



The Kidney Health Initiative is pleased to announce two new projects and request participation on the project workgroups.

Clinical Trial Endpoints for Dialysis Vascular Access

Dialysis Vascular Access is both the "Lifeline" and "Achilles Heel" for hemodialysis patients. Despite the magnitude of the clinical problem there are currently no truly effective therapies for dialysis vascular access dysfunction. An important barrier to the development of safe and effective therapies could be the lack of consensus as to the "right" clinical trial endpoints for this condition. The current project aims to bring together the diverse stakeholders in this area (Patients, Physicians, Industry, Dialysis Organizations, Federal Agencies [FDA, CMS, NIH]) and other important players to develop a set of consensus clinical trial end points in this field. The project is intended to clarify appropriate trial endpoints for vascular access trials best suited to inform clinical, regulatory, and coverage decisions, in those circumstances where clinical data is required to support the decisions. Click [here](#) to learn more about this project and workgroup opportunity.

Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease

The Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA) has emphasized the importance of incorporating patient preferences into product development programs and into regulatory decision making, but the relevant stakeholders (including industry, patients, and regulators) have an imperfect understanding of best practices for creating the tools to capture and analyze data related to patient preferences. KHI will convene a workshop where regulators, the device industry, and patient advocacy groups can come together to discuss the barriers and solutions to developing the necessary tools to facilitate the incorporation of patient preferences into product development and regulatory decision making for medical devices in kidney disease. Click [here](#) to learn more about this project and workgroup opportunity.

The KHI Board of Directors endorsed these projects from the proposals submitted by KHI members during the first submission cycle (August-September 2013). A sub-group of the Board of Directors will review the applications and identify a chair or co-chairs as well as the members of the workgroup. While you do not need to be a KHI member to apply, KHI members and the author of the proposal may represent excellent candidates for both the chair and member positions. To review the process for workgroup selection, click [here](#) . Please consider applying to serve on the new project workgroups.

Thank you to all the KHI members that submit project proposals during the first cycle. Several other proposals from the original nine submissions are in development. All KHI members can submit a project proposal via the online project portal. A second project submission cycle will open in April 2014 with a presentation of proposals at the Second Annual Stakeholders Meeting which will be held on Thursday, June 12 in Bethesda, MD.

Our greatest strength is the diversity and commitment of the KHI members. Please consider applying to serve if you or colleagues have an interest or expertise in either of these two projects. The deadline for applications is **Thursday, February 20**.

If you have any questions about the two new projects, the workgroup selection process, or KHI, please do not hesitate to contact KHI Project Director, Melissa West at mwest@asn-online.org.