



## SynterActive System: A Full-Featured IWRS

Below are the common clinical trial processes the SynterActive System supports. Please note the SynterActive System is a web based system and does not have phone/voice capability.

### REAL TIME REPORTING AND NOTIFICATIONS

Sponsors can follow enrollment progress, trial supply managers can track inventory, key stakeholders have access to KPIs, and any user can receive IWRS email notifications, keeping them up to date on study progression.

- Transactional notifications (screening, randomization, visits, etc.)
- Browser based reporting
  - Exportable (PDF, EXCEL, Word)
  - Tables
  - Charts
  - Pivot Grid
  - Bar
  - Pie/Doughnut
  - Area
  - Range Views
  - Data Analysis

### SCREENING, ENROLLMENT AND SUBJECT STATUS

Subjects can be entered and tracked in the SynterActive System from screening or enrollment through to completion.

### ELIGIBILITY CALCULATIONS

The SynterActive System can be configured to determine if subjects meet eligibility based on specified criteria including test results over time and calculations based on specified criteria.

## RANDOMIZATION AND DOSE ASSIGNMENT VISITS

From simple permuted block randomizations to the most complicated enrollment patterns. Testing and verification processes ensure patient randomizations and treatment assignments are accurate.

- Multiple Arm
- Open Label
- Double Blind
- Dose Titration
- Multiple Phases
- Extensions Phase
- Multiple Randomizations per Subject
- 3+3 Dose Escalation
- Dynamic Randomization (SAS Driven)

## SUBJECT OR DATA UNBLINDING

- Specific Roles Set-up to Unblind
- Unblind data reporting for safety monitoring

## IP AND SUPPLIES DISPENSATION, DOSE MANAGEMENT AND DOSE CALCULATIONS

Visit defined IP and Supplies dispensation can be coupled with treatment arm and patient dose escalation and de-escalation. Additionally, doses can be based on dosing factors like age or weight.

- Scheduled Visits
- Unscheduled Visits
- Dose Management
- Multiple Dosing Factors

## IP SUPPLIES MANAGEMENT

- Integrates with Major Drug Distributors
- IP and Supplies Shipment and Receipt
- IP Quarantine
- IP and Supplies Status Updates
- IP and Supplies Management
- Automated Ordering (Buffered, Predictive or a Combination)
- Drug Expiration
- Minimize Waste

## SYSTEM INTEGRATION

Push or pull data to or from external systems including:

- Medidata Rave
- DataTrak EDC
- Clinical Ink SureSource
- Drug Distributors

## ALERTS AND CAPS

- Low Inventory Alerts
- Upcoming IP Expiration Alerts
- Cap almost any process

## SUPPORT OPTIONS AND TEAM AVAILABILITY

- 6 AM - 6 PM Pacific
- Optional 24/7/365 support
- Optional EU based support

## TO LEARN MORE, CONTACT

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