CRITICAL PATH INSTITUTE

Critical Path Institute to be Honored with Reagan-Udall Foundation Innovation Award

Award honors regulatory science advances with measurable public health impact; ceremony December 9, 2025, Willard InterContinental, Washington, D.C.

TUCSON, Ariz., October 14, 2025 — Critical Path Institute® (C-Path) announced it has been selected to receive the 2025 Innovation Award by Reagan-Udall Foundation for the FDA, part of the Foundation's Innovations in Regulatory Science & Policy Awards. The Foundation will recognize this year's honorees on December 9, 2025, at the Willard InterContinental Hotel in Washington, D.C.

The Innovation Award acknowledges an individual, team, or organization whose specific advances in regulatory science or policy have measurably improved public health. In announcing its selection, the Foundation cited C-Path's record of creating practical tools and cross-sector collaborations that shorten drug development timelines and improve regulatory decisions.

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

"This honor belongs not only to C-Path but also to the collaborators who put in the hard work alongside us every day," said M. Wainwright Fishburn, J.D., Chairman of C-Path's Board of Directors. "It means a great deal to see regulators and developers put these tools to work in real decisions that improve patient outcomes. We are grateful to the Reagan-Udall Foundation and congratulate our fellow honorees who continually show how shared evidence improves public health."

"This recognition is not only a testament to the groundbreaking science we advance, but also to the spirit of collaboration that defines our work," said Klaus Romero, M.D., M.S., FCP, C-Path Chief Executive Officer. "Innovation in regulatory science is only possible when diverse partners come together with a shared vision of accelerating medical drug development for those in need across the country, and the world. By transforming data integrated in our world-class platform into regulatory grade biomarkers, outcomes, and clinical trial simulators, our teams are delivering tools that regulators and developers use to optimize real decisions every day, and we will keep pushing to help treatments reach people sooner."

Each year the Reagan-Udall Foundation recognizes leadership that elevates the field, policy work that removes barriers, and innovation that measurably improves public health.

"Our 2025 honorees exemplify vision and innovation, and their work is already making a lasting difference in the lives of individual Americans—by enhancing the safety of fresh produce, improving the efficiency of developing new treatments, and assuring the patient is at the center of product development," said Susan C. Winckler, RPh, Esq., Foundation CEO. "We are excited to celebrate their accomplishments and impact."

Now, more than ever, reliable drug development rests on neutral convening, rigorous methods, and shared platforms. Those elements support clear decisions across complex modalities, smaller trials, and patient-relevant evidence.

To find out more about the Reagan-Udall Foundation and the Foundation's Innovations in Regulatory Science & Policy Awards, visit reaganudall.org.

Founded in 2005 in response to the FDA's Critical Path Initiative, C-Path builds neutral, global collaborations that deliver regulatory-grade tools, data, and methods used across diseases and modalities. The Institute works with U.S. and international regulators, industry, academia, and patient organizations to lower risk and improve the evidence behind key development choices. C-Path is headquartered in Tucson, Arizona, with a European subsidiary in Amsterdam.

For additional information on C-Path and its initiatives, visit c-path.org.

Event details: Innovations in Regulatory Science & Policy Awards, December 9, 2025, Willard InterContinental, Washington, D.C. The 2025 honorees are the Produce Safety Alliance for Leadership, Critical Path Institute for Innovation, and Loren A. Eng for Advocacy/Policy.

About Critical Path Institute
Founded in 2005, as a public-private partnership in response to the FDA's Critical Path Initiative, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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