

## Critical Path Institute Celebrates 20 Years of Advancing Drug Development through Innovation and Collaboration

**TUCSON, Ariz., May 8, 2025** — The year 2025 marks a historic milestone for Critical Path Institute® (C-Path), as the organization celebrates 20 years of transforming the landscape of drug development through collaboration, regulatory science, and next-generation strategies. Founded in 2005 by Raymond Woosley, M.D., Ph.D., with the support of leaders across multiple sectors in the pharmaceutical industry and regulatory agencies, as well as visionary elected officials like Congresswomen Gabby Giffords and Marsha Blackburn (now Senator), C-Path has played a pivotal role in accelerating the development of safe and effective treatments for individuals and families worldwide.

Since its inception in Tucson, Arizona, C-Path has grown from a small team of six employees to a globally recognized leader that has generated more than 160 job opportunities to stimulate innovations that accelerate drug development and advance regulatory science through data-driven solutions.

With a unique, neutral, precompetitive model that unites industry, regulators, academia, patients and patient groups, C-Path has spearheaded groundbreaking initiatives to generate tangible solutions that have accelerated drug development in areas such as infectious disease, rare disease, neurology, and pediatrics.



“C-Path was built on the vision that no single entity can solve the challenges of the drug development process alone,” said former C-Path CEO Dr. Woosley. “Over the last 20 years, C-Path has transformed that vision into reality, bringing together experts and communities to accelerate progress and improve patient outcomes.”

### A Legacy of Innovation and Impact

From its early days supporting the FDA's Critical Path Initiative, published in 2004, to leading the first multi-stakeholder biomarker qualification efforts, C-Path has driven numerous regulatory advancements. A sample of the organization's milestones include:

**2005–2010:** C-Path quickly emerged as a pioneer in accelerating drug development by launching landmark consortia and earning early regulatory endorsements for innovative safety kidney biomarkers by FDA, EMA, and PMDA.

**2011–2015:** C-Path gained global recognition for its trailblazing biomarker qualification work, model-informed drug development collaborations, patient-focused drug development initiatives, and international data-sharing and regulatory collaborations, leading to groundbreaking achievements, such as the first-ever clinical trial simulator endorsed by FDA and EMA (for Alzheimer's disease).

**2016–2020:** C-Path expanded its disease focus—spanning rare and orphan diseases, pediatrics, as well as neurodegenerative, metabolic, and infectious conditions—while launching major data platforms, international headquarters, and initiatives with global health authorities.

**2021–Present:** C-Path has intensified its global impact by advancing regulatory science across diseases, expanding its partnerships, seeing pivotal drug approvals being facilitated by the tools generated through C-Path collaborations, and hosting its inaugural Global Impact Conference—culminating in its 20th anniversary celebration in 2025.

“C-Path's work has fundamentally changed the way the industry approaches drug development,” said Wainwright Fishburn, J.D., Chair of C-Path's Board of Directors. “Through its leadership in regulatory science, data integration, and patient-centered research, the organization has made an undeniable impact on the lives of people worldwide.”

### **Looking to the Future: Leading Innovation in Drug Development**

Entering its third decade, C-Path stands at the intersection of human ingenuity and technological advancements, trailblazing novel solutions to realize the promise of innovations in AI, digital health, real-world data, and computational tools to turn modern drug development challenges into opportunities. As such, C-Path continues to drive smarter, faster pathways to accelerate the development of better medicines that matter.

“Our mission remains clear: to accelerate the path to new treatments by fostering innovation, scientific rigor, and collaboration,” said C-Path CEO Klaus Romero, M.D., M.S., FCP. “With a future focused on actionable precision medicine, data-driven insights, and global leadership, C-Path is poised to lead the acceleration of the next era of drug development.”

To mark its 20th anniversary, C-Path will host a series of impactful events, uniting key stakeholders to explore future opportunities in accelerating and facilitating biomedical innovation.

Kristen Swingle, M.S., C-Path President and Chief Operating Officer, reflected on the organization's success and growth over the past two decades: “C-Path's success is built on the dedication and expertise of our talented team. Over the last 20 years, we have transformed from a small group of visionaries to a global leader in regulatory science and drug development. Our evolution in the cutting-edge jobs we have created, and the impact they have had, is a testament to the collaborative spirit and unwavering commitment of our staff, partners, and stakeholders.”

As part of this milestone year, C-Path's annual Global Impact Conference will take place in Washington, D.C., September 9–11, 2025. This gathering will convene global experts in drug development, regulatory science, and patient advocacy to foster collaboration and accelerate progress. We encourage members of the biomedical community to participate in shaping the future of healthcare. Registration details can be found [here](#).

For more information on C-Path's 20th Anniversary events and its continued impact on drug development, visit <https://c-path.org/20-years-of-impact/>.

### **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](https://c-path.org).

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