PERCEPTIVE MyTrials®

A PAREXEL® eClinical Platform

CLINPHONE® RTSM

AGILE, FLEXIBLE AND SCALABLE RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT FOR PHASE II/III STUDIES

KEY FEATURES

- Randomization and supply chain strategy expertise
- Configurable systems delivered in 4 to 8 weeks
- Rapid turnaround of study changes
- More control given to study teams and sites to quickly access data and actions

ADDRESSING THE BREADTH OF STUDY SIZES, TIMELINES AND COMPLEXITY IN PHASE II/III CLINICAL TRIALS

Phase II/III studies have the greatest combination of complexity of protocol and size. The acceleration of clinical research often means that studies must start with shorter lead times and limited trial supplies. Study start-up is not the only stage that is under time pressure, the whole trial timeline is critical to reaching a decision to proceed or not, as soon as possible, making it vital that any changes to study 'in-flight' must be rapidly executed with minimal disruption. The increasing complexity and global nature of studies makes the logistics of maintaining medication supplies at each study site more difficult, labor-intensive and risky. Randomization and Trial Supply Management (RTSM) services, enabled by IRT (Interactive Response Technology), can manage real-time recruitment, randomization, treatment allocations, dosing and tracking of clinical supplies to ensure timelines are met or reduced, while minimizing trial risks.

Randomization and Trial Supply Management expertise

PAREXEL's sophisticated Randomization and Trial Supply Management algorithms are the subject of continued research and development to optimize medication supply chain processes and provide the greatest drug savings and the most robust inventory control. Our experience on thousands of studies enables us to provide:

- An extensive range of validated randomization methods including static blocked randomization lists, stratification, minimization with biased coin assignment and Zelen's method
- Access to our team of experienced statisticians for consulting expertise, including advice on treatment allocation schemes, simulations for balance on stratification factors and predictability of randomization schemes, dynamic randomization methods, custom randomization algorithms and open label study considerations

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- Advanced methods for solving difficult supply issues, such as managing adaptive clinical trial designs, titration regimens or medication pooling across multiple protocols
- Consulting on supply chain management strategies and algorithms to optimize an efficient use of available supplies; and medication kit configuration
- Global, 24/7/365 technical and clinical support, including emergency medical escalation and code break (unblinding)

Configurable Interactive Response Technology (IRT)

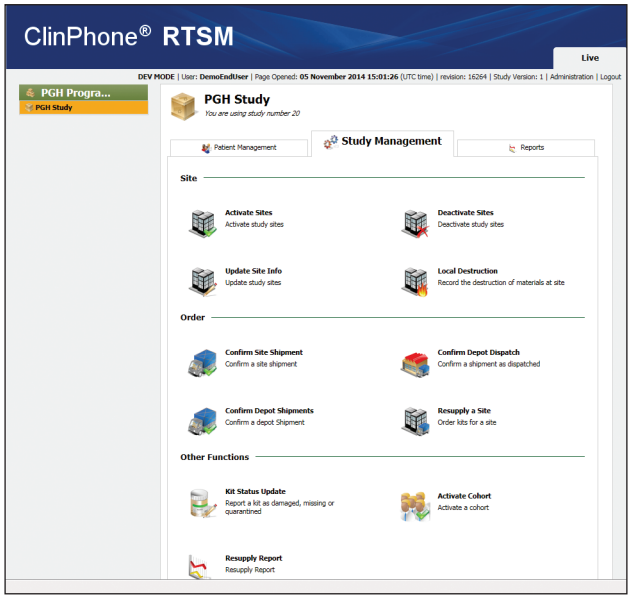
Typically, the process to design IRT systems has involved the creation and review of lengthy, complex specification documents. The next generation ClinPhone® RTSM services utilize configurable technology that enables a faster and simpler system design, build and test process. Your study is iteratively developed using demonstrable versions of the system enabling you to quickly understand what has been implemented, provide instant feedback to the PAREXEL team and rapidly receive the next update. Systems can be typically delivered in 4 to 8 weeks, subject to the specific study requirements. Late-breaking study changes both pre and post go-live can also be turned around quickly without disrupting the live system.

The IRT capabilities are delivered through a primary web interface with IVR (Interactive Voice Response) back-up. Study teams and sites can quickly access the data and actions they need to perform patient management, site management, inventory management and drug accountability tasks. Access to tasks is governed by role-based controls.

Automated site and depot medication inventory control includes support for temperature logging, with alerts generated if data is not uploaded from the temperature logger devices, or is not confirmed as being within range.

From our randomization and supply chain experts, to our experienced project management and support services teams, you can be sure that you are putting your trial in safe hands.

Part of the Perceptive MyTrials® framework, enabling integration with clinical trial software applications to help users plan, design and conduct clinical trial programs in a single place.



Study Management in ClinPhone® RTSM

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