

# CLINICAL PHARMACOLOGY UNIT

## AN INTEGRATED APPROACH TO EARLY PHASE DRUG DEVELOPMENT

The Medpace Clinical Pharmacology Unit (MCPU) is dedicated to the conduct of early-phase studies in healthy participants, 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

Located on our dedicated research campus in Cincinnati, Ohio—and fully embedded within Medpace’s global, full-service CRO model—the Medpace Phase I Unit is purpose-built to support today’s most demanding early phase studies. In addition to the CRO and the MCPU, the Medpace clinical research campus 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

The 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 Sponsor’s specifications.

### STATE-OF-THE-ART FACILITY

The Medpace CPU is easily accessible for study participants. It offers excellence in research capabilities and provides high-end amenities to participants.

### SITE FEATURES

- Four independent inpatient units, designed to accommodate a broad range of clinical pharmacology studies
- 85-bed capacity, including semi-private suites and patient-centric design to enhance retention and protocol continuity
- A dedicated, licensed Investigational Drug Services Pharmacy, equipped for complex investigational products
- On-campus access to central labs, imaging, biostatistics, and medical writing
- Physician oversight with 24/7 ACLS-certified staff and embedded early-phase specialists

## BREADTH OF CAPABILITIES

- First-in-Human (FIH)
- Single Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Dose Escalation, Multiple Cohort, and Adaptive Designs
- PK/PD
- Food Effect
- Drug-Drug Interaction
- Bioavailability/Bioequivalence
- Thorough QT/QTc
- Phase IIa and Proof-of-Concept
- Device and Diagnostics

## STUDY PARTICIPANT AMENITIES

- Free Wi-Fi
- Streaming-enabled widescreen TVs and gaming systems
- Desktop computers
- Recreation lounges and personal lockers
- Comfortable semi-private or dorm-style rooms
- Private phone rooms
- Outdoor courtyard
- Catered meals and snacks tailored to your study

## FACILITY EQUIPMENT

- Mortara Surveyor Telemetry System (32 channels)
- Spirometers
- FibroScan devices
- 12-lead ECG machines
- Automated vital signs machines
- Breathalyzers
- Glucometers
- Synchronized IP based master clocks
- Generator-backed power systems
- Large capacity refrigerated centrifuges
- 24/7 monitored refrigerators and freezers (-20°C & -80°C)

## KEY LEADERSHIP AND STAFFING



**Shabaz Khan, MD**  
*Sr. Director, MCPU*



**Leela Vrishabhendra, MD**  
*Sr. Medical Director*

### **Shabaz Khan, MD** *Sr. Director, MCPU*

Shabaz Khan, MD, is a board-certified emergency medicine physician with more than 22 years of industry experience and currently serves as Senior Director of the Medpace Clinical Pharmacology Unit (MCPU). Dr. Khan brings extensive expertise in the conduct and oversight of Phase 1-2 clinical trials, including BA/BE and PK/PD studies. In his role, he is responsible for MCPU operations across all aspects of study execution, including staffing, training, and regulatory inspections. Dr. Khan provides oversight for all studies conducted at the MCPU, from protocol finalization and study planning through enrollment, conduct, and completion.

### **Leela Vrishabhendra, MD** *Sr. 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.

## PATIENT RECRUITMENT AND RETENTION

The MCPU has a dedicated staff for both the recruitment and screening of study subjects. A participant 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 (Operates 6 days/week)
- Project-specific recruitment plans
  - Integrated mass media, traditional, nontraditional and social media campaigns
  - Community activities and association relationships (E.g. ADA)
- Substantial recruiting population
  - Metropolitan tri-state (Indiana, Ohio, Kentucky) population of ~2.2 million
  - Robust student population
- Additional regional populations
  - Dayton, OH (45 minutes)
  - Indianapolis IN, Columbus OH, Louisville KY and Lexington KY (2 hours)

## DEMOGRAPHICS OF THE MEDPACE CPU PARTICIPANT DATABASE

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



## 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.

