Health Decisions

Women's health

Capabilities in Women's Health Studies

Health Decisions is the leading CRO in women's health, with deep design expertise and unmatched operational excellence in clinical development of products for a wide range of indications in general gynecology, contraception, sexual health, infertility, obstetrics, menopause, osteporosis and other female health issues. Health Decisions tailors its services to the needs of each sponsor, from full-service trial management and execution for phase 1-4 drug studies to studies of diagnostics and other medical devices and consulting about regulatory strategy and study design.

Health Decisions offers the therapeutic, operational and regulatory expertise to reduce risk and timelines and increase efficiency for investigative products in all aspects of women's health. Health Decisons supports development not only of products for women-only indications, but also indications that affect women disproportionately or profoundly, including migraine, depression, autoimmune disorders and male-factor infertility. If it matters to women's health, it matters to Health Decisions.

Experience in Women's Health

- 28 years designing and conducting reproductive health and women's health studies
- >100 protocols developed and studies conducted
- Health Decisions has served as Statistical and Clinical Coordinating Center for Contraceptive Research for the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) since 1996
- Extensive international experience, including designing, managing and monitoring large global trials
- Experience serving as a virtual clinical development organization providing full development services to companies that prefer a lean business model
- Experience at all levels, including senior scientists, PMs, CRAs, data management and biostatistics
- Relationships with numerous investigators, including KOLs, in the US and internationally

Design and Operational Considerations

Health Decisions' team of clinical experts understands the key design and operational challenges in reproductive and women's health studies:

Indications/Products

- Contraceptives
  - Oral contraceptives
  - Spermicides
  - Microbicides
  - Emergency contraceptives
  - Diaphragms
  - Vaginal rings
  - Female condoms
  - Male condoms
- In Vitro Fertilization
- Vasomotor symptoms
- Sexually transmitted infections
- Human papilloma virus
- Dysmenorrhea
- Amenorrhea
- Female sexual dysfunction
- Vaginitis
- Endometriosis
- Osteoporosis
- Pain management following hysterectomy
- Metastatic breast cancer
- Bacterial vaginosis
- IVDs for reproductive health:
  - Risk of preterm birth
  - High-risk HPV
  - Chlamydia/gonorrhea

Design Considerations

- Developing clear primary and secondary endpoints for regulatory approval
- Determining the sample size and other parameters that will maximize chances of meeting regulatory requirements (e.g., number of cycles, statistical requirements for demonstrating success)
- Deciding on a superiority or noninferiority design and negotiating noninferiority margin with regulatory agencies
- Evaluating the use, purpose and value of sub-studies
- Defining subject requirements (inclusion and exclusion criteria) that will select the right population but also allow rapid enrollment (e.g., taking into account high BMI, age, sexual activity)

Operational Considerations

- Relationships with investigators
- Access to the right subjects
- Identifying enrollment/recruitment challenges and developing effective contingency plans
- Determining subject-retention risks and developing effective retention strategies
- Developing risk-based monitoring plans that simultaneously reduce SDV% and increase data quality.
- Identifying potential risks to data quality based on site performance, personnel, CRFs
- Ensuring consistency and quality in subject-reported data, including patient diaries

CASE STUDY

Emergency Contraceptive Program Support from Preclinical through FDA Approval

Ensuring Rapid Program Advancement for an Emergency Contraceptive Through International Phase 3 Study

Phase: Preclinical through phase 3 program

Challenges Faced:

- Accelerate early phase development
- Rapidly and successfully transition program from institutional to commercial sponsorship
- Support successful commercial phase 3 study resulting in FDA marketing approval

Risk Management and Mitigation: Health Decisions supported development of an emergency contraceptive from preclinical research through FDA marketing approval. Health Decisions supported the institutional program in a full-service capacity that included protocol development, clinical site monitoring, data collection and management, regulatory document collection, project management, statistical analysis and preparation of study reports for two phase 2/3 studies. Health Decisions also transitioned key study documents and databases to the sponsor with commercial rights. The commercial sponsor selected Health Decisions to provide monitoring support for the large international phase 3 study that led to FDA approval.

Unmatched Expertise in Women's Health

Whether advising on overall development strategy, program planning and study design, or planning individual trials and ensuring optimal trial management and execution, Health Decisions' senior professionals use their extensive development expertise, experience, and advanced data-driven analytics to provide insights that improve planning and execution of every Health Decisions study. Health Decisions' systems and processes provide streaming data and role-specific information that enable earlier, better decisions at all levels of trial management and execution throughout the life-cycle of each study.

If you are developing women's health products -

Make Your First Decision the Right Decision - Health Decisions

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.

Health Decisions
2510 Meridian Pkwy.
Durham, NC 27713

Tel: +1.919.967.1111
Toll Free: +1.888.779.3771
Email: contact@healthdec.com

For more information please visit
www.HealthDec.com

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