

NEPHROLOGY AND RENAL DISEASES CLINICAL RESEARCH

Medpace has global experience conducting Phase I-IV trials for a variety of nephrology and renal diseases. An international network of nephrology sites and strong relationships with Key Opinion Leaders (KOLs) streamlines the development process and is enhanced by our experience and history in recruiting hard to enroll patient populations. Expertise across medical, regulatory and operational teams combine to provide the strategic direction and efficient execution of clinical trials.

Nephrology and Renal Disease Indications

- Renal insufficiency and failure
- Genetic or rare kidney diseases including Vasculitis and Enteric Hyperoxaluria
- Glomerulonephritis such as GN 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

Medpace has conducted more than 60 Phase I-IV nephrology studies at 3,500 sites with over 13,000 patients spanning both adult and pediatric populations.

MAKING THE COMPLEX SEAMLESS™

EXPERTS

- In-house nephrologists experienced in clinical drug development
- A nephrology team comprised of seasoned medical, operations, regulatory, and clinical project leaders
- Cross-functional medical expertise in diverse comorbid indications as well as rare disease

EXPERIENCE

- Phase I-IV renal disease clinical trials spanning adult and pediatric populations
- Thorough understanding of the complex metabolic conditions and complications associated with CKD and ESRD, as well as the medical sequelae experienced by this population
- Specialized expertise in rare disease and orphan indications

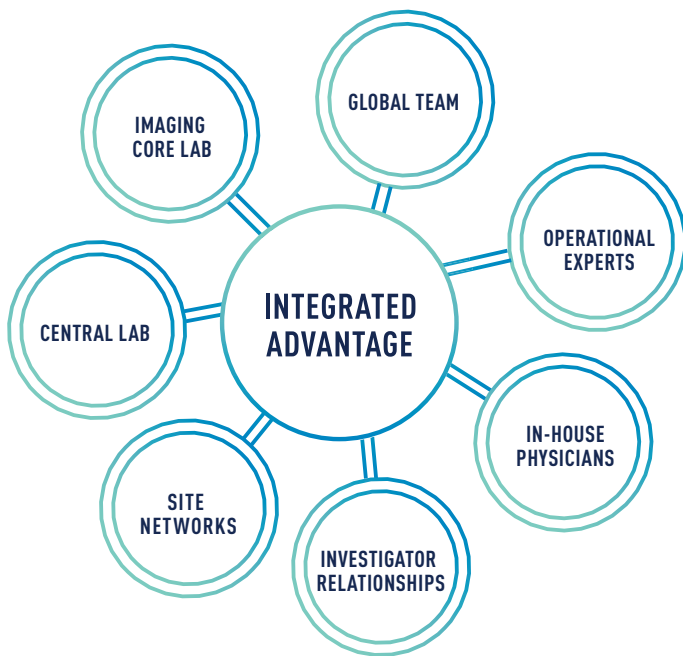
EXECUTION

- Well-established international relationships with experienced sites, networks, and KOLs
- Global experience in regulatory and contracting procedures for nephrology
- Central laboratory services, ensuring seamless logistics, review, testing and safety
- Core imaging laboratories experienced in complex CT, MR, US, and DXA assessments
- Regulatory submissions team with a track record for fast study start-up and contracting



AN INTEGRATED ADVANTAGE

As a therapeutically-focused 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. Sponsors gain a competitive edge with our integrated full-service approach in the ever-evolving landscape of disease and drug clinical development. Our experience, coupled with our strong relationships with KOLs and investigative sites as well as our in-house central lab and imaging core lab services, set Sponsors up for long term success.



SCIENTIFICALLY-DRIVEN CLINICAL DEVELOPMENT

Our scientifically-driven approach to clinical development provides Sponsors with the advantage of early and ongoing insight and guidance from therapeutic experts from trial design to execution. Our medical doctors work closely with our regulatory and operations experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout every study, providing greater depth and the ability to tackle complex and challenging diseases.

Our nephrology and renal disease teams understand that renal patients often have comorbidities such as cardiovascular disease, diabetes, and obesity. These teams collaborate with our in-house experts to ensure proper and accurate care.

CENTRAL LAB

Medpace's four wholly-owned central laboratories integrate seamlessly to support testing needs. Standardized testing platforms, a comprehensive test menu, and strong project management teams deliver quality and consistency.



IMAGING CORE LAB

Medpace Core Imaging Labs has long been a leader in imaging for endocrine and metabolic clinical trials, closely linked to nephrology studies. Medpace Core Imaging Laboratories has extensive clinical trial experience with complex CT, MR, US and DXA assessments—and their respective analysis and quality control checks. With highly experienced and knowledgeable leadership by physicians and scientists, Medpace offers significant advantages in experience, systems, data integrity, and compliance.

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.

