Article

IRT: The Unsung Hero of Modern Clinical Trials

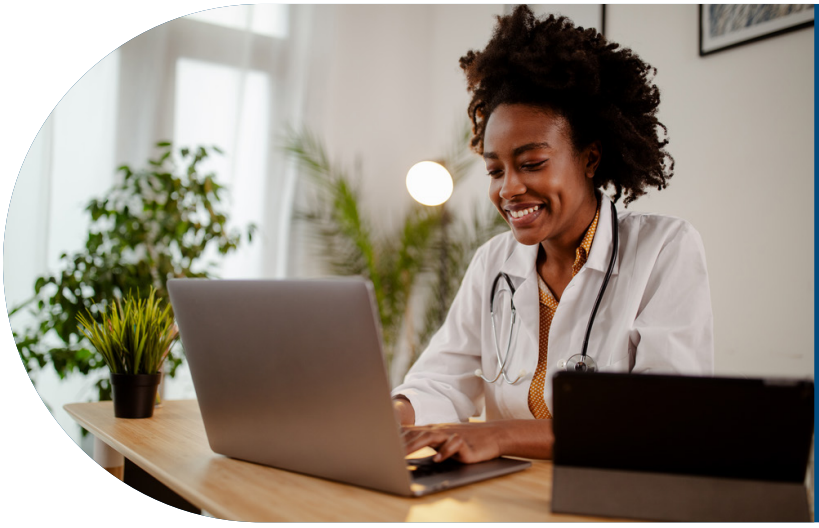
HIT Consultant: By Kevin Landells, Vice President, Delivery, Patient Technology

The modern landscape of clinical trials is expanding to include hybrid and decentralized approaches to conducting research. As the methods of conducting clinical trials diversify, clinical trial logistics also increase in complexity. In 2024, experts estimate that 50% of clinical trials* will be conducted via hybrid or decentralized methods. Though increasing remote access in clinical trials improves convenience, reduces costs and expands diversity, it also presents new challenges in navigating remote monitoring and ensuring efficiency in decentralized clinical trials.

In theory, increasing decentralized clinical trials improves efficiency and flexibility by providing a more patient-centric approach to research. However, organizers continue to struggle to maintain patient engagement in remote and hybrid environments. For example, Apple's ResearchKit successfully recruited thousands of participants remotely via mobile devices for diverse chronic disease studies. However, a significant portion of participants subsequently withdrew from the project within weeks. What organizers have failed to consider is the increased amount of logistics required to manage patient recruitment, patient visits and additional operational needs, such as drug supply. Managing multi-system site and sponsor workflows adds to the challenge of hybrid and remote trial orchestration. This can lead to a lack of efficiency in providing accurate investigational product forecasting and optimization of trial supply. It also creates challenges in navigating ongoing fluctuations in enrollment patterns and presents difficulties in integrating strategies to streamline workflows and promote data visualization.

The consequences of failing to ensure proper logistics management in hybrid and decentralized clinical trials include increased risk of errors, increased overall costs and potential adverse outcomes. Integrating data across multiple sources, such as wearables, medical records and patient input can create more confusion and complexity, risking inaccuracies and can often lead researchers to resort to manual entry, occupying valuable time that could be spent with patients.

Without centralized management of randomization, drug dispensing and inventory, organizations can fall victim to manual error, inconsistencies and missing data. Without the proper technology, clinical trial sponsors and researchers have no method of monitoring medication adherence and dosage information, which is critical to ensure safety and accurate results in a decentralized setting.



*IQVIA Internal

Streamlining decentralized clinical trial operations with Interactive Response Technology

To solve these challenges, stakeholders must consider the implementation of a robust Interactive Response Technology (IRT), to support controlled randomization, the automation of supply management and intelligent, timely reporting via analytics. The right IRT will supply stakeholders with ample project management support by driving simple, automated configuration of intelligent supply chain optimization, reducing risk, waste and cost across supply chain operations. IRT tools reevaluate and assign optimal supply strategies for various sites daily, minimizing the risk of errors through automation, improving efficiency and freeing up valuable resources for greater use by clinical research teams.

Predictive supply management platforms support organizations' efforts to improve clinical trial operations by optimizing stock automatically and providing forecasting capabilities to improve study agility. Study start-up and management are accelerated when an agile IRT is employed to respond to protocol amendments in a timely manner. Diverse trial design is improved by an IRT that has the flexibility to toggle between at-home or on-site treatment dispensation options.

In this context, IRT improves risk-based monitoring with comprehensive drug accountability, traceability and returns management support. Finally, the ability to reduce data duplication and simplify interactions with intelligent data integrations allows for valuable insights into clinical trial operations and reduces administrative burden with integrated solutions and drug management supply tools.

By embracing technologies, such as IRT, all parties, including patients, researchers and sponsors, benefit from this increased optimization across clinical trials. Specifically, each stakeholder experiences results ranging from:

Patient satisfaction

Technology facilitates drug dispensation and reconciliation, ensuring patients take the proper drug and dosage at the correct time, minimizing patient burden. Electronic drug accountability also assists in the monitoring of patient compliance.

Researcher benefits

By implementing IRT, researchers benefit from a site-friendly interface, that allows for improved data insights, integrating shared workflows across locations, to perform faster, more efficient transactions. Further, they benefit from turn-key integrations that reduce administrative burden and allow more time for direct patient support.

Sponsor results

Through self-service tools that facilitate trial activities, enhance insights and improve communication, sponsors benefit from rapid study design processes, which reduces time to first patient-in and improves quality in design prototyping and templates. Intelligent tools and automation technology optimize drug forecasting and resupply, potentially saving Sponsors millions in deferred costs from IP waste and excess shipments.

With the diversification of modern clinical trials, stakeholders will require a solution that supports flexible randomization, improves forecasting, automates supply management, reduces data duplication and enhances risk-based monitoring. Mastering the logistics of clinical trial management with IRT allows stakeholders to automate and optimize clinical trial supply, improving overall trial costs and allowing medical experts more time to engage with patients and focus on improving clinical outcomes.

About Kevin Landells

Kevin Landells, Vice President, Delivery, Patient Technology at IQVIA, has over 25+ years of experience in the IRT/ RTSM industry, having worked across many technical and project management leadership roles. Experienced with developing and leading global teams delivering managed services spanning Operations, Project Management, Client Partnerships and Business Transformation.

IQVIA TECHNOLOGIES

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