FAST TO PATIENT:

ALIGNED FOR ACCELERATED EARLY PHASE RESULTS

MEDPACE

Therapeutically specialized clinical development

FAST TO PATIENT STUDY DESIGN

Critical Components – Early Phase Programs

Fast to patient strategies have radically changed how studies are conducted. Innovative Early Phase strategies are key considerations when planning for a clinical proof of concept outcome. Precision medicine – encompassing novel study design, genomics and biomarker support, technology, and laboratory support systems - has come about as a result of genomics and the ability to design precise treatments to fight diseases. The cost of clinical development in later phases continues to rise, based on high failure rates and large populations necessary to test both efficacy and safety. Early phase studies are critical - making the "go-no go" decision for compounds based on efficacy critical in the early phases to avoid the potential for a costly failure. These innovative studies improve the likely hood of desired patient outcomes in the long term.

Testing compounds as quickly as possible in target patient populations allow better decision making in getting to a clinical-proof-of-concept.

The advent of genomics as a science has spurred new scientific discoveries. Developing a "Fast to Patient" study design requires integrated functions and processes. Key industry physicians and scientists can integrate many of these processes-including biomarker strategies, genomics, clinical pharmacology, central labs and bioanalytical analysis to spur faster development at the early stages, when the investment is smaller. Innovation in study design including SAD/MAD study design with early collection of safety information is allowing earlier recognition of drug efficacy.

These projects are the future of clinical development, allowing skilled researchers to bring personalized techniques to accelerate medical therapeutics.

Regulatory Guidance for end of Phase IIa meetings

Early phase strategies include regulatory integration of planning with particular focus on the end of Phase IIa meeting. **Preparation for end of Phase IIa meetings are a critical decision point for understanding efficacy and as well as dosing and response.** Understanding the appropriate strategies early on and working with the FDA at this stage of the IND requires a combination of expert science and regulatory expertise to reach a positive proof of concept for a study compound.

Strategic Biomarker Support

The use of biomarkers has the potential to facilitate the availability of safer and more effective drug or biotechnology products, to guide dose selection, and to enhance their benefit-risk profile.

Today drug companies are placing significant focus on completely understanding the biology and genetic pathway of a disease. This has resulted in; genomics and proteomics research to be increasingly integrated into their discovery and development programs.

These technologies play a pivotal role in the modern pharmaceutical and healthcare industries. Together with their downstream products (i.e. molecular biomarkers and diagnostics), genomics and proteomics are currently and will continue to be at the frontier of research for drug development efforts of the Pharmaceutical industry. The failure rate is thus expected to be significantly reduced.

Medpace Central Labs has the global capability to support programs requiring a biomarker component. Highly accredited scientists, backed by a full menu of tests and analytics can set the course for successful early phase programs.

Medpace Clinical Pharmacology Unit (CPU) with state of the art instrumentation

A critical component for Early Phase Studies is a clinical pharmacology unit with the highest level of instrumentation and the ability to test new compounds in both Normal Healthy and target populations. The integration of the unit with key Early Phase components is a vital part of a well-designed Early Phase program. The Medpace CPU is designed to conduct studies with these populations, including safety rigor and the support of Medpace labs and CRO, all on one research campus.

Physician Led 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.

AN INTEGRATED APPROACH TO
EARLY PHASE DRUG DEVELOPMENT

New 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

- 60,000-square-foot in-patient and out-patient facility
- Two dormitory style units with 48 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
- Glucose clamp studies
- Device

Volunteer Amenities

- Internet access for personal laptops
- Desktop computers
- 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 12-lead ECG machines
- Braun IV Infusion Pumps
- Welch Allyn Spot Vital Sign machines
- Capable of pulse oximetry measurements
- Fully-stocked emergency crash carts
- Zoll M Series defibrillator and external pacing device
- Master clocks with synchronization to the official atomic time
- Generator back-up for continual power supply

Specialized Equipment

- Mortara Surveyor Telemetry Central System with 32 telemetry channels
- Continuous glucose monitoring systems (Medtronic MiniMed CGMS)
- Platelet Aggregometers
- YSI STAT Plus Glucose Analyzer
- Calorimetry machine
- Seimens Acusan Sequoia 512 Ultrasound machines

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)

RELATIONSHIP **EXPERTS**

Relationship management is the key to every stage of the drug development process. Medpace Lab's focus is on communication, collaboration, and commitments, helping us see eye to eye with our sponsors. This focus helps manage expectations from project initiation to regulatory submission. Medpace Labs is adept at putting together strategic teams every step of the way, ensuring that the quality of our wholly owned laboratory testing and clinical operations standards is consistent across the global network of laboratory facilities.

Full Integration for Study Support:

We are dedicated to the highest degree of service. We listen to our clients and develop the scientific, operational and logistical approach that is flexible enough to meet sponsor needs - retaining regulatory integrity and maintaining our high standards for quality and efficiency.

Quality Assurance
- Global analytical integrity and combinable data are maintained utilizing identical methodologies, reagents, calibrators, reference ranges, consistent control programs, and strict compliance to regulatory guidelines

Biorepository Services
- Current storage capacity of >2,000,000 samples
- Secured access and 24/7 temperature monitoring with back-up generator
- Led by a Subject Matter Expert for Clinical Biorepository with >25 years experience
- Procedures follow ISBER Best Practices for Repositories and NCI Best Practice for Biospecimen Resources

Data Management - ClinTrak® Lab
- ClinTrak Lab is a fully integrated decision support system providing real-time information–integration with Medpace ClinTrak
- Real-time global tracking and tracing of specimens
- Real-time data cleaning
- Web-based data portal provides seamless data management delivered "on time" in a single integrated global database

MEDPACE Labs

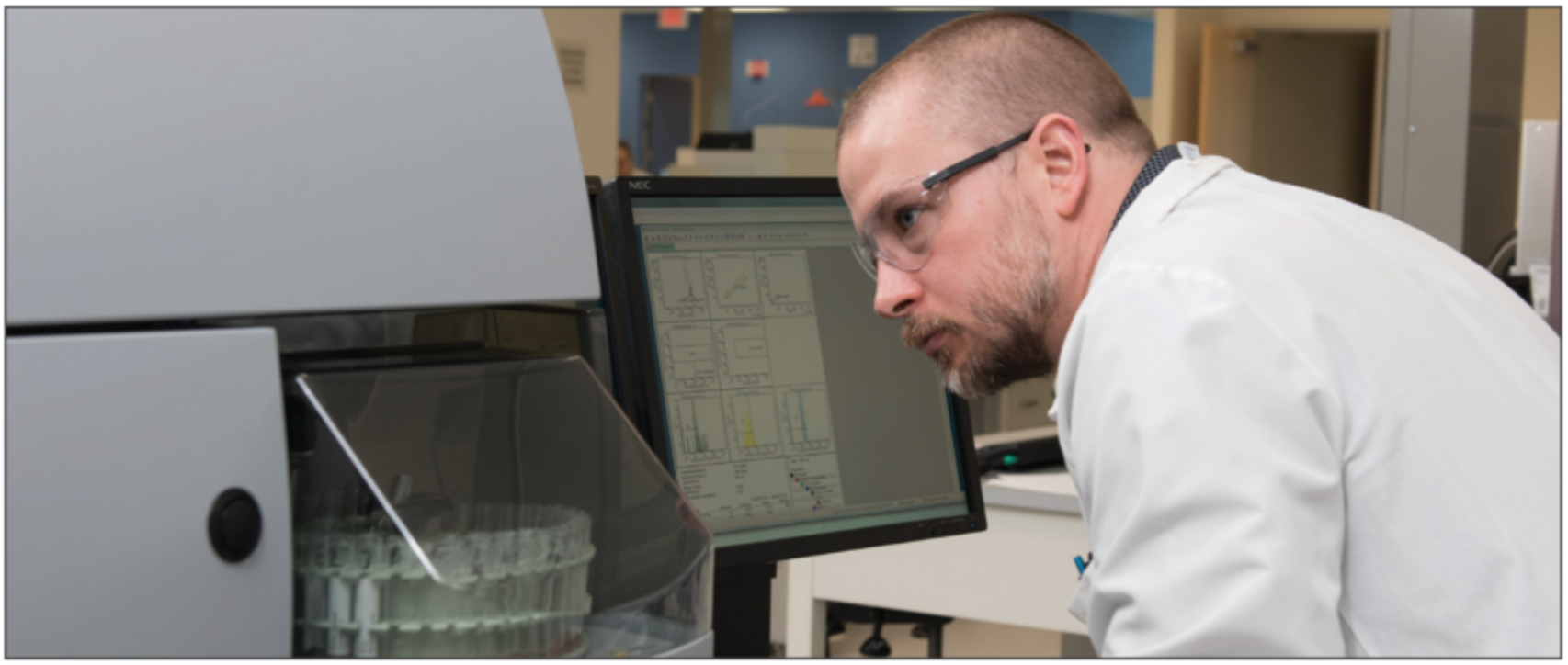
Logistics
- Customized kits and supplies for all projects
- Microsoft AX system for inventory management
- IATA compliant shipping supplies
- Lab Manuals and Kits–logistics tracking–detailed specific collection and processing instructions
- Relationships with top global couriers–99% on time performance across regions

Project Management
- Served by dedicated project teams who own your project from start to finish on a global basis
- Scientific teams consult regarding assay selection, method development, transfer and validation to appropriate regulatory guidelines

QUALITY DRIVEN
BIOMARKER SUPPORT

Enhanced study outcomes benefit from well planned, scalable and quality driven biomarker strategies at the earliest stages of study design. Medpace provides support from early development through Phase I-IV Clinical Studies.

Biomarkers and the development of Companion Diagnostics play a significant role in study design. A well-defined biomarker strategy should maintain a balance between access to all the traditional platforms and techniques, proteomics, molecular and cellular pathology, and genomics while also offering additional access to “Best in Class” novel biomarker tools supported with therapeutic and scientific understanding. This approach should be medically & therapeutically aligned by impeccable science and quality. The successful execution of a biomarker strategy would require a flexible, fully integrated, modular approach, often integrating several specialist or niche labs with a customer focused project and data management structure to support and serve a truly global patient demographic. Medpace Labs modular and fully integrated approach has benefitted current biopharmaceutical clients.



Flow Cytometry

Quality Biomarker Support through Phase I-IV

Medpace Advantage

Biomarkers - Medpace Value Plus

Biomarkers - Medpace Value

Quality Driven Excellence

- Global Central Laboratory
- 20+ Years Experience
- Science & Therapeutic Focus
- High throughput Biomarker Platforms
- DNA/RNA Services
- Ligand Binding Assays
- Flow Cytometry
- LC- MS/MS/GC/MS/UPLC
- Multiplex Platforms
- Fluorescence Microscopy
- Global Project & Data Management
- GCP/CLIA/CAP

All housed in Medpace Global HQ

Applied Science/Knowledge

- Scientific Advisory Board (Medical & Regulatory Advice)
- Extension of Assay performance
- Bespoke & New Assay development
- Large & Small Molecule Expertise
- Functional + Receptor Assays
- Tech Transfer of Additional Platforms
- IVD development & support
- Biobanking & Sample Tracking
- GCP/GLP PK/PD FDA Validations
- Fully Integrated Reporting

All housed in Medpace Global HQ

Innovation/Future Science

- Anatomical & Molecular Pathology
- Genomics Method Development
- IHC testing , FISH & Cytogenetics
- Circulating Tumour Cells & Liquid Biopsies
- Companion Diagnostics Development
- Cell Based Assays
- Microbiology/Virology
- Bioinformatics & Data Mining
- Continuing Investment in new & Evolving Technology & Service

Fully integrated / strategic partners
All managed with one contact through Medpace HQ

In house offering - Science & quality driven flexible approach at core of our service

Extended service with innovative strategic partners

BIOANALYTICAL LAB

Early Phase drug discovery demands not only therapeutic expertise in program development, but a group of full-service partners to deliver exceptional laboratory services quickly and efficiently. Partnering with Medpace as a full-service clinical research organization (CRO) can provide full service capabilities for studies requiring bioanalytical analysis, central laboratories, and clinical pharmacology.

Medpace Bioanalytical Laboratories (MBL)

Medpace Bioanalytical Laboratories is led by an executive management team and dedicated PhD and masters-level scientists averaging 10-20 years of pharmaceutical and bioanalytical study experience. Medpace Bioanalytical Laboratories focus on providing accurate, high-quality results in a timely, secure, and cost-effective manner. Our experts work in collaboration with the medical, regulatory, and imaging experts at Medpace to partner with your team to transfer, develop, validate methods, and ensure fast turnaround of analyses.

Medpace Bioanalytical Laboratories is a leading provider of bioanalytical services in all stages of drug development – from discovery to post-marketing.

- Custom-built GLP-compliant laboratory
  - ~30,000 sq feet
- State-of-the-art instrumentation
  - AB Sciex LC-MS/MS
  - Automated sample preparation
  - Multiplex immunoassay
  - Flow cytometry
- Highly trained scientists
  - Over half with advanced degrees
- Method development and validation
  - Small and large molecules
  - Drug and biomarkers
- Watson LIMS
- Sample storage capability
  - 4°C, -20°C, -80°C units
  - Secure and electronically monitored
- QC specialists/On site QA

Breadth of Capabilities:

- Many years of combined experience with small and large molecules
  - >1000 studies (method validations and preclinical/clinical studies)
  - chiral compounds
  - protein, mAb and ADC
  - MS, HRMS, MS/MS
  - cell immunology and flow cytometry experience
- Discovery projects
  - In vitro/vivo metabolite screening, P450, drug targets
  - Rapid turnaround pharmacokinetic studies
  - Cassette dosing PK
- Preclinical projects
  - Method development/method validation
  - GLP TK and PK sample analysis
  - Mouse, rat, rabbit, dog, pig, monkey, etc
  - Analysis of unconventional biological tissues
  - Dose formulation analysis
- Clinical projects
  - Method development/method validation
  - Analysis of Phase I-III clinical samples
  - Dried blood spot with automation

Instrumentation

- AB Sciex 5600 High resolution QTOF LC-MS/MS System
- AB Sciex 6500 High sensitivity QTRAP LC-MS/MS Systems
- Sciex QTRAP 5500 Systems (with SelexION-Ion Mobility)
- Sciex API-4000 LC-MS/MS Systems
- HPLC Systems:
  - Shimadzu UFLC/HPLC LC-30XR Systems (19,000 PSI) & (4) UFLC/HPLC LC-20XR (9,000 PSI) with UV, Fluorescence, and Diode Array detectors
  - UFLC/HPLC LC-20AD (6,500 PSI) Systems
  - Waters ACQUITY I Class UPLC (18,000 PSI)
  - Eksigent MicroLC (ekspert MicroLC 200)
- ELISA instruments (Biotech: Synergy H1, GIMINI XPS etc.) with Absorbance, Fluorescence, Luminescence
- ECL: MSD Sector Imagers 2400 Multiplex; MESO QuickPlex SQ 120.
- Eppendorf Real-time PCR(Realplex)
- GC-MS with Headspace autoinjector (Shimadzu GCMS-QP2010)
- Flow Cytometer (Attune Next-Acoustic Focusing) and Microscope (EVOS FL Auto)
- PerkinElmer ICP-MS NexION 300X for Metal compounds
- Automated sample preparation, including Tomtec Quadra4 SPE
- Validated Watson LIMS with Validated PK Package & Phoenix WinNonlin digitally linked to Watson
- Fully Validated (IQ/OQ/PQ of Equipment and Software) Systems

Bioanalytical Experience Include:

- Advanced, mass spectrometry technologies for bioanalytical analysis
- Ligand-binding assays for pharmacokinetics (PK) and immunogenicity assays
- qPCR for nucleic acid drug pharmacokinetics (PK) or pharmacodynamics (PD)
- All bioanalytical aspects for small and large drug molecules according to cGLP, OECD,and ICH compliances
- Rapid transition of methods between species and matrices while providing performance according to FDA, OECD, and ICH guidelines

EARLY PHASE LEADERSHIP

Early Phase Leadership fully embedded at each step of the process

Clinical Pharmacology
Lukasz Biernat, MD,
Medical Director

Clinical Pharmacology
Leela Vrishabhendra, MD,
Medical Director

Medpace Central Labs
Traci Turner, MD, MT(ASCP)
Executive Director,
MRL Operations & MARC

Bioanalytical Labs
Yong-XI Li, PhD,
Executive Director,
Medpace Bioanalytical Labs

MEDPACE CRO
Richard Scheyer, MD,
Vice President, Medical Director

MEDPACE CRO
Frank Smith, MD.
Vice President,
Hematology/Oncology

Clinical Pharmacology

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.

Medpace Central Labs

Traci Turner, MD, MT(ASCP) is the Executive Director, MRL Operations & MARC. She is board certified in Internal Medicine and served as a key MRL manager prior to obtaining her medical degree from the University of Cincinnati School of Medicine. She has 15 years of Med Tech experience from the bench to management.

Bioanalytical Labs

Yong-XI Li, PhD, is the Executive Director of the Medpace Bioanalytical Laboratories (MBL). Since its inception in 2008. Dr. Li directs all MBL operations and activities in the areas of method transfer, development, validation, and analysis of preclinical and clinical biological samples, including bioanalytical aspects for small and large drug molecules. Dr. Li has many years of bioanalytical experience at major laboratories. Dr. Li has authored numerous scientific and clinical publications in the fields of proteomics and quantitation analysis and is an industry expert who has developed over 300 methods to analyze drug compounds.

Medpace CRO

Richard Scheyer, MD, Vice President, Medical Director is a pioneer in translational medicine and Phase I/IIa drug development, with special interest in early demonstration of clinical efficacy. Prior to joining Medpace, Dr. Scheyer held a number of leadership roles at major biopharmaceutical firms where he was responsible for early clinical, biomarker, and pharmacogenomic strategy and execution for more than 60 development candidates, including diabetes and lipid therapeutics, and the use of magnetic resonance imaging and spectroscopy for quantification of hepatic lipids. Dr. Scheyer received his B.S. in Physics from Stanford University, his M.D. from The State University of New York, Upstate Medical University, and completed residency training in Neurology and fellowship training in Epilepsy and Clinical Pharmacology at Yale University before joining the Yale faculty, serving as Associate Professor of Neurology. He has served on the Foundation for the NIH Biomarkers Consortium, and on Board of Directors of the Serious Adverse Event Consortium. Dr. Scheyer is highly-regarded author, speaker, and industry participant and has published over 60 manuscripts and abstracts, with focus on clinical pharmacology and therapeutic activity in areas ranging from diabetes to oncology.

Frank Smith, MD is Vice President, Hematology/Oncology with leadership specifically focused on Medpace's hematology studies. Dr. Smith serves as a Medical Monitor on multiple hematology/oncology studies. He provides ongoing training, particularly focused on the operations group, in hematology/oncology, and ongoing support for the Medpace team during these complex trials. Prior to joining Medpace, Dr. Smith served as the Director of the Division of Hematology/Oncology at Cincinnati Children's Hospital Medical Center, Vice Chair of the Children's Oncology Group and most recently, Clinical Director of the University of Cincinnati Cancer Institute. Dr. Smith received his medical degree from the University of South Carolina and post-doctoral training in Pediatrics and Pediatric Hematology/Oncology at the University of Florida and University of Washington. Dr. Smith has clinical and scientific expertise in the fields of bone marrow failure syndromes, blood and marrow transplantation and malignant hematology. He has had numerous scientific manuscripts published in prestigious medical and scientific journals nationally and internationally. Dr. Smith remains active in academia with various international and national committees, societies and board of directors.

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