

C-Path Q2 2025 Newsletter

Hello to our C-Path Community,



This year marks a historic milestone for Critical Path Institute® (C-Path) as we celebrate 20 years of advancing regulatory science, accelerating drug development, and, most importantly, driving impact for people in need. What began in 2005 as a bold idea—brought to life by our founder Dr. Raymond Woosley with the support of regulators, industry leaders, and forward-thinking policymakers—like then Congresswomen Gabby Giffords and Marsha Blackburn (now Senator)—has grown into a global force for innovation and collaboration.

From our origins in Tucson, Arizona with just six employees, C-Path now consists of a dynamic team of over 160 professionals united by a shared commitment: to develop data-driven, regulatory-grade solutions that address unmet medical needs. Our precompetitive approach as the neutral convener continues to bring

together diverse stakeholders—regulatory agencies, pharmaceutical and biotech companies, academia, and nonprofits—to solve some of the most complex challenges in drug development.

In this special edition of our quarterly newsletter, you'll find updates that reflect the strength and breadth of that collaboration. Highlights include:

- **Our latest co-authored publication in *Nature Reviews Drug Discovery***, developed with the Innovative Health Initiative (IHI), offers a strategic roadmap for maximizing regulatory impact in consortium-based projects.
- **Upcoming meetings and events** where C-Path's work will be showcased, from our global impact conference to regulatory workshops.
- **Recent accomplishments across our consortia and programs**, including efforts in translational therapeutics, neurology, rare disease, and pediatric drug development.

As we honor two decades of progress, we are also looking forward—with ambitious goals and renewed purpose. Thank you for being part of this journey. We invite you to celebrate **#CPath20Years** with us, and to help shape what comes next.

With gratitude,

Klaus Romero, MD, MS, FCP



Chief Executive Officer
Critical Path Institute

Register Now: 2025 Global Impact Conference, September 9-11, Washington, D.C.

You don't want to miss this year's C-Path Global Impact Conference! The event will include multiple panels and breakout sessions throughout September 9-11 at the Washington Marriott at Metro Center. These panels will include esteemed speakers with backgrounds in patient advocacy, rare diseases, neonatal drug development, and more.

On previous communications we have highlighted key sessions across the conference. This time, we invite you to a powerful, town hall-style session on day 3, led by patient advocates who are driving change in drug development, scientific research, and healthcare innovation. In this dynamic and thought-provoking discussion, "Today's Voices, Tomorrow's Treatments: The Growing Role of Patient Advocacy in Innovation," patient advocates will share their personal stories, challenges, and successes, highlighting how advocacy is reshaping the drug development ecosystem and inspiring new pathways for collaboration, policy change, and scientific breakthroughs.

What to expect:

- Authentic, first-hand perspectives from patient advocates who are influencing research, regulatory decisions, and innovation.
- A discussion on key challenges in advancing effective treatments and cures—and how we can overcome them together.
- C-Path's role in strengthening partnerships between advocacy groups, scientists, policymakers, and industry leaders.
- Opportunities for deeper collaboration between advocates, researchers, and decision-makers to accelerate progress.

Register now: [C-Path Global Impact Conference 2025](#)

More panelists and speakers are added daily, so be sure to check in before the big event. We'll see you in September!

The poster features a blue background with a faint image of the Washington Monument and cherry blossoms. At the top left is the C-Path 2025 logo, which includes a stylized globe icon. Below the logo, the text 'GLOBAL IMPACT CONFERENCE' and 'WASHINGTON, DC | SEPT 9-11' is displayed. The main title, 'Today's Voices, Tomorrow's Treatments: The Growing Role of Patient Advocacy in Innovation', is centered in white. A yellow banner below the title indicates the date and time: 'September 11, 2025 | 9:30 - 10:30 AM ET'. At the bottom, three headshots of speakers are shown with their names and titles: Jenn Kendra (VP of Strategic Partnerships, C-Path), Wanda Smith (Founder, CureGRN), and Cami Samuels (Partner, Non-profit and Venrock boards).

**C-PATH
2025**

GLOBAL IMPACT CONFERENCE
WASHINGTON, DC | SEPT 9-11

**Today's Voices, Tomorrow's Treatments: The Growing
Role of Patient Advocacy in Innovation**

September 11, 2025 | 9:30 - 10:30 AM ET

Jenn Kendra
VP of Strategic Partnerships
C-Path

Wanda Smith
Founder
CureGRN

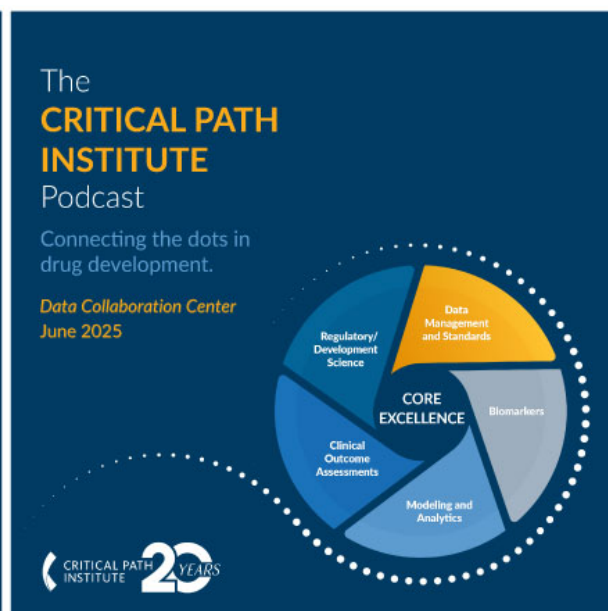
Cami Samuels
Partner
Non-profit and Venrock
boards

NEW Episodes from The Critical Path Institute Podcast

In our latest episodes of the Critical Path Institute Podcast, we dive into the first in the Electronic Clinical Outcome Assessment (eCOA) Conversations series and an in-depth exploration of one of C-Path's core teams: the Data Collaboration Center (DCC). The eCOA panel features industry veterans reacting to the question, "What makes a good eCOA partner?" In addition to host eCOA Consortium Executive Director Scottie Kern, the panel includes Dr. Florence Mowlem, Chief Science Officer at uMotif, YPrime's Vice President of eCOA and Patient Technologies, Dr. Karl McEvoy, and Brian Lillis, Director of Clinical Outcome Technologies at ICON.

The new DCC podcast features C-Path's DCC Director Ramona Walls and Chief Technology Officer Rick Liwski with our CEO Klaus Romero discussing how data functions as one of the organization's five core competencies. The podcast explains the types of data integrated by DCC—including clinical trial data, electronic health records, imaging, digital device data, and preclinical findings—and how the team successfully manages complex processes for data acquisition, standardization, privacy, and accessibility.

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!](#)



Access:





NEW! Episode 4 [Connecting the Dots with the Data Collaboration Center](#)

NEW! Episode 3 [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:

			
Podbean	Apple	Spotify	YouTube

Impact



Ron and his wife, Carrie. Photo Credit: ALS Northwest

Our impact stories offer a powerful glimpse into the lives of those whose journeys deeply influence our work at C-Path. These stories highlight the real-world impact of drug development, showcasing how we invite those with lived experiences to the table. Whether you are an individual or a family living with a given condition, an advocate, or partner, these stories will inspire and reinforce the importance of what C-Path does.

Read our latest Impact story, [ALS Advocate Ron Newbury Pushes for Progress, Positivity Amidst Adversity](#).

Ron is a former attorney, teacher, and is a lifelong outdoor enthusiast. He was diagnosed with amyotrophic lateral sclerosis (ALS) in July of 2022. Like many living with ALS, he had years of unexplained symptoms before his diagnosis: a weakened golf swing, feeling his arms would tire quickly during routine tasks, and more. However, it was during one of his cherished bike trips that things progressed to the point of needing some answers.

“I see C-Path more focused, with an aggregation of expertise that may not exist other places. These other groups are great, but with C-Path, we can have conversations that aren’t possible in other forums. I was really intrigued by that early on, in terms of a key difference that C-Path offers,” explained Ron.

For our most recent [impact stories](#) and blogs visit, [here](#).

Additionally, in honor of **Huntington’s Awareness Month**, C-Path held a session with Hope4HD’s Lauren Holder on Research and Development focusing on Huntington’s disease which you can watch [here](#). In honor of **ALS Awareness Month**, we reflected on the powerful words of former NFL player and ALS advocate Steve Gleason, who helped kick off last year’s C-Path Global Impact Conference. Watch, [here](#).

Latest News

[C-Path’s Translational Therapeutics Accelerator Announces New Grant Award for Drug Development Project in Type 1 Diabetes](#)

[New Paper in Nature Reviews Drug Discovery Highlights How to Maximize the Regulatory Impact of Consortium-Based Projects](#)

[C-Path Translational Therapeutics Accelerator, Sontag Foundation Award Grant for Drug Development Project Targeting Pediatric Brain Tumors](#)

[C-Path and Citizen Health Partner to Accelerate Drug Development for Neuromuscular Disorders](#)

[Translational Therapeutics Accelerator program has awarded an \\$815,000 grant to the team at the Queensland Emory Drug Discovery initiative at UniQuest in Brisbane, Australia](#)

For more C-Path press releases and additional media, click [here](#).

Events

- Connect with Sonya Eremenco [International Progressive MS Alliance Digital Tools Workshop](#), June 25-27
- Connect with Sorin Fedeles and Wendy Ruyle at FASEB – [The Future of PKD Research](#), June 29 – July 3
- Connect with Scottie Kern at [PCT Europe 2025](#), June 30 – July 2
- Connect with Nadine Tatton and the CPAD team at [AAIC 2025](#), July 27-31



On Demand now:

- Coming Soon: 21st 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](#)