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White Paper

From Adoption to Integration

A Three-Year Evolution of Decentralized Clinical Trials in the Era of AI & Digital Health Technologies

Subproject of 2025-G-Y-005 :
Research on the Risk-Based Classification Framework, Tiered Implementation Pathway & Capacity-Building System for Quality Management in Drug Clinical Trials

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EXECUTIVE SUMMARY

Drawing on one of the largest consecutive three-year assessments of China's decentralized clinical research ecosystem (2023-2025; n=2,776), this white paper identifies a fundamental shift in the industry's priorities. The challenge is no longer whether digital technologies can be adopted, but whether they can be integrated into scalable, interoperable, and governance-ready clinical research ecosystems.

Following rapid expansion during the COVID-19 pandemic, decentralized clinical trials (DCTs) have entered a phase of pragmatic stabilization. Hybrid trial designs have consistently emerged as the preferred operating model, particularly in oncology and cardiovascular/metabolic research, demonstrating that digital innovation is increasingly being deployed where it delivers measurable scientific and operational value.

Yet digital maturity has exposed a new bottleneck: Integration Friction, the operational, data, and governance complexity created when multiple digital solutions fail to function as a coordinated ecosystem.

Our findings show that nearly four in five stakeholders report unclear responsibilities across multi-vendor environments, more than half struggle with decentralized source data and data integrity, and almost three-quarters identify unified data standards and interoperability as the essential prerequisite for future scale. These findings indicate that the industry's greatest constraint is no longer technology itself, but the absence of an integrated operating model.

This integration gap is also slowing AI adoption. While organizational interest in AI continues to grow, routine implementation remains limited because the foundational requirements for trustworthy AI, including interoperable data infrastructure, validated digital endpoints, standardized governance, and operational readiness, have yet to mature. AI readiness therefore depends not only on better algorithms, but on stronger clinical research ecosystems.

This white paper proposes Collaborative Ecosystem Orchestration as the next operating model for China's life sciences sector. By aligning sponsors, CROs, healthcare institutions, technology providers, and policymakers around interoperable platforms, standardized governance, and shared accountability, organizations can systematically reduce Integration Friction, accelerate AI readiness, and build a more resilient, patient-centric, and globally competitive clinical research ecosystem.

China's next phase of clinical innovation will be defined not by deploying more digital technologies, but by integrating data, governance, and collaboration to build trusted, interoperable, and AI-ready clinical research ecosystems.

1. INTRODUCTION

Clinical research is undergoing a structural transition from site-bound experimentation toward digitally mediated, distributed systems of evidence generation[1,2]. Decentralized clinical trials (DCTs), enabled by digital health technologies (DHTs) and increasingly augmented by artificial intelligence (AI), have been widely promoted as a means to address the long-standing inefficiencies and high costs of traditional, site-centric trial models[3-5]. Despite rapid adoption accelerated by the coronavirus disease 2019 (COVID-19) pandemic, the expected gains in efficiency, scalability, and patient-centricity have not been fully realized, contributing to a recent slowdown in DCT implementation[2,4,6]. This gap between theoretical promise and real-world maturity reflects persistent operational complexity, increased site burden, and global digital disparities[2,4,7].

This disconnect reflects a critical inflection point for the field, where the central challenge is no longer technology adoption, but technology integration[2]. Early DCT implementation focused largely on deploying discrete digital tools, such as electronic consent (eConsent), remote monitoring, and direct-to-patient (DTP) logistics. However, emerging evidence suggests that fragmented implementation of these tools can create additional operational burdens, disrupt established workflows, and increase regulatory complexity[4,7,8]. We define this phenomenon as a technology paradox, in which the proliferation of disconnected digital solutions increases, rather than reduces, site-level complexity. This is reflected in reports that trial sites may be required to navigate more than six separate platforms for a single study[9].

At the same time, the field is entering a second phase of transformation, driven not only by digitization but also by integration and intelligence[10]. Advances in AI and continuous-monitoring DHTs are shifting attention toward predictive analytics, real-time risk detection, and novel digital endpoints[1,5,11,12]. Nevertheless, this transition also exposes unresolved structural challenges, including digital biomarker validation, algorithmic opacity, and the governance of cross-border health data[11-13].

Despite the strategic importance of these issues, the current evidence base remains fragmented and largely cross-sectional, providing limited insight into how digital transformation evolves over time within real-world clinical ecosystems[2,4,14] . Longitudinal, system-level evidence remains particularly scarce. To address this gap, this study presents a three-year longitudinal analysis (2023-2025) of China's evolving clinical trial ecosystem using a repeated cross-sectional survey design. We analyzed three independent nationwide datasets collected between 2023 and 2025 across sponsors, contract research organizations (CROs), and clinical sites (n=2,776)[15,16]. This sample captures both strategic decision-making and operational realities across the full clinical research spectrum, with strong representation from tertiary hospitals and experienced professionals engaged in digital trial delivery[15,16]. By examining the transition from rapid DCT adoption, through subsequent operational recalibration, to the emerging frontier of AI-enabled trials, this study provides one of the first system-level analyses of digital integration in real-world clinical trial ecosystems.

2. THE ADOPTION CURVE

2.1 Post-Pandemic Correction

Following rapid expansion during the COVID-19 pandemic, DCT adoption in China has entered a phase of recalibration and strategic consolidation. As highlighted above, speed remains a critical success factor in clinical research, given the exceptionally high costs and lengthy timelines required to bring novel therapeutics to market. Consequently, the theoretical promise that DCTs could accelerate recruitment and reduce trial timelines made them a highly attractive investment[17].

Driven by these expectations, our repeated cross-sectional survey data show that overall DCT adoption increased significantly from 28.8% in 2023 to 37.4% in 2024, before moderating to 33.7% in the current 2025 dataset[16]. This trajectory suggests a broader market correction and closely aligns with recent academic evaluations indicating that the global clinical research enterprise is undergoing a reality check regarding the gap between the expectations and real-world performance of decentralized models[6]. Although the theoretical cost savings of DCTs remain attractive, the removal of pandemic-era mobility restrictions has prompted sponsors to critically re-evaluate the true risk-cost-benefit profile of remote trial execution[3,4,6,17]. The Chinese clinical research ecosystem appears to have moved beyond the peak of inflated expectations, recognizing that upfront technological investments and complex integration risks associated with fully remote trials can, in some cases, offset anticipated financial savings. As a result, the industry is increasingly shifting toward selective, disciplined, and strategically targeted deployment of DHTs.

2.2 The Dominance of Hybrid Trial Models

This stabilization of risk and cost is most clearly reflected in the industry's structural preference for specific trial. The three-year data demonstrate a marked retreat from fully decentralized trials, which declined sharply from an initial pandemic-era level of 19.9% in 2023 to 9.1% in 2024[16], before rebounding modestly to 13.6% in the primary 2025 findings. This retreat represents a pragmatic acknowledgment of operational limitations. For complex interventions, complete decentralization may be less favorable because they lack the necessary physical infrastructure and clinical oversight, raising investigator concerns regarding patient safety, data integrity, and regulatory compliance[9].

In contrast, hybrid designs have remained remarkably resilient and stable, consistently hovering around 30% of adoption across the three-year period (32.4% in 2023, 29.4% in 2024, and 31.1% in the 2025 cohort). This empirical consistency indicates that the industry has increasingly converged on a balanced model that selectively integrates digital tools with traditional site-based operations. As noted, hybrid architecture combines the rigorous control and physical oversight of traditional trial sites with the flexibility and broader geographic reach of remote technologies[18]. This preference is also shaped by participants themselves, who continue to place high value on direct, face-to-face interactions with healthcare providers[7].

Furthermore, empirical evaluations suggest that hybrid models may offer operational advantages. A recent retrospective study of clinical monitoring reported that hybrid approaches improved operational efficiency and reduced trial costs while supporting the timely detection of safety issues[19]. Rather than representing a transitional compromise, hybrid trials are increasingly recognized by global data management consortiums as the most practical, sustainable, and dominant configuration for real-world clinical trial execution[20].

2.3 Repositioning Across Trial Phases and Therapeutic Areas

Concurrently, the application of DCT elements has become increasingly targeted, shifting away from exploratory settings toward more rigorous clinical development contexts. Our repeated cross-sectional data reveal a substantial systemic shift away from post-marketing and academic studies. In 2023, decentralized elements were predominantly used in Phase IV/post-marketing surveillance trials (54.8%), real-world studies (32.3%), and investigator-initiated trials (IITs; 29.6%). However, by 2025, reliance on these formats had declined markedly in the primary findings, with Phase IV decreasing to 11.8% and IIT utilization falling to 8.8%.

Instead, the industry appears to show growing confidence in the reliability and regulatory acceptability of DCT approaches by integrating these elements more heavily into earlier-phase and pivotal commercial trials. By 2025, DCT utilization remained robust in Phase II (19.7%) and Phase III (25.2%) trials. This pivot suggests that sponsors increasingly view decentralized methodologies and digital biomarkers as suitable for capturing critical efficacy endpoints in regulatory submissions, particularly when the investment is justified by the high financial stakes and substantial expected net present value (eNPV) returns associated with pivotal trials[3].

Although global analyses based on United States-centric databases, such as clinicaltrials.gov frequently identify rare diseases and central nervous system (CNS) disorders as major drivers of DCT adoption, our primary survey data reveal a distinct trajectory within the Chinese market[4,8]. In China, therapeutic application has consolidated around high-volume, high-need disease areas.

Most notably, oncology adoption remained prominent, increasing from 10.2% in 2023 to 17.0% in 2024 before stabilizing at 12.2% in 2025. This pattern reflects a patient-centric shift aimed at reducing the substantial physical and logistical burdens experienced by patients with cancer, making oncology a strong candidate for hybrid DCT models incorporating DTP drug delivery and remote symptom monitoring[21]. This was followed by cardiovascular and metabolic diseases, which increased from 8.7% in 2023 to 14.4% in 2024 before stabilizing at 10.8% in 2025. The concentration of DCT adoption in cardiovascular and metabolic research underscores the suitability of these therapeutic areas for remote physiological data capture through wearables[2]. CNS disorders maintained the third-highest adoption rate throughout the study period, increasing from 6.6% in 2023 to 10.3% in 2024 before moderating to 7.2% in 2025. Other fields including dermatology (7.8% in 2025) and hematology (5.2% in 2025), also showed steady integration. Collectively, these therapeutic trends suggest that DCT elements are no longer being adopted merely for their novelty; rather, they are being integrated where they offer clear scientific, regulatory, and patient-centered advantages.

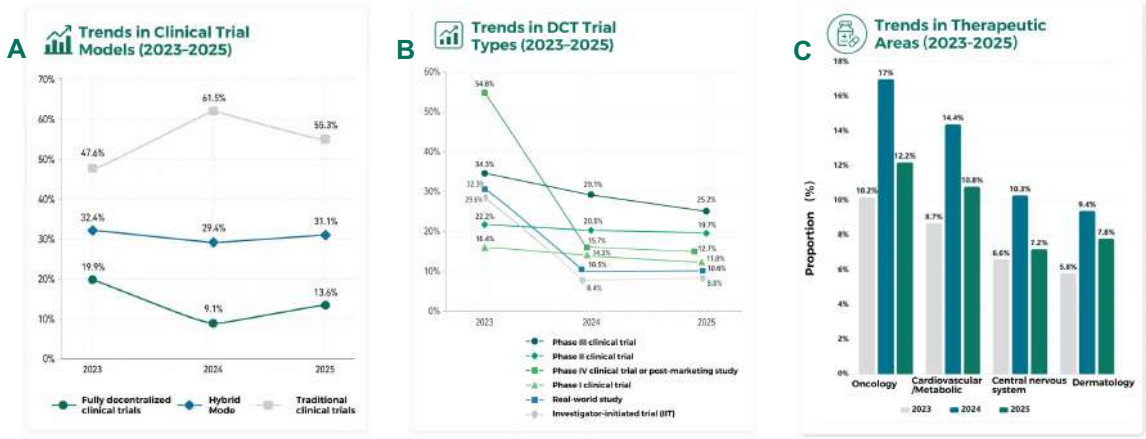

Figure 1. Structural and therapeutic repositioning of DCT. (A) Trial Architecture Dyamics,3-year consecutive dataset demonstrates a post-pandemic market corection. **(B)** Shift in Clinical Phase Application: Between 2023 & 2025, the application of DCT elements shifted dramatically away from exploratory, post-marketing studies. Phase IV,RWS & IITs experienced a steep decline in 2024 that persisted into 2025 and transiioned toward rigorous, early-phase and pivotal commercial trials (PI, PII and III) demonstrated a highly resiient baseline of utlization. **(C)** Top 4 Therapeutic Area Drivers. Unlike Wester registries that heavily index rare diseases, Chinese DCT adoption is predominantly driven by high-burden conditions. Oncology, CV/Metabolic diseases, and CNS disorders consistently lead the market, reflecting a strategic alignment between continuous remote monitoring technologies and the specific clinical needs of these patient populations. (Source: Primary survey data; n = 889(2023), 989(2024), 898(2025)

3. THE INTEGRATION FRICTION

The evolution of DCTs has entered a highly complex phase defined by a central paradox: as industry confidence in the underlying digital technologies grows, the operational friction associated with integrating them at scale has intensified. This marks a transition from isolated technological pilots to systemic integration challenges. Findings from a three-year repeated cross-sectional survey (2023 - 2025) suggest that the current model, in which stakeholders independently manage multiple point-solution vendors, is becoming increasingly unsustainable as trial complexity grows [9].

3.1 The Technology Paradox and Source Data Challenges

Our repeated cross-sectional data indicate a steady maturation of the clinical technology ecosystem in China. Through the three-year study period, stakeholder satisfaction with DHTs increased consistently. In 2023, only 24.9% of respondents reported that existing clinical technology solutions adequately met their needs; this proportion rose to 37.5% in 2024 and stabilized at 38.3% in the primary 2025 findings[15,16]. Over the same period, outright dissatisfaction declined substantially from 19.7% in 2023 to 6.4% in 2024[15,16], before reaching 8.1% in 2025. This shift suggests that foundational tools, such as eConsent, electronic clinical outcome assessment (eCOA), and remote monitoring, are increasingly perceived as reliable and functional components of clinical research infrastructure.

However, this functional improvement has created a technology paradox: although individual digital tools are increasingly capable, their fragmented implementation introduces new layers of operational strain at clinical sites. As sponsors shift from deploying isolated digital tools in observational settings toward integrating interconnected digital ecosystems within pivotal Phase II and Phase III trials, the primary bottleneck is no longer device functionality but workflow coherence. Although the basic technologies are operational viable, stakeholders continue to report substantial friction in human-technology interaction[4]. For example, despite widespread adoption of eCOA platforms and wearable sensors, stakeholders highlight persistent unmet needs related to ensuring “ease of use for all age groups” and establishing a clear “understanding between subjects and clinical staff on data capture” [15,16]. Similarly, although eConsent platforms are technically robust, researchers continue to identify major bottlenecks in optimizing “eConsent management processes” to align seamlessly into site operations[15].

Ultimately, the challenge in this phase of decentralization is no longer the clinical validity of digital tools, but the logistical friction associated with deploying them across trial sites. Rather than streamlining clinical workflows, the rapid proliferation of disparate, poorly integrated digital tools has inadvertently shifted the investigative burden from managing paper records to managing multiple isolated software portals and vendor interfaces, a phenomenon frequently describe by trial personnel as digital overload[22]. This fragmented technological landscape creates substantial organizational strain, directly contributing to role ambiguity and site-level burnout, both of which now threaten the scalability of the decentralized model[4,7].

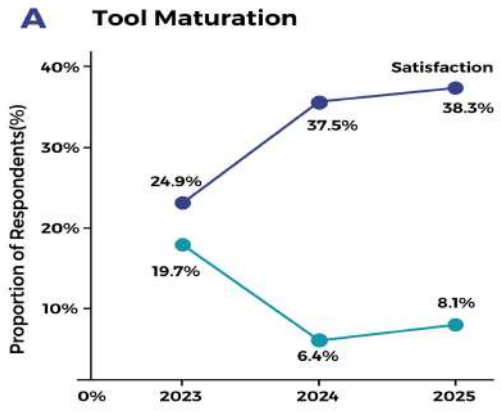

Figure 2. Evolution of clinical technology satisfaction and the fragmentation of decentralized elements (2023-2025). (A) Evolution of industry satisfaction with clinical technology solutions. Over the 3-year study period, the proportion of stakeholders reporting that digital solutions adequately met their operational needs, expanded significantly from 24.9% to 38.3%, while dissatisfaction plummeted from 19.7% to 8.1%. These trajectories suggest that core software functionality and user interface maturity are no longer the primary bottlenecks in digital trial execution. (Source: Primary survey data; n = 889(2023), 989(2024), 898(2025)

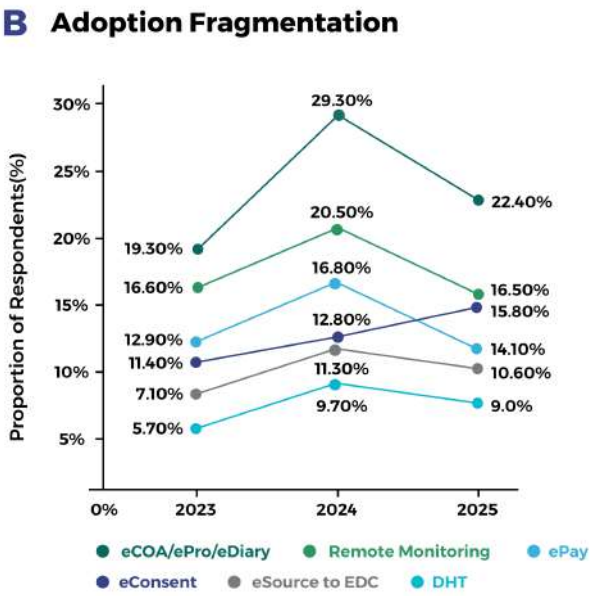

Figure 2. Evolution of clinical technology satisfaction and the fragmentation of decentralized elements (2023-2025). (B) Adoption trajectories of disparate DCT elements. The multi-line plot illustrates the simultaneous, fluctuating deployment of unintegrated tools. While e-Consent demonstrates unique, continuous year-over-year growth (11.4% to 15.8%), the incosistent adoption of eCOA/ePRO/eDiary (which peaked in 2024 at 16.8% before declining to 14.1%), and digital health technologies (DHTs) emphasizes a highly fragmented landscape. This lack of integration precipitates site-level workflow friction, characterizing the "technology paradox" where improved tool quality is offset by implementation complexity. (Source: Primary survey data; n = 889(2023), 989(2024), 898(2025)

3.2 The Human Layer and Role Ambiguity

While technological capabilities have advanced rapidly, the human and organizational infrastructure required to execute DCTs has struggled to keep pace. The integration of DHTs has transformed the clinical trial ecosystem from a relatively linear model into a multi-stakeholder network, placing increasing demands on coordination and oversight. Research teams are now required to manage an interconnected, multi-vendor landscape that includes DTP logistics providers, home-health networks, and specialized software vendors. Although these additions may enhance patient-centricity, they also substantially increase operational friction[9]. This expansion is taking a measurable toll, our primary 2025 findings reveal that 34.6% of stakeholders now view "increased complexity in project implementation and management" as a critical barrier to DCT adoption.

As the stakeholder ecosystem expands, traditional boundaries of responsibility have become increasingly blurred, creating a severe challenge related to role ambiguity. Our repeated cross-sectional survey data highlight a concerning decline in operational clarity. In 2024, 30.6% of industry respondents believed that the responsibilities of different parties in DCT implementation were "clearly defined with formalized allocation"[16]. By 2025, this perception of clarity had declined to 21.4%. As a result, 78.6% of the industry now operates under conditions of ambiguity, with roles described as either only "partially clear" (51.2%) or entirely "unclear/undefined," leading to poor communication without formal system support (27.4%). This ambiguity has important implications for data governance and regulatory compliance. Under emerging guidelines such as the International Council for Harmonisation (ICH) E6 Revision 3 (R3) Good Clinical Practice (GCP) guidelines, investigators retain ultimate responsibility for trial-related activities delegated to external service providers, making clear oversight essential[23]. When accountability is distributed across numerous vendors and platforms, maintaining data integrity becomes increasingly challenging. This concern is reflected in the 59.6% of 2025 stakeholders who reported significant challenges in ensuring that all parties properly record and retain source data.

Rather than alleviating the burden on investigative sites, this poorly integrated multi-vendor environment appears to contribute to increasing site-level burnout. The erosion of role clarity underscores the reality that the industry is attempting to run next-generation clinical trials using legacy operational frameworks. Qualitative analyses of trial personnel further suggest that navigating disparate digital interfaces frequently duplicates work and increases administrative burden[22]. Our empirical findings validate this strain: 60.9% of 2025 survey respondents identified "incomplete DCT-related standard operating procedures (SOPs) at research centers" as a critical barrier to deployment, while nearly half of the industry (49.7%) cited "increased human resource demands," such as learning new technologies and coordinating multiple vendors, as a primary roadblock.

To resolve this human and organizational friction, the industry must shift toward collaborative ecosystem orchestration. This integrated coordination model emphasizes the alignment of diverse stakeholders, harmonization of SOPs, and establishment of clear, end-to-end accountability for data generation and validation across platforms. Moving beyond fragmented management of multiple point-solution vendors, an orchestration approach directly addresses current operational bottlenecks. By standardizing workflows, breaking down cross-functional data silos, and clarifying multi-vendor oversight, these approaches could mitigate integration challenges and enable investigators to refocus their critical human capital on patient care and scientific oversight [4,20].

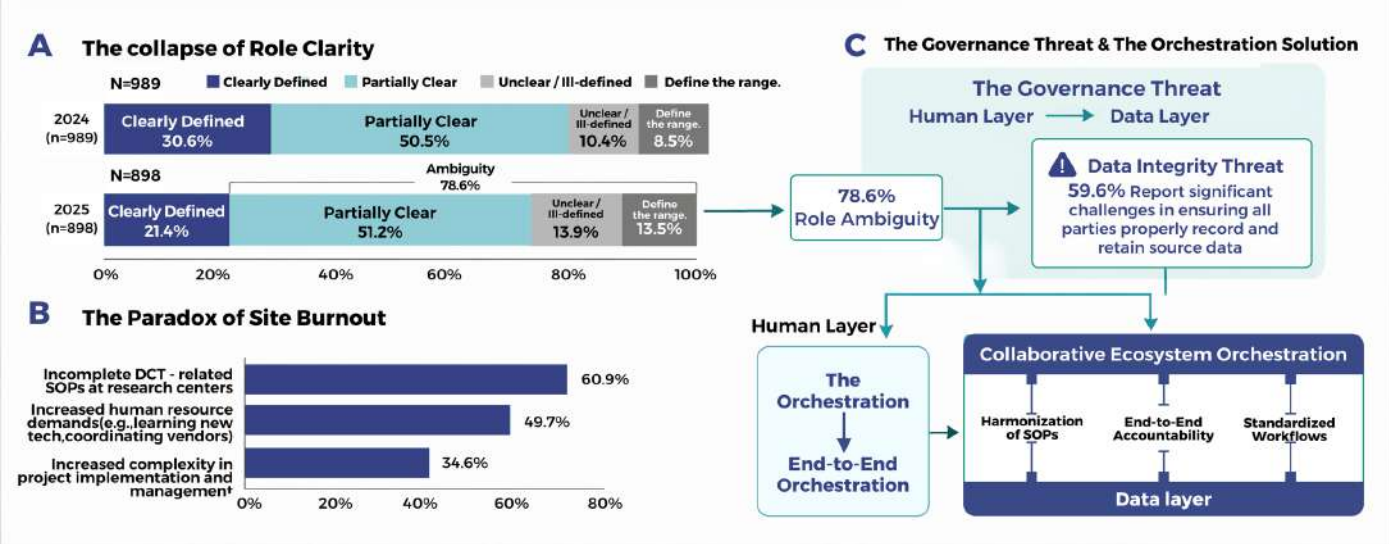

Figure 3. Role ambiguity and operational burden create governance risks, highlighting the need for collaborative ecosystem orchestration. (A) Survey findings demonstrate a marked increase in role ambiguity between 2024 and 2025, suggesting that roles and responsibilities in DCTs are becoming progressively less well defined. **(B)** Major Operational barriers, including incomplete DCT-related standard operating procedures (SOPs), increasing resource demands, and growing implementation complexity, were identified as the primary contributors to site burnout in 2025 **(C)** Based on these findings, a collaborative ecosystem orchestration framework is proposed to mitigate governance risks through strengthened cross-stakeholder coordination, harmonized SOPs, end-to-end accountability, and standardized workflows. (Source: Primary survey data; n = 989(2024), 898(2025).

4. TECHNOLOGY DEEP DIVE

As DCTs transition from exploratory pilots to mainstream methodologies, the technological focus is also shifting. The industry is moving beyond basic digital enablement tools toward advanced, data-generating ecosystems powered by medical-grade DHTs and AI. In the early phase of DCT adoption, sponsors primarily used digital tools to replicate traditional paper-based processes, such as eConsent and eCOA. Today, the frontier has expanded toward “intelligent systems.” Instead of merely digitizing subjective patient inputs, the industry is increasingly leveraging DHTs to capture continuous, objective physiological data while exploring AI enabled approaches to automate complex trial workflows, process large multimodal datasets, and accelerate clinical decision-making [10,11,12,18].

4.1 Adoption of Medical-Grade DHTs

The integration of medical-grade DHTs represents a critical shift from episodic, clinic-based assessments toward continuous, real-world data generation [14,18]. Our primary 2025 findings reveal that nearly half of the respondents (48.1%) now report practical experience deploying medical-grade DHTs to capture protocol-defined digital endpoints. Adoption is highly concentrated in therapeutic areas requiring rigorous and continuous physiological monitoring. Metabolic and endocrine studies lead the market, with 32.0% of stakeholders reporting the use of continuous or portable glucose monitors. Cardiovascular trials represent the second-largest adoption cohort, using portable ambulatory blood pressure monitors (22.5%)

and portable electrocardiogram (ECG) sensors (17.6%) to capture cardiovascular events outside traditional clinical settings. In addition, smart pillboxes were used by 15.8% of the respondents to continuously track medication adherence.

This transition is driven by a strong scientific imperative. When asked about the primary rationale for DHT adoption, 32.5% of stakeholders cited theneed to "enhance data objectivity and continuity", thereby minimizing recall bias associated with traditional patient-reported outcomes[10]. Furthermore, 23.1% reported using these tools to "support novel digital endpoint development," aligning closely with the 18.0% of respondents who introduced DHTs in response to regulatory agencies' explicit encouragement of innovative trial methodologies, including the United States Food and Drug Administration (FDA) guidance on DHTs for remote data acquisition[24].

4.2 Emerging Use Cases of AI in Clinical Trials

As DHTs substantially increase the volume of continuous patient data, AI is rapidly transitioning from a theoretical concept to an operational necessity. Although fully autonomous AI systems remain on the horizon, the industry shows strong and pragmatic demand for AI-driven automation to manage growing data complexity.

Currently, the market demonstrates a stark adoption gap between operational demand and actual deployment. Our primary 2025 findings reveal that widespread AI integration remains nascent, with only 5.8% of the cohort reporting that AI tools are "formally in use" and 17.6% reporting that they are "currently in pilot or exploration stages." However, the industry appears to be on the verge of a major technological shift, as an additional 30.2% of organizations report formal plans to initiate AI integration. This impending wave of adoption is driven by substantial demand for intelligent automation to address the industry's most critical bottlenecks. Specifically, stakeholders identified three urgent operational domains in which AI intervention is required:

- Data management and anomaly detection (62.9%): utilizing machine learning (ML) algorithms to automatically clean data, detect outliers, and flag inconsistencies across diverse sensor inputs. As recent studies demonstrate, automated AI systems can reduce traditional data-cleaning time by up to 80%[5].
- Patient recruitment and cohort screening (62.0%): leveraging natural language processing (NLP) and large language models (LLMs) to mine unstructured electronic health records (EHRs) and match patients to complex eligibility criteria, addressing one of the industry's most persistent sources of delay[1].
- Medical and safety monitoring (57.5%): deploying predictive analytics to continuously monitor patient data streams for early signs of adverse events, clinical deterioration, or digital biomarker anomalies, with prior evidence indicating sensitivity of up to 90% when real-time alert systems are used [5].

When queried about the ideal outcomes of AI integration, qualitative responses from the 2025 cohort converged around three themes: workflow automation, operational efficiency, and precision patient matching. The industry views AI not merely as an analytical tool, but as a proactive trial orchestrator[1]. Reflecting this demand for comprehensive technical support, stakeholders expect intelligent systems to automate complex trial designs (41.2%), streamline document generation (25.5%), and actively mitigate participant dropout risk (48.3%) through intelligent patient engagement and early-warning predictive strategies.

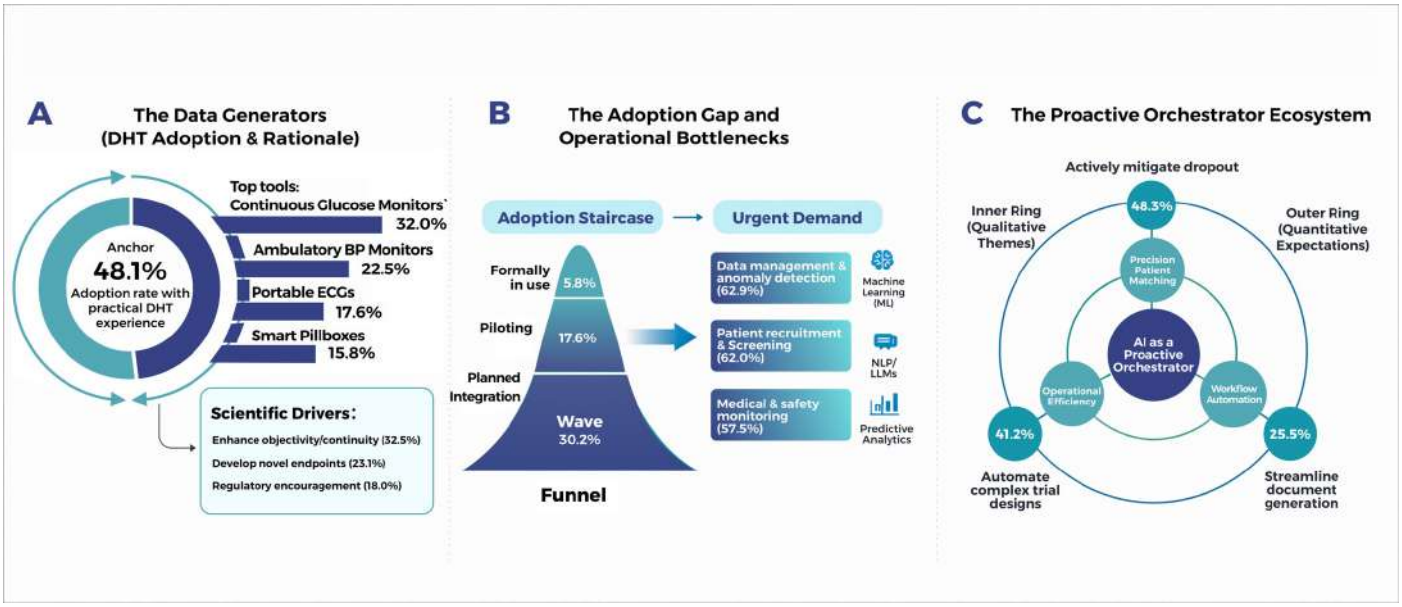

Figure 4. The technological transition toward intelligent, data-driven clinical trial ecosystems. (A) Adoption of Medical-Grade DHTs: Nearly half of the respondents (48.1%) reported current DHT adoption, reflecting the growing generation of continuous, real-world patient data across DCTs, with implementation concentrated in metabolic and cardiovascular monitoring. **(B) The AI Implementation Gap:** Despite the exponential increase in continuous patient data, AI adoption remains limited, with only 5.8% of the respondents reporting routine implementation, nearly half of respondents are actively piloting AI tools or planning AI integration, reflecting strong demand for intelligent automation to address critical operational bottlenecks, particularly in data management, patient recruitment, and safety monitoring. **(C) Conceptual framework of an AI-enable collaborative ecosystem:** As AI evolves from a decision-support tool to a proactive orchestrator, stakeholders anticipate its role in automating workflows, improving operational efficiency, enabling precision patient matching, streamlining document generation, and mitigating participant dropout risk through predictive, end-to-end clinical trial management (Source: Primary survey data; n = 898(2025).

4.3 Barriers to Scaling AI and DHT Integration

Despite this enthusiasm, the industry maintains a realistic timeline for AI maturity. Our primary 2025 findings reveal that early adopters (13.9%) anticipate large-scale, mainstream application of AI in clinical research within 1-2 years, whereas the majority (52.0%) predict a 3-5 years timeline, and 34.0% maintain a highly conservative or uncertain outlook. This realistic, multi-year timeline reflects the fact that the transition from isolated pilot programs to scaled ecosystems is currently facing substantial operational and structural friction, primarily related to data architecture, scientific maturity, and human-resource constraints.

The most prominent technical hurdle is fragmentation of the current clinical data infrastructure. For AI models to function effectively, they require large, continuous datasets; however, 53.0% of the industry identifies a “lack of high-quality, standardized training data” as a primary challenge, which is further compounded by “medical data silos” (46.8%) that prevent seamless data sharing across institutions [12,25,26]. This fragmentation extends deeply into the hardware and source-data levels. Nearly half of respondents (49.2%) report that the complexity of integrating DHTs with existing clinical systems, such as electronic data capture (EDC), is a major bottleneck, a technical integration barrier also highlighted by recent pilot studies of eSource data mapping [27]. This directly mirrors the 46.1% of stakeholders who reported similar difficulties in integrating AI software into legacy systems. Furthermore, defining and managing these novel data streams creates substantial operational strain: 59.6% of stakeholders reported challenges in ensuring that all parties properly record and retain source data, 55.3% found it difficult to clearly define DHT source data and documents before trial initiation, 51.1% reported significant difficulty in ensuring overall data integrity to support regulatory inspections, and 47.7% struggled to maintain data consistency when deploying diverse digital tools simultaneously. Consequently, an overwhelming 73.2% of the industry identified the establishment of “unified data standards and interoperability frameworks” as an essential prerequisite for future scale, a conclusion strongly aligned with the broader scientific consensus that data standardization is critical for regulatory acceptance of digital tools [10].

Beyond data integration, the scientific validation of these technologies has not yet caught up with their computational potential. Currently, 21.6% of stakeholders cite the “lack of verified and reliable algorithms” as a severe barrier to AI deployment. On the hardware side, the immaturity of the digital biomarker landscape is also evident: 45.1% note that currently available digital endpoints are too limited to meet complex scientific objectives, 48.4% point to a lack of standardized validation for these digital tools, and 23.3% report a shortage of suitable medical-grade DHT devices in the domestic market. To address these limitations, 40.6% of the industry emphasizes the need to expand the library of validated digital endpoints and broaden the scientific applicability of these tools. This aligns with global calls for rigorous Verification, Analytical Validation, and Clinical Validation (V3) frameworks to ensure that digital measures are scientifically fit for purpose before deployment [10,28]。

Finally, the scaling of intelligent technologies must account for the limitations of human end-users and organizational resources. Our primary 2025 findings reveal that more than half of the industry (50.3%) identifies “patient usability obstacles,” such as operational difficulties or low adherence among elderly populations, as a major barrier to DHT deployment. This domestic challenge is strongly corroborated by prior research, which notes that cognitive decline, functional impairment, and limited digital literacy among older populations frequently hinder engagement with digital trial tools[29]. In addition, 29.7% of organizations report that their internal clinical teams currently lack the AI-related technical capabilities needed to manage these platforms effectively.

The fragmented vendor ecosystem also imposes substantial financial and logistical burdens on sponsors. Within our cohort, stakeholders reported significant challenges related to insufficient vendor support and delayed response times (33.0%), compounded by prohibitive DHT implementation costs (29.4%) and high AI investment requirements (15.1%). This ground-level financial strain reflects broader global trends. For example, recent evaluations of AI deployment in oncology trials indicate that integrating AI into existing electronic medical record infrastructures can cost up to $500,000 per healthcare system, representing a major barrier to entry[5].

Addressing these operational realities requires a concerted effort to improve the digital literacy of both research centers and patients (47.2%), strengthen vendor ecosystem cooperation and localization support (45.9%), and ultimately reduce the total cost of ownership (TCO) across the ecosystem (48.1%). These domestic priorities align closely with global imperatives to overcome digital health inequities through local capacity-building[4], and to ensure the long-term economic sustainability of healthcare AI infrastructures[25].

While these technical and operational bottlenecks define the day-to-day friction of scaling DCTs, the ultimate ceiling for AI and DHT adoption is shaped by a higher-level force: the evolving regulatory, legal, and compliance landscape.

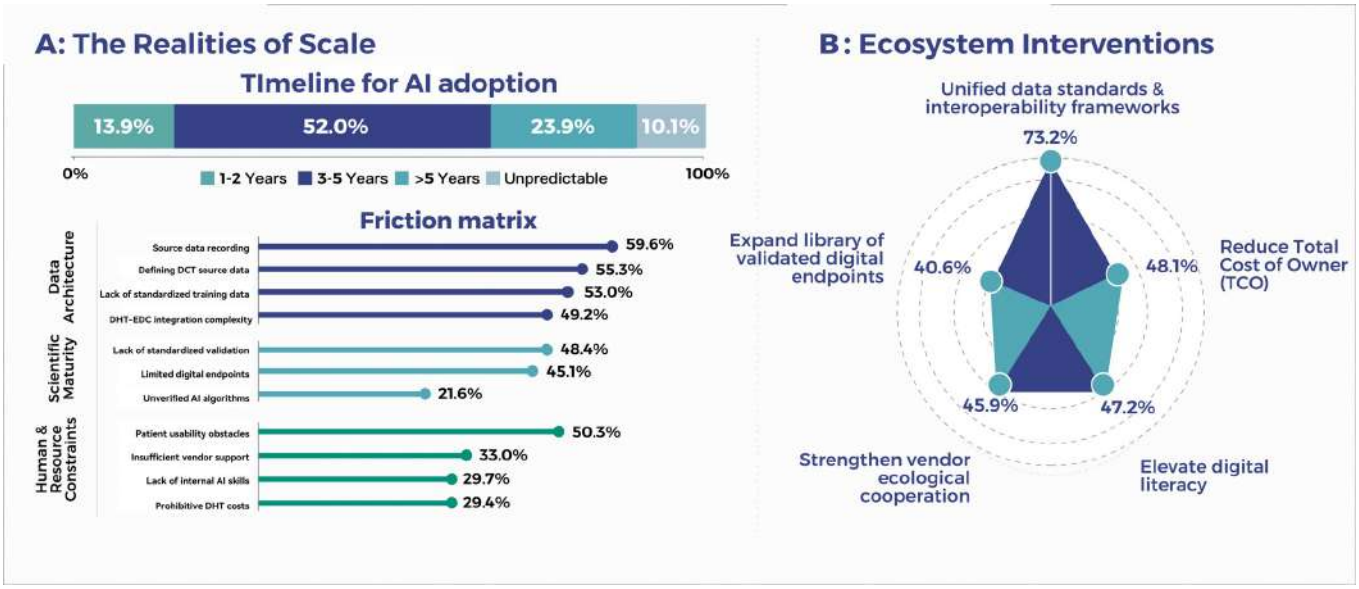

Figure 5. The pragmatic timeline, structural bottlenecks, and interventional priorities for scaling intelligent clinical trial ecosystems. (A)The Timeline and Friction Matrix: Despite high enthusiasm, the industry anticipates a delayed, multi-year horizon for AI and DHT maturity, with 86.1% forecasting mainstream adoption at 3+ years or viewing it as unpredictable. This delay is driven by compounding friction across three operational pillars. The most severe bottlenecks exist within data architecture, specifically the operational strain of ensuring proper source data recording (59.6%) and a lack of standardized training data (53.0%). Scientific maturity is hindered by missing validation frameworks (48.4%), while human and resource constraints, such as patient usability (50.3%) and high vendor costs (29.4%), limit ground-level execution. **(B) Interventional Priorities:** To resolve this structural friction, the industry exhibits overwhelming consensus (73.2%) that unified data standards and interoperability frameworks are the absolute prerequisite for scale, alongside targeted interventions to reduce the total cost of ownership (48.1%), elevate the digital literacy of end-users (47.2%), and expand the library of validated digital endpoints (40.6%). (Source: Primary survey data; n = 898(2025).

5. FROM FRAGMENTATION TO GOVERNANCE

5.1 The Governnace Gap: Fragmentation, Opacity, and Compliance Uncertainty

As decentralized trials scale from localized pilots to multi-regional clinical trials (MRCTs), regulatory compliance has evolved from a background governance issue into a primary operational constraint. This intensifying friction does not reflect a global regulatory rejection of decentralization or AI, but rather the cumulative effects of a highly fragmented and increasingly stringent data governance environment. Sponsors conducting MRCTs must now navigate overlapping, and at times conflicting, privacy regimes, including China's Personal Information Protection Law (PIPL), the European Union's General Data Protection Regulation (GDPR), and the United States Health Insurance Portability and Accountability Act (HIPAA). Comparative regulatory analyses have shown that these unharmonized frameworks can obstruct one another in practice, particularly in relation to remote monitoring, secondary data use, and cross-border data transmission, thereby increasing compliance costs and delaying trial execution[13,30]. Beyond procedural burden, uncertainty also persists regarding whether real-world data (RWD) generated under divergent healthcare systems will be accepted for regulatory or health technology assessment (HTA) decision-making once transferred across sovereign jurisdictions, where regulators continue to prioritize internal validity and local contextual relevance over global data aggregation[31].

Our primary 2025 findings reveal that these structural pressures have translated into a rapid escalation of compliance anxiety at the operational level. Within a single year, the proportion of industry stakeholders identifying "participant privacy and data security" as a key concern when deploying DHTs nearly doubled, rising from 22.2% in 2024 to 42.8% in 2025[16]. Similarly, concern regarding "navigating multi-regional laws and regulatory complexity" increased from 22.9% to 44.3% over the same period[16]. Crucially, these anxieties have begun to materialize as tangible project-level consequences: 20.5% of respondents in the 2025 cohort reported that unresolved compliance issues had already disrupted implementation, forced remedial protocol changes, or

contributed to trial termination, with 6.0% explicitly citing blocked cross-border data transmission as the point of failure. These findings suggest that the feasibility of MRCTs has not been eliminated but has become conditional on substantially higher evidentiary and governance thresholds.

The introduction of AI into DCT ecosystems has further intensified this pressure, not by introducing entirely new regulatory risks, but by amplifying existing governance weaknesses through multiple layers of opacity. Within our primary 2025 dataset, 54.3% of stakeholders identified lack of transparency and explainability as a primary AI-related regulatory concern, while 65.7% expressed concern that AI deployment could increase the risk of data privacy breaches under GDPR and HIPAA aligned regimes. Importantly, these concerns extend beyond technical explainability to encompass epistemic uncertainty and institutional accountability. More than half of respondents (56.8%) reported apprehension regarding model instability across heterogeneous patient populations, and 38.1% specifically raised concerns that algorithmic bias could distort trial outcomes. These concerns align with broader regulatory hesitancy toward AI-mediated clinical decision support, where population-specific performance variability directly challenges scientific validity and ethical legitimacy[13,32].

These forms of opacity culminate in a pronounced liability vacuum, as the involvement of multiple parties, from clinicians to algorithm developers, complicates accountability[33]. In the absence of harmonized global frameworks defining responsibility for AI model validation, deployment oversight, and continuous auditing, our primary findings reveal that 57.9% of stakeholders reported severe anxiety over unclear legal liability should AI-assisted processes contribute to clinical error. This governance gap is reinforced by international regulatory fragmentation, with 37.8% of respondents noting the lack of unified standards among major agencies for AI approval pathways and lifecycle monitoring[32]. Although sponsors and CROs may retain negotiation leverage or architectural discretion, the burden of this ambiguity disproportionately accumulates downstream at the clinical site level. Within our 2025 cohort, 11.8% of respondents reported the absence of clear site-level compliance standards, 12.1% struggled with ambiguous data validation requirements, and 10.0% encountered difficulties auditing or qualifying third-party technology vendors, despite sites having limited authority over upstream system design.

Ultimately, these compounding systemic challenges surrounding cross-border data transfer, unresolved technological bottlenecks, and widespread organizational strain indicate that the current DCT integration model has reached its operational limits. The challenge confronting the industry is no longer whether decentralization and AI are desirable, but under what governance architectures they can be scaled without exacerbating compliance risk, liability ambiguity, and site-level paralysis[20,25]. This tension forms the backdrop against which China's evolving regulatory approach and market dynamics warrant closer examination as a potential alternative pathway for reconciling data sovereignty, AI oversight, and DCT scalability.

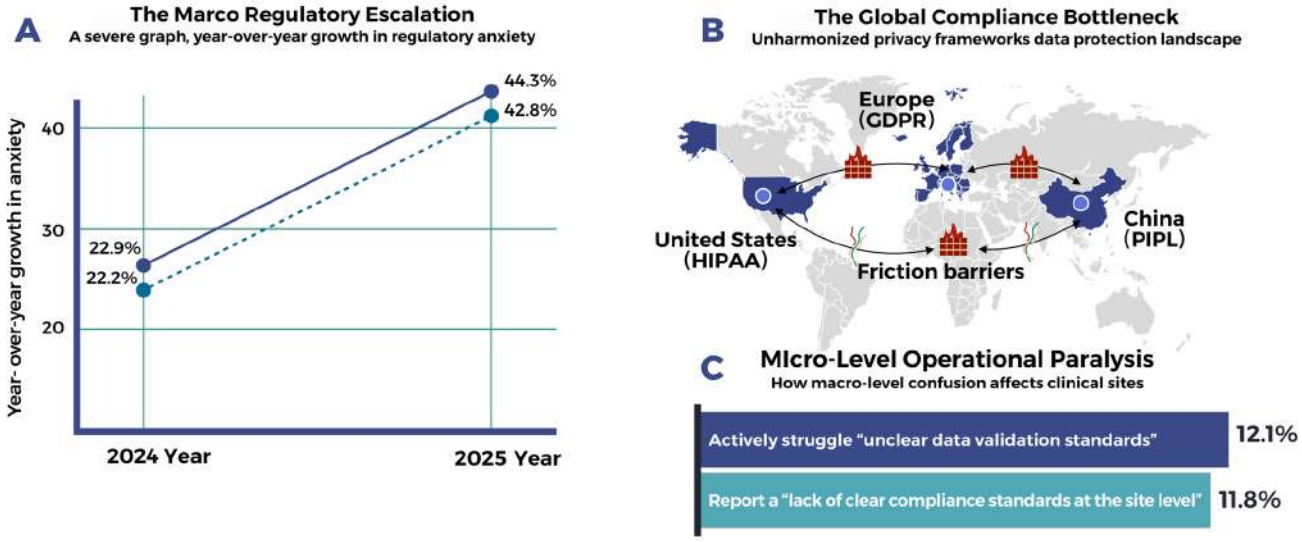

Figure 6: The escalating impact of global regulatory fragmentation on decentralized clinical trial (DCT) execution. (A) Escalation of Regulatory Anxiety: comprehensive 3-years consecutive dataset reveals a severe, near 100% year-over-year increase in compliance friction. Between 2024 and 2025, stakeholder challenges regarding the navigation of multi-regional laws (22.9% to 44.3%) and the protection of participant privacy within digital health technologies (22.2% to 42.8%) surged dramatically. **(B) Cross-Border Data Transfer Bottlenecks**: As trials scale to multi-regional clinical trials (MRCTs), sponsors face immense compliance burdens driven by conflicting international data protection mandates, specifically the unharmonized interplay between Europe's GDPR, the US's HIPAA, and China's PIPL. **(C) Site-Level Operational Paralysis**: This macro-level regulatory ambiguity directly trickles down to clinical research centers, where stakeholders report significant micro-level friction, including unclear data validation standards (12.1%) and a lack of actionable site-level compliance frameworks (11.8%), necessitating an industry pivot toward AI-driven compliance orchestration. (Source: Primary survey data; n = 985(2024), 898(2025).

5.2 China in Transition: Consolidation and Adaptive Capacity

Against the backdrop of escalating global regulatory fragmentation and AI-related governance uncertainty, China represents a distinctive and increasingly influential case in the evolution of DCTs. Unlike jurisdictions characterized by dispersed regulatory authority and incremental guidance, China's DCT trajectory is shaped by a more centralized regulatory architecture, strong policy signaling, and an industry environment accustomed to operating under evolving compliance thresholds[16]. This configuration has not eliminated regulatory anxiety, but it has altered how compliance risk is interpreted, absorbed, and operationalized across the clinical trial ecosystem.

Our primary 2025 findings reveal a pronounced shift in stakeholder expectations toward centralized regulatory governance of AI in clinical research. Rather than relying on sponsor-led or ad hoc risk mitigation, respondents consistently prioritized formal regulatory standards. Specifically, 64.9% identified the development of "technical review guidelines for AI" as the most urgent reform need, followed by 60.7% who called for "formal AI algorithm validation and auditing guidelines." Importantly, governance concerns extend beyond technical oversight: 52.9% of respondents explicitly requested clarification of "legal liability boundaries" for AI-assisted clinical errors, reflecting a perceived accountability gap as intelligent systems become increasingly embedded in trial design, conduct, and monitoring.

These signals align with structural observations from recent analyses of China's regulatory framework for AI-enabled drug development and clinical trials. Existing governance mechanisms remain primarily anchored in data integrity and procedural compliance, with comparatively limited explicit treatment of adaptive algorithm behavior, model drift, or lifecycle management[13]. The survey results therefore reflect practical exposure to unresolved regulatory questions encountered by sponsors, investigators, and technology vendors, rather than speculative concerns.

Against this backdrop, the National Medical Products Administration (NMPA) has demonstrated a distinctly pragmatic regulatory trajectory by consolidating digital data governance as a foundational control layer. Building on the "Technical Guiding Principles for the Implementation of Patient-Centric Clinical Trials", regulatory activity has increasingly centered on the reliability, traceability, and auditability of electronic clinical data[34]. This orientation is further reinforced by the "Guideline on Computerized Systems and Electronic Data in Drug Clinical Trials (Draft for Comments)," which formally adopts the attributable,

legible, contemporaneous, original and accurate (ALCOA++) principles as the benchmark for data reliability across the entire data lifecycle, including audit trails, system validation, contemporaneous documentation, and controlled data modification[35].

From a regulatory logic perspective, this data-first approach represents a cautious and risk-proportionate response to the rapid digitization and decentralization of trial operations. Strengthening electronic data integrity stabilizes the evidentiary foundation upon which regulatory decision-making depends, particularly in multicenter and digitally mediated trial environments. However, as reflected in both the survey findings and emerging academic analyses, robust data governance alone does not fully address the governance challenges introduced by adaptive AI systems, including nondeterministic outputs, population-specific performance variation, and allocation of responsibility across the AI lifecycle[13,33]. China's current posture therefore illustrates substantial adaptive capacity, but also clear boundaries within existing regulatory instruments. This reality has also been acknowledged by the NMPA itself, which recently highlighted the urgent need to transition toward a comprehensive "data-algorithm-ethics" regulatory framework[13].

5.3 The Policy Imperative: Harmonization as Infrastructure

Taken together, the global constraints and China's adaptive but bounded response point to a clear policy implication: incremental, data-centric governance is no longer sufficient to support the next phase of AI-enabled DCTs. Industry stakeholders are not merely seeking better compliance tools; they are increasingly demanding coherent, top-down governance frameworks capable of aligning data integrity, algorithm behavior, and legal accountability across the full clinical trial lifecycle.

Our primary 2025 findings make this demand explicit. Stakeholder priorities center not on further local experimentation, but on system-level clarity, with 68.6% of the industry calling for harmonized data-sharing standards, 60.7% demanding formal AI algorithm validation and auditing guidelines, and 52.9% urgently requesting clarification of legal liability boundaries for AI applications. Importantly, this demand is not jurisdiction-specific; similar pressures are emerging across regulatory systems, even where governance tools are more mature.

International regulatory experience reinforces this conclusion. In the United States, the FDA's Predetermined Change Control Plan (PCCP) framework reflects a shift away from static approval toward lifecycle-based oversight of adaptive AI, enabling predefined post-market model changes within regulator-approved boundaries[36].

In parallel, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) AI Airlock sandbox has demonstrated the value of supervised regulatory experimentation, allowing regulators and sponsors to jointly identify governance gaps related to nondeterministic behavior, explainability trade-offs, synthetic data validation, and post-market monitoring[37]. Importantly, neither approach treats technical explainability as sufficient on its own; instead, both prioritize structured change governance and institutional accountability[32].

For China, these developments illuminate a critical inflection point. Although ALCOA++-based data integrity provides a strong foundation, AI-enabled DCT ecosystems now require governance models that extend beyond data chains to encompass algorithm evolution, continuous validation, and responsibility attribution[13]. The policy mandate emerging from industry signals is therefore not deregulation, but harmonization: a coordinated, top-down approach that integrates data governance, adaptive AI oversight, and ethical accountability into a single, intelligible regulatory logic.

This mandate sets the stage for strategic recommendations. The question is no longer whether regulatory harmonization is desirable, but how it can be operationalized in ways that balance innovation, safety, and scalability across increasingly intelligent and decentralized clinical trial systems.

6. STRATEGIC RECOMMENTDATIONS AND CONCLUSION

The transition from fragmented DCT pilots to scaled, AI-driven intelligent ecosystems requires a fundamental paradigm shift. Based on the compounding friction identified in our repeated cross-sectional survey, scaling DHTs and AI is no longer a purely technological challenge; it is an ecosystem-wide orchestration challenge. To safely unlock the next generation of clinical research, we propose a targeted strategic blueprint for sponsors, technology providers, and policymakers.

6.1 For Sponsors and CROs: Transition to Ecosystem Orchestration

Sponsors and CROs must shift from fragmented, vendor-siloed execution models toward integrated ecosystem management. Our primary 2025 findings reveal that 76.4% of sponsors and 76.2% of CROs are pragmatically implementing DCT elements ahead of complete regulatory clarity[16]. However, this accelerated adoption must be supported by structured, top-down governance.

To address the severe role ambiguity reported by 78.6% of stakeholders, sponsors must modernize site-level operational frameworks and standardize digital-first SOPs. This aligns directly with the modernized data governance expectations outlined in the ICH E6 (R3) GCP guidelines, which emphasize building quality into the scientific and operational design of clinical trials[23]. With 47.2% of the industry calling for interventions to improve digital literacy, sponsors must invest substantially in continuous, high-quality training for investigators. These efforts should extend beyond basic software instruction to focus on managing end-to-end decentralized workflows, thereby reducing site-level burnout.

6.2 For Technology Providers: Prioritize Interoperability and Traceability

Technology providers play a central role in resolving the industry's "technology paradox." The commercial focus must shift from standalone, proprietary innovation toward open interoperability, transparency, and usability.

With 73.2% of stakeholders identifying "unified data standards and interoperability" as the top prerequisite for scale, technology providers must move away from closed-loop ecosystems and toward vendor-agnostic, unified data architectures[20]. Solutions should leverage standardized data formats, such as Health Level Seven (HL7), and robust application programming interfaces (APIs) to ensure seamless integration across sponsor platforms, including EDC and clinical trial management systems (CTMS), as well as hospital-based EHRs[27]. As 55.3% of stakeholders struggle to define source data across platforms, providers should also implement tamper-resistant, automated audit trails. To comply with evolving global expectations and the NMPA Draft Guidelines on Computerized Systems[35], systems must clearly track data provenance from patient-level collection, such as wearable sensors, directly to sponsor databases, while strictly adhering to ALCOA++ principles.

6.3 For Policymakers and Cross-Industry Coalitions: Adaptive Governance

Innovation cannot scale in a liability vacuum. To address severe anxieties surrounding cross-border data sovereignty and the algorithmic "black box," regulators and cross-industry consortia must establish dynamic, adaptive governance frameworks.

We strongly urge regulatory bodies to respond to the industry's call, reflected in our primary 2025 findings, for definitive AI technical review guidelines (64.9%) and clear legal liability boundaries (52.9%). Policymakers should evaluate global adaptive mechanisms, such as the FDA's PCCP framework, which allow ML models to iteratively improve within pre-approved safety parameters without requiring repeated resubmission[36]. Concurrently, establishing national regulatory sandboxes, modeled after the MHRA AI Airlock program, would provide controlled environments for safely testing nondeterministic algorithmic behavior[37]. To address the lack of high-quality training data reported by 53.0% of stakeholders, the industry should invest in privacy-preserving analytical models, such as federated learning, which allows institutions to collaboratively train AI algorithms without transferring sensitive raw patient data across sovereign borders[38].

Furthermore, digital endpoints must be universally validated through rigorous, globally accepted methodologies, such as the Verification, Analytical Validation, and Clinical Validation (V3) framework, which has recently evolved into the V3+ framework to explicitly incorporate human-centered usability testing alongside clinical validation[10, 11, 28].

REFERENCE

1. Badani A, de Moraes FY, Vollmuth P, Chung C, Mansouri A. AI and innovation in clinical trials. npj Digital Medicine. 2025 Nov 18;8(1):683. Available from: https://doi.org/10.1038/s41746-025-02048-5
2. Cho KH, Lee SW. Association between decentralised clinical trial adoption and trial duration: a retrospective cross-sectional study of metabolic disease trials. BMJ Open. 2026 Mar;16(3):e103938. Available from: https://doi.org/10.1136/bmjopen-2025-103938
3. DiMasi JA, Smith Z, Oakley-Girvan I, Mackinnon A, Costello M, Tenaerts P, Getz KA. Assessing the financial value of decentralized clinical trials. Therapeutic Innovation & Regulatory Science. 2023 Mar;57(2):209-19. Available from: https://doi.org/10.1007/s43441-022-00454-5
4. Kijewski S, McBride C, Owens E, Bernheim E, Vayena E. Decentralized clinical trials: A comprehensive analysis of trends, technologies, and global challenges. PLOS Digital Health. 2026 Jan 16;5(1):e0001191. Available from: https://doi.org/10.1371/journal.pdig.0001191
5. Olawade DB, Fidelis SC, Marinze S, Egbon E, Osunmakinde A, Osborne A. Artificial intelligence in clinical trials: A comprehensive review of opportunities, challenges, and future directions. International Journal of Medical Informatics. 2025 Oct 8:106141. Available from: https://doi.org/10.1016/j.ijmedinf.2025.106141
6. Jiang Y, Leng Y, Wu Q, Hou Y, Dong X, Zeng C, Wu D, Fang H, Tang Y, Huang H, Li N. Understanding the gap between expectations and reality in decentralized clinical trials. npj Digital Medicine. 2025 Jul 4;8(1):408. Available from: https://doi.org/10.1038/s41746-025-01811-y
7. Barge R, Floody P. Comparison of participant and site perceptions of decentralized clinical trials in the USA. Mayo Clinic Proceedings: Digital Health. 2025 Jun 1;3(2):100201. Available from: https://doi.org/10.1016/j.mcpdig.2025.100201
8. de Jong AJ, Grupstra RJ, Santa-Ana-Tellez Y, Zuidgeest MG, de Boer A, Gardarsdottir H. Which decentralised trial activities are reported in clinical trial protocols of drug trials initiated in 2019–2020? A cross-sectional study in ClinicalTrials. gov. BMJ open. 2022 Aug 1;12(8):e063236. Available from: https://doi.org/10.1136/bmjopen-2022-063236
9. Betcheva L, Kim JY, Erhun F, Oraiopoulos N, Getz K. Applying systems thinking to inform decentralized clinical trial planning and deployment. Therapeutic Innovation & Regulatory Science. 2023 Sep;57(5):1081-98. Available from: https://doi.org/10.1007/s43441-023-00540-2
10. Izmailova ES, Maguire RP, McCarthy TJ, Müller ML, Murphy P, Stephenson D. Empowering drug development: leveraging insights from imaging technologies to enable the advancement of digital health technologies. Clinical and translational science. 2023 Mar;16(3):383-97. Available from: https://doi.org/10.1111/cts.13461
11. Knapen DG, van Kruchten M, de Groot DJ, Broekman KE, Fehrmann RS. Artificial intelligence for clinical trial design, conduct, and analysis: a narrative review. ESMO Real World Data and Digital Oncology. 2026 Mar 1;11:100682. Available from: https://doi.org/10.1016/j.esmorw.2026.100682
12. Miao M, Ma P. Applications of artificial intelligence in clinical research: a narrative review of recent advances and challenges. Journal of Medical Artificial Intelligence. 2026 Jan 1;9:17. Available from: https://doi.org/10.21037/jmai-2025-114
13. Fan Y, Wu Y, Wang Z. Exploring the ethical issues posed by AI and big data technologies in drug development. Frontiers in Public Health. 2025 Oct 20;13:1585180. Available from: https://doi.org/10.3389/fpubh.2025.1585180
14. Chodankar D, Raval TK, Jeyaraj J. The role of remote data capture, wearables, and digital biomarkers in decentralized clinical trials. Perspectives in Clinical Research. 2024 Jan 1;15(1):38-41. Available from: https://doi.org/10.4103/picr.picr_219_22
15. China Society for Drug Regulation (CSFDR), Hangzhou Tigermed Consulting Co., Ltd. <2023年数字化/去中心化临床试验行业发展现状调研分析报告 《国内外药品研制环节有关管理法规与技术指南体系研究》子课题> [Research report: 2023 decentralized clinical trials: decoding industry dynamics: sub-project on research on domestic and foreign regulations and technical guidelines for drug development] [Internet]. Beijing: China National Medical Products Administration; 2024 [cited 2026 Apr 17]. Available from: https://www.tigermedgrp.com/files/29015f0169ccd7f317c60919317ee923.pdf
16. China Society for Drug Regulation (CSFDR), Hangzhou Tigermed Consulting Co., Ltd, China Medical Advance Committee (CMAC). <2024年数字化/去中心化临床试验行业发展现状调研分析报告> [Research report: 2024 decentralized clinical trials: decoding industry dynamics] [Internet]. Beijing: China National Medical Products Administration (NMPA); 2024 [cited 2026 Apr 17]. Available from: https://www.tigermedgrp.com/files/090c396afd203a83786a198ccfd359f3.pdf

17. Smith ZP, DiMasi JA, Getz KA. New estimates on the cost of a delay day in drug development. Therapeutic Innovation & Regulatory Science. 2024 Sep;58(5):855-62. Available from: https://doi.org/10.1007/s43441-024-00667-w
18. Rimok J, Larkin-Kaiser KA. From lab to life: Wearables, real-world data, and the future of autonomic research. Autonomic Neuroscience. 2025 Dec 26:103377. Available from: https://doi.org/10.1016/j.autneu.2025.103377
19. Fu Z, Liu X, Zhao S, Yuan Y, Jiang M. Reducing clinical trial monitoring resources and costs with remote monitoring: retrospective study comparing on-site versus hybrid monitoring. Journal of Medical Internet Research. 2023 Jun 27;25:e42175. Available from: https://doi.org/10.2196/42175
20. Lemaire W, Nadolny P, Andrus J, Schaffer C, Cameron S. SCDM Executive Committee Perspective: The Future of Clinical Trials with AI and Decentralized, Hybrid and Data-driven approaches. Journal of the Society for Clinical Data Management. 2025 Sep 25;5(3). Available from: https://doi.org/10.47912/jscdm.448
21. Adesoye T., Katz MHG, Offodile AC. Meeting Trial Participants Where They Are: Decentralized Clinical Trials as a Patient-Centered Paradigm for Enhancing Accrual and Diversity in Surgical and Multidisciplinary Trials in Oncology. JCO Oncology Practice. 2023;19(6):317-321. Available from: doi:10.1200/OP.22.00702
22. Coyle J, Rogers A, Copland R, De Paoli G, MacDonald TM, Mackenzie IS, Trials@ Home Consortium. Learning from remote decentralised clinical trial experiences: a qualitative analysis of interviews with trial personnel, patient representatives and other stakeholders. British Journal of Clinical Pharmacology. 2022 Mar;88(3):1031-42. Available from: https://doi.org/10.1111/bcp.15003
23. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Guideline for good clinical practice E6(R3) [Internet]. 2025 [cited 2026 Apr 17]. Available from: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf.
24. Food and Drug Administration (FDA). Digital health technologies for remote data acquisition in clinical investigations: guidance for industry, investigators, and other stakeholders [Internet]. Silver Spring (MD): U.S. Department of Health and Human Services; 2023 [cited 2026 Apr 17]. Available from: https://www.fda.gov/media/155022/download
25. Raghupathi W, Raghupathi V. Big data in healthcare and medicine revisited design and managerial challenges in the age of artificial intelligence. Health Information Science and Systems. 2026 Feb 6;14(1):38. Available from: https://doi.org/10.1007/s13755-026-00433-2
26. Zhang P, Kamel Boulos MN. Privacy-by-design environments for large-scale health research and federated learning from data. International journal of environmental research and public health. 2022 Sep 20;19(19):11876. Available from: https://doi.org/10.3390/ijerph191911876
27. Yuan Y, Mei Y, Zhao S, Dai S, Liu X, Sun X, Fu Z, Zhou L, Ai J, Ma L, Jiang M. Data flow construction and quality evaluation of electronic source data in clinical trials: pilot study based on hospital electronic medical records in China. JMIR Medical Informatics. 2024 Jun 27;12(1):e52934. Available from: https://doi.org/10.2196/52934
28. Goldsack JC, Coravos A, Bakker JP, Bent B, Dowling AV, Fitzer-Attas C, Godfrey A, Godino JG, Gujar N, Izmailova E, Manta C. Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs). npj digital Medicine. 2020 Apr 14;3(1):55. Available from: https://doi.org/10.1038/s41746-020-0260-4
29. Wang Y, Miao M, Wang Q, Yin Y, Zhao H, Zhao S, Yang H, Wang X. Embracing the Digital Revolution: How Artificial Intelligence is Transforming Clinical Trials in Older Participants. Drugs & Aging. 2026 Mar 4:1-2. Available from: https://doi.org/10.1007/s40266-026-01288-8
30. Tatineni N. Regulatory frameworks for decentralized clinical trials: a comparative analysis of FDA and EMA guidelines. World J Pharm Sci Res. 2025;4:758-75. Available from: https://doi.org/10.5281/zenodo.15274465
31. Jaksa A, Arena PJ, Chan KK, Ben-Joseph RH, Jónsson P, Campbell UB. Transferability of real-world data across borders for regulatory and health technology assessment decision-making. Frontiers in Medicine. 2022 Nov 16;9:1073678. Available from: https://doi.org/10.3389/fmed.2022.1073678
32. Lenarczyk G, Minssen T, Price N, Rai A. The future of AI regulation in drug development: a comparative analysis. Journal of Law and the Biosciences. 2025 Jul;12(2):lsaf028. Available from: https://doi.org/10.1093/jlb/lsaf028

33. El-Sayed A, Lovat LB, Ahmad OF. Clinical implementation of artificial intelligence in gastroenterology: current landscape, regulatory challenges, and ethical issues. Gastroenterology. 2025 Mar 22. Available from: https://doi.org/10.1053/j.gastro.2025.01.254
34. National Medical Products Administration, Center for Drug Evaluation. < 以患者为中心的药物临床试验实施技术指导原则(试行)> Guidance on the implementation technology of patient-centric drug clinical trials (trial implementation) [Internet]. Beijing: Center for Drug Evaluation; 2023 Jul 27 [cited 2026 Apr 17]. Available from: https://www.cde.org.cn/zdyz/domesticinfopage?zdyzIdCODE=fa322e171cb0c7d0c47de8e944b7e29b
35. National Medical Products Administration, Center for Drug Evaluation. . <药物临床试验计算机化系统和电子数据指导原则 （征求意见稿） > [Guideline for computerized systems and electronic data in drug clinical trials (draft for comments)] [Internet]. Beijing: Center for Drug Evaluation; 2025 Nov 24 [cited 2026 Apr 17]. Available from: https://www.cde.org.cn/main/news/viewInfoCommon/e77074132fe8e9e32ec8a078b48de6a8
36. Food and Drug Administration (FDA). Marketing submission recommendations for a predetermined change control plan for artificial intelligence-enabled device software functions [Internet]. Silver Spring (MD): U.S. Department of Health and Human Services; 2025 [cited 2026 Apr 17]. Available from: https://www.fda.gov/media/166704/download
37. Medicines and Healthcare products Regulatory Agency (MHRA). AI Airlock Sandbox Pilot Programme Report [Internet]. London: MHRA; 2025 [cited 2026 Apr 17]. Available from: https://assets.publishing.service.gov.uk/media/68ee1fb88427701993d5e02c/AI_Airlock_Sandbox_Programme_Report_Final.pdf
38. Rieke N, Hancox J, Li W, Milletari F, Roth HR, Albarqouni S, Bakas S, Galtier MN, Landman BA, Maier-Hein K, Ourselin S. The future of digital health with federated learning. NPJ digital medicine. 2020 Sep 14;3(1):119.Available from: https://doi.org/10.1038/s41746-020-00323-1

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