Top 5 Dos and Don’ts of RTSM

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For both sponsors and vendors, there are several best practices, as well as many common mistakes that we all have encountered. Despite our collective experience, these issues continue to arise repeatedly. Here’s a list of common dos and don’ts to help you identify and mitigate these recurring challenges.

Note: These are in no particular order and reflect my personal opinion.

Do remember what is being purchased

In our industry, the focus is RTSM as a software system. We emphasize functionality, whether features are configured or customized, what SDLC is being followed and on timelines when RTSM services are contracted. While these aspects are crucial and cannot be overlooked, there is an even more important factor.

When RTSM is purchased, it’s being purchased from a vendor, a vendor with specialist experience and expertise that may not be available within the sponsor or CRO organization. Utilize this expertise as much as using the software and its capabilities. Although expertise and experience might not be explicitly listed on the quotation, they are an integral part of the service provision.

It’s a purchase of expertise as much as it is a purchase of software.

Don’t think just about First Patient In

First Patient In (FPI) is one of the most critical milestones in a study, deserving significant focus. However, consider this: an RTSM system is built for a study within 4

to 6 weeks, while the study itself can last anywhere from 2 to 5 years. During the study build, everything is tightly controlled, and quality is paramount. But once the study goes live then, as the saying gets paraphrased "no study survives through to the end without change following contact with a patient." Studies always change.

Therefore, it's important to think not just about the study at its inception but also about how it will be managed and evolve post-FPI. When designing an RTSM for a study, incorporate resilience and forward-thinking features that can potentially save the need for enhancements down the line.

Do consider the impact of decisions

A lot of decisions get made during the design of a clinical trial; be they decisions on data or packaging and distribution design. Often those decisions are made in isolation but have a large downstream impact. Let's consider the decisions we make and think about the impact on all of the stakeholders. A decision taken about the study design, that changes something simple for RTSM into something complicated which may affect timelines is a decision that RTSM should be involved with, not left to accept later after the decision has been made.

Don't involve RTSM too late

If it's beneficial to involve RTSM early, then conversely, it's a bad thing to leave RTSM development until closer to FPI. That's common sense. But why? Delaying RTSM development increases the risk of compromises, phased deliveries, or worst-case scenario, needing enhancements mid-study. RTSM vendors often work miracles and given the levels of configuration available they usually meet the requirements in time. But there is a perception that RTSM is on the critical path, it doesn't have to be if vendors are involved early.

Do adhere to the protocol

For everyone involved, the protocol is ultimately the user requirements of the study. Aligning RTSM with the protocol is the easiest thing to do, not least because RTSM integrates with a lot of other systems within your trial landscape. It's essential to ensure RTSM aligns with the protocol, especially for the visits it manages. Consider the RTSM in the context of the entire study, how it will integrate with other systems, and how it can be best used within the broader landscape.

Do think study, not software

A clinical trial comprises more than just RTSM data, EDC data, or lab data—it's a convergence of various data points. With all these disparate sources and systems, there is one commonality throughout, the site and their patients. Sites are not software experts, nor particularly technical in nature. Therefore, both RTSM vendors and study teams must adopt a study-centric approach rather than solely focusing on the software. By designing, configuring, and customizing with the study in mind, we ensure the trial is user-friendly for doctors and nurses who rely on it to collect valuable data. So, let's prioritize the study, not just the software.

Don't be afraid of customization

If configuration means zero programming, and customization means anything involving programming or more technical mechanisms than pushing buttons, then we'd all probably be surprised how much customization happens in any one study, regardless of which vendor is in consideration. It's often a dirty word, but it need not be. Any reputable RTSM vendor should have robust processes for creating and managing customization effectively. That is not to say that is should be a free-for-all, and there is a difference between "must have" and "nice to have" of course. If we concentrate on the requirements of the study, the method of implementation should be owned by the vendor.

Do embrace the new

In the clinical trial landscape, there's a common belief that "if passes audit, no need to change." However, this mindset overlooks the continuous evolution and improvement of vendor solutions. At Signant Health, we have introduced Study Data Release, Direct to Patient, TSS Integration, robust API integrations for reporting and CTMS integration, Free Picking and other new technologies and features. Embracing new technologies and features is essential for staying at the forefront of clinical trial management. Each innovation is designed to enhance the efficiency and effectiveness of RTSM studies for our customers. Rather than fearing change, consider the opportunities new technologies can bring to streamline study processes and improve outcomes.

By remaining open to innovation and actively exploring new solutions, you can leverage the latest advancements to optimize your clinical trials and drive meaningful progress in healthcare. Let's embrace the future of clinical trial management together.

Don't rinse and repeat

Unless a new study is genuinely the same as a previous study, and time is of the essence, then there is no reason why an RTSM should be created by duplicating an existing study. While it's beneficial to learn from previous experiences, there's always room for enhancement and innovation. Each new study presents an opportunity to integrate new technologies, leverage diverse perspectives, and refine our approaches. Failure to embrace those different views, to honestly evaluate previous studies and improve rather than repeating them will lead to stagnation of our industry, not just RTSM. By critically evaluating past studies and actively seeking ways to enhance them, we can drive continuous improvement and propel the industry forward.

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