Health Decisions

Women's health

Capabilities for Clinical Studies in the Genitorurinary Syndrome of Menopause (GSM)

New Terminology for Common Postmenopausal Indications

The Genitourinary Syndrome of Menopause (GSM) is a new term that encompasses multiple effects of the postmenopausal reduction in levels of estrogens and other hormones. Previously used terms such as vulvovaginal atrophy and atrophic vaginitis captured only some of the effects of reduced hormone production following menopause. Symptoms of GSM can include dryness, burning sensations, and irritation in the genital area; poor vaginal lubrication, discomfort or pain during sex; and urinary urgency, dysuria and recurrent urinary tract infections (UTIs).

Operational and Methodological Considerations in GSM Trials

Clinical trials in a postmenopausal population with symptoms of GSM involve considerations shared with other indications as well as a variety of challenges that are unusual or unique to GSM. Such considerations include:

- Performing screening mammograms
- Inclusion/exclusion criteria related to potential risk of deep vein thrombosis, such as exclusions for a history of thromboembolic or cardiovascular disease
- Inclusion/exclusion criteria for BMI and hypertension
- Inclusion/exclusion criteria based on the Vaginal Health Index assessment (% of superficial cells) and vaginal pH
- An endometrial biopsy
- Consideration of a transvaginal ultrasound when an endometrial sample is not possible
- Outcome measures such as severity scores for dyspareunia or urinary incontinence

The Potential Breadth of Benefits of Therapeutics for GSM

Biopharma companies may consider conducting clinical trials that evaluate the safety and efficacy of investigative products for one indication, such as vulvovaginal atrophy, that is associated with reduced hormone levels or for the syndrome, GSM. It will be interesting to observe the primary and secondary endpoints selected by sponsors and approved by regulators for GSM studies by comparison with endpoints for studies in indications before the transition to language grouping multiple indications as a syndrome.

Key Risks and Mitigations in GSM Studies

Risk 1: Difficulty obtaining endometrial biopsy samples in postmenopausal women with a uterus

The requirement for endometrial biopsies in postmenopausal women with a uterus presents challenges because of potential cervical stenosis.

Mitigations

- Ensure precise training in allowed biopsy techniques.
- Allow use of a tenaculum.
- Allow use of devices that offer the greatest likelihood of success.
- Allow use of small dilators (1 to 4 mm) to gently dilate the cervical canal.
- Allow use, if necessary, of a paracervical block to lessen a subject's discomfort.
- Allow multiple passes when required to ensure specimen adequacy.
- Allow use of medications for cervical dilation prior to biopsy.

Risk 2: Difficulty in meeting enrollment timelines or subject retention

A disappointing enrollment rate is a risk in many studies including those for women in menopause. The difficulties of discussing symptoms when dyspareunia is an outcome can impact retention of the study as well.

Mitigations

- Compensate subjects appropriately for invasive study procedures.
- Provide stipends for meals and transportation.
- Implement a communication plan with sites defining frequency and methods for subject visit reminders.
- Provide sites and study personnel with recruitment materials and training to support conversations with potential subjects around the study and GSM, in particular dyspareunia.
- Consider a central advertising campaign.

For Assistance With Your GSM Program

GSM affects a vast population of postmenopausal women, compromising health and quality of life. As a CRO committed to improving healthcare outcomes for women, Health Decisions is determined to advance and accelerate clinical development of improved treatments for GSM. In addition, the Health Decisions clinical team understands how to address key operational issues and mitigate risks in GSM trials. Please contact us to explore how Health Decisions can assist with efficient, timely development of your investigative product for treatment of endometriosis.

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

Health Decisions

©2018 Health Decisions. All rights reserved. All brand names are trademarks or registered trademarks of their respective company.