HPA INC
HEALTH POLICY ASSOCIATES INC

DATA MANAGEMENT AND ANALYSIS

As industry standards have evolved over the last 20+ years, HPA has nimbly responded to changing requirements and the particular needs of our clients. In addition to our regulatory and clinical experience, HPA has robust database management capabilities including software development and a wide scope of data analysis services.

Database Development and Data Management

- HPA works with our clients to develop study-specific, customizable databases and electronic data capture interfaces, including:
  - QSR workflow and database design
  - User acceptability testing and validation documentation
  - Customized databases and applications for CAPA management, clinical data, complaint handling and MDR reporting
  - Database development in STDM standard format
  - Case Report Form design and CDISC-compliant annotated CRFs
  - Customized training manual and training sessions for EDC users
  - Real-time dashboard overview of data
  - EDC help desk for end users
- Clinical data can be entered electronically by trial sites, through paper data entry at HPA, or a combination of the two:
  - All paper data double entered and verified by HPA
  - SAS-based query identification and resolution
- Part 11 compliance gap analysis

Data Analysis

- Our team of SAS-certified programmers performs detailed statistical analyses:
  - QSR coding using SAS version 9.3 or higher
  - A priori tables, figures and listings, ad hoc requests
  - Contract with top statisticians and biostatisticians
- Develop and execute statistical analysis plans:
  - Identify primary and secondary endpoints and appropriate statistical tests
  - Table/figure/listing shells for pre-approval by client
- Format datasets to SDTM and ADaM standards for easy submission:
  - Convert pre-existing non-compliant datasets into CDISC standards per developing industry standards
- Provide MedDRA and WHODD coding for adverse events, medical histories, and concomitant medications
- Write and review Clinical Study Reports:
  - Data analysis and interpretation
  - Present and defend data upon delivery
- Support FDA presentation and submission activities, including panel meetings and FDA requests

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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