



PRESS RELEASE

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KIDNEY HEALTH INITIATIVE URGES INVESTIGATORS TO INCLUDE PEOPLE WITH KIDNEY DISEASES IN CLINICAL TRIALS FOR CORONAVIRUS 2019 (COVID-19) THERAPIES

Highlights:

- People with kidney diseases are often excluded from clinical trials because of the complexity and high morbidity of kidney disease.
- COVID-19 puts people with kidney diseases at a two to sixteen-fold increased risk of severe symptoms.
- All investigators should include people with kidney diseases when developing vaccines, preventative therapies or treatments related to COVID-19.

Washington, DC (June 9, 2020) — Clinical trials often exclude people with kidney diseases. This practice could have significant consequences, if continued, during the Coronavirus – 2019 (COVID-19) pandemic and for the 37 million Americans with kidney diseases who are at high risk of severe disease.

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. An effective response to the COVID-19 pandemic should include people with kidney diseases.

The KHI Board of Directors considered a variety of issues impacting drug and device development in the kidney community during the COVID-19 pandemic and identified inclusion of people with kidney diseases in clinical trials for COVID-19 therapies as central to improving care. The recent statement, written by members of the Board of Directors is titled "[Making the Case for Change: Including People with Kidney Diseases in COVID-19 Trials](#)".

"Given their increased risk, people with kidney diseases deserve to be prioritized in the development of novel therapies for COVID-19," said Raymond C. Harris, MD, FASN, Co-Chair of KHI, "KHI urges sponsors and investigators to come alongside the US Food and

Drug Administration (FDA) and the patient community to expand their research into this vulnerable population.”

The FDA encourages enrollment practices that lead to clinical trials better reflecting the population most likely to use and benefit from the therapy being studied. This can be achieved through novel trial designs or broadening eligibility criteria, when appropriate, to increase enrollment of underrepresented populations. A recent guidance from the FDA titled [“COVID-19: Developing Drugs and Biological Products for Treatment or Prevention”](#) explicitly encouraged sponsors to include people with kidney diseases in their COVID-19 trials.

As the largest consortia in the kidney community and a public-private partnership between the American Society of Nephrology and the FDA, KHI urges all investigators to include people with kidney diseases when developing vaccines, preventative therapies or treatments related to COVID-19. This population demonstrates increased risk of exposure, infection, and severe morbidity, and inclusion of people with kidney diseases in trials would benefit all aspects of health care.

Individuals who are interested in learning more about KHI, should contact Melissa West, Acting Vice President for Research, Discovery and Innovation, at mwest@asn-online.org.

The Kidney Health Initiative (KHI) is a key part of the newly created ASN Alliance for Kidney Health. KHI is uniquely positioned to realize ASN's vision of a world without kidney diseases. As a public-private and collaborative partnership with the FDA and more than 100 organizations and companies, KHI catalyzes innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases. Learn more at www.kidneyhealthinitiative.org.

Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients. ASN has more than 21,000 members representing 131 countries. For more information, please visit www.asn-online.org or contact the society at 202-640-4660.

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