



# **Best Practices and Lessons Learned Conducting Clinical Trials During COVID-19: A Fireside Chat with Stakeholders**

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# Welcome & Introduction



# Accelerating Technology Development During a Pandemic to Bring More People with Kidney Failure Home



### Accelerating Technology Development During a Pandemic to Bring More People with Kidney Failure Home

*Position Paper*

*Kidney Health Initiative*

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*Founded in 2012, the Kidney Health Initiative (KHI) is a public-private partnership between the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA) committed to catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases. With over 100 member organizations, KHI is the largest consortium in the kidney community. The KHI Board of Directors considered a variety of issues impacting drug and device development in the kidney community during the Coronavirus – 2019 (COVID-19) pandemic and identified accelerating development of home therapies as central to improving care.*

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The COVID-19 pandemic is unmasking the shortcomings of in-center hemodialysis for people with kidney failure. Individuals with kidney failure who rely on in-center dialysis do not have the luxury of social distancing during a pandemic. In-center dialysis exposes people with kidney failure and healthcare workers to potential infection. Additionally, in-center hemodialysis patients are exposed to other discomforts and inconveniences associated with strict infection control and isolation policies necessitated by emergencies like pandemics.



# Making the Case for Change: Including People with Kidney Diseases in COVID-19 Trials



### Making the Case for Change:

#### Including People with Kidney Diseases in COVID-19 Trials

Clinical trials often exclude people with kidney diseases. This means that 37 million people in the United States are rarely represented in the kind of research that advances change in treatment and care. The challenges that result from such exclusion are highlighted by the current COVID-19 crisis.

Preliminary [studies](#) indicate that people with kidney diseases demonstrate an increased risk (two-to sixteen-fold) for developing severe COVID-19 symptoms. These data support US statistics that show acute kidney injury occurs in up to 5% of hospitalized COVID-19 patients and 50-90% of patients in the intensive care unit. ([reference](#)) Responding effectively to the COVID-19 pandemic should include people with kidney diseases.



# Ensuring the Resilience of Kidney Trials

- Maintain the investment and continue innovation in the kidney space.
- Provide resources for investigators and sponsors to be innovative and novel in continuing their research.





# Today's Objectives

- Understand patients' perspectives on trial participation during a pandemic
- Learn rationale and strategies to maintain trial engagement, conduct and best practices during a pandemic: past and future
- To connect KHI members for future interactions and sharing







# Fireside Chat



Jay Elliott, PhD

- US Medical Affairs Executive Scientific Director at Bayer Pharmaceuticals
- Oversees medical strategy for Bayer's cardiovascular and renal portfolio with current focus on Finerenone
- 15+ years in industry including time at Medpace and Boehringer Ingelheim



Andrew Hegedus, MBA

- Senior Vice President, Global Clinical Development at Covance Inc.
- Responsible for development strategy and execution of all clinical development programs at Covance
- 12+ years in industry prior to Covance including time at Pfizer, Roche and Sanofi



Kristen Hood, MSN, RN

- Director, Clinical Outreach at NephCure Kidney International
- Prior to NephCure, she served as an assistant professor of nursing in a pre-licensure Bachelor of Science Nursing program
- In her current role, she focuses on teaching patients, families and advocates within the community for clinical research and treatment options



Colin Meyer, MD

- Chief Research and Development Officer and Executive Vice President at Reata Pharmaceuticals
- 17+ years in industry becoming Reata's second employee in 2003
- Has served in various roles at Reata including clinical, regulatory and product development and serving as Chief Medical Officer for seven years prior to his current role





# Q & A



**SAVE THE DATE!**

## **Monthly KHI Member Town Halls**

*Wednesday, August 5, 2020 4:00PM EDT*

*Wednesday, September 2, 2020 4:00PM EDT*