Dear Kidney Health Initiative Members,

On behalf of the Board of Directors, we would like to thank you for your participation in the Kidney Health Initiative (KHI). KHI has seen its membership grow from 47 organizations in September 2013, to over 70 organizations in November 2015. We would like to recognize and thank our members, as KHI’s early success is entirely due to the hard work, contributions and dedication of its membership.

KHI advances its mission through a portfolio of innovative, collaborative, and member-driven projects that have been submitted through four project submission cycles. The initiative has or is on target to complete six of its thirteen initial projects by the end of 2015:

- Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy
- Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions
- Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease
- Outcome Measures in Lupus Nephritis
- Pragmatic Trials in Dialysis: Challenges and Opportunities
- Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease

This Annual Review summarizes KHI’s efforts and successes and is a tribute to the contributions of each and every one of our members.

In addition to its portfolio of projects, KHI looked to further advance its efforts to improve patient safety and promote the development of therapies for diseases that affect the kidneys, by establishing a Patient and Family Partnership Council (PFPC) in 2015. The PFPC has worked closely with the Board of Directors, interacting, advising, and making recommendations on KHI member proposals, projects, and efforts so that patient involvement is meaningful and effective. The Board of Directors looks forward to continued collaboration with the PFPC and look forward to updating the membership of their progress.

KHI was also awarded a renewable R18 grant from the U.S. Food and Drug Administration (FDA) during the summer of 2015. The award ($500,000) is intended to support KHI activities during the budget period September 1, 2015 – August 31, 2016. The FDA’s continued support of KHI reflects its commitment to patient safety and its desire to foster innovation in kidney disease.

Again, thank you for your support of KHI and we look forward to KHI’s future successes and to seeing many of you at our Fourth Annual Stakeholders Meeting in 2016.

Sincerely,

Patrick Archdeacon, MD
KHI Co-chair, U.S. Food and Drug Administration
Patrick.Archdeacon@fda.hhs.gov

Prabir Roy-Chaudhury, MD, PhD, FASN
KHI Co-chair, American Society of Nephrology
Proychaudhury@deptofmed.arizona.edu
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The Kidney Health Initiative is a public-private partnership founded in September 2012 by the American Society of Nephrology (ASN) and the U.S. Food and Drug Administration (FDA). Since its inception, KHI has steadily increased its membership to its current number of over 70 member organizations.

2015 Highlights

Announced the Inaugural Patient and Family Partnership Council.

Welcomed 10 new members including:
- Blood Purification Technologies, Inc.
- Frenova Renal Research
- Humacyte, Inc.
- Keryx Biopharmaceuticals, Inc.
- Oxalosis and Hyperoxaluria Foundation
- PharmaLink
- Society of Interventional Radiology
- Takeda Pharmaceuticals Inc.
- TVA Medical
- ZS Pharma

Completed or on target to complete six of the thirteen initial projects by the end of 2015:
- Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy
- Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions
- Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease
- Outcome Measures in Lupus Nephritis
- Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease
- Pragmatic Trials in Dialysis: Challenges and Opportunities

Completed two additional project submission cycles bringing the total number of proposals submitted to KHI since its inception, to 31.

Received second year of funding from the five year, renewable R18 grant issued and supported by the U.S. Food and Drug Administration. The KHI Board of Directors appreciates the FDA’s remarkable commitment to patient safety and to fostering innovation in kidney disease.
Kidney Health Initiative Background

More than 20 million Americans have kidney disease, and more than 600,000 Americans have kidney failure, also known as end-stage renal disease (ESRD)(1). Despite these staggering statistics, the number of randomized clinical trials published in nephrology is lower than other specialties in internal medicine (Figure 1)(2). Kidney disease was the ninth leading cause of death in the United States in 2012, but little progress has been made to treat this disease in the past few decades(3).

Recognizing both the lack of clinical trials and the huge unmet clinical need in kidney disease, the American Society of Nephrology (ASN) and the U.S. Food and Drug Administration (FDA) established the Kidney Health Initiative (KHI) in September 2012 under a Memorandum of Understanding. KHI is dedicated to improving patient safety and promoting the development of the best possible therapies for diseases that affect the kidneys and quality of life for millions of people around the globe.

There are many barriers to innovation in kidney disease. Some key obstacles are (a) an inadequate characterization of the pathogenesis of renal disease progression; (b) poorly defined molecular pathways and targets; (c) poorly characterized animal models of kidney disease; (d) the lack of well-defined clinical trial endpoints and timelines; and (e) a limited clinical trial infrastructure and supportive personnel. KHI seeks to identify and develop solutions that target the current stagnation within the realm of kidney disease research. These solutions include, but are not limited to, opportunities to elucidate clinical trial endpoints, to improve clinical trial design and execution, to discuss the use of patient registries, and to create avenues for closer collaboration with FDA and other stakeholders. Ideally, these solutions will advance awareness, and therefore funding, of kidney disease.

The mission of 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 Food and Drug Administration (FDA) and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products.”

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Members of the Kidney Health Initiative

One of KHI’s greatest strengths is its diverse and broad membership. KHI currently has over 70 members and includes all major stakeholders in the field of kidney disease: patient and health professional organizations, commercial entities (large pharmaceutical companies, device manufacturers, dialysis providers, and small start-ups), research institutions, and federal agencies.

If you are interested in learning more about how to become a member of KHI, please visit the KHI website at www.kidneyhealthinitiative.org.

KHI would like to thank its over 70 members, especially its Pioneer Members.
### PIONEER MEMBERS

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<tr>
<th>AAKP</th>
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<td>ClinMet</td>
<td>DCI</td>
<td>Duke Clinical Research Institute</td>
<td>Enamine Pharmaceuticals</td>
<td>Hospira</td>
<td>IKFD</td>
<td>JDRF</td>
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KHI brings together its members throughout the year to connect stakeholders across different fields, share ideas, collect feedback, and collaborate on new projects. KHI members are invited to attend an Annual Stakeholders Meeting, held in the spring, and any event organized by KHI workgroups.

**Third Annual KHI Stakeholders Meeting**

The Initiative held its Third Annual Stakeholders Meeting on May 20-21, 2015 in Bethesda, Maryland. The meeting brought together KHI’s diverse membership from the kidney community, and connected members across different fields, allowing them to share ideas, discuss ongoing projects, collect feedback, and collaborate on new projects. Of the more than 100 participants at the Third Annual KHI Stakeholders Meeting, nearly one-third represented FDA and government agencies, one-third were affiliated with industry, and one-third represented patients and health professionals.

The Third Annual KHI Stakeholders Meeting’s keynote speakers were

Robert Temple, MD  
Deputy Director for Clinical Science, Center for Drug Evaluation and Research, FDA

Jula K. Inrig, MD, FASN  
Global Medical Director and Therapeutic Strategy Lead in Nephrology, Quintiles Global Clinical Research Organization

Robert Califf, MD  
Deputy Commissioner of Medical Products and Tobacco, FDA

Dr. Temple discussed biomarkers and surrogate endpoints while drawing from his experience as the FDA’s Deputy Director for Clinical Science. Dr. Inrig provided her perspective on the nephrology trial landscape, with regard to why clinical trials fail, and how KHI can impact drug development. Dr. Califf covered a diverse range of key topics that included biomarkers, fast-track approval and patient preferences.

Following the keynote presentations, small group breakout sessions allowed members to review current KHI projects and provide feedback to authors of project proposals in interactive presentations. New to this meeting, sessions were devoted to brainstorming discussions about larger goals and topic that need to be addressed. To review the meeting’s entire agenda, please visit KHI’s meeting page online at www.kidneyhealthinitiative.org.
Initiative Events

Workgroup Sponsored Events

The KHI workgroup, “Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease”, has been charged with focusing on the importance of incorporating patient preferences into product development programs and into regulatory decision making.

The workgroup hosted a workshop titled “Understanding Patients’ Preferences: Stimulating Medical Device Development in Kidney Disease” on August 12-13, 2015 at the Hilton Baltimore BWI Airport. The KHI workshop built on the lessons learned at the FDA Public Workshop on September 18-19, 2013 on patient preferences and provided a forum for interactive discussions between FDA regulators and other stakeholders to find practical solutions to address patient preference issues relevant to kidney health. Patients were able to share their ideas directly with the FDA, scientists, doctors, nurses and technicians. The workshop was attended by more than 100 participants including over 50 patients, care partners and family members plus over 50 participants who joined remotely via a live stream.

The keynote speakers for the KHI workshop were

Paul T. Conway
Kidney Transplant Recipient, President of the American Association of Kidney Patients

Robert Califf, MD
Deputy Commissioner of Medical Products and Tobacco, FDA

More information including program information, captured sessions and speakers’ slides are available on the workshop’s page of the Patient Info section on the KHI website: www.kidneyhealthinitiative.org.
KHI advances its mission through a portfolio of innovative, collaborative, and member-driven projects. KHI has developed an inclusive and transparent project submission process where members submit project proposals via an online portal and obtain feedback from their peers through an open comment period.

Once the submission portal closes, proposals are reviewed by the KHI Board of Directors and evaluated based on the proposal’s ability to meet the KHI mission, make a lasting impact, and outline a deliverable that is feasible before endorsement as an official KHI project. Once a project is endorsed, multi-disciplinary workgroups are endorsed. The formation of workgroups is an open process by which an application to serve as a workgroup member is posted on the KHI website. When a workgroup is established and operational structure is finalized, deliverables are identified, a timeline is set, and work begins.
Strategic Priority Areas of KHI Project

KHI has initiated thirteen projects since its establishment in 2012. The projects can be divided into several strategic priority areas which include:

**Advancement of Patient and Family Partnership and Funding of Kidney Disease**
- Workshop to Elucidate Role of Patient Preferences in Support of the Center for Devices and Radiological Health Regulatory Actions in Kidney Disease
- Advancing Technologies to Facilitate Remote Management of Patient Self-Care in Renal Replacement Therapy (RRT)

**Closer Collaboration with the FDA and Other Government Agencies**
- Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions
- Regulatory Policies and Positions Affecting Device Approval in the United States: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease

**Clinical Trial Endpoint and Design**
- Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy (CRRT)
- Outcome Measures in Lupus Nephritis
- Clinical Trial Endpoints for Dialysis Vascular Access
- Pragmatic Trials in Nephrology: Challenges and Opportunities

**Clinical Trial Infrastructure and Developing the Evidence Base**
- Data Standards in Diabetic Kidney Disease
- Data Harmonization in Kidney Transplantation

The KHI Board of Directors thanks the workgroup, Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions, for developing the framework for these strategic priorities.
# Completed Projects

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<th><strong>Project:</strong></th>
<th>Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy (CRRT)</th>
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<tbody>
<tr>
<td><strong>Deliverable:</strong></td>
<td>White paper and workshop</td>
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<tr>
<td><strong>Contact:</strong></td>
<td>Thomas D. Nolin, PharmD, PhD, FASN, Assistant Professor in the School of Pharmacy, Department of Pharmacy and Therapeutics, University of Pittsburgh and Stuart L. Goldstein, MD, Professor of Pediatrics and Director, Center for Acute Care Nephrology at Cincinnati Children’s Hospital Medical Center</td>
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<tr>
<th><strong>Project:</strong></th>
<th>Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions</th>
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<tr>
<td><strong>Deliverable:</strong></td>
<td>White paper</td>
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<tr>
<td><strong>Contact:</strong></td>
<td>Peter G. Linde, MD, FASN, Project Leader, Renal &amp; Immunology Development, AbbVie Inc.</td>
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Kidney Health Initiative Project Portfolio
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<th>Projects Listed by Categories</th>
<th>Concept</th>
<th>Endorsed</th>
<th>Call for Workgroup</th>
<th>Workgroup Selected</th>
<th>Project Plan Finalized</th>
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Kidney Health Initiative Projects Supporting the Advancement of Patient and Family Partnership and Funding of Kidney Disease
Workgroup Co-Chairs: Dolph Chianchiano, JD, MPA, Health Policy Consultant, National Kidney Foundation
Frank Hurst, MD, FASN, Nephrologist and Medical Officer, Center for Devices and Radiological Health, U.S. Food and Drug Administration

KHI Board of Directors Liaison: Carolyn Y. Neuland, PhD, Chief of Renal Devices Branch of the Center for Devices and Radiological Health, U.S. Food and Drug Administration

Patient Care Issue: Although patients are the final consumer, they rarely have an opportunity to influence products that come to market. The success of a new product is based on many factors, including the usability by patients. Finding appropriate and fulfilling ways for patients to participate in the development of new products is a vital goal.

Challenge: The Center for Devices and Radiological Health (CDRH) at FDA has emphasized incorporating patient preferences for risk over benefit into product development programs and into regulatory decision making. However, the relevant stakeholders (patients, health professionals, industry, and federal agencies) have an imperfect understanding of best practices for creating the tools to capture and analyze data related to patient preferences.

KHI Solution: KHI formed a workgroup charged with planning a workshop where patients, health care professionals, device manufacturers, and regulators 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 products in kidney disease.

Status: The workgroup developed and launched a short animated video to engage patients and encourage them to attend educational webinars held in April 2015. The video has been viewed over 1,600 times, resulting in more than 160 patients expressing their interest in attending the webinars (and 245 total registrants). The webinars educated patients on the product lifecycle, the role of the FDA/CDRH, the CDRH Patient Preferences Initiative, and increased patients’ interest and knowledge before participating in the workgroup’s workshop. The workgroup’s video and webinar slides can be viewed in the Patient Info section of the KHI website: www.kidneyhealthinitiative.org

The workgroup also hosted a workshop titled “Understanding Patients’ Preferences: Stimulating Medical Device Development in Kidney Disease” in August that featured discussions between FDA regulators and other stakeholders to find solutions to address patient preference issues in kidney health. More information including program information, captured sessions and slides can be viewed on the workshop’s page of the Patient Info section on the KHI website: www.kidneyhealthinitiative.org.

Deliverables:
1. Workshop (completed)
2. White paper(s) to define the major barriers and solutions to developing patient preference tools for medical devices within therapeutic areas relevant to with kidney disease.
Advancing Technologies to Facilitate Remote Management of Patient Self-Care in Renal Replacement Therapy (RRT)

Workgroup Co-Chairs: Patrick Brophy, MD, MHCDS, Vice Chair Clinical Innovation, Director of Pediatric Nephrology, Dialysis & Transplantation, Professor of Pediatrics and Surgery at the Carver College of Medicine, University of Iowa

Susie Lew, MD, FACP, FASN, Medical Director, Peritoneal Dialysis Unit, George Washington University Medical Center-Gambro Healthcare / DaVita, Attending Physician, Division of Nephrology, Department of Medicine, George Washington University Medical Center

KHI Board of Directors Liaison: James A. Sloand, MD, FASN, Global Medical Director for Peritoneal Dialysis, Baxter Healthcare

Patient Care Issue: Digital and mobile-based technologies present new and possibly better disease management options for patients and healthcare professionals. These technologies hold the potential of improving outcomes through individualized patient-centered education, remote communication and data exchange, in-home clinical guidance, prescription/treatment adherence or changes, and a rapid alert system for health professionals. This responsiveness empowers patients and family care providers and has the potential to increase the number of patients receiving home-based therapies.

Challenge: There is uncertainty regarding the approval of advanced medical devices, accessories, software, and mobile medical applications for consumer use. Reimbursement policies vary significantly across Medicaid, Medicare, and commercial insurance. This regulatory and payer misalignment and the knowledge gap is hindering patient access to technologies and services that have potential to improve outcomes for patients on home based therapies.

KHI Solution: KHI is assembling a workgroup tasked with addressing the state of remote monitoring wireless health/telemedicine technology that can be utilized to treat patients with kidney disease, assessing the potential clinical and economic value, and both the need and potential pathways. This information will be used to address key regulatory, legal, legislative, and reimbursement barriers affecting the adoption and usage of such technologies. The workgroup will develop a white paper and present their findings at a workshop.

Status: To best understand the opportunities and challenges, KHI held a strategy session on May 7, 2015 with various stakeholders to discuss

- Current landscape of remote monitoring and telemedicine
- Current healthcare clinical experiences and perspective
- Patient perspectives
- Regulatory and Legal framework of remote technologies
- Telemedicine Industry and Reimbursement perspectives

The workgroup will review the findings of the strategy meeting and prioritize the barriers and proposed solutions.

Deliverable: White paper and workshop that addresses the state of remote monitoring and telemedicine technology that can be utilized to treat patients with ESRD and renal illness.
Kidney Health Initiative Projects Supporting Closer Collaboration with the FDA and Other Government Agencies
Regulatory Policies and Positions Affecting Device Approval in the United States: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease

Workgroup Co-Chairs: Stephen R. Ash, MD, FACP, Interventional Nephrologist and Clinical Associate Professor, Indiana University Health Arnett, Chairman, and Director of R&D, HemoCleanse, Inc. and Ash Access Technology, Inc., Lafayette, Indiana

Douglas M. Silverstein, MD, Pediatric Nephrologist and a Medical Officer in the Renal Devices Branch of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration

KHI Board of Directors Liaison: Carolyn Y. Neuland, PhD, Chief of Renal Devices Branch of the Center for Devices and Radiological Health, U.S. Food and Drug Administration

Patient Care Issue: There have been few innovative therapies marketed for patients with CKD or ESRD during the last decade. In contrast, a number of new therapies have been approved and marketed outside of the United States.

Challenge: It is vital that device manufacturers and other stakeholders have optimal information on the standards of approval of clinical trial protocols and market approval for drugs and devices at FDA.

KHI Solution: KHI assembled a workgroup that has defined and is studying a few broad categories of devices that have been marketed outside of the United States. The workgroup is determining the value of these devices in patient care, ascertaining pathways to expedite approvals in the United States (if felt to be appropriate), and will then summarize their findings in a white paper.

Status: The workgroup has selected to focus on central venous catheters and hemodiafiltration systems.

Proposed White Paper Outline:

Outline the unmet health need that the device is intended to address, including but not limited to:

- A general description of the device category
- How the device provides a therapeutic option that is not currently available

Identify common issues (“deficiencies”) raised during prior review processes. Anonymity of all prior submissions will be honored. An example of an “issue” would be biocompatibility test requirements for a 510(k) submission. For each major issue:

- Cite the standard or reason provided by the FDA for the requested information
- Identify the difficulties/barriers for sponsors/investigators to satisfactorily fulfill the request

Identify issues that should be considered in assessing the benefit and risk for the device category, including patient preferences, for the intended use population.

Identify recent technological advances that should require special consideration by the FDA in future study/marketing applications, and determine if the technologic changes will require unique types of testing and/or considerations for change/innovations in the regulatory pathway.

List limitations to the currently available technology that require research or device modification.

Deliverable: The workgroup will generate parallel white papers that outline the current requirements for IDE studies and marketing applications for central venous catheters for hemodialysis and hemodiafiltration systems, and identify issues that should be considered in assessing the benefit and risk for these devices.
Kidney Health Initiative Projects Supporting Clinical Trial Endpoints and Design
Outcome Measures in Lupus Nephritis

Workgroup Chair: Brad Rovin, MD, FACP, FASN, Professor of Medicine and Pathology, Vice Chairman of Research for Internal Medicine, and Director, Division of Nephrology, The Ohio State University

KHI Board of Directors Liaison: Patrick Archdeacon, MD, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, and Prabir Roy-Chaudhury, MD, PhD, FASN, Professor of Medicine and the Division Director for Nephrology at the University of Arizona, KHI Co-chairs

Patient Care Issue: Approximately 1.5 million Americans have systemic lupus erythematosus, and up to 60% of those patients may develop lupus nephritis(1)(2), an inflammation of the kidney that can lead to chronic kidney disease (CKD) or end-stage renal disease (ESRD).

Challenge: Clinical trial endpoints measure success or failure of therapies being tested. Unfortunately, no well-defined endpoints exist for lupus nephritis. Without clear endpoints, researchers and industry face challenges developing new therapies for the disease. This is an important barrier to innovative drug development in this field.

KHI Solution: A KHI workgroup (in partnership with the Lupus Nephritis Trial Network) is analyzing existing data to test for clear, valid endpoints for lupus nephritis trials. The workgroup contacted pharmaceutical companies that have completed trials in lupus nephritis to discuss the inclusion of their data in this project. Recognizing the value of including physicians treating these patients, the workgroup also recruited global cohort sites to participate in the project.

Upon completion of the data analysis, the workgroup will recommend a core set of outcome measures, biomarkers, surrogate markers, and clearly defined terms that should be incorporated into all future lupus nephritis trials. Developing these measures will make it much more feasible for companies to invest in the research necessary to improve treatments for patients with this serious disease.

Status: The KHI workgroup (in partnership with LNTN) has recruited more than 10 global cohort sites to participate in the project, aggregated a data set of over 800 patients, and is in the analysis phase of the project.

Deliverable: White Paper

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Pragmatic Trials in Dialysis: Challenges and Opportunities

Workgroup Chair: Laura M. Dember, MD, Professor of Medicine, Hospital of the University of Pennsylvania

KHI Board of Directors Liaison: Michael Flessner, MD, PhD, Director, Inflammatory Renal Disease Program at the Division of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases

Patient Care Issue: Defining the benefit of a therapy in routine clinical experience is an important opportunity for kidney disease. There are almost 400,000 hemodialysis patients in the United States. This patient population has a mortality rate approaching 50% at three years from the start of hemodialysis, incurring Medicare expenditures in excess of $24 billion annually.1

The TiME Trial is a large pragmatic clinical trial that is being conducted through the NIH Health Care Systems Research Collaboratory, a Common Fund initiative that aims to integrate clinical trials into healthcare delivery. The objective of the trial is to determine whether dialysis facility implementation of a hemodialysis session duration of at least 4.25 hours for incident patients improves clinical outcomes and quality of life.

Challenge: Few randomized clinical trials have been conducted in this setting due to various perceived barriers – including FDA regulations related to data collection, lack of clarity around best practices for ensuring human subject protections, and cumbersome CMS requirements related to billing for patients involved in research.

KHI Solution: KHI is supporting a workgroup comprised of TiME Trial investigators. The goal of the project is to provide the kidney community with information about the potential use of pragmatic trials to answer important clinical questions. In addition, the workgroup will recommend solutions to operational, regulatory, and business issues that may hinder routine conduct of clinical trials embedded in the provision of clinical care.

Status: The workgroup is actively meeting and drafting the white paper.

Deliverable: Phase I: White Paper; Phase II: Workshop (to be determined)

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Clinical Trial Endpoints for Dialysis Vascular Access

Workgroup Co-Chairs:
Surendra Shenoy, MD, PhD, Associate Professor of Surgery, Washington University School of Medicine in St. Louis
Haimanot (Monnie) Wasse, MD, MPH, FASN, Associate Professor in Medicine-Nephrology, Northwestern University Feinberg School of Medicine

KHI Board of Directors Liaison: Prabir Roy-Chaudhury, MD, PhD, FASN, Professor of Medicine and the Division Director for Nephrology at the University of Arizona, KHI Co-chair

Patient Care Issue: Hemodialysis vascular access has been called the “lifeline” for patients on hemodialysis. Unfortunately, due to the many problems associated with dialysis vascular access (stenosis, thrombosis, infection), it is also the “Achilles Heel” of hemodialysis. Specifically, more than 50% of arteriovenous fistulae (AVF) are unsuitable for hemodialysis four to five months following creation(1); the primary patency of arteriovenous grafts (AVG) has been reported to be as low as 23% at one year(2); and only 9% of tunneled dialysis catheters (TDCs) are still functional at one year(3).

Challenge: 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.

KHI Solution: This project convenes the diverse stakeholders in this area (health professionals, industry, dialysis organizations, and federal agencies) 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 such decisions.

Status: At an organizational level, it is important for this project to be operationally nimble but also very inclusive. Ideally, each stakeholder must participate. Therefore, the workgroup is comprised of a small core group that will allow for quick operational decisions as well as a larger steering committee with international advisers, which will allow for the voices of all the stakeholders in this area to be heard. The workgroup is further broken-down into three Content Development Teams (Catheter, Fistula, and Graft) that are drafting the workgroup’s white papers with guidance from the Core and Steering Committees.

Deliverable: Three parallel white papers on catheters, fistulas, and grafts endpoints.

Kidney Health Initiative Projects Supporting Clinical Trial Infrastructure and Developing the Evidence Base
Data Standards in Diabetic Kidney Disease

Workgroup Co-Chairs:
Richard Haynes, DM, MRCP, Clinical Trial Service Unit & Epidemiological Studies Unit, University of Oxford
Amy K. Mottl, MD, MPH, Clinical Associate Professor of Medicine, UNC Kidney Center

KHI Board of Directors Liaison: Jula Inrig, MD, MHS, FASN, Senior Medical Director, Quintiles Global Clinical Research Organization

Patient Care Issue: Nearly one-half of patients with CKD, approximately 10 million Americans, have diabetes mellitus(1). Diabetes accounted for 44% of new cases of kidney failure in 2007(2). In diabetic kidney disease (also called diabetic nephropathy); cells and blood vessels in the kidneys are damaged, affecting the organs’ ability to filter out waste. The progression from initial kidney injury due to diabetes, to diabetic kidney disease, to ERSD severely affects patients’ quality of life, and is responsible for a very significant morbidity and economic cost.

Challenge: There is a lack of consensus for not only clinical trial endpoints in this area, but also for established standards for clinical research data collection, in order to support the acquisition, exchange, and comparisons of future trials.

KHI Solution: In coordination with the Clinical Data Interchange Standards Consortium (CDISC), Coalition for Accelerating Standards and Therapies (CFAST), FDA, and TransCelerate BioPharma, Inc., KHI has assembled a workgroup to help define appropriate standards in the therapeutic area of diabetic kidney disease. KHI’s specific role is providing clinical and medical expertise.

Status: The standardization effort is expected to evaluate the following areas of specific interest to Diabetic Kidney Disease:

1. Labs (includes key inclusion criteria and primary/secondary endpoints based on urinary albumin-to-creatinine ratio or urinary protein-to-creatinine ratio, creatinine and cystatin C, eGFR and hemoglobin A1c, and key safety endpoints based on cardiovascular morbidity/mortality, serum potassium, acute kidney injury and blood glucose profiles)
2. Glucose Profile: patient self-monitored blood glucoses, HbA1c, laboratory blood glucoses, and hypoglycemia
3. Patient reported outcomes
4. Diabetes History (Type I vs Type II vs latent autoimmune diabetes of adults, duration of diagnosis, complications) including presence/absence of retinopathy, peripheral neuropathy, and macrovascular complications
5. Comorbid conditions: hypertension, mineral metabolism abnormalities, anemia, hypercholesterolemia
6. Concomitant medications: Antihyperglycemic agents and concomitant medications with potential to impact on the primary endpoint (e.g., ACE inhibitors, ARBs) or those used to control relevant comorbid conditions
7. Endpoints: CV events/outcomes (AMI, heart failure, stroke or peripheral vascular interventions), ESRD and/or death, acute kidney injury requiring hospitalization.

Deliverable: CDISC Therapeutic Area User Guide for Diabetic Kidney Disease (including concept maps, Shared Health And Clinical Research Electronic Library (SHARE) metadata, Study Data Tabulation Model - Implementation Guide (SDTM-IG) type examples, Clinical Data Acquisition Standards Harmonization (CDASH) annotated Case Report Form examples, and CDASH metadata examples).

Data Standards in Kidney Transplantation

Workgroup Co-Chairs: Rita Alloway, PharmD, FCCP, Professor of Medicine, Director of Transplant Clinical Research, Director of Transplant Specialty Residency and Fellowship at the University of Cincinnati

Roslyn B. Mannon, MD, Professor of Medicine and Surgery, Director of Research, Comprehensive Transplant Institute, University of Alabama at Birmingham

KHI Board of Directors Liaison: Patrick Archdeacon, MD, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, KHI Co-chair

Patient Care Issue: Lack of data standards for nephrology trials can pose particular challenges for investigators/industry/regulators trying to harmonize and compare completed trials. Uniform definitions for datasets are required within many therapeutic areas within nephrology. To facilitate drug development in the nephrology space, KHI will collaborate with partners already operating in the data standards arena to ensure the timely creation of tools to support research in kidney disease.

Challenge: There is a lack of consensus for not only clinical trial endpoints in this area, but also for established standards for clinical research data collection, in order to support the acquisition, exchange, and comparisons of future trials.

KHI Solution: KHI is currently working on data standards for diabetic kidney disease (DKD) trials with the Clinical Data Interchange Standards Consortium (CDISC) and the Coalition for Accelerating Standards and Therapies (CFAST). FDA’s priority list for data standards also includes solid organ transplantation – with kidney transplant as a target therapeutic area. KHI, CFAST, and CDISC will extend its current collaboration to address kidney transplantation. CFAST has developed a process for developing data standards that requires a group of therapeutic area clinical experts. Similar to its role in the DKD data standards project, KHI will provide a workgroup of medical experts to serve with FDA representatives as the therapeutic area clinical experts.

Status: KHI waiting for CFAST to launch this project, anticipated for late 2015.

Deliverable: CDISC Therapeutic Area User Guide for Kidney Transplantation
Workgroup Participants

The membership has worked diligently through KHI to improve patient safety and promote the development of optimal therapies for diseases that affect kidneys and the quality of life for millions of people. KHI members are involved in the selection and execution of a variety of projects: co-authoring white papers; collaborating to leverage previously conducted and ongoing clinical studies, research infrastructure, and databases; and promoting dialogue on kidney health pertaining to drug, device, biologics, as well as food product development, evaluation, and safety.

The KHI Board of Directors would like to all of the individuals who are serving on a KHI workgroup for their hard work and effort this past year.

Kevin Abreo, MD
Louisiana State University Health Sciences

Ahmed Al-Jaishi, BSc-MSCI, MSc
London Health Sciences Center

Michael Allon, MD ‡
University of Alabama at Birmingham

Patrick Archdeacon, MD§ *
Center for Drug Evaluation and Research (CDER), FDA

Stephen R. Ash, MD, FACP†
HemoCleanse, Inc. and Ash Access Technology Inc., Indiana University Health Arnett
(Liaison for the American Society of Diagnostic and Interventional Nephrology)

Lynda K. Ball, CNN
Everett, WA
(Liaison for the American Nephrology Nurses’ Association)

Amrutha Baskaran, MD, MSCR, Post-Doctoral Scholar
University of California, San Diego

Kevin M. Baskin, MD
University of Pittsburgh

Gerald A. Beathard, MD, PhD, FASN‡
University of Texas Medical Branch

Donna Bednarski, MSN, RN, ANP-BC, CNN, CNP
Harper University Hospital

Terri Bonadio
Fresenius Medical Care

Kay Bregel, RN, CNN
NxStage Medical, Inc.

Matthew D. Breyer, MD, FASN‡
Eli Lilly and Company

Patrick Brophy, MD, MHCDS†
University of Iowa

Deborah J. Brouwer-Maier, RN, CNN‡
Fresenius Medical Care

Steven K. Burke, MD
Protein Therapeutics

Benard Canaud, MD
Fresenius Medical Care - Germany

Celeste Castillo Lee¶
Ann Arbor, MI
(Liaison for the Vasculitis Foundation)

Deepa H. Chand, MD, FASN
Rush University Medical Center
(Liaison for the American Society of Pediatric Nephrology)

Paul Chandeysson, MD
Center for Devices and Radiological Health (CDRH), FDA

* KHI Board of Directors  † KHI Workgroup Chairs  ‡ KHI CDT Chairs  § KHI Co-Chairs  ¶ KHI PFPC
Will G. Herrington, MBBS
Clinical Trials Service Unit and Epidemiological Studies Unit, University of Oxford

Martin Ho, MS
Center for Devices and Radiological Health (CDRH), FDA

Thomas S. Huber, MD, PhD‡
University of Florida
(Liaison for the Society for Vascular Surgery)

Frank Hurst, MD, FASN†
Center for Devices and Radiological Health (CDRH), FDA

Jula Inrig, MD, FASN*           Quintiles Global Clinical Research Organization

Garth James, PhD
Montana State University

Kenneth Kalunian, MD
University of California, San Diego

Alethia Karkanis, BSN, MSN-CRM
W.L. Gore & Associates

Reshma Kewalramani, MD, FASN*         Amgen, Inc.

Paul Kravitz
NxStage Medical, Inc.

Mahesh Krishnan, MD, MPH, MBA, FASN†
DaVita Healthcare Partners

Robert Kossmann, MD, FACP, FASN
Fresenius Medical Care - North America

Eduardo Lacson Jr., MD, MP

Larissa Lapteva, MD, MHS
Center for Drug Evaluation and Research (CDER), FDA

Jeffery Lawson, MD, PhD
Duke University

Timmy C. Lee, MD, FASN
University of Alabama at Birmingham

Martin L. Lesser, PhD, EMT-CC
Feinstein Institute for Medical Research

Susie Lew, MD, FACP, FASN†
George Washington University Medical Center

Peter Linde, MD, FASN†
AbbVie, Inc.

Shari M. Ling, MD
Centers for Medicare and Medicaid Services

Charmaine E. Lok, MD‡
University Health Network-Toronto General Hospital

Meggan Mackay, MD, MS
Feinstein Institute for Medical Research
North Shore-Long Island Jewish Health System Foundation

Gordon McLennan, MD
Cleveland Clinic
(Liaison for the Society of Interventional Radiology)

Michele H. Mokrzycki, MD, MS
Montefiore Medical Center

Amy K. Mottl, MD, MPH†
UNC School of Medicine

Carolyn Y. Neuland, PhD‡
Center for Devices and Radiological Health (CDRH), FDA

Brooke Newcomb
C.R. Bard

* KHI Board of Directors  † KHI Workgroup Chairs  ‡ KHI CDT Chairs  § KHI Co-Chairs  ¶ KHI PFPC
Wing Ng
Medtronic, Inc.

Helen Nickerson, PhD
JDRF International

Vandana D. Niyyar, MD
Emory University

Meda E. Pavkov, MD, PhD*
Centers for Disease Control

Michael Perelman, MD
Humacyte, Inc.

Ronald L. Pisoni, PhD
Arbor Research Collaborative for Health

Kevan Polkinghorne, PhD, MBChB
Monash University, Australia

Marlon Pragnell, PhD
JDRF International

Lillian Pryor, MSN, RN, CNN
Jersey City, NJ
(Liaison for the American Nephrology Nurses)

Andrew Narva, MD
National Institute of Diabetes and Digestive and Kidney Disease

Miguel C. Riella, MD, PhD
Catholic University of Parana, Brazil
(Liaison for the International Federation of Kidney Foundations)

Brad Rovin, MD, FACP, FASN†
The Ohio State University

Prabir Roy-Chaudhury, MD, PhD, FASN‡*
University of Arizona

Bradley Roynon, RAC
Baxter International Inc.

John R. Sedor, MD, FASN
Case Western Reserve University
(Liaison for the American Society of Nephrology)

Shoba Sharma, MS
ClinMet

Douglas M. Silverstein, MD†
Center for Devices and Radiological Health (CDRH), FDA

James A. Sloand, MD, FASN‘
Baxter International Inc.

Surendra Shenoy, MD, PhD†
Washington University School of Medicine, Barnes Jewish Hospital

Roman Shingarev, MD
University of Alabama at Birmingham

Kimberly Smith, MD, MS
Center for Drug Evaluation and Research (CDER), FDA

Todd Snell
NxStage Medical, Inc.

Jennifer Snook, PharmD
Chicago, IL

Laura Straub
Immune Tolerance Network

Jim Summerton
Nephros, Inc.

Donna C. Syracuse, RN
Cryolife

Aliza Thompson, MD
Center for Drug Evaluation and Research (CDER), FDA

Melissa Threlkeld, MHA, FACHE
Austin, TX

Jan Tordoir, MD, PhD
University Hospital Maastricht, Netherlands
(Liaison for the Vascular Access Society)
Scott Trerotola, MD  
University of Pennsylvania

Katherine Tuttle, MD, FASN*  
University of Washington

Margo Underwood  
C.R. Bard

Aris Q. Urbanes, MD  
Lifeline Vascular Access

Linda Upchurch, MBA, MHA  
NxStage Medical, Inc.

Jorg Vienken, PhD  
Nephro-Solutions AG - Germany

Haimanot (Monnie) Wasse, MD, MPH, FASN†  
Northwestern University

Bridget Wildt, PhD  
Center for Devices and Radiological Health (CDRH), FDA

Karen Woo, MD, MS  
University of Southern California

Jack Work, MD  
Asheville, NC

Shen Xiao, MD  
Center for Devices and Radiological Health (CDRH), FDA

Theodore H. Yuo, MD, MSc  
University of Pittsburgh

* KHI Board of Directors  † KHI Workgroup Chairs  ‡ KHI CDT Chairs  § KHI Co-Chairs  ¶ KHI PFPC
Patient and Family Partnership Council

The mission of KHI is to enhance patient safety and foster innovation in kidney disease. Patients and their care partners are at the heart of the KHI mission. In order to advance KHI’s efforts to improve patient safety and promote the development of the therapies for diseases that affect the kidneys, this spring, KHI communicated to the membership the opportunity to serve on the inaugural Patient and Family Partnership Council (PFPC).

The KHI PFPC was established to work closely with the KHI Board of Directors and staff and to advise and make recommendations on member project proposals, KHI projects and overall efforts of KHI so that the patient’s voice, experience and involvement is meaningful and effective.

The KHI PFPC has been charged with providing strategic guidance to KHI about how to activate and include the patients, their families and care partners in KHI activities, including but not limited to:

1. Advising KHI members regarding patient involvement in their project proposals
2. Outlining opportunities for patients to serve once a project has been endorsed
3. Identifying patients to serve on project workgroups
4. Collaborating on developing patient centered project(s) to submit for KHI endorsement

KHI would like to thank the inaugural members of the KHI PFPC for their service and leadership:

Ms. Celeste Castillo Lee, Chair and Liaison to KHI Board of Directors (2018) (Vasculitis Foundation)

Ms. Denise Eilers, BSN, RN (2017) (Home Dialyzors United)

Mr. Richard D. Fissel (2016) (NephCure Kidney International)

Mr. Kevin J. Fowler (2016) (PKD Foundation)


Mr. Sam Pederson (2015) (American Association of Kidney Patients)

Ms. Roberta L. Wager, MSN, RN (2017) (American Association of Kidney Patients)

Ms. Caroline Wilkie (2017) (National Kidney Foundation)
Board of Directors

Thank you to the Board of Directors for their leadership and support of KHI. A special thanks for members of the Board of Directors whose terms end in 2015 -- Nancy M. Gallagher, RN, CNN, Kristine Kuus, PhD, and Sam Pederson.

Co-Chairs
Patrick Archdeacon, MD
*Office of Medical Policy, Center for Drug Evaluation and Research (CDER), FDA*

Prabir Roy-Chaudhury, MD, PhD, FASN
*American Society of Nephrology*

Members

Matthew D. Breyer, MD, FASN (2017)
Eli Lilly and Company

Dolph Chianchiano, JD, MPA (2016)
National Kidney Foundation

Mark Costanzo (2016)
Fesenius Medical Care North America

Ronald J. Falk, MD, FASN (2018)
University of North Carolina

Michael Flessner, MD, PhD (2018)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Nancy M. Gallagher, RN, CNN (2015)
Nephrology Nursing Certification Commission

Stuart L. Goldstein, MD (2017)
Cincinnati Children’s Hospital

Jula K. Inrig, MD, FASN (2017)
Quintiles Global Clinical Research Organization

Reshma Kewalramani, MD, FASN (2017)
Amgen, Inc.

Alan S. Kliger, MD (2016)
Yale University

Mahesh Krishnan, MD, MPH, MBA, FASN (2016)
DaVita Healthcare Partners

Kristine Kuus, PhD (2015)
The Binding Site

Celeste Castillo Lee (2018)
Ann Arbor, MI & Vasculitis Foundation

Peter G. Linde, MD (2017)
AbbVie, Inc.

Joe Muldoon (2016)
FAST BioMedical

Carolyn Y. Neuland, PhD (2018)
Center for Devices and Radiological Health (CDRH), FDA

Meda E. Pavkov, MD, PhD (2018)
Epidemiology and Statistic Branch (ESB), Centers for Disease Control (CDC)

Sam M. Pederson (2015)
Seattle, WA & American Association of Kidney Patients

James A. Sloand, MD, FASN (2017)
Baxter International, Inc.

James P. Smith, MD, MS (2018)
Center for Drug Evaluation and Research (CDER), FDA

Katherine R. Tuttle, MD, FASN, FACP (2016)
University of Washington

A liaison for the Center for Food Safety and Nutrition (CFSAN) at the FDA has been identified and will be involved as projects are identified. Current vacancies on the KHI Board of Directors include: the Agency for Healthcare Research and Quality (AHRQ), Center for Biologics and Research (CBER) at FDA, Centers for Medicare & Medicaid Services (CMS) and National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH). Filling these vacancies is a priority for KHI.
Co-Chairs

Patrick Archdeacon, MD
Medical Officer, Office of Medical Policy
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)
Email: Patrick.archdeacon@fda.hhs.gov

Prabir Roy-Chaudhury, MD, PhD, FASN
Professor of Medicine
Division Director for Nephrology
University of Arizona
Email: proychaudhury@deptofmed.arizona.edu

Staff

Melissa West
Project Director
Kidney Health Initiative
Phone: 202-740-7891
Email: mwest@asn-online.org

Ryan Murray
Project Associate
Kidney Health Initiative
Phone: 202-400-2485
Email: rmurray@asn-online.org