

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

► Zach Cahill

**Kidney Health Initiative**



School of Medicine  
& Health Sciences

THE GEORGE WASHINGTON UNIVERSITY

# 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.



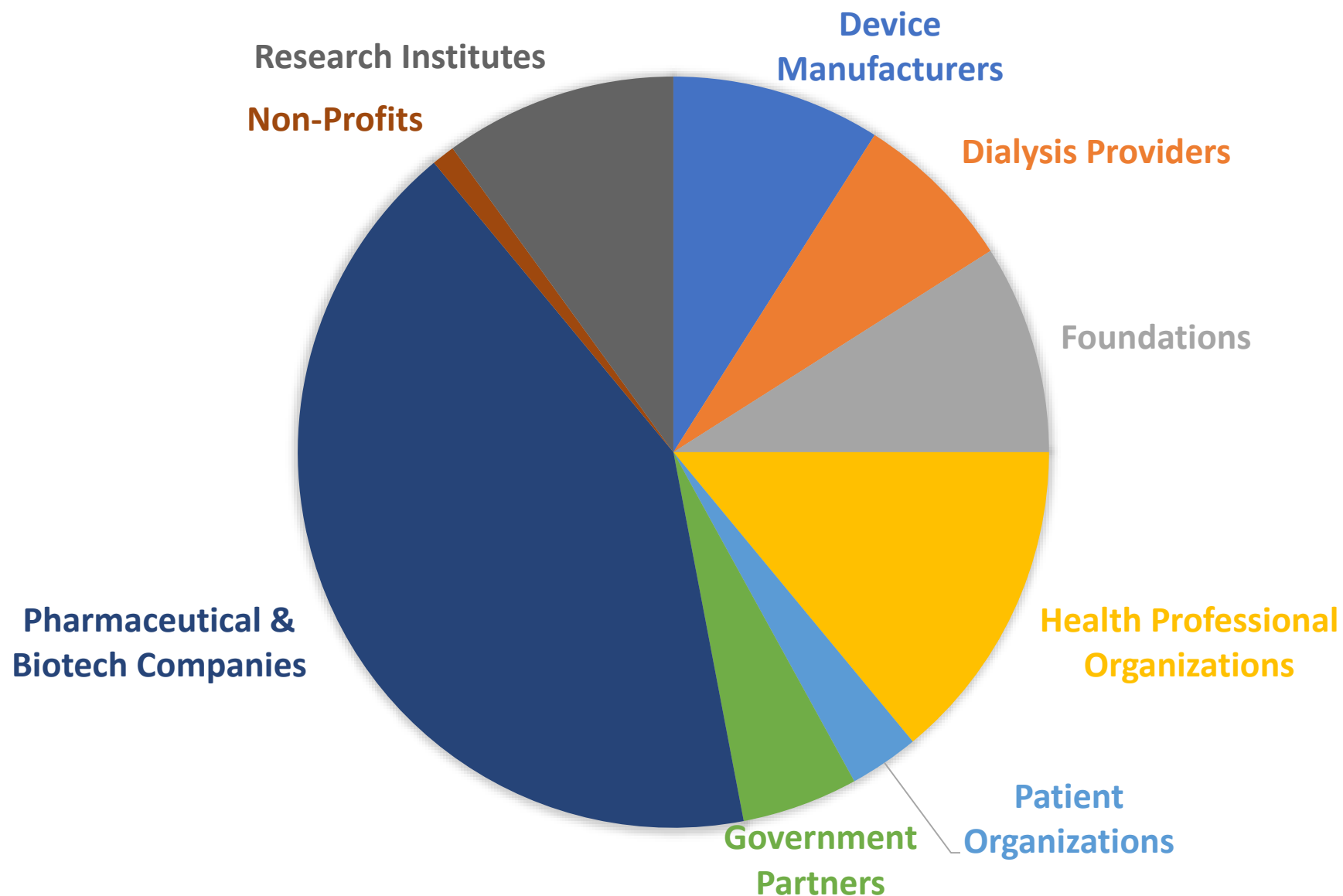
**"As the largest consortium in the kidney community, our members recognize the potential and power of collaboration to address barriers to innovation. Our work is an extension of the expertise of patient organizations, industry, research institutions, the federal government, and others, representing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

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



KIDNEY HEALTH INITIATIVE

# 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



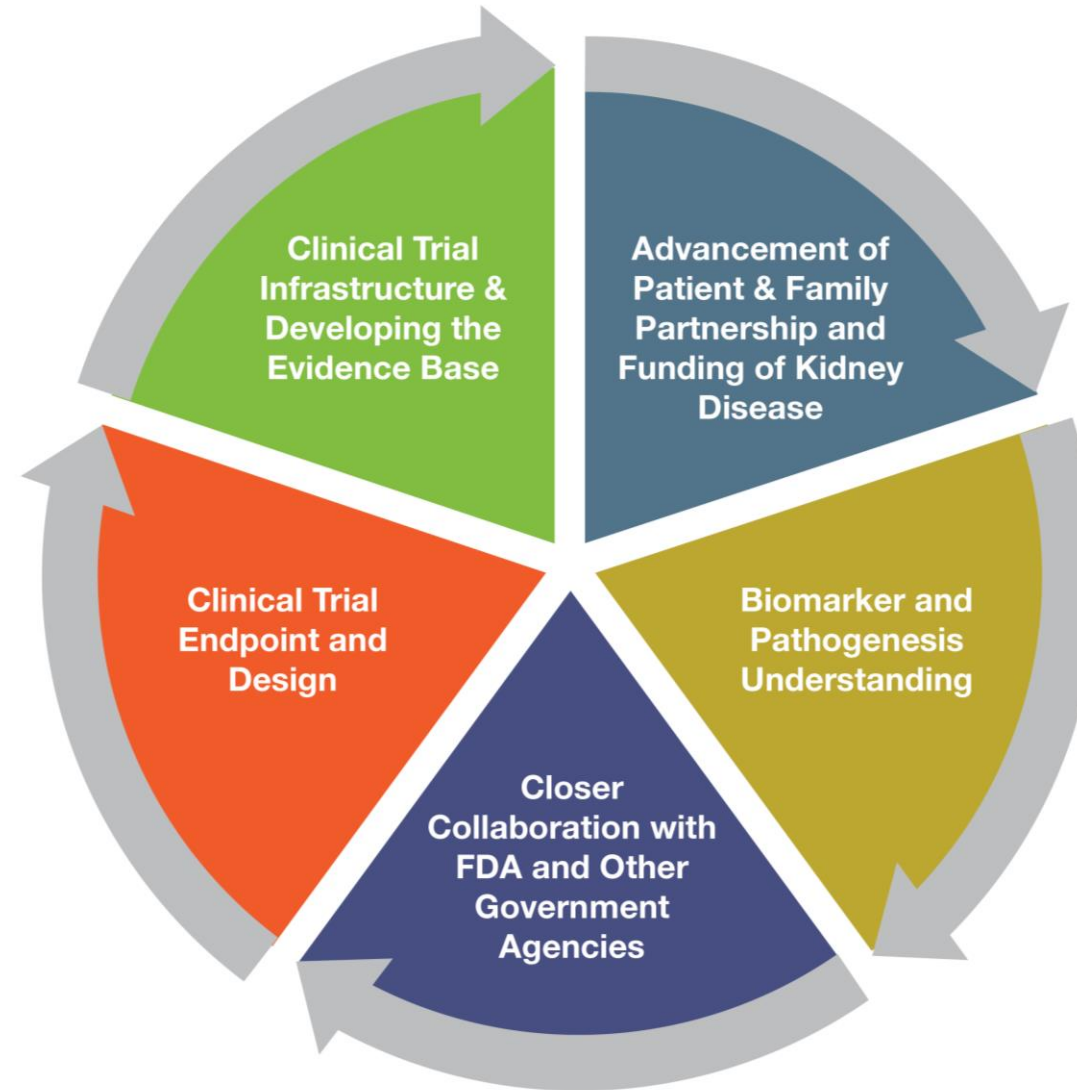


**KIDNEY HEALTH** INITIATIVE

## Patient & Family Partnership Council

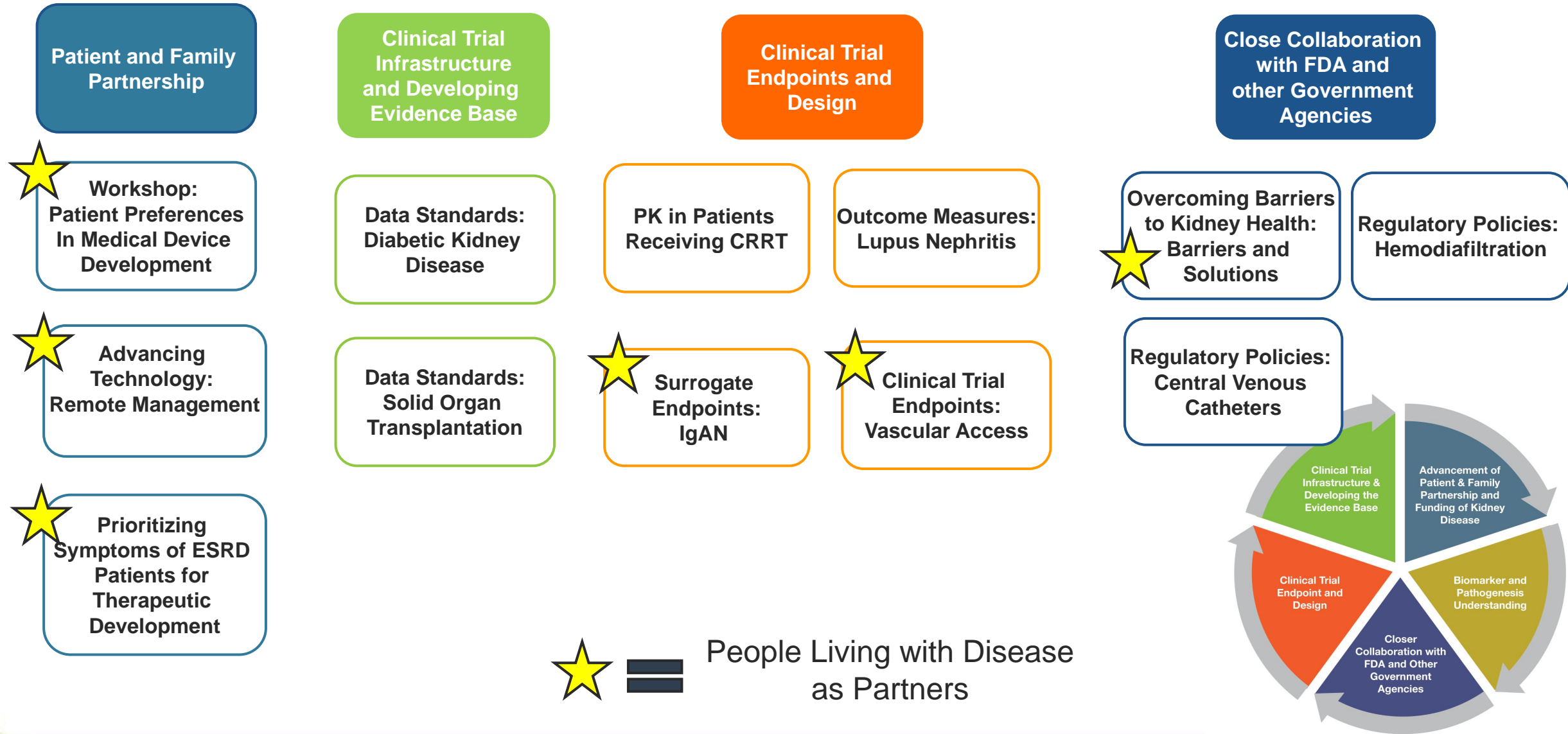


# Strategic Priorities

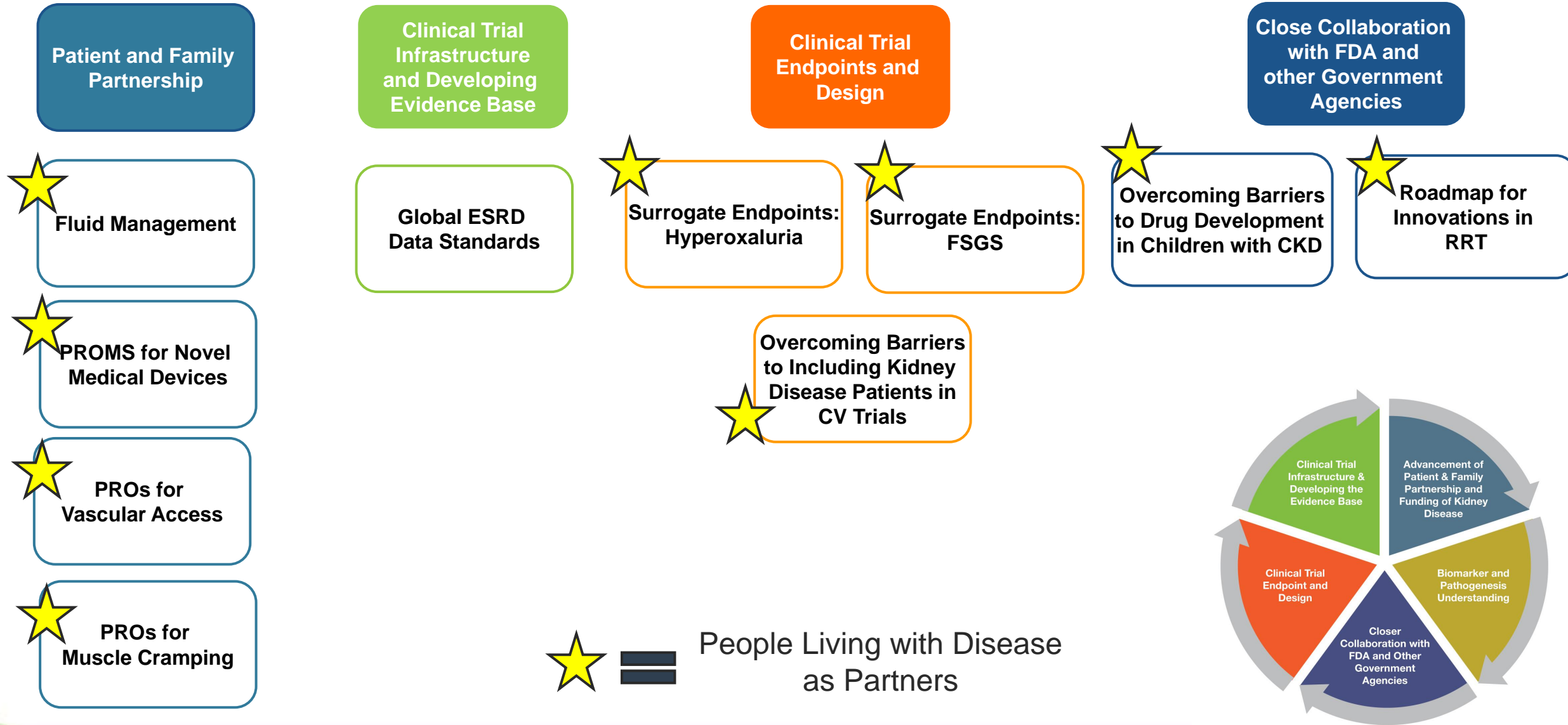




# 13 Completed Projects: 50% with “Patients”



# 10 Ongoing Projects: 90% Involve “Patients”



# 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**

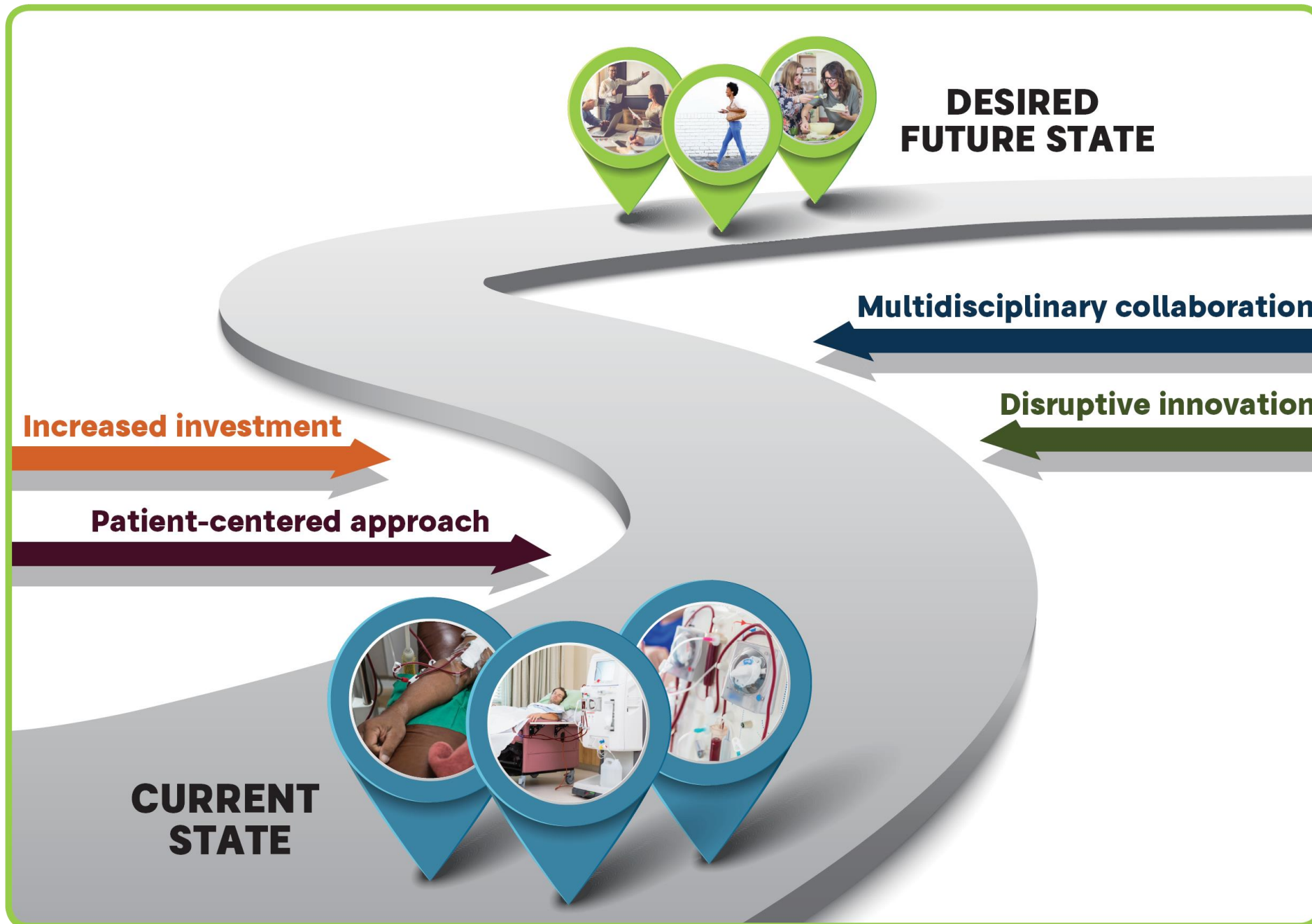


**Reduced financial  
impact**

## **KHI RRT Initiative: Patient-Focused and Collaborative**







# SOLUTION PATHWAYS



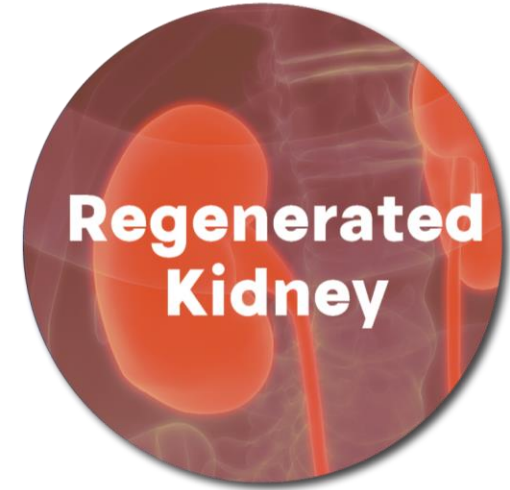
- **Encourage incremental improvements to existing dialysis therapy (equipment size, transportability, and volume and blood pressure shifts)**



- **Provide alternatives to stationary treatment options**

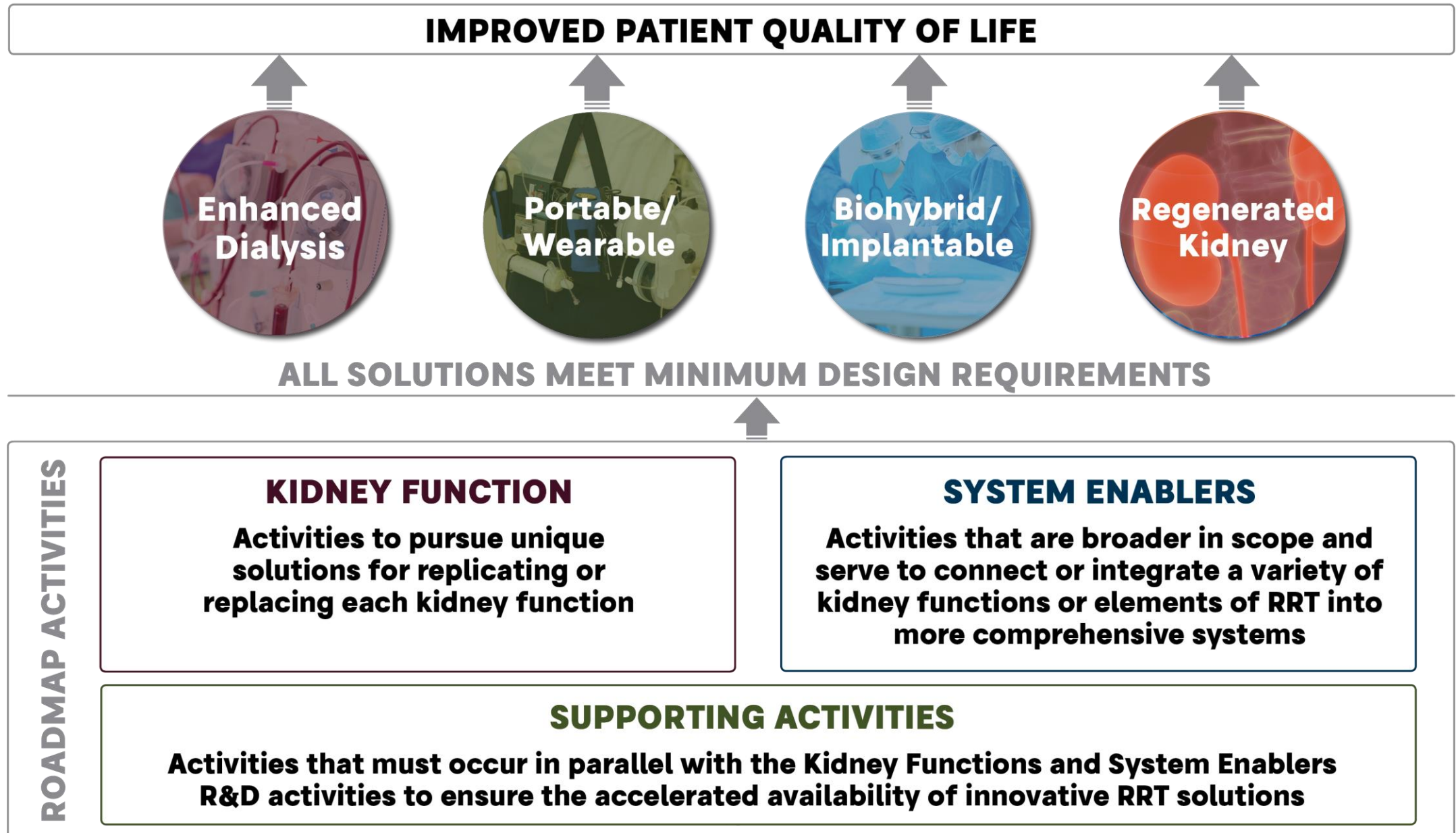


- **Develop products that closely mimic normal physiology**
- **Develop suitable organs for transplantation (e.g., xenotransplantation, chimeras)**
- **Develop bioengineered kidney**



- **Restore endogenous biological kidney function**

# ROADMAP STRATEGY



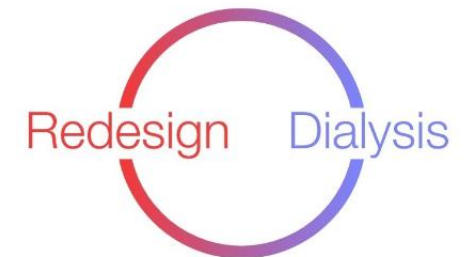
# Innovation at the American Society of Nephrology

ASN Foundation  
for Kidney Research

**Time for a Cure**



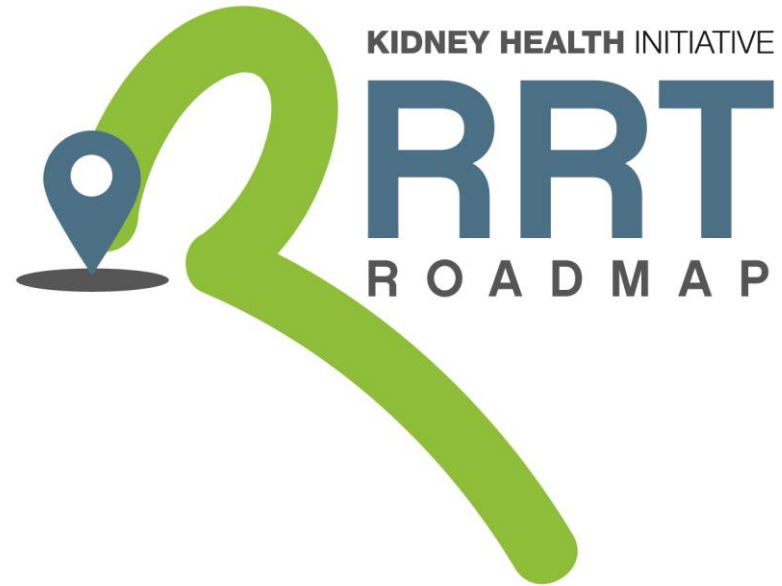
**KIDNEY HEALTH** INITIATIVE



Pre-clinical/clinical

Pre-Competitive/Translational

Commercialization



**Learn More:**  
**[khi.asn-online.org/rrtroadmap](http://khi.asn-online.org/rrtroadmap)**



# Thank You

Zach Cahill

Kidney Health Initiative

[www.kidneyhealthinitiative.org](http://www.kidneyhealthinitiative.org)

[zcahill@asn-online.org](mailto:zcahill@asn-online.org)



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