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Annual Report



kidneyhealthinitiative.org



The Kidney Health Initiative (KHI) is a public-private partnership among the American Society of Nephrology (ASN), the US Food and Drug Administration (FDA), and over 70 member companies and organizations committed to catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases.

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Message from the Chair KHI's Board of Directors

Looking back at the past year, I am filled with optimism and hope for the future of kidney health. Innovation in kidney disease research and treatment is accelerating like never before, bringing new possibilities within reach.

For decades, hope for people with kidney diseases was based on the promise of future treatments. Today, that promise is becoming reality—new therapies are being developed, tested, and approved. With multiple late-stage clinical trials underway and continued momentum in research, we anticipate life-changing treatments reaching patients in the years ahead.

To drive this progress forward, the Kidney Health Initiative (KHI) is shaping the next generation of safe, effective, and patient-centered kidney disease therapies. In 2024, we launched the inaugural Kidney Innovation Conference, bringing together experts to advance drug, device, and biologics development. Through this and other events, we explored key topics such as genetic kidney diseases, acute kidney injury, sickle cell kidney disease, transplantation, vascular access, pediatric kidney diseases, and precision medicine, while also working to strengthen the patient voice in innovation.

KHI also continued its focus on clinical trial readiness, hosting webinars and workshops on IgA nephropathy and patient-centered dialysis care. Our publications and presentations helped expand the knowledge base that will shape the future of kidney care. By engaging patients, researchers, regulators, and industry leaders, KHI is fostering a culture of collaboration that moves discoveries from a concept to real-world treatments.

The future is now. With your support, we will continue pushing the boundaries of what is possible, turning hope into reality for millions of people living with kidney diseases. It is my great honor to work alongside you, and I sincerely thank you for your dedication to our shared mission.

With appreciation,

Uptal D. Patel, MD

Chair, Board of Directors
Kidney Health Initiative



Message from the Chair

KHI's Patient and Family Partnership Council

As the Chair of KHI's Patient and Family Partnership Council (PFPC), I have led a dedicated cohort focused on enhancing kidney health outcomes. Our mission prioritizes integrating patient and caregiver insights into the evolving landscape of kidney health innovation.

The PFPC is committed to establishing a patient-centric paradigm within the kidney health ecosystem. This involves active engagement with patients and families to advocate for their needs and integrate their experiences into research, clinical practice, and product development. We believe that patients' lived experiences play a crucial role in developing effective healthcare solutions, supporting the strategic objectives of the Kidney Health Initiative. Reflecting on our achievements in 2024, I feel proud of our progress but acknowledge that our work is ongoing. We remain dedicated to improving health outcomes for all kidney patients and their families.



Patient Advisory Board Roundtable and Mixer:

The PFPC facilitated a Patient Advisory Board Roundtable prior to the Kidney Innovation Conference. This initiative featured a series of informational videos on patient contributions and effective strategies for industry and organizations to engage patient advisory boards. In September, a follow-up virtual mixer with the KHI community, *Strengthening the Patient Voice in the Innovation Process*, synthesized feedback into actionable recommendations for advancing this initiative. The event showcased the expertise of PFPC members such as Vice-Chair Jack Lennon, MBA, Mary Baliker, Precious McCowan, PhD, MS, Curtis Warfield, MS, and Lisa Bonebrake, all of whom facilitated discussions that bridged patients' lived experiences with industry practices for developing innovative kidney products.

Town Hall on Mental Wellness:

During the Holiday Season, we hosted a pivotal November town hall on Mental Wellness with mental health advocate Renée Bova-Collis, highlighting the often-ignored mental health challenges confronting people with kidney diseases and their families. It offered essential resources and coping strategies while fostering a supportive community atmosphere.

Transitioning from Pediatric to Adult Care Mixer:

Acknowledging the hurdles faced by pediatric patients transitioning to adult care, the PFPC organized a virtual mixer with the KHI community. The event provided guidance, resources, and support for young people with kidney diseases and their families during this critical phase.

Future Directions for the Patient and Family Partnership Council:

Looking ahead, the future of the PFPC remains bright under the leadership of the incoming 2025 Chair of the PFPC, Curtis Warfield, MS, and Vice Chair, Thelma Barber. Their stewardship promises to continue the momentum in advocating patient-centered initiatives, fostering inclusivity, and exploring innovative approaches to kidney health. Reflecting on our accomplishments and challenges, the commitment to improving health outcomes for all people with kidney diseases and their families remains unwavering.

Sincerely,

Patrick O. Gee, Sr., PhD, JLC

Chair, Patient and Family Partnership Council
Kidney Health Initiative

2024 KHI Impact and Highlights

Under the direction of KHI Board of Directors, all KHI activities addressed one or more of the following objectives:

1. Convene and communicate a culture of innovation.
2. Support the design and conduct of clinical trials.
3. Address innovation opportunities for pediatric populations and transplant recipients.

KHI achieved these objectives through:

Kidney Innovation Conference

Convened experts to discuss collaboration opportunities that advance innovations in drug, device, and biologics development. In addition to presentations and panel discussions, this inaugural conference included networking and presentations by innovators from ASN's KidneyX and KidneyCure programs. View the 2024 [agenda](#).

KHI Virtual Mixers

Topics included:

- APOL1 Kidney Disease
- Collaborating with Children with Kidney Diseases Hosted by the PFPC
- Communicating Risk to Potential Clinical Research Participants
- Enhancing Innovation in AKI Management
- Meet the KHI Board of Directors
- Meet the KHI Federal Liaisons
- Strengthening the Patient Voice in the Innovation Process

Webinars

[Data Sharing to Advance Clinical Development of IgAN Therapies Webinar](#) to exchange perspectives of the industry, people with kidney diseases, and caregivers on the importance, barriers, and opportunities for sharing non-published data.

APOL1 KD Roadmap Webinar Series:

- [Increasing Awareness and Education of APOL1 Kidney Disease](#) to discuss the first goal of the APOL1 Kidney Disease Roadmap - *increasing the awareness and understanding of APOL1 kidney diseases*. Speakers emphasized the importance of continuously engaging communities across multiple outreach settings.
- [Empowering the Kidney Community: Increasing Access to and Awareness of Genetic Testing and Counseling](#) to discuss the second goal of the APOL1 Kidney Disease Roadmap - *increasing genetic testing of APOL1 KD and associated counseling*. Speakers highlighted the importance of equitable access to genetic testing and counseling.
- [From Awareness to Action: Navigating Clinical Trial Enrollment](#) to discuss the final goal of the APOL1 Kidney Disease Roadmap - *empowering patients to make informed decisions regarding clinical study participation*. Speakers discussed how to empower individuals affected by APOL1 kidney disease as they consider participation in clinical studies.

Kidney Precision Medicine Project (KPMP):

Encouraged collaborations with industry, academia, and foundations to advance treatments by sharing how KPMP leverages cutting-edge science and patient engagement.

Community Engagement

KHI PFPC Hosted a Town Hall discussion on Mental Wellness.

In-Person Workshop

Patient Centered Dialysis Access Innovations: Discussions on the patient, care partner, and clinician call-to-action for safer and pain-free dialysis access innovations, with perspectives from investors, regulators, and innovators.

Publications and Presentations

- KHI's Dialysis Access Workshop highlighted in [Patients on Dialysis Advocate for Needleless Access](#).
- Published [Xenotransplantation and the Role of the Patient Voice](#).
- Presented an [abstract](#) on KHI's APOL1 Kidney Disease Roadmap at the 2024 National Kidney Foundation Spring Clinical Meeting in Long Beach, CA.
- Published [Developing Therapies for C3 Glomerulopathy: Report of the Kidney Health Initiative C3 Glomerulopathy Trial Endpoints Work Group](#) that evaluated data on plausible clinical trial endpoints as measures of clinical benefit for candidate treatment(s).
- Published [Proteinuria as an End Point in Clinical Trials of Focal Segmental Glomerulosclerosis](#) (FSGS) that evaluate data on plausible clinical endpoints as measures of clinical benefit for candidate treatment(s).
- Presented an [abstract](#) on the Sickle Cell Kidney Disease project at Kidney Week Meeting 2024 in San Diego, CA.
- Presented a [abstract](#) on Pediatric IgAN Artificial Intelligence for Data Extraction at Kidney Week 2024 Meeting in San Diego, CA.



3
Publications



3
**Completed
Projects**



7
**New
Members**

2024 New KHI Member Organizations

In 2024, seven new organizations joined KHI. Learn more about these organizations:



AWAK Technologies

A patient-centric device company that aims to develop products that will transform the lives of people with kidney diseases.



Critical Path Institute

A nonprofit that generates solutions to facilitate scientific and regulatory pathways that accelerate the development of therapies for people with unmet medical needs.



Human Immunology Biosciences

A clinical-stage biotechnology company focused on discovering and developing precision medicines for people suffering from immune-mediated diseases.



ITB-MED LLC

A biotechnology company developing innovative therapies to provide immunosuppression freedom for transplant patients.



The National Forum of ESRD Networks' Kidney Patient Advisory Council promotes the role of patients in its mission to promote optimal dialysis and transplant care across the United States.



Veloxis Pharmaceuticals

Is developing new therapies and programs to help transplant healthcare providers and the patients they treat.



Roche-Genentech

A biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases.

Member Organizations

Foundations and Patient Organizations



Research Institutions



Health Care Professional Organizations



Other Non-Profit Organizations



Member Organizations

Device Manufacturers, Diagnostics and Digital Health Companies



Pharmaceutical and Biotechnology Companies



Kidney Care and Dialysis Providers



Federal Partners



Message from the Chair KHI's Board of Directors Drug Committee

KHI remains dedicated to driving innovation and collaboration in the development of therapies for kidney diseases. Over the past year, our focus on advancing drug development has led to significant progress, including key publications and workshops on pediatric clinical trial drug development. Additionally, we continued critical discussions on kidney precision medicine at the Kidney Innovation Conference, reinforcing our commitment to shaping the future of kidney disease treatment.

Our efforts have been particularly focused on improving therapies for rare and complex kidney diseases, including the establishment of endpoints for Complement 3 Glomerulopathy (C3G), Focal Segmental Glomerulosclerosis (FSGS), and pediatric IgA Nephropathy (IgAN). Through strategic partnerships and a patient-centered approach, we aim to accelerate the development of safe and effective therapies that address the urgent needs of those affected by these conditions.

Looking ahead, I am eager to see KHI continue its work in advancing pediatric kidney disease research, furthering kidney precision medicine, and reassessing efforts surrounding acute kidney injury. It has been an honor to chair the Board of Directors' Drug Committee, and I am grateful for the collaboration and dedication of everyone involved in these important initiatives.

Sincerely,

Amit Sharma, MD, FASN, FACP, FNKF
Chair, KHI Board of Directors Drug Committee



Catalyzing Drug Development

Completed Projects and Initiatives

In 2024, KHI successfully completed projects that advanced surrogate endpoints for clinical trials on treatments for C3G and FSGS, and collaborated with NephCure and the National Kidney Foundation to advance data-sharing efforts on FSGS clinical trial endpoints.

To further KHI's APOL1 Kidney Disease Roadmap, a series of webinars aimed to engage and educate the community who could implement the Roadmap's action items.

Below are publications and descriptions of completed projects and initiatives that advance drug development for treating people with kidney diseases.

Developing Therapies for C3 Glomerulopathy (C3G)

This publication shares critical insights into clinical trial surrogate endpoints for C3G, a rare kidney disease with limited therapeutic options. By establishing consensus-driven endpoints, this work accelerates the development of new treatments by paving the way for more efficient and effective clinical trials.

Proteinuria as an End Point in Clinical Trials of Focal Segmental Glomerulosclerosis (FSGS)

This publication underscores the importance of proteinuria as a reliable surrogate endpoint for FSGS clinical trials. By evaluating proteinuria as a surrogate marker for disease progression, this work addresses a significant barrier to the approval of new therapies and supports the use of accelerated regulatory pathways.

PARASOL Effort Progresses to Address Clinical Trial Endpoints in FSGS

The Proteinuria and GFR as Clinical Trial Endpoints in FSGS (PARASOL) initiative marks a significant collaborative milestone in addressing the need for treatments for this rare and devastating disorder. The PARASOL initiative sought to establish a traditional or reasonably likely surrogate endpoint to facilitate accelerated approval of novel therapies. As a collaboration with NephCure and National Kidney Foundation, PARASOL exemplifies the power of collaboration in driving progress toward effective treatments.

APOL1 Webinars

In alignment with the APOL1 Kidney Disease Roadmap, KHI hosted a series of webinars to disseminate knowledge and foster community engagement. Each webinar highlighted specific roadmap goals, including:

- Raising awareness of APOL1 genetic testing and counseling.
- Promoting community education and engagement to increase clinical trial enrollment.
- Addressing disparities and barriers to care in affected populations.

These webinars provided a platform for sharing experiences, discussing challenges, and exploring strategies that advance goals of KHI's roadmap.

Ongoing Projects and Initiatives

In 2025, KHI continues efforts that advance drug development for treating kidney diseases by fostering partnerships, engaging with diverse constituents, and prioritizing patient-centered approaches. This includes a focus on pediatric kidney populations, as described in the 2024 KHI Objectives.

Pediatric Clinical Trials: Making them Family Centric

Following a workshop co-led with NephCure on SGLT2 inhibitors, a Pediatric Workshop at the KHI Annual Meeting in 2023 and a KHI-sponsored session at KidneyWeek 2023, key gaps were identified in educating families about clinical trial participation. In response, KHI launched a project to:

- Publish a comprehensive resource guide for patients and caregivers to support trial enrollment.
- Address industry challenges in clinical trial protocol analysis.
- Showcase successes in pediatric clinical trials through a future webinar.

Pediatric Clinical Research Priorities Survey

Each year, new drugs, biologics, and devices are tested primarily in adults, with limited pediatric evaluation. This survey will identify and prioritize key areas for pediatric clinical trials, establishing a consensus on the top three priorities identified by the community. These findings will be summarized and shared as a resource that advocates for pediatric nephrology needs.

Clinical Trials in Pediatric Patients with IgA Nephropathy (IgAN)

In recent years, there has been a dramatic increase in drug development for treating IgAN; however, clinical trials are largely being conducted in adults. At this time, it is not clear whether the efficacy and safety of these treatments should also be assessed in children with IgAN, and, if so, how best to design studies to obtain the data needed to support use of novel therapies in this population. In 2025, KHI will submit a manuscript to summarize findings in a peer-reviewed publication.

Message from the Chair KHI's Board of Directors Devices Committee

As we look back on 2024, I am proud of the strides the KHI Devices Committee has made in advancing patient-centered innovations, particularly in vascular access solutions. Our focus on improving the lives of individuals with kidney diseases through collaborations with patients, healthcare providers, and technology developers has been a cornerstone of our work. The 2024 Dialysis Vascular Access Workshop highlighted the urgent need for needle-free, pain-free dialysis access solutions, with patient and caregiver voices driving the conversation around the daily challenges of current access methods.

The workshop showcased exciting advancements, including emerging needle-free technologies and infection prevention solutions, which offer hope for a future where dialysis no longer involves daily pain. Overcoming barriers in funding, regulation, and usability will require continued collaboration, and I am optimistic that we are moving closer to creating solutions that truly improve quality of life for people with kidney diseases.

As my term on the KHI Board of Directors concludes, I am confident that the work we have started will continue to progress. I am deeply grateful to all those who have contributed their time, energy, and expertise to drive this important work forward. Together, we will keep pushing for innovation that prioritizes patients and transforms the future of dialysis access.

Sincerely,

Jennifer E. Flythe, MD, MPH, FASN

Chair, KHI Board of Directors Devices Committee



Catalyzing Device Development

Projects and Initiatives

In 2024, KHI's Devices Committee continued its commitment to transforming the device development landscape with a strong focus on advancing vascular access solutions that reduce patient pain, improve safety, and improve quality of life. Through workshops, roundtables, and ongoing partnerships, KHI continues to drive forward innovations that prioritize patient and care partner needs, aiming to improve outcomes and enhance the quality of life through a collaborative platform among patients, care partners, healthcare teams, and technology developers.

Completed Initiatives

Dialysis Vascular Access Workshop

The Dialysis Vascular Access Workshop brought together a diverse community to discuss the future of dialysis access technologies. Key highlights included discussions around the urgent need for needleless and pain-free access solutions. Patients and care partners shared first-hand experiences of the daily challenges with current access methods to emphasize the need for innovation. Presentations from innovators highlighted promising needle-free technologies and infection prevention solutions, while experts called for collaboration to overcome funding, regulatory, and usability barriers in the development of these devices.

In a [Kidney News article](#), dialysis patients shared powerful messages from the Vascular Access Workshop, voicing their preferences for needle-free and durable access solutions. Their personal experiences underscored the daily pain and challenges of dialysis, urging innovators, funders, and regulators to prioritize patient-centered designs. The article also discussed emerging innovations and the importance of collaboration to break down barriers for developing new technologies, leaving attendees hopeful for a future where dialysis access is no longer a daily struggle for patients.

Continuing Projects and Initiatives

In 2025, the KHI Devices Committee continues efforts that advance innovations and devices development for people with kidney diseases. KHI launched a project, *Catalyzing Patient-Centered Vascular Access Innovations*, to address many of the challenges and concerns discussed at the Dialysis Vascular Access Workshop.



Message from the Chair KHI's Board of Directors Biologics Committee

The KHI Biologics Committee had a productive and impactful year with a clear focus on advancing key initiatives in the biological and kidney diseases ecosystem. From hosting events to initiating collaborative projects, we helped foster critical dialogue and collaboration between diverse members of our community, professional and patient organizations as well as different medical specialties, which is invaluable in shaping the future of kidney research.

Some of our accomplishments from 2024 included the virtual mixer on Communicating Risk in Clinical Research and the launch of the Sickle Cell Kidney Disease (SCKD) project, laying a solid foundation for continued success in 2025. New projects—such as Xenotransplantation and immunosuppression safety in kidney transplantation—demonstrate a clear commitment to addressing both emerging challenges and ongoing concerns in the field.

Looking ahead, the exploration of gene therapy and cell therapy concepts within the context of kidney disease is an exciting direction. Given the rapid advances, ensuring that people with kidney diseases are considered in these trials is a critical issue.

Sincerely,

Alain Romero, PharmD, PhD

Chair, KHI Board of Directors Biologics Committee



Catalyzing Biologics Development

Continuing Projects and Initiatives

In 2024, two new projects were initiated that included partnerships as a core component.

Sickle Cell in Kidney Disease: Natural History and Clinical Endpoints

In partnership with the American Society of Hematology's Research Collaborative, KHI initiated a project to develop a framework for regulatory pathways by characterizing the natural history of SCKD and identifying biomarkers and endpoints for sickle cell patients at high risk of kidney disease.

Kidney Xenotransplantation

Previous projects by KHI and National Kidney Foundation (NKF) highlighted the need for patient and care partner information to make decisions on participating in clinical trials for kidney xenotransplantation. KHI is developing a collaborative project with the FDA Center for Biologic Evaluation and Research and NKF to facilitate community readiness by developing resources that promote understanding and communication about clinical trials for kidney xenotransplantation for patients, care partners, and healthcare teams.

Acknowledgments

Thank you to the members of KHI's Board of Directors, Project Workgroup Chairs, and Patient & Family Partnership Council for making this work possible.

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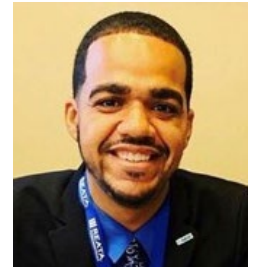
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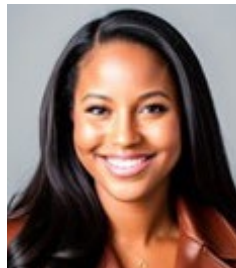
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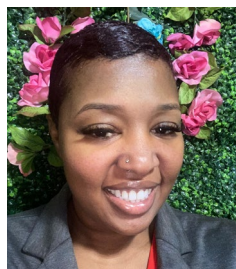
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KHI's 2025 Objectives

The Kidney Health Initiative continue to advance its mission of catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases. In 2025, KHI's objectives focus on the following:

1. Convene and communicate a culture of innovation.

- 1.1. Develop toolkits that communicate benefits, risks, and science to potential clinical trial participants.
- 1.2. Serve as a neutral forum that defines challenges and identifies collaboration opportunities that strengthen pipeline of kidney innovations

2. Support design and conduct of clinical trials.

- 2.1. Integrate perspectives, preferences, and other measurements from people with kidney diseases and care partners in clinical trials.
- 2.2. Evaluate clinical trial endpoints that could accelerate development of candidate products for rare kidney diseases.
- 2.3. Advance participation of people with kidney diseases in clinical trials while also addressing participant diversity and underrepresentation.
- 2.4. Advance clinical trials as a treatment option.

3. Address innovation opportunities for pediatric kidney populations and people with kidney transplants.



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