

Application Programming Interfaces (APIs) in Randomization and Trial Supply Management (RTSM)

With an increased number of players involved in conducting clinical research, from Contract Research Organizations (CROs) to sponsors and from device management companies to courier providers, data collaboration has become crucial to thriving in the modern clinical study landscape. Many RTSM systems in this landscape depend on data points from other systems to complete simple tasks like tracking, or to handle more complex workflows that can be triggered based on events from external systems. These real-time data transactions via Application Programming Interfaces (APIs) have taken center stage to enable collaboration across different stakeholders involved.

Below are the core components of RTSM technology:

- Technology to enable protocol specific randomization, dosing, and study conduct requirements
- Technology to manage investigational supplies in adherence with global regulations, supported by automated resupply algorithms to provide "hands-off" study management
- Clinical Data Handling, with support for project level integrations, reporting, and administration

Signant SmartSignals RTSM has advanced capabilities to support everything from simple, local studies to the most complex, global oncology studies. To find out more about our RTSM solution, see here.

There are two types of APIs offered by RTSM:

Reporting APIs:

- RTSM is a "real-time system" that sites must use to allocate medications to subjects that are participating in studies. As events happen within RTSM, such as randomization of a participant or drug dispensation during a study visit, these events are made available via RTSM reporting APIs in chronological order of occurrence.
- The typical consumer for RTSM reporting APIs is a data warehouse solution or analytics



platform. They can consume these events and may process them further to report on a variety of operational metrics that suit their needs.

- As the events are made available when they occur within RTSM, API consumers gain near real-time access to study progression.
- Study monitoring and reporting use cases are possible with the integration of RTSM data into receiving applications.

Clinical Trial Management System (CTMS) APIs:

- Study setup is a complex and time-consuming process, often involving site and user creation. The master copy of users and sites is typically maintained within the sponsor's CTMS system.
- As new studies begin, the study director at a sponsor organization shares a list of users, sites, and their attributes to project teams for setup within RTSM.
- This manual, dual-entry system makes the process extremely inefficient and prone to human errors.
- CTMS APIs enable automatic creation of users and sites, such that a user or site is duplicated from CTMS into RTSM within minutes. Any changes to these users or sites in a sponsor's CTMS system thereafter are propagated to RTSM within minutes.
- Automatic synchronization of users and sites increases efficiency and accuracy through less manual intervention, faster user access to the study, and overall higher user satisfaction.

Both reporting and CTMS APIs can streamline workflow efficiencies through automated processes, increase collaboration across all stakeholders involved, and help mitigate human errors and inaccuracies. If you would like to gain further insights into the benefits of API integration, visit this page to connect with our experts and learn more about RTSM systems.



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