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The Signal

Bringing RTSM in From the Cold: Integrated Approaches for Optimized Trial Conduct

In the fast-paced world of clinical research, Randomization and Trial Supply Management (RTSM) systems play a pivotal role in ensuring the success of trials. However, a common challenge is that these systems are often one of the last to be considered in eClinical systems implementation for any particular study. In my recent presentation for Clinical Leader's IRT Solution Expo in October 2023 which you can view below, I explore the importance of integrating RTSM with Electronic Data Capture (EDC), electronic Clinical Outcome Assessments (eCOA), and other eClinical solutions from the outset for optimal outcomes. Here is a summary:

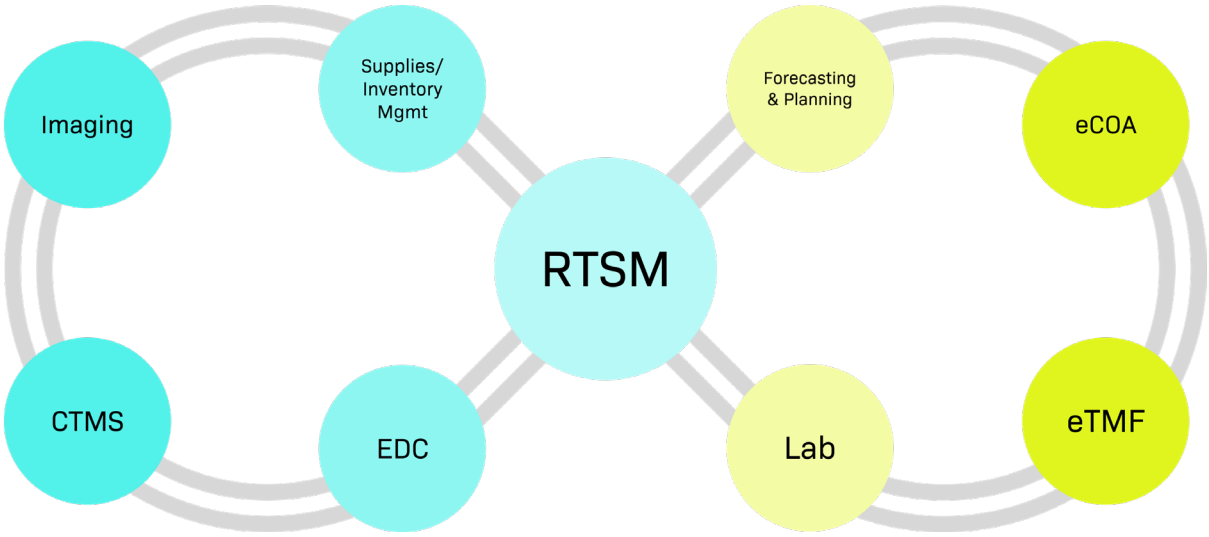
The Challenge of RTSM as the Last Consideration

As leaders in RTSM solutions for over 20 years, we know that RTSM is typically one of if not the last items on the checklist during trial planning. Whether part of a comprehensive platform or not, the design and implementation of RTSM often come late in the process, facing the pressure of meeting the "first patient in" milestone.

Late integration of RTSM means it inherits decisions made upstream in the trial process. Packaging design, dispensing considerations, and other critical elements may not align with the needs of RTSM (or enable a better RTSM solution), leading to a domino effect of challenges that could need to be addressed post-implementation, depending on complexity. The rush to meet milestones exacerbates these issues and often leads to an RTSM design that may not scale with the needs of the study, given we know that all studies change from their first initial protocol version.

RTSM as a Part of a Comprehensive Platform

If we approach RTSM as an integral part of an eClinical ecosystem, we can align the RTSM system design with EDC, eCOA, supplies inventory management, CTMS, and other components from the beginning. The trial benefits from a cohesive structure that minimizes integration challenges and optimizes processes. RTSM per-study can also consider what may change in the protocol, and build in scale to the study to reduce the number of study enhancements required.



The Need for Upstream Involvement

I recommend a shift in the paradigm and for stakeholders to involve RTSM in the trial's early stages. By treating RTSM as part of a platform and not merely a standalone software, decision-making upstream can be streamlined, potentially reducing its perceived role on the critical path. Our goal should be to deliver a clinical trial suite that works with the trial, with the users, and most critically, with the patients so that the study as a whole is successful.

Reducing Site Burden

Another benefit to early consideration of RTSM design and to Signant's integrated-platform approach is reduced burden on trial sites. Integrating RTSM seamlessly into the trial process, guiding sites through patient interactions, and adopting a patient-centric approach contribute to a smoother and more efficient workflow.

RTSM as Both Clinical and Inventory Management

RTSM systems serve both clinical and inventory management functions. While a centralized platform ensures cohesive data capture, an enterprise-level inventory management tool such as Signant SmartSignals GxP Inventory enhances visibility and reduces redundancy, among many other improvements in IP management. We need to start thinking about trials as part of a portfolio, rather than per study systems/implementations/designs.

Bringing RTSM in From the Cold

In conclusion, the integration of RTSM into a comprehensive eClinical platform marks a paradigm shift in the approach to clinical trials. By considering RTSM early in the trial design process and aligning it with other critical components, stakeholders can mitigate challenges,

reduce site burden, and ultimately improve the overall success of clinical research.

Watch my short presentation from Clinical Leader's recent IRT Solutions Expo for additional details on each of these items above:

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