

Clinical One™ Randomization and Supplies Management Cloud Service

Simple, Flexible, Fast

Randomization and 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 get things done in a matter of days, instead of weeks?

Designed for Today's Trial Complexity

Trial design complexity has increased exponentially in recent years, putting strain on old, outdated, randomization and supply management systems.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 Cloud Service is a versatile solution. Study teams can manage studies themselves in real-time through the 100% self-service platform and intuitive user interface of Clinical One – from initial study design and start-up, to mid-study changes – or; they can leverage the vast experience of Oracle's team to assist with the design, build and deployment of their studies. Having these options enables organizations to focus on their expertise and get studies up and running as quickly as possible.

Ultimate Flexibility

If there's a single requirement for eClinical solutions right now, it's flexibility. With the changing complexity of trials, the greater volume of data being collected and used, and the continued demand for faster trials, agility and adaptability are paramount.

With Clinical One Randomization and Supplies Management, study teams gain the ultimate flexibility in managing trails. Study designers, whether it be in-house or through Oracle's services team, have the ability to model multiple design options ahead of time, so when the decision on a model



"We needed an established, standards-based cloud system to simplify the drug supply management process, and we have already determined we made a great choice by selecting Oracle's Clinical One Randomization and Supplies Management. Within 29 days, we were fully implemented and are now in phase III of our oncology trial"

XIAOPING ZHANG
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is made, it's ready to go. The platform also allows study teams to make mid-study changes, such as protocol amendments quickly and easily, on their own with a few clicks of a button, or, with the help of Oracle services. The result – instant, real-time efficiency and savings.

Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.

Randomization Design

With the Randomization Design function, study teams use a step-by-step, guided, randomization design tool with an easy, simple-to-use, user interface. The tool can define and configure a randomization strategy by study, site, or region, and assign it to specific events in the study.

Randomization Management

With the Randomization Management function, study managers can update limits, as well as set notifications for a study.

Drug Accountability and Reconciliation

The drug accountability functionality allows clinical supply managers to track and show that study drug was dispensed and administered according to the protocol. Investigator 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 investigational sites followed procedures for product destruction, as well as approve destruction or return of drugs.

Trial Supply Management

The Trial Supply Management function allows study teams to forecast the supplies needed for subjects at the clinical 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 system 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.

ULTIMATE FLEXIBILITY

They can manage everything – from initial study design and start-up to mid-study changes – independently, in real-time.

LEARN MORE

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