

ARTICLE

When “Everything” Is the Pain Point:

Rethinking RTSM for Real-World Use

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When attendees at a recent industry forum were asked a simple question—“What are your top pain points as they relate to RTSM?”—one response cut through immediately for its honesty:

“Everything.”

That single word captured what many study teams feel but rarely say out loud. RTSM is foundational to trial execution, yet it often becomes a source of friction—introducing risk, rework, and rigidity instead of control and confidence. During the session, Melissa Chapman, Senior Solutions Architect at Endpoint Clinical, unpacked what’s really behind the “everything” response by listening closely to how teams experience RTSM in practice and examining where AI—when guided by experienced professionals—can help deliver meaningful, durable value.

▶ The Reality Behind RTSM Frustration

- **The burden of system updates**

A common theme was the time, process, and cost involved in updating RTSM systems. Even small changes can feel heavy—requiring coordination, revalidation, and delays that slow the study rather than support it.

- **Limited ability to correct errors**

Several attendees highlighted the frustration of not being able to correct data that was entered in error, even when the mistake is obvious and well-documented. This lack of flexibility forces teams into workarounds that erode trust in the system itself.

- **Titration and dosing flexibility**

For studies involving titratable drugs, teams struggle with balancing dosing flexibility against accurate forecasting. Static designs and rigid logic make it difficult to adapt as patient needs and enrollment realities evolve.

- **Forecasting supply at the site level**

Predicting what sites actually need—and when—remains a persistent challenge. Over or undersupply drives waste, shortages, and emergency shipments, all of which add cost and operational stress.

- **Data privacy, security, and strategy**

Concerns around data privacy and security surfaced alongside a broader issue: many teams lack a cohesive data strategy for RTSM. Data exists, but it’s fragmented, underutilized, and difficult to translate into insight.

Taken together, it’s easy to see why “everything” feels broken.



Moving RTSM from Rigid Systems to Responsive Design

- ▶ Melissa’s presentation reframed RTSM challenges through a practical lens: most issues stem from complexity, disconnected systems, and a lack of actionable insight—not from a lack of data or effort. Her approach focused on how AI, when embedded thoughtfully and guided by experienced teams, can help mitigate these challenges across design, execution, and long-term optimization.



Reducing Workflow Inconsistencies Through Intelligent Design and Context-Aware Workflows

Rather than relying on manual monitoring alone, AI—applied within well-designed workflows—can help teams analyze protocol requirements and operational patterns to support smarter system behavior. By extracting relevant data from the protocol and aligning it with real-world workflows, RTSM systems can help prevent common workflow inconsistency scenarios—such as inappropriate dispensing or delayed accountability transactions—before they escalate.

Context-aware alerts and automated checks act as a support layer for users, helping guide correct actions while maintaining flexibility, reducing downstream corrections and reconciliation challenges.



Addressing Complexity and Cost Through Smarter Design Decisions

One of the most persistent RTSM challenges highlighted in the session was complexity—both in system design and in the number of technologies required to support a study. By leveraging AI to augment expert analysis, teams can better understand how study complexity impacts cost by:

- Analyzing design requirements early
- Predicting cost drivers based on protocol and historical data
- Supporting more efficient designs with built-in quality

This allows teams to move away from overengineered solutions and toward right-sized systems that reduce overhead without increasing risk.

“Most issues stem from complexity, disconnected systems, and a lack of actionable insight—not from a lack of data or effort”



Improving Supply Chain and Inventory Strategies with Predictive Insight

Melissa emphasized that supply challenges are often the result of static planning models. When paired with strong operational expertise, AI-enhanced RTSM systems can help aggregate data across depots and sites into unified views, enabling:

- Predictive insights that help minimize shipment costs and waste
- Real-time inventory visibility
- Automated supply triggers based on enrollment patterns and site behavior

These capabilities support more responsive supply strategies, particularly for complex or titratable studies where flexibility is essential.



Breaking Down Data Silos to Deliver Real-Time, Actionable Insights

RTSM data is often abundant but underutilized. By leveraging AI as an analytical extension of experienced teams, organizations can interpret historical trials, enrollment trends, and regional constraints more effectively surfacing real-time dashboards and insights that reduce latency in decision-making.

This approach transforms RTSM data from static records into a knowledge powerhouse, enabling teams to understand what worked, what didn't, and how to optimize future designs.



Driving Design Consistency and Long-Term Optimization

A key theme in Melissa's presentation was learning from past trials. With AI supporting data analysis and pattern recognition, teams are better equipped to:

- Forecast enrollment curves more accurately
- Identify high-performing sites and regional trends
- Apply lessons learned from previous designs to new studies

This leads to greater design consistency, fewer quality issues, and continuous optimization across a portfolio—not just within a single study.

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► Conclusion: From “Everything Is Broken” to Architecture That Works

The RTSM challenges surfaced during the event presentation were not edge cases or outliers. They reflected systemic friction points experienced across studies, sponsors, and therapeutic areas—workflow inconsistencies, inflexible systems, costly updates, limited ability to correct errors, supply uncertainty, and fragmented data strategies. When viewed collectively, it becomes clear why many practitioners describe their RTSM pain point as “everything.”

Melissa Chapman’s session demonstrated that these challenges are **not the result of poor execution or insufficient effort. Rather, they stem from RTSM systems that were not designed to adapt to the realities of modern clinical trials.** Complexity, disconnected data, and rigid logic introduce risk where there should be control—and slow progress where agility is required.

That perspective was central to the broader discussion in Reimagining Clinical Trials: AI-Driven Innovation Across the Study Lifecycle, where the conversation focused on how **AI adoption is best grounded in real-world operational needs.** The session reinforced a critical point: from a solution architecture perspective—where theoretical capability must translate into operational reality—the question is not whether AI can be applied, but how it is implemented responsibly, measurably, and at scale. The takeaway is not that AI is a cure-all, but that the combination of strong architecture and experienced teams—supported by AI—helps ensure the right systems and processes are developed. When AI is applied thoughtfully—grounded in protocol context, historical insight, real-time data, and validated workflows—it becomes a powerful extension of team expertise. It can help reduce inconsistencies, improve forecasting, streamline change, and transform operational data into actionable insight, all while preserving compliance and human oversight.

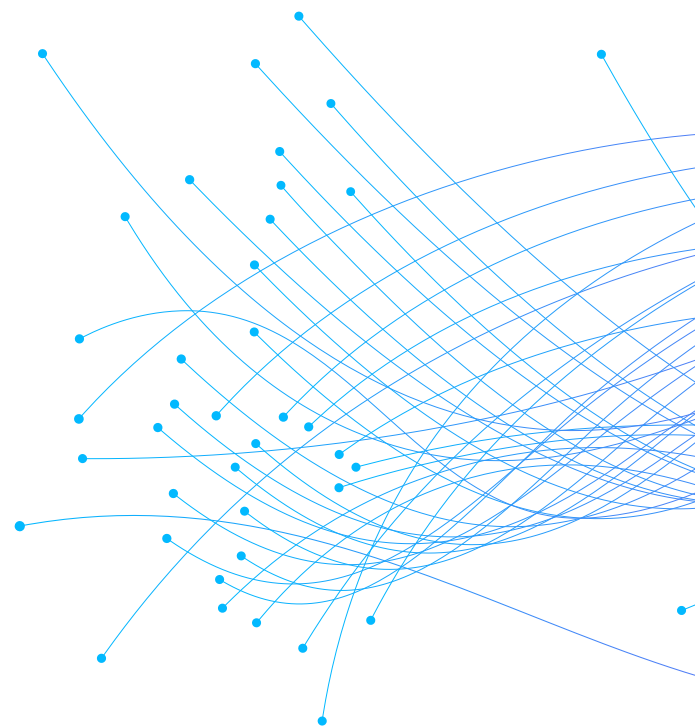
Ultimately, moving RTSM forward **requires shifting from static systems to responsive design—systems that learn, adapt, and support teams** rather than constrain them. Addressing “everything” does not mean solving every problem at once. It means building RTSM architectures that are resilient, scalable, and capable of evolving alongside the studies they support.

That is where meaningful progress begins.

► About the Author

Melissa Chapman is a Senior Solutions Architect and Certified Scrum Product Owner with more than 20 years of experience designing and delivering complex technology solutions within regulated environments, including clinical research. She specializes in Randomization and Trial Supply Management, with a focus on translating protocol and operational complexity into scalable, secure, and adaptable system architectures.

Her work emphasizes the practical, responsible adoption of emerging technologies, including AI, grounded in real-world workflows, data governance, and validation requirements. Melissa brings a multidisciplinary background spanning product development, business strategy, operational optimization, and cybersecurity, and is known for bridging technical rigor with pragmatic execution.



► Is Your RTSM Ready for What Comes Next?

AI is already reshaping clinical trials. The question is whether your RTSM is keeping pace.

Discover how an architecture first approach to AI can reduce complexity, increase adaptability, and drive smarter trial execution.

Connect with Endpoint to explore what modern RTSM can deliver:

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