

PHT's StudyPad® System

Single device solution for mobile data capture at sites



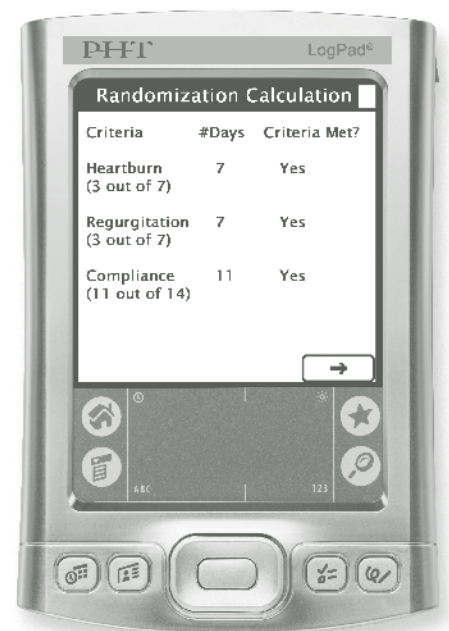
Capturing the right data with the highest level of accuracy helps make a clinical trial effective and cost efficient. Paper diaries lack the speed, reliability and efficiency that are attained through electronic patient reported outcome (ePRO) solutions. Electronic patient diaries collect symptom data at the point of experience and ensure that all subject responses are complete, logical and legible. This improves data quality, reduces variance and enables better scientific conclusions. Study sponsors benefit from ePRO solutions by streamlining trial timelines, reducing sample sizes and providing more reliable self-reported patient data to the FDA.

PHT's **StudyPad System** is a single device solution for mobile data capture at sites. StudyPad enables sites and subjects to record subject experiences as they happen. StudyPad's intuitive graphical user interface features body diagrams, visual analog scales and other easy-to-use data collection elements that facilitate precise, accurate reporting of data. Site coordinators and sponsors can review subject data collected by StudyPad over the Web in real time.

StudyPad provides study coordinators and other site personnel with a single product for directly capturing subject data. Data captured with StudyPad can be accessed through StudyWorks, PHT's Web-based reporting and management tool. StudyPad's flexible, standards-based architecture means data collected using StudyPad can be integrated into other clinical data management systems.

Larger-screen devices can be utilized to accommodate more text-intensive surveys and quality of life questionnaires. These devices include the **Palm TX**, which PHT has validated for use in clinical research.

StudyPad is ideal for studies that include quality-of-life questionnaires or subject self-assessments, as well as studies that would benefit from the benefits of mobile capture, i.e. outpatient data collection and studies that collect data as electronic source (eSource). StudyPad has been successfully used in the largest ePRO trial to date, which included 20,000 subjects and 4,000 investigator sites.



StudyPad Features:

- ❖ Easy-to-use, mobile, eSource capture product that supports subject self-assessment entry as well as traditional Case Report Form entry by sites
- ❖ Customized graphical and intuitive data entry screens programmed to the specification of the protocol that are easy for subjects and investigators to complete
- ❖ Validated electronic Visual Analog Scales (eVAS)
- ❖ Body diagrams
- ❖ Edit checks, branching logic and derivations
- ❖ Larger-screen devices and multiple platforms
- ❖ Time-stamped data
- ❖ Handwritten signatures and comments
- ❖ Authentication and management for multiple users
- ❖ Mid-trial changes while StudyPads are in the field
- ❖ Secure, encrypted data transmission and entry
- ❖ Use of a tested, proven and reliable platform



Larger-screen devices such as the Palm TX enable the use of more text-intensive diaries and questionnaires

Key Benefits of Using StudyPad:

- ❖ Immediate access to data as it's collected for analysis and monitoring
- ❖ Ability to collect data at the point of experience as eSource
- ❖ Edit checks to ensure entry of clean and complete data
- ❖ Easy intuitive user interface for sites and subjects to enter data rapidly
- ❖ Increased speed in performing clinical trials - i.e. hours versus days for time to database lock
- ❖ Part of PHT's fully integrated mobile and Web clinical data capture product suite

The StudyPad Experience

Subjects, sites and sponsors report positive experiences using StudyPad. Because StudyPad captures data directly from the source, sites can focus their time and energy on caring for subjects. StudyPad helps eliminate data transcription errors that commonly occur with paper transcription such as missing, inconsistent, out-of-range and invalid data, so sponsors can focus on managing the trial. FDA and other regulatory authorities have approved new drug applications that include endpoint data collected using PHT's Product Suite. PHT's trial experience and expertise includes a wide variety of therapeutic areas, indications, subject demographics and clinical site locations around the world. For more information, visit www.phtcorp.com.

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