Why You Should Expect More from Your IRT/RTSM

Getting More Out Of Your IRT: Beyond Basic RTSM

3 Study Areas Where Your IRT Vendor Should Do More

When considering Interactive Response Technology (IRT), many think only about its base functionality – ensuring effective randomization and trial supply management (RTSM) while maintaining the blind during clinical trials. However, today, these critical functions have become a baseline for what the industry expects of this technology.

Since its inception over three decades ago, IRT has evolved to meet the ever-changing needs of the clinical development industry. Gone are the days of IRT only being used for basic RTSM functions in large late-phase trials. Today, IRT is frequently relied on to:

- Support Phase I trials
- Accommodate all trial designs, including cohort & adaptive/platform trials
- Perform complex calculations and logic as per complex protocols

"The "T" in IRT is only part of the story; for effective and efficient clinical trials, the expertise and experience of the people behind the solution are what make the difference."

– Beth Crawley, Product Director, Perceptive eClinical

Clinical trial sponsors also expect more from the people behind their IRT solutions. A reliable IRT vendor should act as a partner and provide expert advice and guidance about the proper and efficient implementation of their IRT system. They should work to understand and analyze each study's unique requirements and develop a strategy to meet the trial's goals, identify and mitigate risks, and allow flexibility for the future.

Here we present specific examples of what an advanced IRT system and the people behind it can deliver, beyond the basic expectations of RTSM.

Randomization

Your RTSM Vendor Should Enable Effective Randomization

Using an IRT for randomization functionality not only helps to ensure data and study integrity by eliminating bias, but it also manages the risks of randomization imbalance.

Randomization and Beyond

Can your RTSM vendor tackle complex randomization?

Although blocked randomization is the methodology used for most clinical trials, IRT systems are increasingly being used to accommodate highly complex dynamic allocation methods. For example, minimization helps reduce imbalances across treatment arms while considering prognostic factors such as disease stage.

An advanced IRT can be used to facilitate this and other equally complex dynamic allocation methods, such as Zelen's, hierarchical dynamic, Urn methods, and Bayesian response. Adaptive and platform studies can also be supported. You should be able to rely on your IRT vendor to provide expert guidance on the most appropriate methodology to meet your study's randomization needs.

"We relied heavily on Perceptive eClinical IRT expertise and followed their recommendations for overcoming our studies' complex randomization challenges, resulting in a solution that perfectly met our RTSM needs for two complex gout trials."

– Professional Study Lead, LG Chem LTD

Case study

Medication Management

Your IRT Vendor Should Manage Medication

One of the most challenging aspects of global clinical trials is the management and distribution of materials between contract partners, sponsors, and logistics organizations. At a minimum, an IRT must:

- Track the study drug to the smallest unit throughout its journey from QP approval/release to patient allocation to destruction
- Manage the efficient supply of drug across global sites
- Ensure the right drug is sent to each site at the right time for its ongoing patients

- Manage expiry to remove the risk of medication expiring in the patient's hands

Every IRT system should be expected to manage this complexity via the setting of study parameters, including depot shipping time to sites, drug expiry dates/shelf life, patient visit schedule, and treatment regimen.

Medication Management and Beyond

Does your IRT/RTSM vendor do more than core medication management?

However, simply adding IRT to a trial does not guarantee an efficient supply chain solution.

Depending upon the complexity, the number of drug types, which country each lot of medication can be used in, regions, countries, shelf-life, and patient dosing schedules, the resulting supply chain solution may function, but questions will remain around its efficiency and cost-effectiveness.

An advanced IRT system should be able to right-size resupply shipments, help reduce waste to support sustainability goals, and prevent site stock-outs – all while maintaining the blind. Systems designed by RTSM experts who understand the protocol and the sponsor's needs will manage this complexity and:

- Automatically ensure patients can be resupplied, regardless of the complexity of the visit schedule/s & patient treatment regimen
- Minimize monitoring effort by automating site resupply, adapting to real-world changes such as recruitment rate

You should be able to rely on your IRT vendor to provide expert guidance about the optimal supply settings at the start of the trial and how best to amend those settings as the study progresses.

Data Management & Data Quality

Your IRT/RTSM System Should Improve Data Management

The data management side of a trial usually accounts for a substantial proportion of the total cost when procedural, site monitoring and staff time are all factored in. IRT should support data management and integrity by:

- Removing duplicate data entry, where practical
- Enabling real-time data validation
- Enabling real-time guidance for users
- Allowing sites to amend authorized data themselves e.g. date of birth

An effective IRT will design the system in alignment with each trial protocol, tailoring it to what the site sees and guiding them to enter the exact data needed at the right time for the IRT system to make patient treatment decisions.

Data Management and Beyond

Does your IRT/RTSM system go beyond standard integration?

Data stored in IRT, whether entered directly into the system by users or provided by IRT to users, should integrate with any eClinical system the sponsor utilizes e.g. EDC, preventing the need for double data entry which is subject to additional human error.

This is another area of increased complexity, as the type and number of eClinical systems the IRT needs to integrate with, has grown as new eClinical technologies are being used in clinical development.

An advanced IRT system will be able to manage integrations of all types and liaise directly with third-party vendors, from requirements gathering to user acceptance testing.

For Optimized RTSM, People Make the Real Difference

What makes the real difference in a clinical trial is not just the technology. For successful trials, you need access to expert teams in design, randomization, trial supply management, integrations, and project management. Expert support must be available to you during the life of the trial, from an IRT team who knows the study and the study team who can resolve issues faced during its execution effectively and efficiently.

The “T” in IRT is only part of the story; as usual, expertise, experience, and communication/collaboration are what make the difference.

Ready to find out more about what Perceptive eClinical can do for your trials, contact us for a product demonstration.