

Trial Success Program™


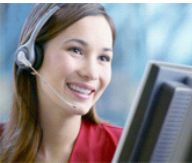
Minimize deployment time and maximize client satisfaction

Established Best Practices-Based Deployment Strategy

At PHT, we use our market-leading trial experience to provide customers with the smartest tools and strategies for deploying successful clinical trials around the world. PHT created our best practices-based deployment strategy, the **Trial Success Program™ (TSP)**, to deliver smooth and efficient trial delivery. PHT's clients vary from first-time ePRO users to companies that have been using eDiaries since their inception and small biotechnology companies with one sponsor project manager to large pharmaceuticals using a CRO. The TSP has the flexibility to maintain the same structure for data collection and management processes while tailoring the specific details to each trial team's specific needs.

The Four Phases of TSP

PHT works closely with clients to efficiently develop and deploy a protocol-specific ePRO solution to meet the needs of the study sponsor and site coordinators. Using rapid custom application design coupled with a systematic delivery process, TSP ensures a successful trial with four stages:

Study Setup	
<ul style="list-style-type: none"> Project planning Design best practices Specification generation Prototypes and system built and tested User site testing Training 	<p>Requirements Signed 8 – 12 weeks on average Project Deploys</p>
Deployment	
<ul style="list-style-type: none"> Database goes live StudyWorks users setup Devices prepared Initial shipments to sites 	<p>ISO Certification</p> <p>PHT is the only handheld eDiary provider with ISO certification, which ensures trustworthy deployments through continually improving SOPs</p> 
Tracking	
<ul style="list-style-type: none"> Regular sponsor reviews Compliance, enrollment monitoring Inventory management Data Change Forms Site reviews Help desk ticket analysis 	 <p>Study Support Center</p> <p>PHT does not outsource its help desk. It is staffed by multi-lingual internal experts, 24x7, who are trained on every client study, have immediate escalation access, and resolve 95% of issues on the first call.</p>
Closeout	
<ul style="list-style-type: none"> Inventory reconciliation Database lock Site audit support Close any issues Final data transfer Study Archive delivery 	<p>Pharmaceutical Auditor:</p> <p><i>"PHT's archive is best-in-class! Not only are they strategically placed for the archiving demands of today, but most importantly, for tomorrow."</i></p>

Key Benefits of TSP

Faster Time to Trial Deployment – Custom electronic diary patient diary (EPD) development is accomplished through rapid application prototyping. Using PHT's ePRO Designer, requirements quickly translate from a paper CRF to a LogPad EPD. The sponsor's feedback is then immediately incorporated into the LogPad prototype. By leveraging the power of our experience, development costs are kept to a minimum and Study Deployment can happen in as few as four weeks, depending on the trial's complexity.

Data Reliability and Validity – The PHT delivery methodology, which was developed through years of worldwide trial deployment success, provides an organized process during your study. The PHT Client Services team supplies the expertise, a proven process, and industry best practices to maintain secure, valid data collection as well as FDA and EMEA compliance. PHT is the only handheld eDiary provider to achieve ISO 9000:2001 certification. PHT's successful recertification was due to not only maintenance, but improvement, of best practices and quality standards.

Client Satisfaction – Not only does PHT supply fast application development and a track record for organized study planning and delivery, but we also provide global support services, ranging from site reviews to personal training and 24x7 study support during Study Deployment. PHT has helped dozens of clients conduct successful trials involving tens of thousands of subjects worldwide. Clear communication and specific criteria for reviewing success at project checkpoints along the way make sure that we set realistic expectations, avoid surprises and provide efficient communication.