
Optimize RTSM for Efficient Clinical Trial Implementation

Because Every Patient Counts

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The most challenging aspects of conducting a randomized controlled trial (RCT) include the timely setup of the systems required for the conduct of the study, recruitment, retention, and randomization of patients, and trial supply logistics.

The optimization of Randomization and Trial Supply Management (RTSM) is not always straightforward, especially as clinical trial designs become more complex (e.g., adaptive designs). Rapid changes in standard-of-care treatment—especially in oncology studies—can make a clinical trial protocol obsolete before the sponsor implements a study. Further, global clinical trials face mounting competition for patients in an environment with tightening privacy and security considerations for patients and trial supplies, respectively. Specifically, the recently passed General Data Protection Regulation (GDPR), which regulates personal data in the European Union,¹ not only affects European drug sponsors but is relevant to every multinational company with a European presence.

Furthermore, expectations remain high that clinical development teams will successfully implement and execute clinical programs, despite few available resources.

In this context, drug sponsors turn to sophisticated RTSM systems, supported by highly proficient teams, for rapid and efficient implementation of clinical trials. This approach instantly configures systems to address all required trial elements (e.g., randomization, trial design considerations, trial supply dispensation, study endpoints).

Overall, selecting the optimal RTSM system can be a daunting task: there are dynamic components to track, and multiple systems and stakeholders are involved in the decision-making process. However, appropriate planning and implementation significantly minimize the risks and complexities associated with RTSM.

In this paper, we discuss the benefits that an optimized RTSM system can have for clinical trial sponsors.

The Importance of Optimizing an RTSM System

Improper implementation of RTSM systems can lead to stakeholder frustration, significant financial losses, and delays in medicines reaching patients.

The way in which clinical trials are designed and implemented impact patients' and investigators' decision to participate; patients may even be switched into a competitor's trial. Risk increase if the underlying systems used for trial setup, recruitment, and randomization do not operate flawlessly.

Dispensing the investigational product must proceed perfectly, and the underlying systems must be reliable to supply the product appropriately at investigational sites. Once a site has randomized, suboptimal systems can create trial supply issues. Outlining an optimal supply plan at the outset ensures that drug products are shipped at the appropriate intervals, so that inventory is not held at sites with slow or no enrollment. Having the right amount of investigational drug product at each site to match the respective subject enrollment rates is no small feat, and getting the supply right is key because investigational drug products can be expensive to produce, store and transport. Good implementation significantly reduces labeling and shipping costs and packaging waste.

¹ https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-does-general-data-protection-regulation-gdpr-govern_en

In our experience, studies that suffer from trial supply issues are riddled with underlying difficulties that quickly escalate and cause major frustration for clinical staff and patients. These studies are flagged as being afflicted with trial supply problems, and investigators and site physicians are then dissuaded from enrolling patients into the study, especially if there is a competing trial without these issues.

Appropriate Planning and Implementation Is Key

Whether a clinical trial runs efficiently hinges not only on the design of the study but also on proper consideration and planning in the design of the RTSM system to be used. Additionally, the efficient conduct of a study depends on the level of experience of the professionals responsible for configuring the RTSM systems. Appropriate upfront planning coupled with a proven implementation process (backed by a skilled and experienced team) can circumvent common hazards and frustrations that result from the many complexities associated with study conduct and trial supply logistics.

Advancements in computer hardware and software technologies have enabled the development of phenomenal applications to support the efficient conduct of clinical trials. While earlier interactive voice response and web response systems adequately handled static, predefined requirements, today's clinical trials take place in an adaptive environment with constantly changing requirements and priorities. Therefore, systems with great flexibility are necessary to not only handle predefined demands but also implement changes quickly and easily without having to program de novo code, which can be slow and costly.

Currently available solutions eliminate disparate software applications and offer unified platform solutions that are user friendly and allow for management of data collected from all the different components of study conduct in a centrally located source that is available on demand. The best solutions are fully configurable and encourage study implementation to happen on an accelerated timeline.

In partnership with a drug sponsor, Medidata co-developed a new functionality in Rave RTSM that enables users to pool clinical supply inventory across multiple clinical trials at the same research site. The effect of this enhanced functionality is as follows:

40% ↓
Packaging Waste

34% ↓
in Shipping Costs

35% ↓
in Data Entry Time

Further benefits include:

- Simple and fast data entry in a single system, which leads to less frustration from multiple cumbersome systems
- Time saved by learning a single system with single sign-on credentials
- Significantly reduced implementation times because custom coding is not required. Implementation can be as quick as three weeks, compared to 12 weeks or more for custom-coded solutions.
- Quick resolution of data clarifications and data-entry errors
- Optimization of trial supply plans so the investigational drug is not overstocked, overrun, or expiring. Ideal systems run nightly predictive shipping algorithms and conduct regular surveillance across sites to make sure trial supplies are adjusted based on enrollment. Resupplying only when necessary keeps shipping and labeling costs under control.

“I’ve worked with Medidata before at different stages of my career, but specifically working with this team [Rave RTSM Live Study Management Services]. I’ve not seen that level of understanding a clients’ needs parlayed into actual work...and to get it done efficiently. It was a great experience”

Castle Creek Interview

Experienced Partners Increase Efficiencies

In addition, working closely with an experienced partner pays huge dividends in the long run. An experienced and technology-savvy partner provides and valuable insights that only come with hundreds of client experiences and decades of work in clinical trial design and implementation.

Experts of this caliber circumvent common pitfalls that are often overlooked and increase the risk of trial failure. Sponsors can focus on what they do best, while leveraging the expertise of partners to optimize RTSM efficiencies.

Additionally, relying on an experienced partner to perform the operational aspects of a clinical trial (e.g., Live Study Management) offers the benefit of deep expertise with RTSM and execution that goes smoothly because of familiarity with many of the common challenges. This level of depth means that an expert support team either has the knowledge or can find the information needed to accomplish a task quickly or solve a problem efficiently.

Partners that engage in Live Study Management see a tremendous value-add that can be the difference between a successful trial and a failure. Seek partners that not only use optimized clinical trial technologies but also:

- Have intimate understanding of study designs, including important criteria and underlying assumptions
- Monitor study progress on an ongoing basis, including enrollment and trial supplies
- Regularly monitor key performance indicators (e.g., enrollment), which is crucial for adaptive trial designs
- Offer the ability to open/close cohorts on the fly, adjust patient caps for cohorts, and adjust study design and supply. These modifications allow studies to reach endpoints earlier. Medidata's Edit Live Design for Rave RTSM is one example of a solution with this capability.

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