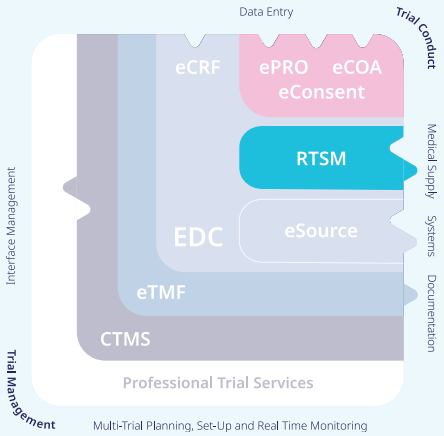
oomnia RTSM



ADVANCED RANDOMIZATION AND SUPPLY MANAGEMENT WITH OOMNIA RTSM

Randomize participants directly in the eCRF and manage supplies in real-time

Elevate your clinical trial management with oomnia RTSM, an integral part of our unified clinical research software. This tool streamlines randomization, blinding, treatment allocation, and trial supply management with unmatched precision and compliance. Seamlessly integrated, it automatically communicates with other modules enabling randomization and allocation to treatment directly within the eCRF.

- ✓ Automatic randomization and IP allocation
- ✓ Simplified real-time tracking
- ✓ Efficient blinding
- ✓ Controlled user access

BENEFITS OF OUR UNIFIED RTSM

Experience precision and efficiency

ACCESSIBILITY

oomnia streamlines clinical trial management by integrating eCRF and RTSM access, enabling a single login for seamless randomization, treatment allocation, and low stock alerts.

REAL-TIME REPORTING

Our tool enhances clinical trial efficiency with real-time tracking of Investigational Medicinal Products (IMPs) and automated low stock notifications to prevent recruitment delays.

RESOURCE MANAGEMENT

oomnia RTSM enables real-time tracking and automated tasks, ensuring swift IMP distribution, optimal inventory management, and prompt kit delivery to participants.

ERROR REDUCTION

oomnia integrates RTSM and eCRF to automate and ensure accurate randomization and IMP allocation, eliminating reconciliation needs. It tracks the status of all IMPs, including quarantined, missing, or damaged, to ensure only suitable IMPs are allocated.

TIME SAVINGS

Seamlessly integrated with a comprehensive ecosystem, oomnia RTSM boosts efficiency by providing instant IMP availability across sites and enabling real-time reporting. This reduces manual errors and accelerates trial management, saving valuable time.

COST SAVINGS

oomnia RTSM optimizes randomization workflows by automatically prioritizing the allocation of kits nearing expiration, reducing labor and cutting costs. The system also minimizes new drug shipments and kit wastage, optimizing resource utilization.

ADVANCED FEATURES OF OOMNIA RTSM

Unlock the full potential of your clinical trials

RANDOMIZATION

FEATURES	DESCRIPTION
Dynamic centralized randomization	• Support any randomization schedule or scheme, including multiple arms, stratified and/or block randomization, and more • Randomization history and audit trial is immediately available in real-time
Patient stratification	• Automatically stratify participants based on predefined criteria such as country, site, age, sex, or any other characteristic entered into the eCRF
Automatic allocation to treatment	• Automatically present the appropriate IMP kit number to investigators directly in the eCRF • The seamless nature of the system allows for real time tracking of IMP allocation, status, and easy reconciliation
Adaptive trial design	• Easily modify randomization schedules after interim data analysis and sample size reassessment

BLINDING

FEATURES	DESCRIPTION
Secure and integrated blinding mechanism	• oomnia RTSM ensures that all stakeholders are blinded to participant randomization to study arms • Only IMP kit numbers are presented to study staff within the eCRF
Controlled access to unblinded data	• Strict Role-based access to unblinded information • Assign Roles that can perform emergency unblinding • Robust audit trail and promotes transparency and accountability in the unblinding process
Easy end of study unblinding	• At the end of a study activate access to the unblinded randomization history and audit trial with a couple of clicks • Easy export for the biostatisticians and for the creation of randomization reports or reconciliations

MANAGEMENT OF STUDY MEDICATION AND MATERIALS

FEATURES	DESCRIPTION
Integrated inventory management	• oomnia RTSM provides real-time tracking and management of IMP inventory at each investigational site and depot
IMP dispensation and return tracking	• The system tracks the dispensation of study drugs to participants and monitors the return of unused medication, maintaining detailed accountability logs • Real-time reporting of IMP kit status and location
Automated reorder triggers	• Based on predefined thresholds, the system automatically notifies when stock levels are low to prevent shortages • oomnia RTSM allows you to send IMP from one site to another with ease
Expiration date tracking	• Medication and material expiration date tracking • Prevent IMP kit allocation close to the expiration date
Temperature control	• Require the upload temperature logs prior to allowing allocation of IMP • Track and automatically notify appropriate user Roles of temperature excursions • Put IMP in quarantine to automatically disable quarantined IMP allocation until its release

DATA INTEGRATION AND REPORTING

FEATURES	DESCRIPTION
External integrations	• Easily integrate with external systems, whether EDC or logistics
Unlimited reporting capabilities	• Integrate graphical reports can be created to track any aspect of Randomization or IMP supply, allowing the right user Roles to manage IMP supply
Data export	• Export data in various formats to facilitate further analysis or sharing with external stakeholders or regulatory bodies • Data from any graphical report can be exported in a tabular format