TRIAL DESIGN, MANAGEMENT AND ANALYSIS

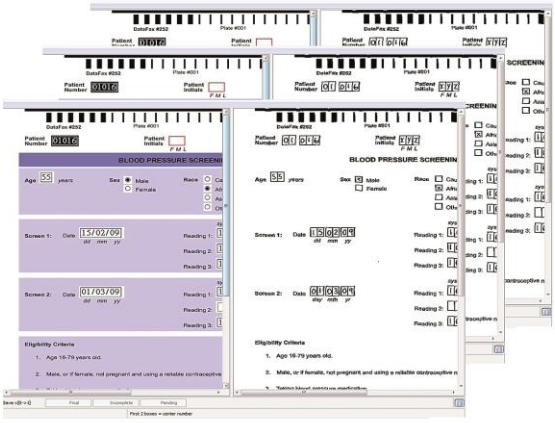
PATH can provide a vast range of expertise and infrastructure support to facilitate and conduct studies such as:

- RCTs testing the efficacy of a new drug or procedure
- Observational studies for disease progression and outcomes
- Patient or disease registry
- Field evaluations to observe how a technology works in the “real world”
- Assistance with electronic data capture and management
- Assistance with, or analysis of, trial registry or patient outcome data

We have a designated clinical trial team to assist in forming testable research questions, in planning study designs, in developing a study synopsis to facilitate discussions amongst investigators and key stakeholders and in developing detailed study protocols outlining the study background, design, methodology, outcome measures, sites and sample size calculations, and overall study management and analysis.

Our clinical trial team has decades of experience in developing study Case Report Forms (CRFs) and have developed efficient strategies to help simplify and streamline data collection.

A number of data collection and entry options are available to accommodate sites participating in a trial ranging from traditional paper CRFs, to data fax forms, to completely web-based electronic data capture and entry systems that streamline data queries.



Our statisticians are experienced at developing detailed Statistical Analysis Plans for studies and have a long track record of providing consultation support for a wide range of study designs in a variety of disease areas. Similarly, our contracts and regulatory team is very experienced at expediting the often lengthy contract development and negotiation stage of studies and ensuring studies meet the detailed requirements of regulatory agencies and institutional Research Ethics Board (REB).

PATH has developed a comprehensive set of Standard Operating Procedures (SOPs) to ensure consistency and the highest possible standards during all aspects of design and conduct of the trial and in analyses and interpretation of the results.