



WOMEN'S HEALTH

CLINICAL RESEARCH CAPABILITIES

Altasciences offers a multitude of specialized solutions for sponsors developing therapeutic products and diagnostics in the area of women's health. We combine our clinical sites' robust female databases with a network of community physicians to support the design, recruitment, conduct, and oversight of studies in this therapeutic area.

We have conducted over 100 clinical trials in the area of women's health. Our clinical pharmacology units are located in densely populated areas, which allows access to a wide variety of ages, ethnicities, lifestyles and health conditions. The result is a diverse patient database which includes over 100,000 of women who are actively interested in participating in our clinical trials.

Altasciences' large and small molecule bioanalytical expertise and comprehensive research support services ensure an integrated, efficient, and holistic solution for your women's health studies.

Clinical Development Highlights

Therapeutic Areas

- Antifungals
- Antivirals
- Breast cancer
- Chronic lymphocytic leukemia
- Contraception and emergency contraception
- Endometriosis
- HIV prevention
- HRT/vasomotor symptoms
- Hyposexual desire disorder
- Hyperlipoproteinemia
- Osteoporosis/bone health
- Cardiovascular disease
- Female infertility
- Postmenopause
- Heavy menstrual bleeding associated with uterine fibroids
- Pregnancy

Study Types

- Alcohol interaction
- Comparative BA/BE
- Drug-drug interaction
- Driving impairment
- Proof of concept, efficacy
- Transdermal adhesion/HRIPT
- FIH (SAD/MAD)
- Food effect
- Genotyping PK
- Renal impairment
- Safety, PK, tolerability

Number of Female Participants	101,000
Genotyped	778
Age	
18-25	> 6,100
26-34	> 29,500
35-44	> 30,500
45-55	> 18,000
56+	> 17,100
Reproductive Status	
Woman of child-bearing potential	63,800
Using hormonal contraception	> 19,400
Women of non-child-bearing potential	> 17,800
Smoking Status	
Non-smoker	74,053
Light smoker	20,179
Regular smoker	12,010

WOMEN'S HEALTH CASE STUDIES

Population: 102 healthy non-pregnant and 102 healthy pregnant females in their first trimester of pregnancy

Enrollment Period: 5 months

Study Design: Early-detection pregnancy diagnostic whereby participants underwent a series of four pregnancy tests: twice with the investigational device, once with an approved device, and once through a blood test. Device needed to generate results accurately in 99.9% of tests.

Challenges: Due to the first trimester requirement, participants could not be easily identified through OBGYNs; requiring comprehensive marketing and recruitment campaign.

Results: Successfully enrolled 204 participants within the required timeframe, allowing the sponsor to meet an important corporate milestone

Population: 32 healthy women of childbearing potential, ages 21-40, on a stable regimen of oral control or hormonal contraceptives

Enrollment Period: 3 months

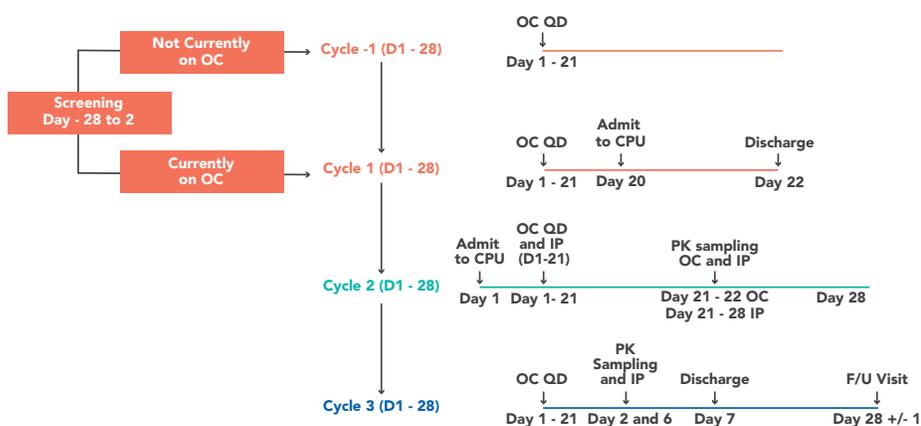
Study Design: Open-label, multiple-dose, single sequence, crossover

- Screening period of up to 28 days prior to the beginning of the study period
- Optional "lead-in" cycle lasting up to 28 days prior to Cycle 1
- Cycle 1 lasting up to 28 days, including oral contraceptive treatment on Day 1 to 20
- Cycles 2 and 3 lasting up to 57 days including:
 - Confinement period of 35 nights
 - Follow-up visit approximately 28 days following discharge

Challenges:

- Identifying eligible subjects who were willing to be confined for 35 nights
- Training OC-naïve vparticipants on proper usage (at home dosing) and ensuring compliance of contraceptive use reporting throughout the entire study

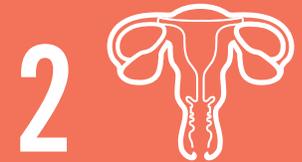
Results: Successfully enrolled 32 participants within the required timeframe, of which 27 completed all activities, allowing the sponsor to move onto the next stage of development



contact@altasciences.com
altasciences.com



1
Large volume pregnancy test



2
Extended confinement study in women of childbearing potential (WOCBP)

Altasciences' Comprehensive Full-Service Offering

Available as stand-alone services, or as part of a development package:

- Manufacturing and analytical services for small molecules
- Scientific, regulatory, and strategic Guidance
- Protocol development
- Project management
- Bioanalysis (small and large molecules)
- Data management
- Biostatistics
- Reporting
- CDISC
- Archiving