C-Path's Inaugural Global Impact Conference Charts the Future of Drug Development

WASHINGTON, Sept. 12, 2024 — Critical Path Institute (C-Path) successfully concluded its inaugural Global Impact Conference (CGIC) on September 11, 2024, at the Washington Marriott at Metro Center in Washington, D.C. This landmark event brought together industry leaders, regulatory agencies, academic experts, and patient advocacy groups, all dedicated to advancing drug development and regulatory science for rare diseases.

C-Path CEO Klaus Romero delivers opening remarks at #CGIC2024

The conference opened with remarks from C-Path CEO Klaus Romero, M.D., M.S., FCP. Dr. Romero outlined the importance of the conference and its pivotal role in shaping the future of healthcare through impactful collaboration. "2024 marks the 20th anniversary of the Critical Path Initiative document from the FDA, which laid the groundwork for today's efforts to accelerate drug development through public-private partnerships," said Dr. Romero. "As we celebrate this milestone, we reflect on how these collaborative solutions have transformed multiple paradigms for drug development, connecting dots across various therapeutic areas and advancing imaging markers that help identify clinical trials early in the disease process. This collaboration is the driving force behind our success in bringing together the deepest expertise.

The inaugural day, themed 'Innovative Methods and Approaches,' set the tone for a series of discussions and workshops dedicated to exploring new frontiers in medical research and drug development.

C-Path was also honored to have FDA Commissioner Robert Califf, M.D., MACC, participate in a panel during the opening session, where he emphasized the importance of collaborative efforts to tackle the complexities of drug development.

"In general, there is a real need across an array of areas where science is shared. Whether you're a regulator, an academic institution or part of the industry that's producing products or clinical practice," said Dr. Califf. "I think part of the Critical Path Initiative and the Critical Path Institute has been the development of the methods and the playbook. Because, on the one hand, as regulators, we're collaborating with the entities that we're regulating. On the other hand, there are regulatory decisions to be made, and those really need to be kept apart."

Day two of the conference centered on ‘The Power of Every Precious Data Point in Rare and Orphan Diseases,’ emphasizing the transformative role of data in the treatment of rare and orphan diseases. The discussions throughout the day highlighted this theme, featuring compelling remarks by former NFL player and ALS advocate Steve Gleason. Gleason shared his personal experiences and underscored the profound impact that technology has on patient care, inspiring participants and highlighting the urgent need for continued innovation in this field.

C-Path CEO Klaus Romero with FDA Commissioner Robert Califf

“I’m speaking to you as a proponent of relentless collaboration. The magic happens when patients, researchers, industries, and regulators converge with a shared goal: to transcend boundaries and embrace the public-private partnership models like those championed by C-Path,” said Gleason in his taped remarks.

“These collaborations ensure that no resource is left untapped in our quest to save and extend the quality of life. Despite the challenges, I am optimistic. I believe in the power of science and the spirit of collective effort. I am hopeful that — together — we can push the boundaries of what’s possible, making bold progress in how we fight rare diseases. We can turn fear into frontiers of opportunity. We can turn suffering into stories of success. We can turn challenges into catalysts for innovation.”

Building on this momentum, ALS Patient advocate Stacy Lewin Farber shared her powerful personal experience in a session titled “Lived Experiences in Action: Advocacy Updates Across Rare Diseases.”

“Reflecting on my journey from the early symptoms to my ongoing advocacy, I’ve realized the power of resilience and proactive engagement in our health,” said Farber. “Diagnosed with ALS in July 2020, I quickly saw the necessity of understanding one’s own health to expedite diagnosis and treatment. Through my involvement in clinical trials and numerous patient advocacy groups, I have channeled my medical background and personal experience to push the boundaries of what we can achieve in drug development. The importance of events like C-Path’s Global Impact Conference cannot be overstated as they provide a crucial platform for integrating patient insights to shape future therapies that are not only innovative but deeply informed by our lived experiences.”


ALS Patient advocate Stacy Lewin Farber (middle) on panel at #CGIC24

The conference concluded with a day dedicated to ‘Navigating Novel Therapies with Novel Evidence Sources.’ The schedule was packed with workshops and discussions focused on innovative therapies and emerging research avenues. These sessions highlighted how cutting-edge technologies and methodologies are integral to enhancing patient care. The discussions fostered a deep understanding of the latest approaches in the field, illustrating the critical connection between novel therapeutic strategies and novel evidence sources in improving treatment outcomes.

“Thank you for being here this week. We encourage everyone to carry this momentum forward and stay energized — that’s how we’ll continue to be the best partner for those with living experience, our regulatory colleagues, our existing pharma partners, and the new ones on the horizon,” Romero said in his closing remarks.

“Our mission isn’t just a slogan; it’s something we live by every day. Over these three days, we didn’t just talk about the future of drug development — we’re actively shaping it.”

The resounding success of this inaugural event established C-Path’s Global Impact Conference as a crucial forum where stakeholders from various sectors of drug development convened to share strategies, insights, and innovations. The outcomes from this event highlighted C-Path’s ongoing commitment to lead initiatives that accelerate drug development processes and enhance patient outcomes globally, setting a strong foundation for future CGIC events, which will continue to build on these discussions, fostering an environment of collaboration and progressive solutions for years to come.

As C-Path looks to the future, plans are already underway for the next Global Impact Conference, tentatively scheduled for the week of September 7, 2025. This event will not only continue the tradition of fostering groundbreaking discussions but will also serve as a commemorative celebration of C-Path’s 20th anniversary, highlighting two decades of leadership and innovation in drug development and healthcare.

About Critical Path Institute??

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona and?C-Path in Europe?is headquartered in Amsterdam, Netherlands with additional staff in multiple other locations. For more information, visit?c-path.org.?

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) and is 55% funded by the FDA/HHS, totaling $17,612,250, and 45% funded by non-government source(s), totaling $14,203,111. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.??

Media Contacts:???

Roxan Triolo Olivas? ?
C-Path? ?
520.954.1634? ?
rolivas@c-path.org???

Kissy Black?
C-Path?
615.310.1894?
kblack@c-path.org?