

# Extensive Nephrology Experience in Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)



PPD has **extensive expertise in conducting CKD and ESRD studies** in both dialysis and non-dialysis patients and can provide strategic planning and regulatory guidance to guide your trial to success.

PPD has deep nephrology experience in **executing CKD and ESRD studies**. Within the past five years, PPD has conducted over **56 trials** focused on CKD/ESRD with pre-dialysis and dialysis patients. This experience draws on our **long-standing relationships with large dialysis organizations (LDOs), experienced nephrology research sites and investigators**. We understand the logistics, regulatory requirements and endpoint consideration of these trials and can apply knowledge gained from our experience to your study, proactively mitigating risks and providing proven solutions.


PPD is dedicated to improving the quality of nephrology clinical studies and to substantially enhance the evidence base for the safe and effective treatment of patients with kidney disease.

## A Wide Range of CKD/ESRD Experience

Our CKD/ESRD experience includes work with biopharmaceutical, biotech, medical device and government organizations.

## In the past five years we have:

Conducted  
**56+**  
CKD and  
ESRD trials



Enrolled  
**10,825+** patients



Worked with  
**1,700**  
investigators  
around the world



Key areas of focus or complication in CKD/ESRD studies include anemia, medical devices, infectious disease, hypertension, renal transplantation, type 2 diabetes mellitus, amyloidosis, hyperphosphatemia and early development PK/PD assessments.

## Dialysis Organization Partnerships to Drive Success

PPD has established partnerships with large dialysis organizations (LDO) in the U.S. Through this arrangement, PPD can access the electronic medical records (EMRs) of approximately two thirds of the dialysis patients in the U.S that these major LDO's currently treat. This EMR access will allow PPD teams to rapidly identify patients and sites for CKD and ESRD studies, resulting in expedited start up and overall study timelines.

**We combine our medical, clinical and operational expertise with our knowledge of the challenges associated with CKD and ESRD studies to plan and execute trials effectively. Our medical, scientific and global team of professionals provide:**



Access to a broad array of global key opinion leaders (KOLs), investigator networks and sites with proven experience.



A comprehensive understanding of the global regulatory landscape to anticipate regulatory queries and local nuances that can help accelerate the submission process and expedite study startup timelines.



Tailored protocol optimization recommendations using our expertise in renal disease to ensure issues are fully explored, and appropriate considerations are built into the study design.



Subject matter experts who can support your program by leveraging their experience to develop adaptable solutions that provide direct therapeutic support to the project through our medical monitors specializing in nephrology and our global product development experts.