



PRESS RELEASE

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KIDNEY HEALTH INITIATIVE LAUNCHES PROJECT TO MEASURE PATIENT PREFERENCES FOR NOVEL KIDNEY DEVICES

Washington, DC (October 24, 2019) —The US Food and Drug Administration (FDA) has awarded a contract to the Kidney Health Initiative (KHI) to study patient preferences for innovative renal replacement therapy (RRT) devices. The three-year project, “Building Capacity to Incorporate Patient Preferences into the Development of Innovative Alternatives to Renal Replacement Therapy” will capture patient preference and risk tolerance data from people with kidney failure to drive innovations in RRT.

This new project contributes to Object 1, Goal 2 of the *Advancing American Kidney Health* initiative, which instructs the FDA to “develop a new survey to gain insight into patient preferences for new kidney failure treatments.” The project is being directed by a KHI project steering committee.

“Patient preference information can drive innovation by underscoring the priorities of patients who rely on lifesaving medical devices and interventions. Capturing and using this data, in addition to clinical safety and efficacy data, is a priority for the FDA”, said Anindita Saha, director of Partnerships to Advance Innovation and Regulatory Science in the FDA’s Center for Devices and Radiological Health. “As part of our ongoing efforts to advance the goals of the Administration’s kidney health initiative, tools like this survey can help the kidney community expedite and design innovative solutions that take into account preferences that matter most to patients when it comes to kidney care and treatment.”

“There has been little rigorous research aimed at quantifying patients’ risk tolerance and perspectives on benefit when it comes to innovative RRT devices. In today’s moment of increased interest in innovating kidney care and treatment, there is no better time.” said Jennifer E. Flythe, MD, FASN, chairperson of the Project Steering Committee and member of the KHI Board of Directors from the University of North Carolina Kidney Center, “The results of this work will give innovators, regulators and clinicians important insights into patient risk tolerance, informing regulatory decision-making and future device design as well as enhancing shared medical decision-making.”

This new endeavor builds on the work of the patient survey used in the [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#), KHI’s [“Patient Reported Outcomes for Novel Renal Devices”](#) project and the Standardized Outcomes in Nephrology (SONG) Initiative.

“As the largest public-private partnership in the kidney community, KHI has a unique strength as a convener,” said Raymond C. Harris, MD, FASN, KHI Co-Chair, “We are excited for another opportunity to work closely with the FDA, provide the community new tools, and support the goals of the *Advancing American Kidney Health* initiative.”

While a new project for the kidney community, the KHI project steering committee is following a model successful used by the Michael J. Fox Foundation. To inform the survey, the project will prioritize, capture, and inventory patient perspectives on the benefits and risks of innovative devices. People with kidney failure serving as “Patient Partners” for the project will help collect patient data from fellow kidney failure patients. The project steering committee expects to produce a variety of publications concerning best practices learned in development of the survey.

Individuals who are interested in learning more about this project, should contact Melissa West, Acting Vice President for Research, Discovery and Innovation, at mwest@asn-online.org.

The Kidney Health Initiative is a key part of the newly created ASN Alliance for Kidney Health. KHI is uniquely positioned to realize ASN’s vision of a world without kidney diseases. As a public-private and collaborative partnership with the FDA and more than 100 organizations and companies, KHI catalyzes innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases. Learn more at www.kidneyhealthinitiative.org.

Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients. ASN has more than 20,000 members representing 131 countries. For more information, please visit www.asn-online.org or contact the society at 202-640-4660.

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