
Prevail Randomization & Trial Supply Management System



RISE
ABOVE

The world's most adaptable RTSM solution for the industry's 2nd biggest operational problem*

Prevail's patented RTSM technology platform delivers fast, accurate, and controlled randomization and trial supplies management while keeping your budget in check.

A large, semi-transparent blue-tinted image of a hand holding a vial with a label, serving as a background for the lower half of the page.

“Wow. Just wow. It’s been 6 short weeks to understand our requirements, put together a whole process, develop an innovative predictive algorithm that meets our requirements. Wow!”

Head of Supplies Management,
Large Biotech

*Failure to account for disposition of study drugs - Dr. Janet Woodcock, FDA

3 Reasons To Choose Prevail RTSM

1. Avoid wasted time and product

With just-in-time delivery based on predictive site level supply needs, temperature/expiry tracking and complex inventory level tracking, you will never have to waste drug or not have it available when needed - avoiding industry's average 25% waste rate.

2. Implement quickly, without breaking your budget

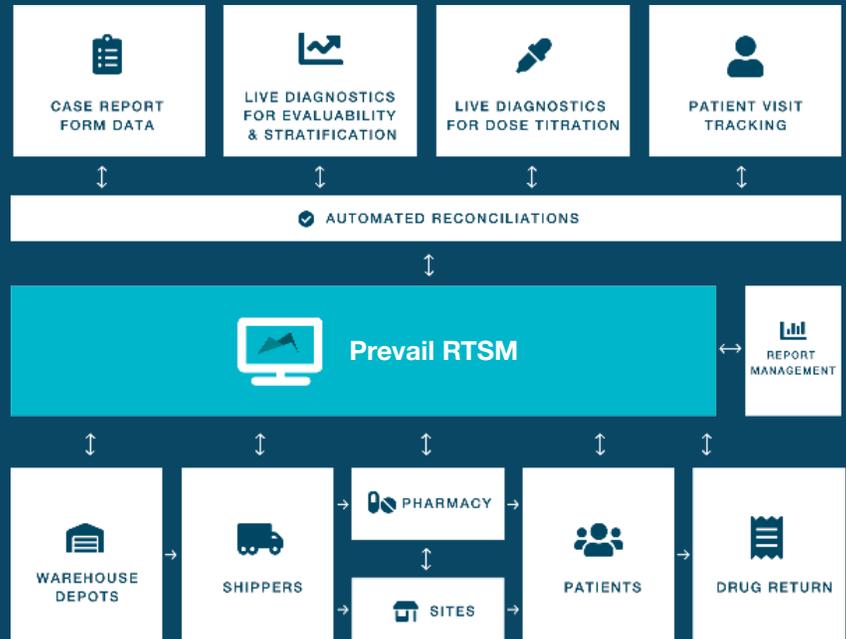
Pre-validated drag-and-drop functionality without the need to program each step offers setup times of 4-6 weeks and modifications in just a few days, delivering clear value that gets budgets signed off in hours.

3. Adapt easily to any protocol design and protocol amendment

Unparalleled configurability without requiring programming, integrated real-time analytics and visualizations, and fast data turnaround for interims let you easily manage complex protocols, adaptive designs, and the most challenging drug supply and randomization strategies.

Gain Control Over Your Complete Clinical Trial Supply Chain

Prevail's unique RTSM solution aggregates real-time data from every component of the clinical supply chain, providing the visibility and control you need to reduce inefficiencies, waste, and errors – enhancing patient safety and trial success.



Key Prevail RTSM Features At-A-Glance

- Fast Setup
- Multi-Language 24/7 Support
- Expiry/Stability/Temp Tracking
- 15 Years Experience
- Successfully FDA Audited Central Balance and Minimization Capability
- Automated Predictive and Trigger Resupply & Just-In-Time Delivery
- Advanced Supplies Management at all Depots, Centers, and in Transit
- Order Suggestion Report
- Alert System
- Fast Two-Way Integration with any other Databases
- Predictive Forecasting
- Real-Time Randomization
- Global Experience in 6 Continents
- Cohort Progression
- Manage Dose Titration
- Multicenter Trial Dosing
- Manage Emergency Unblinding / Code-Breaking
- Regulatory Compliant: 21 CFR Part 11- GCP Compliant and FDA Inspected
- Adaptive Trials
- Robust and Configurable Reporting Engine with Actionable Analytics
- Automated Reconciliation with eCRF

**PREVAIL RTSM
SELECTED CUSTOMER RESULTS**

By utilizing the highly adaptable Prevail RTSM system and our extensive domain expertise, we have helped our customers successfully:

Rescue mid-study an excel-based Phase 3 that was close to failing due to a vendor's inflexible and costly supply plan that did not reflect the protocol and actual patient recruitment

Conduct a rapid turnaround of a failing global Phase 2 study from an IWR system that didn't have the flexibility to make adjustments needed due to study changes

Overcome challenges caused by COVID-19 limitations such as delayed enrollment and current depot inventories not prepared for a pandemic

KEY STATS

System setup in as little as

2 Weeks

Average on-time drug delivery of

97%

Wasted kits reduced by

60% over industry average



Enhance Patient Safety and Improve Trial Quality

As a flexible, fully integrated system, Prevail's RTSM system provides control over your complete clinical trial supply chain from initial supply forecasting, inventory tracking, and randomization, through patient visit tracking, live diagnostics for stratification and dosing, and automated reconciliation.

By dynamically managing integrated randomization and drug supply data in real-time, you have the critical information you need at the right time to help ensure trial performance according to the protocol:

Enhance Patient Safety

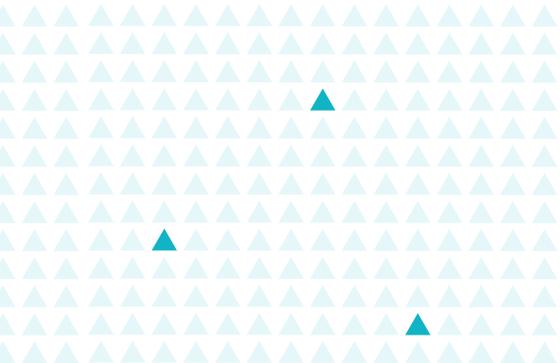
Real-time alignment and updating of treatment inventory based on actual trial activity means patients have access to the correct treatment in the proper dosage – even in trials that include an adaptive design component.

Increase Site Productivity

Instead of spending valuable time on supply-related issues, investigator sites can focus their efforts on patient enrollment and GCP – increasing the speed and accuracy of patient screening, qualification, stratification, and treatment.

Improve Trial Quality

Predictive monitoring and automation of product supply to sites helps ensure that treatment is available when a patient is enrolled and throughout the trial, minimizing involuntary dropouts and data loss due to missed treatments - improving quality and increasing the likelihood of trial success.



Maintain Quality Control with Unified Management Across Your Clinical Supply Chain

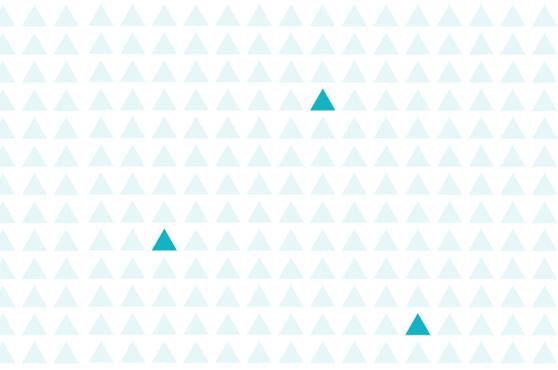
Prevail's RTSM system dynamically manages the end-to-end randomization and drug supply process in real-time from a single console, increasing the speed and accuracy across the entire process. You minimize the risk of delays due to stockouts or misallocation of drug, and easily manage complexities such as import/export requirements, multiple regional shippers, and multiple kits per site or patient.

You can screen, qualify, stratify and treat patients while always knowing the quantities of drug at the depots and sites. You can forecast and receive alerts for just-in-time re-supplies, order supplies, track the shipments, and automatically maintain a drug accountability log.

Prevail RTSM lets you centrally manage clinical supplies inventory easily from API through to patient - including patient allocation, site inventories, depot inventories at kit or component level, and expiry and stability management at kit and component level.



Prevail can handle complex logistics globally, working with and managing inventory for multiple depots in any continent (blue pins in the map are depots, all others are sites).



By integrating seamlessly with warehouse depots, shippers, pharmacies, and sites, Prevail RTSM surpasses industry norms in percentage of kits not wasted (<10% wasted versus industry's 25%) as well as on-time deliveries and reduction of incomplete kits. Randomization can be web- or phone-based, or a hybrid approach to account for different regions and patient populations.

It supports multiple blinded and un-blinded user types with emergency and safety un-blinding capabilities. The system can manage dose titration, maintains balance across strata and can include a minimization system.

Key Benefits of Using Prevail RTSM

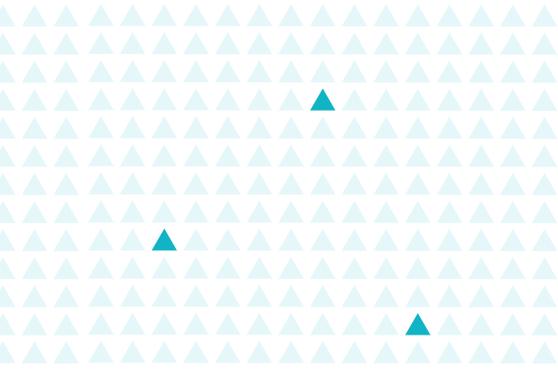
A drag-and-drop configuration system allows for fast system set-up and easily accommodates multiple dose, cohorts, strata or stages in adaptive designs. Training material are provided to help sites and depot partners get up to speed faster.

Manage Even the Most Complex Treatment Protocols with Powerful and Configurable Functionality

The Interactive Web Randomization system can be programmed to account for any study design, randomization style, numbers/type of cohorts, balancing of strata and decision-tree of stages. Whether you have multiples vials of materials that need to be mixed at the site pharmacy or an autologous stem cell product with days of stability, the Prevail system is flexible to accommodate any challenge.

Adapt and Update Rapidly for Changes Due to Protocol Amendments

Instead of a simple out-of-the-box system, the Prevail solution allows for amendments, corrections and emergency redistributions on the fly so that lessons learned and changing realities can be incorporated instead of worked around.



Save Time and Cost with Just-in-Time Delivery

An integrated randomization and supply system allows for enrollment to dictate how much drug stock is needed at a particular site, reducing the amount of excess inventory necessary to be held in waiting. Sophisticated forecasting and triggers reduces manufacturing, packaging and shipping costs and reduces the amount of drug needed to be destroyed and accounted for at the end of the study.

Reduce Risk of Supply Issues with Real-time, Integrated Inventory Tracking

Keep track of all inventory levels, whether at the site, country depot, production or packaging distribution center or elsewhere. Track shipments via all major carriers to ensure timely delivery. Manage this supply chain thanks to integrations, barcode scanning and custom phone or web interfaces – whatever it takes to get the job done.

Track Temperature, Stability and Expiry

Ensure that study medications never go beyond acceptable temperatures or expiry dates with automated tracking and alerts.

Reduce Regulatory Risk

Easily provide data reviewers and regulatory agencies with detailed reports and visualizations, including audit trails, while a study is underway or following study closeout – allowing you to clearly explain your randomization and trial supply management processes and minimize disruption.



RISE
ABOVE

© 2022 Prevail InfoWorks
211 N 13th Street
Philadelphia, PA 19107
+1 267.797.2001
www.prevailinfoworks.com

About Prevail InfoWorks

Prevail is a pioneering life sciences software company with a unique combination of clinical expertise and engineering prowess, delivered through a best-in-class, modular eClinical ecosystem with sophisticated analytics and visualizations and supported by Prevail domain experts.

Our innovative and patented technology quickly and easily integrates, normalizes, reconciles, and presents aggregated data, analysis, trends, and metrics encompassing all study-related data sources through a single interface - making clinical development faster and easier, while reducing trial risk. With Prevail, trial sponsors can obtain unmatched, real-time answers to virtually any clinical, operational, and financial question regarding a study or program.