WHITE PAPER

The Innovation Implementation Gap

Why valuable RTSM capabilities still get left behind

Executive Summary

Modern RTSM platforms can support a wide range of advanced capabilities that strengthen control, improve visibility, and reduce operational burden. Yet many of these capabilities still fail to make it into live studies. The issue is not a lack of innovation. It is that useful functionality is too often evaluated through the lens of study launch, rather than through the realities of live study execution and maintenance.

Introduction

Sponsors continue to ask more of RTSM. They want systems that are flexible, operationally robust, and capable of supporting increasingly complex studies. Modern RTSM platforms can now support advanced functionality designed to improve control, reduce manual effort, strengthen visibility, and enable more scalable study execution.

What Starts as	*What Quickly Follows*	*What RTSM Must Support*
A dose, a cohort, a supply strategy ..	Schedule shifts, dose changes, cohort expansion, patient movement	Controlled adaptation without loss of oversight

Yet many of these capabilities still fail to make it into live studies. In many cases, the functionality is recognised early, discussed during planning, and understood to be useful. The problem is not that innovation is missing. It is that useful innovation does not always survive the move from planning into execution. As timelines compress and teams focus on getting the study live, capabilities that are seen as non-essential to launch are often scaled back, deferred, or left out altogether.

The result is an implementation gap. Valuable functionality exists. Sponsors express interest in it. The operational need for it is real. But when the system goes live, the study often moves forward without it.

> ***One should always think study maintenance first.***

Jon Sendall
Senior Manager, Product Management

Why Valuable Functionality Gets Left Behind

The reasons are rarely simple. Most study teams are working against immediate deadlines, with study go-live as the primary objective. In that scenario, the essential functions of screening, randomisation, dispensing, and core supply operations understandably come first. Capabilities that sit outside those immediate needs can lose momentum, even when they may offer clear value later in the study.

A common pattern is that the functionality itself is not the issue. The friction appears when implementation requires more than a simple yes or no decision. Some capabilities depend on additional process definition, internal alignment, IT support, quality input, site readiness, or broader sponsor infrastructure. That extra layer is often enough to push the feature out of scope during the initial build.

This is especially true when the operational benefit will be felt later rather than immediately. If the pain point is not yet visible at study start, the capability can feel optional, even if it would ultimately save time, reduce manual intervention, or strengthen control once the study is underway.

Key Takeaway: Operational pain often appears after study go-live, not before it.

The Real Issue is Not Launch, it is Longevity

One of the most important shifts in thinking is to assess advanced RTSM functionality across the full study lifecycle, rather than limiting evaluation to the initial build. A study build may take only a few months. The study itself may then run for years. Teams live with the consequences of those early design decisions for far longer than they spend making them.

This is where the implementation gap becomes more significant. A capability that feels non-essential during build may prove highly valuable once the study is live and operational reality begins to take shape. Manual workarounds accumulate. Study teams spend time managing avoidable friction. Sites encounter processes that are technically workable but inefficient. Requests for changes emerge only after the burden becomes visible.

For that reason, advanced functionality should not be evaluated only on whether it is needed to get the study live. It should also be evaluated on whether it improves how the study will run once it is live.

Build and live study realities are not the same

Build phase	*Live study phase*
Shorter in duration	Much longer in duration
Focused on launch readiness	Defined by maintenance, change, and continuity
Decisions feel immediate	Consequences are felt over time

Key Takeaway: Capabilities that look optional during build can become valuable during maintenance.

> ***You've got to live with what you've built for many, many times longer than it took to do the build phase.***

Jon Sendall
Senior Manager, Product Management

Where the Gap Shows Up Most Clearly

These decisions do not tend to centre on fringe functionality. More often, they involve capabilities with clear operational value that are discussed seriously during planning, but do not always make it through to live implementation.

Commonly valued. Not always carried through.

Operational workflow	• Temperature excursion auto resolution • Accountability design • Ancillary drug management
Traceability and control	• Barcoding • Single sign-on • Just-in-time labelling
Supply and planning	• Advanced forecasting and resupply logic • Depot forecasting

The reasons vary by capability, but the pattern is consistent. These are rarely dismissed because they lack value. More often, they are deferred because implementation requires broader readiness, added coordination, or a longer view of what the study will need once live. Temperature excursion auto resolution is a clear example. The logic is compelling. It can help sites assess affected kits more quickly and reduce delays in availability decisions. But because excursions may be infrequent in many studies, the setup and validation effort can feel difficult to justify during build.

Barcoding follows a similar pattern. It offers clear advantages in traceability, accuracy, and site efficiency. Yet its success depends on upstream consistency, kit data structure, and broader process readiness beyond the RTSM itself. The value proposition is strong, but adoption often relies on elements that sit outside the immediate study team's control.

Accountability is another area where the gap often appears. Sponsors may include accountability at a basic level because it is clearly required, but the more advanced design decisions that improve usability, reflect real site workflows, and support cleaner execution are sometimes deferred until pain is experienced in live use.

Single sign-on also illustrates the issue well. It is widely understood as valuable, particularly in larger organisations seeking more connected systems and smoother access across users and teams. But because it depends on broader sponsor infrastructure and coordination beyond the immediate study build, it can be pushed aside even when the long-term usability case is obvious.

Depot forecasting, just-in-time labelling, and more adaptive resupply logic fit the same overall pattern. They can support more resilient operations, particularly in complex supply environments, yet they are often treated as enhancements rather than enablers of long-term execution.

Feature Snapshot

Capability	*Why it gets deferred*	*What it supports later*
Temperature excursion auto resolution	The need may feel infrequent during build	Faster operational response, site time savings
Barcoding	Depends on broader readiness	Traceability and site efficiency
Single sign-on	Requires enterprise coordination	Easier access and connected use
Accountability design	Can be treated too narrowly at build	Better real-world usability
JIT labelling and resupply logic	Can feel secondary to launch	Greater supply flexibility and planning control

Where the Gap Shows Up Most Clearly

The consequences are rarely visible on day one. When a study launches successfully, it can appear that the right trade-offs were made. But the impact of excluding useful functionality tends to emerge gradually through additional manual effort, weaker standardisation, slower response to change, and reduced operational visibility.

Over time, these gaps can affect more than convenience. They can influence how quickly teams respond to study events, how efficiently sites work, how clearly supply decisions can be traced, and how confidently operational processes can scale. A capability that looked optional during planning may turn out to be a source of resilience once the study begins to evolve.

This matters even more as studies become more dynamic. Adaptive designs, cohort changes, regional expansion, and evolving supply needs all increase the value of systems that are built not only for launch, but for the realities of live study management.

Key Takeaway: Advanced RTSM functionality should not be evaluated only on whether it helps a study launch. It should also be evaluated on whether it helps a study run well once live.

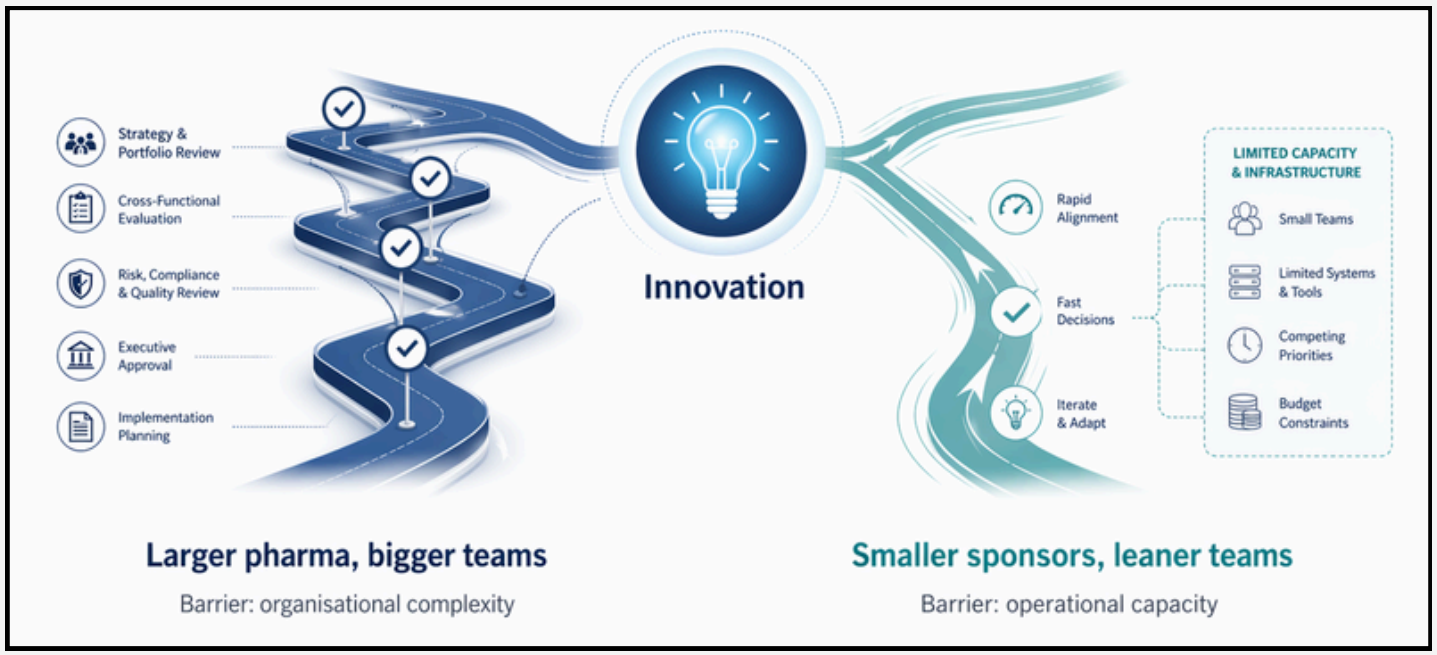
Why Sponsor Type Matters

Smaller and emerging sponsors may be highly receptive to innovation and open to new ways of working, but they may not always have the internal infrastructure, specialist support, or cross-functional readiness needed to operationalise more advanced functionality. In those settings, the appetite is there, but the supporting framework may not be.

Larger organisations face a different version of the same issue. They may have the governance, experience, and scale to support more advanced functionality, but implementation often depends on standards, internal alignment, broader ownership, and decisions that extend beyond a single study team. In those environments, adoption can slow not because the value is questioned, but because the path to implementation is broader and more structured.

That distinction matters. It suggests that the challenge is not simply whether sponsors value innovation. It is whether the organisation is set up to carry that innovation through to live execution.

Large and small sponsors do not differ in whether they value innovation. They differ in what makes innovation harder to carry through into live execution.



A Better Way to Evaluate Advanced Functionality

Not every capability belongs in every study. The goal is not to add functionality for its own sake. The goal is to make more deliberate decisions about what is included, what is deferred, and what those choices will mean once the study is live.

Instead of asking only, “Do we need this for go-live?”, sponsors should also ask whether the capability will reduce operational burden later, improve responsiveness or control once the study is underway, and solve a problem the team is likely to feel six months into execution rather than six weeks before launch.

The most successful adoption of advanced functionality often depends on bringing together the people who will feel its impact over time, not only those responsible for launch. When maintenance, operations, supply, quality, and long-term usability are part of the evaluation, better decisions can be made earlier.

> ***So, investing in maintenance during the build phase then pays off many times over.***

Jon Sendall
Senior Manager, Product Management

Conclusion

The industry does not lack useful RTSM innovation. The challenge is ensuring that valuable functionality survives the move from planning into execution. As studies become more complex, connected, and operationally demanding, the cost of leaving helpful capabilities behind becomes harder to ignore.

The most effective RTSM decisions are not only the ones that support launch. They are the ones that continue to support the study long after launch, when change, complexity, and operational reality begin to take hold. Sponsors that evaluate functionality through that longer lens will be better positioned to close the implementation gap and build studies that are not only live, but genuinely equipped to run well.

A Practical Lens for Future Study Planning

Traditional launch question	*Is this required to get the study live?*
Stronger implementation question	Will this reduce friction, improve control, or save time once the study is live?
Decision timing	Evaluate not only pre-launch requirements, but also the operational burden likely to emerge during maintenance.
Who should be involved	Include the teams who will maintain, monitor, and support the study over time, not only the teams responsible for build.

Biography

Get to know Jon Sendall

Jon Sendall

Senior Manager, Product Management

4G Clinical

Jon Sendall, Senior Manager; Product Management at 4G Clinical, has over 20 years of experience as a product manager and technical lead implementing clinical trial technologies, including RTSM systems, at CROs and RTSM vendors. Jon led the development of a highly successful configurable RTSM system and has led the qualification and on-boarding of several RTSM vendors for a CRO. He has a passion for delivering quality solutions which exceed client expectations. He has a Bachelor of Science (BSc) in Physics from The University of Birmingham and away from work enjoys trail running.

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