## Kidney Health Initiative (KHI)

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### Research Areas
- Tool Development
- Resource
- Basic Research

### At a Glance
- **Status:** Active Consortium
- **Year Launched:** 2013
- **Initiating Organization:** American Society of Nephrology
- **Initiator Type:** Third-party organization
- **Location:** North America

### Abstract

The goal of the Kidney Health Initiative (KHI) is to advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for diseases that affect the kidney by creating a collaborative environment in which the U.S. Food and Drug Administration (FDA) and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products. This consortium is managed by the American Society of Nephrology.

### Mission

KHI is a consortium that brings together the kidney community (i.e., patient advocacy groups, industry, government agencies, and professional organizations) to overcome existing challenges, including regulatory and nonregulatory barriers and to optimize the development and safety of products that impact kidney health.

KHI’s goals are as follows:
Consortium History

March 2012: The American Society of Nephrology (ASN) expressed concerns to FDA about stagnancy in product development related to kidney health and the safety of other products with the potential to impact kidney health. Representatives from FDA and ASN met to discuss their shared interest in optimizing efforts to address public health issues related to kidney health. Although several options were discussed, the public-private partnership model was deemed especially attractive given the successes of previous such efforts. Both parties noted that the partnership model provides continuity and sustainability — critical elements of an effort intended to transform a sector of medicine as opposed to simply fix an isolated issue.

Structure & Governance

The KHI Board of Directors represents the diversity of stakeholders in the kidney community and includes representation from other federal agencies, including the Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, and National Institutes of Health. KHI is cochaired by an ASN representative and an FDA physician.

Member organizations can submit project concepts as long as they aim to improve safety or foster innovation. Project ideas are evaluated by the KHI cochairs and the Board to ensure all the selected projects are strongly aligned with KHI’s overall mission, efficiently leverage KHI resources, and have a well-defined strategy for execution.

After project concepts are finalized and endorsed by the Board, KHI will post a work group opportunity so that all members may apply to participate. The final composition of the work group will be determined by the Board after review of the applications; the Board will make its work group selections after assessing the applicant’s professional qualifications, willingness to dedicate protected time to the project, and manageability of any potential conflicts of interest.

Financing

KHI received seed funding from FDA ($2.5 million) in the form of a formal public-private partnership
with ASN. Member organizations pay an annual fee based on their size. Fees primarily support KHI’s operational cost. It is also anticipated that KHI could, in future years, consider seeking competitive grant funding to support specific projects from private or public entities.

Data Sharing

Specific details were not available. As a principle, KHI encourages researchers to not enter into agreements that interfere with their access to all of the data and/or their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, then the authors should so state.

Several patient organizations are founding members of KHI, including the American Association of Kidney Patients, NephCure Foundation, Renal Support Network, PKD Foundation, and National Kidney Foundation.

Links/Social Media Feed

Homepage http://www.asn-online.org/khi/
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