Chronic Kidney Disease (CKD) is a disease frequently caused by hypertension and diabetes mellitus. CKD results in significant morbidity, mortality and high cost of medical therapy, (dialysis, renal transplantation). Treatment of CKD represents a high unmet medical need since treatments are only moderately effective and CKD often progresses on to end-stage renal disease (ESRD). Cardiovascular disease (CVD) is strongly associated with CKD; indeed the mortality from CVD is 10-100 fold greater among patients with CKD, according to the National Kidney Disease Education Program. The American Society of Nephrology reports that the prevalence of CKD has increased by 16% from the previous decade based on an aging population, diabetes, hypertension and obesity. In fact, the US incidence rate of CKD is the highest in the world.

Medpace has long been considered an industry leader in drug development for diabetes, obesity, and metabolic disorders. More recently, Medpace has conducted several large trials in diabetic nephropathy patients and CKD patients and, as a result, has developed the relationships and therapeutic expertise for development projects dealing with renal disorders. Medpace understands the complex metabolic conditions that cause CKD and, perhaps more importantly, understands the medical complications experienced by patients with CKD and ESRD. In addition, Medpace has a working knowledge of the international landscape of nephrology investigative sites which regularly participate and successfully enroll in nephrology studies.

Medpace: A therapeutically-focused clinical development partner
Medpace has the experience to conduct trials in renally-impaired patients, including patients currently undergoing dialysis, and in patients suffering from diabetic nephropathy as well as other chronic kidney diseases (CKD).

Our expertise in nephrology drug development enables us to collaborate closely with sponsors on clinical and regulatory aspects of their drug development programs. Our multinational network of investigative sites specialized in the nephrology therapy area, and collegial relationships with these sites provides sponsors with confidence that programs are completed on time and within budget.

Medpace and Regulatory Expertise
Bernard Ilson, MD, FACP, is a Therapeutic Medical Director providing expert support for nephrology development programs. He is a nephrologist with over 24 years of experience in clinical drug development, with companies such as GlaxoSmithKline (GSK) and Cardiokine. During his tenure with GSK, Dr. Ilson carried several drugs through from early phase development to regulatory approval and product launch, including Teveten® and Coreg®. He was responsible for the design and conduct of the Levitra® and Vesicare® thorough QT studies, resulting in their regulatory approval. He has been Principal Investigator for more than 200 clinical trials. More recently, Dr. Ilson served as Chief Medical Officer of Cardiokine, a specialty pharmaceutical company focused on development of pharmaceuticals for the treatment and prevention of heart failure and related cardiovascular indications. Dr. Ilson is board certified in Internal Medicine, Nephrology/Hypertension, and Clinical Pharmacology.

Dr. Ilson received his undergraduate (B.S., Biology) and graduate degrees (M.S., Biochemistry) at the University of Connecticut before matriculating at the NYU School of Medicine. Subsequent to receiving his medical degree from NYU, Dr. Ilson completed Internal Medicine training at the Medical College of Virginia in Richmond and then completed a Nephrology/Hypertension fellowship at Temple University Hospital. In addition to his duties at GSK, Dr. Ilson was Clinical Associate Professor of Medicine at the Presbyterian Medical Center of Philadelphia, affiliate of University of Pennsylvania School of Medicine where he had an academic practice of nephrology for 12 years and also served on the Institutional Review Board (IRB) and Pharmacy and Therapeutics Committee. Dr. Ilson is board certified in Internal Medicine, Nephrology/Hypertension and Clinical Pharmacology.
The Medpace Advantage:

Integrated Project Teams: Medpace currently conducts 35% of business in the metabolic and renal area. Not only do our medical monitors specialize in these areas, but Medpace project teams - including CTMs, CRAs, data managers, statisticians, safety managers, medical writers, and regulatory managers - are well-versed in conducting trials in these core areas. All team members are involved from project initiation to completion - producing truly seamless drug development.

Strong Site Relationships: Broad and successful relationships with key investigative sites specializing in the nephrology area contribute to accelerated patient recruitment. Named Top CRO by investigative sites in the CenterWatch site survey, relationships with these specialized sites on a global basis provide Medpace a competitive edge in study start up, patient recruitment, and query resolution.

Full Service Advantage: A one-stop approach to drug development utilizing services from Medpace Reference Laboratory, Medpace Clinical Pharmacology, Medpace Bioanalytical, Imagepace, and Medpace Medical Device ensures study efficiency.

Real time system support: Fully integrated real time information is supported with Clintrak, Medpace’s proprietary web-based decision support system. Clintrak has the capabilities to serve IVRS, study management, data management, laboratory management and image management needs for all studies.

The Medpace Services:

- Therapeutically focused consulting services for protocol and project development
- Study Start-up
- Investigative site selection and management
- Regulatory submissions
- Medical Writing / Safety / QA
- Clinical Monitoring and Safety experience for renal studies
- Pharmacovigilance
- Data Management and Biostatistics
- Electronic Endpoint Adjudication capabilities coupled with strategic consultation and management of all outcomes regulatory requirements.
- EDC / IVRS through Clintrak, a proprietary, web-based decision support system
- Central Laboratory services on a global scale. Medpace Reference Laboratories are headquartered in the US with fully developed labs in Beijing and Mumbai.
- Core Imaging capabilities

Examples of Recent Experience in Nephrology Studies:

- Full conduct of two large international Phase III diabetic nephropathy studies.
- Phase II-III Overt nephropathy study, involving 272 Investigative sites in 23 countries (including the US) and approximately 2,400 randomized patients.
- Several CKD studies evaluating novel phosphate-binding agents in patients with severely impaired renal function.
- Study in patients with diabetic nephropathy and stage 4 CKD, evaluating safety and tolerability of a novel anti-diabetic compound.

Who We Are:

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled experienced and therapeutically focused teams to execute at every level of the company’s operations, providing complete and seamless drug development services.