Health Decisions

Clinical Consulting Services

A CRO That Tailors Services to Your Needs

Health Decisions is a full-service CRO and more – a CRO+. We often provide full-service trial management from study inception through regulatory filing. However, we tailor our services to the needs of each client. Whether you prefer consulting agreements for specific projects, outsourcing on a Functional Service Provider (FSP) model or a strategic partnership with a formal governance structure, Health Decisions will design a consulting program that works for you.

Our unique combination of development insight and expertise has enabled us to assist many sponsors in regulatory strategy, program planning, protocol development, study design and optimization of operations. We consistently ensure efficient resource utilization and optimize likelihood of marketing approval. We provide services when you need them, from pre-IND meetings through NDA submissions for biopharma products and from pre-sub and IDE through 510(k) and PMA submissions for diagnostics and other medical devices. We also offer extensive experience and expertise in biostatistical analysis and medical writing.

Project-Specific Consulting Agreements

Health Decisions will work closely with you to design a consulting agreement that ensures delivery of precisely the services that best address your needs, whether determining regulatory strategy, program planning, protocol development, performing interim analyses, organizing Advisory Board meetings, or authoring Clinical Study Reports, Investigator's Brochures and regulatory submissions. Our assigned staff will effectively become members of your team and complete the designated tasks to your specifications.

Functional Service Provider Model

In today's costly and competitive environment for clinical trials, pharmaceutical companies must be more productive, cost-efficient and agile than ever. As an experienced Functional Service Provider (FSP) as well as a full-service CRO, Health Decisions delivers cost-efficient, flexible services in functional areas including clinical monitoring, biometrics and data management. Health Decisions has extensive experience providing services on a Functional Service Provider model across all service areas. Our FSP resources will operate as an extension of your team. Communications plans at both the portfolio and study level will keep you fully informed and escalate decisions in accordance with your preferences to ensure that you remain in control.

We offer consulting services including:

- Regulatory Strategy & Consultation
- Submission Planning & Preparation
- Program Planning
- Protocol Development
- Biostatistical Analysis
- Organizing Advisory Board Meetings
- Performing Interim Analyses
- Identifying Key Decision Points & Criteria
- Advising on Go/No-Go Decisions
- Medical Writing
  - Investigator's Brochures
  - Clinical Study Reports
  - SAE Narratives
  - Publications
  - Protocols
- Gap Analysis
- Functional Service Provider

Strategic Partnership

After learning about your goals and preferences, Health Decisions will collaborate with you to forge a program governance model that addresses relationship strategy, program planning, resource management, executive oversight, roles and responsibilities, objectives, operating standards, risk management, communication and escalation. We agree on a vision and joint objectives as the core drivers for the relationship, forge strong relationships at all levels of governance, leverage expertise of both parties and establish a shared sense of accountability for delivery of programs and improvement of the partnership.

Consulting for Biopharma Development

Health Decisions' service offerings for biopharma development include:

- Selecting the optimal regulatory pathway
- Program planning
- Development of drug labeling information
- Performing interim analyses
- Authoring Clinical Study Reports
- Protocol development for:
  - phase I safety testing
  - proof of concept
  - dose finding
  - dose selection
  - confirmatory trials
  - adaptive trials
  - postmarketing studies

Consulting for Diagnostics and Device Development

Health Decisions offers consulting services for development of diagnostic, therapeutic and surgical devices, supporting:

- Investigational Device Exemptions (IDEs)
- 510(k), PMA and CLIA waiver submissions
- Class II and Class III devices
- Qualitative and quantitative diagnostics
- Analysis of sensitivity and specificity
- Analysis of safety and effectiveness for therapeutic and surgical devices

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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