CRITICAL PATH INSTITUTE

C-Path Newsletter Q2 2026: New Leadership, New Science

Dear C-Path Community,

What a quarter it has been. Building on the strong momentum of the first quarter, we have continued to deepen collaboration, accelerate innovation, and drive meaningful impact across the global drug development ecosystem and I couldn't be more energized by what our community has accomplished together.

I am especially pleased to share some exciting news on the leadership front. We welcomed Karen Bernstein, co-founder and chair of BioCentury Inc., as the new Chair of our Board of Directors, a fantastic addition whose deep industry insight will help sharpen our strategic vision as we look ahead. Karen succeeds Wainright Fishburn, and on behalf of all of us at C-Path, I want to extend our deepest gratitude to Wain for five years of dedicated leadership and service as Board Chair. We also had the pleasure of welcoming two outstanding new members to our Board: Milad Alucozai and Yalonda Howze, whose expertise in biotech investment and life sciences law will strengthen our Board as C-Path continues to grow.

Karen Bernstein, Ph.D.

Milad Alucozai, DrPH

Yalonda Howze, J.D.

Our science kept pace with equal momentum. In May, we launched the New Approach Methodologies Developer Coalition (NAMs-DC), a first-of-its-kind precompetitive coalition bringing together developers of organ chips, complex in vitro models, and computational tools to build a shared qualification framework and reduce reliance on animal testing, a genuinely exciting step toward more human-relevant drug development. And in June, following the FDA's accelerated approval of the first disease-modifying therapy for stage 3 type 1 diabetes, we reaffirmed our commitment to advancing the regulatory-science foundation for this next wave of T1D therapies, expanding our C-peptide evidence base to 74 clinical trials in the process. It's the kind of collaborative, precompetitive work our community does best, and I'm proud of what our T1D Consortium has built.

Looking ahead, I am thrilled about the momentum building toward the 2026 C-Path Global Impact Conference, September 15–17 in Washington, D.C. This is one of my favorite times of year, a chance for our entire community of patients, researchers, regulators, and industry partners to come together and chart the path forward for the science and tools that are changing lives. Registration is open here. I hope to see many of you there.

There is so much more to come this year, and I am grateful every day for the trust, partnership, and shared purpose that make C-Path's mission possible. Thank you for being part of this journey with us.

With gratitude and excitement,

Klaus Romero

Klaus Romero, MD, MS, FCP
CEO, Critical Path Institute

Make the Most of Your GCIC Experience: Two Reasons to Extend Your Stay

While you're in Washington, D.C. for CGIC, consider bookending your trip with two more opportunities happening at the same hotel.

Got Data? Evaluating Real-World Data Suitability to Inform Regulatory Decision-Making

Monday, Sept. 14 | 9 a.m. – 12:30 p.m. | Free

Real-world data holds real promise for regulatory decision-making, especially in rare diseases, but only when it's fit for purpose. Join our Rare Disease Cures Accelerator team for an interactive workshop introducing a structured framework for evaluating RWD quality and suitability. Space is limited.

Register Now

Evidence Generation for Scalable Advanced Therapies | A focused half-day convening from One to Millions

Thursday, Sept. 17 | 8 a.m. – 12 p.m. | $249

Stay an extra day for a deep dive into One to Millions, C-Path's initiative to scale individualized breakthroughs into global solutions. This interactive half-day session brings together KOLs, advisors, and members to shape the next phase of the initiative, a chance for engagement beyond the core conference agenda. Limited space; additional fee applies.

Register Now

NEWEST Episodes from 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 13: Connecting the Dots: Advancing Drug Development on a Global Scale

NEW! Episode 12: The Critical Path Institute Podcast: Accelerating Drug Development in Friedreich's Ataxia

Listen and subscribe here:

Apple	Spotify	YouTube

Honoring Awareness, Advancing Action

C-Path's Ragasudha Botta Sits Down with Bio.News in Honor of Women's Health Month

May was Women's Health Month and in observation, Bio.News sat down with Ragasudha Botta, MBBS, Ph.D., MMSc, Senior Scientific Director, of C-Path's Critical Path for Parkinson's consortium to discuss how women's lived experiences with Parkinson's disease have too often been overlooked in clinical research and treatment development — and have even resulted in later diagnoses.

Read the full interview here: Parkinson's disease in women: Research and treatment challenges.

Advancing Hope in Progressive Supranuclear Palsy: Collaboration, Data, and Innovation During PSP Awareness Month

Each May, Progressive Supranuclear Palsy (PSP) Awareness Month shines a light on a devastating neurodegenerative disease that remains widely underrecognized, despite its profound impact on patients, families, and caregivers. PSP is a rare brain disorder that affects movement, balance, speech, swallowing, vision, and cognition. Over time, people living with PSP often experience increased difficulties with mobility and daily function, while facing a significant lack of effective treatment options.

Read more here: Advancing Hope in Progressive Supranuclear Palsy: Collaboration, Data, and Innovation During PSP Awareness Month.

Huntington's Disease Awareness Month: Advancing Drug Development Through Lived Experience

Huntington's Disease Awareness Month serves as an important opportunity to raise visibility for Huntington's disease and recognize the urgent need for continued scientific innovation, advocacy, and collaboration in the pursuit of meaningful therapies for individuals and families affected by this devastating condition.

Read the blog here: Huntington's Disease Awareness Month: Advancing Drug Development Through Lived Experience.

ALS Awareness Month: Connecting the Dots in ALS Research

Under the neurodegenerative disease umbrella, C-Path co-stewards the ALS Knowledge Portal infrastructure with the NIH and helps shape regulatory endpoints for the ALL ALS natural history study. Digital health technology working groups, including the teams analyzing the actigraphy data, sit directly inside this program.

Reusing curated information prevents researchers from wasting years by recreating foundational knowledge. Collin Hovinga recently addressed this urgency during an episode of The Critical Path Institute Podcast, noting that every precious data point counts.

Read the blog here: ALS Awareness Month: Connecting the Dots in ALS Research.

LATEST NEWS

C-Path Awards $250,000 Grant to Advance New Treatment for Sepsis-Associated Neurocognitive Dysfunction.

Critical Path Institute Awards $249,719 Grant to Odylia Therapeutics to Advance Gene Therapy for USH1C-Associated Vision Loss.

Critical Path Institute Awards $456,000 Grant to Advance Next-Generation Therapy for Rare Glycolipid Storage Disorders.

AIRNA Joins C-Path's Alpha-1 Antitrypsin Deficiency Consortium to Advance Innovative AATD Treatments.

C-Path's Translational Therapeutics Accelerator Awards $501,000 Grant to Advance Novel Treatment for Cryptosporidiosis in Children.

For more C-Path news, click here.

Connect with C-Path team members at upcoming events:

- Alzheimer's Association International Conference | July 12–15 | London
- DIA Oligonucleotide-Based Therapeutics Conference | September 23–25 | Arlington, VA
- 2025 NORD Breakthrough Summit | October 25–27 | Washington, D.C.

Miss a recent Webinar? They're always available on our YouTube channel:

- Public Private Partnerships for Rare Neurodegenerative Disease
- 2026 Clinical Outcome Assessment Program Annual Meeting
- Scalable Approaches to Patient-Centered Benefit–Risk: Defining Patient-Focused Drug Development in Precision Medicine
- Moving Biomarkers from Research to Better Real-World Care for Patients
- Meeting Patients Where They Are: Validating Remote Digital Tools for Multi-Indication NMD Research
- 27th NIH Tissue Chip Consortium Meeting + CIVM Qualification Framework Public Workshop Recap