

StudyWorks™ System

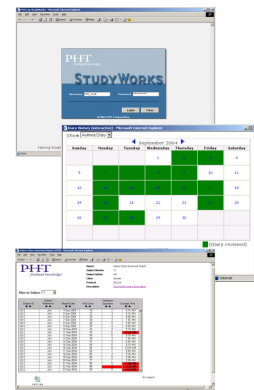
Maximize the Benefit of Real-Time Data Capture

Custom Real-Time Access to Patient Data

StudyWorks, PHT's online portal, offers a greater degree of management control at every stage of a clinical trial. StudyWorks allows real-time access to data collected via PHT's LogPad System or SitePad Tablet. Powerful standard and custom data summaries and reports streamline trial management and enable study sponsors to gain immediate insight into site and subject activity.

Firsthand Knowledge

Site coordinators, study nurses, CRAs, and sponsors alike use StudyWorks to monitor and view study data. StudyWorks makes it simple for site coordinators to proactively manage enrollment and subject diary compliance. Email alerts bring subjects with low compliance or safety concerns to coordinators' and monitors' attention. By reviewing individual diary data as it is transmitted, site personnel can monitor subject symptom scores for safety and identify subjects who exhibit low compliance - and intervene *before* it becomes a trend.



Key StudyWorks Highlights

Features	Benefits
<ul style="list-style-type: none"> • Real-time access to study and subject data • Powerful system reports and data summaries of data captured by LogPad and SitePad Tablet • Simple, easy-to-use interface for sites and monitors • Workflow driven "Tasks" list for sites and monitors • Integrated messaging between StudyWorks users and LogPad users • Complete, automatically generated audit trail of data changes • Full archive of all trial data and metadata and audit trails for sites and study sponsors delivered on secure CD-ROMs • Ability to deploy mid-study changes seamlessly • XML-based, CDISC-compliant data architecture • Email Alerts for compliance, safety and Project Management 	<ul style="list-style-type: none"> • Improved safety and compliance through close monitoring of trial subjects in real-time • Proactive trial management by enabling sponsors to view diary performance such as enrollment and compliance in real-time • Integrated messaging enables easy communication with trial personnel and subjects - all documented in the audit trail • Earlier interference if there are problems identified with the trial • Reduction in queries compared to paper diary trials • Database lock in hours vs. weeks, resulting in a reduction of overall trial timelines • CDISC-compliant, XML-based data architecture that enables easy integration with existing data management • Ability to utilize electronic source (eSource) to streamline overall trial processes and decrease trial timelines • Ability to securely archive all of the trial data and metadata that enable the reconstruction of the trial for the required retention period

Data Security and Integrity

StudyWorks ensures the security and integrity of all data collected and managed during each trial. It uses electronic signatures and 128-bit encryption and is fully compliance with all FDA and EMEA regulations and guidelines, including 21 CFR Part 11. StudyWorks is accessed securely online, via SSL, over any Internet connection, using specific authorization.

The StudyWorks Experience

PHT's integrated Product Suite has been used to collect self-reported patient data in clinical trials around the globe. Sites discover firsthand how StudyWorks' data summaries allow them to actively manage subjects between visits. Monitors find that by using the StudyWorks system, communication with investigators is easier to manage. Sponsors enjoy the flexibility of both standard and custom reports and data summaries to exactly suit their trial design needs. FDA and other regulatory authorities have approved new drug applications that include endpoint data collected using PHT's Product Suite. For more information, visit www.phtcorp.com