

## PHT Trial Success Program™

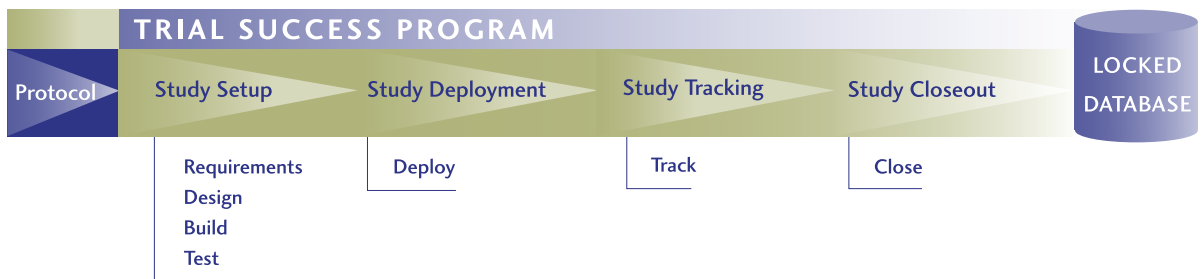
Minimize deployment time and maximize client satisfaction



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 has developed the industry's only institutionalized best practices-based deployment strategy, our Trial Success Program™ (TSP). TSP allows study sponsors to focus on the trial itself by delivering peace of mind that data collection and management processes will happen smoothly and efficiently.

### The Four Phases of TSP

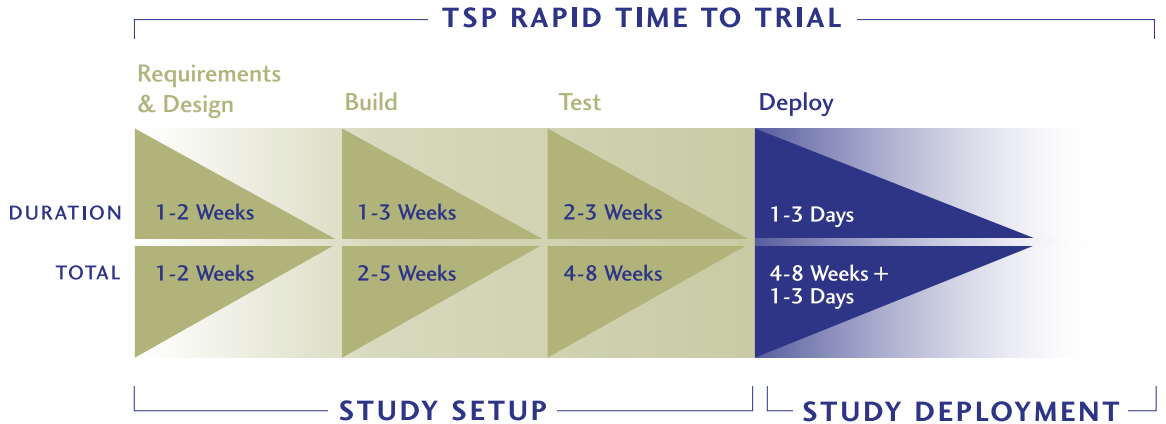
PHT works closely with clients to efficiently develop and deploy a protocol-specific ePRO solution to meet the needs of the study sponsor and site coordinators. Using rapid custom application design coupled with a systematic delivery process, TSP ensures a successful trial with four-stages:



- ❖ Study Setup - PHT works with clients to plan the study as well as to design, build and test the LogPad®/StudyPad® prototype. Project expectations are set and all responsibilities are clearly delineated between the study sponsor and PHT. Once the diary requirements are approved, we create working prototypes by using our quick, iterative design methodology that leverages our proprietary ePRO Designer tool. Prototype feedback from the sponsor is instantly translated into LogPad revisions. While LogPad testing is carried out, PHT provides interactive, hands-on training at the Investigator Meeting in preparation for deployment.
- ❖ Study Deployment - Once the final eDiary is approved, PHT prepares the study database and ships devices to the sites. The deployment phase may take one to three days, depending on the configuration of the trial.
- ❖ Study Tracking - PHT's internal 24x7 Study Support Center provides multi-lingual support throughout the trial. StudyWorks™, PHT's online portal for real-time data access that enables site coordinators, study nurses, CRA's and sponsors to enter and review study data. Its powerful data summary reports enable site coordinators to proactively manage the trial, enrollment and subject compliance. PHT also conducts frequent best practices reviews and monitors study progress with regular status updates.
- ❖ Study Closeout - Upon completion of the trial, PHT delivers a full XML source archive of study data in the format required, as well as all supporting study documents per FDA and EMEA regulations. A final set of TSP criteria is reviewed and evaluated to close any outstanding issues.

## Key Benefits of TSP

**FASTER TIME TO TRIAL DEPLOYMENT** - Custom electronic 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 provider in the handheld ePRO industry to achieve ISO certification.



**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 around the world. Clear communication and specific criteria for reviewing success at project check points along the way make sure that we set realistic expectations, avoid surprises and provide efficient communication.

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