Drug Development for Women's & Men's Health

There are certain conditions and diseases that pertain to women or men only. These sex-specific indications often require specialized assessments and medical expertise. Celerion is exceptionally well positioned to successfully execute women's and men's health clinical studies, leveraging to our robust participant database, study experience, and medical specialist partnerships.

Focus on Women's Health

Women's health covers a wide range of conditions and indications, which include menstruation, endometriosis, pregnancy, lactation, menopause and polycystic ovarian syndrome (PCOS) as well as breast and cervical/uterine cancers. This term can also extend to conditions that disproportionally affect women such as osteoporosis and cardiovascular disease (CVD).

Access to Participants

- Healthy women of childbearing potential
- Healthy women of non-childbearing potential
- Oral contraceptive-naïve women
- Lactating women
- Sterilized women
- Healthy postmenopausal women

Study Experience

- COC with cycle-dependent dosing
- Dysmenorrhea and endometriosis products
- Healthy volunteer osteoporosis, CVD and oncology studies

Combined Oral Contraceptive Drug-Drug Interaction Studies

Combined oral contraceptive (COC) medications contain synthetic progestin and ethinyl estradiol to regulate menstruation cycles.

A drug-drug interaction (DDI) study with COCs is often recommended for investigational products in development that are moderate or weak CYP3A inducers or inhibitors to evaluate potential drug interactions.

These studies commonly enroll premenopausal adult women under the age of 45 years.

Celerion has conducted more than 30 COC drug interaction studies since 2010.

Specialized Assessments

- Pelvic exams and pap smears
- Transvaginal ultrasound
- Mammography *(US only)*
- Ultrasound and DEXA scans
- Testing for sexually transmitted infections, including human immunodeficiency virus (HIV), human papilloma virus (HPV), chlamydia and gonorrhea
- Testing for bacterial vaginosis and trichomonas

Case Study Combined Oral Contraceptives

NEED: A pharmaceutical company developing a COC was seeking a partnering CRO to conduct a home dosing study in healthy adult females who are not currently using oral contraceptives.

– Check-in and randomization varied for each participant based on the first day of their menstrual cycle.

APPROACH: A dedicated Admissions Specialist was assigned to the study to confirm enrollment and randomization

– The Admissions Specialist closely tracked each screened participant's cycle to schedule their baseline visit.
– Participants received thorough training on how to use the dosing diary and blister pack for home dosing.
– Phone calls were scheduled every 2 days for AEs collection and to remind participants to continue dosing.
– Diary and drug reconciliation were completed at weekly return visits.

BENEFIT: Applying an adaptive and flexible study start for each participant maximized the number of women randomized in the study.

– With a large database of COC-naïve women, enrollment of 24 participants and initiation of study drug dosing occurred within 1 month.
– Close communication between the participants, Admissions Specialist, Principal Investigator and study team ensured all eligible subjects were randomized in a timely manner.

Supporting Men's Health

Men's health research focuses on prostate and testicular cancer as well as erectile dysfunction (ED), testosterone supplementation and other chronic conditions that are prevalent in men such as heart and lung diseases.

Access to Participants

– Healthy men
– Sterilized men
– Men with ED

Study Experience

– Treatments for ED
– Testosterone supplements
– Healthy volunteers for prostate and testicular oncology studies

Specialized Assessments

– RigiScan® assessment and penile plethysmography
– Sperm count analysis
– ED and sexual activity monitoring questionnaire
– Sexually transmitted infection testing
– Testosterone assessment

Testicular Toxicity Testing

Some drugs have a risk of testicular toxicity in humans, which may warrant evaluation of testicular toxicity in healthy male volunteers. This typically involves repeated semen analysis prior to dosing, after one spermatogenic cycle of 13 weeks following drug administration and at least one spermatogenic cycle after drug discontinuation or complete elimination. In addition, other biomarkers of testicular injury such as gonadal hormone levels may also be assessed. Dedicated testicular safety trials may be indicated to confirm findings on testicular function.

Celerion has extensive experience with the design and conduct of testicular safety trials in healthy male volunteers, requiring evaluations over at least 26 weeks.

Leveraging Medical Specialists across our 3 Clinical Pharmacology Units

We partner with local medical experts, experienced in clinical research to support women's and men's health trials.

Medical Specialists	Belfast, UK	Lincoln, NE	Phoenix, AZ
Andrologist	✔	✔	✔
Gynecologist	✔	✔	✔
Radiologist	✔	✔	✔
Sonographer	✔	✔	✔
Urologist	✔	✔	✔

RESOURCES:

Women's Health: Maximizing Study Design of Combined Oral Contraceptives Drug Interaction Studies

Semen Clinical Studies