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Finding the Optimal IRT/RTSM Design for Your Clinical Trial

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Multiple elements feed into finding the optimal IRT design for each trial. Here's a glimpse at how Perceptive eClinical 's expert IRT designers consider the main elements to deliver effective randomization and trial supply management (RTSM) and meet your trial's needs.

1.1 Understanding and Anticipating Risks

Risk should be a driver of IRT design, along with quality, patient safety, and data integrity. At Perceptive eClinical , our focus is on understanding the protocol and the needs of the study team, then translating those into a solution that reduces risks.

Not just the risks you may expect, such as those related to the randomization algorithm and balance, patient dispensing and dosing, and unintentional unblinding. But also, the risks we anticipate, for example, those related to the potential for future adaptations and amendments, recruitment delays, data reconciliation, and supply chain concerns.

Perceptive eClinical 's expert team knows what challenges a trial can face because we've managed a diverse range of risks across many protocol designs, study needs, and packaging plans in the 30 years we've been implementing IRT in clinical trials.

This knowledge and the experience of Perceptive eClinical 's IRT designers translate into a deep understanding of how to mitigate risk; this serves as the foundation for each trial's specialized, ongoing risk assessment and every IRT design we recommend.

1.2 Seeking to Understand

We start by understanding the protocol, including any unknowns, as well as the study team's aims, end goals, and concerns. We don't just ask what you want. We ensure we understand the why behind any requests.

By understanding the why, we can design an optimal solution that's simplified for investigative site use and makes it easier to avoid data reconciliations and manage inevitable protocol amendments.

What is the optimal IRT/RTSM design for your trial?

Meets the "Why"	Reduces Risks	Considers the Users	Flexible & Future-proof	Leverages Experiences
				
Meets the needs of the protocol Achieves the aims of the study team	Assures patient resupply & safety, protocol adherence & data integrity	Easy for users Considers data reconciliation/ duplication in other systems	Considers common, planned & potential changes during the trial	Robust core system tailored to incorporate expert recommendations & best practices

1.3 Considering the User

Investigative site personnel use many different systems, and their time is precious, so the IRT system for each study must be easy for site personnel to use and understand.

An optimal IRT design considers the consequences for the investigator/site users for the life of the trial, including the need for data reconciliation and (protocol-permitted) flexibility as sites and patients can't always stick to the visit schedule.

One consideration is if the IRT system is used to register non-dispensing visits following randomization. Except for withdrawal and completion, this has dual risks of data reconciliation and user compliance with registering visits in the IRT system. When the site obtains nothing during an IRT transaction, e.g., a subject number or a kit number, compliance is reduced, so data recorded in the IRT system is poor.

1.4 Considering the Life of the Trial

An effective IRT design takes into consideration everything that happens until database lock and study closure. With that in mind, Perceptive eClinical IRT is designed to be flexible and to minimize future effort.

Perceptive eClinical IRT designers are responsible for ensuring the sponsor is aware of the real-world implications of decision-making regarding data collection in IRT, which has risks of reconciliation and compliance issues as well as increased effort for site personnel.

For example, if patient data is collected both in the eCRF/EDC and the IRT system, this can lead to data reconciliation issues. An experienced IRT partner should collaborate with the study team to understand the reason behind any request to collect duplicate data in the IRT system if it is not needed to make patient treatment decisions.

1.5 Flexible and Future-proof

An optimal IRT system is designed to be flexible to make immediate changes as and when needed – from increasing enrolment caps to reflect changes to recruitment to including new countries and depots, etc. And the system should be future-proof to anticipate possible changes – from immediately adding new doses for new cohorts of patients or closing treatment arms following a safety review.

1.6 Teamwork

Every study has a dedicated team advising on all aspects of protocol and study design, including Perceptive eClinical subject matter experts (SMEs) in randomization, trial supply management, integrations, and reporting.

Each study's randomization and trial supply expert, as well as its IRT project manager, remains in the dedicated study team until its closure, supporting the inevitable issues that sponsors face during the running of a trial.

For sponsors who work with Perceptive eClinical across many trials, we can extend the support to define standards that ensure consistency and reduce effort across their development programs.

1.7 Focus on Complexity

Perceptive eClinical 's IRT solution designer leverages Perceptive eClinical 's core of pre-validated functionality designed to support all trial needs, covering study, site, and subject management, randomization and dosing, and trial supply management from lot release to destruction – all with corresponding reports. We advise which core functionality is required and we customize it to best meet the needs of each protocol, with no limits to the level of complexity we can address.

We start design discussions by presenting what the Perceptive eClinical SME team has prepared – our understanding of the protocol and patient journey and a design approach based on a review of initial known risks. We can then focus on any complexities, directing time and attention to what's important for each study.

2 CONCLUSION

The objective of Perceptive eClinical ’s IRT team is to design an optimal system that is right for you, and right for the life of the trial, taking into consideration your aims and needs as well as the interests of site personnel and all system users.

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