Health Decisions

Comprehensive Early-Phase Services and Capabilities

Health Decisions is a full-service CRO and the clinical development partner of choice for early phase studies for forward-looking biopharma and medical device companies worldwide. Our unique combination of development insight, expertise, processes and technology provides excellence in every aspect of clinical research. Our flexible, high-speed, high-quality approach to early-phase studies delivers excellent results across the full range of testing, including first-in-human, dose-escalation, bioavailability/ bioequivalence and PK/PD.

Comprehensive Early-Phase Services

Health Decisions provides robust research capabilities for early-phase studies, including:

- 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

Flexibility, Speed and Independent Oversight in Early Testing

Health Decisions partners with a variety of experienced phase 1 units, selecting the unit for each trial that best meets sponsors needs and providing independent oversight and monitoring. Health Decisions actively manages phase 1/2a research sites. From experience, we understand that early-phase studies benefit from a separate monitoring and oversight team to manage the phase 1 unit as well as provide an independent review of its work. The success of early-phase studies depends on issues such as accurate dosing and PK sampling collection. Independent oversight ensures close adherence to the dosing regimen, accurate completion of dosing and blood draw logs, etc. The combination of flexibility in site selection and rigorous, independent oversight ensures delivery of high-quality services for each Health Decisions early-phase study.

Early-Phase Experience:

Working closely with partner phase 1/2a research units, Health Decisions offers project and site management and monitoring for the following types of phase early-phase studies:

- First-in-human
- Dose escalation
- Bioavailability/ bioequivalence
- PK/PD
- Qt/QTc
- Human challenge
- Vaccine development

Rapid Data Access for Key Decisions

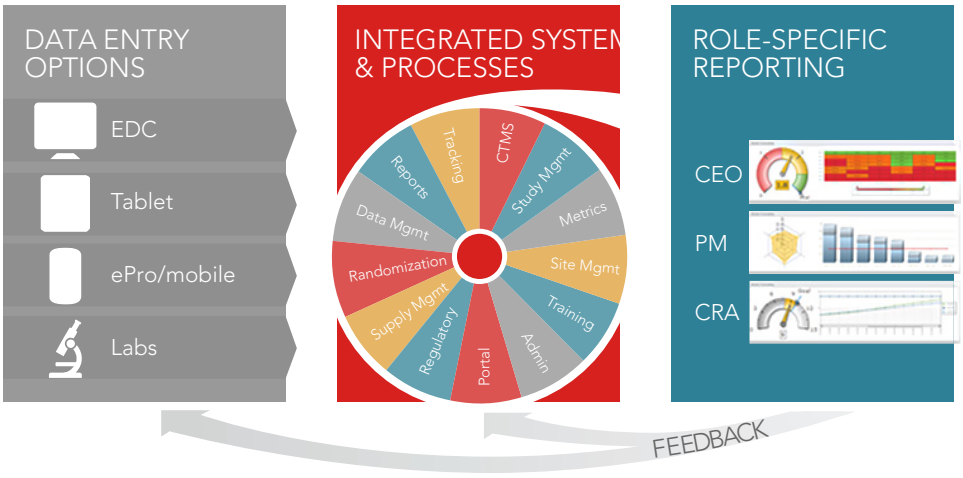
Health Decisions provides a selection of data-capture methods to ensure rapid data access, of particular importance in successful execution of early-phase trials, where timely access to safety information is always of paramount importance and the timelines are often dependent on availability of data for dose-escalation decisions. Health Decisions offers webEDC but finds computer tablets are often the optimal solution for rapid early-phase data capture and access for timely decision-making. Tablets have the advantage of portability combined with screen size adequate for convenient display of questions and related instructions for typical CRFs.

A Better Way of Running Clinical Trials: Agile Clinical Development

Health Decisions' innovations enable earlier, better decisions throughout the life cycle of each study, driving high-quality execution that reduces risk and time to market. Health Decisions' Agile Clinical Development methodology optimizes every aspect of clinical development, comprehensively optimizing trial operations and, when appropriate, selectively optimizing trial design. Adaptive trial design utilizing techniques such as the Continual Reassessment Method (CRM) for dose-finding can greatly accelerate early-phase studies.

LiveTrial™ – The Information Engine for the Agile Approach

LiveTrial is the integrated information engine for Agile Clinical Development and contributes to the success of every Health Decisions early-phase study. LiveTrial's three major components – the LiveTrial Clinical Trial Management System, Clinical Data Management System and Study Collaboration & Management Portal – work from a single database, eliminating typical data transfers from multiple internal systems and ensuring rapid data availability for the study team. Integrated dashboards rapidly transform data into actionable information to support earlier, better decisions throughout the life-cycle of each study.



Streaming LiveData™ and Key Performance Indicators from the LiveTrial™ information engine provide role-specific information and drive rapid, high-quality execution.

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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