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

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Kidney Health Initiative
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 patient-centered 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

Pharmaceutical & Biotech Companies

Government Partners

Health Professional Organizations

Patient Organizations

Foundations

Dialysis Providers

Non-Profits

Research Institutes

Device Manufacturers
Celeste Castillo Lee

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

- Clinical Trial Infrastructure & Developing the Evidence Base
- Advancement of Patient & Family Partnership and Funding of Kidney Disease
- Clinical Trial Endpoint and Design
- Biomarker and Pathogenesis Understanding
- Closer Collaboration with FDA and Other Government Agencies
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
  - Data Standards: Solid Organ Transplantation

- **Clinical Trial Endpoints and Design**
  - PK in Patients Receiving CRRT
  - Surrogate Endpoints: IgAN
  - Clinical Trial Endpoints: Vascular Access

- **Clinical Trial Infrastructure & Developing Evidence Base**
  - Outcome Measures: Lupus Nephritis

- **Close Collaboration with FDA and other Government Agencies**
  - Overcoming Barriers to Kidney Health: Barriers and Solutions
  - Regulatory Policies: Hemodiafiltration
  - Regulatory Policies: Central Venous Catheters

- **People Living with Disease as Partners**

- **Clinical Trial Endpoint and Design**
  - Clinical Trial Infrastructure and Developing Evidence Base
  - Regulatory Policies: Hemodiafiltration
  - Close Collaboration with FDA and other Government Agencies
  - Clinical Trial Endpoints and Design
  - Data Standards: Diabetic Kidney Disease
  - Data Standards: Solid Organ Transplantation
  - PK in Patients Receiving CRRT
  - Surrogate Endpoints: IgAN
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- **Clinical Trial Infrastructure & Developing Evidence Base**
  - Outcome Measures: Lupus Nephritis

- **People Living with Disease as Partners**
10 Ongoing Projects: 90% Involve “Patients”

- Fluid Management
- PROMS for Novel Medical Devices
- PROs for Vascular Access
- PROs for Muscle Cramping
- Global ESRD Data Standards
- Surrogate Endpoints: Hyperoxaluria
- Surrogate Endpoints: FSGS
- Overcoming Barriers to Drug Development in Children with CKD
- Roadmap for Innovations in RRT

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

Kolff-Brigham Kidney

2017

Boston Globe

Future

Wearable

Implantable

Repair Kidney
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
Increased investment

Patient-centered approach

Multidisciplinary collaboration

Disruptive innovation

CURRENT STATE

DESIRED FUTURE STATE
SOLUTION PATHWAYS

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

- **Portable/Wearable**
  - Provide alternatives to stationary treatment options

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

- **Regenerated Kidney**
  - Restore endogenous biological kidney function
ROADMAP STRATEGY

IMPROVED PATIENT QUALITY OF LIFE

- Enhanced Dialysis
- Portable/Wearable
- Biohybrid/Implantable
- Regenerated Kidney

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

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