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CLINICAL PHARMACOLOGY OF MIAMI, LLC



Kenneth C. Lasseter, M.D.
Stacy C. Dilzer, R.N., B.S.N.

Clinical Pharmacology of Miami, LLC

Miami, Florida

PHASE 1
FIRST IN HUMAN
SAD/MAD
PK/PD
BA/BE
DDI
FOOD EFFECT
FIRST TO FILE
THOROUGH QT/QTc

RENAL IMPAIRMENT
HEPATIC IMPAIRMENT
NORMAL HEALTHY
VOLUNTEERS
HEALTHY GERIATRIC
POST MENOPAUSAL
HYPERTENSIVE
OBESITY
TYPE 2 DIABETES
SLEEP APNEA
SMOKERS



INVESTIGATORS

Kenneth C. Lasseter, M.D., is the Vice President and Medical Director of Clinical Pharmacology of Miami, LLC. 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 38 years, he has served as Principal Investigator on over 1,800 clinical trials and has contributed to approximately 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 development of safe and effective new drugs.

Dr. Lasseter began his research career while at the University of Miami, School of Medicine. He has served as an Assistant and Associate Professor of Pharmacology and Medicine at the University of Miami, School of Medicine, and as an Adjunct Professor of Pharmacology at the University of Miami Miller School of Medicine. He is a frequent lecturer for post-graduate courses and medical programs. Dr. Lasseter earned his doctorate degree from the University College of Medicine in Gainesville, Florida. He completed his residency at University of Kentucky in Lexington, Kentucky and a postdoctoral fellowship in Clinical Pharmacology and Cardiology at the University of Miami School of Medicine, Miami, Florida.

Stacy C. Dilzer, R.N., B.S.N., serves as President of Clinical Pharmacology of Miami, LLC. Ms. Dilzer is the Clinic Director and lead Project Manager, personally supervising each clinical study. During the last 25 years, her positions have included Study Coordinator, Project Manager and Director of Clinical Operations, Chief Compliance Officer and Vice President of Clinical Operations. She has been the primary contact for the Food and Drug Administration audit teams and for pharmaceutical sponsor audit over the past 15 years, hosting numerous successful audits. Her experience and expertise includes the overall management and supervision of all phase I-IV clinical trials including bio availability and pharmacokinetic studies in special populations and in normal subjects. Ms. Dilzer leads and manages all aspects of the day-to-day operation of Clinical Pharmacology of Miami, LLC. She is readily available to converse with sponsors, staff and volunteers alike.

STAFFING

Total Number of Staff	40
Sub-Investigators.....	5
RNs/Nurse Practitioners.....	6
CRCs.....	8
Pharmacists.....	1
Recruitment Staff.....	3

PATIENT DATABASE

Total Number of Subjects	5,000
Renal.....	40
Hepatic.....	45
NHV.....	3,850
Diabetic Type 2.....	500
Healthy Geriatric.....	170
Post Menopausal.....	120
Hypertensive.....	80
Obese.....	65
Hypo gonadal.....	70
Hepatitis C.....	60

STUDY EXPERIENCE

Total	1,853
Renal (last three years).....	35
Hepatic (last three years).....	48
DDI.....	42
Diabetic.....	28
SAD/MAD (last three years).....	16
BA/BE (last three years).....	22
QTc.....	24
Inhalation.....	12
Anticoagulant and Subcutaneous.....	26

CLINICAL PHARMACOLOGY OF MIAMI, LLC

Clinical Pharmacology of Miami, LLC is a proven and trusted resource for the conduct of complex early phase trials in subjects with renal insufficiency, hepatic impairment, type 2 diabetes, obesity and hypertension among others. The company's founders, Kenneth Lasseter, M.D., Stacy Dilzer, R.N., B.S.N., and Cooper Shamblem, Vice President of Clinical Operations, have over 90 years of combined experience managing first-in-man, drug-drug interaction, TQT, food effect, PK/PD, SAD/MAD, BA/BE and first-to-file studies in healthy adults and elderly subjects. The clinical staff is made up of a combination of foreign medical graduates, RNs, experienced technicians and phlebotomists.

FACILITY

Clinical Pharmacology of Miami, LLC 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 and two spacious recreational areas. 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 strictly secured with locked doors accessible only by staff members with swipe-cards/push-button security codes.

Clinical Pharmacology of Miami, LLC maintains a secure, alarm monitored pharmacy department and double-locked drug storage room, equipped with a validated environmental monitoring system to ensure the quality and integrity of all pharmacy room temperatures; a large, secure PK processing lab with minus-20 and minus-70 degree sample storage, and electronic monitoring and recording; and QTc clinical trial 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 sirens at all times to secure controlled access to and from Clinical Pharmacology of Miami, LLC. In the event of a power outage, a 40-watt natural gas generator automatically provides power to all essential area and equipment within the facility.

Clinical Pharmacology of Miami, LLC is conveniently located to both Miami International Airport (20 minutes) and Ft. Lauderdale/Hollywood International Airport (30 minutes).