CRITICAL PATH INSTITUTE

C-Path Q3 2025 Newsletter

Hello to our C-Path Community,

TAs we close another impactful quarter, I'm proud to share highlights of the important milestones we've achieved together. From convening global leaders at our 2025 Global Impact Conference, to launching the Global Evidence in Medicine for Parkinson's Disease (GEM-PD) initiative and celebrating C-Path's 20th anniversary in Washington D.C., this season has underscored the power of collaboration to advance regulatory science and improve lives worldwide.

This newsletter captures those moments, along with exciting updates on new partnerships, recognition of our achievements, and stories that bring our mission to life. I encourage you to explore these updates and celebrate the progress we are making together.

With gratitude,

Klaus Romero, MD, MS, FCP

Chief Executive Officer
Critical Path Institute

C-Path's 2025 Global Impact Conference

On behalf of C-Path, I want to extend my deepest gratitude to each of you that joined us at this year's Global Impact Conference. Your presence, insights, and commitment made this gathering truly remarkable.

This conference is more than an event — it reflects our shared mission to accelerate the development of therapies, strengthen collaborations across sectors, and improve lives around the world. The dialogue, ideas, and partnerships sparked here will continue to shape the future of regulatory science and global health.

Thank you for lending your time, your expertise, and your passion. Together, we are making a meaningful impact, and I look forward to continuing this important work with you in the months and years ahead.

Full session recordings are available on C-Path's YouTube channel here.

Global Evidence in Medicine for Parkinson's Disease

C-Path hosted the launch of Global Evidence in Medicine for Parkinson's Disease (GEM-PD) on September 9, 2025, at the National Museum of Women in the Arts. The event featured expert perspectives from Catherine Kopil, Ph.D. (The Michael J. Fox Foundation), Soania Mathur, M.D. (Unshakeable MD), and Bola Grace, Ph.D. (University College London).

GEM-PD is a global initiative focused on closing a critical gap in Parkinson's research — understanding how the disease uniquely affects women through sex-specific biological factors. By applying data science, digital health technologies, and regulatory science expertise, the initiative seeks to drive the development of more personalized therapies.

Through integrating sex-specific insights into clinical trial design, regulatory pathways, and therapeutic development, GEM-PD aims to support more effective treatments for everyone living with Parkinson's.

Learn more here: Critical Path for Parkinson's.

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20 Years of Impact – Honoring the Journey. Shaping What's Next.

Together, we celebrated the enduring collaborations and visionary contributions that continue to advance our mission.

This event took place at Andrew Mellon Auditorium and featured an inspiring agenda that both celebrated our successes as well as provided an exciting vision for the future of our collaborations. A fireside chat was led by CEO Klaus Romero, and included Kathryn Bryant Knudson (The Speak Foundation), Ron Bartek (C-Path Board Member, Friedreich's Ataxia Research Alliance) and Anita Goel, M.D., Ph.D. (Nanobiosym). At C-Path, data sharing is the foundation of our collaborative model. By bringing together information from diverse stakeholders — including industry, academia, regulators, and patient groups — we accelerate the path from scientific discoveries to actionable medical products, reduce duplication of efforts, and create a more complete picture of disease and treatment development.

Celebrating Outstanding Achievement in Regulatory Science

The Reagan-Udall Foundation for the FDA has announced the honorees for the 2025 Innovations in Regulatory Science & Policy Awards, which celebrate extraordinary leadership, innovation, and advocacy in advancing regulatory science and protecting public health.

We're honored that Critical Path Institute will be recognized alongside the Produce Safety Alliance and Loren A. Eng at the awards ceremony on December 9, 2025.

C-Path will receive the Innovation Award, which highlights individuals, teams, or organizations that have improved public health through a specific regulatory science or policy innovation. This recognition reflects our role in creating groundbreaking tools and partnerships that accelerate drug development, advance life-saving therapies, and redefine how regulatory science improves public health.

Scientific American Feature

Scientific American recently featured C-Path CEO Dr. Klaus Romero in its article "The Agenda Setters: Bringing Science to Life."

The piece explores the concept of healthspan — the years of life lived free from serious disease — a topic gaining momentum both in the popular press and within the scientific community focused on longevity research.

We're proud to see Dr. Romero's leadership and perspective highlighted in this important conversation.

Read more here: Scientific American October 2025.

BizTucson Special Report 2025: Critical Path Institute

As C-Path celebrates 20 years of advancing regulatory science and reshaping how new treatments are developed for Alzheimer's, Parkinson's, type 1 diabetes, rare and pediatric conditions, and more, BizTucson has published a special report: "Critical Path Institute: Moving Drugs to Market, Smarter, Faster for 20 Years."

The issue features a milestone timeline, insights from founder Dr. Raymond Woosley, Board Chair M. Wainwright Fishburn, and Tammy McLeod of the Flinn Foundation, along with highlights of C-Path's impact in neurology and rare disease. It also spotlights CEO Klaus Romero and President & COO Kristen Swingle, M.S., who are leading C-Path into its next decade of innovation, and celebrates Swingle's recognition as one of BizTucson's 2025 Women Leading the Region.

Read the full special issue here.

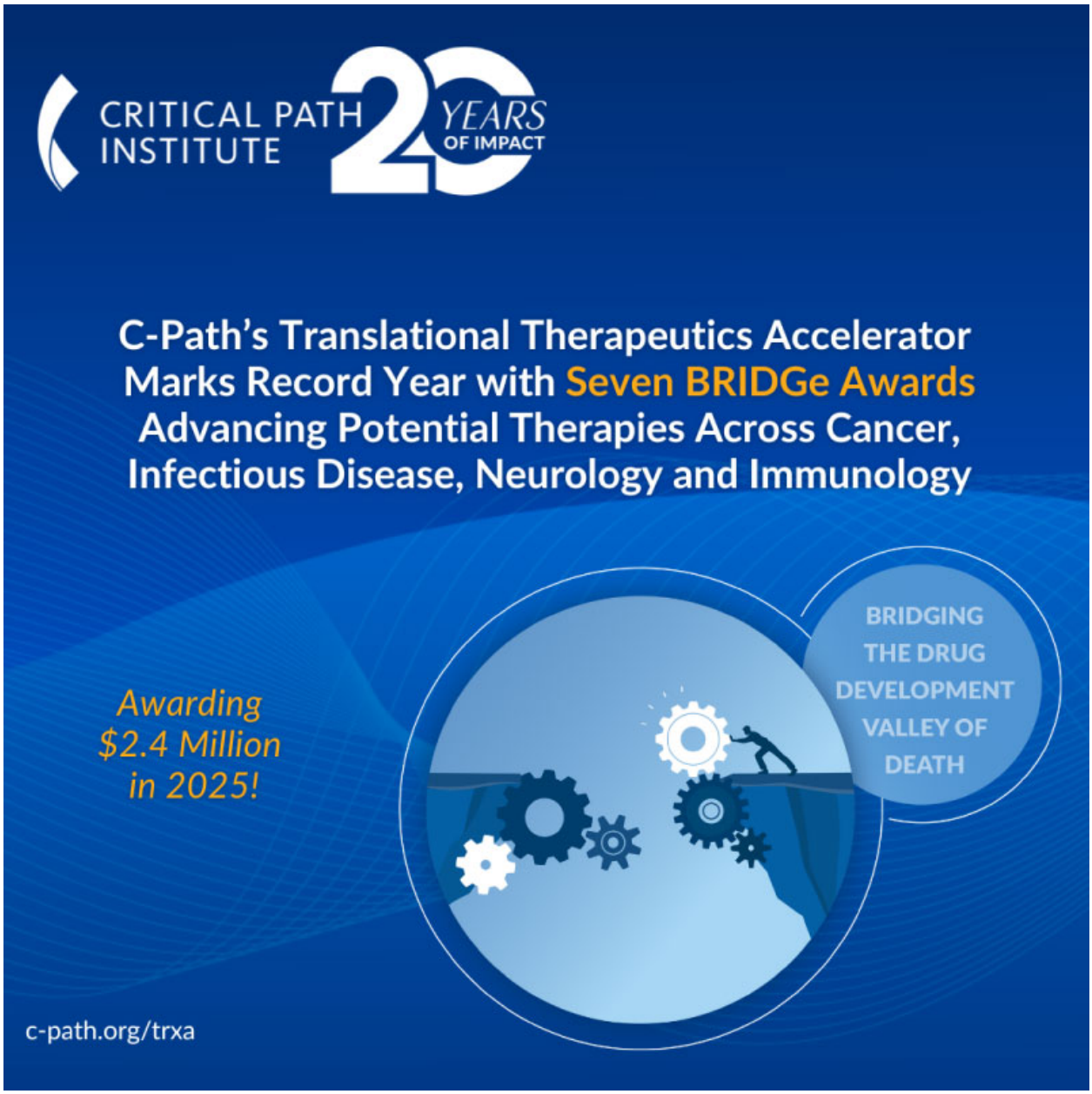
Read Kristen Swingle's "Women Leading the Region" feature here.

We are proud to mark this milestone with our partners, collaborators, and community — and remain committed to improving global health for decades to come.

C-Path's Translational Therapeutics Accelerator Marks Record Year with Seven BRIDGe Awards

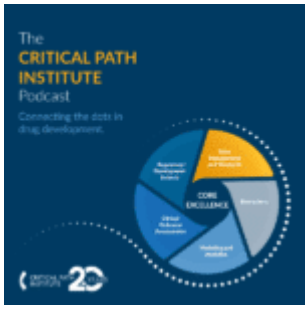
Critical Path Institute (C-Path) announced that its Translational Therapeutics Accelerator (TRxA) program has completed a record year of funding and mentorship, awarding seven BRIDGe grants to academic drug development teams.

Launched in 2022 and awarding its first grants in 2023, TRxA reached a new milestone in 2025 by supporting its largest annual cohort to date, advancing seven innovative projects toward clinical translation.



Read more here.

The Critical Path Institute Podcast



We hope you enjoy these engaging discussions that truly highlight C-Path's collaborative approach to advancing drug development and improving global health outcomes. Subscribe today!

NEW! Episode 6: The Critical Path Institute Podcast: Connecting the Dots in Pediatrics.

NEW! Episode 5: Connecting the Dots in Quantitative Medicine.

Episode 4: Connecting the Dots with the Data Collaboration Center.

Episode 3: The Critical Path Institute Podcast: Electronic Clinical Outcome Assessment (eCOA) Conversations.

Episode 2: Connecting the Dots Between Type 1 Diabetes and Parkinson's.

Episode 1: Connecting the Dots with COA VP Dr. Cheryl Coon.

Listen and subscribe here:

Apple	Spotify	YouTube

Impact

At C-Path, our impact stories spotlight the lives and voices that shape our work — from patients and families to researchers and advocates — reminding us why advancing regulatory science matters.

ICYMI | Forging New Paths in Prostate Cancer Treatment

Dr. Peter Wipf

Dr. Peter Wipf of the University of Pittsburgh shares how support from C-Path's Translational Therapeutics Accelerator (TRxA) is accelerating his team's research in prostate cancer. Funding and expert guidance from TRxA have been critical in advancing preclinical studies and scaling up lead compounds.

For our most recent impact stories and blogs visit here.

Latest News

C-Path Names Colin Hill to Board of Directors.

C-Path Concludes 2025 Global Impact Conference with Progress Across Rare Diseases, Neurology and Pediatrics.

C-Path Welcomes Rare Disease Advocacy Leader Ronald J. Bartek to Board of Directors.

HDYO Joins C-Path's Huntington's Disease Consortium to Amplify Youth Voices in Drug Development.

Critical Path Institute Appoints Dr. Aoife Brennan to Board of Directors.

Find more C-Path press releases and additional media, here.

Connect with C-Path team members us at upcoming events:

- 2025 PD Therapeutics Conference | October 15 – October 18 | Cheryl Coon
- ISOQOL | October 22 – October 25 | Cheryl Coon, Barbara Brandt, Sonya Eremenco, and Maria Mattera
- PPMD Duchenne Drug Development Roundtable | October 22 – October 23 | Ramona Belfiore-Oshan
- PROMIS Health Organization Meeting | October 26 – 28 | Sonya Eremenco
- ADDC Colloquium | October 28 – October 29 | Maaike Everts
- ASN Kidney Week | November 4 – November 9 | Sorin Fedeles, Wendy Ruyle, and Katrina Peron

NEW On Demand:

- 21?? Century Trials in New-Onset T1D Virtual Workshop.
- Webinar: RDCA-DAP and NORD's IAMRARE Platform to Platform Federation: Lessons Learned.
- Webinar: ACE Inhibitors as a Cardioprotective Treatment in Dystrophinopathies.
- Webinar: Vivli and RDCA-DAP: Data Platform Partnerships to Promote Rare Disease Data Sharing.