

LEADING THE AI REVOLUTION:

ORCHESTRATING CLINICAL TRIALS WITH AI AGENTS

Strategic insights for life science leaders transforming clinical trial operations



Table of Contents

1. The Persistent Complexity Of Clinical Trials
2. The AI Paradox In Clinical Research
3. What's Needed? Integrated Workflows & Orchestration
4. Rewiring Clinical Trials For Orchestration
5. The Impact When Orchestration Works Well
6. Starting On The Journey To Orchestration
7. The Road Ahead
8. Veridix: Orchestrating Next-Generation Clinical Trials



The Persistent Complexity of Clinical Trials

Clinical trials shouldn't be this hard. And yet, they are.

Despite decades of investment, trials remain slow, fragmented, and inefficient. Protocols take months to draft and are revised again and again. Startup relies on disconnected systems and manual trackers. Sites are overloaded, and patients often drop out.

Trials still follow linear processes, handoffs, and CRO models built on billable hours. What should be adaptive remains reactive and manual — resulting in rework, delays, and frustration.

These challenges persist because clinical trial operations are fundamentally disconnected. Each function relies on its own systems, workflows, and tools — making it difficult to coordinate, adapt, or scale effectively. From protocol design to data management to final submission, every transition introduces risk and slows progress.

The result is an execution model that is out of step with the growing complexity and pace of clinical research. And unless we address this underlying fragmentation, meaningful improvement will remain out of reach.

The longer we wait to confront this issue, the more costly and unsustainable it becomes.

The Cost of Disconnected Trials

3.5 Average number of amendments per Ph III trial

260 Days to implement protocol amendments

\$535k Cost to address each Ph III amendment

80% Trials delayed or closed due to poor recruitment

30% Cost growth of Ph III trials due to more complexity

283% Increase in data points captured in past 10 years

These stats reveal a deeper truth: clinical trials aren't just complex — they're disconnected.

The AI Paradox In Clinical Research

In recent years, AI has been positioned as a solution to the inefficiencies of clinical trials. Tools now exist to help write protocol language, flag anomalies in EDC, summarize safety narratives, and support a range of isolated tasks.

And while these innovations offer value, clinical trials haven't become significantly easier to run. That's because most AI today is applied at the task level — automating pieces of the process in isolation. These point solutions can improve speed or reduce effort in specific areas, but they don't address the underlying issue: the disconnected nature of how trials are designed and executed.

1) Limited Scope: Each AI tool operates in a narrow lane. It lacks awareness of upstream decisions or downstream consequences.

2) Fragmented Adoption: Teams experiment independently, leading to redundant tools, inconsistent results, and limited synergy.

3) No Cumulative Value: Even if individual tools deliver 10-15% efficiency gains, they rarely connect in ways that compound benefits across the study.

4) Change Fatigue: Teams are asked to adopt new tools with different interfaces and workflows, creating resistance and confusion.



AI that works in isolation — no matter how impressive — can't fix a system that's fragmented by design. Instead of reducing complexity, these tools often add to it: more vendors, more interfaces, more handoffs.

To truly improve trial execution, we need a solution that goes beyond automating individual tasks. We need a new model that addresses the root of the problem.

What's Needed? Integrated Workflows & Orchestration

Despite widespread investment in AI, most organizations are still grappling with a fundamental problem: **lack of coordination**. Even with AI tools in place, documents, data, and processes remain disconnected. Teams work in silos, systems don't talk to each other, and critical updates get lost in handoffs. Why? Because they operate in isolation.

The real opportunity – and the real power of AI – comes not from isolated tools, but from **orchestrating how documents, data, and processes work together across the full lifecycle of a trial**. That requires a shift in mindset, architecture, and execution: from fragmented task automation to integrated, AI-powered workflows that are intelligently connected and continuously aligned.



Integration: Connecting the Core Elements

Clinical trials are driven by 3 core elements:

- **Documents:** Protocols, investigator brochures, statistical analysis plans, clinical study reports, submission packages, and more
- **Data:** Captured across EDC, CTMS, labs, imaging, and various external systems
- **Processes:** Including study startup, site mgmt, monitoring, and regulatory submissions

In most organizations, these components exist in silos. Protocol changes may not update eligibility logic in the EDC. CSR authors might manually rewrite content that already exists in the protocol. Site performance data may sit idle while enrollment slows.

AI embedded in integrated workflows solves this by connecting those elements:

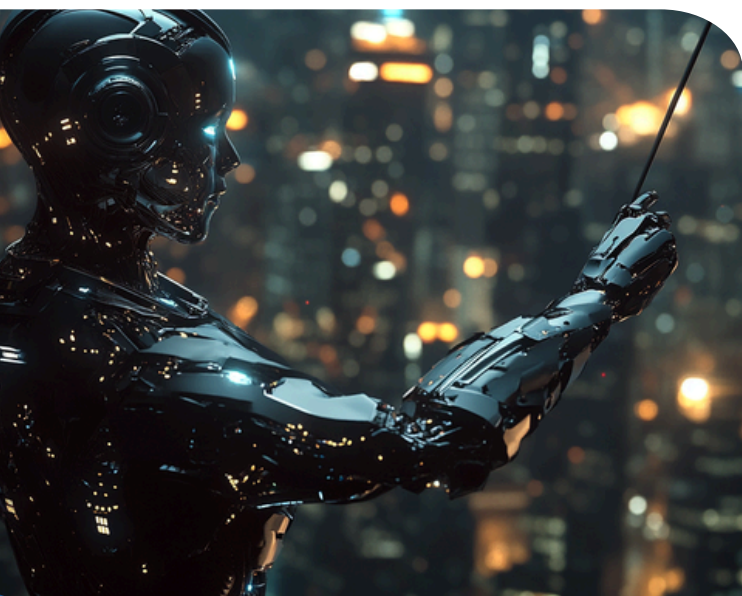
- Understanding the relationship between protocol endpoints and eCRF design
- Reusing structured content from the protocol in downstream documents
- Flagging inconsistencies between datasets and written conclusions
- Driving dynamic, cross-functional actions when conditions change

But integration alone isn't enough. To realize real value, these connections must be coordinated – they must move together. That's where orchestration comes in.

What Happens Without Orchestration?

- Trial documents fall out of sync, introducing inconsistencies and risks during regulatory review.
- Critical updates are missed or delayed across systems, requiring rework or corrections downstream.
- Operational friction grows – more emails, more reconciliation, more risk.

In short: fragmented execution kills efficiency – and AI deployed without orchestration only amplifies the noise.



Orchestration: AI as the Conductor of the Clinical Trial

If integration ensures the instruments are tuned and connected, orchestration ensures they play in harmony.

Orchestration is the real-time coordination of tasks, decisions, and data across people and systems to keep trials moving intelligently and consistently.

With orchestration, AI doesn't just assist individual contributors – it enables the entire organization to work as a synchronized whole.

For example:

- A protocol amendment automatically updates downstream documents, EDC forms, and triggers new training for sites.
- Slower-than-expected enrollment activates AI-based site re-ranking, triggers outreach, and adjusts timelines in the CTMS.
- As safety signals are detected, draft narratives are generated, formatted, and queued for medical review – all without waiting for a manual handoff.

This is where AI transcends being a tool and becomes a workflow layer – a digital conductor that keeps every part of the trial moving on time.



Rewiring Clinical Trials For Orchestration

Clinical trial execution has evolved from paper-based processes to digital tools like EDC, then toward more connected intelligence platforms with greater visibility and insights. Now, the industry is entering a new phase: AI-enabled operations, where workflows adapt in real time and decisions are guided by intelligent systems.

But most current platforms still manage tasks in isolation. Orchestration requires something more — systems that are designed to work together, respond dynamically, and keep trials moving in sync. That shift demands a new kind of eClinical architecture: one that connects data, documents, and decisions by design — and supports continuous coordination, not just control.



The power of orchestration lies in:



Contextual Awareness

AI understands the relationship between data, documents, and operational steps.



Dynamic Response

AI can react to real-world events in real time — adjusting workflows, content, and decisions automatically.



Cross-functional Visibility

AI provides a unified view across functions, reducing silos and improving alignment.

Orchestration isn't about replacing people — it's about empowering them with systems that stay in sync and adapt intelligently.

What It Takes To Build Integrated Workflows

Orchestration doesn't happen by accident. It's not something that emerges from a tool or a platform alone. True AI-powered orchestration requires purposeful design and committed investment across multiple layers of capability — not just to connect systems, but to enable them to think and act together. It depends on 6 foundational elements:

Unified Data Architecture

Clean, structured, and connected data across systems is essential. AI can't orchestrate what it can't see.



Shared Semantic Models

Aligned terminology and structure across systems and documents to "speak the same language".

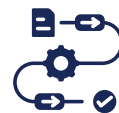
Workflow Integration

Linking previously siloed functions to enable seamless transitions and automated handoffs.



Workflow Engines

Tracking and monitoring trial state and triggering coordinated actions in real time



Reusable AI Agents

Agents operating across functions – for example, a language model that helps with protocol writing, CSR drafting, and regulatory responses.

Human-In-The-Loop Feedback

AI learns and improves when people remain engaged. Feedback loops ensure reliability, trust, and continuous refinement.



This is a redesign of how work happens, not just a technology play. It's guided by AI but grounded in human expertise and oversight. With orchestration in place, trials become faster, more adaptive, and more aligned — with less waste, less rework, and fewer surprises.

Key Takeaway

The future of AI in clinical trials is all about smarter orchestration.

When documents, data, and processes are connected and AI can coordinate how they move together, you unlock real speed, quality, and efficiency – full lifecycle acceleration.

The Impact When Orchestration Works Well

When AI orchestration is fully realized, the benefits are transformative – not incremental. Instead of isolated time savings, organizations see material improvements in how trials are planned, conducted, and submitted:



Faster trial startup through streamlined protocol design, site activation, and document readiness



Fewer protocol amendments due to AI-driven scenario modeling and better initial feasibility assessments



Earlier database lock by reducing query backlogs and coordinating cross-functional data review



Improved cross functional alignment leading to faster decisions and fewer miscommunications



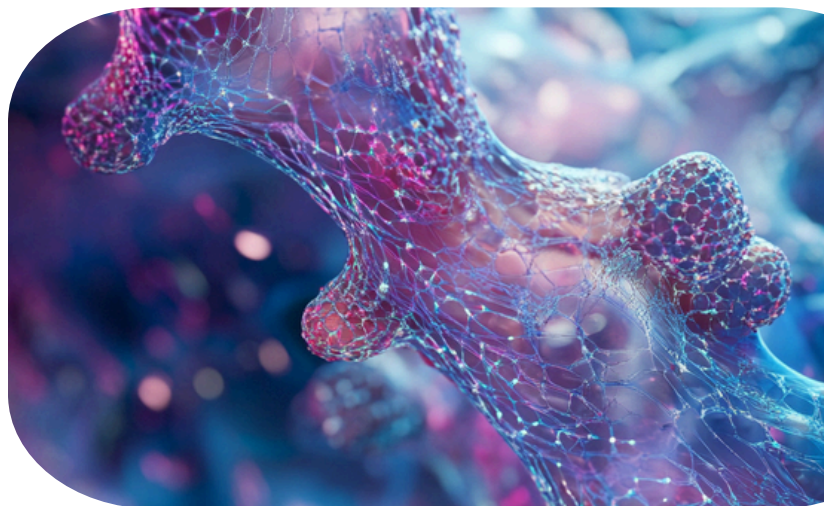
Submission readiness with AI-generated drafts of key sections and real-time document reconciliation



More predictable timelines improving stakeholder confidence and planning accuracy

AI becomes the connective tissue that transforms a clinical trial from a series of handoffs into a continuously adapting system. The result is not just speed – it's quality, efficiency, and confidence in execution.

The organizations that embrace orchestration will not only see better outcomes — they'll redefine what's possible in clinical research.



Starting On The Journey To Orchestration

Seeing the promise of AI-powered orchestration is just the start. The real challenge — and opportunity — is turning that vision into action through a phased, coordinated approach across people, process, and technology.



Step 1 - Define The Value

Identify workflows where orchestration would have the greatest impact. Look for:

- High-friction, manual processes with lots of handoffs
- Frequent inconsistencies between documents, data, and systems
- Functions where delays ripple downstream (e.g., protocol amendments, site activation, CSR authoring)

Anchor your AI strategy not around capabilities, but around value. What matters is not what the AI can do – but what it can improve.



Step 2 - Build Cross Functional Alignment

AI orchestration touches many functions: clinical operations, data management, biostatistics, medical writing, regulatory affairs, IT. Without cross-functional buy-in, orchestration efforts stall. Engage stakeholders early to:

- Map existing workflows
- Identify inefficiencies and disconnects
- Establish shared success metrics

AI cannot succeed in isolation – it must be a team sport



Step 3 - Start Small, Prove Value

Don't try to orchestrate everything at once. Instead, pilot a narrowly scoped, high-impact workflow:

- Protocol-to-EDC alignment
- Query management and SDV/SDR optimization
- CSR drafting using structured content from upstream documents

Use these early wins to build confidence and refine your AI deployment model.



Step 4 - Invest in Scalable Infrastructure

To scale AI orchestration, you'll need:

- Access to clean, structured data across systems
- Interoperability between your CTMS, EDC, eTMF, and authoring platforms
- AI agents that can be reused across multiple workflows
- Governance frameworks to ensure responsible, transparent use

This isn't a one-time integration. It's an ongoing capability.



Step 5 - Empower and Upskill Your Teams

Orchestration isn't about replacing people – it's about amplifying their effectiveness. Equip teams to:

- Interpret and refine AI recommendations
- Train models using their domain expertise
- Design new workflows with orchestration in mind

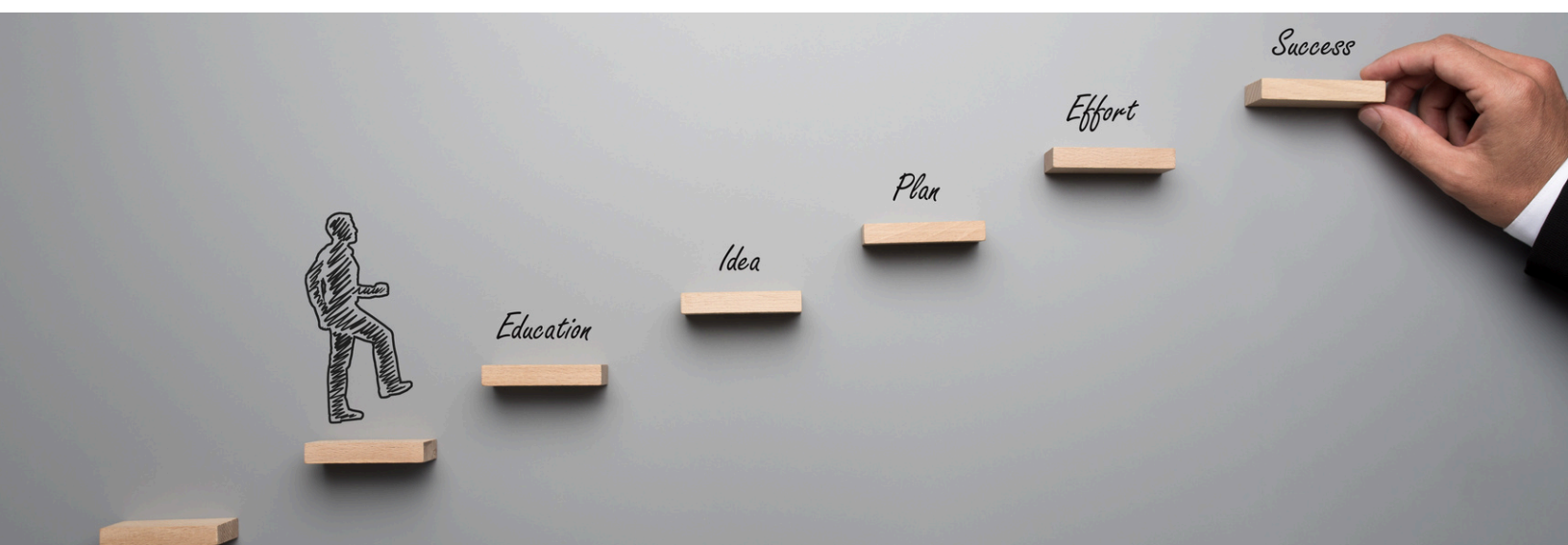
Provide training, change management, and clear communication to drive adoption.



Step 6 - Orchestration is a Journey

The organizations that succeed with AI won't be the ones who implement the most tools, but the ones who rethink how they work – who embrace integration, empower collaboration, and use AI not just to automate, but to orchestrate.

Start where the friction is greatest. Build where the value is clear. And orchestrate toward a smarter, faster, more connected clinical trial future.



The Road Ahead

Over the next 3-5 years, clinical trial execution will change dramatically. The industry is already moving past fragmented tools and reactive processes toward a more connected, intelligent, and adaptive model of execution — one where AI doesn't just assist, but orchestrates the work .

In this future, workflows will no longer be siloed and independent. They'll be connected from protocol to submission. And when changes occur, the system won't scramble to catch up, instead it will adapt in real time.

- Protocols will be designed with downstream impacts in mind.
- Study startup will flow seamlessly, with contracts, budgets, and submissions aligned.
- Enrollment is continuously monitored and optimized in real time.
- Documents write themselves – or nearly – based on structured data inputs.
- Every system – EDC, CTMS, eTMF – speaks the same language, orchestrated by AI.



Who's Poised to Lead

The organizations that benefit most from this shift won't be the ones with the most AI pilots, but the ones embracing orchestration as an operating model.

These organizations will:

- Invest in shared data and semantic infrastructure
- Build workflows spanning departments, not tasks
- Adopt AI not as a bolt-on, but as a connective layer across functions
- Empower teams to work differently

The result will be not just more efficient trials, but more scalable portfolios, stronger partnerships, and a lasting competitive edge.

The Opportunity

For those ready to act, the next phase of clinical trial execution isn't just about improvement — it's about reinvention. AI-powered orchestration offers a rare opportunity to reimagine how trials are run from the ground up.

And while technology will continue to evolve, the organizations that commit now to transforming how they work — integrating systems, aligning teams, and enabling real-time coordination — will set the pace for the industry.

Because the future of clinical trials isn't just digital. It's orchestrated.

Veridix: Orchestrating Next Generation Clinical Trials

Veridix is built to transform clinical trial execution by orchestrating the workflows that connect data, documents, and processes across the trial lifecycle.

Veridix AI Agents

Our modular, reusable agents are embedded across your workflows — coordinating tasks, adapting to changes, and accelerating execution from start to finish.

✓ Document Generation Agent

Automates the drafting of structured content across protocols, CSRs, IBs, and other key documents using live data and pre-approved language libraries.

✓ Biostatistics Agent

Assists in the generation, review, and QC of statistical outputs — supporting programming and TLF validation with contextual AI.

✓ Data Management Agent

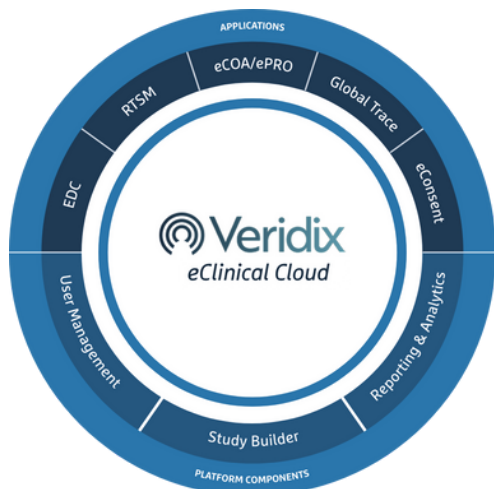
Flags anomalies, accelerates query resolution, and aligns data validation across systems in real time. Reduces manual review and shortens time to database lock.

✓ VERA Reporting Agent

Connects operational and clinical data to generate live dashboards, KPIs, and submission readiness summaries — continuously updated as trials evolve.

Veridix eClinical

The Veridix eClinical platform unifies core trial systems into one connected environment, streamlining execution, eliminating silos, and delivering real-time visibility across the trial lifecycle.



Unified Data Layer

AI-Powered

DCT-Enabled

Real-Time Monitoring

Chain Of Custody

Built-In Standardization

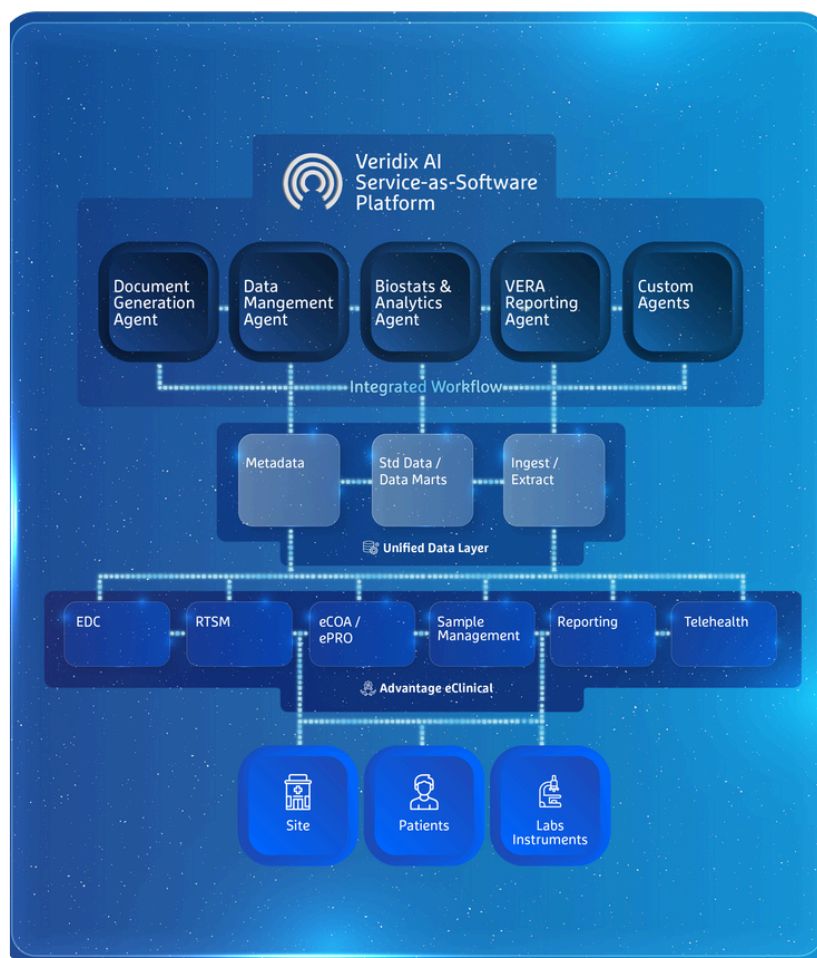
Veridix Service as a Software Platform For Next-Gen Trials

Integrated Workflows Powering Orchestration

Veridix enables true orchestration by connecting the disconnected:

- Unified data fabric across protocol, EDC, CTMS, TMF, and reporting systems
- Connected document models that link protocol elements to downstream content
- Workflow engines that trigger updates, escalations, and handoffs automatically
- End-to-end visibility so teams operate on the same version of truth

No more disconnected trials. Just continuous coordination across functions.



AI Impact At A Glance

AI agents deployed within Emmes Group trials have delivered the following results:

- **40–60%** faster study build with AI-powered EDC configuration
- **30–50%** reduction in LPV-to-database lock time
- **50–70%** fewer manual queries via AI-driven data checks
- **Up to 40%** of DM hours reallocated to higher-value tasks
- **50%** faster CSR drafting using gen AI
- **20–30%** drop in protocol deviations through real-time risk detection

Get In Touch

401 N Washington St.
Rockville, MD 20850
www.theemmesgroup.com
marketing@emmes.com



301-251-1161

About Emmes Group: Emmes Group is a global CRO combining scientific rigor and technology to accelerate research and improve public health.

About Veridix: Veridix is the AI and innovation arm of Emmes Group, building tools to streamline and modernize clinical trials.



Produced by: Emmes Group
Publish date: June, 2025

