

## MARY UNRUH, MSN, R.N.

---

### PROFESSIONAL EXPERIENCE

March 2008 – present

**SNBL Clinical Pharmacology Center, Inc., Maryland**

Associate Director of Operations

February 2005 – December 2007

**National Hospitals**

Consultant, Study Implementer/Manager

November 1989 – February 2005

**Wyeth Research Clinical Pharmacology Unit**

Director of Operations (1999-2005)

Associate Director (1995-1999)

Assistant Director (1991-1995)

Clinical Research Manager of CPU (1989-1991)

### EDUCATION & TRAINING

1985-1989

**Post master credits in Health Education**, University of Maryland

1979

**Master of Science in Nursing**, University of Pennsylvania

1976

**Bachelor of Science in Nursing**, Widener University

### PROFESSIONAL LICENSURE

- Licensed Registered Nurse - Maryland
- Licensed Registered Nurse – Pennsylvania

### PROFESSIONAL AFFILIATIONS & MEMBERSHIPS

- Pennsylvania and Maryland Nurses Associations
- Association of Clinical Pharmacology Units (ACPU). Co-founder 1990, President 2000

## RESEARCH EXPERIENCE

### 2009

- A Phase I Double-Blind, placebo-controlled, single-center dose escalation study to evaluate the safety and tolerability and pharmacokinetics of intramuscular administration of a new oxime
- A Phase I, Double-blind Crossover Study of the Acute Tolerability of Immediate Extended Administration of Methotrexate in Normal Healthy Volunteers.
- A Longitudinal Study in healthy Adult Volunteers Aged 18 to 85 Years to Describe Antibody Levels to Antigens Expressed by *Staphylococcus aureus* and  $\beta$ -Hemolytic *Streptococci* Species, and to Describe Carriage of These Bacteria
- A Phase 2a Randomized, Double Blind, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of a Trivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine (recombinant) in Healthy Adults

### 2008

- An open label, single dose, randomized, active controlled, two-period, two-sequence crossover pharmacokinetics study to assess the bioequivalence of the XXXX, a XXXX transdermal formulation versus Emsam 12mg/ day after a single dose in healthy volunteers.
- A phase I open label placebo controlled multiple dose study to evaluate the pharmacokinetics of XXXX for injection dosed twice and three times daily in healthy subjects.
- A Randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- A Phase I, Open Label, PET Study in Healthy Subjects Following a Single Oral Dose of XXXX
- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Schizophrenia.
- A placebo-controlled, ascending multiple-dose study to evaluate the safety and pharmacokinetics of XXXX in healthy subjects.
- An Open-Label Formulation Screening Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of a Single Dose and Multiple Doses of Delayed Release XXXX in Healthy Subjects.
- A randomized, open-label study to assess the effect of ketoconazole on XXXX pharmacokinetics and pharmacodynamics.
- A Randomized, Double-Blind, Sequential, Ascending Multiple Dose, Placebo Controlled, Parallel Group Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXXX in Healthy Young Male Subjects.
- A Randomized, Double-Blind, Placebo Controlled Vaccination-Challenge Study of XXXX to Determine Efficacy Against the Symptoms of Moderate to Severe *Campylobacter jejuni* Infection in Normal Healthy Volunteers.
- Single dose pharmacokinetics and safety/tolerability of two formulations of XXXX transdermal systems compared to oral XXXX in healthy volunteers
- An open-label study to assess the effect of XXXX inducers on XXXX pharmacokinetics and pharmacodynamics
- Additional cohort - A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A Three Part Study In Healthy Males and Females Assessing the Relative Bioavailability and Food Effect of Two Formulations of XXXX, the Estimated Bioavailability of XXXX, The Single and Repeat Dose Safety, Tolerability and Pharmacokinetics of Escalating Dose

- A randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- An open-label Phase I multiple dose trial to assess the safety, tolerability and efficacy of capsules containing cross-linked polyelectrolyte giving to ESRD patient.
- A 2-Period, 2-Panel, Double-Blind, Randomized, Placebo-Controlled Pilot Study of Experimental Models for the Assessment of the Perception of Potentially Injurious Heat in Household Settings After the Administration of XXXX in Healthy Subjects
- A Double-Blind, Randomized, Placebo-Controlled, 5-Arm Titration Study to Evaluate the Efficacy and Safety of XXXX When Compared With Valsartan and Olmesartan in Subjects with Essential Hypertension
- A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A multiple-center, single-ascending dose, randomized, observer-blinded, placebo-controlled, study to investigate the safety, tolerability, and pharmacokinetics of XXXX following intravenous administration in individuals with allergic rhinitis.
- A Phase II Dose Finding Study with XXXX in Subjects with Recurrent Episodes of Genital Herpes
- An open label, randomized assessment of the relative bioavailability of a single dose of XXXX administered as a 15mg tablet, one 5 mg tablet or five 1 mg tablets compared with the 15 mg capsule and the effect of a high fat meal on the bioavailability of
- An open-label, dose escalating study to evaluate the safety of intravaginal oxybutynin in subjects with urge urinary incontinence

## 1985-2005

Over 200 trials in the following therapeutic areas:

- Psychiatric (Schizophrenia, Anxiety and Depression)
- Central Nervous System
- GI (Gerd)
- Anti-Inflammatory (Rheumatoid Arthritis)
- Immunology (Organ Transplant Rejection, Hepatitis, Various Vaccines)
- Pulmonary (Asthma)
- Pain Control Studies