Whitepaper

MAXIS
CLINICAL SCIENCES

Evolving Sponsor-CRO Collaborations Through Decentralized and Hybrid Trials

Executive Summary

Decentralized and hybrid clinical trials took shape out of necessity during the COVID-19 pandemic, but they have since become a permanent part of how research is run. Between 2020 and 2022, trials with decentralized elements grew rapidly, with a **50% increase** in 2021 followed by another **28%** in 2022[1]. While growth slowed slightly in 2023, the trend has not reversed. In fact, adoption is projected to rise again by **5.46%** in 2024 [2]. Industry analyses reported that approximately **1,291** decentralized trials were initiated in **2021**[3], increasing to nearly **1,300** in **2022**—a **28%**[4] growth that underscores the continued shift toward long-term investment in decentralized strategies.

This shift is changing more than just trial logistics; it is reshaping the way sponsors and CROs work together. With data coming in from wearables, apps, labs, and remote visits, clinical trials now span multiple systems, touchpoints, and timelines. In this environment, traditional models built for predictable, site-based workflows often struggle to keep pace.

That is leading to a broader rethinking of collaboration. Sponsors are adjusting how they engage CROs, sometimes bringing critical functions in-house, while CROs are investing in tools and platforms built for distributed trials. Still, alignment is not always seamless: recent industry data shows that **60% of research sites** and **43% of sponsors and CROs**[5] cite tech integration and process coordination as ongoing pain points.

This white paper looks at how these trends are driving a new approach to sponsor–CRO partnerships. It explores the limitations of older models, the demands of today's decentralized environments, and the opportunity to build more connected, responsive ways of working—designed for where clinical research is headed next.

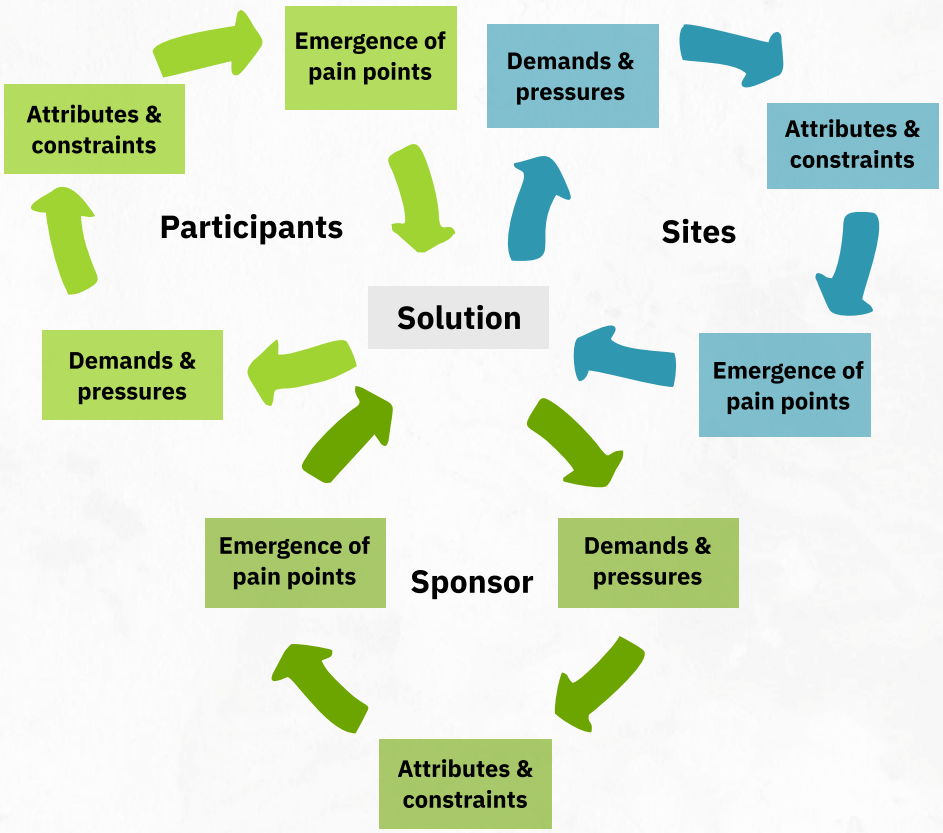
Why Sponsor–CRO Collaboration Must Evolve

For a long time, the sponsor–CRO relationship followed a familiar rhythm. Sponsors laid out the strategy; CROs handled the execution. Roles were clearly defined, responsibilities rarely overlapped, and the model worked, especially when trials ran in a straight line. Patients came through sites, visits were planned months ahead, and data was mostly collected face to face.

But that clarity starts to fade in today's decentralized and hybrid trial landscape.

Now, on-site visits are blended with remote check-ins. Data does not just come from one system, it flows in constantly from wearables, apps, local labs, and providers. Patients might be thousands of miles away, participating from their homes. And keeping them engaged means thinking beyond protocol—to logistics, communication, even digital literacy.

In this setting, the classic "vendor–client" framework starts to strain. CROs need more access to evolving protocol decisions. Sponsors need real-time insight into distributed trial operations. Both sides are being asked to move faster, with fewer handoffs and more shared decisions.



What is needed now is not just a working relationship; it is a partnership. One where both sides actively co-design, adapt together, and share access to tools, platforms, and insights. When that happens, you do not just get more efficient operations, you build the transparency and trust that today's patient-centered trials demand.

Traditional Collaboration Models: Strengths and Limits

Functional Service Provider (FSP) models have long been a cornerstone of clinical trial execution. They offer scalability, access to specialized talent, and the ability to manage global operations with precision and cost efficiency. For many sponsors, especially in trials with well-defined scopes and stable timelines, this model continues to deliver consistent value.

However, the operating environment for clinical trials is shifting rapidly.

Decentralized and hybrid designs have introduced new levels of complexity. Patients now participate remotely. Data flows continuously from wearables, mobile apps, and decentralized sources. Protocols are more adaptive, and execution needs to adjust in real time. In this context, the traditional FSP model designed for predictability can struggle to keep pace.

Several structural limitations begin to emerge:

- Siloed functional teams may lack the contextual awareness to respond dynamically.
- Rigid scopes of work constrain flexibility as study needs evolve.
- Communication cycles are often too slow for a fast-moving operational environment.
- Sponsors are left with limited visibility and delayed decision-making power.

These challenges are not theoretical. Protocol amendments are rising in both frequency and cost, and each adjustment can add months of delay and substantial operational burden. The need for speed, coordination, and real-time oversight has never been greater.

Recognizing this, several CROs are rethinking how functional partnerships should operate in today's environment. As noted by industry leaders, implementing modern technologies without redesigning operational models can backfire especially when sponsors retain rigid oversight structures while expecting real-time flexibility.

At Maxis Clinical Sciences, we have evolved the FSP model to meet the demands of modern trials—particularly those that blend on-site and decentralized elements. Our **tech-enabled FSP** approach retains the proven strengths of functional outsourcing while embedding shared governance structures, integrated data environments, and real-time collaboration tools.

From Functional Outsourcing to Integrated Execution

Traditional FSP Model	Tech-Enabled FSP Model (Maxis Approach)
• Task-based delivery	• Outcome-focused collaboration
• Fixed scopes and rigid oversight	• Adaptive scopes with shared governance
• Periodic updates via static reports	• Real-time dashboards and alerts
• Fragmented systems and communication silos	• Integrated platforms and protocol-aware tools
• CRO executes; sponsor oversees	• Joint execution and co-navigation
• Works best in predictable trial environments	• Built for decentralized and hybrid trial complexity

Maxis Clinical Sciences is evolving the FSP model to meet the demands

Rather than operating in isolation, sponsor and CRO teams work in synchrony—leveraging shared dashboards, co-developed playbooks, and aligned decision-making processes. This model ensures both sides can respond quickly, manage complexity more effectively, and maintain full visibility throughout the trial lifecycle

This is not a departure from traditional models. It is a strategic evolution—one designed to support the agility, transparency, and operational integration that decentralized and hybrid trials demand.

The Rise of Decentralized and Hybrid Trials

Decentralized and hybrid trial designs are not just a trend, they have become mainstream. In early 2024 alone, over **1,170 studies** worldwide featured decentralized elements, marking a **26% increase** compared to the previous year[6].

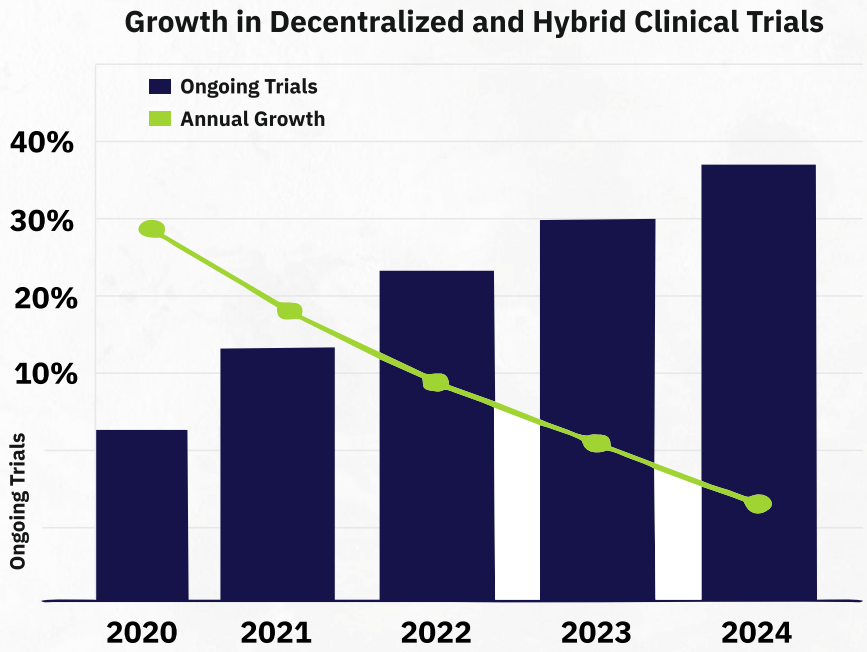


Figure 1: Global growth of decentralized and hybrid clinical trials (2020–2024). While the steep rise seen between 2020–2022 has leveled, adoption continues to grow steadily.

Sponsors and CROs are embracing this shift not as a backup plan, but as a strategic path to enhance recruitment, retention, and real-world representation.

At the core of this transformation is flexibility. Decentralized trials meet people where they are—whether that's telehealth consults, ePROs via mobile apps, or home health services coordinating lab draws and dosing. Hybrid models blend these remote components with in-person site visits, offering greater convenience for participants and clearer visibility for research teams.

The impact is tangible:

- **Dropout rates drop** mobile visits in Phase III trials show roughly **50% lower dropout rates** than traditional trials[7].
- **Faster completion:** those same trials wrapped up **41% quicker**[6].
- **Enhanced diversity:** participation among Hispanic/Latino communities rose to **90%,** and for Native American participants nearly **doubled to 30%[6].**

That said, decentralized trials are not just about adding tools—they bring complexity. Remote lab work, virtual visits, mobile nurses, and wearable data platforms all need tight orchestration. Established playbooks and weekly check-ins are not enough to tie it all together.

As decentralized approaches scale, the lines between sponsor and CRO roles continue to blur. CROs are doing more than delivering services—they are communicating with patients, managing logistics, and troubleshooting tech in the field. The solution demands **shared platforms, real-time dashboards**, and **integrated governance,** not siloed handoffs.

When decentralized and hybrid trials are done well, the rewards are clear: faster timelines, improved data quality, and a smoother participant experience. The catch? It all hinges on a new kind of partnership—one that is agile, tech-enabled, and built on mutual trust. And that transformation is already happening today.

Digital Infrastructure as the New Operational Backbone

Digital infrastructure is no longer a support function, it is the operational backbone of decentralized and hybrid trials. *According to recent industry reports, over two-thirds of sponsors and service providers cite system integration challenges as the top barrier to effective DCT execution*[8].

Traditional systems like EDC and CTMS are no longer sufficient when operating alongside eConsent tools, wearable sensors, telehealth platforms, and logistics partners. Disconnected systems do not just delay reconciliation or increase error risk, they place an added burden on research teams and make trial participation more challenging for patients.

That is why the shift is no longer just toward *more* tools, it's toward **integrated ecosystems**. Emerging platforms are bringing together everything from **unified patient engagement hubs** (e.g., scheduling, eConsent, symptom tracking) to **clinical data lakes** that consolidate inputs from EMRs, sensors, and labs. **Clinical data hubs** now sit at the center of trial operations, enabling clean data flows and holistic visibility. These are not incremental upgrades; they are a new foundation for digital trials.

Sponsors and CROs are increasingly turning to cloud-based platforms that enables real-time dashboards, centralized monitoring, and embedded communication tools. Crucially, these systems are also designed with **privacy and compliance in mind** supporting HIPAA, GDPR, and 21 CFR Part 11 requirements. This builds trust and ensures patient data remains secure while enabling flexibility.

As recent analysis suggests, integrated platforms are no longer a competitive advantage, they are a baseline expectation. Trials that embed interoperable digital infrastructure from the outset are seeing measurable gains: reduced protocol deviations, faster cycle times, and stronger patient retention. For instance, one study found that mobile visits in Phase III trials resulted in nearly **50%** lower dropout rates compared to traditional site-only models, underscoring the role of digital access in improving participant adherence[9].

Regulatory Alignment: Navigating Change with Confidence

One of the most significant questions surrounding decentralized and hybrid trials is: will regulators accept them? Fortunately, the answer is increasingly yes—with the right guardrails.

Over the past three years, regulatory agencies worldwide have taken meaningful steps to support decentralized models. **The FDA's 2023 draft guidance on decentralized clinical trials**[10] formalized many of the flexibilities first introduced during the COVID-19 pandemic. It acknowledged that telemedicine, home health visits, and digital endpoints can be safely and effectively used, provided patient safety and data integrity are preserved. The guidance emphasizes risk-based oversight and encourages early engagement with the agency when novel technologies or delivery models are involved.

Such early engagement is essential because many of these innovations like AI-based patient monitoring, remote sensors, or algorithm-driven decision support present challenges that traditional frameworks are not equipped to fully address. Validating new tools, ensuring data security across decentralized systems, and resolving emerging ethical concerns (e.g., algorithmic bias or consent in virtual settings) all require proactive dialogue to align expectations and reduce regulatory uncertainty.

Similarly, the **European Medicines Agency (EMA)** and the **Heads of Medicines Agencies (HMA)** released a joint recommendation outlining when and how decentralized elements can be used in trials conducted under the EU Clinical Trials Regulation. *Their stance is clear: decentralization is acceptable if it is justified, proportionate to the risk, and appropriately documented.*

But navigating these frameworks still requires care. Sponsors must be prepared to demonstrate that remote elements such as eConsent or direct-to-patient IMP shipment are fit-for-purpose and supported by validated systems. Data privacy and local laws must be respected, especially when studies span multiple regions. For example, an eConsent tool accepted in the U.S. may not meet identity verification standards in certain EU countries. And while telemedicine is broadly supported, physician licensing requirements vary widely across jurisdictions.

CROs play a critical role here. Their operational footprint and regulatory familiarity in different countries can help sponsors proactively address these variations. In fact, joint regulatory planning is becoming a hallmark of modern Sponsor–CRO partnerships. Whether drafting the protocol or preparing for a health authority meeting, teams now collaborate earlier and more often to align on risk mitigation strategies, documentation plans, and data validation approaches.

This shift toward proactive regulatory engagement is also changing how oversight is structured. Rather than relying solely on in-person site visits, regulators are showing growing comfort with remote monitoring provided there's sufficient documentation, audit trails, and centralized data access. Real-time dashboards and electronic source uploads once considered “nice to have,” are fast becoming baseline expectations.

Ultimately, regulatory alignment is not just a compliance issue, it is a driver of trust, quality, and trial continuity. Sponsors and CROs that treat regulators as collaborative partners, not just reviewers, are better positioned to move quickly and confidently in this evolving landscape.

Operational Challenges and Risk Mitigation

Despite their benefits, decentralized and hybrid trials introduce distinct operational complexities that require new management strategies. Based on recent industry analysis, one of the most persistent challenges is the **fragmentation of data streams**. In a traditional site-based model, data is primarily collected through visits and consolidated centrally. In decentralized models, data flows in from multiple channels—remote visits, ePRO tools, wearables, home health visits, local labs, and courier-managed drug delivery. The chart below summarizes some of the most frequently cited operational challenges in decentralized trial execution.

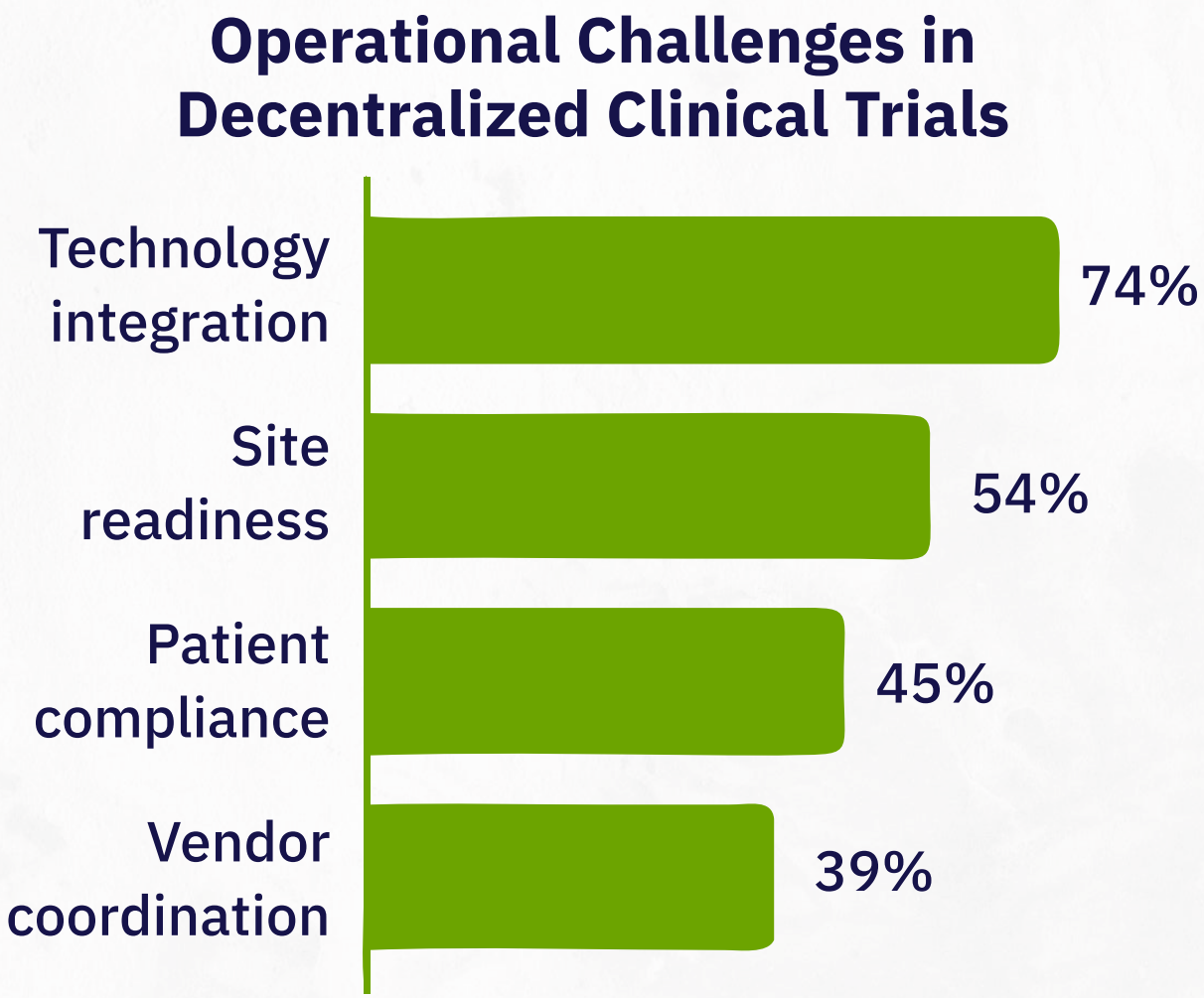


Figure 2: *Top operational challenges in decentralized clinical trials, with technology integration and site readiness leading as key barriers.*

When these elements are not well-integrated, research teams face a cascade of issues: gaps in visibility, misaligned timelines, delayed query resolution, and disjointed safety monitoring. Vendor proliferation further compounds this challenge. One analysis noted there are *'15 different possible vendors for every single activity or step that goes into running a clinical trial,' creating a 'tsunami effect' that complicates interoperability and oversight*[8]. Platform fragmentation has emerged as a commonly reported challenge in decentralized trial adoption. Disconnected systems, such as eConsent tools, wearable platforms, and telehealth solutions often require manual reconciliation, slowing operations and increasing risk.

Site readiness presents another hurdle. A 2022 survey by Medidata and SCRS referenced in a Cambridge University analysis highlighted that sites frequently decline participation in decentralized trials due to ***insufficient budgets for training or integrating modern technologies.*** This includes lack of infrastructure for virtual visits, limited training on eConsent platforms, and confusion around patient-facing technologies[11].

Patient burden is also a key risk area. While decentralization is often pitched as more convenient, poorly designed workflows can have the opposite effect. Clunky apps, inconsistent tech support, and unclear device instructions increase dropout risks. Real-world DCTs have shown that even small missteps like delayed wearable activation or unresponsive helplines can severely affect engagement.

Geographic variation in regulatory acceptance further complicates execution. What is permissible in one jurisdiction (e.g., remote dosing or telehealth consults) may face restrictions in others. Without early planning, these variations can lead to protocol deviations and even compliance violations.

To mitigate these risks, high-performing sponsor–partner teams are adopting proactive measures:

- Integrated operational models that align data flow and vendor coordination from day one.
- Site readiness assessments and just-in-time training programs
- Participant journey mapping to preempt digital pain points.
- Shared dashboards with real-time metrics on adherence, safety, and engagement
- Cross-functional scenario planning that builds flexibility into contingency response.

These strategies shift trial oversight from retrospective to real-time, enabling faster response to issues and reducing risk across the board. With the right planning and infrastructure, decentralized models are not just viable, they are scalable and resilient for the future of clinical research.

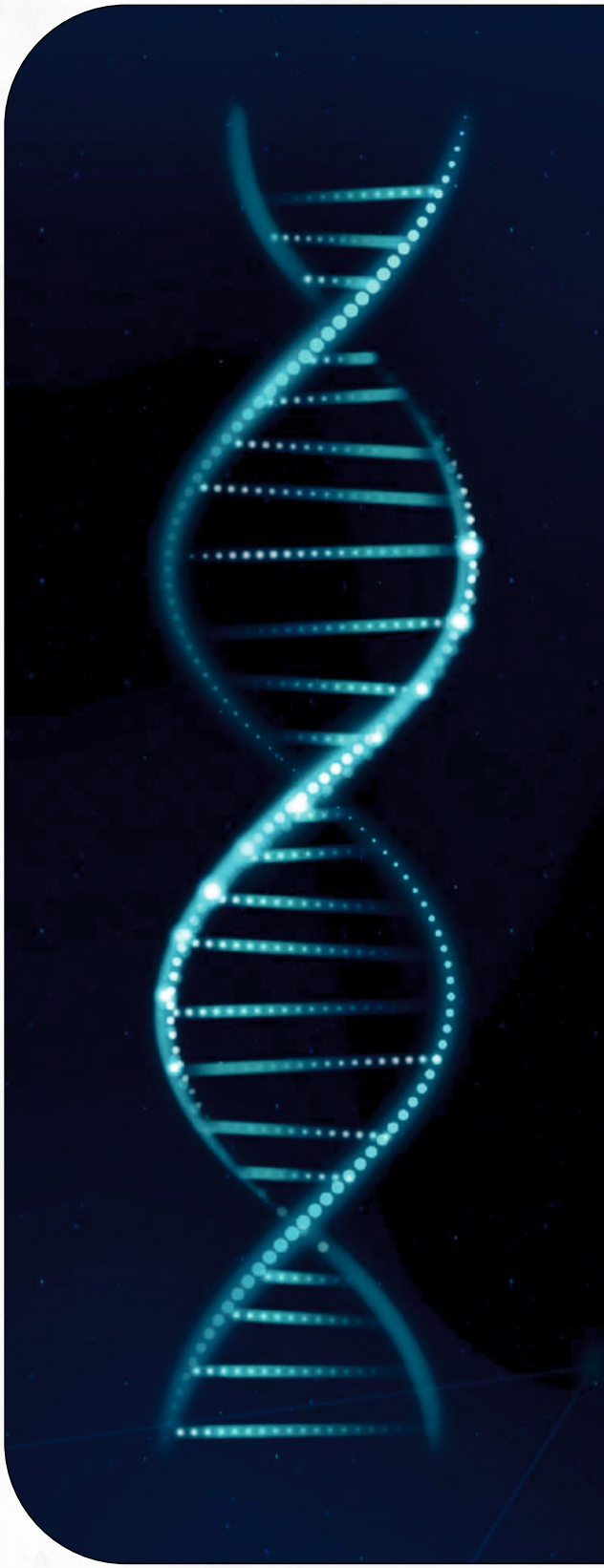
Case-Based Insights

1. **COVID-19 Hybrid Trials: Onboarding in Weeks, Not Months**
   During the COVID-19 pandemic, many sponsors were forced to shift from traditional site-based models to hybrid designs within compressed timelines. These pivots included the rapid deployment of eConsent, remote patient monitoring, and home health services. Industry examples report that such transitions enabled continuity without compromising safety, and in many cases led to stronger patient adherence and faster-than-expected enrollment timelines.

2. **Rare Disease Programs: Reducing Dropout While Expanding Reach**
   Rare disease trials, which often depend on geographically dispersed patients, have increasingly adopted decentralized elements like ePROs, mobile nurse visits, and direct-to-patient lab kits. Sponsors report improved retention due to real-time monitoring and personalized outreach strategies critical in studies where each participant provides highly unique clinical data. These adjustments reflect broader strategies for sustaining engagement in hard-to-reach populations.

3. **Oncology Trials: Widening Access Through Decentralization**
   In oncology trials targeting underserved populations, decentralized tactics such as telehealth screening and direct-to-home IMP shipments have been used to reduce logistical barriers. While specific demographic improvements vary by study, industry analysts suggest that decentralized trials can support broader inclusion by reducing travel demands and enabling more flexible participation.

4. **Platform Trials: Command Centers for Global Oversight**
   Complex platform studies, particularly those spanning multiple countries and vendors, increasingly rely on centralized command centers and real-time digital oversight tools. These integrated environments improve visibility across diverse operational components reducing protocol deviations and enhancing first-patient-in timelines. This reflects a growing industry trend toward shared dashboards and harmonized SOPs for decentralized execution.



Evolving Contracts, Shared Governance, and the Embedded Future

Traditional fixed-scope contracts and milestone-based oversight structures no longer support the fluidity required in decentralized trial operations. According to industry insights many sponsors are now shifting toward modular contracts that allow for flexible resource allocation and trial amendments without the need to re-negotiate large scopes of work.

At Maxis Clinical Sciences, we have seen this shift firsthand. Several of our decentralized trial engagements now operate under modular FSP models—where therapeutic, geographic, or functional elements can be scaled up or down without triggering full contractual revisions. This flexibility has been especially critical in trials involving novel endpoints or adaptive protocols, where responsiveness to mid-study changes is essential for both compliance and continuity.

Instead of relying solely on time-and-effort models, more partnerships are linking compensation to shared outcomes such as improved diversity, accelerated enrollment, and protocol adherence. These outcome-linked agreements reflect the expanding role of service providers in co-designing trial strategies and owning delivery quality.

Governance models are evolving in parallel. Weekly updates are giving way to continuous oversight via shared digital platforms. Virtual steering committees, protocol development workshops, and real-time risk review meetings are increasingly common. These integrated governance structures allow for earlier issue identification and faster decision-making.

Moreover, embedded operating models are gaining traction. In these setups, sponsor and service provider teams work side by side both virtually and in-person on key planning activities like protocol development, feasibility assessments, and country/site selection. This approach encourages a shared sense of ownership and allows for ongoing adjustments based on real-time trial dynamics.

In response, we have evolved our FSP model to align with the embedded approach today's decentralized trials demand. Our tech-enabled model combines functional expertise with integrated oversight, interoperable digital platforms, and shared governance structures. Rather than operating in parallel, sponsor and Maxis teams co-develop strategy, collaborate in real time, and adapt continuously based on operational data and participant insights. This integrated way of working is designed to manage complexity, enhance transparency, and improve trial resilience across decentralized and hybrid environments.

Ultimately, these shifts are more than operational tweaks, they represent a strategic redefinition of partnership. In decentralized and hybrid trials, where agility, patient experience, and regulatory responsiveness are key, embedded collaboration has become not only valuable but essential.

These emerging models pave the way for continuous learning, adaptive operations, and trial continuity, hallmarks of high-performing clinical development organizations in a decentralized world.

Value and ROI for Sponsors and CROs

Quantifying the return on investment (ROI) in decentralized and hybrid trials requires a shift in perspective. Traditional metrics like cost-per-patient or number of sites activated no longer capture the broader value these models create. ROI today is increasingly defined by operational resilience, trial continuity, participant experience, and regulatory readiness.

Key value drivers include:

- **Faster Enrollment and Expanded Reach:** Decentralized and hybrid designs reduce geographic barriers and bring trials closer to patients. This enables faster enrollment in diverse populations and accelerates time to first-patient-in particularly valuable in therapeutic areas with urgent timelines.
- **Greater Retention and Data Completeness:** Trials that offer home visits, ePROs, and mobile engagement tools reduce participant burden. According to recent survey findings, studies using decentralized components report higher participant retention and better adherence.
- **Enhanced Operational Continuity:** These models offer built-in resilience during disruptions whether from pandemics, supply chain issues, or local site inaccessibility. Digital workflows and remote monitoring help maintain trial momentum.
- **Increased Diversity and Representativeness:** Decentralized approaches allow sponsors to reach underrepresented populations by reducing the need for travel and offering localized services. This supports regulatory and payer priorities for generalizability of results.
- **Strategic Relationship Value:** Organizations that prioritize digital maturity and flexible partnership models report stronger long-term collaboration. Embedded service models enable faster decision-making, shared accountability, and trial-wide visibility.

As organizations increasingly evaluate clinical trial performance across metrics like speed, adherence, data quality, and participant diversity, the ROI of decentralized and hybrid models becomes clear not only in financial terms but in accelerated development timelines, broader access, and more resilient operations.

Future Outlook and Strategic Recommendations

The decentralized and hybrid trial model is no longer experimental, it is becoming the default approach across many therapeutic areas. As of 2023, most sponsors report using at least one decentralized element in their trials, and a majority indicate plans to expand investment in decentralized and hybrid approaches over the next few.

The digital infrastructure underpinning these models is expanding rapidly. According to 2023 industry analysis, decentralized trials featuring digital data capture methods (e.g., ePROs, wearables) increased from fewer than 20 annually in the early 2010s to over 310 initiated in 2023 alone[12]. Moreover, a survey found that 95% of trial sponsors and CROs are actively working to establish unified digital foundations to improve site support and data collaboration, yet only 56% believe these models have significantly improved patient experience[13]. The projected adoption curve reflects growing confidence in decentralized methods across sponsor portfolios, as illustrated below.

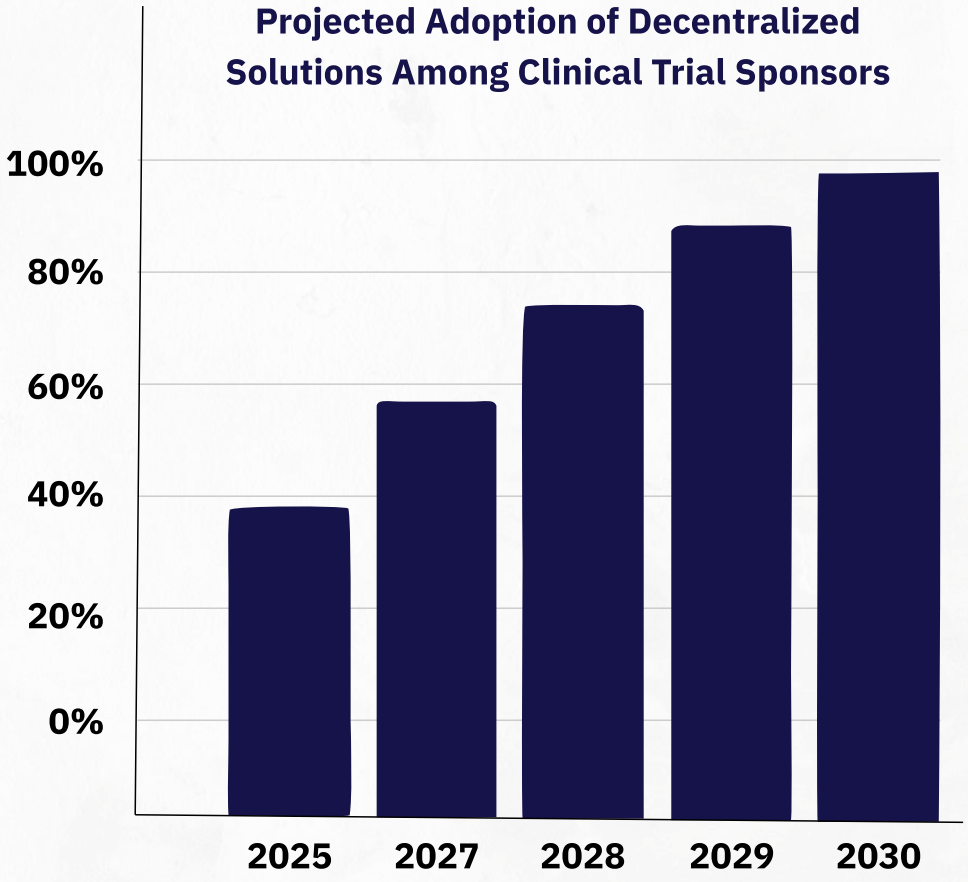


Figure 3: *Projected adoption of decentralized solutions among clinical trial sponsors (2025–2030), showing steady year-over-year growth toward near-universal adoption by 2030.*

Key imperatives include:

1. **Design with Flexibility from the Outset**
   Trial designs should incorporate decentralized elements during protocol development rather than as retrofits. This includes virtual feasibility assessments, remote monitoring readiness, and proactive site engagement planning.

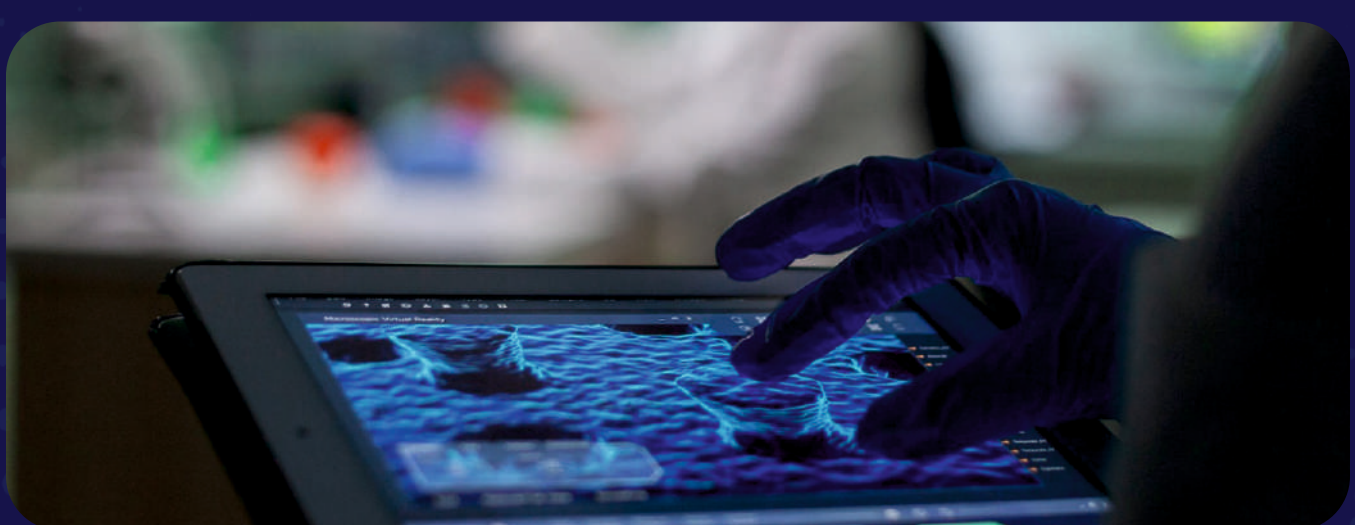
2. **Build Around Interoperable Technology**
   Fragmented digital ecosystems are a leading barrier to decentralized trial performance. According to a survey, more than two-thirds of respondents cited platform integration as one of the most persistent operational pain points. Sponsors and partners must invest in cloud-based, interoperable platforms that integrate data flows across ePRO, eConsent, wearables, and remote visits. This creates real-time visibility and reduces site and patient burden.

3. **Align Governance on Shared Objectives**
   Governance frameworks should include shared dashboards, co-developed SOPs, and regular joint decision-making sessions. These structures help manage trial complexity, reduce delays, and foster accountability.

4. **Elevate the Participant Experience**
   Participant journey mapping should be a standard practice in decentralized trials. From intuitive interfaces to real-time patient support, the experience must be personalized, accessible, and continuously refined based on feedback. For example, intuitive interfaces might include mobile apps with simplified navigation, visual dose reminders, or gamified elements that encourage adherence and engagement. Real-time support can take the form of AI-powered chatbots for common queries, dedicated remote tech support lines, or live nurse chat features to guide participants through procedures or troubleshoot devices.

5. **Strengthen Embedded Partnerships**
   Service partners should be involved early co-authoring protocols, contributing to risk mitigation strategies, and participating in regulatory planning. Embedded collaboration models improve agility and enhance the strategic value of partnerships.

By embracing these strategic shifts, sponsors and their partners will not just adapt to decentralized trials, they will shape what comes next in global clinical development.



Conclusion

Decentralized and hybrid trials are not a temporary trend, they are part of a structural evolution in clinical development. As these models become more widely adopted, they are reshaping how trials are designed, executed, and overseen.

To succeed in this environment, sponsors and their operational partners need to break out of legacy roles and embrace new ways of working, ones grounded in transparency, responsiveness, and shared accountability. The future of clinical research depends on collaboration models that are not only technically capable but operationally aligned and centered around the needs of participants.

This shift is not just about embracing new tools or digitizing old workflows. It is about cultivating partnerships that are built to handle complexity, adapt to change, and deliver better results, not just for the organizations involved, but for the patients who depend on these trials.

Organizations that proactively embrace this transformation will not only adapt but lead. In a landscape defined by agility, inclusion, and innovation, those who invest early in integrated, participant-centered models will set the pace for the future of clinical trials.

The imperative is clear: embed flexibility into contracts, align oversight models with real-time digital operations, and prioritize patient experience at every step. Regulatory shifts are accelerating. Participant expectations are evolving. Technologies are advancing faster than traditional models can accommodate. Success in this environment will depend on an organization's ability to anticipate change, not just respond to it.

Those who recognize that decentralized trials are not a disruption but an opportunity to build something better will be the ones who thrive in the next generation of clinical research.

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