



KIDNEY HEALTH INITIATIVE

Kidney Health Initiative Receives Second Round of Proposals

Nearing its two-year anniversary this September, the Kidney Health Initiative (KHI) continues to make advances toward fulfilling its mission of encouraging innovation and patient safety in kidney disease through its collaborative partnership between the FDA and the kidney community.

The Kidney Health Initiative held its Second Annual Stakeholders Meeting in June in Bethesda, MD. The annual meeting brought together its diverse membership from the kidney community, connecting members across different fields and allowing them to share ideas, discuss ongoing projects, collect feedback, and collaborate on new projects. Of the more than 100 U.S. and international attendees, nearly a third represented FDA and government agencies, a third were affiliated with industry, and a third represented patients and health-care professionals.

Mark McClellan, MD, PhD, provided his perspective during the opening session on the intersection between incentives and innovation in the context of the unique infrastructure that has evolved around the management of kidney disease in the United States. Dr. McClellan currently serves as the senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution, and his presentation drew from his wealth of experience in this area from his time as FDA Commissioner and CMS Administrator.

Following Dr. McClellan's presentation, small group breakout sessions allowed members to review current KHI projects and provide feedback to authors of project proposals in interactive and engaging presentations. In order to review the meeting's entire agenda please visit KHI's meeting page online at www.kidneyhealthinitiative.org.

As a member-driven initiative, KHI seeks to meet its mission and objectives through the completion of various projects proposed by members across all areas of the kidney community. KHI recently collected submissions from members for project ideas via an online web portal with its second project proposal submission cycle in June 2014. During the second cycle, KHI received the following 12 project proposals seeking endorsement from the KHI Board of Directors. The proposals reflect the diversity of KHI's membership and interests and also the huge potential to be able to make an impact on kidney disease through such projects.

- Advancing Technologies to Facilitate Remote Management of Patient Self-Care in Renal Replacement Therapy (RRT)
- Aligning Existing Voices | KHI Kidney Patient Voices Project
- Barrier to Clinical Trials—Increasing the Number of Nephrology Investigators to Facilitate the Formation of CKD Consortia and Centers of Excellence in Clinical Research
- Design of Clinical Studies in Acute Kidney Injury

- Designing Patient-Centered Studies that Address Supportive Care for Frail Older Adults with Advanced Kidney Disease
- Educational Video to Increase Kidney Patient Participation in Clinical Studies
- Enhancing Quality of Life for Patients Undergoing Maintenance Dialysis: Exploring the Role of Patient-Reported Outcomes for Drug Approval
- Pragmatic Trials in Nephrology: Challenges and Opportunities
- Priorities for Drug Safety Evaluation Across the Spectrum of CKD
- Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease
- Unified Kidney Fact Sheet
- Vascular Access Data Collection

The KHI Board of Directors will meet later this summer to determine which proposals will be officially endorsed. Project workgroups will begin to form and meet in September 2014.

The web-based project portal provides KHI members with an opportunity to submit brief project proposals and also to discuss and refine submissions through this online forum. ASN members may submit project ideas for KHI by contacting the appropriate ASN Advisory Group. KHI has planned its third project proposal submission cycle for winter 2014/2015. To learn more about KHI's current projects, workgroup members, and proposals visit KHI online at www.kidneyhealthinitiative.org.

KHI will also continue to foster dialog among its members with an upcoming workshop at ASN Kidney Week in Philadelphia on November 11, 2014. The workshop will be presented by workgroup members of the KHI Pilot Project: Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy, which finalized their recommendations earlier this year. The workshop will present and discuss the workgroup's recommendations. For more information about this topic, visit the KHI website at www.kidneyhealthinitiative.org or contact KHI staff at KHI@asn-online.org.

As KHI approaches its two-year anniversary, the Initiative looks forward to continued growth and interaction among its diverse membership in order to facilitate the passage of drugs, devices, and biologics into the kidney space. If interested in receiving more information about KHI or enrolling as a member, please contact the KHI staff at KHI@asn-online.org. ●