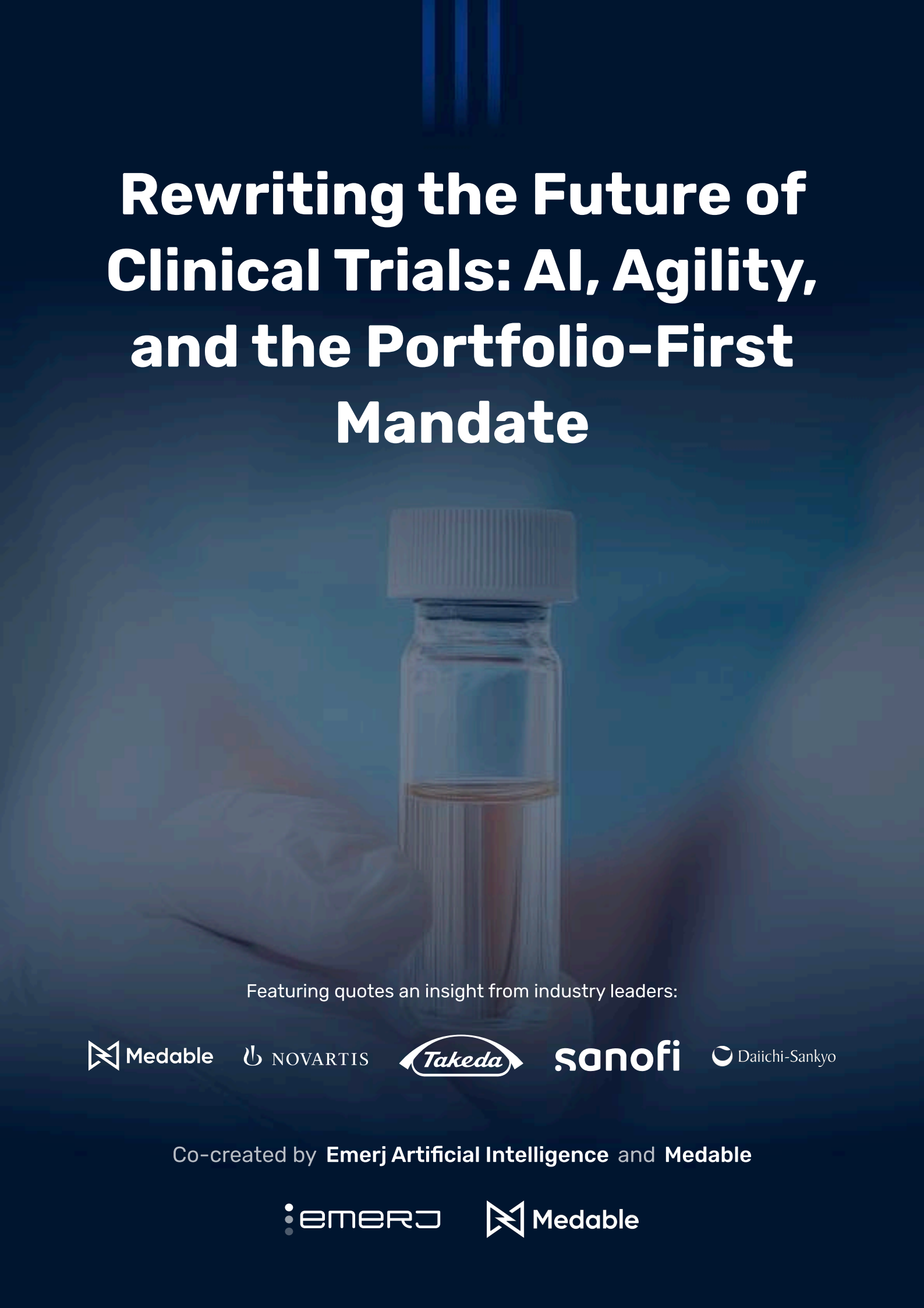
Rewriting the Future of Clinical Trials: AI, Agility, and the Portfolio-First Mandate



Featuring quotes an insight from industry leaders:

Medable NOVARTIS Takeda sanofi Daiichi-Sankyo

Co-created by **Emerj Artificial Intelligence** and **Medable**

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INTRODUCTION

The life sciences sector faces increasing pressure to deliver clinical trials that are faster, more efficient, and more patient-centered. Yet persistent challenges slow innovation. Clinical trial costs continue to rise, timelines remain unpredictable, and critical data is often siloed across departments and partners. These are not abstract problems — they directly hinder pipeline velocity and affect patient outcomes.

$500K

A 2024 peer-reviewed study by the Tufts Center for the Study of Drug Development estimated that delays in drug development result in approximately **$500,000** in lost sales per day for each new medicine launch. The same study found that the mean direct cost to conduct a clinical trial is about $40,000 per day for Phase II and as much as $55,716 for Phase III trials.

$800K

A follow-up Tufts analysis published later that year raised the average lost revenue per delay day to approximately **$800,000**, highlighting how shifts toward smaller patient populations and specialized therapies affect launch economics).

$4.5b

A 2021 systematic review published in PharmacoEconomics reinforces this picture, estimating that the total average capitalized pre-launch R&D costs vary widely — from $161 million to **$4.54 billion** (2019 USD) — with clinical trial phases, particularly Phase III, contributing the greatest share due to high complexity and failure rates.

The rise of decentralized trials, real-world evidence integration, and personalized therapies has increased data complexity in clinical development. Many sponsors still struggle to generate real-time insights from fragmented systems, making it difficult to adapt protocols or optimize site performance.

Without structural and technological transformation, pharmaceutical firms risk locking their innovation inside workflows that no longer reflect how modern trials are conducted or how patients engage. The next wave of industry leadership will depend on confronting these challenges head-on.

The pharmaceutical industry faces a crossroads and leaders across the field agree: incremental improvements are no longer enough.

The promise of AI in clinical trials has moved beyond theory. A growing cohort of technology leaders is reshaping how trials are designed, executed, and optimized. This white paper draws on insights from five of those leaders.

Together, their insights reveal a shared vision for clinical development—one rooted in cross-functional intelligence, responsible AI, and scalable digital systems. The sections that follow explore key takeaways from their work:

OPERATIONALIZING PORTFOLIO-WIDE INTELLIGENCE IS KEY TO TRIAL AGILITY

Clinical development has historically evolved in silos — each function, therapeutic area, or trial team pursuing outcomes on its own terms. According to Michelle Longmire, this model is no longer viable.

During her podcast appearance, she explains how clinical teams are often operating up to 10 trials in parallel. With real-time data becoming more accessible, she emphasizes that the opportunity to apply insights across studies has never been greater. The shift in capabilities enables teams to design agentic platforms and digital strategies that support the drug's full lifecycle, not just individual protocols:

> *"Instead of waiting years for actionable feedback, sponsors can now evaluate trial performance by site, apply learnings immediately, and accelerate subsequent launches. That's where real leverage comes from—thinking programmatically, not episodically."*

Michelle Longmire
Co-founder and CEO at Medable, Inc.

Medable

Leaders are now pushing toward systems that provide visibility across programs, enabling teams to understand which designs are working, which sites are most efficient, and how patient cohorts can be better identified across studies. These changes mean clinical trial teams will need to adjust from a "study-by-study" mindset to one focused on portfolio intelligence.

Michelle describes this shift as a reorientation of organizational focus, one that empowers data science and clinical operations teams to engage in more proactive, cross-functional trial planning. The ability to evaluate timelines, resource loads, and risk factors in parallel allows for faster decision-making at the executive level.

Longmire also notes that AI has made this model viable where it once wasn't:

> *"Two years ago, this wasn't a problem worth solving—data took too long to materialize. But today, sponsors are running multiple trials in parallel and accessing insights in real time. That makes it possible to apply learnings across studies, optimize site selection, and refine strategy between trial launches. Programmatic thinking is no longer aspirational—it's a critical source of competitive leverage."*
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> **Michelle Longmire**
> Co-founder and CEO at Medable, Inc.
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> Medable

At Novartis, Xiong Liu reinforces this idea of evolving beyond point solutions:

> *"Traditionally, machine learning models required centralized patient data, raising significant privacy concerns. Today, with federated learning, hospitals can keep patient data local while still training shared AI models. This privacy-preserving approach allows institutions to collaborate without compromising sensitive information—enabling more accurate, scalable AI systems for decentralized clinical trials."*
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> **Xiong Liu**
> Director of Data Science and AI at Novartis
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> NOVARTIS

For example, instead of creating individual machine learning pipelines for every trial's recruitment workflow, Novartis now prioritizes reusable components and modular architecture. This allows them to capture learnings across trials and use that data to improve both future study designs and mid-trial interventions.

The portfolio-first mindset isn't just a technological requirement — it's a leadership imperative. Teams need executive buy-in to align across programs, and they need the right KPIs to measure success beyond any single protocol.

LINKING DATA ACROSS SYSTEMS ENABLES REAL-TIME STRATEGY

The most successful AI deployments don't operate in isolation. They connect clinical data across fragmented ecosystems — between CROs, EDC systems, regulatory databases, and real-world evidence sources — to unlock insights that inform and accelerate strategy.

Damion Nero explains this challenge from Takeda's perspective:

> *"One of the biggest challenges we face is integrating post-market surveillance with early-stage R&D. When insights from patient outcomes and pharmacovigilance aren't connected back to design and feasibility workflows, we miss critical opportunities to reduce delays and improve evidence quality. The barrier isn't just technical—it's organizational. We're focused on building the connective tissue across medical affairs, clinical operations, and R&D to ensure insights flow seamlessly and support smarter, faster decisions."*
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> **Damion Nero**
> Head of Data for U.S. Medical at Takeda Pharmaceuticals

If insights from patient outcomes and pharmacovigilance aren't fed back into design and feasibility workflows, organizations are missing opportunities to prevent delay and enhance evidence quality.

> *"The hesitation stems from a lack of internal trust in AI-generated outputs and limited visibility into how external partners are developing these tools. When AI is delivered as a black box, without explainability or transparency, it's difficult to build confidence across the organization. If we want to scale AI responsibly and with impact, we need to invest in in-house capabilities that foster trust and ensure shared understanding across functions."*
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> **Damion Nero**
> Head of Data for U.S. Medical at Takeda Pharmaceuticals

Recent findings support Nero's emphasis on integration. A 2020 report by the National Academies of Sciences, Engineering, and Medicine underscores the role of digital health technologies in enhancing post-market surveillance and feeding insights back into early-stage development.

Michelle Longmire echoes this need for integrated intelligence, especially in decentralized trial models. Medable's platform leverages AI to continuously monitor patient and site performance, feeding that data back into trial ops to support adaptive strategies.

This allows trial sponsors to adjust eligibility, outreach, or site support mid-trial based on what the data is telling them. Such interventions have been shown to improve enrollment timelines, reduce drop-out rates, and increase diversity in trial populations.

Longmire adds:

> *"AI gives us a much clearer view of what's working and what's not—while it's happening. That real-time visibility allows us to optimize the clinical trial process as it unfolds, not just track results after the fact."*
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> **Michelle Longmire**
> Co-founder and CEO at Medable, Inc.
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> Medable

Ultimately, real-time strategy requires not only interoperable systems but new roles and team structures that can act on insights as they arise. Several guests emphasized the growing importance of cross-functional data stewards who can act as interpreters between AI systems and clinical business units.

INTEGRATING STRUCTURED AND UNSTRUCTURED DATA ENABLES SMARTER DECISIONS

At Sanofi, Mathew Paruthickal is leading a shift away from narrow AI applications toward connected intelligence that links structured trial data with unstructured documents. Rather than chasing use cases in isolation, his team is building an ecosystem that allows cross-functional teams to extract insights, automate content creation, and improve compliance.

> *"We're using structured data tools and document intelligence in tandem. That allows us to extract context, summarize findings, and even generate regulatory documents across languages and formats."*

Mathew Paruthickal
Global Head of Data Architecture, Utilization, and AI Engineering at Sanofi

sanofi

87%
ACCURACY

Research presented on arXiv introduced a pipeline leveraging large language models (LLMs) to match patients to clinical trials by analyzing both structured and unstructured electronic health record (EHR) data. This approach achieved an 87% accuracy rate in real-world settings and reduced the average patient eligibility review time by 80%, from traditional manual chart reviews to under 9 minutes per patient.

Paruthickal's team is developing live AI agents to summarize safety events, draft protocols, and connect insights across pharmacovigilance, clinical operations, and regulatory affairs. Their approach emphasizes interoperability and compliance from day one—treating trust and traceability as equal priorities alongside speed.

By merging structured and unstructured sources into a unified system, Sanofi is reducing redundant work, surfacing proactive signals, and accelerating the generation of audit-ready content. This ecosystem approach reflects a broader evolution in life sciences: from reactive data processes to intelligent systems that anticipate what comes next.

DIGITAL OUTCOME MEASURES REQUIRE CAREFUL DESIGN AND GOVERNANCE

Dr. Xiong Liu of Novartis highlights the growing importance of electronic Clinical Outcome Assessment (eCOA) platforms in making clinical trials more flexible, inclusive, and patient-centric. As trials evolve beyond traditional site models, eCOA tools offer a direct channel for collecting rich, real-time feedback from patients—whether at home or in hybrid settings.

eCOA platforms represent a critical step forward in modernizing trials. They allow sponsors to capture data from wearable sensors, mobile apps, and patient-reported outcomes in a more dynamic and continuous way. However, scaling these systems requires thoughtful design to ensure the data remains standardized, privacy is protected, and patient trust is preserved.

Research from organizations like the Clinical Trials Transformation Initiative (CTTI) and the National Library of Medicine have emphasized the importance of common data standards—such as those developed by CDISC—to support interoperability and regulatory submission readiness. These efforts help sponsors unify eCOA data across vendors and formats, enabling easier aggregation, monitoring, and insight generation.

To address data sensitivity, Novartis has invested in **federated learning**, a privacy-preserving approach that allows models to learn across institutions without moving raw data. This innovation supports:

- **Real-time safety monitoring across trial locations**
- **Seamless integration of eCOA with EHR and sensor data**
- **Compliance with privacy regulations like HIPAA and GDPR**
- **Greater transparency in how AI interacts with sensitive patient inputs**

“Technologies bring a lot of innovation and challenges at the same time,” Liu explains. “We have to think systematically. AI is not a one-size-fits-all solution.”

For Novartis and other leaders, the future of clinical development depends on harmonizing these systems. When deployed with care and strategy, eCOA tools don’t just support compliance—they accelerate feedback loops, boost patient engagement, and unlock new opportunities for AI to improve both trial operations and outcomes.

AGENTIC AI DEMANDS TRANSPARENCY AND STRATEGIC ONBOARDING

Michael Zaiac, Head of Medical Oncology Europe and Canada at Daiichi Sankyo, underscores:

> *"While agentic AI — AI systems capable of semi-autonomous decision-making—holds great promise, it comes with substantial barriers. Pharma is not necessarily the place where you see the most innovative AI technology. What you see is AI technology being perfected to the degree of high levels of accuracy."*

Michael Zaiac
Head of Medical Oncology for Europe and Canada at Daiichi Sankyo

Daiichi-Sankyo

He emphasizes that success requires balancing efficiency gains with stakeholder trust and regulatory precision. In his view, advanced analytics — deterministic tools to improve enrollment and accelerate study timelines — currently deliver the clearest ROI. These tools help sponsors reduce time to file, extend market exclusivity, and ensure a higher quality dataset. For generative and agentic AI, however, the picture is more complex.

Several academic studies illustrate why:

Workflow Misalignment and Clinician Burden

Research from *PLOS Digital Health* shows that poorly integrated agentic systems can increase workload and confusion among clinicians, complicating trial operations and slowing adoption.

Data Interoperability Gaps

As noted by *Nature Digital Medicine*, AI deployment in trials often runs up against fragmented EHR and eCOA systems, making it difficult for autonomous agents to standardize and reconcile patient records.

Transparency and Explainability Deficits

Studies have shown that when agentic systems make opaque recommendations, clinical teams struggle to validate outputs, eroding confidence and slowing time to value. Zaiac's experience reinforces this: "We spend a lot of time making the black box of AI transparent to diverse stakeholders…so the outcomes are truly accepted rather than criticized as machine-generated."

Ethical and Regulatory Constraints

Emerging frameworks like the EU AI Act create further requirements for explainability and risk management, meaning AI deployments often must operate at the highest risk level—imposing longer timelines to reach consensus and approval.

Dr. Zaiac emphasizes that agentic AI must be deployed with precision and stakeholder alignment. In the highly regulated clinical trial environment, Zaiac sees agentic tools as promising, but inherently collaborative technologies. "Start with your stakeholders," he advises. "If you don't, they will block you—for good reason."

Unlike deterministic tools that deliver clear ROI through faster recruitment and trial execution, agentic systems require deeper scrutiny. Zaiac draws a clear line between using generative or agentic tools for internal support tasks—like summarizing protocols—and deploying them for externally validated outputs. "We are not yet in a position of enough internal trust to use AI-generated results in patient reporting," he explains. This trust gap is amplified by third-party development, where models often function as black boxes, leaving clinical teams unable to explain or audit results.

To mitigate risk and maintain credibility:

- Daiichi Sankyo uses agentic AI primarily for behind-the-scenes efficiencies
- All use cases are vetted with legal, regulatory, and compliance teams upfront
- Internal ROI is measured in terms of hours saved, not just outcomes delivered
- Internal stakeholders must be engaged early and continuously

Zaiac also notes that progress requires humility and discipline. Within a conservative, risk-aware sector like pharma, agentic AI must be constrained and comprehensible to earn broad adoption.

> *"We make [the AI] less, rather than more—but we make it less with intent."*

Michael Zaiac
Head of Medical Oncology for Europe and Canada at Daiichi Sankyo

Daiichi-Sankyo

CRITICAL TAKEAWAYS: TURNING AI AMBITION INTO CLINICAL TRIAL ADVANTAGE

AI is reshaping the clinical trial landscape — but only for firms prepared to align data strategy with operational execution. Leaders featured in this paper emphasize that transformation is not about deploying more tools; it's about rethinking workflows, architecture, and stakeholder engagement to unlock lasting value. The following takeaways offer a blueprint for executive teams driving innovation:

- **Think in programs, not protocols:**
  Sponsors must move beyond trial-by-trial execution toward portfolio-wide intelligence. Shared infrastructure, agentic platforms, and real-time insight loops empower teams to learn across studies and drive faster, more adaptive launches.
- **Integration is the lever for speed and evidence quality:**
  Connecting siloed datasets across the trial continuum — from feasibility to post-market surveillance — enables faster decision-making and stronger strategic alignment. Firms that establish real-time feedback loops between medical, R&D, and clinical ops will lead in pipeline velocity.
- **Connected data beats isolated models:**
  Structured data and document intelligence must work together. Teams at Sanofi and Novartis are showing that linking unstructured records with structured workflows enhances automation, improves regulatory compliance, and accelerates content generation.
- **The best eCOA systems balance innovation with trust:**
  As decentralized models expand, digital outcome assessments introduce real benefits. Sponsors must prioritize standardization, privacy-preserving AI, and transparent governance to maintain patient trust and ensure data reliability at scale.
- **Agentic AI thrives where strong leadership meets innovation:**
  Advanced systems that act semi-autonomously require rigorous oversight, clear communication, and stakeholder buy-in. Early wins come from applying these tools behind the scenes — not in high-stakes outputs — with explainability and compliance as core design principles.

The executives featured here are not chasing AI hype. They are deploying measured, scalable strategies that align with evolving trial complexity and regulatory realities. The lesson is clear: success in the next era of life sciences will favor organizations that build for agility, plan for governance, and lead with transparency.

ABOUT MEDABLE

Medable's next-generation AI-powered eCOA platform is built for speed, control, and global scale, with unmatched experiences for study teams, sites, and patients. We modernize research, replacing outdated processes with an intelligent, unified ecosystem of clinical trial technologies. Awarded Best Digital Health Solution by the Galien Foundation, our offerings accelerate study timelines with significant efficiencies, improve patient adherence, and enhance data quality across various therapeutic areas, including oncology, vaccines, rare diseases, and more.

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