

**Annual Stakeholders Meeting**  
**September 6-7, 2023**  
**Grand Hyatt Washington**  
**Washington, DC**

*“Defining the Next Decade of Kidney Innovation”*

Wednesday, September 6, 2023

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- 1:00 PM Pre-Workshops – *Spots are limited*
- APOL1 Kidney Disease: A Roadmap from Community Awareness and Screening to Clinical Trial Participation*  
Join the launch of KHI’s APOL1 Kidney Disease Roadmap to the kidney community. This workshop aims to gather your thoughts and experiences to inform how KHI can further engage community-based organizations. Registered workshop participants will receive an early copy of the roadmap.  
[Registration is required](#)
- SGLT2 Inhibitors: Conducting Pediatric Clinical Trials*  
In July 2023, together with KHI member, Nephcure, and key stakeholders from the United States and Europe, a workshop was organized to discuss the need for clinical trials of SGLT2 inhibitors in pediatric chronic kidney disease. This session will highlight the key conclusions of the workshop and will solicit input from the community on how to foster awareness of the need for clinical trials of SGLT2 inhibitors in the pediatric nephrology community and patient populations.  
[Registration is required](#)
- 3:30 PM Pre-Meeting Networking
- Join us for light refreshments and informal networking to highlight KHI projects, members, the Board of Directors, and staff.*
- 5:00 PM Welcome and Opening Comments  
*Uptal D. Patel, MD*  
*Chair*  
*Kidney Health Initiative*
- 5:15 PM Reflection on Current and Future Priorities for the FDA Commissioner  
*Robert M. Califf, MD*  
*Commissioner*  
*US Food and Drug Administration (FDA)*

- 5:45 PM            A Patient Advocacy Group's Impact on Clinical Trial Infrastructure: The Cystic Fibrosis Foundation's Therapeutics Development Network  
*John P. Clancy, MD*  
*Senior Vice President of Clinical Research*  
*Cystic Fibrosis Foundation*
- 6:15 PM            Dinner
- 6:45 PM            Celebrating 10 Years of the Kidney Health Initiative  
*Prabir Roy- Chaudhury, MD, PhD, FASN, Moderator*  
*Reshma Kewalramani, MD, FASN*  
*Barbara S. Gillespie, MD, FASN*  
*Brigitte Schiller, MD, FASN*
- 7:30 PM            Dessert Reception and Networking

### **Thursday, September 7, 2023**

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- 8:00 AM            Breakfast
- 8:30 AM            Current and Future Priorities for the FDA CDRH Director  
*Jeffrey Shuren, MD, JD*  
*Director*  
*Center for Devices and Radiological Health (CDRH)*
- 8:45 AM            From Napkin Sketch into Patient Hands: Innovative Device Development  
*Brigitte Schiller, MD, FASN, Moderator*  
*Dawn Edwards*  
*Sarah Lee*  
*Paul Komenda, MD*  
*Manisha Dadhania, MBA*
- 10:00 AM           Break
- 10:30 AM           Current and Future Priorities for FDA CBER Director  
*Peter Marks, MD, PhD*  
*Director*  
*Center for Biologics Evaluation and Research (CBER)*

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- 10:45 AM      Cell and Gene Therapy...What Can the Kidney Community Learn from Others?  
*Reshma Kewalramani, MD, FASN, Moderator*  
*Keziah Lukombo (Fireside chat with Moderator Barbara S. Gillespie, MD, FASN)*  
*Jeremy Duffield, MD, PhD, FRCP*  
*Celia Witten, MD, PhD*
- 12:00 PM      Lunch and Networking
- 1:00 PM      Utilizing Patient Advisory Boards to Accelerate Innovation  
*KHI Patient and Family Partnership Council*  
*Patrick O. Gee, Sr., PhD*
- 1:30 PM      From Predictive Analytics to Personalized Care: Unleashing the Power of Data to Accelerate Clinical Drug Development  
*Amit Sharma, MD, FASN, Moderator*  
*Ravindra L. Mehta, MBBS, MD, FASN*  
*Lesley Ann Inker, MD, MS*  
*Robert A. Star, MD*  
*Aliza M. Thompson, MD, MS*  
*Curtis Warfield, MS*
- 3:00 PM      Closing Comments and Next Steps  
*Uptal D. Patel, MD*

The KHI Board of Directors would like to thank the Program Committee Co-Chairs:

Barbara S. Gillespie, MD, FASN  
Reshma Kewalramani, MD, FASN  
Brigitte Schiller, MD, FASN

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