

Worldwide's Nephrology Experience











Broad individual and combined team experience across multiple indications in both common and rare renal disorders

Lupus nephritis, kidney disease, C3 glomerulonephritis, IgA nephropathy, FSGS, diabetic nephropathy, HUS, metastatic renal cell carcinoma, polycystic kidney disease, primary hyperoxaluria type I, and XLH



Clinical Trial Technology and Other Core Services for Nephrology

- Established collaborations with specialized service providers
- Central Laboratory
- Bioanalytical Labs (PK/PD, Biomarkers)
- Renal Pathology
 - Light microscopy
 - Electron microscopy
 - Immunofluorescence
- Imaging (MRI & ultrasound)
- ePRO & eCOA
- Home Health
- Scale & PRO management, identification, & procurement
- Rater training and experience assessment



Expert Renal Endpoints: Experienced Clinical and Medical Team

- 24-hr Urine Collections
- First Morning Void Urine Collection
- Urine Protein Creatinine Ratio (UPCR)
- Urine Albumin Creatinine Ratio (UACR)
- Glomerular Filtration Rate (GFR)
- Total Kidney Volume (TKV)
- Height-adjusted TKV (HtTKV)
- Kidney Biopsies
- Disease-specific Patient-reported Endpoints



Differentiated Scientific Service Offerings

- Portfolio evaluation, clinical development plans, and synopsis/protocol development
- KOL engagement and regulatory meeting support (FDA/EMA/MHRA)
- Expertise in FastTrack, Breakthrough, Orphan Drug, and RPDD designation strategies

Subject Toolkit and Logistics

- Detailed video instructions for urine collection procedures
- Male/female collection containers and cooler backpacks for confidential sample transport
- Home urine sample pickup organized where possible



Study Delivery | Enrollment Strategy

- Site selection based on indication experience and patient access
- Global site network and patient advocacy group support
- Cross-border enrollment, travel concierge services, and patient navigators



Patient Advocacy Groups & Investigator Networks

- Collaborations with indication-specific investigator networks for site accrual
- Partnerships with patient advocacy groups to support education, study awareness, referrals, and enrollment

Extensive Global Nephrology Network

- 550+ unique nephrology sites across 48 countries
- Over 50% of sites involved in repeat studies
- Strong presence in North America, Europe, Asia-Pacific, and South/Latin America





