

EVOLUTION RESEARCH GROUP

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CLINICAL PHARMACOLOGY OF MIAMI

Miami, Florida



STUDY EXPERIENCE

Total 1,800

First in Human

SAD/MAD

PK/PD

BA/BE

DDI

Food Effect

First to File

Cardiac Safety/TQT/QTc

Renal Impairment

- Chronic Kidney Disease

Hepatic Impairment

- CFLD
- NASH

Monoclonal Antibodies (MaB)

Sexual Dysfunction

Drug Delivery Administration

- Oral
- Inhalation
- IV
- Depot
- SQ
- Transdermal

AUDIT SUCCESS

10+ Sponsor Audits Annually

3 FDA Audits:

- March 2017
- January 2015
- October 2014

Clinical Pharmacology of Miami (CPMI), a subsidiary of Evolution Research Group, is a proven and trusted resource for providing its clients with unique capabilities, executing on complex trials in normal healthy volunteers and highly specialized populations. 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. CPMI's mission is to perform safe, precise and scientifically valid clinical research studies, applying years of experience, education, skills and integrity.

FACILITY HIGHLIGHTS

- 24,000-square-foot, state-of-the-art inpatient and outpatient, custom-designed clinical pharmacology research unit
- 120 clinical research beds with six private rooms
- Two indoor recreational areas and secured outdoor patio
- Large screening area with interview and exam rooms and a prescreening lab
- Large, secure PK processing lab with -20 and -70 degree sample storage and electronic monitoring and recording
- Telemetry/Holter monitoring
- Double-locked, climate controlled pharmacy with laminar flow hood
- Validated environmental monitoring system for drug and sample storage
- Secured, monitored and alarmed unit with key-card and push-button access for designated staff
- 40-watt natural gas generator
- Smoking room
- Negative pressure room
- Located within 30 minutes of two major international airports
- Close proximity to local imaging facilities and sleep lab
- Located in the heart of a vibrant, diverse community, providing access to 7 million individuals in the Greater Miami Area
- Experienced, long-term staff includes bilingual medical graduates, registered nurses, technicians and phlebotomists
- Located 3.5 miles (about 5 minutes) from an emergency room



An Evolution Research
Group Portfolio Company

SPECIALTY PROCEDURES AND EQUIPMENT

CSf/cCSf
Smoking Room
Surgical Procedures
Negative Pressure Room
Crash Cart
Holter Monitoring/Telemetry
Laminar Flow Hood
Pulse Oximetry
Pulmonary Function Testing
Ultrasound

OFF SITE

MRI/fMRI
PET
X-ray
CT Scan
DaT Scan
Polysomnography
EEG/qEEG

SUBJECT AND PATIENT DATABASE.....9,800

Diabetes
Geriatric
Healthy Volunteers
Hepatic Impaired

- CFLD
- NASH

Hypertensive
Low Testosterone
Obese
Renal Impaired

- Chronic Kidney Disease

Post-Menopausal
Smokers

STAFFING

Total Number of Staff.....40

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

MEET CPMI

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 1,800 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.

E. Cooper Shamblen is the Vice President of Clinical Operations. His research career started as an Adjunct Assistant Professor at the University of Miami School of Medicine, Department of Pharmacology. In 1977, he and Dr. Kenneth C. Lasseter founded Clinical Pharmacology Associates. With 36-plus years of experience in partnership with Dr. Lasseter, he has been involved in all aspects required to successfully perform over 1,800 clinical research studies. Mr. Shamblen is readily available to discuss issues with sponsors, staff and volunteers alike. His reputation and experience in the pharmaceutical industry will make your choice to engage the services of CPMI a pleasure, as well as a success.

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.