



## A FLEXIBLE APPROACH TO FEMALE HEALTHCARE CLINICAL TRIALS

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WHEN YOUR FOCUS IS CLINICAL TRIALS,  
QPS' global clinic network provides the  
ideal support for your Phase I - IV clinical  
trials from initiation through filing.



## QPS EXPERTISE IN CLINICAL TRIALS INVOLVING FEMALE HEALTHCARE

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. QPS provides all of the clinical, bioanalytical and gynecological experts to fulfill your clinical development needs in the field of women's health care.

### QPS CONDUCTS PHARMACODYNAMIC AND SAFETY ASSESSMENTS IN THE FIELD OF GYNECOLOGICAL ENDOCRINOLOGY

Sex differences can play a significant role in how a treatment will affect a patient. QPS has deep experience in the conduct of clinical trials where women are the primary study subjects. Some of the tools and techniques that we commonly use include:

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





## TYPICAL CLINICAL STUDIES IN FEMALE HEALTHCARE

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QPS conducts a wide variety of clinical studies to gather clinical evidence to document how drugs, devices and biologics will affect and interact with females. Typical study types 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 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



## QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

### BENEFIT FROM THE RESOURCES OF A GLOBAL CRO



Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of clinical trial services to support drug development needs from discovery, through clinical development and regulatory filing.



CUSTOM-BUILT RESEARCH™

**TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.  
CONTACT THE QPS BUSINESS DEVELOPMENT  
TEAM TODAY!**

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