



# Federal Contracting Capabilities Overview

## Full-Service Specialty CRO

Health Decisions is a full-service specialty CRO providing services for a variety of commercial and institutional sponsors, including agencies of the United States government. Health Decision has more than 27 years of experience conducting more than 300 clinical studies, including phase 1 – 4 trials of drugs and biologics as well as PMA, 510(k) and other types of trials of diagnostics and other medical devices.

Health Decisions provides comprehensive clinical development services, including trial management and execution, site management and monitoring, patient recruitment, Federal Information Security Management Act (FISMA)-compliant data management, protocol development, statistical programming, analysis and reporting, medical writing, medical and safety monitoring, pharmacovigilance and regulatory oversight and compliance.

## Experienced Federal Contractor

As a federal contractor, Health Decisions has been awarded multiple contracts to serve as Statistical and Clinical Coordinating Center for the Contraceptive Clinical Trials Network of the National Institute of Child Health and Human Development (NICHD). Health Decisions' current NICHD contract runs through 1919. In addition, Health Decisions is serving as a teaming partner on a contract from the National Institute of Allergy and Infectious Diseases (NIAID) for development of novel anti-infectives.

Health Decisions has managed and monitored 25 federally-sponsored phase 1-3 clinical trials, including the following:

- Phase 1 trials: **9**
- Phase 2 trials: **11**
- Phase 1 – 2 trials: **1**
- Phase 3 trials: **4**

In its role as a statistical and clinical coordinating center and a full-service CRO for federally-sponsored clinical trials, Health Decisions has provided services including but not limited to protocol development, project management, site monitoring, statistical analysis, medical writing, investigator meeting coordination, Data Safety Monitoring Board support and project continuation for commercial rights holders.

## Summary of Services:

- Site Network Coordination
- Project Management
- Site Monitoring
- Protocol Development
- Biostatistical Analysis
- Organization of Advisory Board Meetings
- Data Safety Monitoring Board Coordination
- Investigator Meeting Coordination
- Performing Interim Analyses
- Project Continuation for Commercial Rights Holders
- Medical Writing

## FISMA-Compliant EDC Solution

Health Decisions has developed and operates a proprietary EDC system, called LiveTrial, to manage clinical trials data. LiveTrial has been in operation since 2013, has been continuously upgraded and improved with new features and functionality, and meets the rigorous security and privacy requirements of FISMA and 21 CFR Part 11. Health Decisions' LiveTrial platform has the flexibility to meet data management requirements within a FISMA-compliant environment for sponsors, other CROs, and academic institutions. Organizations facing FISMA compliance requirements can partner with Health Decisions for full-lifecycle clinical trials support or for FISMA-compliant data management services.



Health Decisions data management outsourcing provides a turnkey solution for data management that includes CRF design, study configuration and build, edit checks, deviation and SAE reporting, data closeout and validation, and final database delivery, all within a FISMA compliant environment. The LiveTrial implementation benefits both Federal and commercial sponsors by:

- establishing a security framework and approach that goes beyond technical controls and involves management, stakeholders, and all functional areas of the organization;
- promoting the concept of near real-time risk management and ongoing information system authorization through the implementation of robust continuous monitoring processes;
- encouraging the use of automation to provide senior leaders the necessary information to make cost-effective, risk-based decisions with regard to clinical information systems;
- integrating information security into the enterprise architecture and system development lifecycle;
- emphasizing the selection, implementation, assessment, and monitoring of security controls, and the authorization of information systems;
- linking risk management processes at the information system level to risk management processes at the organization level through a risk executive/function;
- establishing responsibility and accountability for security controls deployed within clinical and organizational information systems and inherited by those systems (i.e., common controls).

## Small Business Certification

Health Decisions is certified as a small business with less than 500 employees as defined by NAICS Code 541712 and has active certification with the General Services Administration System for Award Management.

### 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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