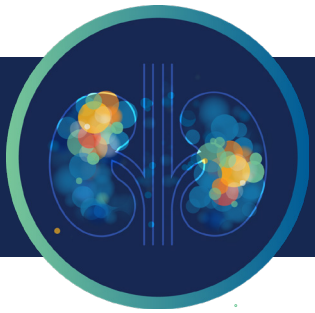
MEDPACE

A DEEPER DIVE INTO NEPHROLOGY & RENAL DISEASE CLINICAL DEVELOPMENT



AN INTEGRATED ADVANTAGE

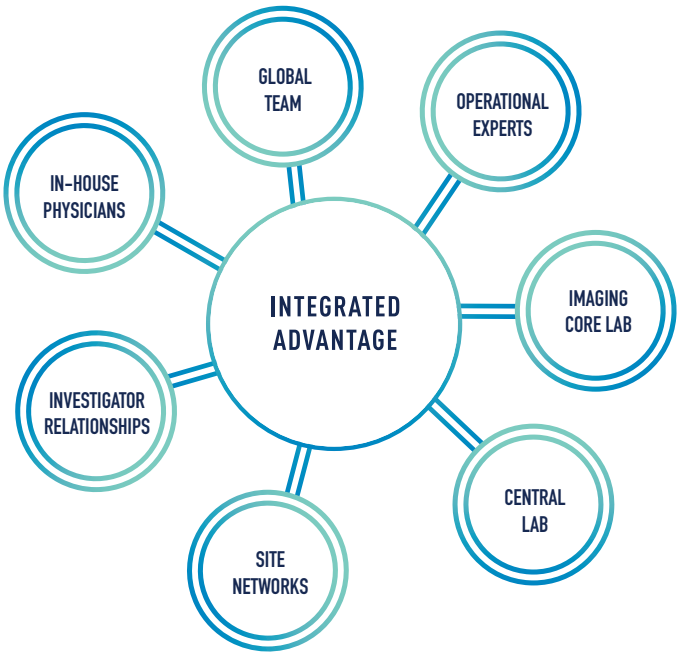
As a therapeutically-focused Clinical Research Organization (CRO), Medpace specializes in the design and conduct of global trials in nephrology and renal diseases. With our proven full-service outsourcing model, Medpace delivers high-quality results. Our experience, coupled with our strong relationships with KOLs and investigative sites as well as our integrated in-house central lab and imaging core lab services, delivers efficiencies that will accelerate the clinical development of your compound.

Key Differentiators Include:

- In-house board-certified nephrologists with strong backgrounds in academic and clinical practice and pharmaceutical development
- Experienced nurse practitioners provide therapy area training to site staff and an understanding of clinical settings
- Global experience conducting Phase I-IV renal disease clinical trials spanning adult and pediatric populations
- Strong relationships with successful, experienced investigative sites which regularly participate and successfully enroll nephrology studies
- A seasoned clinical operations staff with specific experience in conducting renal disease trials
- Thorough understanding of the complex conditions that cause CKD, as well as the medical complications experienced by patients with CKD and ESRD
- Cross-over medical expertise in related therapeutic areas including metabolic, cardiovascular, and autoimmune
- Specialized expertise in rare disease and orphan indications
- Integrated core imaging, ECG and central laboratory services

COLLABORATIVE & CROSS FUNCTIONAL TEAMS

Medpace is unique in its scientifically driven approach to clinical research. Our model gives Sponsors the advantage of early and ongoing insight and guidance from a team of therapeutic experts throughout trial design and execution. Our highly experienced team of medical, regulatory, and operational experts work collaboratively to conduct clinical trials. We understand issues from the perspective of Sponsors, clinical investigators, scientific key opinion leaders, and regulatory agencies. With this insight, we successfully define and execute clear development plans from first time in human (FTIH) studies, Phase I-IV, through to project registration (NDA, MAA).



EXPERTS

Serving as therapeutic team leaders, our in-house Medical Directors provide strategic direction for study design and planning, train operational and site staff, work with Investigators, provide medical monitoring, and engage with regulatory agencies. Medpace Medical Directors work closely with our global regulatory affairs experts to provide strategic guidance to accelerate approvals. Our Medical Directors are embedded and engaged with project teams for the duration of projects, providing depth of expertise and the ability to take an entrepreneurial approach to complex issues.



Ajay Srivastava, MD, FASN
Sr. Vice President Medical Department



Priscilla Smith, MSc, MBBS, FRCP
Medical Director, Medical Department



Ineta Sosare, MD, PED, NEP
Medical Director, Medical Department

ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by a team of ACPs whose unique perspective brings added value to the clinical development team. These highly trained experts with advanced degrees and hands-on clinical experience provide an additional layer of knowledge and insights that can streamline your studies and address potential challenges early in the study planning. ACPs are embedded in the teams to ensure your study is feasible and operationalized for efficient execution by looking at the protocol through the lens of the patient and site staff. ACPs also help with the review of safety events, ongoing team education, recruitment strategies, and study document review. Their understanding of what works in a clinical setting makes them a valuable part of our embedded medical expertise model.



Sudha Alphonse, RN, NMP, MSc, PGCert, Dip GNM
Advanced Clinical Practitioner



Kimberly Harrell, MSN, AGPCNP-B
Advanced Clinical Practitioner



Prudence King, MSN, AGPCNP-BC
Advanced Clinical Practitioner



Sara Rhoten, MSN, RN
Advanced Clinical Practitioner

Scientific expertise, global experience, central labs, imaging labs and site relationships combine to drive efficiencies and quality results.

IN-HOUSE MEDICAL TEAM BIOGRAPHIES

Ajay Srivastava, MD, FASN

Sr. Vice President, Medical Department

Dr. Ajay Srivastava is an ABIM board-certified internist and nephrologist with an extensive background in both clinical and academic medicine, and opinion leader in nephrology at local and national levels.

Experience Summary

- Specializing in adult nephrology, he brings 13+ years of experience in both the common and rare conditions of the kidney, renal replacement therapies, ICU nephrology including IV fluid resuscitation and management, and comorbid conditions such as cardiorenal syndrome and hypertension
- Opinion leader on acute and chronic kidney disease including their comorbid conditions as well as end-stage renal disease
- As an interventional nephrologist, he provided education, assistance, and evaluation regarding matters of dialysis vascular access including the performance of interventional procedures to preserve, optimize, and salvage these hemodialysis accesses
- Has held several leadership positions including the Medical Directorship of dialysis facilities, Director of Nephrology Fellowship training, Division Chief of Nephrology, and Interim Chair of Medicine, and has served on a number of departmental, hospital, and university committees

Education Summary

- Doctor of Medicine, University of Texas
- Postgraduate medical training was completed at the University of Rochester Medical Center and includes his internal medicine residency and Nephrology fellowship

Priscilla Smith, MSc, MBBS, FRCP

Medical Director, Medical Department

Dr. Priscilla Smith is a nephrologist with more than 15 years of clinical and research experience and specialized expertise in renal medicine, cardio-renal-metabolic syndrome, genetic and immune-mediated renal disease.

Experience Summary

- Extensive inpatient and outpatient nephrology experience, including renal transplantation, complex immunosuppressive therapies, and multidisciplinary care for patients with cardiorenal disease and diabetes
- Served as Principal Investigator and Sub-Investigator across numerous Phase 2 and Phase 3 nephrology studies evaluating novel therapies for conditions including IgA nephropathy, chronic kidney disease, and focal segmental glomerulosclerosis
- Co-led the King's Renal Pregnancy Clinic, caring for women with pre-existing or new renal disease in pregnancy, including patients receiving dialysis and renal transplant recipients
- Led King's Adolescent Renal Service supporting transition from paediatric to adult nephrology and contributed to London Kidney Network (LKN) working group on Adolescent renal care.
- Clinical research experience in nephrology and women's health, with several peer-reviewed publications on kidney disease in pregnancy, acute kidney injury, and reproductive health

Education Summary

- Doctor of Philosophy in Obstetric Nephrology, King's College - London, United Kingdom
- Master of Science in Clinical Trials, London School of Hygiene and Tropical Medicine - London, United Kingdom
- Bachelor of Medicine and Bachelor of Surgery, Monash University - Melbourne, Australia

Ineta Sosare, MD, PED, NEP

Medical Director, Medical Department

Dr. Ineta Sosare is a board-certified nephrologist and pediatrician with more than 18 years of therapeutic expertise gleaned from her roles as a physician and in academia.

Experience Summary

- Extensive medical monitor experience in phase II-III global studies in autoimmune disorders, glomerulonephritis, chronic kidney disease, kidney transplant, and pediatric trials including phenylketonuria, familial hypercholesterolemia, infantile hemangioma
- Experience as a consulting nephrologist and medical faculty lecturer for pediatrics and nephrology
- Provided medical expertise to project teams on clinical drug development, throughout the lifecycle of compounds, including supporting study design and generating study protocol
- Provided safety and protocol training to sites and study teams

Education Summary

- Diploma in Nephrology, Medical Academy of Latvia – Riga, Latvia
- Diploma in Paediatrics, Medical Academy of Latvia – Riga, Latvia
- Doctor of Medicine, Medical Academy of Latvia – Riga, Latvia

Sudha Alphonse, RN, NMP, MSc, PGCert, Dip GNM

Advanced Clinical Practitioner

Ms. Alphonse is a NMC registered Nurse (Adult), Teacher and Nurse Prescriber providing support to the Medpace Clinical Operations and Medical Monitor teams focused in Nephrology.

Experience Summary

- 14 years of clinical renal specialized experience including Dialysis – Haemodialysis and Peritoneal dialysis, Vascular access complications, Renal Transplantation, Plasma Exchange, Low Clearance and renal transplant follow up Clinics
- Experience providing expert nephrology consultations in both outpatient and inpatient environment for conditions such as Acute Kidney Injury, various stages of Chronic Kidney Disease, Pre-dialysis and Dialysis, Hepatorenal syndrome, Autoimmune diseases within the leading private healthcare facility and national healthcare services
- Supports the study activities by providing therapeutic and clinical expertise, team training, and offers insight into best practices to identify and recruit trial subjects

Education Summary

- Master of Advanced Nurse Practitioner (Expected completion: Sept 2023), Kings College – London, UK
- PG Certificate in Education for Healthcare
- Professionals, Kings College – London, UK
- Renal (UG Level) Course – Nephrology & Hemodialysis Nursing, Kings College London, UK
- Diploma in Nursing and Midwifery, Armed Forces Medical Board, School of Nursing, Command Hospital (AIR FORCE) – Bangalore, India
- Master of Psychology, Madras University – Chennai, India
- Bachelor of Mathematics, Madras University – Chennai, India

Kimberly Harrell, MSN, APRN, AGPCNP-BC

Advanced Clinical Practitioner

Ms. Harrell is a board-certified adult-gerontology primary care clinical practitioner. She brings over 10 years of experience in Clinical Research and Clinical Practice.

Experience Summary

- Extensive experience in the hospital and clinic setting managing a full spectrum of renal indications, specializing in CKD, ESRD, hemodialysis, peritoneal dialysis and plasmapheresis
- 5 years critical care nursing experience
- Served on education committees and educated nurses, residents and nephrology fellows on dialysis modalities
- Developed order sets for peritoneal dialysis and plasmapheresis
- Active member in professional nursing and nephrology organizations

Education Summary

- Bachelor of Science in Nursing, University of Cincinnati
- Master of Science in Nursing, University of Cincinnati

Prudence King, MSN, AGPCNP-BC

Advanced Clinical Practitioner

Ms. King is a board-certified adult gerontology primary care nurse practitioner. She brings over 28 years of clinical renal specialized experience.

Experience Summary

- Extensive experience in dialysis for adults and pediatrics - hemodialysis and peritoneal, and CAVH/CVVH
- Provided expert nephrology consultations in both outpatient and inpatient environments for conditions such as acute kidney injury and various stages of chronic kidney disease
- Served as Clinical Director of Dialysis, where she managed the day-to-day operation of outpatient dialysis center, inpatient unit, and peritoneal dialysis clinic
- Extensive experience in public health nursing including home care, hospice, and palliative care

Education Summary

- Master of Science in Nursing Education, Keuka College – Keuka Park, NY
- Bachelor of Science in Nursing, Keuka College – Keuka Park, NY



Sara Rhoten, MSN, RN
Advanced Clinical Practitioner

Ms. Rhoten is a board-certified family nurse practitioner. She brings more than 20 years of clinical expertise in kidney disease management and transplantation.



Experience Summary

- Extensive experience managing chronic kidney disease (CKD) and end-stage kidney disease in outpatient settings, including the provision of hemodialysis care
- Provided patient education of CKD and dialysis modalities, with a focus on preventing disease progression and preparing patients for dialysis
- Provided care for kidney transplant recipients, including assessment for infection and rejection and management of immunosuppression under the guidance of the attending physician
- Served as a kidney and pancreas transplant coordinator, supporting candidate evaluation and listing, patient education, and post-transplant follow-up care
- Collaborated with transplant research teams to support post-transplant and desensitization studies, coordinate study-related laboratory testing, and communicate potential side effects and medication changes

Education Summary

- Master of Science in Nursing, Family Nurse Practitioner, Northern Kentucky University - Highland Heights, KY
- Bachelor of Science in Nursing, Northern Kentucky University - Highland Heights, KY

EXPERIENCE

Clinical research in renal diseases is a key therapeutic focus for Medpace. Well-established Sponsor relationships, exceptional clinical operations, and committed study teams drive your success. Medpace has built a team of medical, clinical, and regulatory experts who have successfully managed and executed nephrology trials encompassing Sponsor/CRO project management and site study coordination from the patient care perspective. All team members are engaged from project initiation to completion, producing truly seamless drug development.

Medpace has conducted Phase I-IV trials around the world. Our physicians and staff are experienced in the following areas:

- Renal insufficiency and failure
- Genetic or Rare kidney diseases including Vasculitis and Enteric Hyperoxaluria
- Nephrolithiasis
- Glomerulonephritis associated with ANCA vasculitis, IgA nephropathy, membranous nephropathy, C3 glomerulonephritis and focal segmental Glomerulosclerosis
- Bone & Mineral Metabolism (including hyperphosphatemia)
- Metabolic acidosis/alkalosis, electrolyte Disorders
- Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) including dialytic therapies
- Diabetic Nephropathy
- Anemia/CKD



SPECIALIZED MEDICAL DEVICE EXPERTISE

There is a growing number of nephrology and renal disease devices and diagnostics in various stages of research and development. With a dedicated Medical Device division, Medpace brings together medical and regulatory experts into a collaborative team that understands the nuances from both the drug and device perspectives. Medpace is experienced in helping clients meet regulatory compliance and ensuring patient safety while accelerating their medical device or product to market.

EXECUTION

Medpace offers a distinct advantage to Sponsors developing therapeutics for nephrology and renal diseases. We have the in-house experts, extensive experience, as well as a unique model for execution that includes the integration of critical services such as labs, imaging and safety.

KEYS TO SUCCESSFUL EXECUTION

Committed Teams: Your studies are assigned the best team from the onset and, with turnover rates that are lower than the industry standard, that team is with you from project initiation to completion. As a result, we typically develop better team dynamics that are based on trust and respect

Resourcefulness: Medpace promotes a culture of problem-solving. Our global operational staff proactively identify potential issues and communicate solutions, ensuring your sites and studies are managed effectively and efficiently.

Site and KOL Relationships: Through our experience and relationships with Investigators and key opinion leaders (KOLs) worldwide, we can select the best sites for your specific study or program. This provides an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards from sites recognizing Medpace as a leading global CRO, particularly noting the excellence and training of our CRAs and site staff.

Regulatory Support: Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support.

INTEGRATED SERVICES

Medpace offers comprehensive and fully-integrated services including global central labs, a bioanalytical lab, an imaging core lab, an ECG core lab, and a Phase I unit. The built-in collaboration and efficiencies of working with a single vendor facilitates a streamlined strategy for executing trials of all sizes and scope.

CENTRAL LAB: PD ANALYSIS, BIOMARKER ASSAY DEVELOPMENT AND VALIDATION



Medpace's central laboratories have unmatched experience and expertise to seamlessly support nephrology testing.

Relevant Sample Areas Include:

- Chronic Kidney Disease (CKD)
- Acute Kidney Injury
- Autoimmune Disorders
- Inflammation
- Lipids
- Nonalcoholic Steatohepatitis (NASH)
- Endocrine disorders
- Obesitye pe endis core quo cus prae si odipsum eum idero que.

Key staff involves doctors, managers, and technologists with considerable expertise in the area of central laboratory operations for the pharmaceutical industry and federally funded programs, from discovery and proof of concept through large, long term global trials.

- Four global, harmonized, Medpace owned and operated, purpose built central lab locations: US, Belgium, Singapore, China
- A global team of hands-on laboratory PhDs who actively engage with your study team to identify and validate additional biomarkers to support your study program
- Experienced and stable project management team
- Medpace is continually validating new biomarkers to support our sponsors' programs

Our Extensive Test Menu of Validated Biomarkers and Tests Include:

- Albumin
- ANA
- Beta 2 Microglobulin
- Calbindin
- Ceruloplasmin
- Clusterin
- Complement factors
- Creatinine
- Cystatin C
- Epidermal Growth Factor (EGF)
- Fibroblast Growth Factor 23, c-terminal (FGF-23)
- Immunoglobulins
- Interleukins
- Kidney Injury Molecule 1 (KIM-1)
- Myeloperoxidase (MPO)
- N-Acetyl-beta Glucosaminidase (NAG)
- Neutrophil gelatinase-associated lipocalin (NGAL)
- Osmolality
- Osteoactivin
- Podcalyxin
- Proteinase 3 (PR3)
- Serum Electrophoresi (SPEP)
- Serum Immunofixation
- Transforming Growth Factor Beta 1 (TGF-β1)
- Trefoil Factor 3
- Tumor Necrosis Factors (TNFs)
- Urinalysis (including 24 hour collections)
- Urine Electrophoresis (UPEP)
- Urine Immunofixation
- Vascular Endothelial - Growth Factor (VEGF)

BIOANALYTICAL LABORATORY: PK ANALYSIS

- Leveraging state-of-the-art instrumentation, techniques, and facilities, our team of experts has experience in a broad range of small and large molecule bioanalytical and biomarker support
- Working in a good laboratory practice (GLP) compliant setting, the Medpace Bioanalytical Laboratories provide method development, transfer, validation, and analysis of preclinical and clinical biological samples
- We have extensive expertise in developing sensitive methods for LC-MS/MS — qualifying multiple-analytes, metabolites, prodrugs, and light- and temperature-sensitive compounds
- Our discovery team regularly supports Phase I, FTIH studies which require rapid analysis of PK blood samples, bioavailability, and early toxicology studies

IMAGING CORE LAB

- Board-certified radiologists, nephrologists, cardiologists, and endocrinologists demonstrating extensive clinical trial experience with complex CT, MR and DXA assessments
- In-house, registered CT, MR and DXA technologists who maintain a widespread knowledge in qualifying sites with customized and advanced data and acquisition protocols
- Integrated team of technologists, physicians, and medical physicists collectively possessing years of experience with imaging studies, that utilize the CT, MRI and DXA modalities, and their respective analysis and quality control checks
- Imaging project managers that specialize in managing imaging trials utilizing these modalities, designing and testing novel phantoms specifically for hepatic fat fraction assessment in MR Imaging
- In-house, validated software tools for advanced quantitative image analysis CT, MR and DXA assessments related to renal morphology and function

ECG CORE LAB

Given the importance of accessing cardiovascular risk and cardiovascular monitoring in many nephrology and renal disease trials, Medpace's ECG core lab provides yet another layer of integrated efficiency.

- Provides ECG acquisition and analysis services utilizing industry standard devices and systems, allowing ECG results to be interpreted in the context of all other Medpace data
- In-house physicians with excellent peer to peer relationships with KOLs
- Extensive global experience with trial design, data interpretation and analysis, global study management, and regulatory strategy consultation

CLINTRAK® STUDY MANAGEMENT TECHNOLOGY

ClinTrak (centralized CTMS) provides access to comprehensive study details in a single sign-on, facilitating team coordination and decision support for sponsors and sites.

Lab: The ClinTrak Lab component is a full-scale Laboratory Information Management System (LIMS) that provides access to daily lab reports, management information, cumulative results and trend graphing, secure role-based access, and study specific project management pages.

Imaging: The ClinTrak Imaging component integrates image tracking, quantitative and qualitative analysis, and data management to store and manage data from all imaging and reading centers.

Patient Reported Outcomes (ePRO/eDiary): Patients are more likely to be engaged in clinical trials when the process is transparent and they can understand their role in the research that may lead to advancements in the treatment or diagnosis of their conditions. Our TrialPACE™ app allows for the safe and secure collection of PRO data directly from patients through multiple platforms.

Sites: Our OnPace™ site app was developed to assist sites in preparing for each study visit by providing a clear overview of all assessments, access to study documentation such as the protocol and IB and links to all study websites.

RECRUITMENT AND RETENTION PLATFORM

Our wholly owned predictive feasibility model supports successful and expedited patient recruitment. Driven by external and internal data sources (including our proprietary study management system, ClinTrak), we leverage our well-profiled network of sites and relationships with PIs and KOLs to determine feasibility and to develop a well-vetted recruitment strategy. Once identified, our specialized recruitment teams ensure well-coordinated and efficient execution.

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.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS®

