

## THIEVON-WRIGHT CONSULTING GROUP

12 New Providence Road  
Watchung, NJ 07069

**Office:** 908.756.4411

**Fax:** 908.756.1122

www.cnssites.com

info@cnssites.com

FOLLOW US ON  

# CLINICAL PHARMACOLOGY OF MIAMI

Miami, Florida



## INVESTIGATORS

Kenneth C. Lasseter, M.D.

Samuel Obertstein, M.D.

Antoinette Sulpizi, M.D.

## CLINIC LEADS

Pablo Suso, Pharm.D., R.Ph.

Barbara Valero, A.R.N.P

Stacy C. Dilzer, R.N., B.S.N.

## PHASE 1 CAPABILITIES

First in Human

SAD/MAD

PK/PD

BA/BE

DDI

Food Effect

First to File

**Kenneth C. Lasseter, M.D.**, is the Vice President and Medical Director of Clinical Pharmacology of Miami. Dr. Lasseter is a clinical pharmacologist certified by the American Board of Clinical Pharmacology and is board eligible in Cardiology and Internal Medicine. Over the past 40 years, he has served as Principal Investigator on over 1,900 clinical trials and has contributed to more than 60 successful NDAs. Dr. Lasseter has published over 300 articles and abstracts in the area of clinical pharmacology and continues to be active in studies pertaining to the development of safe and effective new drugs.

**Samuel Oberstein, M.D.**, is the Assistant Medical Director/Investigator at Clinical Pharmacology of Miami. Dr. Oberstein has worked in clinical research for over 20 years and has served as the Principal Investigator on over 130 clinical trials. He is board certified in Obstetrics and Gynecology.

**Antoinette M. Sulpizi, M.D.**, is one of the Investigators at Clinical Pharmacology of Miami. Dr. Sulpizi is board certified in Internal Medicine and Cardiology in Pennsylvania and Florida. She recently joined the clinical team at Clinical Pharmacology of Miami, and has contributed to over 30 studies during her tenure in research. Dr. Sulpizi has published and presented 15 articles and abstracts in the area of cardiology.

**Stacy C. Dilzer, R.N., B.S.N.**, serves as President of Clinical Pharmacology of Miami. Ms. Dilzer is the Clinic Director and lead Project Manager. During the past 25 years, her positions have included Study Coordinator, Project Manager, Director of Clinical Operations, Chief Compliance Officer and Vice President of Clinical Operations. Her experience and expertise include the overall management and supervision of all Phase I-IV clinical trials. Ms. Dilzer leads and manages all aspects of the day-to-day operation of Clinical Pharmacology of Miami.

## **STUDY EXPERIENCE.....1,900**

First in Human  
SAD/MAD  
PK/PD  
BA/BE  
DDI  
Food Effect  
First to File  
Renal Impairment  
Hepatic Impairment  
Diabetes Type 2  
Geriatric  
Healthy Volunteer  
Post-Menopausal  
QTc  
Smoking

## **PATIENT DATABASE.....7,000**

Diabetes - Type 2  
Geriatric  
Healthy Geriatric  
Healthy Volunteers  
Hepatic Impaired  
Hypertensive  
Low Testosterone  
Obese  
Renal Impaired  
Post-Menopausal  
Smokers

## **STAFFING**

### **Total Number of Staff.....40**

Principal/Sub-Investigators  
RNs/Nurse Practitioners  
CRCs  
Pharmacists  
Recruitment Staff

# CLINICAL PHARMACOLOGY OF MIAMI

Clinical Pharmacology of Miami is a proven and trusted resource for the conduct of complex early phase trials. The company's founders, Kenneth Lasseter, M.D., Stacy Dilzer, R.N., B.S.N., and Cooper Shamblen, Vice President of Clinical Operations, have over 100 years of combined experience managing these clinical studies. The clinical staff is composed of a combination of bi-lingual medical graduates, R.N.s and experienced technicians and phlebotomists.

## **FACILITY**

Clinical Pharmacology of Miami is a 24,000-square-foot, state-of-the-art inpatient and outpatient, custom-designed clinical pharmacology research unit. It offers 120 clinical research beds with six private rooms. Patients' recreational space consists of two indoor areas and a controlled and secured outdoor patio. Study subjects enter the facility into a large screening area with interview and exam rooms and a prescreening lab. Separation between volunteer inpatient and outpatient areas is secured with locked doors accessible only by staff members with swipe cards/push-button security codes.

Clinical Pharmacology of Miami maintains a secure alarm-monitored pharmacy department and double-locked drug storage room that is equipped with a validated environmental monitoring system to ensure the quality and integrity of the pharmacy room temperatures. Also included is a large secure PK processing lab with -20 and -70 degree sample storage and electric monitoring and recording. For QTc studies, there are ECG monitored research areas equipped with individual telemetry units.

Security cameras are strategically placed throughout the research facility, both inside and outside to monitor and record all activity 24 hours a day, seven days a week. Entry and exit doors including fire exits, are alarmed with audible outage. A 40-watt natural gas generator automatically provides power to all essential areas and equipment within the facility.

The Miami International Airport is located 20 minutes away from the unit and the Fort Lauderdale/Hollywood International Airport is 30 minutes away.