The Kidney Health Initiative: How FDA & ASN Convened a New Era of Collaboration

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Kidney Health Initiative



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Disclosures

Employer: American Society of Nephrology

The following is my personal view and does not represent the FDA.



Mission:

To catalyze innovation and the development of safe and effective <u>patient-centered</u> therapies for people living with kidney diseases.

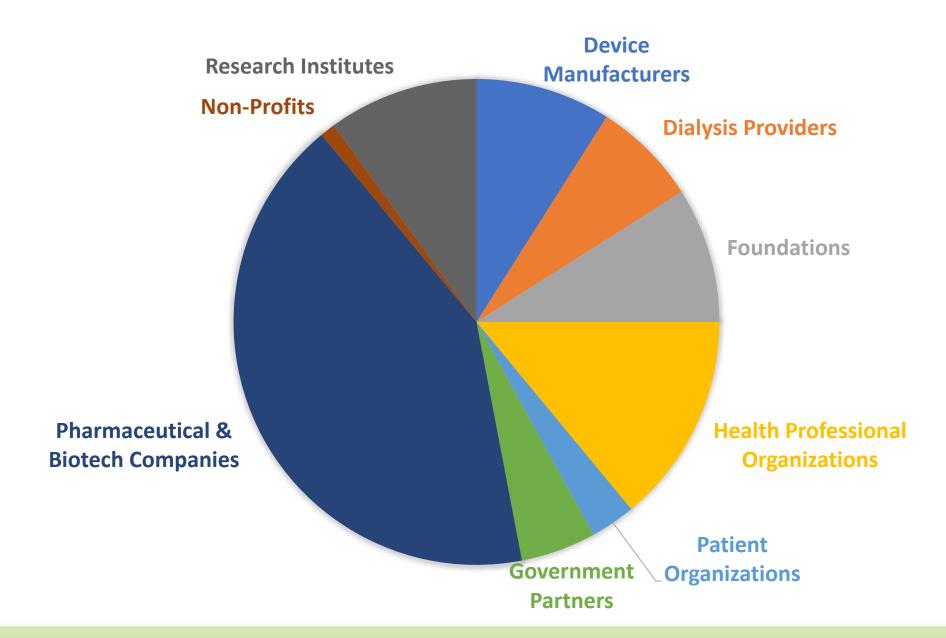


"As the largest consortium in the kidney community, our members recognize the potential and power of collaboration to address barriers to innovation. Our work is an extension of the expertise of patient organizations, industry, research institutions, the federal government, and others, representing the entire kidney community."

Raymond C. Harris, MD, FASN Kidney Health Initiative Co-Chair

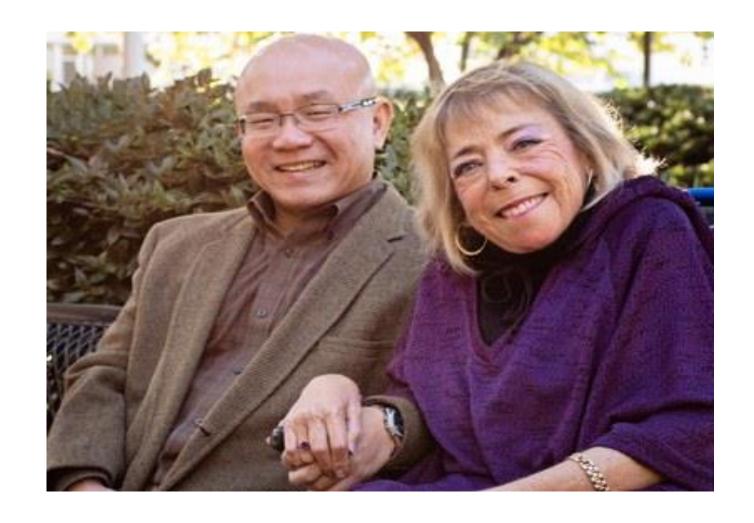


102 Members as of May 2019



Celeste Castillo Lee

KHI Patient and Family
Partnership Council (KHI PFPC)
Founding Chair
July 26, 1965 - February 9, 2017





Patient & Family Partnership Council













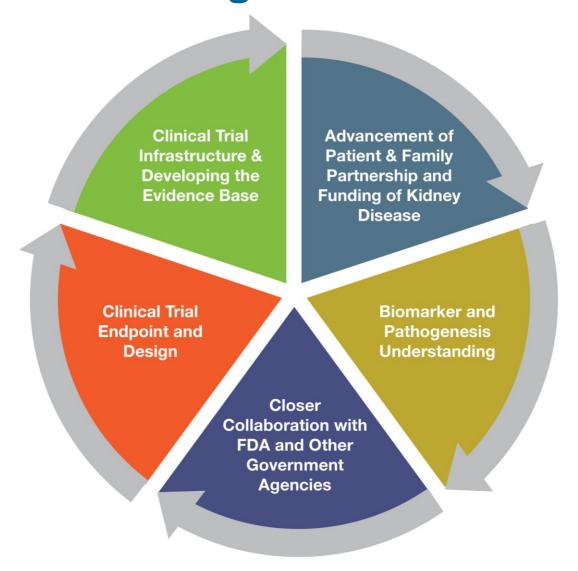








Strategic Priorities



13 Completed Projects: 50% with "Patients"

Patient and Family Partnership

Workshop:
Patient Preferences
In Medical Device
Development

Advancing
Technology:
Remote Management

Prioritizing
Symptoms of ESRD
Patients for
Therapeutic
Development

Clinical Trial Infrastructure and Developing Evidence Base

Data Standards:

Diabetic Kidney

Disease

Clinical Trial Endpoints and Design

PK in Patients Receiving CRRT Outcome Measures: Lupus Nephritis

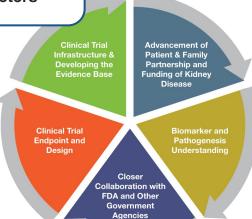
Surrogate Endpoints:

Clinical Trial Endpoints: Vascular Access Close Collaboration with FDA and other Government Agencies

Overcoming Barriers to Kidney Health:
Barriers and
Solutions

Regulatory Policies: Hemodiafiltration

Regulatory Policies: Central Venous Catheters



Data Standards:
Solid Organ
Transplantation



People Living with Disease as Partners

10 Ongoing Projects: 90% Involve "Patients"

Patient and Family Partnership

Fluid Management

PROMS for Novel **Medical Devices**

PROs for Vascular Access

PROs for Muscle Cramping

Clinical Trial Infrastructure and Developing **Evidence Base**

Global ESRD Data Standards

Clinical Trial Endpoints and Design

Surrogate Endpoints: **Hyperoxaluria**

Surrogate Endpoints: **FSGS**

Close Collaboration with FDA and other Government **Agencies**

Overcoming Barriers to Drug Development in Children with CKD

Roadmap for Innovations in **RRT**

Overcoming Barriers to Including Kidney **Disease Patients in CV Trials**



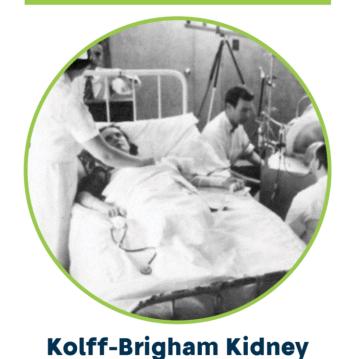
People Living with Disease as Partners



The Kidney Health Initiative (KHI) RRT Project

Brings stakeholders together to foster innovation to address patient's need for alternatives to dialysis for renal replacement therapy (RRT).

1950



2017



Boston Globe

Future



IMPROVED PATIENT QUALITY OF LIFE



Minimized impact/ intrusion of therapy on family and social life



Increased treatment choices



Reduced disease and treatment complications



Improved ability to work and travel



Liberalized diet and fluid regulation



Reduced disease maintenance and interventions



Increased mobility and physical activity



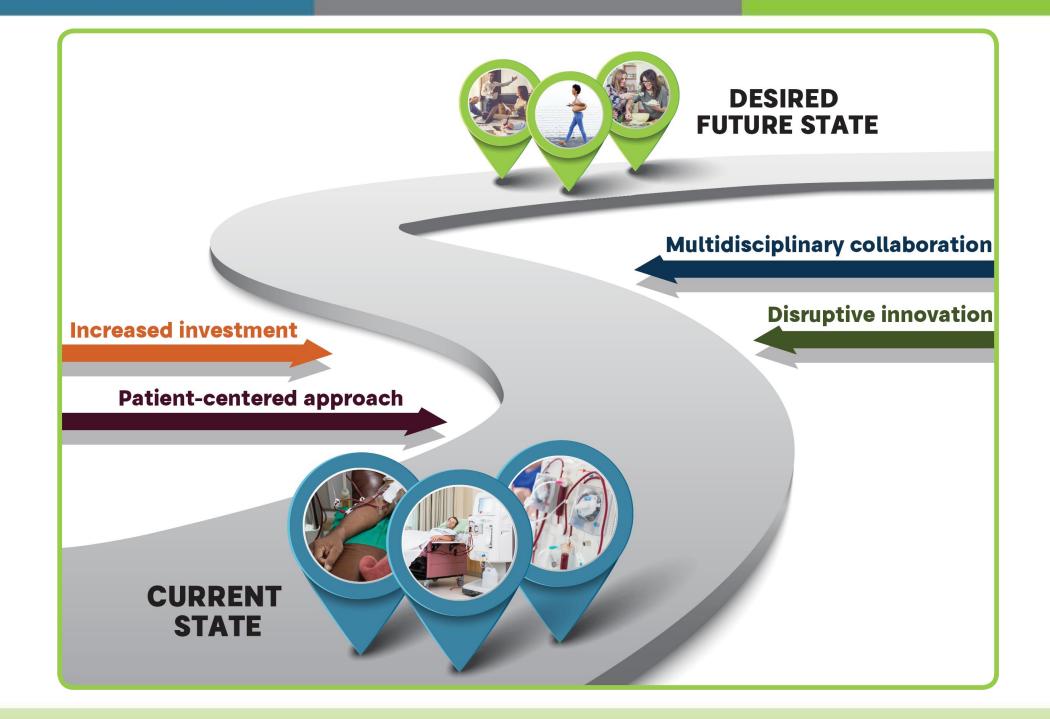
Reduced medication burden



Reduced financial impact

KHI RRT Initiative: Patient-Focused and Collaborative





SOLUTION PATHWAYS



 Encourage incremental improvements to existing dialysis therapy (equipment size, transportability, and volume and blood pressure shifts)



Provide
 alternatives
 to stationary
 treatment
 options



- Develop products that closely mimic normal physiology
- Develop suitable organs for transplantation (e.g., xenotransplantation, chimeras)
- Develop bioengineered kidney



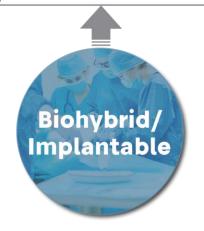
 Restore endogenous biological kidney function

ROADMAP STRATEGY

IMPROVED PATIENT QUALITY OF LIFE









ALL SOLUTIONS MEET MINIMUM DESIGN REQUIREMENTS



KIDNEY FUNCTION

Activities to pursue unique solutions for replicating or replacing each kidney function

SYSTEM ENABLERS

Activities that are broader in scope and serve to connect or integrate a variety of kidney functions or elements of RRT into more comprehensive systems

SUPPORTING ACTIVITIES

Activities that must occur in parallel with the Kidney Functions and System Enablers R&D activities to ensure the accelerated availability of innovative RRT solutions

Innovation at the American Society of Nephrology







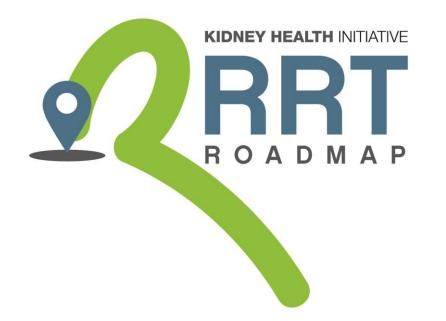




Pre-clinical/clinical

Pre-Competitive/Translational

Commercialization



Learn More: khi.asn-online.org/rrtroadmap

Thank You

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