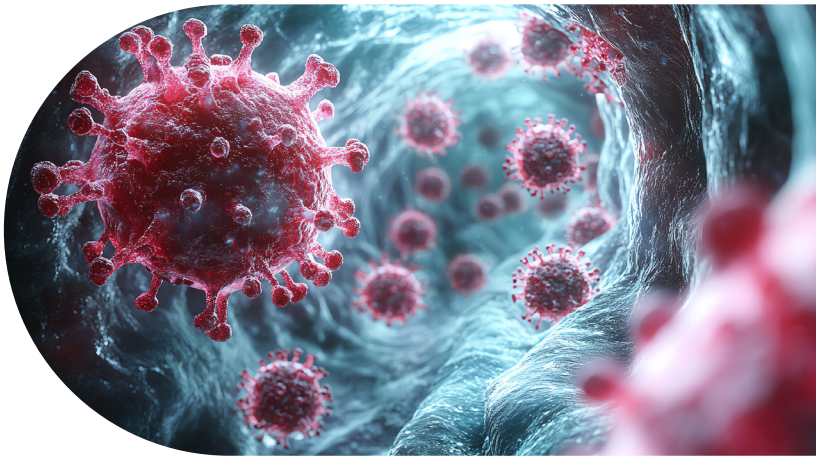
Article

Revolutionizing Personalized Medicine: How IRT Platforms are Transforming Cell and Gene Therapy Trials

PharmaPhorum: By Cara Woodruff, Director of Product Management, IQVIA IRT

Cell and gene therapies offer transformative benefits to patients, including revolutionary treatment potential for cancer, AIDS, and hereditary diseases. However, even with record funding, the logistics of managing patient-specific treatments have been a major obstacle.



The unique challenges of CGT trials

When it comes to CGT trials, teams are dealing with more than typical clinical study challenges. These trials represent a whole new complexity, where every treatment is as unique as the patient receiving it. Think about it: from the moment a patient's cells are collected, through multiple processing stages to the final treatment delivery, each step requires meticulous tracking of various unique identifiers and individual patient materials throughout the supply chain, including sample IDs, manufacturing numbers, lot numbers, and release numbers — all specific to individual patients.

This complexity is heightened by strict time constraints and the need for precise temperature control across the supply chain. It's like orchestrating a precision dance, where every move must be perfectly documented as well as timed.

IRT platforms: A comprehensive solution

These logistical challenges require innovative solutions, and Interactive Response Technology (IRT) plays a critical role in tracking and managing complex trial workflows.

From day one, the flexible architectures of modern IRT platforms adapt to the specific requirements of each trial. The journey often begins with the pre-assignment and tracking of apheresis collection bags, each requiring detailed documentation of collection dates, volumes, and handling procedures. As materials move through the manufacturing process, IRT platforms maintain careful oversight of status changes, location tracking, and chain-of-custody documentation. This includes managing the critical transition from collection materials to manufactured treatment, where precision and accuracy are paramount.

One of the most crucial aspects of IRT platforms is their ability to handle the “release” process with individual expiration dating. Due to the personalized nature of CGT treatments, each batch has its own unique timeline and handling requirements. IRT systems can dynamically generate and track expiration dates, ensuring that treatments reach patients within their viable windows.

This oversight becomes particularly crucial during the transition from collected materials to the final manufactured treatment — there’s zero room for error.

Enhanced process control through technology

The success of CGT trials hinges on maintaining strict control over critical process points while retaining the flexibility to adapt to trial complexity. Modern IRT platforms achieve this through real-time status tracking of treatments in various states, from pre-use through ready-to-use and in-transit stages. This comprehensive visibility enables trial managers to maintain oversight of the entire process and respond quickly to any issues that arise.

Temperature monitoring and environmental control tracking are particularly crucial for CGT products. IRT systems can integrate with monitoring devices to maintain continuous oversight of storage conditions, triggering alerts if parameters deviate from acceptable ranges. This level of control extends to the tracking of shipping conditions, ensuring that treatments remain viable throughout their journey to the patient.

The consultative partnership approach

Success in CGT trials requires more than just technology — it demands a true partnership between sponsors and technology providers. Even the best technology needs the right partner to make it work effectively. The most successful IRT providers have evolved beyond being mere software vendors to become strategic partners in a trial’s success. They bring valuable experience to the table, helping sponsors avoid common pitfalls and design efficient processes that keep regulators happy while minimizing errors.

Different sponsors bring different levels of experience to the table, and effective IRT providers adapt accordingly. For emerging biopharma companies new to CGT trials, providers offer deep consultation services to help navigate the complexity of these studies. More experienced sponsors might require different forms of support, such as assistance with scaling operations or optimizing existing processes.

Data integrity and regulatory compliance

Data integrity remains absolutely critical in CGT trials. IRT platforms help eliminate common challenges, like manual entry errors or discrepancies between tracking systems. By providing a single source of truth for all trial-related data, these platforms significantly reduce the risk of data reconciliation issues that could compromise trial validity.

The regulatory landscape for CGT trials continues to evolve, and IRT platforms must stay ahead of these changes. Modern systems are designed with built-in compliance features that help ensure adherence to current Good Manufacturing Practice requirements and other relevant regulations. This includes maintaining detailed audit trails, enforcing proper documentation procedures, and ensuring appropriate access controls.

Looking ahead: The future of CGT trials

As the field of gene therapy continues to rapidly evolve, IRT platforms must advance to meet new challenges. The future will likely bring greater protocol complexity, larger patient populations, and more diverse therapeutic applications. Technology providers must continue to innovate, developing new features and capabilities to support these advancing needs while maintaining the highest standards of reliability and security.

The success of CGT trials depends on the careful orchestration of complex processes, with zero tolerance for error. IRT platforms, combined with experienced implementation partners, provide the comprehensive solution needed to navigate these challenges successfully. As the industry continues to push the boundaries of personalized medicine, these technologies will remain fundamental to bringing revolutionary treatments to patients safely and efficiently.

For organizations embarking on CGT trials, selecting the right IRT platform and partner is crucial. The technology must offer both flexibility and rigid control, while the partner should bring deep experience and a consultative approach. With these elements in place, sponsors can focus on advancing their groundbreaking treatments, confident in their ability to manage complex logistics and maintain the highest standards of patient safety and regulatory compliance.

About the authors

CARA WOODRUFF

Director, Product Management, IQVIA

A highly motivated IT product management professional with over 29 years of experience in the biopharmaceutical service industry, she executes product strategy, defines product vision and roadmaps, develops customer-driven product requirements incorporating human-centered design, drives product release cycles using Agile methodologies, and collaborates with cross-functional teams to deliver high quality solutions on time. Prior roles include IT product owner, IT business partner, integrated processes and technologies POC project/product manager, predictive analytics lead SAS developer, biostatistics senior SAS statistical programmer, statistical programming manager, clinical data programmer, and associate biostatistician.

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