FEMALE HEALTH CARE

Knowledge of sex differences as a key biological variable in product development must be considered at every step in the development of drugs, devices and biologics. Failure to consider sex differences during data collection and analysis will severely limit the usefulness of clinical data in the regulatory evaluation of product safety and efficacy, and may jeopardize the applicability of study results to clinical practice and personalized medicine. This is particularly important for studies of diseases or therapies that exhibit a known sex difference. Together with our collaboration partner Dinox, a unique center of excellence in the field of female health care, QPS Netherlands provides all of the clinical, bioanalytical and gynecological experts to fulfill your clinical development needs in the fields of gynecological endocrinology and clinical pharmacology.

What Types of Clinical Studies Do QPS and Dinox Typically Work Together On?

Sex differences can play a significant role in how a treatment will affect a patient. QPS and Dinox work together on a wide-variety of clinical studies to gather clinical evidence to document how drugs, devices and biologics will affect and interact with females. Clinical studies QPS and Dinox typically work on together include:

- Drug-drug interaction studies with oral contraceptives
- Trials with new contraceptives
- Infertility trials
- Clinical lactation studies i.e. trials which are designed to assess:
  - The influence of lactation on maternal pharmacokinetics
  - The extent of drug transfer into breast milk
- Bioavailability and bioequivalence studies in healthy, pituitary-suppressed female subjects
- Trials requiring frequent transvaginal ultrasonography (TVUS) assessments
- PK/PD studies in healthy pituitary suppressed women with various hormonal measurements and multiples TVUS assessments to determine follicular growth and/or endometrial thickness
- Studies in which the timing of the study drug administration is to be done menstrual cycle-dependent or, in other words, should be done dependent on follicle size

- Trials with drugs that are developed for the treatment of:
  - Infertility
  - Female Sexual Dysfunction
  - Premenstrual Syndrome
  - Acne
  - Menstrual pain
  - Menopausal complaints

Frequently Applied Pharmacodynamic and Safety Assessments and Safety Assessments in the Field of Gynecological Endocrinology

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- Transvaginal ultrasonography (TVUS)
- Gynecological examination
- Cervical smear
- Endometrial thickness
- Endometrial biopsy
- Hormones/biomarkers

QPS and Dinox

QPS and Dinox have the experience and resources to gather clinical evidence and safety data, while following the strict regulatory requirements needed to get your drug, device or biologics on the market. The advantages of QPS and Dinox working together on your clinical development needs include:

- QPS and Dinox are both located in the same building at the premises of the University Medical Center Groningen (UMCG), which facilitates an intensive collaboration.
- QPS and Dinox both have large volunteer databases available -- especially for the recruitment of female subjects – to call upon for clinical trials on your drug, device or biologics.
- QPS and Dinox's have a full staff of clinical, bioanalytical and gynecological experts available to assist you with the clinical development of your drug, device, or biologics.
- QPS and Dinox both work in compliance with the principles of Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) to meet your high quality standards and regulatory requirements.

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