

**CNS Research, Inc.**  
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## **Patricia J. Epple, RN, BS, CCRC, Sr. CRA**

### **CNS Research, Inc.**

1997 – Present

#### **Research Director & President** – Providence, RI

I founded CNS Research, Inc. in 1997 as a multi-site PPPN, (Private Practice Physician's Network). Today my responsibilities include acquisition of new clinical trials, budget negotiations, promotion and supervision of ongoing projects. CNS Research provides clinical research services to six investigators at the following three locations:

450 Veterans' Memorial Parkway #11, East Providence, RI 02914  
360 Kingstown Rd Unit 102, Narragansett RI 02882  
814 Metacom Ave, Bristol, RI 02809

### **MHICC**

2009 - Present

#### **Montreal Heart Institute - Coordinating Center**

**Independent Contract Sr. CRA** on assignment for the Hoffmann La-Roche ALECARDIO Study on behalf of the Montreal Heart Institute. Responsible for site recruitment, training and monitoring of sites in the Northeast.

### **INC Research, Inc.**

1996 - 1998

#### **ROM (Regional Operations Manager), Senior CRA** – Providence, RI

- Developed a regional network of CNS research sites in the New England area.
- Monitored CRC's for compliance with protocols, CRF's and queries.

### **Miriam Hospital**

1992 – 2009

#### **Site Manager Division of Neurology** – Providence, RI

- Responsibilities include acquisition of new clinical trials, budget negotiations.
- Coordinated over 20 Phase II & III studies in Alzheimer's and Stroke.
- Coordinator of the Stroke Team at the Miriam Hospital ER.

### **Allergy Center**

1980 - 1990

#### **Research Nurse** – Providence, RI

Responsible for conducting patient studies in immunology and allergy.

- Pfizer Pharmaceutical Company: Phase 3 study of Cetirizine, a non-sedating antihistamine.
- Sandoz Pharmaceutical Company: Phase 3 study of KETOTIFEN for the treatment of asthma.

### **Oceanside Publications**

1984 – 1990

#### **Managing Editor** - - Providence, RI

Managed two international medical publications: American Journal of Rhinology (circulation 7,500) and Allergy Proceedings

- 1972 – 1975                    **Staff Development Instructor** - *Rhode Island Hospital* – Providence, RI
- Responsible for teaching all levels of nursing personnel.
  - Developed Surgical Nursing Course and Respiratory Therapy Course.
- 1969 – 1972                    **Assistant Medical-Surgical Nursing Instructor** - *St. Lukes Hospital School of Nursing* – New Bedford, MA
- Developed and taught courses in fundamentals of nursing.
- 1967 – 1969                    **Staff Nurse** - *New England Deaconess Hospital* – Boston, MA
- Medical-surgical unit and float assignments.

**ACADEMIC DEGREES & CERTIFICATIONS:**

Bachelor of Science in Nursing and Health Science, Northeastern University – Boston, MA, 1969

Associate of Science Degree in Nursing, Northeastern University – Boston, MA, 1967 Dean’s List

Certification, Clinical Research Coordinator (CCRC), ACRP- Washington, D.C., 1997

**PRESENTATIONS & PUBLICATIONS:**

Institutes of International Research, National Forum, Investigator Sites, Insites ’98, January 1998  
 “Examining the Benefits of Centralized Clinical Trial Support Services at Academic Medical Centers”

**Alzheimer’s Disease Clinical Trials Experience**

Protocol AVA102675- REFLECT 4

An open label extension study of the long term safety and efficacy of rosiglitazone extended release tablets as adjunctive therapy to acetylcholinesterase inhibitors in subjects with mild to moderate AD.

Protocol AVA102670

A 54 week, double-blind, randomized, placebo-controlled, parallel-group study to investigate the effects of rosiglitazone (extended release tablets) as adjunctive therapy to acetylcholinesterase inhibitors on cognition and overall clinical response in APOE e4-stratified subjects with mild to moderate Alzheimer’s Disease.

E2020-G000-326

Double-Blind, Parallel-Group Comparison of 23 mg Donepezil Sustained Release to 10 mg Donepezil Immediate Release in Patients with Moderate to Severe Alzheimer’s Disease.

CL – 758007 Phase III Study of the Efficacy and Safety of Alzhemed in Patients with Mild to Moderate Alzheimer’s Disease.

#### ONO-2506

A Double-blind, Phase II, safety and efficacy evaluation of ONO-2506 in patients with mild to moderate Alzheimer's Disease

#### Exelon (rivastigmine)

A Prospective, 26-Week, Open-label, Single-arm, Multicenter Study Evaluating the Efficacy and Safety of Exelon (rivastigmine tartrate) in Patients with Mild to Moderate Alzheimer's Disease Who Are Responding Poorly to Aricept (donepezil) Treatment

#### GAL-INT-26

Johnson & Johnson PRD, GAL-INT-26, A randomized, double-blind, placebo-controlled trial to evaluate the safety & efficacy of galantamine in the treatment of dementia secondary to cerebrovascular disease.

#### GAL-USA-10

Janssen Research Foundation: GAL-USA-10, A double-blind, placebo-controlled multicenter study of safety and efficacy in Alzheimer's disease.

#### METRIFONATE

BAYER Corporation: A 26 week multicenter, open label comparison of METRIFONATE to standard therapy in patients with Alzheimer's disease.

#### MILAMELINE

PARKE-DAVIS: A 26 week, randomized, double-blind, parallel -group, placebo-controlled, multicenter study of MILAMELINE in patients with Alzheimer's disease.

#### SELEGILINE

SOMERSET PHARMACEUTICALS: A 12 month, double-blind, placebo-controlled, investigation of the safety and efficacy of SELEGILINE Transdermal System in patients with dementias of the Alzheimer's type.

#### MENTANE

HOECHST PHARMACEUTICALS: A double-blind, multicenter comparison of MENTANE and placebo in outpatients with Alzheimer's disease.

## Stroke Clinical Trials Experience

A phase III, randomized, multi-center, open label, 900 subject clinical trial that will examine whether a combined intravenous (IV) and intra-arterial (IA) approach to recanalization is superior to standard IV rt-PA (Activase) alone when initiated within three hours of acute ischemic stroke onset – IMS III – Interventional Management of Stroke

A Randomized, Double-Blind, Placebo-Controlled Study of Viprinex™ (Ancrod Injection) in Subjects Beginning Treatment within 6 Hours of the Onset of Acute, Ischemic Stroke Protocol No.: NTI-ASP-0502

A randomized, double-blind, placebo-controlled, multi-center study of the effects of ONO-2506 intravenous infusion on the amelioration of the neurological damage and improvement of stroke assessment scale scores in patients with acute ischemic stroke

A multicenter, stratified, randomized, double-blind, placebo-controlled study to evaluate neurologic function and disability in patients with acute ischemic stroke given tissue plasminogen activator plus YM872 or tissue plasminogen activator plus placebo.

BRISTOL-MYERS SQUIBB: A double-blind, placebo-controlled, multicenter study of safety, efficacy and dose response in acute stroke.

Blockade of the GP IIB/IIIA Receptor to Avoid Vascular Occlusion (BRAVO). A Double-Blind, Placebo- Controlled, Parallel-Group, Dose-Response Study to Evaluate Efficacy and Safety

PARK-DAVIS: A double blind, placebo-controlled, parallel-group, 3 day treatment and 3 month follow-up, multicenter study of intravenous FOSPHENYTOIN in patients with acute ischemic stroke.

## MS Clinical Trials Experience

109MS301: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis

TEVA/LEMMON Company: Long-term, open label study to evaluate the safety of COPOLYMER 1 in patients with relapsing-remitting Multiple Sclerosis.

BiogenIdec: 109MS303: A Dose-Blind, Multicenter, Extension Study to Determine the Long-Term Safety and Efficacy of Two Doses of BG00012 Monotherapy in Subjects with Relapsing-Remitting Multiple Sclerosis.

Novartis Pharmaceuticals Protocol No.: CFTY720DUS01

A 6-month, Randomized, Active Comparator, Open-label, Multi- Center Study to Evaluate Patient Outcomes, Safety and Tolerability of Fingolimod 0.5 mg/day in Patients with Relapsing Forms of Multiple Sclerosis who are candidates for MS therapy change from Previous Disease Modifying Therapy (EPOC)

## Migraine Clinical Trials Experience

AMDC-104-202: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Single-Dose Efficacy and Safety Study of Staccato® Loxapine for Inhalation in Outpatients with Migraine Headache.

Phase III, "A Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate in the Prophylaxis of Migraine

Premere™ PFO Closure System for the Effect of Septal Closure of Atrial PFO on Events of Migraine with Remere (ESCAPE Migraine) Trial.

## Neuropathy Clinical Trials Experience

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Trial of Fidarestat (SNK-860) in Patients with Diabetic Polyneuropathy.

MEM-MD-006" Evaluation of the Safety and Efficacy of Memantine in the Treatment of Chronic Pain in Patients with Diabetic Neuropathy

A Double-Blind, Placebo-Controlled Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of Compound versus Placebo in the Relief of Pain in Diabetic Peripheral Polyneuropathy."

A Randomized, Double Blind, Parallel Group Study of the Safety and Efficacy of Latranal Compared to Doxepin Cream and Placebo in Patients with Chronic Low Back Pain.

## Epilepsy Clinical Trials Experience

A Randomized, Double-Blind, Parallel Group, Monotherapy Study to Compare the Safety and Efficacy of Two Doses of Topiramate in the Treatment of Newly Diagnosed or Recurrent Epilepsy

Elan Pharmaceutical: A Double-Blind, Randomized, Multicenter, Parallel Group Study to Establish Dose-Response, Safety and Efficacy of Zonisamide (Zonegran™) as Monotherapy in Patients With Newly Diagnosed Epilepsy.