

SIMPLIFIED AND COST-EFFECTIVE MANAGEMENT OF LARGE PERI/POST- APPROVAL STUDIES

KEY FEATURES

- Manage large volumes of sites and patients
- Simple site user interface
- IVR/IWR translated into local language
- Manage just-in-time supply/re-supply
- Integrate with ePRO/eCOA (electronic Patient Reported Outcomes/electronic Clinical Outcome Assessments)

RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT IN PERI/POST-APPROVAL STUDIES

Once treatment is near or even through the approval process, the next step is to demonstrate long-term safety, efficacy and value to gain effective market access and successful commercialization. Late phase clinical trials and observational research studies can involve enrolment and management of hundreds of sites and tens of thousands of patients, with increasing global reach. Monitoring of enrolment, dispensing, and supplies can be challenging to manage manually. Randomization and Trial Supply Management (RTSM) services provide expertise and IRT (Interactive Response Technology) to enable effective management and real-time reporting of patient progress, medication assignments and supplies.

Challenges in Peri/Post-Approval studies

Late phase studies often involve sites with less or no experience of clinical trials and medical professionals for who are not proficient in English. Without simple user interfaces in local language, eClinical systems can be difficult or impossible to use and can be a barrier, rather than an aid, to support site success. Sites don't have significant storage capacity for supplies, so they run the risk of not having enough stock to dispense to patients.

RTSM services for Peri/Post-Approval studies

Through experience in thousands of studies, PAREXEL has developed a ClinPhone® RTSM service for Peri/Post-Approval studies that delivers:

- Scalability to manage large volumes of sites and patients
- Simplicity of site user interface to aid those less experienced in clinical trials
- Translation of IVR and IWR into local languages
- Management of supplies to ensure sufficient and timely re-supply appropriate to the site storage facilities

- Rapid system configuration and changes to make systems more cost-effective
- Integrations with ePRO/eCOA systems to maximize patient reported outcomes compliance

With our randomization and supply chain experts, our experienced project management and our support services teams, you can be sure that you are putting your late phase study 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.

The screenshot displays the ClinPhone® RTSM interface for a 'PGH Study'. At the top, it shows 'DEV MODE | User: DemoEndUser | Page Opened: 05 November 2014 15:00:41 (UTC time) | revision: 16264 | Study Version: 1 | Administration | Logout'. The main content area is titled 'PGH Study' and includes a 'Patient Management' section with a search bar and an 'Apply' button. Below this is a table of patient records:

Site Number	Patient Code	Status	Enrolled	Next Visit
1001	0001	Active	05/Nov/2014	Visit 1 Treatment
1001	0002	Active	05/Nov/2014	Visit 1 Treatment

Below the table, a 'What do you want to do?' dropdown menu is open, showing options: 'Withdraw' (Withdraw this patient from the trial), 'Update' (Update patient details), and 'Return To Home' (Return to the options screen).

A simple Patient Management screen for sites in ClinPhone® RTSM