Health Decisions

Diagnostics Health

Integrated IVD Development Services

Health Decisions provides IVD developers with capabilities for streamlining clinical trials and reducing timelines and risk. Health Decisions' integrated IVD development services offer the design and operational excellence, regulatory expertise and laboratory capabilities required to develop IVDs successfully and eliminate risk of delays in the 510(k) clearance or PMA review process. Our experience includes molecular diagnostics, immunoassays and other types of IVDs. Our capabilities for helping diagnostics companies make a rapid, successful transition from early sample-collection and validation studies to large subject-based studies are unmatched.

IVD 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
- Data Management
- Statistical Programming, Analysis and Reporting
- Supply Management
- Sample Management
- Medical Writing
- Medical Monitoring
- Safety Management
- Quality Assurance

IVD Trial Management Services

Health Decisions has exceptional strength in large subject-based studies of IVDs. For example, Health Decisions established the gold standard for best practices in studies of HPV and other molecular diagnostics and we have equally strong capabilities in development of immunoassays and other types of IVDs. Our trial-management capabilities include:

Sample Handling: We have expertise in sample handling and provide guidance to investigational sites on preparation, stability, shipment and other requirements.

Sample Tracking: Our LiveTrialTM system has integrated capabilities for tracking multiple samples per subject from kit distribution to final storage.

Collecting and Monitoring Pathology Data: We have extensive experience collecting and monitoring pathology data for consistency with inclusion/exclusion criteria and comparison with results from the test diagnostic.

Experience with Medical Device Studies

- Molecular diagnostics, immunoassays and other IVDs
- HPV molecular diagnostic
- Colorectal cancer blood-based diagnostic
- Colorectal cancer stool-based diagnostic
- Diagnostic for urothelial cell carcinoma
- Thyroid cancer diagnostic
- Diagnostics for STDs, e.g. chlamydia, gonorrhea
- Preterm birth diagnostic
- Influenza diagnostic
- Many other oncology and infectious disease IVDs

Enrollment Management: Our capabilities for tracking enrollment in IVD studies by subtypes of results enable us to enroll the required number of subjects for each serotype or age stratum and promptly stop enrollment upon reaching that number.

Agile Risk-Based Monitoring+: Health Decisions' Agile RBM+ enables simultaneous reductions in SDV and increases in data quality. We work with each sponsor to determine whether risk-based monitoring makes sense for an IVD study and, if applicable, to tailor an optimal RBM approach for each study

Regulatory Services

Health Decisions delivers a full range of regulatory services that enable IVD developers to address relevant regulations and successfully bring their products to market. Regulatory services include formulating strategy, drafting submissions and assisting with quality management. These services have supported successful development of a wide range of assays. Our regulatory services include:

- Regulatory strategy for 510(k) submissions, PMAs, IDEs, CLIA Waivers, LDTs and CE Mark
- Pre-IDE process guidance and document development
- Identification of analytical and clinical data required to support FDA submissions
- Design of trials to demonstrate clinical utility
- Analytical study SOP development
- Annual reports for significant-risk products
- Technical file development and CE Mark assistance

Laboratory Services

Health Decisions works closely with preferred provider laboratories to provide comprehensive laboratory services for IVD development. Available services include:

- Assay development
- Validation
- Biomarkers
- Immunongenicity
- Pharmacokinetics
- Cell-based assays
- Sample analysis
- Critical reagents
- Secured sample storage
- Refrigerators & freezers with automatic monitoring
- Secure, environmentally controlled archive
- Samples accessioned through validated electronic system
- Variety of platforms and bioanalytical services based on methods including:
  - ELISA
  - MSD-ECL
  - Luminex
  - DELFIA
  - Randox
  - ProteinSimple Peggy
  - Flow cytometry
  - Alpha LISA
  - Gyros
  - HTRF
  - FIA
  - FP
  - Near-IR Li-Cor

The Leading Full-Service Women's Health CRO from Pre-IND or -IDE to Regulatory Approval and Beyond

Health Decisions is a full-service CRO specializing in clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health as well development of diagnostics for all therapeutic areas. Our experience, expertise, site network and KOL and investigator relationships enable us to address the challenges of developing women's health products in areas including general gynecology indications, contraception, sexual health, infertility, obstetrics, menopause and osteoporosis and other indications that affect women disproportionately and profoundly, including autoimmune disorders and male-factor infertility. Health Decisions is headquartered in Durham, NC.

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