

SMOKING CESSATION 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 smoking cessation 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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CONTACT INFORMATION

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Previous Smoking Cessation Studies

The Center for Pharmaceutical Research has conducted 1 smoking cessation study with outstanding success. In the brief enrollment period we consented 26 subjects and randomized 17. When the sponsor closed enrollment, many interested, qualified subjects were left waiting for our next smoking cessation trial. The following chart highlights our smoking cessation research experience and reflects CPR's practiced expertise in locating and enrolling qualified subjects.

	Number of Subject Responses	Sponsor's Enrollment Goal	Number of Subjects Screened	Number Actually Enrolled	% of Enrollment Goal
Smoking Cessation/ Obesity	167	10	26	17	170%

Missouri Smoking Statistics

Smoking continues to be a major health concern for the state of Missouri. Over the last several years Missouri's smoking rates have remained consistently above the national average of 20%. Statistics from the Missouri Department of Health and Senior Services show that smoking is the leading cause of premature death in the state of Missouri. Please see the statistics below for more detailed information regarding Missouri smokers.

- 2005 statistics show that **23.4% of Missourians smoke**, making Missouri the **eleventh highest smoking state** in the country.
 - 1,004,755 of Missouri adults smoke
 - 68,656 high school students in Missouri smoke.
 - 19,294 middle school students in Missouri smoke
- **24.6% of Kansas City residents smoke (418,200 people)**
- Nearly 50% of these smokers have tried to quit smoking.
- Almost **10,000 Missouri residents die** of smoking-related illness each year.
- Missourians spend \$1.96 billion each year to treat smoking related illnesses.
 - Of this \$1.96 billion, \$490 million is paid by state Medicaid.
- Between 1998 & 2005, Missouri tobacco revenues totaled \$1.83 billion
 - \$952 million was from Master Settlement Agreements
 - \$880 million was generated from Tax Revenues

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."

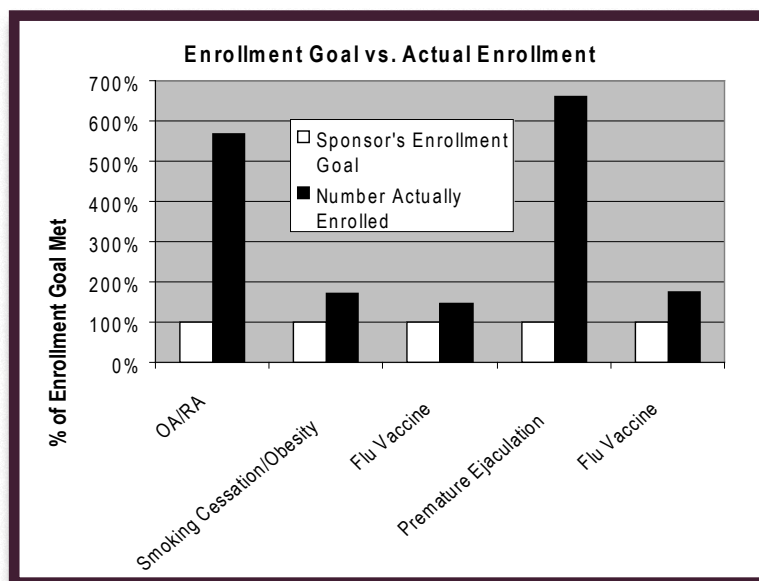
-Astra Zeneca monitor

"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

Previous 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 previous clinical trials.



Specialized Staff Members

- 3 board-certified pulmonologist sub-investigators
- 5 board-certified psychiatrist sub-investigators
- 1 psychiatrist sub-I board-certified in **Addiction Medicine**
- Several certified Tobacco Dependency and Cessation counselors
- 4 registered dieticians
- 17 Clinical Research Coordinators
- 11 Coordinator Assistants
- 4-member business staff that facilitates timely completion of budget and contract

Enrollment Strategies

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

- Offer a generous patient stipend
- Letter to databases of >32,000 subjects
- Newspaper advertisements
- Community fliers and news letters
- Fliers and posters in sub-investigators's offices and hospital
- Sub-Investigator patient populations

Over 11,872 subjects in our databases currently smoke