Health Decisions provides medical device developers with capabilities for streamlining clinical trials and reducing timelines and risk in a challenging area. The challenges of device development are substantial and growing. Uncertainty about the type of evidence required, perceived inconsistencies in regulatory review, increasing data requirements and long timelines are frustrating for device developers. Health Decisions offers the design and operational excellence and regulatory expertise required to overcome frustrations and accelerate development while also collecting high-quality data to eliminate the risk of delays in the 510(k) clearance or PMA review process. Our capabilities for conducting large subject-based IVD studies are the best in the industry.

Medical Device Development Services

- Protocol Development
- Regulatory Affairs
- Strategic Consulting
- Project Management
- Protocol/Study Feasibility
- Site Feasibility and Selection
- Site Management
- Patient Recruitment and Retention
- Monitoring, including Risk-Based Monitoring
- Data Management
- Statistical Programming, Analysis and Reporting
- Supply Management
- Sample Management
- Medical Writing
- Medical Monitoring
- Safety Management
- Quality Assurance

Medical Device Clinical Trials: Strengths in IVD Studies

Health Decisions has exceptional strength in large subject-based studies of IVDs. For example, Health Decisions established the gold standard for subject-based studies of HPV and other molecular diagnostics. Experience with such studies has made Health Decisions the CRO of choice when transitioning to FDA-required subject-based studies. Our gold standard best practices include:

**Sample Handling:** We have expertise in sample handling and provide guidance to investigational sites on preparation, stability, shipment and other specific requirements for proper performance of each diagnostic under test.

**Sample Tracking:** Our LiveTrial™ system has integrated capabilities for tracking samples from kit distribution to final storage, including tracking multiple samples and different types of samples for each subject.

Experience with Medical Device Studies

- HPV molecular diagnostic
- Colon cancer diagnostic
- Diagnostics for STDs, e.g. Chlamydia, gonorrhea
- Diagnostic for urothelial carcinoma
- Diagnostic for influenza
- Implantable devices
- Therapeutic devices
- Carotid artery stents
- Endovascular stent grafts
- Stent graft in arteriovenous graft for hemodialysis
- Surgical devices
- Combination drug/device
- Devices in reproductive health, e.g. vaginal rings, diaphragms, male & female condoms
Case Study: 4,006-Subject PMA Study of HPV Diagnostic

Rapid Enrollment and Timely Completion of a Large PMA Study of an IVD

Type of Study: PMA
Active Sites: 48
Patients Enrolled: 4,006

Study Design: Study to Evaluate the Performance and Clinical Predictive Value of device X and device Y for the Detection of Human Papillomavirus in Cervical Cytology Samples

Challenges Faced:
- Enable sponsor to win the race to market against large competitor
- Enroll the study rapidly but efficiently
- Maintain the highest data quality
- Limit monitoring costs without compromising quality
- Lock the database rapidly to support early filing for regulatory approval

Risk Management and Mitigation: Health Decisions advised the sponsor that our systems and processes could gather and report information quickly enough so that women could undergo Pap tests as Standard of Care and then the study could enroll only the target number of women with each abnormality, along with an adequate sample of normal patients to follow forward in time to measure potential false negatives. Health Decisions provided the study team and sponsor with full transparency on the study and immediate access to key information such as Pap results, enrollment by serotype and screenfals. Health Decisions used an efficient data-driven monitoring approach, allocating monitoring visits based on the number of unmonitored fields at each site and utilizing real-time data to monitor remotely between site visits. Health Decisions performed continuous data checks and progressive data lock during the study to ensure high data quality and minimize the time required for database lock and submission.

Results:
- Rapidly completed development of the first test approved by the FDA for genotyping the HPV 16/18 types
- Exceeded every target endpoint for quality and timeliness
- Enabled sponsor to reach market 2.5 years ahead of competitor, generating approximately $500M in additional sales
- Paved the way for acquisition of the sponsor for almost $600M

The CRO of Choice for Forward-Looking Biopharma and Medical-Device Companies

Health Decisions is the CRO of choice for forward-looking biopharma and medical-device companies and a driving force in the modernization of clinical development. Health Decisions uses data-driven insight and agility to deliver clinical development success, reduce timelines and risk and increase quality and returns for biopharma and device companies worldwide. For 25 years and in more than 300 clinical trials involving tens of thousands of patients in many therapeutic areas, Health Decisions has improved the efficiency of clinical development through innovative methodology, processes and technology. Health Decisions' clinical-development services have enabled biopharma and device companies to bring new products to market faster and at lower cost, thus providing the public with earlier access to improved treatments and diagnostics at more affordable prices. Health Decisions received the 2014 ACRP Award for Innovation in Clinical Research and was a 2013 CIO 100 Award Honoree for delivering true business value through its innovative Agile Risk-Based Monitoring+ technology. Health Decisions is headquartered in Durham, NC and operates on five continents.

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