

Nephrology and renal disease

Nephrology and renal disease study experience and expertise

The PPD[™] clinical research business of Thermo Fisher Scientific has deep experience in the design, planning and execution of Phase I-IV full-service global trials across a broad range of nephrology indications.

Experience nephrology and renal disease team

Our renal disease team is rich in clinical talent. Our in-house nephrologists and medical experts are globally positioned and have substantial experience in the clinical development landscape to create a meaningful strategy to guide and execute successful trials with the client's goal in mind. Our team of therapeutically aligned **project leaders** will serve as your point of contact and are accountable for overall project delivery and quality. Medical monitoring is provided by board-certified nephrologists and critical care physicians. PPD has dedicated data management and biostatistics professionals with nephrology and renal disease study experience.



Sponsors conducting clinical research in renal disease benefit from:

- Our **global investigator network includes internists, nephrologists, key opinion leaders**, dedicated clinical research sites, academic institutions and dialysis centers. These diverse resources enable us to provide robust feasibility and consulting services across a myriad of renal disease indications.
- Integrated central laboratory that offers a complete menu of global testing options that delivers real-time integrated data to help clients make better and faster decisions.

Our comprehensive renal and nephrology experience spans a broad range of indications including:

- Chronic Kidney Disease (CKD) and End-Stage Renal Disease, including dialysis
- Diabetic nephropathy
- Hyperphosphatemia
- Vasculitis (i.e., AAV, SLE)
- Acute kidney injury

- Anemia
- Glomerular Diseases (Glomerulonephritis, IgAN, MN, LN, FSGS, including APOL-1 Mediated Kidney Disease)
- Kidney transplantation
- Polycystic kidney disease
- Alport syndrome

- Rare & Genetic Diseases (e.g. Amyloidoisis, Alport and Fabry, Idiopathic Nephrotic Syndromepediatric, Hyperoxaluria, Lupus Nephritis)
- Cell & Gene Therapy (overactive bladder, diabetic kidney disease, CAR-T basket study in B-cell mediated autoimmune disease)

Our nephrology clinical trial experience in the past five years







Our team has experience working with rare renal conditions, having conducted 45 studies in rare nephrology indications, including advanced therapies and C> over the past five years.

Rarer Renal Indications	Studies
Amaloidosis	9
Fabry disease	5
Primary and secondary hyperoxaluria	9
IgA nephropathy	7
Idiopathic nephrotic syndrome (pediatric)	1
Membranous nephropathy	2
APOL-1 mediated kidney disease (FSGS)	3
Lupus nephritis	8
AAV (ANCA-associated vasculitis)	1

Cell and Gene Therapy (C>) Renal Indications	Studies
Overactive bladder (plasmid human cDNA)	1
Diabetic kidney disease (autologous selected renal cells)	3
CD19+ CAR-T in B cell-mediated autoimmune disease (basket protocol)	1

