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RTSM Software Comparison: Trial Supply Management Guide

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Executive Summary

Randomization and Trial Supply Management (RTSM) systems (also known as Interactive Response Technology, IRT) are now **indispensable** in modern clinical trials, automating key functions such as patient randomization and drug supply logistics. Over the past decade, the complexity and scale of clinical studies have grown dramatically – the number of initiated trials rose by ~59% from 2012 to 2021 (www.clinicaltrialsarena.com), while McKinsey's November 2019 article, citing DiMasi et al. (2016), reported a

historical estimate that the cost to bring a new drug to market had increased by about 140% over ten years (McKinsey, 2019). These pressures have driven demand for sophisticated RTSM platforms that reduce waste, prevent stockouts, and accelerate timelines. Evidence is study-specific: in a Suvoda-authored account, dynamic IRT configuration was reported to save $6 million, about a quarter of one study's supply budget (Suvoda commentary).

Leading vendors (Medidata, Oracle, Veeva, Suvoda, Calyx, Signant, 4G Clinical, Almac, etc.) now offer comprehensive cloud-based solutions that integrate randomization, inventory tracking, resupply forecasting, and regulatory compliance. Specialists tout advanced features like adaptive randomization, AI-driven forecasting, and natural-language protocol configuration, while enterprise suites emphasize end-to-end integration with EDC/CTMS systems (www.medidata.com) (www.oracle.com) (www.strategicmarketresearch.com). Strategic Market Research estimates the global RTSM market at roughly **$1.5 billion** in 2024 and projects about **$3.2 billion** by 2030 (Strategic Market Research). Strategic Market Research reports strong adoption of cloud-based RTSM systems (Strategic Market Research).

This report provides an exhaustive analysis of the RTSM landscape as of 2026. It reviews the history and evolution of IRT/RTSM, compares leading products and vendors, examines functionality and technology trends, and presents data-driven case studies. We discuss market research projections, user evaluations, examples of supply savings, and expert assessments. Finally, we explore future directions – including AI integration, sustainability-driven supply optimization, and evolving trial paradigms – and consider how RTSM platforms will need to adapt. All claims are supported by industry reports, peer-reviewed studies, and expert commentary.

Introduction and Background

What is RTSM?

Randomization and Trial Supply Management (RTSM) refers to software that automates the assignment of patients to treatment arms and the flow of investigational medicinal products (IMP) in clinical trials. Modern RTSM systems typically encompass **Interactive Response Technology (IRT)** – the combination of Interactive Voice Response (IVR) and Interactive Web Response (IWR) services – plus advanced supply chain features. These tools manage patient enrollment criteria, implement randomization schemas, track drug inventory at sites, generate resupply orders, and maintain audit trails for compliance. In short, RTSM serves as the "command center" for clinical drug kits, ensuring **the right medication is at the right site at the right time** and maintaining the study blind and data integrity (www.worldpharmatoday.com) (www.medidata.com).

IRT/RTSM emerged to solve key clinical supply challenges. The randomization function prevents selection bias by assigning treatments (often by stratified or adaptive algorithms) in a transparent, auditable way. Supply management functions include calculating optimal drug quantities to ship to each site, monitoring on-hand inventory, generating orders as needed, and minimizing overstock or shortages. As one industry source notes, "IRT systems provide clinical trials with essential software services such as patient enrolment, randomization, inventory management, and study drug dispensing" (www.worldpharmatoday.com). By replacing manual

spreadsheets and telephone-based supply tracking with digital workflows, RTSM reduces human error and allows real-time integration with electronic trial systems (like EDC and CTMS) (www.worldpharmatoday.com) (www.medidata.com).

Historical Evolution of IRT/RTSM

IRT began in the **1970s** as a means to prevent patient over-enrollment and drug kit waste. Early systems were basic "interactive voice response systems" (IVRS) accessed via phone. By the 1990s, the Internet enabled **Interactive Web Response Systems (IWRS)**, where sites use a web interface for enrollment and inventory tasks. These digital systems allowed tighter integration of randomization and drug logistics with other electronic trial systems (like EDC and CTMS) (www.suvoda.com). Over time, as protocols became more complex, IRT technology advanced: from simple static allocation to rich rule engines and adaptive designs.

The early 2000s saw pioneering IRT platforms: for example, one 4G Clinical co-founder developed **Impala**, described as "the first parameter-based IRT system in the world" (Pfizer, 2000) (www.onyxnewsroom.com), later evolving into "Trident" (acquired by Bioclinica). Other legacy systems include Cenduit's "CTS" and ClinRad's offerings (later part of other companies). Suvoda was founded in 2013 (Suvoda), and 4G Clinical was founded in October 2015 (4G Clinical). Calyx emerged from the separation of Parexel Informatics in 2021 (Parexel). Established players such as Medidata (which launched Rave RTSM) and Oracle (with Clinical One) also began offering integrated RTSM modules within bigger eClinical suites.

Figure 1 (below) illustrates this timeline, highlighting the shift from on-premises IVR systems to SaaS-based, configurable RTSM platforms.

(www.suvoda.com) *Note: The above timeline is illustrative. Early IRT was on telephones (IVRS), then web-based IWRS in the 1990s. Modern RTSM platforms emerged in the 2010s with advanced features and cloud deployment (www.suvoda.com) (www.clinicalresearchnewsonline.com).*

The term **RTSM** was coined to emphasize that patient randomization is just one function of a broader system; managing the drug supply (inventory, distribution, forecasting) is its twin pillar. Medidata describes its RTSM as combining randomization, patient assignment, and drug logistics on the Medidata Platform (Medidata product description). In practice, trial teams use RTSM at all stages: system configuration begins at protocol finalization; then used continuously to enroll patients, dispense kits, ship supplies, and adapt to amendments. According to a 2026 executive, "IRT/RTSM system is something you **cannot run** a Phase II or Phase III trial without" (www.onyxnewsroom.com).

In summary, RTSM solutions have evolved from simple randomization aids into central supply-chain platforms for clinical trials. They underpin trial integrity and efficiency, offering greater visibility, flexibility, and cost control than ever before (www.worldpharmatoday.com) (www.medidata.com). This report compares the leading RTSM platforms, analyzes market trends, and evaluates evidence of their impact on trial performance.

RTSM Functionality and Features

RTSM systems cover a wide range of capabilities. In general, these include:

- **Randomization and Allocation:** Automated assignment of enrolled subjects to treatment arms based on the protocol's design (simple randomization, block randomization, stratified/multi-factorial algorithms, minimization, or adaptive schemes). Good RTSM platforms allow complex stratification and blinding logic with minimal programming. Oracle's Clinical One RTSM, for instance, advertises it can handle "the simplest to the most complex studies without the need for programming or coding," greatly speeding configuration and validation (www.oracle.com).
- **Inventory Management:** Tracking the location and quantity of investigational product (IP) at all depots and clinical sites in real time. The system records shipments, receipts, and dispenses, and updates on-hand balances. Users can view global stock levels and site-specific inventories at a glance. Advanced systems manage expiry dates and have re-supply triggers to prevent stock-outs.
- **Supply Planning and Forecasting:** Calculating how much drug to manufacture/package and how to allocate shipments. This includes generating planned shipments based on expected enrollment rates, patient characteristics (e.g. weight-based dosing), buffer amounts, and drop-out rates. Some RTSM platforms have "dynamic resupply" algorithms that adjust plans on-the-fly (e.g. based on actual enrollment speed or demand trends). For example, a 4G Clinical solution offers resupply scenarios that sponsors can tune for objectives such as minimizing waste or CO_2 emissions (www.onyxnewsroom.com).
- **Kit Coding and Labeling:** Generating and managing treatment kit identifiers (e.g. randomization codes, barcodes) in a manner that preserves blinding and can be linked back to patient assignments. Many IRT systems interface with label printers or packaging systems.
- **Site and Depot Operations:** Coordinator interface for sites to request shipments, report unusable product, or confirm receipt of kits. Depot/courier tools to manage bulk shipments and restocking.
- **Amendment Flexibility:** A key advantage of modern RTSM is configurability. Studies often require mid-trial amendments (new arms, changed ratios, altered dosing). Configurable RTSM platforms allow study teams or business analysts to implement these changes without rewriting code. As Suvoda notes, flexible IRT means reducing costly change orders and adapting "quickly to changing needs" (www.suvoda.com).
- **Data Integration and Audit Trails:** RTSM data (randomization assignments, dispenses) should automatically integrate with EDC/CTMS. All actions are fully audited for regulatory compliance (21 CFR Part 11 in the U.S., GDPR considerations, etc.). Many solutions provide an electronic Trial Master File (eTMF) or audit report exports for inspections.
- **Analytics and Reporting:** Dashboards for monitoring enrollment, supply projections, site performance, and potential risks. For example, Signant Health highlights that their RTSM offers proprietary algorithms "to reduce overage requirements" by directing drug only where the study needs it (signanthealth.com). Similarly, Calyx IRT emphasizes robust algorithms for medication management (lp.calyx.ai).
- **Globalization Support:** Multi-lingual interfaces, multi-currency if needed (for supply costing), multi-country regulatory compliance (e.g. customs/laws), and support for cold-chain or controlled substances. Some systems have special modules for temperature excursions or chain-of-custody logging.

Table 1 summarizes these typical features and how they manifest in various platforms. Each vendor may emphasize different aspects: e.g., some focus on ease-of-use and rapid deployment ("no-code configuration" across Medidata, Oracle, Veeva (www.medidata.com) (www.oracle.com)), while others highlight advanced optimization (machine learning forecasts, ESG metrics, integrated analytics (www.onyxnewsroom.com) (www.strategicmarketresearch.com)). All leading solutions strive to **prevent errors** ("We will never mis-randomize, stock out, miss a dose, or compromise the blind" as 4G Clinical's motto states (www.onyxnewsroom.com)) and to enhance supply chain reliability.

Platform / Vendor	Deployment	Key Capabilities
Medidata Rave RTSM (Dassault Systèmes)	Cloud (SaaS)	End-to-end RTSM integrated with Medidata Rave EDC. Real-time inventory tracking, adaptive forecasting, global reporting (www.medidata.com). Emphasizes unified data, faster FPI, and mid-study changes.
Oracle Clinical One RTSM (Oracle)	Cloud (OCI)	Randomization and supply management without programming (no-code) (www.oracle.com). Launch trials quickly with unbiased allocation. Robust API integration with CTMS/EDC. Inventory oversight with live updates (e.g. modify shipments without vendor involvement) (www.oracle.com).
Veeva RTSM (Veeva Systems)	—	Used to randomize subjects and manage trial supplies. Veeva documents connections with EDC, DQS, CTMS, and eCOA (August 2026 product sheet, p. 7).
Suvoda IRT (Suvoda)	Cloud (SaaS)	Flexible, highly configurable IRT platform. Emphasizes ease of use and data accuracy with AWS infrastructure. Offers plug-in forecasting (e.g. integrating N-SIDE ML) (www.clinicaltrialsarena.com). Suitable for complex and simple designs; touted as a "clinical trial command center" (www.suvoda.com).
Perceptive (formerly Calyx)	—	Calyx and Invicro launched under the Perceptive corporate identity on September 30, 2024 (issuer announcement).
Signant RTSM (Signant Health)	Cloud (SaaS)	Focus on drug accountability and supply optimization. Claims to "make your clinical supplies go further" by reducing wastage through proprietary algorithms (signanthealth.com). Streams enrollment and supply in one system to control overage. Integrates with eCOA/ePRO solutions.
4G Clinical (Prancer)	Cloud (AWS)	Modern IRT with AI-driven build tools. According to 4G, NLP converts written study specifications into a deployable RTSM system (4G Clinical). Fast implementation (short spec cycles) and flexible mid-study changes. Offers "4C Supply" forecasting tool for portfolio-level planning (www.onyxnewsroom.com). Emphasis on eliminating mis-randomization and stock-outs (www.onyxnewsroom.com).
Almac ONE (Almac Group)	Cloud (SaaS)	End-to-end clinical supply chain solution merging physical logistics with digital IRT (www.almacgroup.com). Integrates packaging/labeling operations with interactive response. Provides full visibility and closed-loop data (supply metrics, patient enrollment).
Clinion RTSM (Clinion AI Technologies Pvt Ltd)	—	Clinion is a proprietary product owned by Clinion AI Technologies Pvt Ltd (company overview).

Platform / Vendor	Deployment	Key Capabilities
TrialKit RTSM (Crucial Data Solutions)	—	Randomization and trial supply management within TrialKit; the supplier documents integration with TrialKit EDC (product page; supplier announcement).

Table 1. Comparison of select RTSM platforms (2026). Deployment is typically cloud/SaaS. Key features are drawn from vendor information and published literature (www.medidata.com) (www.oracle.com) (www.onyxnewsroom.com) (signanthealth.com).

Each platform has strengths/weaknesses: enterprise suites (Medidata, Oracle, Veeva) offer seamless integration with other trial systems and support huge global studies, but may require longer implementation. Specialized vendors (Suvoda, Calyx, Signant, 4G) often promise faster setups and innovative features (e.g. AI forecasting, supply analytics) to reduce waste. We analyze such trade-offs below.

Market Trends and Growth Drivers

Market Size and Projections

The global RTSM market is substantial and expanding rapidly. Strategic Market Research estimates the RTSM market at approximately **$1.5 billion** in 2024 and projects about **$3.2 billion** by 2030 (Strategic Market Research). This growth is driven by accelerating trial complexity and digital transformation. One analysis notes that between 2024 and 2030, decentralized/hybrid trial models and enlarged trial populations will make an effective RTSM “no longer an operational add-on — it is becoming central to trial strategy” (www.strategicmarketresearch.com).

Strategic Market Research identifies North America as the largest RTSM market in 2024 and projects the highest regional growth rate for Asia-Pacific (Strategic Market Research). The report also describes strong adoption of cloud-based RTSM systems (deployment analysis).

Figure 2 shows a forecast summary of RTSM market expansion:

Year	Global RTSM Market (USD)
2024	1.5 billion (www.strategicmarketresearch.com)
2030	3.2 billion (www.strategicmarketresearch.com)

Table 2. Projected RTSM market size (USD) and CAGR (2024–2030) (www.strategicmarketresearch.com).

Besides total market size, segmentation is notable. By deployment, cloud solutions (e.g. SaaS) are the fastest-growing, offering quicker deployment and easier integration with EDC/CTMS (www.strategicmarketresearch.com). On-premise systems still have niche use (certain government-sponsored

trials), but their growth is modest. By functionality, supply-management modules currently dominate revenue share (since every trial needs supply logistics) even as the randomization-only segment (used in simple studies) remains substantial.

Adoption Drivers

Several macro trends explain the surge in RTSM importance:

- **Clinical Complexity:** Trials today involve more sites (often global multi-center), more arms (e.g. adaptive designs, basket trials), and more data endpoints. Tailored randomization schemes and dynamic dosing rules have become commonplace. For instance, oncology and rare-disease trials often use complex adaptive randomization to balance arms efficiently. This complexity demands RTSM that can support sophisticated protocols without manual errors.
- **Cost Pressures:** McKinsey's November 2019 article, citing DiMasi et al. (2016), reported a historical estimate of about $2.6 billion to bring a drug to market, including failures—a roughly 140% increase over ten years (McKinsey, 2019). Competition and pricing pressures also encourage sponsors to control operational budgets. In a separate 2021 analysis, McKinsey estimated potential clinical drug-supply savings of 15–20% from broader improvements across the supply model. IRT is one contributing tool for forecasting and supply planning (McKinsey, 2021).
- **Decentralized and Hybrid Trials:** The rise of telemedicine, home nursing, and patient self-shipping (especially after COVID-19) means sponsors ship drugs directly to patients or to local pharmacies. Remote dosing requires new logistics capabilities (e.g. tracking outside-site shipments). Modern RTSM must interface with delivery services and handle unanticipated workflows. This trend increases reliance on digital tracking and flexibility of supply algorithms.
- **Regulatory Scrutiny and Data Integrity:** Regulatory agencies (FDA, EMA, etc.) insist on stringent audit trails and data accuracy. Automated RTSM logs exact supply movements and randomization decisions electronically, reducing human transcription errors. In fact, integrated IRT is increasingly considered a best practice to "maintain result integrity" by eliminating selection bias (signanthealth.com) (www.strategicmarketresearch.com). Tighter electronic controls (21 CFR Part 11 compliance, EU Annex 11) have pushed sponsors away from paper or manual methods toward computerized systems.
- **Technological Innovations:** Availability of cloud computing (AWS, Azure, OCI) and high-speed internet globally has made it feasible to deploy real-time global RTSM even in remote locations. Emerging technologies like **AI and predictive analytics** are now entering the R&D domain: pilot integrations (e.g. ML forecasting by N-SIDE with Suvoda) promise to further improve supply predictions (www.clinicaltrialsarena.com) (www.strategicmarketresearch.com). Figure 3 highlights some of these drivers.

(www.clinicaltrialsarena.com) (www.strategicmarketresearch.com) *Figure 3. Key drivers accelerating the RTSM market: increased trial complexity, cost containment, decentralization, regulatory demands, and new technologies (AI/ML).*

Vendor Landscape

The RTSM vendor landscape is dynamic, with consolidation and partnerships among CROs, technology companies, and classic software vendors. Notable players include:

- **Medidata (Dassault Systèmes):** Long an eClinical leader, Medidata offers **Rave RTSM** fully integrated into the Medidata Platform. It serves many large pharma and CROs, emphasizing a single-data-platform approach (www.medidata.com). Medidata claims near real-time supply visibility and predictive forecasting across global trials.
- **Oracle Life Sciences:** Through the **Clinical One** cloud, Oracle recently relaunched its RTSM offering (often called **Clinical One RTSM**). Built on Oracle Cloud, it touts no-code randomization configuration and rapid trial launch (www.oracle.com). Oracle's broad portfolio (including EDC and CTMS) allows end-to-end data connectivity.
- **Veeva Systems:** Veeva announced its acquisition of Veracity Logic on December 13, 2021, offering the solution as Veeva RTSM (acquisition announcement).
- **Suvoda:** Suvoda and Greenphire announced completion of their merger on April 24, 2025. Thoma Bravo is the lead strategic investor, with Bain Capital Tech Opportunities Fund and LLR Partners making a significant minority investment (Suvoda merger announcement).
- **4G Clinical:** Founded in October 2015, the company offers Prancer RTSM (4G Clinical launch announcement). It emphasizes modern architecture (AWS-based) and AI tools. The 4G platform includes **Prancer RTSM** for day-to-day IRT and **4C Supply** for advanced forecasting/portfolio planning. 4G describes NLP as simplifying and accelerating Prancer's system-build process (4G Clinical). An interview with their CEO highlights dynamic resupply algorithms and supply-chain transparency as competitive features (www.onyxnewsroom.com). Despite being smaller (≈400 staff), 4G claims significant market traction in adaptive trial space.
- **Signant Health (formerly CRF Bracket):** A provider of patient data capture (eCOA) that expanded into RTSM. Signant's RTSM focuses on automated supply optimization to stretch medication further. For example, its marketing suggests "proprietary algorithms" reduce overage and consolidate supplies across study programs (signanthealth.com). Signant appeals to existing clients who need integrated patient data and supply logistics.
- **Perceptive (formerly Calyx):** Parexel announced the separation of its Informatics and Medical Imaging business in January 2021, with Parexel Informatics becoming Calyx. Calyx and Invicro launched under the Perceptive corporate identity on September 30, 2024 (Parexel; Perceptive announcement).
- **Almac Group:** Traditionally a clinical supply and packaging CRO, Almac now offers **Almac ONE**, branding it as a unified digital supply chain solution (www.almacgroup.com). It integrates IRT with physical supply services (labeling, logistics), promising "holistic data flow" and closed-loop visibility. This approach targets sponsors looking to outsource both software and hands-on supply management under one provider.

- **Former Clario software offering:** Clario announced the sale of its Software Solutions business to Sitero on August 1, 2023. Its announcement included RTSM/IRT in the eClinical suite to be rebranded and integrated into Sitero Mentor (Clario announcement). The earlier Clario–IDDI partnership should be read in that historical context, rather than as evidence of a current Clario RTSM offering.
- **Boutique Solutions:** Several smaller or region-specific vendors exist (e.g. Clinion, Datatrak, Calyx BI). Many of these focus on mid-sized trials. Additionally, generic EDC systems (e.g. Medrio) have added rudimentary RTSM modules for simple studies (medrio.com).

Veeva provides and supports Veeva RTSM (Veeva product sheet, p. 7). At the same time, nimble vendors like 4G and Suvoda gain niche share by offering faster configurations for adaptive designs (www.strategicmarketresearch.com). In 2025, industry estimates placed the total RTSM market at ~$1.2–1.3 billion, with 4G Clinical holding **under 10%** of share (www.onyxnewsroom.com). This implies a highly fragmented market with room for growth and consolidation.

Current RTSM Solutions in Detail

In this section we describe key RTSM platforms in more detail, highlighting empirical evaluations and user perspectives.

Medidata Rave RTSM

Overview: Medidata (a Dassault Systèmes company since 2019) offers a fully-cloud native RTSM system as part of its Rave Clinical Cloud platform. Medidata stresses that RTSM must “not slow you down” (www.medidata.com), promoting integrated management of supply chains and rapid response to protocol changes. Typical users are large pharma companies and CROs already using Rave EDC or Rave CTMS, making integration seamless.

Features:

- *Integration:* Direct integration with Medidata Rave EDC, CTMS, and Analytics. Real-time data flows allow immediate tracking of drug inventory to patient-level records.
- *Randomization:* Supports common designs (simple, stratified, permuted blocks, minimization) and some adaptive features. Randomization can be configured via tools or spreadsheets.
- *Supply Optimization:* The system generates kit creation lists, manages site buffers, and forecasts inventory needs. It offers “predictive forecasting” algorithms to optimize supplies for current enrollment pace.
- *User Interface:* A web-based global portal for study teams; separate site portal for drug assignments. Workflow-oriented for quick entry.
- *USP:* Tight ecosystem – if a sponsor already uses Rave EDC, then Rave RTSM offers single sign-on and consolidated data.

Evidence / Commentary: Medidata's RTSM fact sheet describes a shared working environment for randomization, supply, and oversight (Medidata RTSM fact sheet). This is a supplier description.

Oracle Clinical One RTSM

Overview: Oracle's Clinical One platform unifies eClinical apps on Oracle Cloud. Its RTSM module (sometimes called "Clinical One Randomization & Supplies Management" or "Rider") is pitched as an innovative SaaS module that requires minimal programming. Oracle emphasizes rapid study start-up – "launch trials swiftly, reliably, and securely" (www.oracle.com) – and support for both localized and decentralized models.

Features:

- *Configuration:* No-code study design tools for randomization and dosing rules (www.oracle.com). Sponsors or CROs can configure complex scenarios (e.g. factorial designs) through graphical interfaces.
- *Pharma Supply:* Real-time inventory dashboard; allow business users to adjust disposition (block or ship instructions) without vendor back-and-forth (www.oracle.com).
- *Globalization:* Supports multi-country studies with automated site activation and shipment plans. Oracle touts high security (OCI infra) for GxP validation.
- *Innovation:* One unique aspect is Oracle's large digital gateway (for connecting disparate data streams) that can tie in RTSM data with other enterprise data lakes.
- *Integration:* Works with Oracle's CTMS and Data Relationship Management.
- *Evidence:* Oracle claims their RTSM "redefines how trials are executed" (www.oracle.com). It appeals to organizations already in Oracle or those wanting an all-Oracle stack. Oracle presents its interoperable RTSM offering as designed to help sponsors start trials quickly, reliably, and securely (Oracle product description).

Veeva RTSM

Overview: Veeva announced the acquisition of Veracity Logic on December 13, 2021. The acquired solution is offered as Veeva RTSM (Veeva announcement).

Features:

- *Purpose:* Randomizes subjects and manages trial supplies.
- *Integration:* Productized connections transfer patient data to Veeva EDC and Veeva eCOA, site information and status from Veeva CTMS, and screening, randomization, and visit data to Veeva DQS (product sheet, p. 7).

Suvoda IRT

Overview: Suvoda was founded in 2013 (Suvoda). It offers an AWS-hosted IRT platform marketed as a "command and control" center for trials (www.suvoda.com). Suvoda caters to both CROs and sponsors, touting full-service support teams and easy study config.

Features:

- *No-Code Configuration:* Emphasizes drag-and-drop study building; claims average of <1 UAT defect per moderate complexity case (www.suvoda.com). Business analysts can edit randomization or supply logic on-the-fly.
- *Flexibility:* Supports "simple or complex" trials with 100% configurable services teams. Suvoda also provides optional ancillary features (e.g. patient diary tools via partnerships).
- *Innovation:* Recently integrated external forecasting (e.g. the N-SIDE ML engine) to improve supply estimates (www.clinicaltrialsarena.com). Advertises AWS reliability and "zero downtime".
- *Evidence:* In user surveys, Suvoda is often praised for its intuitive interface. A Clinical Trials Arena article highlighting Suvoda noted that their platform's cloud architecture and high configurability help reduce the 70% drug waste many sponsors silently endure (www.clinicaltrialsarena.com). (Suvoda's article complains sponsors only budgeted 30% wastage but face ~70% in reality (www.clinicaltrialsarena.com), implying the need for automated tools.)

Calyx IRT

Overview: The Calyx name here refers to the business that emerged from Parexel Informatics in 2021. Calyx and Invicro launched under the Perceptive corporate identity on September 30, 2024 (Parexel; Perceptive announcement).

Features:

- *High-Touch Service:* Calyx assigns experienced biostatisticians and supply specialists to design and operate the system. They handle configuration, site support, and reporting.
- *Technical:* Offers standard and adaptive randomization algorithms. Supports global multi-product trials, multi-dosing (eg. titration studies), and patient-level inventory at sites.

Signant Health RTSM

Overview: CRF Health and Bracket combined in 2018 as CRF Bracket, which launched the Signant Health name in 2019 (Signant Health history). Signant offers an RTSM solution emphasizing lean supply. Its motto is to "make your clinical supplies go further" by using algorithms to reduce overage (signanthealth.com). Signant's selling point is integration with its eCOA/ePRO products and focus on patient-centric trials.

Features:

- *Supply Optimization:* The system can pool unused supplies across studies or compounds, and dynamically allocate stock to sites based on live enrollment. Proprietary logic aims to *minimize excess inventory*. For example, it can route direct-to-patient shipments only for essential visits.

- *Configurability:* Aimed at mid-size trials. Uses configuration rather than code; the site interface is reportedly user-friendly and mobile-friendly.
- *Evidence:* In their product literature, Signant emphasizes algorithmic supply planning. No independent quantitative study of Signant exists in literature, but user testimonials suggest improved control of supply variance. Signant has argued that their overlap with ePRO makes patient compliance data feed back into supply planning.

4G Clinical (Prancer RTSM and 4C Supply)

Overview: 4G Clinical was founded in October 2015 (4G Clinical launch announcement). Its main product **Prancer RTSM** uses AWS cloud and modern software practices. A second product (**4C Supply**) is targeted to large sponsors for enterprise forecasting across portfolios. 4G identifies NLP among its technologies (4G Clinical); the specification-to-system build is described in the Automated Build feature below.

Features:

- *Automated Build:* According to 4G's product-launch announcement, Prancer uses natural language processing to read and interpret written RTSM specifications and build a deployable system automatically (4G Clinical announcement).
- *Supply Forecasting:* 4G describes Prancer as helping supply managers choose a supply strategy through intuitive forecasting interfaces (4G launch announcement).
- *Portfolio Level Planning:* 4C Supply offers cross-study forecasting, enabling sponsors to optimize manufacturing and procurement budgets. It's still maturing but is one of the first IRT vendors to overtly target ESG (e.g. routing via low-emission couriers) (www.onyxnewsroom.com).

Almac ONE

Overview: Almac Group, a global company known for packaging and supply services, has bundled its digital offerings into **Almac ONE**. This is essentially an integrated supply chain platform that includes IRT/IXRS for randomization alongside ATP (automated transfer of product) management and labeling control. The focus is end-to-end – bridging the physical nursing activities with digital trial data (www.almacgroup.com).

Features:

- *Unified Process:* All steps from patient enrollment to final shipment are connected. For example, the same system that randomizes a patient will trigger the kit print and shipping instructions, with a closed-loop data record.
- *Flexibility:* Capable of handling multi-item kits, re-supply from multiple warehouses, managed temperature items, etc.
- *Visibility:* Achieves "enhanced visibility and accuracy throughout the lifecycle of your study" according to Almac's brochure (www.almacgroup.com). Real-time dashboards track shipments, demographics, and supply projections together.

- *Evidence:* Almac has published case stories (one found online showed how shifting IRT rules and consolidated supply planning yielded faster study activation), but peer-reviewed data is scarce. It is mainly targeted at sponsors who already use Almac's packaging or depot services, providing a one-stop-shop for supply chain.

Others (Clinion, TrialKit RTSM, CRO Tools)

Beyond the names above, several other software products exist but with less public detail:

- **Clinion RTSM:** Clinion is a proprietary product owned by Clinion AI Technologies Pvt Ltd (company overview).
- **TrialKit RTSM:** Crucial Data Solutions supplies TrialKit. Its randomization and trial supply management operates with TrialKit EDC (supplier announcement; product documentation).
- **Former Clario software offering:** Clario announced the sale of its Software Solutions business to Sitero on August 1, 2023. The announcement included RTSM/IRT in the suite to be rebranded and integrated into Sitero Mentor (Clario announcement). This is a historical transaction, rather than verification of a current Clario RTSM offering.
- **Clinlogix:** NAMSA's history identifies Clinlogix as a Philadelphia-based CRO it acquired (NAMSA).

Case Studies, Data, and Evidence

Several studies and reports quantify the benefits of modern RTSM systems in real clinical trials:

- **Waste Reduction:** In the Me.Me.Me. metformin trial, Cortellini et al. calculated a 29.5% medication saving against a patient-pack supply approach, comparing the theoretical order with bottles already dispensed plus the estimated bottles needed to finish the study. They estimated about €71,000 in drug-budget savings and about €60,000 after software development and maintenance expenses. The authors caution that their home-grown system lacks external validity (Cortellini et al., 2019).
- **Time to First Patient In (FPI):** Advanced RTSM can accelerate study startup. Vendors claim that a reusable RTSM build shortens the timeline from protocol finalize to site readiness. Medidata promotes aligned supply and randomization strategies to accelerate FPI (Medidata RTSM fact sheet). In practice, sponsors with configurability-heavy systems (like 4G's NLP-driven build process) report achieving rapid go-live, which is critical when trials race to enroll ahead of patent or pipeline deadlines.
- **Operational Cost Savings:** Beyond supply wastage, RTSM reduces manual labor. Historical processes required phone calls or spreadsheets to randomize patients and place kit orders. Now, centralized control means fewer personnel needed for coordination and less room for billing errors. McKinsey's 2021 analysis describes improving clinical drug supply as a way to prevent supply from becoming a bottleneck to successful drug delivery (McKinsey).

- **Quality and Compliance:** With all decision-logs in software, data integrity improves. The WorldPharma Today review notes that converting from IVR to web-based IRT improved data accuracy and eliminated double data entry (www.worldpharmatoday.com). Case audits in trials using RTSM typically find far fewer randomization or dispensing errors. Regulatory agencies increasingly expect computerized randomization to protect blinding.
- **Flexibility with Complex Protocols:** In adaptive trials where arms can change based on interim outcomes, RTSM enables on-the-fly re-randomization strategies. There are case reports (primarily internal CRO examples) of sponsors adjusting randomization ratios and supply buffers mid-study without redoing the entire drug plan, thus avoiding major delays or waste.
- **Documented Trial Context:** Cortellini et al. developed their system for the Me.Me.Me. randomized trial of diet and metformin in people with metabolic syndrome (Cortellini et al., 2019).
- **Evidence Scope:** Cortellini et al. caution that their home-grown trial management system lacks external validity; that limitation should inform interpretation of its reported savings (Cortellini et al., 2019).

It should be noted that quantifying some benefits is challenging due to study heterogeneity and commercial sensitivity. The cited figures (29.5% savings (pmc.ncbi.nlm.nih.gov), $6M savings (www.clinicalresearchnewsonline.com)) come from published case studies and white papers. These individual examples illustrate potential savings, subject to study-specific limitations: Cortellini et al. explicitly identify a lack of external validity for their home-grown system (Cortellini et al., 2019). Evaluate net return and payback using each study's implementation costs and operating assumptions. Indeed, Cortellini et al. report that, even after paying €11,000 for development, the sponsor saved €60,000 net (pmc.ncbi.nlm.nih.gov).

McKinsey identifies IRT as one tool that can support greater flexibility through site and patient forecasting and supply planning (McKinsey, 2021).

Perspectives and Use Cases

Sponsor and CRO Views

- **Pharma/Biotech Sponsors:** They demand solutions that minimize total cost and risk. For a documented example of a different approach, Cortellini et al. describe a small research team building its own CTMS for trial data and drug management (Cortellini et al., 2019). Lead clinical operations executives express that with tight budgets, even a 10% drug spend reduction justifies RTSM procurement. Smaller biotech firms (with fewer internal IT resources) look for turnkey SaaS systems; here solutions like Suvoda or Veeva appeals due to low IT overhead. Complex sponsors (e.g. global oncology programs) often employ specialized RTSM consultants (e.g. Calyx or IDDI) to co-design the system.
- **Contract Research Organizations (CROs):** Top-tier CROs (IQVIA, PPD, Syneos, Parexel, etc.) typically offer RTSM as part of their services. They may internally license a platform (Medidata RTSM is common) or partner with vendors (Suvoda, 4G). Clario's sale announcement stated that Sitero Mentor would continue supporting the existing Clario customer base (Clario announcement). For CROs, a

critical factor is speed: they may support many clients with overlapping timelines, so the ability to spin up new studies quickly is valued. Reusable cloud platforms and study templates are selection criteria to evaluate. Some larger CROs have even hired algorithm experts to internally refine the supply forecasting process.

- **Investigative Sites and Pharmacists:** While less vocal in strategic purchasing, trial sites benefit from RTSM through clearer reporting and few protocol deviations. For investigational pharmacists, RTSM gives confidence that inventory tracking is robust, reducing trial-monitor queries related to missing kits or mis-randomized shipments.
- **Patients:** Indirectly affected, patients see benefits of RTSM in consistent drug availability (no interrupted dosing) and potentially quicker trial ends (if recruitment or dosing are more efficient). Some decentralized trial models even allow patients to receive meds at home via courier, routed by the RTSM system, simplifying the trial experience.

Geographical and Therapeutic Variations

- **Emerging Markets:** In countries like India, China, Brazil, RTSM adoption is growing but not universal. Cost sensitivity is higher there, so some sponsors initially use spreadsheets/IWRS, but the trend is toward cloud solutions. Notably, local Chinese companies (e.g. FDAHC FocusedData) have developed their own IRT software to comply with domestic regulations.
- **Therapeutic Areas:** RTSM is ubiquitous in oncology, neurology, and any field with blinded, multicenter trials. Rare disease studies (often global consortia) almost always require RTSM due to complex dosing and limited drug supply. Vaccine trials also use IRT to manage randomization across arms and schedule logistics. In contrast, simple open-label or single-site healthy volunteer studies may still randomize manually or not at all.

Case Study: Pandemic Vaccine Trial (Hypothetical synthesis)

This is a hypothetical illustration. In a multicountry vaccine trial, an RTSM could trigger site shipments using predefined criteria and dosing schedules, a capability documented by Crucial Data Solutions for TrialKit RTSM (product documentation). The scenario supplies no measured kit-discard rate or historical comparator.

Implications and Future Directions

Efficiency and Cost Savings

Financial returns should be evaluated at study level. In the Me.Me.Me. trial, Cortellini et al. estimated about €71,000 in drug-budget savings and about €60,000 after software development and maintenance expenses (Cortellini et al., 2019).

Beyond monetary returns, sponsors report **improved trial reliability**. One CTMS implementation case described that having RTSM with real-time dashboards kept study leadership aware of potential supply risks (like one country's import delay) and allowed preemptive mitigation. This resilience is particularly critical for patient safety and trust.

With rising emphasis on **sustainability**, trials are also measuring environmental impact. As 4G Clinical's CEO notes, modern RTSM can optimize for CO_2 or waste objectives (www.onyxnewsroom.com). For instance, by clustering shipments or choosing lower-emission couriers, an RTSM can directly reduce a trial's carbon footprint. Although still in early stages, such features appeal to pharma companies with ESG mandates. One industry article highlights "sustainability and ESG" as a growing user priority in selection of trial technology (www.onyxnewsroom.com).

Regulatory and Compliance Considerations

For SaaS RTSM, FDA recommends risk-based validation before use and evaluation and validation of subsequent system changes throughout the system life cycle, depending on risk. All changes to the system should be documented (FDA guidance, Q7).

Technological Evolution

AI and Machine Learning: Already emerging, predictive analytics will become standard in RTSM. As one market report notes, AI-driven randomization and forecasting can "minimize drug wastage and optimize supply chains, particularly for high-cost therapies" (www.strategicmarketresearch.com). We see this in practice with N-SIDE's supply-app partnering with Suvoda, and 4G's usage of ML in 4C Supply. Future features may include reinforcement learning (continually learning from enrollment patterns), NLP-driven consent checking, and digital twins of supply chains. Arxiv research (Noy Klein et al., 2025) indicates advanced adaptive algorithms (Randomize-First Augment-Next) that could one day interface with RTSM when designing Phase III trials (arxiv.org).

Blockchain and Traceability: Some innovators are exploring blockchain to enhance supply traceability (especially in multicenter international trials). For example, Applied Clinical Trials has discussed blockchain as a means to create immutable supply chain records (www.appliedclinicaltrialsonline.com). While not widespread in 2026, pilot projects exist. A blockchain-backed RTSM could guarantee chain-of-custody for drug shipments, which appeals for high-value or cold-chain biologics (like CAR-T treatments).

IoT and Digital Sensors: Internet-of-Things devices for cold-storage monitoring are integrating with RTSM. If a temperature excursion is detected at a depot, the RTSM can automatically flag and generate a recall or replacement. This automation reduces risk of compromised doses. Vendors have begun partnerships with IoT specialists, enabling "smart supply" trials.

Platform Convergence: There is a trend towards single-vendor eClinical suites. As Veeva demonstrates, the lines blur between EDC, CTMS, eTMF, and RTSM modules. We expect more cross-platform linkages: eConsent systems triggering enrollment in RTSM, wearable data streams adjusting supply decisions, even financial management systems receiving automated IMP costing reports. For example, Veeva's Clinical suite is moving toward a common data model (CDM) across modules.

Lowering Friction: One future direction is to minimize the need for specialized statisticians to build RTSM. 4G's NLP tool is a step: if an IRT system can read protocol text or structured schemas at launch, the time from concept to deployment can be mere days. Similarly, intent-based user interfaces that let study teams "say what they need" and have the system configure itself (possibly via AI) are under development. This democratizes RTSM beyond big sponsors.

Challenges and Considerations

Despite the benefits, sponsors face challenges:

- **Cost/Complexity:** Initial licensing and services can be non-trivial, especially for custom needs. Mid-size companies may hesitate if trial sizes are small. This is driving the market for pay-per-study or modular RTSM offerings.
- **Data Silos and Integration:** In hybrid tech stacks, exporting RTSM data to other systems can require work. True "single source of truth" is often not fully achieved, and data reconciliation tasks remain for biostatisticians. Vendors are responding by publishing APIs and supporting industry standards (CDISC, HL7-FHIR).
- **Training and Adoption:** Sites unfamiliar with RTSM need training. Robust helpdesk support (provided by vendors) is essential in multi-country deployments. User-error (e.g. incorrect patient randomization entry) is still possible, so interface design and validation checks are crucial.
- **Security and Privacy:** SaaS systems must guard patient IDs and supply chain networks. Although rare, there is heightened awareness that cyber-attack on a trial could disrupt drug supplies. Vendors focus on hardening their cloud services and obtaining certifications (SOC2, ISO 27001).

Conclusion

Randomization and Trial Supply Management platforms have matured into **vital infrastructure** for clinical research. The convergence of trial complexity, globalization, and cost containment policies has made advanced RTSM systems almost mandatory for sponsors aiming to run efficient, successful trials. In this report, we have compared the major RTSM solutions of 2026, analyzed their capabilities, and surveyed evidence of their impact. The savings evidence cited here should be interpreted at study level: Cortellini et al. caution that their home-grown trial management system lacks external validity (Cortellini et al., 2019).

We also see that the market is dynamic and innovating: leading platforms are adopting cloud-native architectures, AI-driven forecasting, and end-to-end integration. Customer expectations highlight ease-of-use and configurability (Minimizing manual steps with auto-generation of study logic (www.onyxnewsroom.com)). The global RTSM market will likely continue its strong growth trajectory (projected around $3.2B by 2030 (www.strategicmarketresearch.com)). In summary, effective RTSM is now recognized not as a discretionary tool but as a **strategic asset** in clinical operations – one that ensures both scientific rigor and economic efficiency in bringing therapies to patients.

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Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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