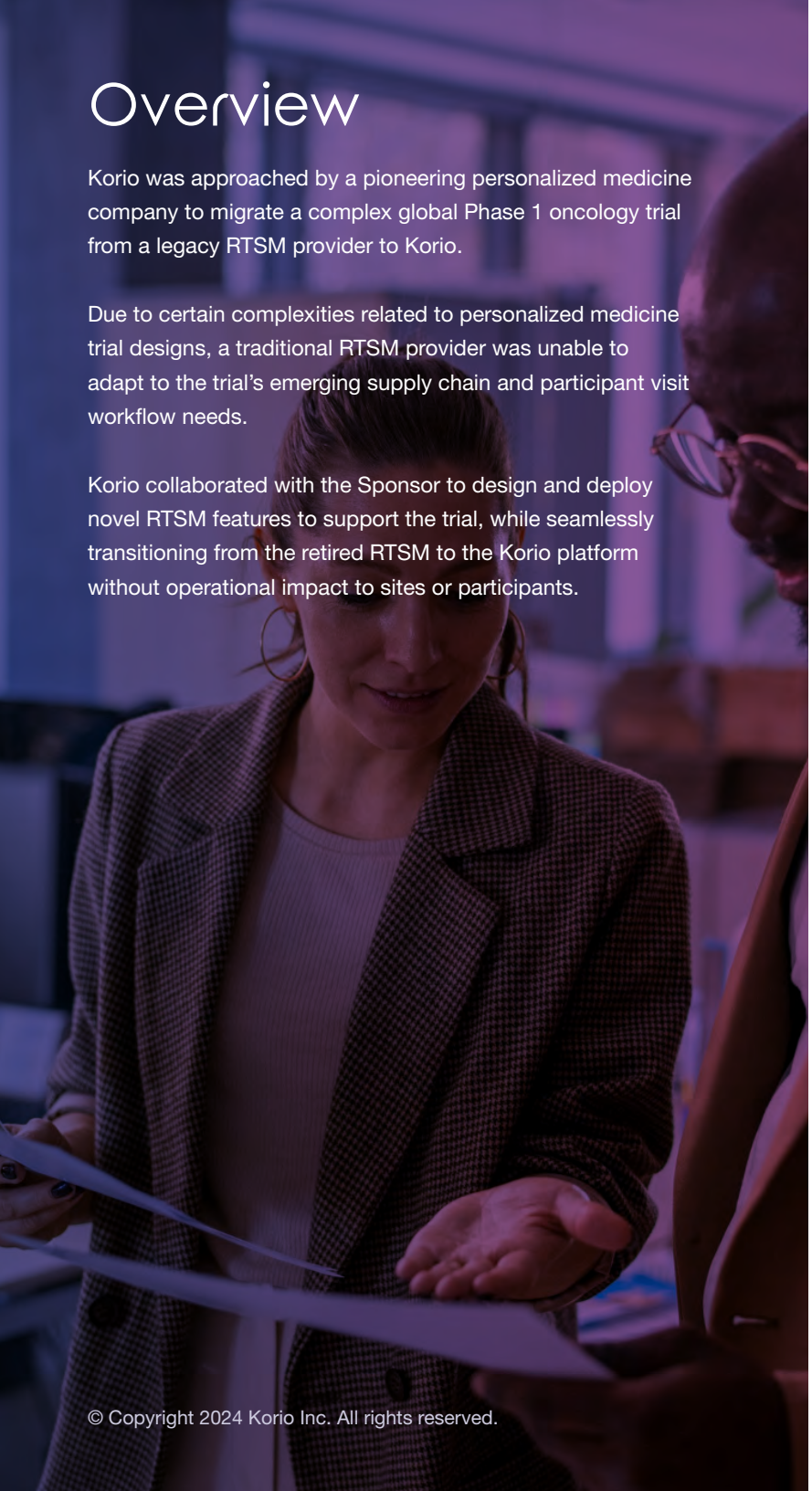


KORIO

CASE STUDY

Korio RTSM Powers Complex Personalized Medicine Oncology Trial

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Overview

Korio was approached by a pioneering personalized medicine company to migrate a complex global Phase 1 oncology trial from a legacy RTSM provider to Korio.

Due to certain complexities related to personalized medicine trial designs, a traditional RTSM provider was unable to adapt to the trial's emerging supply chain and participant visit workflow needs.

Korio collaborated with the Sponsor to design and deploy novel RTSM features to support the trial, while seamlessly transitioning from the retired RTSM to the Korio platform without operational impact to sites or participants.

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The Challenge

As precision medicine becomes more prevalent in the medicine discovery process, certain tried and true approaches to managing clinical trials may no longer be optimal. In particular, the use of traditional RTSM modules alone does not bridge the communication gap between the clinical and manufacturing supply chains needed to achieve seamless trial operation in a personalized medicine (PM) study. The sponsor's specific challenges are further detailed:

Participant-Specific Investigational Product (IP)

Unlike a traditional clinical trial where the IP is a manufactured commodity for distribution across study sites to be administered to one or more participants, this study used custom therapies for each individual participant. Because the IP is participant-specific, additional considerations were required to ensure that each participant's manufactured therapy was made available at the appropriate time and location for that participant for one or several subsequent treatments. The IP was administered alone and in combination with commercially available treatments, and the foundational supply chain features expected with RTSM (temperature sensitive shipments, country-specific shipping requirements, customs lead times, etc.) were required as well.

Workflow Harmonization

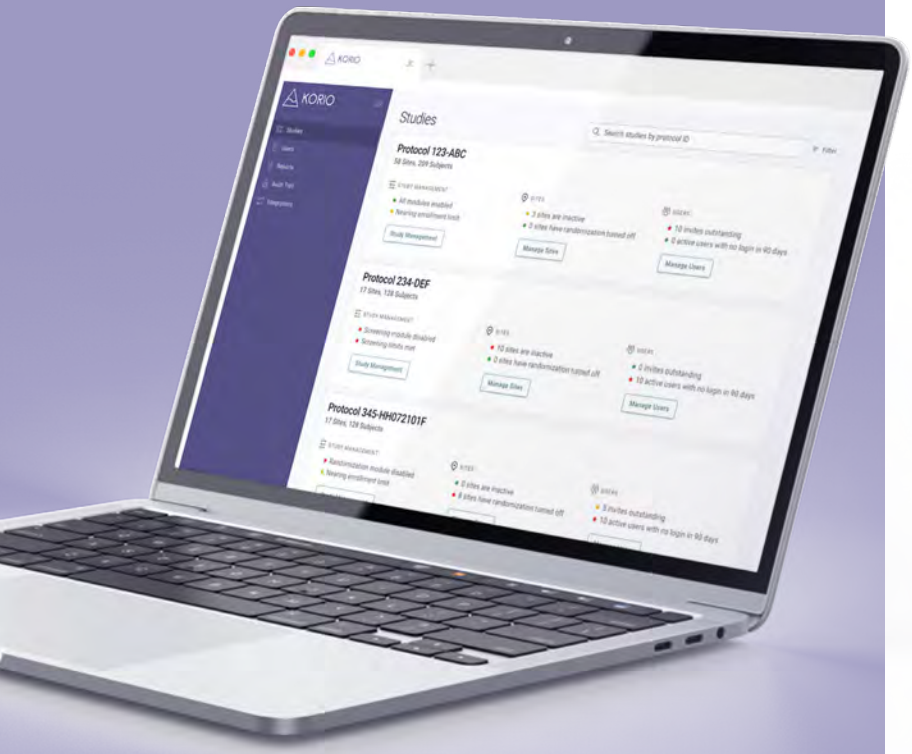
Enhanced communication between the sponsor, clinical sites, Korio and various affiliate services was required to ensure that enrollment, patient scheduling, IP manufacturing, lab assessments, and other critical workflow was transparent and harmonized to enable a seamless experience for the site personnel and participants. As well, despite the increased data collection and workflow options, the RTSM site user experience needed to be intuitive to facilitate site compliance and timely patient treatment.

Rescue RTSM

Because the trial was already active with another legacy RTSM provider, Korio needed to collaborate with the sponsor to migrate existing participant and supply data into the Korio system while simultaneously sunsetting the retired RTSM provider with minimal impact to participant treatment or wasting of existing supplies.

The Korio Solution

Korio resolved the sponsor's challenges through a combination of its platform's adaptability and Korio's decades of RTSM execution including rescue studies. The Korio offering was augmented to support a highly integrated solution that solves for the IP management and communication coordination unique to PM trials. The data migration and rescue of the legacy provider was performed according to Korio's experience with similar challenging technology migration scenarios.



Hyper-integrated Korio RTSM

To create an intuitive and easy-to-use site experience, Korio integrated its RTSM platform with multiple external systems to facilitate a seamless process for managing the personalized IP as well as the interactions between the sites and the Korio platform:

Korio leveraged the benefits of its intuitive RTSM user interface and confidence-building workflow to enable sites to manage the complexities of the study.

Korio embedded itself into a robust integration framework (manufacturing, distribution, EDC, scheduling, diagnostics) to enable just-in-time supply chain management for both personalized medicine and comparator drug to ensure availability of the experimental investigational product at anticipated participant visits. The integrated ecosystem provides sponsor and site transparency and immediate access to critical waypoint data to ensure uninterrupted participant treatment throughout the trial.

This integrated approach ensured orchestrated trial management across multiple providers, while adding to the data integrity throughout the multi-step treatment process.

Data Migration and Rescue

Korio faced the challenge of migrating existing data from the previous RTSM system. The team successfully:

Executed a seamless transition from the previous RTSM system, mapping, restructuring and migrating all relevant data.

Managed in-flight participants and supplies, ensuring no disruption to ongoing trial activities.

Implemented a smooth cutover process, minimizing site burden and maintaining data integrity.

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Results Summary

Korio successfully supported the execution of the trial, including post-go-live protocol amendments and further operational updates to ensure the study's continuity and integrity.

The study sponsor benefited from a robust and flexible RTSM solution that adapted to the unique challenges of this innovative trial design. By integrating seamlessly with various third party platforms, and by performing a seamless cutover from the retired RTSM provider to Korio, the Sponsor was able to ensure a consistent and repeatable site and participant experience.

Importantly, the RTSM solution developed for this study demonstrates significant reusability. Many of the features and workflows established for this complex trial are being adapted for use in the next phase of the study and for additional personalized medicine trials. This reusability not only streamlines the design and setup process for subsequent trials, but it also ensures consistency in data collection and operational procedures across the entire program.

Be Ready for the Trials Ahead with Korio **Schedule a Demo**

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