HPA INC
HEALTH POLICY ASSOCIATES INC

HELPING COMPANIES BRING INNOVATIVE WOUND CARE THERAPIES TO MARKET

Successfully bringing innovative wound care solutions to market presents a number of unique challenges to medical device and biologic companies.

Clinical trials and studies must be designed to balance the need for rigor with the need for efficiency and speed. Patient-reported outcomes need to be accurately and consistently gathered, checked and assessed throughout the study rather than after the fact. The process of collecting health economics data needs to be built into your initial study, rather than running a costly additional study after regulatory approval and incurring delays in reimbursement. Friction can build up between CRO and clinical site personnel during the process of monitoring patient compliance and outcomes if the electronic data capture (EDC) system is not designed to accommodate the unique needs of wound care studies. Finally, gaining FDA approval for new wound care treatments requires specialized expertise in developing strategies and project plans that meet regulatory requirements, and in managing interactions with the FDA during the submission and approval processes.

HPA - Clinical Consulting Expertise for Wound Care Studies

For almost a decade, Health Policy Associates, Inc. (HPA) has been providing an unmatched breadth of clinical consulting expertise to the end-to-end process of bringing innovative new wound care therapies to market. HPA's unique experience includes:

- **Clinical trial strategy/execution:** HPA has worked extensively with clients, including several of the top-10 wound care companies, on numerous studies in a wide range of areas, including:
  - VLUs (venous leg ulcers)
  - Diabetic foot ulcers
  - Burns
  - Incisional/post surgical wounds
  - Chronic and acute wounds
  - VAC (vacuum assisted closure) therapies
  - Pressure wounds (i.e., bedsores, etc.)
  - Open abdominal wounds
  - Stem-cell-derived therapies
  - Deep wounds
- **FDA submissions:** HPA has successfully shepherded a large number of IDE (investigative device exemption), IND (investigational new drug), NDA (new drug application), 510(k), BLA (biologic license application) and PMA (pre-market approval) applications through the FDA.
- **Data management and analysis:** HPA has designed wound-healing-specific, customized electronic clinical databases for multiple indications.
- **Monitoring:** HPA has a proven track record of efficient, site-friendly monitoring, and solid, established relationships with high-enrolling KOL sites.
- **Quality system management:** HPA has unique experience balancing quality system requirements with the need for efficiency and speed to ensure the smooth, rapid delivery of new wound care therapies to market.

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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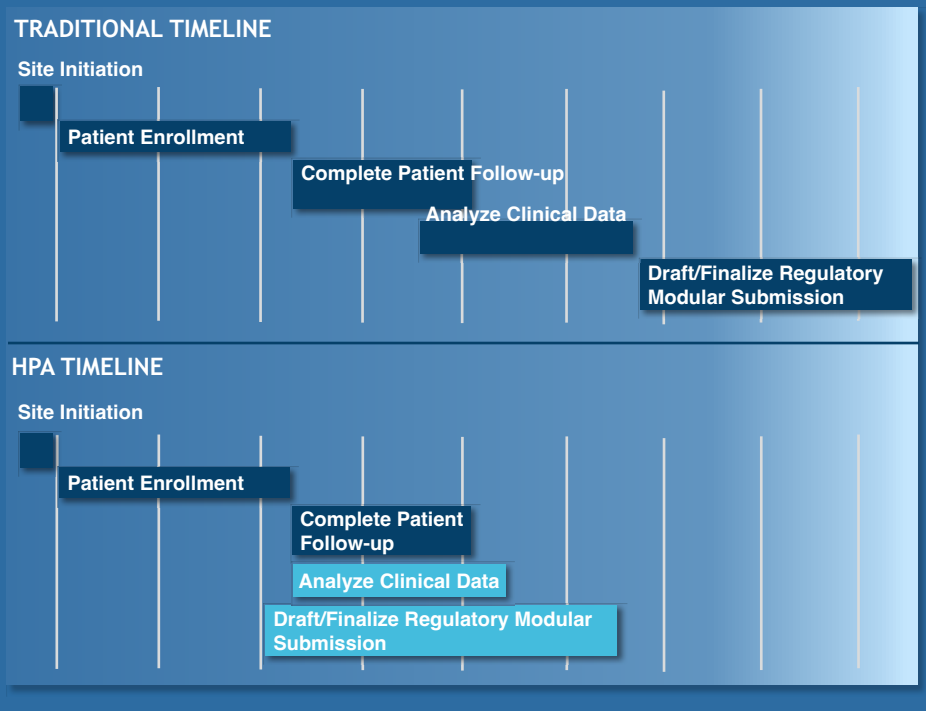
HPA Services

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

The Accelerated Product Delivery Timeline

By analyzing clinical data as it comes in, rather than waiting to analyze results after the last patient is complete, HPA can accelerate the product delivery timetable by 60 days or more.



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