

VACCINE 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 vaccine 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 Vaccine Studies

The Center for Pharmaceutical Research (CPR) has conducted **32 vaccine studies** including 15 flu, 2 swine flu, 3 avian flu, 2 herpes zoster, 3 pneumonia, 2 DTP, 1 botulism/bio-terrorism, 2 hepatitis B, 1 pediatric flu, and 1 pediatric meningitis. Our site is a consistent top-enroller, usually randomizing 60-80 volunteers per day and completing enrollment in less than 3 days. CPR averages 107 randomized subjects per vaccine study, and has enrolled as many as 313 in a single study.

Since 2005, CPR has enrolled over 2,938 total volunteers in vaccine clinical trials. For most studies, all patients are recruited from our patient database with **no advertising**. Please see enrollment statistics from previous studies below.

| Indication | Enrollment Goal | Actual Enrollment | Enrollment Length | % of Enrollment Goal Met |
|-----------------------|-----------------|-------------------|-------------------|--------------------------|
| Avian Flu Vaccine* | 63 | 81 | 3 days | 129% |
| Avian Flu Vaccine | 70 | 70 | 1 month | 100% |
| Botulism Vaccine | 70 | 92 | 5 months | 131% |
| Pediatric Flu Vaccine | 20 | 41 | 6 weeks | 205% |
| Flu Vaccine | 90 | 153 | 5 weeks | 170% |
| Flu Vaccine | 75 | 128 | 9 days | 171% |
| Flu Vaccine * | 200 | 291 | 3 months | 146% |
| Flu Vaccine | 48 | 89 | 1 week | 185% |
| Flu Vaccine | 75 | 130 | 3 days | 173% |
| Flu Vaccine | 80 | 80 | 1 day | 100% |
| Flu Vaccine | 100 | 139 | 1 month | 139% |
| Flu Vaccine | 121 | 151 | 2 weeks | 125% |
| Flu Vaccine | none | 38 | 1 week | 100% |
| Flu Vaccine | 144 | 163 | 2 weeks | 113% |
| Pneumonia Vaccine | 40 | 61 | 3 weeks | 153% |
| Pneumonia Vaccine | 48 | 53 | 14 weeks | 110% |
| Shingles Vaccine | 240 | 314 | 8 months | 131% |
| Shingles Vaccine* | 27 | 83 | 3 weeks | 178% |

*Top enrolling site for the entire study

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 from 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."

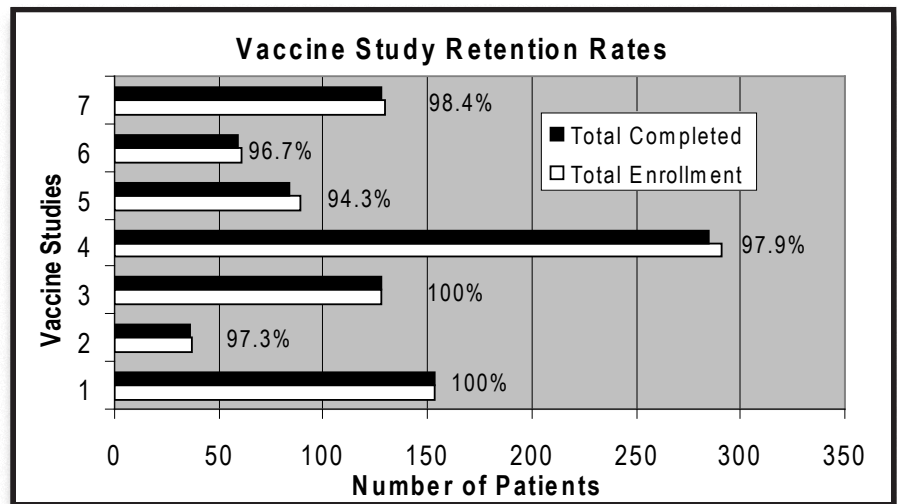
-Astra Zeneca monitor

"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 her assistant have done on enrolling patients and presenting clean data. Great job!"

-Merck monitor

Vaccine Study Retention Rates

The relationships Dr. Ervin and our staff members build with our subjects boost patient retention and encourage subjects to refer their friends and families for future trials. As displayed in the chart below, our vaccine study retention rates are consistently high and average 98.4%.



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 previous vaccine clinical trials:

- Offer a generous patient stipend.
- Database mailing to practice databases of >20,000 adult patients
- Database mailing to 14,000 pediatric/adolescent patients
- Database mailing to independent research database of >17,000
- Email campaigns
- Fliers and posters in medical building lobby
- Hospital newsletter
- Hospital volunteer flier (to target elderly adult population)
- Online ads
- Word-of-mouth

Our Staff and Expertise

Our office is located on the St. Joseph Medical Center campus, in Kansas City, MO. Our experienced staff includes:

- 4 Sub-Investigators
- 17 Study Coordinators
- 11 Data-Entry Assistants
- 4 Enrollment Coordinators
- 2 Regulatory Coordinators

