



# Going beyond the boundaries of a clinical trial: how Dr. Barbara Gillespie is working to address disparities in kidney disease

As a board-certified nephrologist, Vice President & Therapeutic Strategy Leader at Fortrea, Dr. Barbara Gillespie is recognized for her work in advancing clinical development programs for kidney diseases. She also maintains her connection to academia as an adjunct professor at the University of North Carolina, Division of Nephrology & Hypertension, and her efforts to make a difference for patients go beyond the clinic and the boundaries of the clinical research ecosystem.

As part of her commitment to advancing nephrology research, Dr. Gillespie is helping build trust in clinical trials within patient groups. Her efforts will not only support drug development sponsors to meet the FDA's Diversity Plan guidance, but will also encourage more underserved patients to participate in kidney disease clinical trials. She recently shared a few highlights of her involvement with community health initiatives and academic collaborations to reach underserved communities and address unmet medical needs.

## Connecting with patients in the community

In April 2024, Dr. Gillespie was appointed to the Board of Directors of **NephCure**, a nonprofit organization that supports people living with rare kidney disease, such as Focal Segmental Glomerulosclerosis (FSGS), including FSGS mediated by Apolipoprotein L1 (APOL1), IgA nephropathy (IgAN), Membranous Nephropathy, among several others.

Soon after her appointment, Dr. Gillespie was invited to volunteer at a church health screening focused on African American men, which is partially supported by NephCure's health education and kidney disease screening efforts. This event was led by another NephCure board member, Reverend Leroy Miles, a leader at Enon Tabernacle Baptist Church in Philadelphia, PA, which regularly hosts various community awareness events and critical health screenings.

“One of NephCure's goals is to educate people about kidney disease and provide connections to clinical research opportunities and innovative treatment options. Through twice-yearly events at the church with Rev. Miles, they are working to screen thousands of Black men and women for kidney disease,” said Dr. Gillespie. “It was great to be in front of patients at the event, talk to them about kidney disease and their screening results and also discuss the benefits of clinical trials.”

### Creating awareness about APOL1 kidney disease within the Black community

Dr. Gillespie explained the significance of hosting community events through places like churches and Historically Black Colleges and Universities (HBCUs).

“African Americans make up 13% of the U.S. population but account for nearly 35% of people with kidney failure in the U.S.,”<sup>1</sup> she said. “APOL1-mediated Kidney Disease (AMKD) research has shown that 1 in 8 Black and African Americans are at risk for the disease since the high-risk genetic variants are linked to people of Western and Central African descent.<sup>2</sup> This association extends to areas outside of the U.S. through forced African migrations via the Transatlantic slave trade route and, therefore, includes people who self-identify as Afro-Latino or Afro-Caribbean.”

Building awareness and trust in the community also complements Dr. Gillespie's work with the Kidney Health Initiative where she recently co-chaired a steering committee that published a roadmap aimed at increasing three elements for AMDK: 1) awareness of AMDK 2) genetic testing to support a diagnosis; and 3) trial participation for APOL1 kidney disease.

“We want to increase awareness of APOL1 kidney disease among nephrologists who may not routinely check for this genetic mutation in patients,” said Dr. Gillespie.

“Even though there is no cure yet, knowledge is power. One study demonstrated that in a cohort of 2,050 African American patients with high blood pressure, but without kidney disease, disclosure of their positive APOL1 genetic test results (to the patients and their clinicians) was associated with increased kidney disease screening as well as improved blood pressure and related behavior changes.<sup>3</sup> If someone knows from a genetic test that they are more susceptible to AMDK, they may be inspired to work with their primary care provider to modify behaviors, for example, comply with blood pressure medication and a low-salt diet, to better control their blood pressure, ultimately lowering their risk of developing kidney disease,” she explained.



### Building trust and increasing the diversity of trial enrollment

Promoting kidney disease awareness may motivate patients to consider trial participation as an option for care, and increase the number of patients of African descent, participating in studies, especially for AMDK trials.

“There are no approved treatments for AMDK, so we need data generated during trials to support regulatory approvals of novel drugs for these patients,” said Dr. Gillespie. “Recognizing that it's hard to run clinical trials and it's hard to enroll patients, our efforts in the community through screening in the primary care setting and genetic testing can help us earn trust in the community, especially with underserved populations. With a disease based on a genetic mutation, we hope to increase our chance of precision medicine in kidney disease to treat the right patient at the right time.”

### Advancing clinical trial endpoints

Another facet of Dr. Gillespie's extended work that advances Fortrea's mission involves a collaboration with the U.S. FDA, nephrology key opinion leaders (KOLs), NephCure, the American Society of Nephrology's Kidney Health Initiative (KHI), the National Kidney Foundation and the International Society of Glomerular Diseases. She sits on the Steering Committee of the PARASOL workgroup (Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis), which is conducting a large-scale analysis of FSGS cohort data to identify “reasonably likely surrogate and traditional endpoints that will inform feasible trial designs and future regulatory pathways for FSGS.”<sup>4</sup> This work in FSGS mirrors Dr. Gillespie's involvement in a similar data-sharing effort to determine a surrogate endpoint in the rare kidney disease IgAN (as shared in an earlier article) that has facilitated several drug approvals for IgAN.

Dr. Gillespie recently met with PARASOL team members in Reykjavik, Iceland, where they discussed the next steps for data analysis, presentation of results and the eventual submission of a journal article proposing an endpoint for FSGS.

“Everybody in the community is very excited,” she shared. “The collaboration and data sharing across 26 registries will help us determine endpoints for getting drugs approved for FSGS, which currently has no approved treatments.”

### Looking ahead to make a difference for patients

By working across industry and academia and partnering with community leaders and patient advocacy organizations, Dr. Gillespie hopes her efforts will result in faster enrollment and more efficient trials for sponsors.

“The more we speed up clinical development, the sooner we will get approved drugs into the hands of patients, see improved outcomes for people living with kidney disease and address current health disparities,” she said.

“Dr. Gillespie’s outreach is a model for how our industry should step up to improve health,” said Dr. Oren Cohen, Fortrea’s Chief Medical Officer. “In clinical research, we should do more to connect with the community and demonstrate leadership. Not only does this work benefit patients, but our leaders also gain real-world insights that they can apply to our customers’ clinical trial design, execution and monitoring.”

“My mission is to help get drugs approved for more rare kidney diseases overall in the next 5-10 years,” said Dr. Gillespie. “Additionally, I want to walk into a dialysis unit and see that the racial makeup of patients matches that of the general population, thus fewer African American patients with kidney failure than we see today because, hopefully, we have found cures in diseases like AMKD.”

### References

1. United States Renal Data System. 2023 Annual Data Report. <https://usrds-adr.niddk.nih.gov/2023>. Accessed July 9, 2024.
2. National Kidney Foundation. APOL1-Mediated Kidney Disease (AMKD). <https://www.kidney.org/atoz/content/apol1-mediated-kidney-disease-amkd>. Accessed July 8, 2024.
3. Nadkarni G, Fei K, Ramos M, Hauser D, Bagiella E, Ellis S, et al. Effects of Testing and Disclosing Ancestry-Specific Genetic Risk for Kidney Failure on Patients and Health Care Professionals—A Randomized Clinical Trial. *JAMA Netw Open*. 2022;5(3):e221048. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789618>.
4. Damashek L. Announcing the PARASOL Project: Proteinuria and GFR as Clinical Trial Endpoints In Focal Segmental Glomerulosclerosis. Dec. 2023. <https://www.is-gd.org/en/news-from-isgd/announcing-the-parasol-project>. Accessed July 9, 2024.

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