

2025

Annual Report



The Kidney Health Initiative (KHI) is a public-private partnership among the American Society of Nephrology (ASN), the US Food and Drug Administration (FDA), and over 70 member companies and organizations.

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.

Our 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.

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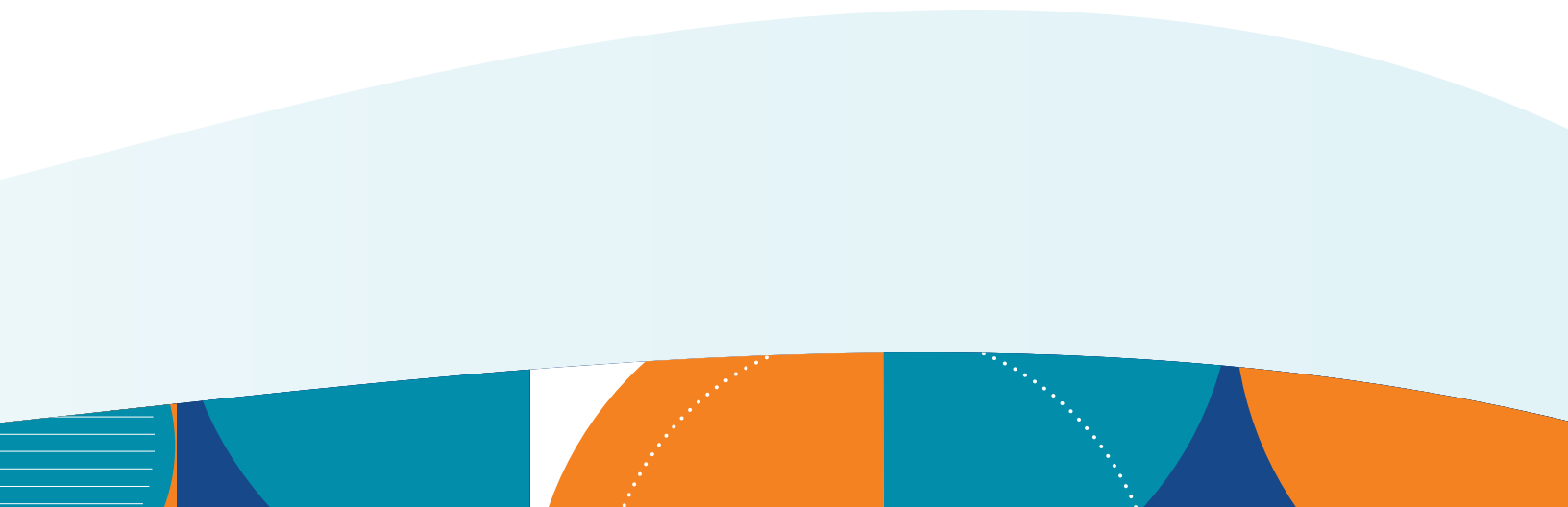
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Message from the Chair of KHI's Board of Directors

This year was an inflection point for the Kidney Health Initiative (KHI) that ended with a confident trajectory for its future. In addition to the projects and events described in this Annual Report, I am very proud that KHI's leadership also produced its first-ever *Three-Year Strategic Plan* for 2026–2028. This plan reiterates KHI's mission to catalyze safe, effective, and patient-centered therapies through pre-competitive collaborations. And by articulating KHI's mission, vision, and guiding values, this plan translates them into three strategic goals: addressing regulatory science gaps, strengthening a patient-centered culture, and implementing a culture of continuous improvement.



This plan was developed by the Board of Directors and the lived experiences and expertise of the Patient and Family Partnership Council, building on recent years of setting annual objectives. To build a forward-looking vision that communicates KHI's ambition and holds us accountable to the community, we assessed where KHI has made the greatest impact, where persistent regulatory and scientific gaps remain, and how effectively KHI integrates patient perspectives into innovation. These opportunities were also explored in context of the exciting collaborations that have emerged with other strategically aligned organizations.

KHI's strength lies in the leadership of the kidney innovation community to leverage a pre-competitive consortium that implements ASN's partnership with the FDA. Through this Strategic Plan, KHI will continue identifying where collective action has the greatest impact by addressing specific gaps, widely sharing resources, framing critical pre-competitive challenges, pursuing strategic partnerships, and monitoring progress across the kidney innovation ecosystem.

This Strategic Plan is a vision set in 2025 and KHI's leadership will regularly evaluate progress, assess emerging opportunities, and adjust priorities that ensure the continued pipeline of innovations that span biologics, devices, and drug development for people with kidney diseases.

On behalf of the Board of Directors, I remain deeply grateful to the patients, care partners, clinicians, researchers, industry leaders, government liaisons, and staff whose dedication made our 2025 achievements a reality. As I end my term as Chair of KHI's Board of Directors, I welcome the incoming Chair, Jerome A. Rossert, MD, PhD. I am confident that KHI is well-positioned to accelerate innovation and move closer to a world without kidney diseases under his leadership.

Sincerely,

Uptal D. Patel, MD

Chair, Board of Directors

Kidney Health Initiative

Message from the Chair of KHI's Patient and Family Partnership Council

As we look forward to 2026, I acknowledge the significant progress made by KHI's Patient and Family Partnership Council (PFPC) in advancing our vision and mission throughout the year. 2025 proved to be exceptional for the PFPC as we focused on enhancing our patient-centered approach. To achieve our objectives and ensure our goals were quantifiable in generating solutions, Vice Chair Thelma Barber and I encouraged PFPC members to collaborate as a cohesive team. The Council modified our initiatives and priorities as needed, recognizing that our environment is characterized by continuous change. We invited members to share their aspirations, ideas, and plans. We encouraged them to extend their reach beyond the PFPC and ensure our voices resonated widely. It was rewarding to witness the successful execution of this vision through the various events and projects undertaken and managed by the PFPC.



We have progressed with our Patient Engagement Project, continuing our objectives to create guidance for innovators on how to involve patients and care partners, as well as to incorporate their insights into the development of new therapies for genetic kidney diseases. Our efforts aim to showcase how patients and care partners can significantly impact the design of effective and safe products. The PFPC is equipped to outline models for integrating patient voices throughout the development and clinical trial process with examples and resources for patient engagement. We extend our gratitude to the initiator of this project, Jack Lennon, MBA, who transformed a roundtable discussion into a comprehensive initiative. With his term for the PFPC now concluded, we express our appreciation to Lisa Bonebrake for stepping into a leadership role and are confident that her dedicated efforts will help us achieve our impact.

PFPC members Precious McCowan, PhD, MS, Sejal R. Patel, MD, FASN, and Seferiana Day, MSW, also spearheaded a new project focused on immunosuppressant drugs and their effects on kidney transplant recipients' quality of life. It is essential to identify the priorities of patients and their care partners regarding immunosuppression so that innovators improve future medicines. Additionally, they outline the role of patients and care partners in fostering innovation. Although the project is still in its infancy, they were successful in proposing a session that was approved for the American Transplant Congress 2026 in Boston, MA. PFPC members also played an active role in the 2025 Kidney Innovation Conference. Kelly Helm, MEd, moderated the patient-centered panel "The Significance of Patient-Centricity in Innovation", with Bonebrake contributing as a panelist and patient representative. Barber and Austin Lee, also facilitated the PFPC breakout session, "Increasing a Culture of Patient Engagement".

The PFPC contributed significantly to the KHI Three-Year Strategic Plan, ensuring that KHI continues to incorporate patients and care partners in every stage of biologics, drug, and device development. The PFPC contributed insights with a goal of creating a patient-centered culture of innovation.

The PFPC will implement strategies that build on the successes of 2025. The PFPC has an optimistic outlook beyond 2026, kicking off with an internal strategy meeting to identify priorities and establish goals that represent all perspectives. Throughout the year, we will continue to fulfill PFPC's mission and achieve the goals in the Strategic Plan. This includes advancing kidney innovation, enhancing and raising awareness about kidney health.

While we miss members whose terms have ended, we are enthusiastic about the new members coming in and carving out their own paths. The vision is bright, and the PFPC is eager to continue its growth.

Sincerely,

Curtis H. Warfield, MS

Chair, Patient and Family Partnership Council
Kidney Health Initiative

2025 Kidney Health Initiative Impact

This report marks an evolution for KHI and moving forward, our annual reporting will reflect a more strategic focus as we continue serving the kidney innovation community.

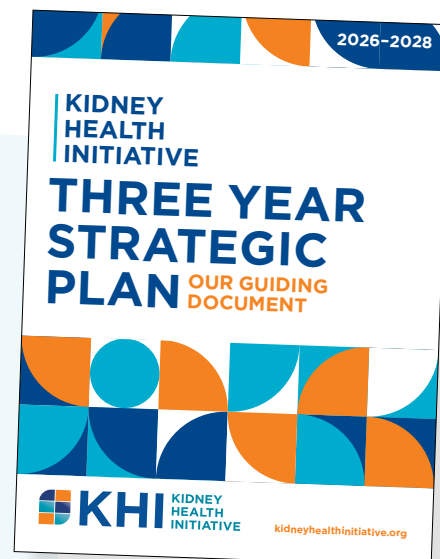
After thirteen years as the only pre-competitive kidney consortium that works across FDA's Biologics, Devices, and Drug portfolios, the Board of Directors recognized that KHI's model from 2012 needed to be updated. The past few years have witnessed the beginnings of numerous kidney innovation pipelines within organizations strategically aligned to KHI. However, there remain infinite opportunities where collaborations have yet been formed to address unmet therapeutic needs.

To ensure KHI continues catalyzing innovations for people with kidney diseases, KHI updated its form and function. Starting with a governance change in 2023 and throughout Uptal D. Patel, MD's leadership, the Board of Directors reorganized its oversight to focus on the needs of the kidney biologics, devices, and drug development communities. Under Curtis Warfield, MS, and Thelma Barber's leadership, the PFPC continued to align its value proposition to ASN's unique partnership with FDA and the KHI community in 2025.

In 2023, KHI's leadership also established its first annual objectives, clearly outlining the initiatives the organization would prioritize in 2024. Progress against those objectives were evaluated to shape Objectives for 2025, which were shared during the Townhall at the 2025 Kidney Innovation Conference and framed this Annual Report. Beyond focusing KHI's leadership on 2025 Objectives, KHI's Board of Directors and PFPC looked further at a vision to 2028. This is described in KHI's first-ever Strategic Plan, which also describes how KHI will continue leveraging collaborations within the community to achieve these ambitions. This Strategic Plan becomes the focus of KHI's leadership and ambitions through 2028, framing KHI's priorities in its activities, meetings, and projects starting in 2026.

Next year's Annual Strategic Report will be an update of progress and lessons learned as KHI focuses on making the Strategic Plan a reality.

Click or scan the QR code to download KHI's full Three-Year Strategic Plan and learn more about the priorities guiding our work through 2028.



2025 Highlights

In addition to finalizing the Strategic Plan, the Kidney Health Initiative continued to advance a mission of catalyzing innovative, safe, and effective therapies through pre-competitive collaborations that improve the lives of people with and at risk of developing kidney diseases. In 2025, KHI's objectives focused on the following:

1. Convene and communicate a culture of innovation.

• Kidney Innovation Conference

KHI hosted the Kidney Innovation Conference in May 2025 in Washington, DC, with over 170 attendees representing the kidney innovator ecosystem. The agenda featured engaging sessions and panelists, keynote remarks from Robert Montgomery, MD, PhD, of NYU Langone Transplant Institute, workshops that obtained deeper insights on KHI's APOL1 Kidney Disease Roadmap and opportunities for Pediatric Data Extrapolation, with networking opportunities that fostered a collaborative environment for industry, patients, care partners, federal liaisons, and providers.

• Connect with KHI at the ASN Communities Lounge

In November 2025, KHI convened the community at ASN Kidney Week in Houston, Texas, to meet KHI's leadership and staff, and launch the Strategic Plan. This event was an opportunity to network, discuss ongoing projects and initiatives, and gather initial feedback and reactions to the plan.

• Connect with KHI's Leadership

KHI hosted two virtual mixers that provided opportunities to meet leaders of the Board of Directors and PFPC. Attendees were introduced to new members, learned about ongoing initiatives within KHI's biologics, devices, and drug development portfolios, and discussed patient engagement.

2. Support design and conduct of clinical trials and 3. Address innovation opportunities for pediatric kidney populations and people with kidney transplants.

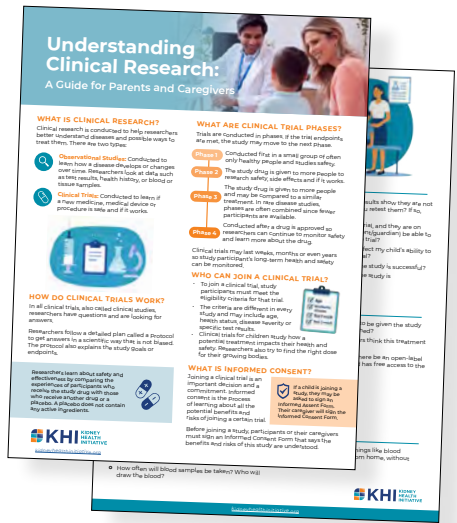
KHI hosted several in-person and virtual events to engage the community on clinical trial design and conduct in both pediatric and adult populations.

More than 50 experts from pediatric nephrology, industry, patient advocacy, biomarker research, and government came together at the Kidney Innovation Conference for a workshop on extrapolating adult data to streamline pediatric clinical trials. This alignment is described in two publications describing how extrapolation of adult data could simplify pediatric trials, including [*The Use of Extrapolation to Promote Clinical Trials in Pediatric Nephrology*](#) in the Journal of the American Society of Nephrology.

In collaboration with the American Kidney Fund, KHI convened a series of topical roundtables that brought together key community members responsible for implementing the KHI APOL1 Kidney Disease Roadmap. These discussions focused on identifying which roadmap action items require additional resources or enhanced cross-sector collaboration to effectively address community needs. Insights from the virtual roundtables informed an in-person workshop at the Kidney Innovation Conference, where patients, industry representatives, and clinicians gathered to build connections and align priorities. As a result of these engagements, new partnerships emerged to expand patient education efforts related to genetic testing.

KHI published a new brochure, *Understanding Clinical Research: A Guide for Parents and Caregivers* and shared updates on its pediatric projects with the community at an October 2025 virtual mixer, Empowering Families in Pediatric Clinical Trials: Questions, Impact, and Action. KHI Board of Directors, PFPC members, and experts led the ASN Kidney Week session Upping Our Game: Advances in Clinical Trials for Pediatric Kidney Diseases.

Adult clinical trial endpoint projects were highlighted in two virtual mixers - Advancing Proteinuria as an Endpoint in FSGS (March 2025) and KHI Project Spotlight: Endpoints for C3G and What's Next (June 2025). The results of the former project, *Proteinuria as an End Point in Clinical Trials of Focal Segmental Glomerulosclerosis*, were published in May 2025.



2025 New KHI Member Organizations

CKDi

The **Center for Kidney Disease Innovation (CKDi)** is a multidisciplinary translational research center at the Icahn School of Medicine at Mount Sinai focused on advancing innovative treatments for kidney disease through discovery science, patient engagement, and clinical trials.



Droice Labs collaborates with healthcare providers, pharmaceutical companies, research institutions, hospital IT solution providers, and key stakeholders across the healthcare ecosystem.

GlomCon

The **GlomCon Foundation** is a mission-driven organization that brings together knowledge, tools, and community to support nephrologists and care teams in improving outcomes for people living with glomerular and other rare kidney diseases.



Judo Bio is pioneering kidney-targeted oligonucleotide medicines, unlocking new treatment options for systemic and renal diseases.



Memo Therapeutics, Inc. develops best-in-class therapeutic antibodies inspired by the natural immunity of elite responders to treat viral infections and cancer.



Renibus Therapeutics is a clinical-stage biopharmaceutical company focused on improving and extending patients' lives through therapies for cardio-renal-metabolic diseases.



SeaStar Medical develops organ-saving therapies to protect critically ill patients from the damaging effects of a cytokine storm.



Trestle Biotherapeutics is a biotechnology company developing bioengineered, implantable therapies for kidney disease. Using advances in stem cell biology and 3D bioprinting, the company aims to help patients with end-stage renal disease reduce reliance on dialysis and delay transplantation, with the goal of improving outcomes for people living with kidney failure.

Member Organizations

Device Manufacturers, Diagnostics, and Digital Health Companies



Foundations and Patient Organizations



Health Care Professional Organizations



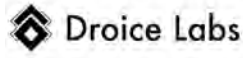
Kidney Care and Dialysis Providers



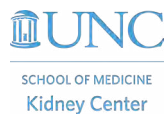
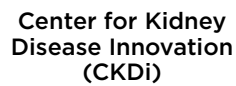
Non-Profit Organizations



Pharmaceutical and Biotechnology Companies



Research Institutions



Federal Partner



Catalyzing Drug Development

The KHI Drug Committee had a highly productive year in 2025, marked by meaningful progress across several pediatric-focused efforts and the launch of new work that will shape the committee's priorities moving forward.

This year, the committee successfully closed out several important projects centered on advancing pediatric kidney disease research. These included work on pediatric IgA nephropathy, the identification of pediatric research priorities, and the development of Pediatric Clinical Trials Guides. Collectively, these efforts reflect the committee's continued commitment to addressing gaps in evidence generation for children with kidney diseases and to supporting patients, families, and researchers with practical, patient-centered resources.

In parallel, 2025 marked the conception of a new Acute Kidney Injury (AKI) project, focused on reevaluating and reviewing the clinical trial endpoints currently used in AKI studies. Through early discussions and community engagement, the committee identified a clear need to better understand whether existing endpoints meaningfully capture patient outcomes and disease complexity, laying the groundwork for deeper exploration in the coming year.

Looking ahead to 2026, the Drug Committee will build on this momentum as we begin implementing KHI's Strategic Plan. A key milestone will be an in-person AKI workshop to examine endpoint selection and opportunities to advance innovation in AKI drug development. In addition, the committee will use insights from this work, and from the Strategic Plan, to identify and prioritize future initiatives that align with KHI's mission and evolving needs across the kidney health ecosystem.

I am grateful to the Drug Committee members, project leads, and collaborators for their dedication and thoughtful engagement throughout the year. I look forward to continuing this important work together as we move into 2026.

Sincerely,

Steven K. Burke, MD

Chair, KHI Board of Directors Drug Committee





COMPLETED PROJECTS

✔ Clinical Trials in Pediatric Patients with IgA Nephropathy (IgAN)

In recent years, there has been a dramatic increase in drug development for treating IgAN; however, clinical trials are largely being conducted in adults. At this time, it is not clear whether the efficacy and safety of these treatments should also be assessed in children with IgAN, and, if so, how best to design studies to obtain the data needed to support use of novel therapies in this population. In 2025, KHI submitted a manuscript based on a working group that summarizes their findings with a call to action. A publication will be shared in 2026.

✔ Pediatric Clinical Trials: Making Them Family Centric

Following a workshop co-led with NephCure on *SGLT2 inhibitors, a Pediatric Workshop* in 2023 and a KHI-sponsored session at ASN Kidney Week 2023, key gaps were identified in educating families about clinical trial participation. In response, KHI completed a project by doing the following:

- Published a comprehensive resource guide for parents and care partners to support pediatric clinical trial enrollment.
- Conducted a focus group to address industry challenges in clinical trial protocol analysis.
- Led a virtual mixer showcasing successes and gaps in pediatric clinical trial enrollment.

✔ Pediatric Research Priorities Survey

Each year, new drugs, biologics, and devices are evaluated for safety and efficacy primarily in adults, with limited clinical trials in pediatric populations. In 2025, KHI surveyed pediatric nephrologists and found that the top two recommendations were to further research on pediatric indications for SGLT2 inhibitors and hemodialysis devices. To read the full report [visit](#).



NEW PROJECTS

💡 Clinical Trials Innovation in Cardiac Surgery-Associated AKI

AKI is a major complication in acutely ill, hospitalized patients and those undergoing cardiac surgery requiring cardiopulmonary bypass. Progress in therapeutic development is hampered by a lack of agreed upon biomarkers, intermediate, surrogate, and clinical endpoints. In 2026, KHI will conduct a workshop to convene key partners to identify promising trial endpoints in phase 2 proof of concept and phase 3 clinical trials.

Catalyzing Device Development

In 2025, KHI strengthened its role in advancing kidney-focused medical device innovation by focusing on community alignment, structured engagement, and the development of shared priorities to support long-term progress. These efforts emphasized building collaborative infrastructure that brings together regulators, industry leaders, clinicians, and patients to address foundational challenges in device development and evaluation.



Building on the outcomes of the 2024 Dialysis Access Workshop, which demonstrated the need for a dedicated KHI initiative focused specifically on patient-centered vascular access innovation, KHI launched the Catalyzing Patient-Centered Vascular Access Innovations Project in 2025. This initiative represents a targeted response to identified gaps and creates a structured forum to advance consensus-building and address unmet needs in this critical area.

Through engagement with regulators, industry representatives, clinicians, and patients, the project has begun aligning the community around scope, terminology, and priority needs related to vascular access for patients. Patient and care partner perspectives remain central to the work, ensuring that lived experiences inform discussions on device design, evaluation, and future innovation pathways. This foundational phase establishes the groundwork for defined outputs and expanded activities in subsequent years.

In 2026, the Devices Committee will expand and deepen this work by advancing the project into its next phase. Key priorities include convening the kidney community to develop standard definitions for adverse safety events to improve consistency in clinical evaluation and regulatory considerations. The portfolio will also explore pathways to support and accelerate innovation in kidney devices development, translating community alignment into actionable strategies. These efforts will align with KHI's Three-year Strategic Plan and position the organization to address critical gaps in vascular access and related technologies.

My sincere appreciation to the Devices Committee members, work group participants, and all collaborators who contributed their expertise, time, and insight to this meaningful project. Their engagement and partnership have been essential to advancing this important work, and I look forward to continuing it in 2026.

Sincerely,

Vandana Dua Niyyar, MD, FASN

Chair, KHI Board of Directors Devices Committee

Catalyzing Biologics Development

2025 was a productive year for the KHI Biologics Committee. We had a clear focus on advancing key initiatives in Sickle Cell Kidney Disease (SCKD), xenotransplantation, and kidney transplantation immunosuppression. Through the execution of these projects, we engaged critical cross-functional and cross-specialty collaborations promoting patient driven innovation to shape the future of kidney research.

Much of the output of these projects will be delivered in 2026, including the SCKD Systematic Literature Review, the American Society of Hematology's Research Collaborative Data Hub's data analysis, and the Xenotransplantation Patient FAQ. The project plan to evaluate endpoints for clinical trials of new immunosuppressants for kidney transplant recipients will also be finalized. The committee continued to demonstrate a clear commitment to addressing both emerging challenges and ongoing concerns in the field while making an impact for the kidney community.

Looking ahead and beyond 2026, the committee will set the stage for exploring clinical/regulatory pathways for genetic and cell therapy focused on kidney diseases while socializing with our patient base the innovation and science in the progress of the renal cell atlas.

Sincerely,

Alain Romero, PharmD, PhD

Chair, KHI Board of Directors Biologics Committee



CONTINUING PROJECTS

In 2025, KHI focused on two projects that included partnerships as a core component.

✔ Sickle Cell in Kidney Disease: Natural History and Clinical Endpoints

In partnership with the American Society of Hematology's Research Collaborative, KHI led a project to develop a framework for regulatory pathways by characterizing the natural history of SCKD and identifying biomarkers and endpoints for sickle cell disease patients at high risk of kidney disease. KHI expects to publish the results of the project in 2026.

✔ Kidney Xenotransplantation

Previous projects led by KHI and National Kidney Foundation (NKF) highlighted the need for patient and care partner information to guide their decisions on participating in clinical trials for kidney xenotransplantation. KHI hosted a project with NKF and liaisons from the FDA Center for Biologics Evaluation and Research to develop resources that promote understanding and communication about clinical trials for kidney xenotransplantation for patients, care partners, and healthcare teams. The FAQ will be finalized and disseminated in 2026.

Acknowledgments

Thank you to the Board of Directors, Project Workgroup Chairs, and the Patient and Family Partnership Council for making this work possible.

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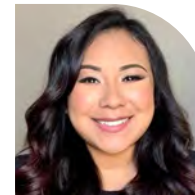
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