4G CLINICAL

From Delivery to Discovery: Lessons Learned from RTSM in Practice

Knowledge Sharing Series

From Delivery to Discovery: Lessons Learned from RTSM in Practice

Introduction

Randomization and Trial Supply Management (RTSM) systems are the backbone of modern clinical trials, ensuring that patients receive the right treatment at the right time. But while the technology is critical, the true differentiator lies in the people, processes, and culture behind its development and maintenance. This white paper offers a behind-the-scenes look at how 4G Clinical has approached the cultural and operational evolution of RTSM, drawing on practical lessons learned to explore best practices for agile collaboration, balancing flexibility with standardization, and shifting industry roles from order-takers to trusted advisors.

Early Lessons: Agility and Its Hidden Costs

In the early days of 4G Clinical, agility was everything. With a small team and a handful of clients, a "yes-first" mentality defined the culture. If a sponsor requested it, the team delivered. This approach fueled creativity and deep client relationships, but it also came with hidden costs. Customizations for one study often became a burden to maintain, and what seemed like flexibility at the start created rigidity later on. This early experience taught us a vital lesson: flexibility fuels innovation, but without boundaries, it creates long-term challenges. Sustainable delivery requires balancing responsiveness with foresight.

Scaling and Structuring: From Silos to Consistency

As 4G Clinical grew, so did the challenge of maintaining consistency. The initial pod structure, self-contained teams managing their own client portfolios, fostered intimacy but also created silos and variability in sponsor experiences. The solution was a hybrid model that combined vertical structures tailored to client types with horizontal functions to ensure consistency across delivery. Two groups became central to this model: the Design Excellence team, serving as the organizational conscience for best practices and ensuring every study benefits from accumulated knowledge, and the Forecasting and Resupply Services Team, composed of seasoned supply professionals who evaluate each protocol and provide expert consultancy on which forecasting and resupply algorithms to utilize prior to system build. Together, these teams bring both design rigor and deep supply chain expertise, enabling trials to launch with greater confidence, efficiency, and long-term sustainability.

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Evolving Roles: Becoming a Trusted Advisor

One of the most important cultural shifts was learning when to push back constructively. In the past, sponsors often expected vendors to simply execute instructions. We learned that true partnership requires understanding the "why" behind a request—the operational and patient realities driving a need. Today, 4G Clinical's client-facing roles have a consultative approach. By drawing on past lessons, implementers can articulate risks, highlight trade-offs, and recommend approaches that optimize both immediate and long-term success. This shift has transformed our relationships, with clients now viewing us as extensions of their study teams, not just task executors.

Building for the Long Game: The Importance of Maintenance

A study doesn't end at go-live—that's just the starting gun for a long maintenance phase where flexibility and foresight become critical. Early experiences taught us that focusing only on the initial build left sponsors struggling with cumbersome amendments and complex reconciliations. To address this, our best practices now emphasize **standardization** where it matters most (e.g., reporting, accountability) and **flexibility** where it matters to patients and trial design (e.g., dosing pathways). We've also created dedicated maintenance teams to ensure knowledge continuity and support studies throughout their full lifecycle.

> *True **partnership** requires understanding the **'why'** behind a request. Today, clients see us as **extensions of their study teams**, not just task executors.*

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Looking Ahead: Complexity, AI, and Patient-Centered Design

The future of clinical trials is defined by rising complexity. Protocols are more intricate than ever, demanding systems that can flex without fracturing. Looking ahead, we see three key themes:

- **Rising Complexity:** Protocols will continue to stretch traditional systems, requiring best practices that evolve alongside product innovation.
- **Artificial Intelligence:** While AI offers promise in automation, it cannot replace the consultative, human element of design—the empathy and operational context that a protocol alone cannot provide.
- **Patient-Centered Delivery:** Every design choice ultimately impacts the patient and site experience. Keeping this perspective central ensures that technology supports not just trial operations but also patient outcomes.

The future of IRT will continue to be an evolving blend of technology, functionality and expertise to best serve our sites and patients?

> *A study doesn't end at **go-live**—that's just the starting gun for a long maintenance phase where **flexibility and foresight** become critical.*

Conclusion

The journey of building best practices in RTSM delivery is one of constant balance: between flexibility and sustainability, innovation and standardization, speed and foresight. At 4G Clinical, our history has shown that the lessons learned along the way are as valuable as the systems we build. By embracing reflection and codifying insights, we continue to strengthen our role as trusted advisors, ensuring that every trial we support is not only delivered successfully but also sustained with care, expertise, and a relentless focus on patients.

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About us

4G Clinical's suite of innovative RTSM and clinical supply optimization software provides the right-sized support for any phase or trial complexity. At 4G Clinical, all studies are supported by a team of RTSM experts to advise trial teams on the best path forward. Our operations team distinguishes itself through their extensive industry expertise and deep understanding of trial designs and mid-study adjustments. As a critical partner throughout clinical development, we can help you seamlessly transition and scale your trials through both protocol and supply complexities to help **bring crucial medicines to those who need them, *faster.***

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