



What Is Women's Health?

Health Decisions is a specialty CRO focused on the clinical development of drugs, diagnostics and other devices to improve health outcomes for women. We define women's health as any health issue or condition that affects females profoundly or disproportionately at any stage of the lifecycle. Thus, women's health encompasses ObGyn indications such as endometriosis, bacterial vaginosis and menstrual disorders, and also a wide range of autoimmune diseases.

No less than 78% of the patients with autoimmune diseases are female. Autoimmune diseases that affect women disproportionately include rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, systemic sclerosis, Graves' disease and myasthenia gravis.

In our view, women's health also includes a variety of other diseases with predominantly female patient populations, including migraine, depression, anxiety disorders, eating disorders and chronic fatigue syndrome. Health Decisions and our clinical staff and therapeutic advisors, as well as the Key Opinion Leaders and PIs in our site network, understand the issues in conducting clinical trials in women's health in areas including site selection, subject recruitment, assessments and safety management.

Extraordinary Experience, Expertise and Resources in Women's Health

Health Decisions has extensive experience in clinical development of women's health products, including:

- More than 3 decades designing and conducting large-scale women's health studies
- >100 protocols developed and studies conducted
- Health Decisions has served as the Statistical and Clinical Coordinating Center for Contraceptive Research for the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) since 1996
- Hundreds of sites with experience in women's health studies
- A Chief Medical Officer who is a board-certified ObGyn
- Extensive relationships with Key Opinion Leaders in women's health

We sum up the Health Decisions definition of women's health simply:

If it matters to women's health, it matters to Health Decisions.

Areas of Specialization

Health Decisions is active in the full range of issues affecting women's health throughout the lifecycle. We briefly describe our expertise and capabilities in key areas of specialization below:

General Gynecology

While the Health Decisions definition of women's health encompasses far more than ObGyn indications, this area remains a core strength. Health Decisions' therapeutic and operational experience and expertise enable us to conduct efficient, high-quality clinical trials in general gynecology indications.

Contraception

Health Decisions has extensive experience and expertise in studies of contraceptives. Just as each type of contraceptive appeals to different women and couples in different life situations, clinical trials of novel contraceptives present different regulatory, design and operational challenges. Health Decisions understands the challenges of protocol development for each type of contraceptive as well as the differing operational challenges in areas including project management, site selection, patient recruitment, informed consent, retention, site management, data management and statistical analysis.

Sexual Health

Health Decisions provides therapeutic and operational expertise and site relationships for clinical development of novel products to address issues in women's sexual health. This encompasses supporting the development of therapeutics and diagnostics for a variety of indications that compromise women's ability to participate in and enjoy sexual activity. Such indications include but are not limited to female sexual dysfunction, sexual desire disorders, coital pain, vaginal atrophy, vaginismus and STIs. Etiology of many conditions in sexual health can involve one or more factors ranging from physical and hormonal issues to affective disorders, stress in personal relationships and side effects of common medications such as antidepressants and contraceptives.

Infertility

Potential causes of infertility are many and varied. Either the male or female partner may have an issue that renders conception impossible or highly unlikely. In perhaps one-third of cases, diagnostic procedures identify problems in both partners. Sometimes exhaustive testing fails to identify a cause in either partner. Oligoovulation, anovulation, tubal blockage, endometriosis, polycystic ovary syndrome and uterine abnormalities are among potential issues for women.

In male-factor infertility, there may be issues in sperm count, motility, morphology, volume, pH and other factors. Thus, the overall population of infertile couples is highly fragmented. While there are millions of infertile couples, the specific population eligible for any individual study may be limited. Health Decisions understands how to address the challenges of infertility studies.

Obstetrics

Health Decisions understands how to address the unique challenges in clinical testing of investigational products to improve outcomes for indications such as preterm labor, preeclampsia and post-delivery analgesia. Studies in pregnant women present obvious issues in minimizing risks to both mother and fetus while making an accurate determination of safety and efficacy. The field of maternal-fetal medicine, devoted to the management of high-risk pregnancies and medical complications during pregnancy, benefits from improvements in areas such as development of diagnostics for determining risk of pre-term birth and preventive drugs and devices.

Menopause and Osteoporosis

Health Decisions has extensive experience in studies of therapeutics for menopausal and postmenopausal women. Menopausal and postmenopausal women face many health challenges. Women in this population are often open to new treatments and willing to participate in clinical trials of novel products. However, women who have found any product that provides relief for vasomotor symptoms will hesitate to agree to discontinue the product or risk randomization to placebo. Health Decisions understands how to address recruitment issues in this population.

Other Female Health Issues

If it matters to women's health, it matters to Health Decisions. Accordingly, we conduct trials in a variety of indications that affect both sexes but women disproportionately or profoundly. Such indications include migraine, depression, anxiety disorders, eating disorders, multiple sclerosis and rheumatoid arthritis. Many of these indications not only affect fundamental health but also quality of life for millions of women worldwide. We are committed to improving health outcomes for women in these indications as well as women-only health conditions.

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 the clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health as well as 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, 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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