sharing may be sufficient to produce change.
4. **Data asset development.** Though market excitement is often directed at advancements in AI methods, success and value creation with AI is most associated with data. In some areas

Risk Management.

Like all emerging technologies, AI brings specific risks that leaders need to mitigate.

Accuracy	<ul style="list-style-type: none"> ● Solution engineering ● Unanticipated data biases ● Improper user training
Cyber-security	<ul style="list-style-type: none"> ● AI-enabled threat actors ● Ungoverned AI tools, models, and code ● New cloud requirements
Legal	<ul style="list-style-type: none"> ● Inconsistent US laws ● Accidental disclosure of customer data ● Vendor policies on data use and retention
Compliance	<ul style="list-style-type: none"> ● Managing acceptable use of models and data ● Establishing auditable evidence of quality ● Evolving international AI policy stances

such as clinical development, the historical approach to data management has been largely study- or program-based; cultivating reusable data assets has not been a high priority. A CRO may have a strategy that focuses on any combination of preclinical, clinical, financial, commercial, and operational data. Regardless of the data mix, competencies such as data product engineering, quality, curation, governance, pedigree, ownership, and performance-aligned storage are needed to ensure AI success. And controlling data proliferation – the uncontrolled spread of data copies across AI tools and storage locations – is critical for protecting information security.

5. **Real-world data partnerships.** Many AI innovation priorities for CROs will not be accessible without better access – either directly or through partners – to real-world data. AI-enabled patient recruitment, for example, is most effective when connected to patient medical records. Advanced work with precision diagnostics and therapeutics involves leveraging richer data formats – sequence data, imaging data, waveforms, streaming device data, and others. CROs do not need to in-source all of these data capabilities, but they do need consistent, scalable channels for provisioning them so they can develop reusable IP. Therapeutic specialization offers unique value accelerator; organizations establishing unique data niches within specific therapeutic areas or modalities gain additional commercial and computational leverage.
6. **Enterprise architecture.** For AI to function and scale properly, the IT strategy, blueprint, and underlying systems need to be intentionally designed, aligned, and managed. Every IT vendor in the CRO's enterprise is pitching AI capabilities. A clear plan for governance and rationalized use is required for scale and cost management. CROs need standardized designs and solutions for addressing common AI scenarios such as access to external models, delivery of tailored AI solutions, authentication, and data controls. As AI use cases increasing focus on workflow automation, interoperability within and across enterprise systems becomes an imperative. As many industry applications were never engineered as enterprise-grade systems, organizations may need some tailored workarounds to accomplish their integration goals. And given that the AI technology landscape will continue to evolve rapidly over the next five years, every CRO needs to plan for continuous change – leverage what is available but avoid compounding technical debt.
7. **Analysis.** In its traditional form, biostatistics may now be a less viable independent service line. While still core to research execution and interpretation, traditional bioanalytical methods (e.g., descriptive and inferential statistics, Bayesian approaches) represent only a fraction of the computational techniques now being applied in supporting drug discovery and development. In addition, the implementation of those traditional methods (e.g., programming, testing, deliverable creation) can be delivered by modern AI models, creating a barrier to high-margin service monetization. However, the human expertise in the appropriate selection, use, and interpretation of AI and bioanalytical methods is not a commodity, creating tremendous opportunity for leveling up the contribution margin of analytical talent.

From a leadership perspective, perhaps the biggest consideration to AI adoption in life sciences – at least in terms of speed and impact – is the industry environment itself. Research variability, scientific complexity, regulatory obligations (both real and perceived), and justifiable concerns over patient protections have often created conservative, less agile cultures. No one wants to be at the source of an audit failure, a delayed study close, or loss of IP. At the same time, many success stories now exist, regulators are actively participating in the journey, and life sciences has successfully adopted many emerging technologies over the past three decades. Leaders need to acknowledge the legitimate nature of these concerns while also delivering confidence-inspiring plans for navigating into the future.

Coming of Age

CROs that move now to embrace the age of AI will be tomorrow's market leaders and high-value investment targets. But AI adoption is a learning journey for every organization, including CROs. For leaders looking to accelerate their AI progression, three tactics show up repeated as best practices among high-performing organizations:

1. Conduct a comprehensive, realistic assessment of your organization's readiness.

Given the issues presented here, it is not surprising that most CROs are not ready to fully embrace AI. Leaders need to be prepared to critically evaluate the maturity of processes and competencies related to:

- Business process standardization and quality control
- Data and information storage, control, quality management, access, and use agreements
- Solution development lifecycles, quality frameworks, and auditability
- IT governance, including vendor assessments and data use terms

2. Develop specific, measurable value creation goals aligned to your corporate strategy and growth opportunities.

Avoid searching for perfect AI applications. Instead, look for current business problems where AI can help.

Prioritize measurable constraints such as situations where you:

- Lose margin due to manual work
- Struggle with people capacity
- Have people allocated below their skill level
- See unmet service quality, capability, or speed
- Find manual work producing delays
- Cannot easily access knowledge resources

3. Launch, don't pilot, AI solution programs to gain the right expertise.

Pilot programs are useful when testing whether a technology works, but they are much less useful when pursuing value creation goals, process re-engineering, or business transformation. The core question is not whether the technology is a good fit for the business today; the core question is about what the business can look like tomorrow. We know the technology works; the goal is creating a more attractive business with it. And the goal is within reach.

About the Author



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