



2026–2028

**KIDNEY
HEALTH
INITIATIVE**

THREE YEAR STRATEGIC PLAN

**OUR GUIDING
DOCUMENT**



OUR MISSION:

**TO CATALYZE
INNOVATIVE, SAFE,
AND EFFECTIVE
THERAPIES THROUGH
PRE-COMPETITIVE
COLLABORATIONS THAT
IMPROVE THE LIVES OF
PEOPLE WITH AND AT
RISK OF DEVELOPING
KIDNEY DISEASES.**





Dear KHI Community,

I am excited to share KHI's Three-Year Strategic Plan as a three-year framework for priorities outlined by our community, Board of Directors, and Patient and Family Partnership Council. This plan defines the path forward for KHI activities through 2028, rooted in our commitment to innovation, patient-centeredness, and continuous improvement.



Over the next three years, KHI will focus on the following strategic goals:

- 1. Address Regulatory Science Gaps** – Continue guiding the development of innovative prevention and treatments across all stages of kidney health, including those impacting kidney transplant recipients and children with kidney diseases. KHI will help define innovation pathways for safer, patient-centered vascular access, expand pediatric clinical trials, and pursue emerging opportunities in cellular, genetic, and other cutting-edge therapies.
- 2. Strengthen a Patient-Centered Culture to Develop Kidney Innovations** – Continue ensuring that people living with or at risk of developing kidney diseases, their care partners, and their communities shape every step of the innovation development process.
- 3. Implement a Culture of Continuous Improvement in an Expanding Kidney Innovation Ecosystem** – Continue to identify and engage in partnerships that move the whole community forward, whether KHI leads or supports the effort. We will also strengthen how we plan, evaluate, and share progress across all our projects—ensuring our work remains objective, transparent, and aligned with the needs of the broader kidney community.

Since 2012, KHI has remained committed to serving as a neutral convener for the kidney innovator community to advance kidney health. We thank you for your continued partnership and look forward to working together to meet these goals.

Sincerely,

Uptal D. Patel, MD

Chair, KHI Board of Directors

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SECTION 1:

What is the Kidney Health Initiative?

The **Kidney Health Initiative (KHI)** is a public-private partnership among the **American Society of Nephrology (ASN)** and the **U.S. Food and Drug Administration (FDA)**. As a pre-competitive consortium, KHI focuses collaborations that address unmet innovation needs for treating kidney diseases.

KHI brings together a diverse community of leaders—including **patients and their care partners, healthcare professionals, researchers, industry, and regulators**—to collaborate and improve pathways for developing safe and effective therapies for people with, and at risk of developing, kidney diseases.

The consortium works to:

- Identify barriers to research and development in kidney diseases and address **scientific and regulatory pathways** for innovation to overcome these barriers.
- Promote **patient-centered approaches** in designing, developing, and evaluating innovative treatments.
- Facilitate the **development and multisector adoption** of tools, data standards, and endpoints that advance new therapies.
- Further **collaborative efforts** among the kidney community and regulatory agencies.

KHI projects produce resources for the broader kidney innovation community to catalyze the development of drugs, biologics, and devices, such as **clinical trial design, patient engagement, and innovation roadmaps**. All with the goal of improving outcomes and quality of life for people with kidney diseases.

MISSION

To catalyze innovative, safe, and effective therapies through pre-competitive collaborations that improve the lives of people with and at risk of developing kidney diseases.

VISION

A world without kidney diseases.

GUIDING VALUES

- **Collaboration:** Across sectors, constituencies, and disciplines.
- **Equity:** In whom benefits from innovation.
- **Transparency:** In methods, partnerships, and impact.
- **Scientific Rigor:** Grounded in evidence and community alignment.
- **Patient-Centeredness:** Rooted in lived experiences.

SECTION 2:

KHI's Impact Trajectory

KHI accelerates innovations as a neutral and pre-competitive platform that collaborates across all Centers of the FDA. Specifically, KHI:

- **Convenes the breadth of leaders within and beyond the kidney community**—including patients and their care partners, clinicians, researchers, industry, and regulators—to collaborate on solutions.
- **Amplifies patient and care partner voices** to focus kidney innovators on priorities sought by people with kidney diseases.
- **Identifies and reduces barriers** for developing innovative drugs, devices, and biologics therapies for kidney diseases.
- **Develops resources** that advance research and regulatory decision-making such as patient preferences and reported outcome measurements, surrogate endpoint evaluations, and technology and collaboration roadmaps.

KHI bridges patient needs, scientific discovery, and product development to increase the number of patient-centered kidney health innovations.

Through this community, KHI:

- **Leads projects** that direct and communicates consensus by, and for, the kidney community through widely shared resources.
- **Leads focused discussions** that define pre-competitive challenges to frame, communicate, and pursue collaborative solutions.
- **Pursues partnerships** with strategically aligned organizations to produce a unique resource created with expertise and perspectives of a broader community.
- **Supports collaborations** led by other kidney-focused organizations through the sharing of KHI's infrastructure and expert communities.
- **Monitors** an expanding kidney innovation community to report progress or evaluate opportunities where KHI and others can further collaborations.

SECTION 3:

Strategic Goals

KHI's three-year strategic plan advances the consortium's mission in response to the evolving needs of its members and the broader kidney community. This plan is guided by three strategic goals across KHI's projects and initiatives, as identified by KHI's Board of Directors (BOD) and Patient and Family Partnership Council (PFPC), and in collaboration with *ex-officio* liaisons from the federal government and ASN leadership.

This Strategic Plan is used by the BOD and PFPC to:

- Align goals and objectives of projects and activities within a portfolio that balances efforts pursued by the PFPC and the BOD's Biologics, Drugs, Devices, and Strategy Committees.
- Forecast and track resources committed to each KHI activity and project.
- Monitor and evaluate activities, projects, and portfolio against KHI's strategy.
- Structure BOD and PFPC decision-making within an evolving innovation ecosystem, including opportunities to adjust goals, objectives, and strategy.

Starting in 2023, the BOD established annual objectives that shaped KHI's direction. These have been expanded as the following strategic framework for all KHI activities in 2025-2028.

1. Accelerate innovations in kidney therapeutics and devices pursued across the entire ecosystem, from research institutions and start-ups to global organizations and companies.
2. Embed patient and community voices throughout innovation pathways to ensure deliverables reflect the totality of key perspectives.
3. Ensure KHI's Guiding Values are implemented within a culture of continuous improvement for internal decision-making and operational processes as well as community-focused activities, projects, and partnerships.

By December 31, 2028, KHI will have:

1. Advanced patient-centered culture by integrating patient and care partner perspectives within design, development, and evaluation of innovations.
2. Clarified clinical trial pathways through: evaluations of proposed surrogate endpoints, tools that support the design and conduct of pediatric clinical trials, and collaboration roadmaps that reduce barriers to developing kidney therapies.
3. Advanced collaborative projects in partnership with, or led by, other strategically aligned kidney organizations.
4. Served as a neutral platform that defines and addresses shared challenges within an evolving kidney innovation ecosystem.

GOAL 1: Address Regulatory Science Gaps

- Guide the development of innovative prevention and treatment options across all ages and all stages of kidney health, including transplant.
- Define innovation pathways that catalyze development of patient-centered and safer vascular access.
- Strengthen prioritization, design, and conduct of pediatric kidney clinical trials.
- Consider, evaluate, and pursue emerging opportunities in cellular, genetic, and other innovative therapies for kidney health.

By December 31, 2026, KHI will have:

1. Published a proposed baseline framework for nephroprotection in sickle cell kidney disease, based on consensus from analyzing literature and data, in partnership with the American Society of Hematology.
2. Published a vision for a collaborative framework that evaluates the potential of adult data extrapolation in simplifying clinical trials for pediatric kidney diseases.
3. Communicated clinical trial priorities to advance treatments for children with kidney diseases.
4. Clarified an innovation pathway for safer vascular access by:
 1. Standardizing definitions of safety issues and severity of cannulation complications.
 2. Summarizing potential clinical trial endpoints and patient reported outcomes (PROs) for vascular access.
 3. Guiding the development of patient-focused technology innovations that impart safer vascular access.
5. Convened the kidney community in the annual Kidney Innovation Conference to discuss and pursue collaborations.

By December 31, 2027, KHI will have:

1. Continued communicating the results of KHI's on-going projects.
2. Completed due diligence on a project that evaluates potential surrogate endpoints with non-published data.
3. Conducted a workshop that supports entrepreneurs pursuing innovative kidney drugs, devices, or biologics treatments.
4. Hosted a summit to address a cross-cutting issue for advancing kidney innovations, as identified by the BOD and/or PFPC.
5. Published a KHI perspective on the evolving kidney innovation ecosystem.

By December 31, 2028, KHI will have:

1. Continued communicating the results of KHI's on-going projects.
2. Evaluated KHI's impact on catalyzing innovations to guide the strategic plan for 2029 to 2031.

GOAL 2: Strengthen a Patient-Centered Culture to Develop Kidney Innovations

- Develop resources that strengthen engagement of patients and care partners with innovators developing patient-centered biologics, devices, and drugs.
- Increase patient participation in kidney clinical trials through resources that inform kidney patient advocacy organizations, families and care partners, and people with kidney diseases.

By December 31, 2026, KHI will have:

1. Published a practical guide to assist families in making informed decisions about participating in a pediatric kidney clinical trial.
2. Published resources for patients and care partners considering xenotransplant clinical trials, in partnership with the National Kidney Foundation.
3. Monitored adoption successes and challenges of KHI's APOL1 Kidney Disease Roadmap, in partnership with the American Kidney Fund.
4. Developed a patient engagement toolkit for the development of genetic kidney diseases therapeutics for industry partners.
5. Communicated quality of life considerations within the design, development, and evaluation of novel immunosuppression agents for kidney transplant recipients.

By December 31, 2027, KHI will have:

1. Created a facilitation template for communication between industry partners and patients.
2. Published a list of prioritized Patient Reported Outcome measurements that can be developed into a tool that advances safer vascular access technologies.

By December 31, 2028, KHI will have:

1. Published a perspective on patient engagement in developing kidney innovations.
2. Expanded the patient engagement toolkit beyond genetic kidney diseases.

GOAL 3: Implement a Culture of Continuous Improvement in an Expanding Kidney Innovation Ecosystem

- Identify opportunities for collaborations within an evolving kidney innovation ecosystem through engagement within and external to KHI's community.
 - › Determine if KHI leads these collaborations or pursues a partnership or supporting role with a complementary organization.
 - › Pursue opportunities that integrate expertise from outside of the kidney community into KHI's activities and projects.
- Establish each KHI activity and project with an evaluation framework, including timelines and deliverables.
- Ensure objectivity and transparency in KHI's governance, decision-making, activities, and projects.
- Communicate to the kidney community on progress towards KHI goals through updates and evaluations of projects and activities.
- Communicate lessons-learned from KHI's strategies, goals, projects, activities, and operational processes to advance other strategically aligned organizations.

By December 31, 2028, KHI will have:

1. Piloted, improved, and established operational, governance, and engagement process that address Goal 3 throughout all internal and external activities.



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