Captivate® RTSM

Flexible, RobustRandomization with Integrated Kit Tracking for Clinical Studies

Product Overview

Captivate RTSM is aweb-based Randomization and Trial Supply Management module designed to support a wide range of randomization strategies while maintaining operational simplicity, compliance, and audit readiness.

Built for sponsors and CROs running interventional studies, Captivate RTSM delivers robust randomization capabilities without the overhead and rigidity of traditional IRT systems. Designed to integrate seamlessly with the Captivate clinical data platform, Captivate RTSM enables study teams to configure and manage randomization schemes, maintain blinding, and track investigational kits within a single, unified environment.

Robust Randomization That Reflects Protocol Requirements

Captivate RTSM supportsmultiplerandomizationmethodologiestoaccommodatebothsimpleand complex study designs.

Key capabilities include:

- Simple randomization
- Stratified randomization across protocol-defined factors
- Permuted block randomization with configurable block sizes
- Dynamic randomization to support balance across treatment arms
- Real-time enforcement of randomization rules at the point of assignment

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Blinding and Unblinding Controls

Captivate RTSM includes built-in support for blinded study designs while preserving participant safety and regulatory compliance.

Key capabilities include:

- Support for single-blind and double-blind study designs
- Role-based access controls to protect blind integrity
- Controlled emergency unblinding workflows
- Full audit trails for all unblinding events

Integrated Kit Identification and Tracking

Captivate RTSM pairs randomization with structured kit ID setup and tracking to support investigational product oversight.

Key capabilities include:

- Centralized kit ID configuration
- Assignment of kits based on randomization results
- Tracking of kit status throughout the study lifecycle
- Visibility into used, assigned, and available kits

Streamlined Workflows for Sites and Study Teams

Captivate RTSM delivers intuitive workflows that support efficient site participation while maintaining centralized oversight.

Key capabilities include:

- Role-based access for sites, monitors, and central teams
- Guided workflows for randomization and kit assignment
- Immediate confirmation of randomization actions Clear
- visibility into subject and kit history

Integrated With the Captivate Clinical Platform

Captivate RTSM operates within the broader Captivate ecosystem, enabling consistent study configuration and unified data oversight.

Key capabilities include:

- Shared subject and study context with Captivate EDC
- Unified audit trails across randomization, kits, and clinical data
- Simplified reporting and exports that include randomization metadata
- Reduced reconciliation effort across systems

Security, Compliance, and Inspection Readiness

Captivate RTSM is designed to meet global regulatory expectations and support audits throughout the study lifecycle.

Key capabilities include:

- Compliance with 21 CFR Part 11, Annex 11, and applicable privacy requirements
- Secure system access and data handling
- Comprehensive audit trails for randomization, blinding, and kit events
- Documented traceability for inspections and monitoring

A Practical Alternative to Traditional IRT Systems

Captivate RTSM delivers robust randomization and blinding capabilities without the cost, complexity, or long implementation timelines of full IRT platforms.

- More flexible than rigid IRT systems that require extensive customization
- More structured and auditable than manual or spreadsheet-based randomization
- Designed to support study needs without unnecessary operational overhead

Who Uses Captivate RTSM

CaptivateRTSMisused by sponsors andCROs running interventional clinical trials that require reliable randomization and controlled blinding.

Common use cases include:

- Phase I–III randomized clinical trials

- Studies requiring stratification or dynamic randomization

- Blinded studies with emergency unblinding requirements

- Trials seeking integrated randomization without full IRT complexity

Why Study Teams Choose Captivate RTSM

- Robust support for multiple randomization methods

- Built-in blinding and emergency unblinding controls

- Integrated kit tracking aligned with randomization outcomes

- Unified workflows with Captivate EDC

- Inspection-ready audit-ability without unnecessary complexity