

Health Decisions Data Management Services

Health Decisions is a full-service CRO but also an experienced Functional Service Provider (FSP) in areas including data management. The Health Decisions Data Management group has extensive experience providing the full range of data management services customized as necessary for each sponsor and clinical trial. HD developed its standard data management processes based on Good Clinical Data Management Processes (GCDMP), forms and tools formatted in CDISC/CDASH format and capabilities refined in many clinical trials in a variety of indications.

Health Decisions data support activities, including near real-time data metrics, data import and imaging, are enabled through its intuitive, robust and highly configurable database platforms. These platforms allow us to provide a total package of data management processes with high efficiency, cost-effectiveness and quality.

Data Management Experience in All Major Therapeutic Areas

Health Decisions and its data management team have extensive experience in data management in a wide range of indications across all therapeutic areas. Upon request, we will provide information on experience with specific indications and related CRFs and assessments.

Tiered EDC Offering

Health Decisions offers sponsors a choice of three EDC systems to meet the needs of each project. After discussing each project with the sponsor, Health Decisions recommends for the sponsor's review and approval the system that appears to offer the best balance of functionality and cost.

We offer data management services including:

- Case Report Form Design
- Database Design and Implementation
- Data Validation (System Edit Checks)
- Study Maintenance
- Data Entry
- Data Trend Reviews
- Data Cleaning
- Data Closeout
- Medical Coding
- Quality Control

Advantages Health Decisions' Data Management Offers Sponsors

Functioning as an extension of our client, Health Decisions offers the following advantages as a data management FSP for sponsors:

<p> Flexibility</p> <ul style="list-style-type: none">• perform comprehensive data management or standalone tasks• manage data within client data management technology or via HD platform(s)	<p> Agility</p> <ul style="list-style-type: none">• harmonize standards and processes with client study procedures• foster continual efficiencies• expeditious study start-up and closeout capabilities• use of HD's extensive CDISC standard CRF library with associated edit checks• increase overall study utilization and in most cases provide cost savings and reduced data-cleaning timelines.
<p> Capability</p> <ul style="list-style-type: none">• provide a dedicated data management team that can address sponsor's needs in a wide range of indications across major therapeutic areas• train and manage staff on client processes or client-approved HD processes• resource specialty staff as needed (ramp up or reduce, depending on need, efficiently and without affecting client headcount)	<p> Quality</p> <ul style="list-style-type: none">• accountability for the quality of data, cleanliness of data, timeliness of deliverables and oversight of data management resources• use of study-specific reports to monitor data inconsistencies, anomalies and inaccuracies

The LiveTrial EDC System

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 the Federal Information Security Management Act (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. As noted above, Health Decisions offers sponsors a choice of three EDC systems. LiveTrial is strongly recommended when FISMA compliance is required.

Contact us to explore how Health Decisions can assist with your data-management needs.

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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