

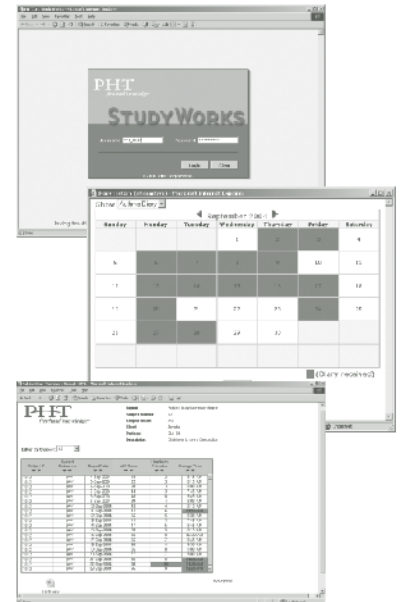
PHT StudyWorks™

Maximize the benefits of
real-time data capture



PHT **StudyWorks** offers a greater degree of management control at every stage of a clinical trial. StudyWorks is a Web-based reporting and management tool that's used by site coordinators, study nurses, CRAs and sponsors. Users can review data submitted from LogPad® and StudyPad®, enter data, manage workflow, add queries, and monitor and view all study data in real time.

StudyWorks makes it simple for site coordinators to proactively manage enrollment and subject diary compliance. By reviewing individual diary data as it is completed (eliminating the lag often associated with paper CRF's), site personnel can check up on subjects to determine whether they are using the eDiaries correctly or if they need further training before it becomes a problem. Powerful data summaries and customizable reports streamline trial management and enable study sponsors to gain immediate insight into what is happening in the trial.



Providing Integrated Choices for Data Capture

StudyWorks is fully integrated with LogPad, PHT's electronic patient diary product, and StudyPad, PHT's mobile data capture device for sites. The fully integrated system enables data capture at the point of experience for patients and sites with an easy to use, online, Web-based review and management system. StudyWorks is also available independent of LogPad and StudyPad as a stand-alone product for Web-based data capture and review.

Data Security and Integrity

StudyWorks ensures the security and integrity of all data collected and managed during your trial. It utilizes electronic signatures and 128-bit encryption and is fully compliant 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.

StudyWorks Features Include:

- ❖ Real-time access to study and subject data
- ❖ Powerful system reports and data summaries of data captured by LogPad and StudyPad to enable proactive management of enrollment and compliance
- ❖ Simple, easy-to-use interface for sites and monitors
- ❖ Workflow driven "Tasks" list for sites and monitors
- ❖ Query generation and resolution
- ❖ Integrated messaging between StudyWorks users and LogPad users
- ❖ 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

Key Benefits of Using StudyWorks Include:

- ❖ Improved compliance through close monitoring of trial subjects in real-time
- ❖ Proactive trial management by enabling sponsors to view diary performance in real time
- ❖ Integrated messaging enables easy communication with trial personnel and subjects that's documented in the audit trial
- ❖ 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 systems such as Clintrial™, Oracle Clinical™ and others
- ❖ 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 enables the reconstruction of the trial for the required retention period

The StudyWorks Experience

PHT's integrated Product Suite has been used to collect self-reported patient data in clinical trials around the globe. Some sites that have used StudyWorks state they would never again work with paper after discovering firsthand how the StudyWorks workflow helps guide them through their daily tasks. Monitors like working with the system and find that by using StudyWorks, communication with investigators is much easier to manage. 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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