Event Insight

Designing for Agility

Rethinking IRT/RTSM in the era of dynamic trials

At CBI IRT 2025 in Boston, a panel moderated by Perceptive brought together experts from **Regeneron**, **Takeda**, and **Astellas**, to explore how protocol agility is reshaping expectations for IRT/RTSM systems. While the discussion offered practical insights, it also pointed to a broader industry imperative: the need to re imagine IRT/RTSM as a strategic enabler of adaptive trial design.

From static systems to strategic infrastructure

IRT/RTSM systems were originally built to support predictable, linear trials. Today, that model is increasingly out of step with reality. Oncology protocols evolve mid-study. Personalized medicine introduces cohort-level complexity. Global trials face country-specific constraints that can disrupt timelines and increase risk. Early phase cohort management trials need to adapt doses and new cohorts quickly.

Agility in this context isn't just about speed, it's about foresight. Sponsors need systems that can flex without friction, and vendors must deliver tools that prioritize quick configuration that can adhere to the customization each trial type and therapeutic area needs.

The objective is clear: enable change, without triggering disruption.

Building flexibility into the foundation

Perceptive's approach focuses on embedded flexibility. That means designing systems with scalable visit schedules, placeholder cohorts, and configurable dose structures from the outset. These features aren't just technical conveniences, they're operational safeguards.

For example, alerting teams when visit cycles are nearing completion can prevent last-minute change orders. Role-based permissions and audit trails ensure adaptability doesn't come at the expense of control. And self-service tools allow sponsors to make adjustments without waiting on vendor timelines, or study enhancements.

Governance that supports change

Flexibility must be balanced with compliance. IRT/RTSM is not a protocol enforcement tool, it's a facilitation mechanism. That distinction matters. Over-engineering systems with complex logic can slow down validation and increase regulatory exposure.

Perceptive advocates for a model of flexibility, one that can adapt to your trial and protocol needs. In some instances the IRT/RTSM is transactional and pharmacy manuals guide the calculations and dosing decisions, and in others IRT/RTSM is more involved in the calculations. This approach supports the changing nature and flexibility of clinical trials, there is no one size fits all approach.

Supporting sites through smarter design

Sites are under pressure, from staffing constraints to protocol complexity. The best IRT/RTSM systems don't just serve sponsors; they support sites. That means intuitive interfaces, clear dispensing logic, and minimal manual workarounds. When sites trust the system, data quality improves, and participant safety is better protected.

Looking ahead

As trials become more adaptive, the IRT/RTSM ecosystem must evolve. Sponsors should expect configurability, not just customization. Vendors must invest in governance frameworks that support automation without compromising oversight. And the industry must align on what agility really means, not just faster builds, but smarter designs.

The future of IRT/RTSM isn't just flexible. It's intentional.

Interested in smarter IRT/RTSM?

If you're exploring how to onboard a more adaptive, intuitive, and site-friendly IRT/RTSM system, we'd welcome the conversation.

Reach out to the Perceptive team at **hello@perceptive.com** to learn more.