

7 Key Considerations for Optimal IRT Design

Designing an Interactive Response Technology (IRT) system for clinical trials involves multiple elements to ensure effective randomization and trial supply management. Here are seven crucial areas to focus on:

1 - In-depth understanding of the protocol

A thorough understanding of the study protocol, including any unknowns, and the study team's goals and concerns is crucial. By comprehending the reasons behind specific requests, a simplified and optimal solution can be designed that minimizes data reconciliation and manages protocol amendments efficiently.

2 - User consideration

The IRT system must be user-friendly for investigative site personnel who interact with various systems and have limited time. An optimal design considers the impact on site users throughout the trial, ensuring ease of use and compliance, especially when registering non-dispensing visits.

3 - Risk anticipation

Risk management is essential in IRT design, alongside quality, participant safety, and data integrity. It's important to understand the protocol and study team needs to create a solution that mitigates both expected and unforeseen risks. These can range from randomization algorithms and participant dosing to future adaptations, recruitment delays, and supply chain issues.



4 - Considering the life of the trial

Effective IRT design encompasses all trial phases until database lock and study closure. Flexibility is key to minimizing future efforts. Your IRT designers must ensure sponsors understand the real-world implications of data collection decisions, helping to avoid reconciliation and compliance issues.

5 - Flexible and future-proof

An optimal IRT system should be adaptable to immediate changes, such as increasing enrolment caps or adding new countries. It should also be future-proof, ready to accommodate new doses or close treatment arms as needed.

6 - Embracing complexity

When designing an IRT system, it's important to recognize and plan for the complexities of your specific trial. This includes understanding the intricacies of study, site, and participant management, as well as randomization and dosing requirements. By leveraging Perceptive eClinical's core of pre-validated functionalities and customizing them to meet your protocol's needs, we can ensure that your IRT system is robust and capable of handling any challenges that arise.

7 - Fostering collaboration

Successful IRT design is a collaborative effort. Engage with a dedicated team of experts in randomization trial supply management, integrations, and reporting. This team should remain involved throughout the trial to address any issues that arise. For sponsors managing multiple trials, defining standards can ensure consistency and reduce effort across development programs. By fostering strong collaboration, you can enhance the efficiency and success of your clinical trials.

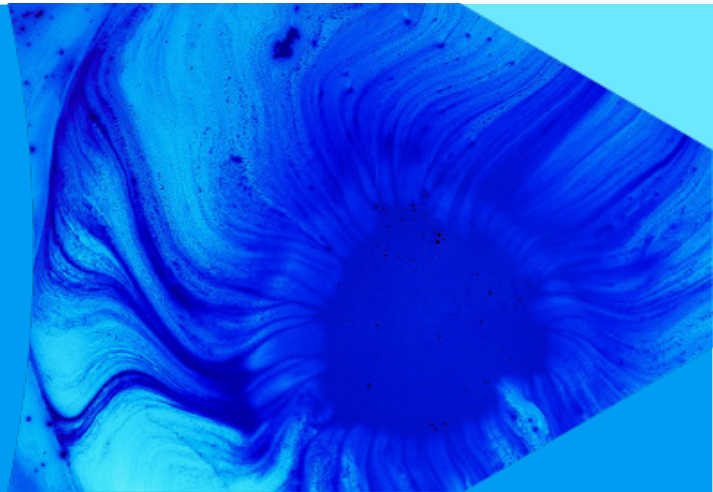
Conclusion

In summary, designing an optimal IRT/RTSM system for clinical trials requires a comprehensive approach that considers risk management, user needs, and the entire lifecycle of the trial.

By focusing on these seven key areas, sponsors can ensure their IRT systems are not only effective but also adaptable to the evolving needs of their studies, ultimately contributing to the advancement of clinical research and participant care.

Why choose Perceptive eClinical?

Experience the difference that over three decades of unmatched expertise can make. Our team of seasoned professionals delivers bespoke solutions, ensuring seamless integration and optimal performance for every clinical trial. Our commitment to innovation and excellence, ensures advanced technology and reliable results.



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