Eighth Annual KHI Stakeholders Meeting
"Meeting Patients Where They Are"

June 23-24, 2021

Wednesday, June 23 *(times listed are EDT)*

3:00 PM – 3:10 PM **Welcome and Opening Remarks**
Raymond C. Harris, MD, FASN, KHI Chair

3:10 PM – 3:30 PM **Plenary Session - 2020 and Beyond: Integrating the Community to Accelerate Innovation**
Moderator: Deidre Crews, MD
Robert Califf, MD, MACC, Verily Life Sciences and Google Health
Patrick Gee Sr., PhD, JLC, KHI Patient and Family Partnership Council

3:30 PM – 4:30 PM **Designing a Patient Advisory Board to Strengthen Clinical Trials and Research**
(Followed by breakout sessions)
Moderators: Patrick Gee Sr., PhD, JLC, Jack Lennon, MBA and David White
KHI Patient and Family Partnership Council Members:
Amanda Grandinetti, MPH
Glenda V. Roberts
Vanessa Evans

4:30 PM – 5:30 PM **Two Silver Linings of Trial Conduct Learned During the COVID-19 Pandemic: Master Protocols and Decentralizing Trials**
(Followed by breakout sessions on each topic)
Moderators: Meg Jardine, MBBS, PhD, and Barbara Gillespie, MD, FASN
Richard Haynes, DM, MRCP, University of Oxford
Colin Meyer, MD, Reata Pharmaceuticals
Samuel Fatoba, PhD, Bayer Pharmaceuticals

5:30 PM - 6:00 PM **Fireside Chat with FDA Center for Drug Evaluation and Research (CDER)**
Aliza Thompson, MD, MS, Deputy Director, Division of Cardiovascular and Renal Products

6:00 PM - 7:00 PM **Networking Opportunity**
We will randomize all attendees to breakout groups for an opportunity to network with other meeting attendees.

Thursday, June 24 *(times listed are EDT)*

3:00 PM - 3:05 PM **Opening Remarks**
Amit Sharma, MD, FASN, Planning Committee Co-Chair

3:05 PM – 4:00 PM **Plenary Session – Idea to Investment: The Journey of Transformative Innovations**
Moderator: Amit Sharma, MD, FASN
Eric Dobmeier, JD, Chinook Therapeutics
Jeff Lawson, MD, PhD, Humacyte Inc.
Leslie Trigg, MBA, Outset Medical

4:00 PM – 4:45 PM **Utilizing Patient Reported Outcome Measurements in Real World Assessments**
Moderator: Mark Unruh, MD, MS
Michelle Tarver, MD, PhD, US Food and Drug Administration
Fraser Bocell, MEd, PhD, US Food and Drug Administration
Terry Litchfield, Patient/Care Partner Perspective

4:45 PM – 5:30 PM **Breakout Sessions**

- **Dialysis Access Collaborative Community: A Model for Real World Evidence Studies for Dialysis Access**
  Moderated by Vandana Niyyar, MD, FASN, and Prabir Roy-Chaudhury, MD, PhD, FASN
- **Integrating Data from Dialysis Facilities That Inform Real World Evidence**
  Moderated by Mahesh Krishnan, MD, MPH, MBA, FASN, and Teri Neal, MD

5:30 PM - 6:15 PM **Leap of Faith: First-in-Human Clinical Trials for Potentially Transformative Products in CBER**
Moderator: Kevin Fowler
Celia Witten, MD, PhD, US Food and Drug Administration
David H. Sachs, MD, Harvard University
Robyn Shapiro, JD, Health Sciences Law Group LLC
Nichole Jefferson, Patient Perspective

6:15 PM – 6:45 PM **Fireside Chat with FDA Center for Devices and Radiological Health (CDRH)**
Carolyn Neuland, PhD, Assistant Director for Renal and Transplantation Devices
Murray Sheldon, MD, Associate Director of Technology, and Innovation

6:15 PM – 6:45 PM **Fireside Chat with FDA Center for Biologics Evaluation and Research (CBER)**
Peter Marks, MD, PhD, Director of CBER

6:45 PM - 7:00 PM **Closing Remarks**
Raymond C. Harris, MD, FASN, KHI Chair
Mahesh Krishnan, MD, MPH, MBA, FASN, Planning Committee Co-Chair