HPA INC
HEALTH POLICY ASSOCIATES INC

# CLINICAL TRIAL AND STRATEGY EXECUTION

HPA utilizes robust and streamlined processes that enable us to accomplish our commitment to quality and timelines within budget for your clinical trials. Our experienced team tailors a project plan to address the varied needs of each project and executes that plan seamlessly in partnership with your team.

## CLINICAL OPERATIONS SERVICES

### Strategy and Study Design

- Determining appropriate study design and endpoints, clinical trial strategies, and data requirements
- Collecting supportive data, publications, and literature
- Preparing study materials such as protocols, CRFs, Informed Consent Forms, study logs, and study worksheets
- Representing sponsor with regulatory agencies

### Study Start Up

- Identifying and qualifying sites and investigators
- Preparing documentation for IRB and/or Ethics Committee approval

### Project Management

- Tracking overall study progress and progress of individual sites
- Customized reports for your team with critical study metrics (including deviations, enrollment rates, and adverse events with trend analyses)
- Developing a randomization scheme and either paper or web-based subject randomization
- Managing study supplies and interactions with third party vendors (including core labs)
- Preparing for meetings with regulatory agencies (including FDA Q-Subs and FDA Advisory Panel meetings)

### Biostatistics

- Developing a Statistical Analysis Plan, randomization schemes, and sample size justifications
- Generating statistical summary tables, graphs, and reports within SAS for regulatory submissions, presentations, and publications
- Performing interim and final statistical analysis

### Clinical Monitoring

- Customizing risk-based monitoring for individual protocols
- Developing a Monitoring Plan detailing study monitoring procedures and risk evaluation
- Programming edit checks to flag increased areas of risk or non-compliance
- Confirming subject eligibility and investigator compliance with applicable regulations (including appropriate consenting practices and adverse event reporting)
- Reviewing and verifying key study data
- Identifying and resolving any problems at individual study sites during trial

### SAS Programming

- Converting raw data into CDISC-compliant formats including SDTM, ADaM, and ECTD for analysis and submission to regulatory agencies
- Generating tables, listings, and figures from derived datasets for inclusion in submissions, books, journals, manuscripts, and web publications

### Clinical Report Preparation

- Summarizing study design, patient assessments, demographic data, data analysis and results, product failures and replacements, risk-benefit analysis, device safety and effectiveness, and other metrics
- Medical writing to reflect trial outcomes and support study objectives

### Audit Preparation

- Preparing for and supporting announced or unannounced inspections of clinical trials by FDA or notified bodies
- Assessing audit readiness with a thorough and inclusive review of quality system, SOPs, staffing levels, organization al structure, and study files
- Customized training & education to ensure a successful audit

## ABOUT HPA

Health Policy Associates has spent more than 20 years providing high quality consulting services to the medical device and biotech community, helping companies bring their innovations to market. As specialists in regulatory compliance and clinical consulting, HPA helps medical and biotech manufacturers optimize their product development processes while avoiding potential pitfalls.

From clinical trial strategy and design to precision data analysis, HPA's team of industry experts has guided leading manufacturers around the globe to regulatory success again and again, with unrivaled accuracy and efficiency. HPA enhances the efficiency with which a company executes its product development timeline by: developing strategies and plans that meet regulatory and market needs, evaluating and supplementing company resources, managing clinical and/or regulatory functions, developing and implementing quality system and compliance strategies, and assisting with venture capital financing strategies and valuation milestones.

Because of our experience focusing exclusively on the medical device and biotech industries and dealing with some of the most unique and complex products under development, our clients are assured that HPA consultants can resolve their problems and address their specific needs.


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## HPA Services

HPA's goal is to provide practical and highly efficient consulting solutions to companies involved in developing new medical device technologies, pharmaceuticals or biologics. HPA's high-quality consulting services include:

- **Clinical Trial Strategy and Execution:** Protocol development/ Case Report Form design, clinical site identification, management and monitoring, database and EDC creation, data analysis, report writing, regulatory submission preparation.
- **Data Management and Analysis:** Database design and hosting, real-time data access and query resolution, customized data analysis and reporting.
- **Worldwide Regulatory Consulting:** Regulatory strategy development, project plans, FDA submission management including presentations, submissions, reports and filings, development of worldwide regulatory strategies.
- **IRO/Data Integrity Auditing:** AIP services including FDA audits and integrity reports, IRO services including OIG work plans, reviews, reporting and submissions.
- **Quality Systems/Compliance Consulting:** Quality system design, compliance strategy development, internal and supplier GMP auditing, FDA inspection assistance, risk management, medical device reporting, application of corrective/preventive action procedures, product recall support.
- **Venture Capital Investing:** VC identification, project plan and timeline development, valuation milestone development

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