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A Novel Approach to Clinical Supply Chain Systems Integration

In an era of rapid transformation in clinical trials, research sponsors are presented with new logistical and clinical supply management challenges that can be addressed by employing a new approach to clinical supply chain efficiency.

As clinical trials continue to grow in complexity and scale, clinical supply management strategies should adapt to accommodate new logistical challenges inherent in modern medical research. Sponsors are collecting more data on more endpoints, often requiring multiple trials to run simultaneously in multiple countries. In addition, costs for investigational products, especially for advanced oncology therapies, continue to rise. From forecasting to distribution, an innovative new approach to Randomization and Trial Supply Management (RTSM) system design – enabling free picking instead of traditional RTSM-based ordering – can simplify supply chain processes, maximise product efficiency across studies, and reduce risks and costs over an entire clinical programme or compound.

Limitations to Traditional RTSM Implementations

In a traditional RTSM implementation, study supply managers have two primary challenges. First, they must pre-allocate protocol-specific stock, estimating quantities needed for an individual trial while building in a supply buffer to account for unexpected spikes. The buffer usually results in overages that necessitate the destruction of the unused supply – a lost investment in the product as well as the additional costs incurred for their manufacturing, labelling, and storage.

Second, study supply teams are also responsible for coordinating supplies between primary depots and sub-depots, sites, and RTSM systems, which usually requires navigating between two or more software interfaces. This creates duplication of effort and opens the door to potential errors.

Supply Systems Integration and Free Picking

Instead of this imprecise forecasting method and inefficient coordination process, an integrated "free picking" interface between the RTSM system and clinical supply management system creates continuity and flexibility by enabling drug pooling across protocols. The new process has minimal impact on familiar workflows: the RTSM system's free picking interface informs the clinical supply management system how much of what drug is required at each site, much like a traditional ordering integration. However, rather than requesting supplies by specific kit numbers, the free picking RTSM system requests supplies by quantity. The warehouse then picks any kits associated with the dosage or type that are available and meet the needs of the requested shipment. The warehouse then records the data into the clinical supply management system, which in turn informs RTSM of the specific kits/lots/expiry to be sent to the clinical site. All downstream activities in RTSM then follow the traditional process of shipment tracking, receipt, allocation, etc.

This free picking approach maximises the usage of investigational compounds across programmes, as kits do not need to be pre-allocated for a particular study. Additionally, the seamless integration between the RTSM and clinical supply management system simplifies the supply management process by reducing duplication of effort and manual data entry. For example, clinical supplies managers no longer need to release the drug into each RTSM. These advances contribute to operational efficiency and reduced costs – less stock is required since the free picking model enables flexibility with medications across studies. However, there are key design considerations to be cognisant of when designing the RTSM solution.

Design Considerations

RTSM systems typically take into consideration a 'do not ship' (DNS) value to prevent the shipment of a drug that may expire before it can be received and allocated to a patient. In the new free picking model, this concept is still applicable but is handled slightly differently. The DNS date will be passed from RTSM based on the specifics of the order, and the clinical supply management system will enforce kit selection based on this input. In an advanced application, a dynamic DNS can be passed based on the specifics of the patient for which it is ordered. For example, a patient in a phase of the trial with extended visit windows could have an order placed with an extended DNS, whereas a patient in the phase with more frequent visits could have a shorter DNS passed. This flexibility helps optimise lot utilisation, especially for investigational products with a short stability profile.

Another major shift to traditional RTSM design is how and where a master kit list is stored. In the new free picking model, the RTSM system does not need to host it, as depot inventory lives exclusively at the clinical supply management level. What this means in practice is that once a lot has been released within the clinical supply management system, it is ready for ordering by RTSM. No releases within RTSM are required. Additionally, common items such as depot transfers, relabelling, or updates to inventory that traditionally had to be replicated in RTSM no longer need to undergo this extra step. This simplifies the design of the RTSM solution, reduces setup effort, minimises user-accepted testing (UAT) effort, and most importantly, simplifies business process in production use.

eClinical Integration

While efficiency and accuracy in study supplies management is a critical factor in the success of clinical trials, sponsors can fully unlock potential time and cost savings across a clinical programme by bringing RTSM into their supplies systems within the larger eClinical ecosystem. At Signant Health, the patient journey begins with electronic informed consent (eConsent), which generates a patient record that then becomes available directly in the RTSM and electronic clinical outcome assessment (eCOA) systems. Critical touchpoints such as patient eligibility or outcomes data, which can directly impact statistical integrity in the randomisation algorithm, can be programmatically shared to avoid the risk of data entry error. This, combined with a free picking interface, helps ensure an accurate and efficient flow for the patient.

In clinical research, time is of the essence. Bringing together a consolidated, integrated platform, simplified through advanced

integrations, will ensure that these technologies do not become the rate-limited factor, either at startup or during amendments. A more continuous, digitised approach to study launch and administration processes can reduce time, costs, and risks associated with navigating a complex landscape of disparate technologies.

Greater Flexibility Today, Future Ready for Tomorrow

Sponsors rely on RTSM for effective and efficient allocation of supplies to patients. As trial complexity grows and use cases expand for RTSM to house more than just investigational products (e.g., ancillary supplies), the advantages of pooling are ever increasing. While the drug pooling concept is not new, a free picking model within an integrated clinical supplies management provides study teams with greater flexibility and more accurate supply management over an entire programme or compound. Additionally, free picking is the first step towards future capabilities associated with just-in-time labelling or manufacturing. The end result is a more efficient, simpler, and more powerful approach to RTSM.

Bart Nicholson

Bart Nicholson leads the RTSM Product Management team at Signant Health. Since joining Signant in 2011, Bart has supported a diverse set of research projects and is passionate about advancing RTSM into the broader clinical technology platform, all while providing thought leadership as the industry moves towards direct-to-patient supply models. Bart has an undergraduate degree in computer engineering from the University of Delaware along with a Master of Business Administration from Drexel's Lebow College of Business.