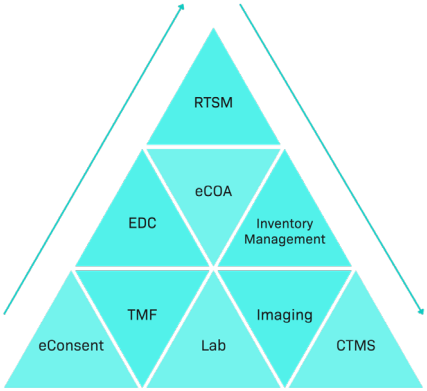
Study, Not Software: Aligning RTSM to the Protocol

James Stringer

Randomization and Trial Supply Management (RTSM) is a crucial component of clinical trials. To ensure successful outcomes, RTSM solutions must align with the study protocol and the other systems in use. However, one of the most critical considerations is often overlooked—how the design of RTSM impacts its users.

The Relationship Between RTSM and Other Systems



RTSM sits at the center of various clinical trial systems that may or may not be integrated. While the connection between RTSM and other systems is important, the bigger question is:

How does the RTSM design serve the study and its protocol?

Data Capture vs. Data Decision

Many clinical trial systems, such as EDC, eCOA, and eConsent, are data capture tools that gather information for analysis at a later stage. RTSM, however, operates differently. It processes data that requires immediate decisions, including:

- Stratifying subjects
- Assigning treatment arms
- Allocating inventory
- Sending notifications
- Determining if site inventory is suitable for subject allocation
- Triggering shipments
- Integrating with other trial systems

Unlike other systems, RTSM demands real-time data accuracy, as decisions made within the system directly influence trial logistics and outcomes.

RTSM: Focusing on the Study, Not Just the System

RTSM platforms, regardless of the vendor, are built to ensure that the correct medication and supplies are available at the right time and location. While they often adhere to study protocol requirements, there's room for more flexibility and creativity in design. Instead of rigidly following protocol guidelines, RTSM design should be flexible enough to accommodate real-world adjustments as in these two common scenarios below.

Flexibility RTSM Design for Real-World Scenarios

Example 1: Mid-study changes

Consider an oncology study, where the protocol says that there will be up to 20 cycles per subject (including a randomization visit). Most RTSM vendors will build in 20 scheduled visits, labeled per the naming convention in the study, and create an integration to send those 20 scheduled visits to EDC. However, oncology studies frequently get extended. Should a change be required mid-study, there is time pressure to deliver that enhancement because patients will be coming in for visit 21.

Good RTSM platforms allow for flexibility in system design to deliver on the requirements of the protocol. Creativity should be part of RTSM design, taking a protocol worth of requirements and thinking about how best to apply the functionality of a platform in ways that best service the study.

In this example, RTSM could use an unscheduled visit feature, renamed as "Allocate New Medication," allowing for additional cycles without requiring mid-study system changes. This would reduce the pressure on users and eliminate the need for rapid system enhancements when protocol changes arise.

Example 2: Weight-based dosing study

Consider a weight-based dosing study where the dose for each subject is calculated. Instead of having RTSM automatically assign the dose, it could allow clinicians the flexibility to select a dose based on their judgment. This flexibility enables clinicians to provide the best care for their patients without the rigidity of predetermined system calculations.

User-centric design reduces the burden of data entry

RTSM is most often used by investigators and clinical research coordinators, but pharmacy users should also be considered. Their main goal is to spend more time with patients and less time navigating the system. Therefore, RTSM should be designed to simplify their workflows.

It is often the first system where data is entered, whether to create a subject record or allocate medication. While it may be tempting to load RTSM with data to integrate with other systems, research conducted by Signant Health shows that site users prioritize patient interaction. Therefore, RTSM should be designed to capture only the necessary data to expedite patient care and study conduct.

Conclusion: RTSM Must Align with the Study Protocol

Good RTSM design isn't just about configuration—it's about creative configuration that serves both the study and its users. The goal is to make the system as intuitive as possible, allowing users to focus on the clinical trial and patient care rather than navigating software. As experts in RTSM solution design and implementation for more than 25 years, we ensure each instance aligns to the protocol, users, and study goals.

Click to learn more about Signant SmartSignals® RTSM?

Interested in reading more blogs from The Signal?

SUBSCRIBE

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.