KORIO



PHASE I | ONCOLOGY

CASE STUDY

A Small Biotech Finally Found an RTSM That Keeps Up

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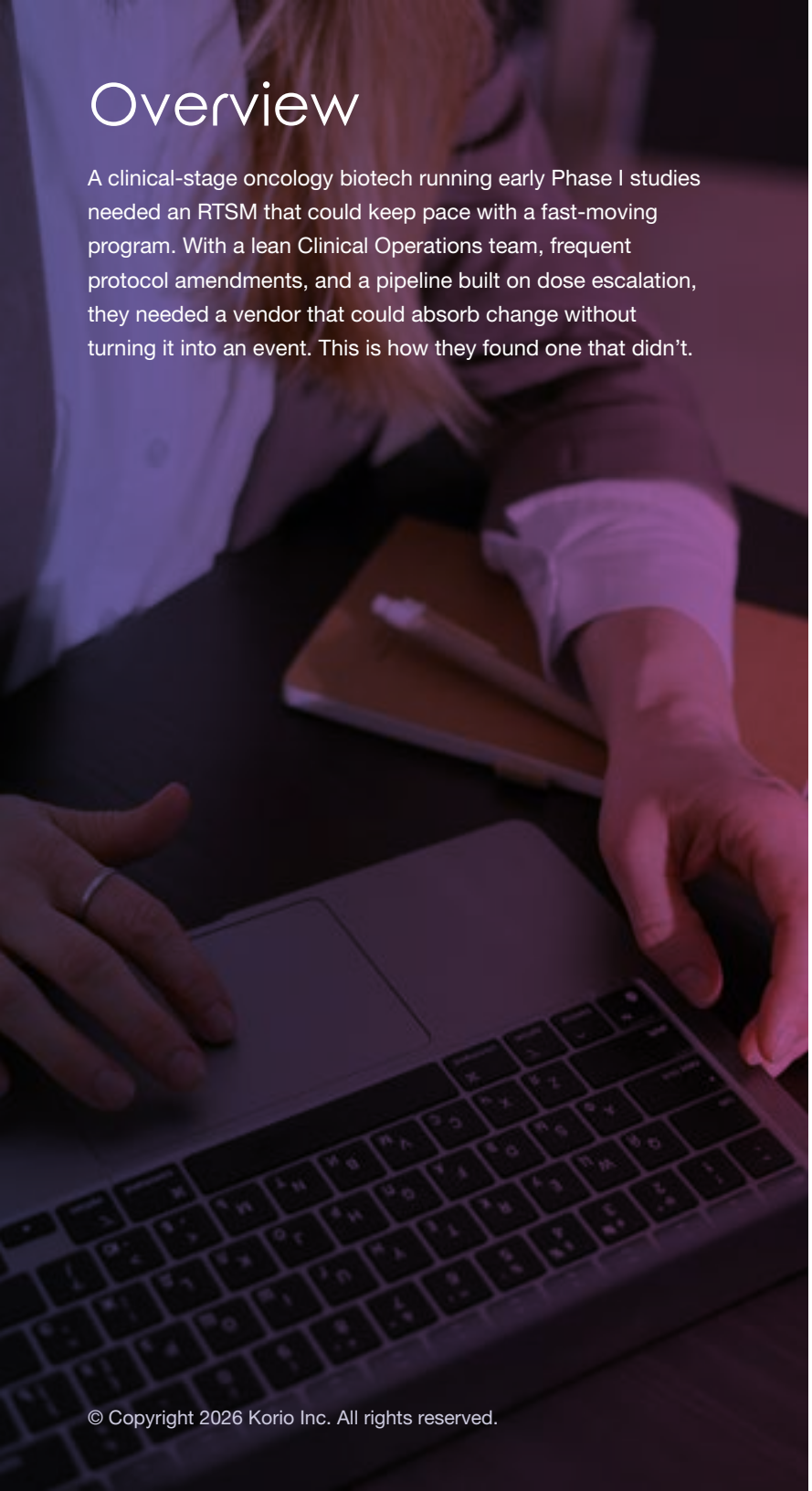

Overview

A clinical-stage oncology biotech running early Phase I studies needed an RTSM that could keep pace with a fast-moving program. With a lean Clinical Operations team, frequent protocol amendments, and a pipeline built on dose escalation, they needed a vendor that could absorb change without turning it into an event. This is how they found one that didn't.

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The Challenge

The Associate Director of Clinical Operations at a small oncology biotech sent a protocol amendment to her RTSM vendor. A routine update. She needed to know two things: what changes would be required, and when could they start.

It took nearly three weeks to get the first answer. The second came with a condition: sign off on the full specification before they would schedule implementation.

> *We always felt like we were being rushed to approve things, to get in line, as they kept saying, for the updates that needed to happen to the system.*
>
> **Associate Director, Clinical Operations**

For a team running early Phase I oncology studies, that kind of delay has a direct cost. Protocol amendments are not exceptions to the work. They are the work. When a new cohort opens on a revised dose, the RTSM needs to be ready. Time spent waiting on a vendor to scope changes is time the study is not enrolling.

The cost structure added to the friction. Mid-study changes could run two to three times the original build cost, and the promise that repeat studies would get faster was one the vendor struggled to honor. The same foundational work tended to get rebuilt each time.

Over the years, the team had also seen the vendor's project staff turn over. Earlier in the relationship, things had worked well. But by the time the Clinical Operations lead was evaluating alternatives, she had found herself relying on a single contact at that vendor for anything she needed answered accurately.

> *There was one person that I was confident knew what he was doing. He was the only person I would ask questions because I did not trust that anyone else could give me an accurate answer.*
>
> **Associate Director, Clinical Operations**

The Korio Approach

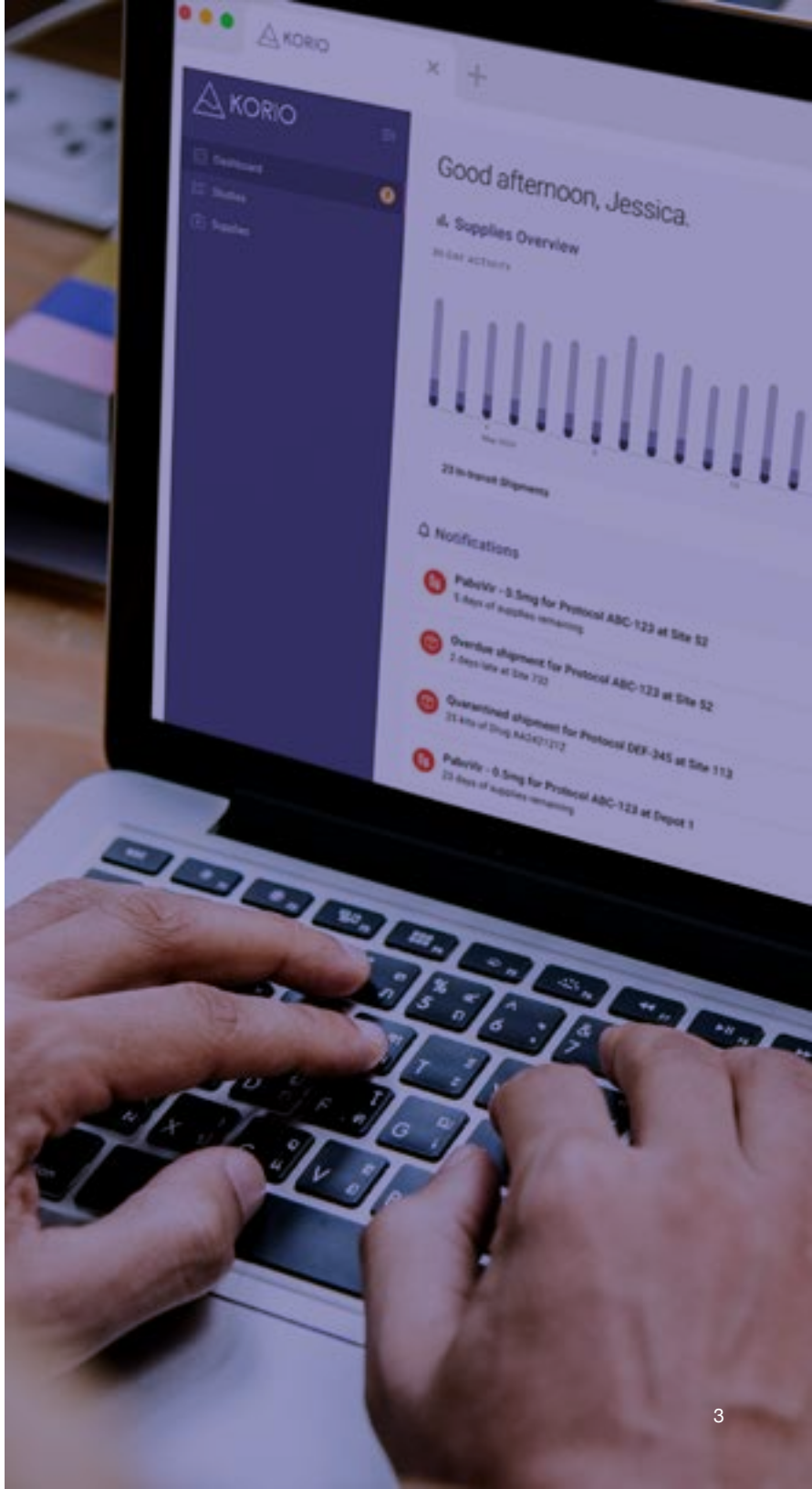
An RTSM built for reuse, not repeated builds

Many RTSM vendors approach each new study as a fresh build. Core logic gets re-engineered regardless of how similar the work is to what came before, and mid-study changes require formal sign-off before anyone will scope the timeline. For Sponsors running repeat studies on similar protocols, that model means paying full price for work that is largely incremental.

Korio's platform starts from a different place. Core functionality is already built and validated. Studies are configured against it rather than constructed on top of it. When the Sponsor launched their second study, the project team was not re-learning preferences or rebuilding familiar logic. They were applying a model they already knew, on a platform that already had the baseline in place.

The difference was noticeable from the kickoff. The conversation wasn't about what needed to be built. It was about what, if anything, would be different this time.

> *It was so smooth, just from that perspective. It's the same PM. She already knew everything. So it was just fast, easy, less friction.*
>
> **Associate Director, Clinical Operations**



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Right-sized documentation

Korio scales documentation to the needs of the Sponsor and the study. A large pharma Sponsor with dedicated RTSM teams and established procedures may want a detailed specification package. A lean biotech team may need something more focused, one that preserves review efficiency without sacrificing access to full supporting detail when it matters. Rather than running every study through a one-size-fits-all requirements model, Korio scopes specifications to the actual study design, operational complexity, and Sponsor preference.

This matters more than it might appear. Behind many ultra-fast delivery claims is a requirements process that moves quickly by staying general, leaving key details undefined until UAT, a later enhancement, or an unexpected issue makes the gap visible. A well-scoped URS isn't about page count. It's about ensuring the study is fully specified before it's built, so the Sponsor isn't discovering missing functionality mid-trial.

When this Sponsor's Supply Chain team reviewed Korio's documentation for their first study, the difference from their previous vendor was immediate. The document was focused, relevant, and clearly aligned to the actual scope of the study.

> *Korio specs are not that long. It's easy to review. Everything's clear and clean and concise. That's feedback we got specifically from Supply Chain when they were reviewing the specifications. They said it was so much easier.*
>
> **Associate Director, Clinical Operations**

RTSM expertise the team could rely on

Korio focuses exclusively on RTSM. That specialization runs through the project management team, where questions about the system get answered by people who know it well. For a Sponsor who had come to rely on a single trusted contact at her previous vendor, having a full team she could turn to with confidence made a practical difference in how the work got done.

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Outcome

The first study gave the Sponsor a clear sense of what working with Korio looked like: a straightforward setup process, right-sized documentation, and a project team that could answer questions directly. The second study gave them something to compare it against.

The same project team was assigned. The kickoff moved faster because the context from the first study was already in place. The Sponsor didn't need to re-establish preferences or re-explain how her studies are structured. The relationship picked up where it had left off.

For a lean Clinical Operations team where timeline is the constant constraint, that kind of continuity is worth more than a feature. It shows up directly in how fast a study can move.

Discuss Your Next Study: **Speak to an RTSM Expert**

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