

# A Proven Dual-Focus Specialty CRO for Women's Health and Diagnostics

Health Decisions is a full-service CRO specializing in clinical studies of therapeutics for women's health indications and studies of diagnostics for all therapeutic areas. Health Decisions has focused on women's health since its inception more than 28 years ago, conducting more than 100 trials in women-only indications such as contraception, postmenopausal vasomotor symptoms, pain management following childbirth, STIs, bacterial vaginosis as well as indications affecting women disproportionately, including depression, migraine and multiple sclerosis. Health Decisions expanded into diagnostics studies with a large PMA trial of a test for high-risk HPV types associated with cervical cancer and has since conducted successful studies of diagnostics in a variety of indications including colorectal cancer, urothelial carcinoma, respiratory indications and sexually transmitted infections (STIs).

## Service Offerings

### Trial Management

Health Decisions provides experienced, proactive project management for phase 1 - 4 trials of women's health drugs, devices and diagnostics as well as trials of diagnostics for all therapeutic areas. Health Decisions utilizes a data-driven approach to trial management that reduces risk and timelines and increases efficiency. Project teams identify key risks and mitigations for each study and track key risk indicators to keep studies on track.

### Trial Monitoring

Health Decisions utilizes monitoring teams of field and in-house CRAs. In-house CRAs serve as primary site contact, perform data checks and provide information enabling field CRAs to perform more efficient site visits. Health Decisions offers risk-based monitoring and reduced SDV as well as 100% SDV.

### Study Design & Protocol Development

The Health Decisions biometrics group has extensive experience developing protocols for phase 1 – 4 trials. Our biostatisticians work closely with sponsors to identify endpoints and inclusion/exclusion criteria and select conventional and adaptive design techniques appropriate for each study.

### Regulatory & Quality

Health Decisions' regulatory services include identifying the optimal regulatory pathway for each drug or diagnostic and supporting sponsors from pre-IND or pre-IDE meeting through regulatory submission. The quality management team ensures the quality of processes and deliverables for each study.

### Data Management and Biometrics

The Health Decisions data management group offers a choice of three EDC systems and implements Good Clinical Data Management Processes (GCDMP) and the CDISC/CDASH format. The biometrics group ensures that data checks focus on areas that defend the statistical analysis.

### LiveTrial EDC

Health Decisions offers its proprietary LiveTrial Data Management System as a service, providing a practical solution for achieving compliance with 21 CFR Part 11 and the Federal Information Security Management Act (FISMA), improving data security and maintaining eligibility for federal contracts.

## Women's Health

*Health Decisions is the leading full-service women's health CRO from pre-IND to NDA and beyond*

### If it matters to women's Health, it matters to Health Decisions

The Health Decisions clinical affairs and biometrics groups have extensive experience in development of a wide range of women's health products and draw on the expertise of a Chief Medical Officer who is a board-certified ObGyn with experience in more than 80 clinical trials in a variety of women's health indications. Health Decisions has a network of principal investigators at more than 280 women's health sites, including numerous Key Opinion Leaders (KOLs) in women's health specialties. Health Decisions' therapeutic and operational expertise enables us to conduct efficient, high-quality clinical trials in areas including:

- General gynecology
- Sexual health
- Infertility
- Obstetrics
- Menopause
- Osteoporosis
- Indications that affect women disproportionately

## Diagnostics

*Health Decisions is the go-to CRO for large subject-based IVD studies*

Health Decisions offers robust capabilities for a variety of IVD studies, with large subject-based IVD studies a noteworthy strength. Health Decisions understands regulatory requirements and operational challenges of PMA, 510(k)

and CLIA-waiver studies. The diagnostics team draws on the expertise of the Health Decisions Scientific Advisory Board, which includes a PhD microbiologist who is a recognized expert on regulatory and other aspects of diagnostics development. Health Decisions offers services for diagnostics studies including:

- PMA studies
- 510(k) studies
- CLIA waiver studies
- Clinical validity studies
- Clinical utility studies
- Repeatability & reproducibility studies

## Studies in Other Therapeutic Areas

In addition to experience in women's health and diagnostics studies, Health Decisions has experience conducting successful studies in a variety of other therapeutic areas, including:

- Endocrine & metabolism
- Infectious disease
- Neurosciences
- Gastroenterology
- Nephrology
- Oncology

## Services Tailored for Each Sponsor

Health Decisions tailors services to the needs and preferences of each sponsor and project. Health Decisions project teams strive to serve as an extension of each sponsor's internal development team, leveraging the expertise of both organizations and functioning as a unified team dedicated to the success of the sponsor's program.

Contact us to explore how Health Decisions can assist with your clinical development 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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