

CLINICAL PHARMACOLOGY UNIT

AN INTEGRATED APPROACH TO EARLY PHASE DRUG DEVELOPMENT

The Medpace Clinical Pharmacology Unit (CPU) is dedicated to the conduct of early-phase clinical pharmacology studies in healthy volunteers, special populations, and patient populations over a spectrum of diseases. Medpace CPU is a fully owned subsidiary of Medpace, Inc.

SHARED CAMPUS OFFERS EFFICIENT, INTEGRATED RESEARCH

A new state-of-the-art facility opened in July 2012 on the Medpace clinical research campus in Cincinnati, OH. In addition to the CRO and the CPU, it houses these core subsidiaries:

- Core ECG laboratory (an official Mortara partner)
- Medpace Central Laboratories
- Medpace Bioanalytical Laboratories
- Medpace Imaging Core Lab
- Medpace Medical Device

The ability to tap a full host of industry experts and experienced project teams supports a full-service model for clinical development. The synergy gained from working within Medpace's campus environment brings heightened efficiencies and standardization.

SCIENTIFICALLY-DRIVEN CLINICAL DEVELOPMENT FOR EARLY PHASE

Medpace CPU is fully integrated with Medpace CRO, a clear advantage for Sponsors. From consultation on protocol designs to developing innovative processes for complex studies, Medpace noted medical doctors provide key support for studies. Medpace has long been regarded as a leader in metabolic and endocrinology, cardiovascular, infectious disease, nephrology, neuroscience, gastrointestinal, and women's health. Therapeutically aligned teams work as innovative partners to deliver projects according to each Sponsors specifications.



STATE-OF-THE-ART FACILITY

The Medpace CPU is easily accessible for patient volunteers and multiple major hospitals are within close vicinity. It offers excellence in research capabilities and provides high-end amenities to volunteers.

SITE FEATURES

- 40,000-square-foot in-patient and out-patient facility
- Dormitory style unit with 24 beds in total
- Two semi-private units with 36 beds in total
- Centralized laboratory processing
- Licensed Investigational Drug Service/Pharmacy
- Centralized food service
- Secure, monitored and alarmed 24 hours a day, 7 days a week

BREADTH OF CAPABILITIES

- Dose escalation
- Single / multiple dose studies
- First-in-human (FIH)
- Bioavailability / Bioequivalence
- Drug-Drug interaction
- Food effect
- Phase IIa / Proof of concept
- Thorough QT/QTc
- Device

VOLUNTEER AMENITIES

- Internet access for personal laptops
- Desktop computers
- Private TVs for each bed
- Recreation rooms outfitted with widescreen televisions, board games, and other activities
- Personal DVD players and library of DVDs
- Video games – Xbox 360
- Tree-lined outdoor courtyard
- Quiet areas
- Catered meals
- Abundant free parking
- Public transportation with convenient dropoff/pickup in front of campus

FACILITY EQUIPMENT

- Mortara Surveyor Telemetry Central System with 32 Telemetry channels
- Mortara 12-lead ECG machines
- Welch Allyn Spot Vital Sign machines
- Fully-stocked emergency crash carts with Zoll M Series defibrillator and external pacing device
- Master clocks with synchronization to the official atomic time
- Generator back-up for continual power supply
- Laboratory processing and storage area with refrigerated centrifuges and -20°C/-70°C freezers

KEY LEADERSHIP AND STAFFING

Lukasz Biernat, MD, Medical Director

Dr. Biernat is a member of the CPU team, having practiced internal medicine in Concord, NH and as a clinical trial researcher at PharmaTrials, Inc. in NJ. He received his medical degree from the University of Silesia in Poland and is a member of the American Board of Internal Medicine.

Leela Vrishabhendra, MD Medical Director

Leela Vrishabhendra, MD, is a licensed internal medicine physician, currently serving as one of three PIs at the MCPU. Dr. Vrishabhendra received her medical degree from JSS Medical College in Mysore, India. She completed her internal medicine residency from Good Samaritan Hospital in Cincinnati in 2001. Prior to joining Medpace in June of 2014, Dr. Vrishabhendra was a practicing primary care physician in a large multi-specialty group in Cincinnati for 12 years.



Lukasz Biernat, MD
Medical Director



Leela Vrishabhendra, MD
Medical Director

PATIENT RECRUITMENT AND RETENTION

The CPU has a dedicated staff for both the recruitment and screening of study subjects. A volunteer database of active potential study subjects for multiple types of clinical trials is continuously developed and nurtured.

- Full-time recruiting and community affairs staff
 - Inbound-outbound call center (6 days/week)
 - Dedicated Physician Relationship Manager
 - Project-specific recruitment plans
 - Integrated mass media, traditional, non-traditional and social media campaigns
 - Community activities – Association relationships (E.g. ADA)
 - Substantial recruiting population
 - Metropolitan tri-state (Indiana, Ohio, Kentucky) population of ~2.1 million
 - Robust student population
- Additional regional populations:
- Dayton, OH (45 minutes)
 - Indianapolis IN, Columbus OH, Louisville and Lexington KY (2 hours)

DEMOGRAPHICS OF THE MEDPACE CPU VOLUNTEER DATABASE:

- Normal Healthy Volunteers
- Cardiovascular Disease
- Diabetes
- Hyperlipidemia
- Hypertension
- Obesity (BMI >30)
- Postmenopausal (natural or surgically sterile)
- Elderly (65+ years)
- Facial Topical
- Osteoarthritis and Rheumatoid Arthritis



FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

