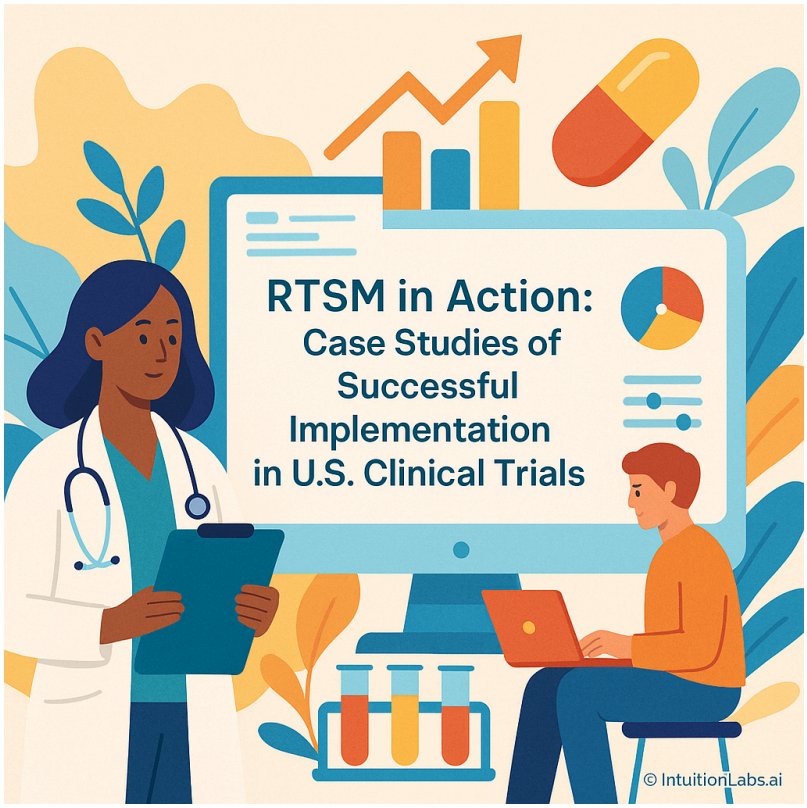
RTSM in Action: Case Studies of Successful Implementation

By IntuitionLabs • 4/30/2025 • 45 min read

rtsm clinical-trials case-studies pharmaceutical trial-management implementation drug-supply randomization clinical-operations best-practices healthcare-technology trial-automation



RTSM in Action: Case Studies of Successful Implementation

Randomization and Trial Supply Management (RTSM) systems have become a cornerstone of modern clinical trials, particularly in the U.S. pharmaceutical industry. RTSM (also known as interactive response technology, or IRT) combines **patient randomization** with **investigational product (IP) supply management**, ensuring that trials run efficiently and compliant with protocols. This report presents several real-world case studies of successful RTSM implementations by U.S.-based sponsors, illustrating how RTSM delivers rapid deployment, seamless integration with Electronic Data Capture (EDC) systems, improved drug accountability, and support for adaptive trial designs. Key statistics on RTSM adoption and impact are also highlighted, with data from industry surveys and trial outcomes. The goal is to provide IT professionals in pharma with insight into **RTSM's tangible benefits** and best practices gleaned from these implementations.

RTSM Adoption and Benefits in the U.S. Pharma Industry

RTSM technology is widely adopted across clinical trials of all phases in the U.S., driven by the need to manage growing trial complexity. In fact, **over 600 sponsors and CROs (including all top-20 pharma companies) have deployed RTSM solutions** as part of their eClinical toolset (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). A recent industry report noted that **61% of surveyed trial professionals consider rapid study start-up the top benefit** when evaluating RTSM providers. Sponsors seek systems that can **go live in under six weeks**, as lengthy IRT build times were identified as a major pain point (New Report Focuses On Clinical Trial Disruption And The Impact On IRT). Modern RTSM platforms address this by offering highly configurable, cloud-based solutions that can be **set up in days rather than months**. They also emphasize flexibility to handle mid-study changes: in one survey, **58% of respondents prioritized faster protocol amendment implementation** as a key need.

Beyond speed, RTSM delivers concrete improvements in trial efficiency and data quality. By automating randomization and drug supply, RTSM **virtually eliminates manual errors** that could occur with paper or spreadsheet systems. According to one 2024 analysis, trials using RTSM/IRT reported **30% fewer data issues** compared to trials without such technology (The Role of IRT in Improving Clinical Trial Data Accuracy). Automation can shorten trial timelines as well – for example, one study was able to **shave four months off its timeline** by leveraging an IRT solution, allowing the drug to reach market faster (The Role of IRT in Improving Clinical Trial Data Accuracy). These gains translate to significant cost savings and reduced operational risk.

Sponsors like Reata Pharmaceuticals have estimated **"per-trial savings from adaptivity were in the millions"** when using a modern RTSM in place of conventional IRT approaches.

From a supply chain perspective, RTSM systems dramatically improve drug accountability and inventory control. They enable **real-time tracking of drug inventory** at sites and depots, with automated resupply triggers to **prevent shortages or overstocking**, thereby minimizing waste (RTSM and IRT in Clinical Trials: Essential Guide-Signant). Early RTSM implementations showed that keeping only near-term stock on site and auto-replenishing based on actual needs could greatly reduce drug wastage (What is RTSM? Randomization & Trial Supply Management 101). Modern RTSM platforms also manage **expiry tracking, returns, and temperature excursions**, ensuring no expired or compromised product is dispensed (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This level of control not only cuts costs but also maintains compliance with regulatory requirements for investigational drug handling.

Finally, RTSM supports innovative trial designs that were previously challenging to execute. Complex randomization schemes (e.g. stratified or adaptive randomization) and **adaptive trials** (with dose adjustments, cohort additions, etc.) can be configured and managed through RTSM without custom programming. The ability to simulate randomization scenarios before deployment and adjust algorithms on the fly has been a game-changer for adaptive trials. For instance, RTSM's built-in simulation tools allow sponsors to test and ensure balance across sites and strata before a study begins. As trials increasingly move toward decentralized and hybrid models (with up to *50% of trials expected to use decentralized methods by 2024* (IRT: The Unsung Hero of Modern Trials - IQVIA)), RTSM provides a backbone to manage logistics and data centrally, ensuring patients receive correct medication on time wherever they are.

The following case studies illustrate these benefits in practice. Each example focuses on a specific aspect of RTSM implementation – rapid system deployment, EDC integration, enhanced drug accountability, and adaptive trial support – drawn from U.S.-based clinical trials or sponsors. **Table 1** summarizes the cases and their outcomes before we dive into detailed narratives.

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
Midmarket Dermatology Phase IV (200 patients, 10 U.S. sites) – *Integrated RTSM/EDC Sponsor:* Mid-sized	– **Rapid deployment:** Configurable RTSM set up in *"days rather than months"* to meet aggressive timeline. – **Unified platform:** Deployed as a pre-integrated module with the EDC system, enabling one	– **On-time launch:** Met aggressive start-up timelines for multi-site trial. – **Efficiency:** Sites used a single, intuitive system for

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
U.S. pharma (skin care)	interface for randomization and data capture.	both patient data entry and randomization, simplifying training and operations. – **Quality:** Built-in randomization simulation ensured balance and robust design before go-live.
Reata Cardiology Phase II (Adaptive) – *Agile RTSM for complex dose trial* *Sponsor:* Reata Pharmaceuticals (Texas, USA)	– **Adaptive design support:** Cloud RTSM configured to handle dose escalations/reductions and dropping of arms mid-study without coding. – **Fast, no-code setup:** *"100% configurable"* system; study build completed in **2 days**, leveraging integration with existing EDC (Medidata Rave).	– **Accelerated timeline:** Condensed what would have been 3 separate studies into 1, and completed RTSM build in **~2 days** (vs. 4–6 weeks typical). – **Mid-study agility:** Performed real-time protocol modifications (dose rule changes, cohort size adjustments) *without vendor intervention*, maintaining momentum. – **Cost savings:** Enabled an ambitious trial design while avoiding custom code; sponsor estimated **millions in**

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
		savings from the adaptive approach. – **Error reduction:** Eliminated manual tracking of 1,152 dosing rules (down to 88 rules configured) – reducing complexity and chance of error.
Schizophrenia Phase II (150 patients, multi-state) – *Drug Dispensation & Accountability* (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) *Sponsor:* U.S. pharmaceutical company (psychiatry)	– **Flexible dispensation:** RTSM accommodated variable visit intervals for patients with unstable schedules, ensuring each patient always had sufficient drug supply until next visit (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). – **Inventory optimization:** Automated use of soon-to-expire kits first and allowed backup kits, preventing patients running out while minimizing waste (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). – **Controls and tracking:** Stratified randomization across 3 subgroups to maintain balance (Case Study - RTSM - Phase II CNS - Schizophrenia Trial); system prevented duplicate enrollments across sites (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). All drug dispensation,	– **No missed doses:** Every patient remained continuously supplied despite irregular visits, thanks to backup kit allocation (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). – **Reduced waste:** No oversupply – drug shipments were precisely tailored, and expiring doses were used first, avoiding unnecessary waste (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). – **Accountability: 100% of dispensation and returns tracked.** Site staff and monitors

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
	returns, and destruction were logged with full audit trails (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial).	accessed automated reports for reconciliation of all returned and destroyed medication (including pill-level accountability) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). – **Data integrity:** The system's safeguards (e.g. duplicate subject alerts) preserved study blind and endpoint reliability (Case Study - RTSM - Phase II CNS - Schizophrenia Trial).
Cardiomyopathy Orphan Drug (Phase II→III) – *Cohort Management & Reporting* (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug	– **Complex cohort logic:** RTSM configured multiple cohorts with different drug combinations and schedules, including on-site titrations and dose adjustments per protocol (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). Ensured **seamless transition** of eligible patients from Phase II into Phase III continuation using the same system (Case Study - RTSM - Phase II Cardiovascular Trial -	– **Streamlined expansion:** Phase II patients rolled into Phase III smoothly with RTSM enforcing eligibility and preventing protocol deviations (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation).

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
Designation) *Sponsor:* U.S. biotech (cardiovascular; FDA orphan designation)	Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). – **Integrated data and reporting:** Provided real-time visibility of dosing and inventory levels to both site and sponsor teams. Adaptive dosing changes by investigators were captured immediately, updating drug supply needs in real time (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation).	– **Timely insights:** Sponsor received **instant reports on drug usage and inventory** across 30 sites, enabling proactive supply management even as dosing regimens varied (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). – **Extended use:** The sponsor was so confident in the system that they continued using it for the Phase III stage, citing strong performance in Phase II (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). – **Regulatory success:** The trial's efficient execution contributed to the therapy being granted **FDA Orphan**

Case Study (Trial)	Focus & Implementation	Outcomes and Benefits
		Drug designation in early 2021 (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation), a critical milestone for the program.

Table 1: Summary of real-world RTSM case studies, their focus areas, and key outcomes. Each case highlights a different facet of RTSM implementation (rapid deployment, system integration, drug supply management, adaptive design support), demonstrating substantial efficiency gains, error reduction, and support for complex trial needs.

Case Study 1: Rapid Deployment and EDC Integration in a Dermatology Trial

One mid-market pharmaceutical sponsor (U.S.-based) provides a clear example of how a modern RTSM can be deployed quickly and in a unified manner. The company was launching a dermatology Phase IV trial (approx. 200 patients across 10 U.S. sites) to evaluate an FDA-approved skin treatment in a new setting. **Speed and efficiency were key**, as the team had only a short start-up window and wanted to avoid delays in randomization and drug supply. They also preferred an integrated technology approach because they were already using an Electronic Data Capture system and hoped to minimize the number of separate tools sites needed to learn.

Solution: The sponsor selected a unified platform – *Medidata Rave RTSM* – which **comes pre-integrated with the Medidata Rave EDC system**. This meant the randomization and supply management module could plug directly into their existing EDC, providing a single interface for site users. Notably, the vendor's RTSM was highly configurable, requiring *no custom programming*, so the study requirements could be built and validated in a matter of days. In fact, the sponsor found that the RTSM could be **"set up for the study design in days rather than months,"** which was critical to meeting the aggressive timeline. The RTSM also included a **simulation tool for randomization** – allowing the team to test different randomization schemes and ensure balance across treatment arms and sites before the first patient enrolled. On the supply side, the system offered **automated inventory management** with configurable re-

supply triggers and predictive algorithms to ensure drug stock at each site was sufficient but not excessive. This would help prevent stock-outs at busy sites while avoiding waste at slower-enrolling sites – an important balance for a study with 10 scattered sites.

Outcomes: By using the unified RTSM/EDC solution, the sponsor was able to **launch the trial on schedule** and with far less effort than a traditional IRT deployment. The **implementation easily met the aggressive study timelines**. A major benefit was seen at the clinical site level: because randomization and data entry shared one system, *site staff only needed to log into one application* to both randomize the patient and capture study data. This streamlined workflow reduced training needs and user errors. The sponsor reported that a "wide range of users were able to be trained quickly" on the combined system. Site personnel also appreciated having **one intuitive interface** for all trial tasks rather than juggling separate IVR/IWRS and EDC systems. From a data perspective, integration meant that patient enrollment info flowed seamlessly into the RTSM for randomization, and treatment assignments flowed back into the EDC, with no manual reconciliation needed.

On the supply front, the RTSM's **predictive drug supply feature** helped the supply managers optimize depot shipments. They could *adjust supply plans per site* based on actual enrollment rates, and the system's alerts prevented any site from running low on the investigational product. At the same time, the drug wastage was minimized compared to past trials, because the system recommended only shipping what each site needed for the near term (instead of large buffer stocks). In sum, this case study showed how an **integrated RTSM+EDC approach** enabled **rapid deployment** and efficient operations. The sponsor successfully embraced a new technology without delaying their trial – a strong proof point that RTSM can **accelerate study start-up while maintaining quality**. Notably, this mid-sized sponsor transitioned from relying solely on EDC to adding RTSM in its toolkit and found that the **unified system "easily met" their needs for speed and integration**.

Case Study 2: Agile RTSM Enables an Adaptive Cardiology Trial (Reata Pharmaceuticals)

Reata Pharmaceuticals, a U.S.-based biotech, faced an ambitious trial design in a Phase II cardiology study. The trial had **multiple objectives and an adaptive design**, requiring the flexibility to adjust dosing and cohort structure based on interim data. The protocol allowed for **dose escalations and reductions** and even dropping or adding treatment arms during the trial as data emerged. Such complexity is challenging for traditional IRT systems, which often require extensive re-programming for any design change. Reata's small patient population and fast-paced development timeline meant they **could not afford lengthy downtime or expensive custom coding** to implement changes. They needed an RTSM that could be **rapidly deployed and easily modified mid-study**, all while ensuring randomization integrity and proper drug

supply management. Integration with their existing data systems was also a priority since Reata was already using Medidata Rave EDC on other studies.

Solution: After evaluating options, Reata chose **Medidata Rave RTSM** for its **configurability and adaptive capabilities**. Uniquely, this RTSM did not require any new coding to set up the study or to make mid-study changes – it was advertised as the *"only 100% configurable solution"* on the market. As a result, the initial study setup was astonishingly fast: the *total time to configure the RTSM for the trial was under two days* (excluding user acceptance testing). (Reata's team noted they "never believed it would be only two days to get Rave RTSM set up" – highlighting how unusual such speed was in their experience.) The RTSM was deployed as a unified module alongside Reata's EDC, so sites would use the **same web portal for entering patient data, randomizing subjects, and managing drug dispensation**.

Critically, the system provided **adaptive trial support** features out-of-the-box. For instance, it allowed rule-based dose titration schemes that could be adjusted on the fly, and the ability to **instantly drop a study arm** if needed. Reata utilized these features to implement their complex dosing algorithm. The platform also included dynamic stratification and randomization capabilities to ensure patient assignments remained balanced even as cohorts changed. During the trial, when interim analysis indicated a need to modify dosing or merge cohorts, Reata's in-house team (with vendor guidance) could make those changes through configuration settings, *without needing the vendor to write new code or pause the study*. This level of self-service was a major shift from typical IRT processes, which might require weeks to deploy a protocol amendment.

Outcomes: Reata's adoption of an agile RTSM paid off significantly. They managed to **merge three planned studies into one**, executing multiple trial objectives under a single protocol. This streamlined approach, enabled by the adaptive RTSM, **saved both time and cost** – the vendor estimated that the ability to design an adaptive trial (versus separate sequential trials) yielded *"per-trial savings… in the millions"* for Reata. In terms of timelines, the **start-up time was dramatically reduced**. Traditional IRT systems often take over a month to build (indeed, an industry survey found 56% of trials take 4–6 weeks to start up on legacy IRT), yet Reata's RTSM was live in roughly **48 hours**. This meant the study enrolled its first patient much sooner than expected, gaining a head start.

During the trial conduct, the **benefits of mid-study flexibility became clear**. Reata was able to perform **real-time, mid-study changes without vendor intervention**. For example, when safety data suggested a dose level should be lowered, the RTSM settings were updated within hours to implement a new dosing schedule for all future dispensations. Similarly, an entire treatment arm could be closed (stopped) through a configuration change, and the RTSM would immediately cease randomizing new patients to that arm – all while maintaining blind and allocation ratios as appropriate. These adjustments did **not require pulling the study offline or lengthy revalidation**; they were applied and effective almost immediately, showcasing the "agility and control" the sponsor gained.

Reata also observed improvements in data quality and operational efficiency. Because the RTSM was unified with their EDC, data consistency was ensured – patient IDs, visit dates, etc., did not need reconciliation between systems. The **integrated platform eliminated error-prone manual data transfers**, reducing risk. Notably, the system drastically **reduced the manual work for managing dosing scenarios**: Reata had initially planned 1,152 separate Excel-based titration rules to cover all dosing permutations, but with the RTSM's rule engine, this was simplified to just 88 rules configured in the system. This *92% reduction* in complexity cut down on opportunities for error and made the trial design far easier to manage.

In the words of Reata's bioinformatics manager, after seeing the results, *"I'm a convert!"* to the new RTSM approach. The successful execution of this adaptive Phase II trial not only kept Reata on track but also demonstrated a model that they could reuse for future studies (scaling up to Phase III). Overall, this case demonstrates how a **highly configurable RTSM enabled rapid start-up and adaptive design execution**, resulting in faster progress and significant resource savings in a U.S. clinical trial.

Case Study 3: Improved Drug Accountability in a Schizophrenia Trial

Effective drug accountability – ensuring that investigational product is dispensed correctly, tracked, and either consumed or returned/destroyed with proper documentation – is a crucial aspect of trial management. A **Phase II schizophrenia trial** conducted by a U.S. sponsor provides a compelling example of how RTSM can strengthen drug dispensation processes. This trial spanned 150 adult patients at 35 sites, and had an unusual challenge: patients' visit schedules were highly variable (due to the nature of the psychiatric condition) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). The investigators needed to give each patient enough drug supply to last until their next visit, which might be an unpredictable number of weeks, but also avoid giving too much (to prevent waste or misuse). Additionally, patients were stratified into three subgroups based on their background medication, each requiring a different blinded dose of the investigational drug or placebo (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). Managing **multiple cohorts and variable visit intervals** made manual drug supply management infeasible. Past trials had seen issues like patients running out of medication or sites accumulating excess, expired drug. Moreover, because some patients sought treatment at multiple sites, the sponsor needed a system to **prevent duplicate randomizations** (the same patient enrolling twice) which could skew efficacy results (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). Finally, the drug being tested was expensive and controlled, so **tracking returns and destruction** of unused supplies was a compliance requirement (Case Study - RTSM - Phase II CNS - Schizophrenia Trial).

Solution: The sponsor implemented *Signant Health's SmartSignals RTSM* to tackle these dispensation challenges (Efficient Drug Dispensation in Schizophrenia Studies-Signant Health).

The RTSM was configured with several key features focusing on drug accountability:

- **Flexible Dispensing Quantities:** For each patient visit, the system calculated the amount of drug needed until the next expected visit, based on the protocol's allowances for visit window variability. Sites could dispense a **custom number of doses per patient** as guided by the RTSM, rather than a fixed kit amount, ensuring patients had enough medication but not excessive oversupply (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). The RTSM also allowed marking an **existing kit as a backup** or requesting an extra kit if a patient's visit was delayed, so that *no patient would ever be left without treatment* (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This capability proved vital in this trial, given patients sometimes missed scheduled visits and came later – the site could give them an extended supply in advance safely.

- **Expiry Management and Kit Allocation:** The system tracked the expiry dates of all kits at sites. It would prompt site pharmacists to use the **soonest-to-expire kits first** when dispensing (first-expiry-first-out), thereby preventing kit expirations on the shelf (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). It also verified that any drug a patient held would remain within potency (stability) range for the duration of use (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This was especially important here because patients might hold drug for longer periods between visits. By automating this, the RTSM ensured compliance with stability requirements and **minimized drug wastage**.

- **Cohort and Randomization Control:** The RTSM enforced the stratified randomization – patients were categorized into the correct subgroup and assigned the appropriate blinded dose or placebo per that subgroup's ratio (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). Even if a patient's visit schedule changed, the system maintained overall **study balance across the three strata**. Furthermore, to address the issue of some patients visiting multiple clinics, the RTSM included a feature to detect potential **duplicate registrations**. It issued warnings if a subject with the same details was enrolled at a second site, thereby preventing the scenario of one patient inadvertently being randomized twice (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This protection preserved the integrity of the data (no double-counting of a single individual's outcomes).

- **Comprehensive Returns Tracking:** Perhaps the most significant improvement was in the area of **drug returns and destruction accountability**. The RTSM kept a **full audit trail** of every kit's status – from release to a site, to dispensation to a patient, to return (if unused or partially used), and final destruction (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). Site staff used the RTSM to log any returned pills or vials when a patient came back or discontinued. The system's reporting module then provided a **"returns accountability summary"** for monitors and stakeholders, listing which kits were returned by which patient, the quantities, and whether they were sent for destruction (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). When destruction occurred (often by an external vendor or pharmacy), that too was logged. Impressively, the RTSM was configured to allow **pill-level accountability** – every single pill dispensed could be accounted for in the logs when returned or destroyed (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). Automated notifications would alert the study team whenever a return was recorded or a destruction was logged, keeping everyone updated (Case Study - RTSM - Phase II CNS - Schizophrenia Trial).

Outcomes: The implementation of RTSM in this schizophrenia trial led to **far better drug management** than previous manual approaches. First and foremost, **no patients went without medication** during the study – even when visits were delayed – because the system anticipated needs and facilitated backup supplies (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This helped maintain treatment continuity, which is critical for both patient well-being and data integrity (avoiding gaps in dosing). Secondly, the sponsor noted that **drug waste was significantly reduced**. By tailoring dispensed amounts to each patient's real needs and using expiring drug first, they avoided the common scenario of sites returning large quantities of expired unused drug at study end.

The **accountability of drug supplies was essentially airtight**. The monitors could generate on-demand reports from the RTSM to reconcile inventory: every single dose shipped, dispensed, returned, or destroyed was time-stamped and traceable (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). This not only satisfied compliance auditors but also freed study coordinators from maintaining complex paper logs. One specific benefit was in detecting duplicate patients – by catching attempted re-enrollments, the system **prevented a serious protocol violation** that could have skewed the trial's efficacy results (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). The notification and reporting features of the RTSM also improved operational transparency; for instance, site pharmacists were immediately alerted to any expiry updates or if a patient's drug kit was recalled, enabling quick action.

In summary, this case demonstrates **improved drug accountability through RTSM**: the sponsor was able to **maintain precise control over drug dispensing and returns** across dozens of sites and unpredictable patient schedules. The RTSM effectively ensured compliance (every dose accounted for) and efficiency (no stock-outs or oversupply). Such robustness is particularly important in psychiatric trials (where patient adherence can be variable) and with controlled substances. By leveraging RTSM, the company achieved a level of control and insight that would be nearly impossible to replicate with manual processes, thus safeguarding both patient safety and data quality.

Case Study 4: Supporting Adaptive Cohort Management in an Orphan Drug Trial

Adaptive trial support is a hallmark benefit of advanced RTSM systems, as shown in a U.S.-led cardiomyopathy trial by an emerging biopharma. This company was testing a new therapy for a rare heart condition, aiming for an FDA Orphan Drug designation. The trial design was **complex, involving multiple cohorts (Phase II and an open-label extension into Phase III)** with different drug combinations and dosing schedules for each cohort (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). Patients who completed Phase II, if eligible, would roll over into Phase III to continue treatment, so the RTSM needed to handle **crossover of patients between phases** without breaking the blind or losing track of

their treatment status (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). Additionally, investigators had discretion to adjust dosing for individual patients based on response (a semi-adaptive approach), meaning the drug supply needs at each site could change dynamically (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). The sponsor required rapid visibility into these dosing changes to manage the supply chain. The challenge was to deploy an RTSM that could **orchestrate all these moving parts** – multi-cohort randomization, mid-study transitions, and real-time inventory updates – in a *single system*.

Solution: The trial team implemented *Signant's SmartSignals RTSM* as the backbone for randomization and supply. The vendor's project team worked closely with the sponsor to configure the RTSM to the detailed protocol needs (Cohort & Inventory Management for Cardiomyopathy Trial-Signant Heath). Some key aspects of the implementation included:

- **Cohort & Phase Transition Management:** The RTSM was programmed with all cohort definitions and randomization ratios. As patients were enrolled, the system placed them into the correct cohort and treatment group per the protocol. Crucially, when a patient in Phase II met the criteria to continue into Phase III, the RTSM *seamlessly "migrated" that patient's record* to the Phase III part, preserving their ID and relevant data (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). It ensured that only authorized patients could roll over (by checking eligibility flags) and prevented any duplicate entry. This automation saved the team from re-registering patients in Phase III and eliminated potential errors in linking Phase II and III data. The sponsor's team highlighted that this **seamless transition capability** was a major reason they chose to switch to Signant's RTSM from their previous provider (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation).

- **Complex Dosing and Visit Schedules:** The RTSM accommodated the **"numerous cohorts, each with varying drug combinations and visit schedules"** as required (Cohort & Inventory Management for Cardiomyopathy Trial-Signant Heath) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). The vendor's setup team studied the intricate on-site titration scheme (where investigators could adjust doses) and configured the RTSM's logic to match it (Cohort & Inventory Management for Cardiomyopathy Trial-Signant Heath). For instance, if a patient increased to a higher dose cohort mid-treatment, the system would recognize this and ensure the next dispensation was the correct new dose. All these dose changes were tracked in the system's data, giving the sponsor confidence that dosing was being executed per protocol for each patient.

- **Real-Time Reporting & Alerts:** Given the adaptive nature of dosing, the RTSM provided **dynamic reports on patient dosing status and inventory**. The sponsor had access to a dashboard showing how many patients were at each dose level in near real time, and how much drug each site had on hand (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). Whenever a patient's dosage changed or a new shipment was triggered to a site, notifications could be sent to the supply manager. This allowed the supply chain team to proactively ship additional drug or reallocate stock if, say, many patients escalated to higher doses (which consume drug faster). Such integration of **clinical data with supply logistics** ensured there were no delays in drug availability despite the trial's adaptiveness.

- **Agile Team and Ongoing Support:** The case study notes that the sponsor benefited from the vendor's expert support team including biostatisticians, solution architects, and project managers who held regular meetings with the sponsor (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). Through this collaboration, the system was finely tuned and any mid-study adjustments (like adding a new cohort or modifying visit frequency) were implemented quickly by the RTSM team. Essentially, the **agile RTSM design and responsive support** meant that the technology kept up with scientific decisions.

Outcomes: The RTSM implementation was pivotal in the success of this trial. All eligible patients were able to **transition from Phase II to Phase III** without incident, maintaining treatment continuity (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). The sponsor later noted they were *"pleased with the performance of Signant's RTSM during Phase II and successfully extended its use into Phase III."* (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) This continuity indicates trust in the system's ability to scale with the trial. The real-time data access provided by RTSM gave the sponsor confidence in decision-making; for example, safety monitoring committees could see up-to-date enrollment and dosing data, and the sponsor could ensure **sites were well-supplied with drug at all times** (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation).

Perhaps the most tangible outcome was that the **compound under study received FDA Orphan Drug designation in early 2021** (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). While many factors contribute to such designations, the sponsor publicly credited the RTSM solution with helping the Phase II trial run efficiently, which in turn allowed them to gather the data needed for the Orphan Drug application in a timely manner (Cohort & Inventory Management for Cardiomyopathy Trial-Signant Heath) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation). In other words, the technology helped accelerate the development process for a therapy in a critical, unmet medical need area.

This case exemplifies how an RTSM can **support adaptive, complex trials** even for smaller biopharma companies. By integrating cohort management, flexible dosing, and supply chain oversight, the RTSM acted as a unifying platform that kept the trial on track. The success of the trial (and progression to Phase III with regulatory recognition) underscores the value of choosing an RTSM capable of handling advanced trial designs. As trials move toward more adaptive and patient-centric designs, having such a system in place becomes increasingly important.

Conclusion

Across these case studies – spanning dermatology, cardiology, psychiatry, and rare disease trials – the advantages of robust RTSM implementations are evident. U.S. pharmaceutical companies have leveraged RTSM to **accelerate study start-up**, with configurable systems that deploy in days rather than the weeks or months required by older interactive response systems.

They have achieved **seamless integration with EDC and other eClinical tools**, eliminating duplicate data entry and reducing errors. In terms of **drug accountability**, RTSM has provided end-to-end visibility of the supply chain: sponsors can track every dose from depot to patient to destruction, preventing misdispensation and ensuring compliance (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial). The technology's support for **adaptive trial designs** has enabled companies to run innovative studies that merge multiple phases or adjust to emerging data – all while controlling cost and maintaining data integrity.

Industry data reinforces these successes. With the majority of sponsors prioritizing faster timelines and flexibility in RTSM solutions (New Report Focuses On Clinical Trial Disruption And The Impact On IRT), vendors have delivered systems that yield significant efficiency gains. RTSM adoption continues to rise as trials grow more complex; the use of such eClinical technologies in R&D was growing ~22–23% annually and expected to continue on that trajectory (New Report Focuses On Clinical Trial Disruption And The Impact On IRT). The real-world cases in this report put numbers to that narrative – for instance, a 92% reduction in manual dosing tasks in Reata's trial, or a 30% drop in data queries/errors observed with IRT use in one analysis (The Role of IRT in Improving Clinical Trial Data Accuracy), and multi-million dollar cost savings from study consolidation.

For IT professionals in the pharma industry, these case studies highlight important **best practices**: choose an RTSM that is highly configurable and **supports rapid changes** (to avoid delays with protocol amendments), ensure it can **integrate with your EDC/CTMS** for single-source data flow, and look for advanced inventory management features to **optimize drug supply and reduce waste**. Additionally, having strong vendor support or in-house expertise to fully utilize the RTSM's capabilities can make the difference in harnessing its full value (as seen with the dedicated teams in the Signant and Medidata examples).

In conclusion, **Randomization and Trial Supply Management systems have proven their worth in real-world U.S. trials** by increasing efficiency, accuracy, and adaptability. Whether it's speeding up a Phase I oncology study or managing the nuance of a Phase III adaptive trial, RTSM technology – backed by sound implementation strategy – can be a game-changer. As clinical trials continue to evolve (with trends like decentralized trials, complex endpoints, and personalized therapies), RTSM will remain an essential tool to ensure that the right patient gets the right drug at the right time, all while maintaining the rigor and reliability of the trial's results. The case studies presented serve as blueprints for success, demonstrating how embracing RTSM innovation can lead to **faster, smarter, and more reliable clinical development** in the pharmaceutical industry.

Sources:

- Medidata Solutions – *Case Study: Meeting Randomization and Supply Challenges in an Innovative Dermatology Study*

- Medidata Solutions – *Case Study: Reata Saves Millions Leveraging the Adaptive Functionality of Rave RTSM*
- Signant Health – *Case Study: Managing Complex Dosing Schemes (Cardiomyopathy Orphan Trial)* (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation)
- Signant Health – *Case Study: Solving Study Drug Dispensation Challenges (Schizophrenia Trial)* (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial)
- Signant Health – *RTSM and IRT in Clinical Trials: Essential Guide* (Blog) (RTSM and IRT in Clinical Trials: Essential Guide-Signant)
- Clinical Leader – *State of the Industry: Embracing Trial Change (Almac report summary)* (New Report Focuses On Clinical Trial Disruption And The Impact On IRT) (New Report Focuses On Clinical Trial Disruption And The Impact On IRT)
- YPrime – *IRT Trends Today & Tomorrow* (Industry Survey Whitepaper)
- Healthy Jeena Sikho (Blog) – *Role of IRT in Improving Data Accuracy* (The Role of IRT in Improving Clinical Trial Data Accuracy)
- IQVIA – *IRT: The Unsung Hero of Modern Trials* (HIT Consultant) (IRT: The Unsung Hero of Modern Trials - IQVIA)
- Signant Health – *About Signant (corporate info)* (Case Study - RTSM - Phase II Cardiovascular Trial - Cardiomyopathy Orphan Drug Designation) (Case Study - RTSM - Phase II CNS - Schizophrenia Trial)

DISCLAIMER

The information contained in this document is provided for educational and informational purposes only. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability of the information contained herein.

Any reliance you place on such information is strictly at your own risk. In no event will IntuitionLabs.ai or its representatives be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from the use of information presented in this document.

This document may contain content generated with the assistance of artificial intelligence technologies. AI-generated content may contain errors, omissions, or inaccuracies. Readers are advised to independently verify any critical information before acting upon it.

All product names, logos, brands, trademarks, and registered trademarks mentioned in this document are the property of their respective owners. All company, product, and service names used in this document are for identification purposes only. Use of these names, logos, trademarks, and brands does not imply endorsement by the respective trademark holders.

IntuitionLabs.ai is an AI software development company specializing in helping life-science companies implement and leverage artificial intelligence solutions. Founded in 2023 by Adrien Laurent and based in San Jose, California.

This document does not constitute professional or legal advice. For specific guidance related to your business needs, please consult with appropriate qualified professionals.