

IRT? RTSM? What's the Difference?

In an industry so full of acronyms, no two are more often interchanged than IRT (Interactive Response Technology) and RTSM (Randomization and Trial Supply Management). Here we take a look at the system behind the letters, how the terms have come to be used interchangeably, and how the technology is only one component of an effective RTSM solution.

What Does IRT / RTSM Do?

An IRT system is a central piece of clinical trial execution that enables participant randomization and real-time drug allocation. Put simply, RTSM is the role of the IRT system. But it's had different acronyms over the decades.

Looking back, the first interactive voice response systems (IVRS) were developed to randomize participants over the phone in the 1980s. Since the 2000s the internet has enabled the use of web-based systems, which were initially referred to as IWRS. This led to another, often-confusing term, IxRS, which was used to describe when a study used both IVRS and IWRS.

Today, we've tossed the modality aside from the acronym and simply refer to IRT as the tool, or system, for delivering RTSM in clinical trials. But it takes more than technology to address the RTSM challenges of today's complex protocols.

Having evolved from its early beginnings as ClinPhone™, Perceptive eClinical IRT is a robust and adaptable platform designed to tackle any RTSM challenge. Since 1993, the world's leading biopharmaceutical companies and CROs repeatedly turn to Perceptive eClinical to meet their RTSM needs. That's 30 years of experience built into the technology, processes, and people who understand what's needed to remove RTSM burdens and reduce your trial risks.

Randomization - the 'R' in RTSM

An IRT system ensures participants are randomized to the appropriate treatment arm, and receive the correct medication throughout a clinical trial per the trial protocol.

Randomized clinical trials have long been considered the gold standard in clinical research. Using an IRT for randomization not only helps to eliminate bias to ensure data and study integrity, but it also manages the risks of randomization imbalance, or mis-dispensing, which can have implications for protocol compliance and participant safety.



If randomization is implemented incorrectly, the scientific integrity of the entire study could be called into question. However effective and reliable randomization requires more than just technology. Insight, expertise, and precise focus on the protocol's needs are required to get randomization right, regardless of the protocol's complexity.

Perceptive eClinical's wide range of <u>fully validated randomization algorithms</u> are configured to meet the needs of each individual study, and our proven IRT platform can be customized to any randomization algorithm, no matter how complex.



Perceptive eClinical's IRT experts routinely design RTSM solutions that ensure the right balance between treatment arms, even in protocols with complex randomization needs.

Read the case study

Trial Supply Management - the 'TSM' in RTSM

IRT supports the challenging task of efficiently managing trial supplies/study drugs across global investigative sites, ensuring they have the right drug available for the right participant at the right time.

At a minimum, an IRT must:

- Track the study drug to the smallest unit throughout its journey from QP approval/release to participant allocation to destruction
- Manage the efficient supply of drug across global sites
- Manage expiry to remove the risk of medication expiring and interrupting participant treatment, which is especially challenging in <u>oncology clinical trials</u>
- Minimize unblinding risks to drive the integrity of the trial

But an advanced IRT can do so much more than this. Coupling the expertise of <u>our RTSM specialists</u> with robust standard and advanced inventory management approaches, Perceptive eClinical IRT helps you:

Reduce your Effort

Perceptive eClinical IRT reduces the burden of monitoring site stock against participant needs, automatically adapting a site's stock to its recruitment rate.

Improve your Carbon Footprint

Perceptive eClinical IRT supports all of your drug supply management aims, from limiting overage and keeping wastage to a minimum, to reducing the number of shipments raised.



Execute Complex Trial Designs

Over the decades, Perceptive eClinical IRT has successfully supported a range of increasingly complex trial designs – including adaptive trials – across all therapeutic areas and phases.

• Improve Trial Efficiencies

Perceptive eClinical's in-house expert statistical design and trial supply consultants can run a Supply Simulation to help sponsors make informed decisions about the optimal quantity of medication to produce for use in clinical development.

Regardless of the acronym, an IRT system is fundamental to the success of a clinical trial. As you consider your RTSM needs, make sure your IRT provider has the right people and a robust solution to drive your trial's success.

At Perceptive eClinical, our RTSM specialists leverage their combined 92 years of IRT experience to advise how to best implement trial designs and account for planned or unplanned trial scenarios. They leverage their vast experience and a system based on 30 years of evolution to deliver an optimal IRT solution based on a comprehensive understanding of your protocol, packaging plan, recruitment rates, and ongoing study needs.

The result? An adaptable, flexible, and reliable system ready to meet your trial's current and future RTSM challenges.

<u>Learn more about Perceptive eClinical IRT and how it helps you achieve successful RTSM and meet your clinical trial needs.</u>