The Kidney Health Initiative (KHI) has a history of convening a diverse community focused on a common goal. Our new logo reflects the variety of KHI’s membership, whose individual perspectives and collective efforts create a comprehensive and meaningful result. This re-branding positions KHI as an integral part of the ASN Alliance for Kidney Health. To match our new logo, KHI has refined its mission to catalyze innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases. The refreshed mission and new logo build on past success and reflect our vision for the future.
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Dear Colleagues,

On behalf of the Board of Directors, thank you for your membership in KHI. The 2019 Annual Review highlights what your membership and involvement in the kidney community have made possible.

This has been an exciting year for KHI and the kidney community in the fight against kidney diseases. Our success would be impossible without the unique partnership we have with the US Food and Drug Administration (FDA). Thanks to our 105 members, we pursued a variety of projects in drug and device development and motivated the community through collaborations and convenings. These efforts serve our refined mission to catalyze innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases. In addition to highlighting KHI’s accomplishments in 2019, this year’s report emphasizes the contributions of our members in developing better treatment options for people with kidney diseases.

This year, KHI surpassed the 100-member mark, making us the largest consortia in the kidney community. Many of those member organizations were represented at the Seventh Annual Stakeholders Meeting, which enjoyed the largest attendance to date. Continuing our commitment to provide the community with the tools to bring new therapies to market, this year KHI produced a publication on clinical trial endpoints for IgA Nephropathy. We expect additional publications on appropriate endpoints for hyperoxaluria trials as well as recommendations for including people with kidney diseases in cardiovascular trials. Building off our signature initiative, the Technology Roadmap for Innovative Approaches to Renal Replacement Therapy, we produced a Patient Edition of the Roadmap and a report on innovations in fluid management. Beyond our traditional projects and meetings, KHI catalyzed innovation through involvement in the first KidneyX prize competition, supporting NephCure Kidney International’s efforts related to clinical trials, and assisting a new ASN Task Force focused on diabetic kidney disease.

From our vantage point at KHI, we have seen the kidney community evolve significantly since our founding in 2012. More drug companies, large and small, are investing in kidney diseases. Both rare diseases, like IgA Nephropathy and FSGS, and common diseases like diabetic kidney disease, are receiving new attention from industry. Patient organizations are increasing their efforts to engage sponsors and the FDA by hosting patient focused drug development meetings, creating patient registries, and sharing information that supports clinical trial enrollment. New innovators are being brought into the field through KidneyX’s prize competitions in the quest to redesign dialysis.

This summer, the announcement of the US Department of Health and Human Service (HHS)’s Advancing American Kidney Health (AAKH) initiative brought national attention to the public health need that is kidney disease. This means for the first time in decades, kidney diseases received attention from the White House. The AAKH emphasized the importance of innovation and discovery in drugs and devices, specifically the artificial kidney. We appreciate the support from the federal government and look forward to catalyzing innovation with the community at large.

This is my first year as ASN Co-Chair for KHI and I look forward to continuing to refine our mission and build on our past successes in some key areas. First, including the patient perspective is foundational to our role in the community and I look forward to amplifying the work of the KHI Patient and Family Partnership Council. Second, the Technology Roadmap for Innovative Alternatives to Renal Replacement Therapy has been well received by the community and provides a model for KHI to replicate in other areas of need. Lastly, over the next year I anticipate KHI will capitalize on new opportunities to help translate basic science into new therapies.

Thank you to our members, Board of Directors, workgroup chairs, workgroup members, and the staff for making 2019 a success. I look forward to continuing our collaboration with you to improve the lives of people with kidney diseases.

Sincerely,

Raymond C. Harris, MD, FASN
ASN Co-Chair for KHI
152 Volunteers
Participating in Workgroups and Committees

14 Completed Projects
3 in 2019
8 Current Projects

Presentations at 67 Meetings

19 Total Publications
2 in 2019

105 Current Members, 11 joined in 2019

- 31 Pharmaceutical Companies
- 15 Health Professional Organizations
- 11 Foundations and Patient Organizations
- 5 Government Partners
- 3 Contract Research Organizations
- 10 Research Institutions
- 19 Device Manufacturers and Biotech Companies
- 4 Non-Profits/Digital Health/AI Companies
- 7 Dialysis Providers
- 5 Contract Research Organizations
- 10 Research Institutions
- 105 Current Members, 11 joined in 2019
There is reason for optimism in drug development for kidney diseases. New collaborations among KHI members and within the broader community are creating an environment ripe for innovation. KHI is working alongside its members and the community by providing tools for industry and regulators to assess new drugs. These drugs will address the causes of kidney failure and progression of disease for the 37 million Americans with kidney diseases.

The landscape is changing. Industry, both small and large, is paying more attention to kidney diseases. Glomerular and rare diseases are attracting new attention, and renewed attention is being paid to diabetic kidney disease. Patient organizations are increasingly receiving an audience at the FDA, and are stepping up efforts to create patient registries, trial networks, and host collaborative scientific meetings.

These activities have occurred, in part, due to KHI’s work in clinical trial endpoints and clinical trial infrastructure. As new trials are started and new molecules discovered, KHI will continue to support the community by bridging the gap between research and new therapies and building the relationships within the community to catalyze innovation.

### Key Publications, Events, and Meetings*

|------|------|------|------|

*This timeline is a representation and is not comprehensive.*
KHI Projects to Support Innovation

<table>
<thead>
<tr>
<th>Project Topic</th>
<th>Current Project</th>
<th>Workshop</th>
<th>Publication</th>
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<tr>
<td>Prioritizing ESRD Symptoms</td>
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<td>IgA Nephropathy Surrogate Endpoints</td>
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<td>Lupus Nephritis Surrogate Endpoints</td>
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<td>Cardiovascular Disease Trials</td>
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<td>FSGS Surrogate Endpoints</td>
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<td>Hyperoxaluria Surrogate Endpoints</td>
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<tr>
<td>Pediatric Drug Development</td>
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</tbody>
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2017

- Total Kidney Volume is a Prognostic Biomarker of Renal Function Decline and Progression to End-Stage Renal Disease in Patients With Autosomal Dominant Polycystic Kidney Disease—Perrone et al. Kidney International Reports, Volume 2, Issue 3, 442 - 450
- NKF/Patient Centered Outcomes Research Institute (PCORI) Patient Meeting on Trial Participation

2018

- Kidney Disease Clinical Trialists Meeting
  - Change in Albuminuria and GFR as End Points for Clinical Trials in Early Stages of CKD: A Scientific Workshop Sponsored by the National Kidney Foundation in Collaboration with the US Food and Drug Administration and European Medicines Agency.—Levey, Andrew S. et al. American Journal of Kidney Diseases, Volume 0, Issue 0
  - Cultivating a Research-Ready Dialysis Community—Flythe et. al. JASN Mar 2019, 30 (3) 375-380; DOI: 10.1681/ASN.2018101059
- NKF/IgA Nephropathy Foundation/FDA Externally Led Patient-Focused Drug Development Meeting

2019

- NKF Scientific Workshop: The Role of the Kidney and SGLT2 in Glucose Homeostasis and Kidney Disease
- ASN Diabetic Kidney Disease Collaborative Launched
- NKF/IgA Nephropathy Foundation/FDA Externally Led Patient-Focused Drug Development Meeting (PFDD) Meeting
Thank you to all our members. Together, we represent the largest consortia in kidney diseases, working collaboratively to catalyze innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases.
The environment around developing new devices for people living with kidney diseases is changing for the better. Today, more than a dozen member organizations are developing innovative devices and diagnostics. Through partnership with the FDA, KHI is addressing barriers to innovation and supporting people living with kidney diseases.

KHI has provided the community with resources to take advantage of this moment. Innovations in vascular access are essential to moving the artificial kidney forward. Publications on vascular access endpoints and trial design laid the foundation for important technologies underlining the artificial kidney. The Technology Roadmap for Innovative Approaches to Renal Replacement Therapy provides guidance for the community to move device development forward on many fronts and is being expanded to address new issues and to reach new audiences. Our patient reported outcomes and patient perspective projects help ensure that tomorrow’s innovations meet the needs of people with kidney diseases.

**Total Product Life Cycle**

**Key Publications, Meetings & Events**

- **2011**: CDRH Entrepreneur-in-Residence Program started
- **2012**: CDRH Innovation Pathway—ESRD Challenge
- **2015**: NIDDK ReBuilding a Kidney Consortium
  - KHI Workshop on Stimulating Patient Engagement in Medical Device Development in Kidney Disease
- **2016**: White House Organ Summit

Adapted from the FDA Center for Devices and Radiological Health TPLC
KHI Projects to Support Innovation

- **Vascular Access**
  - Clinical Trial End Points for Hemodialysis Vascular Access
    — Shenoy S et al. CJASN March 2018; 13 (3) 490-4946
  - Recommended Clinical Trial End Points for Dialysis Catheters
    — Allon M et al. CJASN March 2018; 13 (3) 495-500
  - Definitions and End Points for Interventional Studies for Arteriovenous Dialysis Access
    — Beathard GA et al. CJASN March 2018; 13 (3) 501-512
  - FDA Regulatory Perspectives for Studies on Hemodialysis Vascular Access
    — Hurst FP et al. CJASN Mar 2018; 13 (1) S15-S18

- **Novel Devices**
  - KidneyX Innovation Accelerator Launch
  - KHI RRT Technology Roadmap Release

- **Muscle Cramping**
  - KidneyX Redesign Dialysis Phase 1 and Phase 2 Prize Competitions

- **Patient Reported Outcomes (Current Projects)**

- **Patient Engagement in Medical Device Development**

- **Technology Roadmapping**
  - Innovations in Fluid Management
  - Prioritizing ESRD Symptoms

- **Endpoints**

- **RRT Technology Roadmap**

2017

2018

2019
Making progress in providing better treatments for people with kidney diseases requires including the voice of people with kidney diseases. KHI embeds that idea in everything it does. Patients and care partners vet all project proposals, serve on project workgroups, help plan the Annual Stakeholders Meeting, and lead on the Board of Directors. Signature initiatives, like the Technology Roadmap for Innovative Approaches to Renal Replacement Therapy, and other projects, are built around patient preferences and responding to the needs of people with kidney diseases. These efforts would not be possible without the support of KHI’s members representing patient organizations and foundations across the community.

The KHI Patient and Family Partnership Council (PFPC) pushes the initiative to include the patient voice in drug and device development. This diverse group represents a variety of treatment experiences including home hemodialysis, in-center hemodialysis and transplantation. The KHI PFPC also provides the patient perspective on nearly all of KHI’s projects. The group provides extensive expertise on issues such as clinical trial operations, patient reported outcomes, patient engagement, and pediatric product development.

Thanks to these organizations for supporting the KHI PFPC

- American Association of Kidney Patients
- American Kidney Fund
- Alport Syndrome Foundation
- Dutch Kidney Foundation
- Home Dialyzers United
- JDRF International
- National Kidney Foundation
- NephCure Kidney International
- Oxalosis and Hyperoxaluria Foundation
- PKD Foundation
- Vasculitis Foundation

Left to right: Kevin J. Fowler (Vice-Chair), Patrick O. Gee, Mary Baliker, Pamela Duquette, Denise Ellers, Amanda Grandinetti, Caroline Wilkie, Nichole Jefferson, David M. White (Chair)

Not pictured: Richard Fissel.
Convening the community is one of KHI’s strengths and an important benefit for members. The Seventh Annual Stakeholders Meeting revolved around the theme of “Collaborating for Innovation to Improve Patient Care and Outcomes.” A Planning Committee led by Co-Chairs Paul T. Conway and Mahesh Krishnan, MD, FASN, developed a program that attracted nearly 200 registrants. The “think-tank” style meeting included onstage Q&A with government representatives, presentations from leaders in the kidney community, and member showcases highlighting innovations within the KHI membership.

KHI thanks the 2019 Planning Committee for their hard work and dedication

Paul T. Conway, Co-Chair
Mahesh Krishnan, MD, FASN, Co-Chair
Nieltje Gedney
Duvuru Geetha, MD, FASN
Nicolas J. Guzman, MD
Raymond C. Harris, MD, FASN
Nichole Jefferson
David Kuraguntla
Kristen Miller, PharmD
Joseph Muldoon
Jesse Roach, MD
Prabir Roy-Chaudhury, MD, PhD, FASN
Monnie Wasse, MD, MPH, FASN

Keynote Presentations

Amy Abernethy, MD, PhD, Principle Deputy Commissioner, FDA with Mahesh Krishnan, MD FASN (right)
Adam Boehler, Director of the Innovation Center at the Center for Medicare and Medicaid Services (CMS) with Paul T. Conway (right)
Eric Hargan, JD, Deputy Secretary at HHS
Thank you to the Board of Directors and Project Workgroup Chairs for making KHI’s work possible.

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Eric W. Young, MD
Arbor Research Collaborative for Health
37 million Americans with kidney diseases

726,000 people with kidney failure

$114 billion spent by Medicare on kidney diseases

58% mortality rate on hemodialysis

“PEOPLE WITH KIDNEY FAILURE DIE EVERY DAY WITHOUT SEEING INNOVATIVE NEW DRUGS AND DEVICES. THE TIME IS NOW TO RENEW OUR COMMITMENT TO CATALYZE INNOVATION AND DELIVER A WORLD WITHOUT KIDNEY DISEASES.”

— Raymond C. Harris, MD, FASN, KHI Co-Chair