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SUCCESS STORY

Outgrowing Excel: Implementing RTSM in a Live Phase I Trial

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Overview

A clinical-stage oncology biotech was running a live Phase I study using manual enrollment and drug supply workflows, with key IRT activities handled through manual reviews and Excel spreadsheets. With tight timelines, the administrative lift of this manual approach was becoming harder to sustain for a lean Clinical Operations team.

The Sponsor selected Korio to support a mid-study transition to RTSM, seeking a partner that could step into an active trial, support protocol changes as they arose, and reduce the day-to-day manual workload for both internal teams and sites without slowing momentum. Because staff had limited prior RTSM experience, the Sponsor also needed hands-on guidance to ensure a smooth transition.

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The Challenge

Implementing an RTSM system mid-study required balancing live-study risk with essential operational requirements:

- Replacing manual workflows without disrupting a live trial
- Supporting a team with limited prior RTSM experience
- Executing protocol changes without introducing long delays
- Minimizing site burden in a Phase I oncology setting
- Delivering documentation that could support quality review and audit readiness
- Avoiding project manager turnover and repeated re-education cycles

> *Implementing RTSM while the study is live is a challenge on its own, and you were able to work with us through that.*
>
> **Sr. Director, Clinical Operations**

For a small sponsor, even minor delays or execution issues could materially impact the program.

The Korio Approach

Continuity Through a Live Mid-Study Transition

Korio partnered closely with the Sponsor to bring RTSM online mid-study, preserving continuity, clarity, and execution quality in a live Phase I oncology trial.

The same senior RTSM project team that led early discussions remained accountable through implementation, eliminating handoffs and preserving study context. The system was configured to support Phase I oncology requirements while staying straightforward for study teams and sites new to RTSM technology.

> *The team has been very proactive and very easy to work with. We understood how they worked, and we weren't handed off to someone new we hadn't met.*
>
> **Sr. Director, Clinical Operations**

Practical Onboarding, Clear Documentation, and Fast Change Execution

Korio provided hands-on guidance for team members without prior IRT/RTSM experience and delivered streamlined User Requirements Specification documentation that supported quality review without unnecessary volume. Change requests were implemented quickly, avoiding the extended timelines often associated with legacy RTSM providers.

> *Even early on, you can usually tell when a vendor isn't responding and you have to escalate. We haven't experienced any of that.*
>
> **Sr. Director, Clinical Operations**

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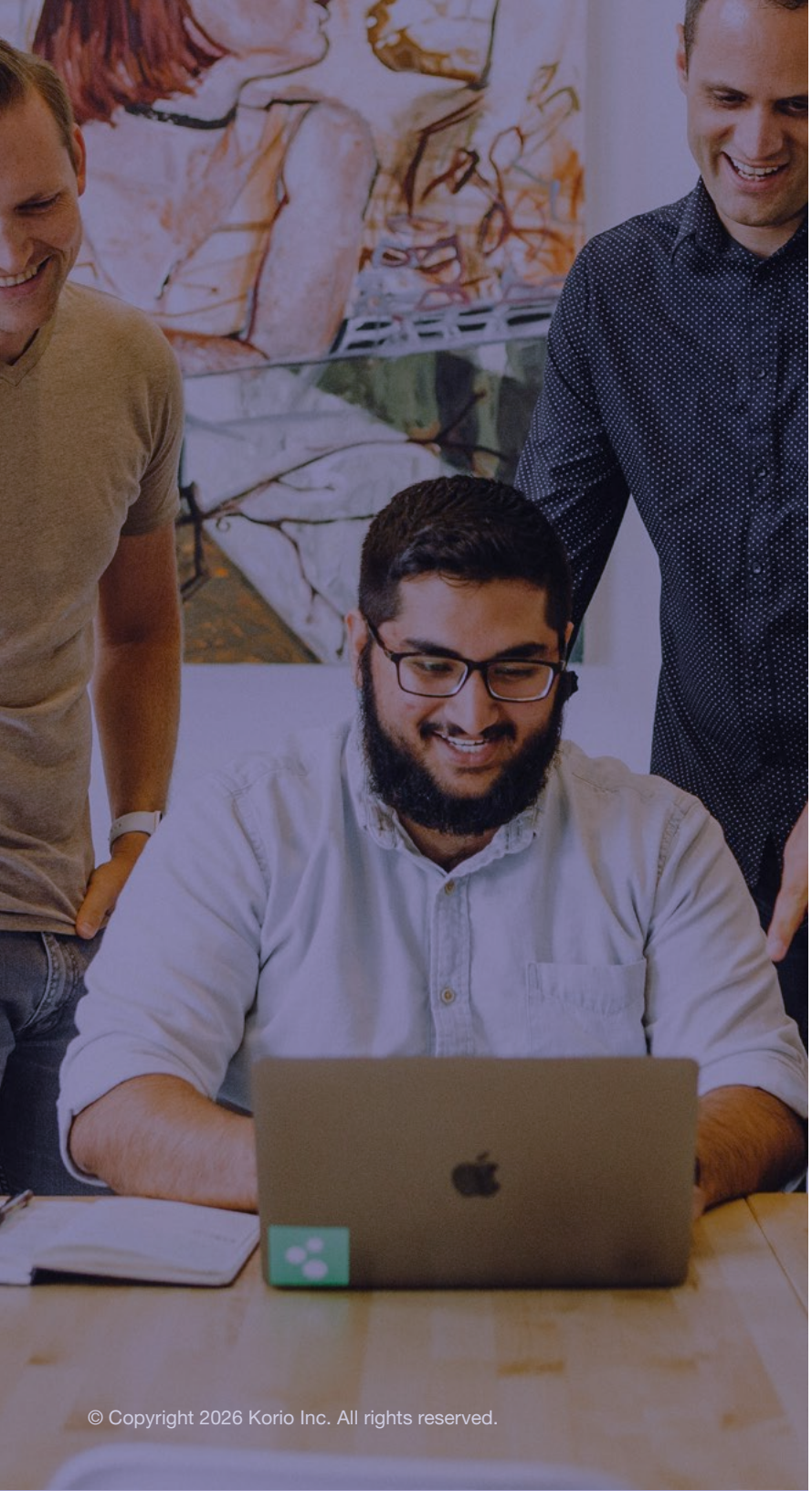

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Sponsor Feedback

Easy system navigation

"The user experience was great. Anyone can go in without thinking, 'What am I doing?' or getting lost trying to figure out the next steps."

Rapid, cost-efficient system changes

"We're not waiting six to ten weeks for small changes like we have with other systems. Korio is also more cost effective overall compared to some of the other vendors out there."

Project team expertise and continuity

"Keeping the same team from demo through implementation was very important to us. The project team has been extremely easy to work with. They knew the system inside and out and answered all our questions."

Support for teams new to RTSM

"Some of my team members have never worked with RTSM before. I asked your team to hand-hold them, and that's exactly what I've seen."

Flexible documentation process

"Your documentation was streamlined and easy enough to review. I've seen URS documents that are 100 pages long. This wasn't like that."

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Outcome

Korio enabled a smooth mid-study transition without disrupting trial progress. The Sponsor gained faster response to change, consistent project ownership, and greater confidence in day-to-day execution, without increasing operational or site burden.

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

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