The IRB Industry Consolidation

How Institutional Review Board oversight consolidated into a two-player market

WHITE PAPER SERIES • PART 2B

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Series Overview

This paper is part 2b of a four-part series examining why consolidation occurs and how it reshapes industries over time. This paper focuses on the consolidation of the IRB (Institutional Review Board) industry.

Part 1 introduces the four-phase consolidation model and explains each phase in detail. This framework serves as the foundation for the entire series.

Part 2 (this whitepaper) applies the four-phase model to the IRB (Institutional Review Board) industry and the CRO (contract research organization) industry through two separate white papers. Both industries have progressed through all four phases, making them useful case studies for understanding how consolidation unfolds in clinical research.

Part 3 applies the same model to the clinical research site sector. It outlines where the site industry stands today and projects how it is likely to evolve based on the patterns observed in Parts 1 and 2.

Part 4 focuses on implications for individual clinical research sites. It examines the strategic options available to site owners and executives given this industry trajectory, including the risks of inaction and the trade-offs of different paths forward.

Executive Summary

Over the past fifteen years, the U.S. Institutional Review Board (IRB) industry has undergone one of the most complete consolidation cycles in the pharmaceutical industry. What was once a fragmented ecosystem of thousands of local and institutional IRBs has evolved into a highly centralized market dominated by two national providers.

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This transformation was driven by sponsor demand for speed and consistency, increasing regulatory complexity, and formal policy changes that favored centralized review. Today, IRB oversight for industry-sponsored, multi-site clinical trials is effectively controlled by two private-equity–backed firms.

This white paper applies a four-phase consolidation model to the IRB industry, explaining how the market evolved from fragmentation to maturity, why consolidation accelerated so rapidly, and what lessons this evolution holds for adjacent sectors in clinical research.

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The 4-Phase Model of Industry Consolidation

Industry consolidation typically follows a predictable trajectory as operational complexity increases and buyers seek efficiency, risk reduction, and consistency. The four phases are fragmentation, scale, mega-consolidation, and maturity.

The IRB industry represents a textbook example of this progression, largely because regulatory policy and sponsor behavior reinforced the same outcome at the same time.

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Phase 1: Fragmentation

Pre-2010

Prior to 2010, the IRB landscape in the United States was highly fragmented.

There were more than 2000 IRBs operating nationwide, the majority affiliated with hospitals, academic medical centers, or large health systems. In parallel, dozens of small independent commercial IRBs operated regionally, often serving specific geographic areas or therapeutic niches.

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Phase 1: Fragmentation (Continued)

During this period, multi-site clinical trials required separate IRB approval at each participating institution. Each local IRB reviewed the same protocol independently, frequently reaching different conclusions, imposing different consent language, or requiring protocol-specific modifications.

The result was slow and inconsistent study startup. Sponsors and CROs faced long approval timelines, redundant reviews, and unpredictable regulatory outcomes. While the system emphasized local oversight, it was operationally inefficient and poorly suited for large, multi-center trials. This is similar to the current clinical trial landscape.

Despite these challenges, the fragmented model persisted because regulatory expectations allowed it and because institutions viewed IRB oversight as a core internal function.

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Phase 2: Scale

2010 to 2016

The shift toward consolidation began as sponsors pushed aggressively for centralized IRB models.

As trials grew more complex and timelines became more critical, sponsors sought ways to eliminate redundant reviews and accelerate startup. Central IRBs offered a clear solution by providing a single review for all participating sites in a multi-site study.

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Phase 2: Scale (Continued)

Independent IRBs such as WIRB, Copernicus, Schulman, and Chesapeake began gaining significant volume. These organizations invested heavily in technology, including electronic IRB platforms, document management systems, and standardized workflows designed to support large, multi-site reviews.

At the same time, institutional IRBs increasingly relied on external central IRBs for industry-sponsored trials. While institutions often retained oversight for investigator-initiated or academic studies, commercial trials began shifting outward to specialized providers.

This phase marked a structural change. IRB review transitioned from a localized, institution-centric function to a scalable service model optimized for volume, speed, and consistency.

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Phase 3: Mega-Consolidation

2016 to 2021

Phase 3 was defined by rapid consolidation and formal policy reinforcement.

Two major mergers reshaped the industry. WIRB merged with Copernicus to form WCG, while Chesapeake merged with Schulman to create Advarra. These transactions created two national IRB platforms with unmatched scale, infrastructure, and sponsor relationships.

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Phase 3: Mega-Consolidation (Continued)

Both firms continued to expand through acquisition, absorbing competitors such as Quorum, Aspire, and New England IRB. This acquisition activity further reduced the number of viable independent IRB providers.

Regulatory policy accelerated the transition. In 2016, the NIH implemented its single-IRB policy for multi-site research. In 2020, revisions to the Common Rule formally mandated the use of a single IRB for most federally funded multi-site studies.

These policy changes effectively institutionalized the central IRB model. Sponsors and CROs increasingly defaulted to WCG or Advarra for nearly all multi-site trials, regardless of funding source.

By the end of this phase, the competitive landscape had narrowed dramatically. Central IRB review was no longer optional. It was the standard.

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Phase 4: Maturity

2021 to Present

The IRB industry is now firmly in a mature consolidation phase.

WCG and Advarra together handle approximately 92 percent of industry-sponsored protocol reviews in the United States. Smaller IRBs have largely been acquired, exited the market, or relegated to narrow use cases such as single-site studies, specialized academic research, or institution-specific oversight.

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Phase 4: Maturity (Continued)

New IRBs face nearly insurmountable barriers to entry. Regulatory complexity, sponsor risk aversion, technology requirements, and entrenched buyer relationships make meaningful competition extremely difficult.

IRB oversight for commercial clinical research has effectively consolidated into two private-equity–backed firms with national reach, standardized processes, and deep integration into sponsor and CRO workflows.

Competition at this stage focuses less on market share and more on service quality, turnaround time, and incremental technology improvements. The structural outcome of consolidation is largely complete.

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Why IRB Consolidation Succeeded So Completely

The IRB industry consolidated faster and more thoroughly than many adjacent sectors due to three reinforcing forces.

First, sponsor incentives were clear and aligned. Centralization reduced startup delays, administrative burden, and regulatory risk.

Second, regulatory policy explicitly favored consolidation. The NIH single-IRB policy and Common Rule changes removed ambiguity and eliminated alternative models for most multi-site research.

Third, IRB services are highly standardized by design. Unlike patient-facing services, IRB review does not rely on local relationships or physical presence, making it easier to centralize without loss of perceived value.

These factors combined to create a near-ideal environment for consolidation.

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Lessons for Clinical Research Infrastructure

The IRB industry illustrates how quickly consolidation can occur when buyer behavior, regulation, and operational efficiency align.

Once a centralized model becomes institutionalized, fragmentation does not return. Late entrants are locked out. Independent operators disappear or are absorbed. Market structure becomes highly stable.

For other segments of the clinical research ecosystem, the IRB experience provides a clear warning and a clear precedent. When scale, standardization, and regulatory complexity converge, consolidation accelerates and becomes irreversible.

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Conclusion

The consolidation of the IRB industry was not accidental. It followed a predictable four-phase trajectory driven by efficiency demands, policy decisions, and capital-backed execution.

What began as a fragmented network of more than 2000 IRBs has become a two-player market controlling the vast majority of industry-sponsored research oversight. This outcome reflects the power of aligned incentives and structural forces rather than individual competitive maneuvers.

Understanding how and why this consolidation occurred is essential for stakeholders across clinical research. The IRB industry shows what happens when a market reaches maturity and what it means when consolidation is no longer a future possibility, but a settled reality.

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Continue the Series

For a deeper application of this framework to clinical research, with a specific focus on IRBs, CROs and clinical research sites, refer to Parts 2, 3, and 4 of this white paper series.

Part 1 introduces the four-phase consolidation model and explains each phase in detail. This framework serves as the foundation for the entire series.

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