

Clinical One Randomization and Supplies Management Cloud Service

Simple, Flexible, Fast

Randomization and trial supply management is critical to any clinical trial. But traditionally, it has put a painful lag on the overall efficiency of the process. What if you could take back control and build your study in a matter of days, instead of weeks?

Designed for Today's Trial Complexity

Trial design complexity has increased exponentially in recent years, putting a strain on old, outdated, randomization and supply management systems. Waiting for weeks to get a trial set up and deployed, or to have changes made, is simply no longer acceptable. Today's study teams require a solution that is flexible, self-service, and on-demand.

Oracle Health Sciences Clinical One Randomization and Supplies Management (RTSM) Cloud Service is a versatile solution that has been used to build, run, randomize and complete studies worldwide. Clinical One RTSM offers an easy-to-use, award-winning user interface (UI) with just-in-time embedded training, a single login, and 24x7 availability.

Ultimate Flexibility

As trial complexity increases with greater volumes and variety of data being collected and used, and the pressure to conduct trials faster grows, agility and adaptability have become paramount.

Now there is a solution to combat these challenges. Clinical One RTSM enables sponsors and CROs to gain unmatched levels of:

- **Speed and Flexibility** – set up your trial in days with point-and-click trial design you can do yourself or through Oracle's services team, a CRO, or a partner.
- **Integration and Efficiency** – easily integrate with Oracle's existing solutions, or other solutions on the market.
- **Simplicity and Control** – ability to make mid-study changes with the click of a mouse.
- **Data Unification** – as part of the Clinical One eClinical platform, data can be shared across people, processes and systems throughout the entire lifecycle of a trial.

“This is one of the fastest IRT startups I've had in my career. We actually saw the UAT (user acceptance testing) and the testing site in a matter of days with Clinical One Randomization and Trial Supplies Management”

KRISTEN STRIFFLER

ASSOCIATE DIRECTOR OF CLINICAL DEVELOPMENT FOR OYSTER POINT PHARMA

Oracle Health Sciences

Winner of the 2018 North American Clinical Trial IT Solutions Enabling Technology Leadership Award

Easy To Use

Clinical One can support a randomization strategy for the simplest to the most complex studies without the need for programming or coding, eliminating the need for prolonged user acceptance testing.

Clinical One RTSM includes support for:

- **Randomization Designs:** cohorts, open label and open label extensions, multiple randomizations, study, region and site stratifications
- **Complex Dispensations:** calculated doses, titrations, including unscheduled dispensation
- **Study Specific Needs:** screening and randomization limits, follow-on study enrollment, query management
- **Flexible Reporting:** built in dashboards, RESTful APIs

Seamless Integration

Clinical One includes a digital gateway for seamless integration of all your clinical systems. Integrations are easily configured, enabling reusability across studies that include drug supply, data capture, and trial management in addition to other systems.

Ultimate Visibility

The drug accountability functionality allows clinical supply managers to track and show that study drug was dispensed and administered according to the protocol. Sites can record the receipt of unused investigational product from subjects and prepare it for either destruction or return, adhering to sponsor and regulatory requirements for drug reconciliation. CRAs can verify site returns and confirm that sites followed procedures for product destruction, as well as approve destruction or return of drugs.

Get Drugs to Patients Faster

The trial supply management function allows study teams to forecast the supplies needed at the sites and raise orders to the supplying depots. The process includes updating inventory systems on the receipt of consignments, as well as updating individual kits that may have been lost, damaged, or otherwise modified. This provides efficiency and accuracy when dispensing kits to subjects during patient visits. In addition, with Clinical One, the data capture capability is enabled to call the randomization and trial supply management service to provide dispensation, in accordance with assigned treatment arms and protocol requirements.

Clinical One

Oracle Health Sciences Clinical One cloud environment unifies clinical development operations and information to help life sciences companies bring therapies to market faster and more cost-effectively.

"Frost & Sullivan believes that Clinical One is the ideal unified eClinical platform that is purpose-built from the ground-up, with shared functions and an easy-to-use interface for clinical trial sites, coordinators, and their counterparts."

FROST & SULLIVAN 2018 BEST PRACTICES AWARD

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