

# WOMEN'S HEALTH CLINICAL TRIAL EXPERIENCE



## From the Principal Investigator

Thank you for your interest in The Center for Pharmaceutical Research.

Over the past 24 years, our site has conducted over 475 clinical trials in all areas of multispecialty research.

As principal investigator, my top priority is providing safe, ethical, cutting-edge medical treatments for our volunteers and clean, quality data for our sponsors. I am extremely interested in your upcoming women's health clinical trial and am confident of our ability to exceed your expectations.

Please take time to review the enclosed packet describing our facility and our experience.

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## Previous Women's Health Studies

The Center for Pharmaceutical Research has conducted 30 women's health studies with outstanding success. Our experience includes studies on the following conditions:

- 3 Abnormal Bleeding
- 2 Genital Herpes
- 1 Hormone Replacement Therapy
- 1 Hot Flashes
- 5 Low Libido
- 1 Menstrual Migraine
- 5 Oral Contraceptive
- 7 Osteoporosis
- 4 Overactive Bladder
- 1 Stress Urinary Incontinence
- 2 Urinary Tract Infection

The following charts highlight our women's health research experience and reflect CPR's practiced expertise in locating and enrolling qualified subjects.

Low Libido					
Condition	Enrollment Period	Enrollment Goal	Number Screened	Total Enrollment	% of Goal Met
HSDD	9 months	15	22	18	120%
FSD	2 months	10	27	18	180%
FSD	7 months	10	26	14	140%
Low Libido	2 months	8	31	13	163%
HSDD	5 months	8	11	11	138%

Birth Control					
Condition	Enrollment Period	Enrollment Goal	Number Screened	Total Enrollment	% of Goal Met
Birth Control	7 months	10	23	19	190%
Birth Control	2.5 months	20	30	23	115%
Birth Control	4 months	8	31	22	275%

Osteoporosis					
Condition	Enrollment Period	Enrollment Goal	Number Screened	Total Enrollment	% of Goal Met
Osteoporosis	26 months	12	70	49	408%
Osteoporosis	5 months	12	71	25	208%
Osteoporosis	5 months	12	94	24	200%
Osteoporosis	8 months	10	32	19	190%
Osteoporosis	6 months	10	21	18	180%

## Comments From Our Customers

*"You and your staff did an excellent job with the study. Enrollment was rapid but I was pleased with the efforts and quality of work for your site. You can be sure that I will continue to call upon you for study placement."*

*-Pharmacia & Upjohn monitor*

*"This site continues to exceed the expectations of the monitoring and sponsor requirements. Issues are resolved quickly, CRF's are completed accurately and recruitment has been one of the best in the study. (Your coordinator) continues to be a pleasure to work with."*

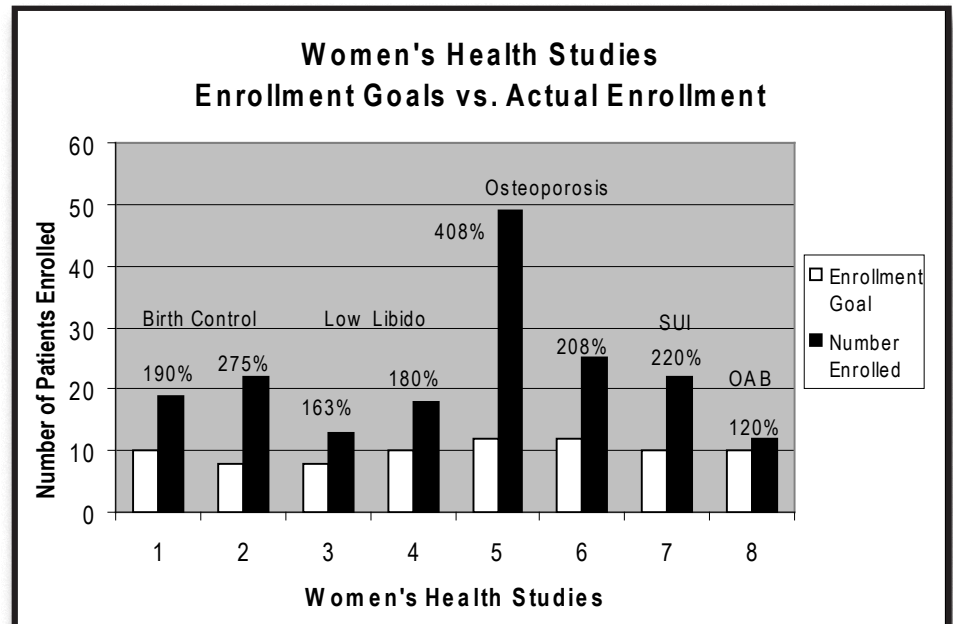
*-Astra Zeneca monitor*

*"When your site enrolled so many patients so quickly I was nervous. But, I was pleased to find very few queries and clean, consistently recorded data. I thought I would be monitoring at your site for days, but I was finished in only one day! I am so pleased with your site and the great job (your coordinator) and Sandra have done on enrolling patients and presenting clean data. Great job!"*

*-Merck monitor*

## Women's Health Study Enrollment

The Center for Pharmaceutical Research consistently over-enrolls on most studies we conduct. The following chart displays actual enrollment vs. enrollment goal for a variety of previous women's health clinical trials.



## Women's Health Expertise

Our staff includes several OB-GYN sub-investigators and a coordinator with over 31 years of women's health experience. The Center for Pharmaceutical Research routinely conducts the following tests and women's health assessment tools and tests, among others:

- PAP and Pelvic
- Colposcopy
- Endometrial Biopsy
- Ultrasound, pelvic and vaginal
- Female Sexual Distress Scale
- Female Sexual Functioning
- Sexual Interest & Desire Inventory
- Vasomotor symptom Questionnaire
- Beck's Depression Inventory
- Patient Global Impression
- Evaluation of Virilization
- Quality of Life Questionnaires

## Enrollment Strategies

Dr. Ervin accepts only studies for which he is confident enrollment goals will be met or exceeded. PharmAsyst, our subsidiary company specializing in clinical research volunteer recruitment, has found the following recruitment strategies to be effective in previous obesity clinical trials:

- Letter to private practice databases >20,000 patients
- Letter to independent research database of >17,000 subjects
- Sub-Investigator patient populations
- Radio advertisements
- Newspaper advertisements
- Community fliers and newsletters
- Patient referrals

Over 22,547 subjects in  
our databases are women