
C-Path Newsletter Q1 2026: Momentum in Motion

Hello to our C-Path Community,

As we close the first quarter of the year, we are energized by the opportunities ahead to further strengthen collaboration, drive innovation, and expand our impact across the global drug development ecosystem.

At Critical Path Institute, our focus remains clear: advancing regulatory science solutions that enable the development of therapies to reach patients more efficiently. The progress we continue to make is a direct result of the strength of our partnerships and the shared commitment to transforming how therapies are developed and delivered.

This quarter, we were pleased to welcome Amitabh Chandra, Ph.D., to our Board of Directors. A renowned health economist and policy expert, Professor Chandra brings decades of experience in biopharmaceutical innovation and health economics. His perspective further strengthens our ability to integrate economic insight with regulatory science—an increasingly important dimension in advancing sustainable, patient-centered drug development.



Amitabh Chandra, Ph.D.

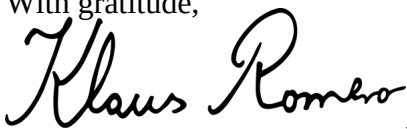
We are also delighted to welcome Chris Lunt as C-Path's Chief Data and Technology Officer. In this role, Chris will lead our Data Collaboration Center and guide the continued evolution of our digital infrastructure, which underpins our core capabilities in regulatory science, quantitative modeling, biomarker development, and clinical outcome assessment.



Christopher Lunt

We look forward to sharing more updates, milestones, and opportunities for engagement in the months ahead, and we thank you for your continued partnership in advancing our shared mission.

With gratitude,

A handwritten signature in black ink that reads "Klaus Romero".

Klaus Romero, MD, MS, FCP

CEO, Critical Path Institute

Registration Opens Monday, April 6, for the 2026 C-Path Global Impact Conference



Critical Path Institute's flagship event is set to return to downtown Washington, D.C. this **September 15-16** at the Washington Marriott at Metro Center. Building on momentum from last year's successful conference, the C-Path Global Impact Conference (CGIC) will host regulators, researchers, industry experts, and patient advocates for two days of thought-provoking discussions, keynote speakers, networking events and more as we set the stage for the next wave of medical and regulatory science innovation. You won't want to miss this exclusive event as we redefine the evidence-generation enterprise for drug development in the 21st

Century with topics focused on innovation in accelerating patient identification, enrichment, and stratification, closing the gap between drug development and clinical care, new approaches to patient centric clinical trials, and more.

Be sure to check in as we publish more details, including speakers, panelists, session titles and the conference agenda.

One to Millions: Continuing the Conversation



Last week, C-Path launched [One to Millions](#), a new public-private partnership designed to help translate individualized therapeutic breakthroughs into scalable solutions that can reach patients worldwide. This initiative reflects a growing need across the ecosystem: bridging innovation at the individual level with pathways that enable broader access and impact.

As part of this launch, we are continuing the conversation through a series of webinars. Our upcoming session on **Wednesday, April 8**, will bring together patients, families, regulators, and industry leaders to explore how benefit-risk is evaluated in the context of highly individualized therapies. Through real-world perspectives, the discussion will examine what outcomes matter most, how uncertainty is navigated, and what it means to make informed, patient-centered decisions in

emerging treatment paradigms.

This discussion builds on insights from our February webinar, [Transforming Drug Development for Precision Medicines — A Practical Path from Evidence Generation to Reimbursement](#), which focused on data strategies, evidence generation, and regulatory pathways. Together, these conversations highlight the shift toward more coordinated, patient-centered approaches in advancing precision medicine.

We invite you to continue engaging with this important work by registering for the April 8 [webinar](#).



Scalable Approaches to Patient-Centered Benefit–Risk: Defining Patient-Focused Drug Development in Precision Medicine

WEBINAR



Wednesday
8 APRIL 2026



Starts At
NOON ET



Register Now



You can also revisit key insights from the February session, [here](#).

Advancing Data Sharing in Rare Disease Drug Development



Data sharing is no longer optional in rare disease drug development, it is essential. At this week's public workshop, **RISE Together: Data Sharing Across the Rare Disease Ecosystem**, co-convened by the Duke-Margolis Institute for Health Policy and the FDA Rare Disease Innovation Hub, leaders from Critical Path Institute joined stakeholders across the ecosystem to address how responsible data sharing can accelerate development and inform regulatory decision-making.

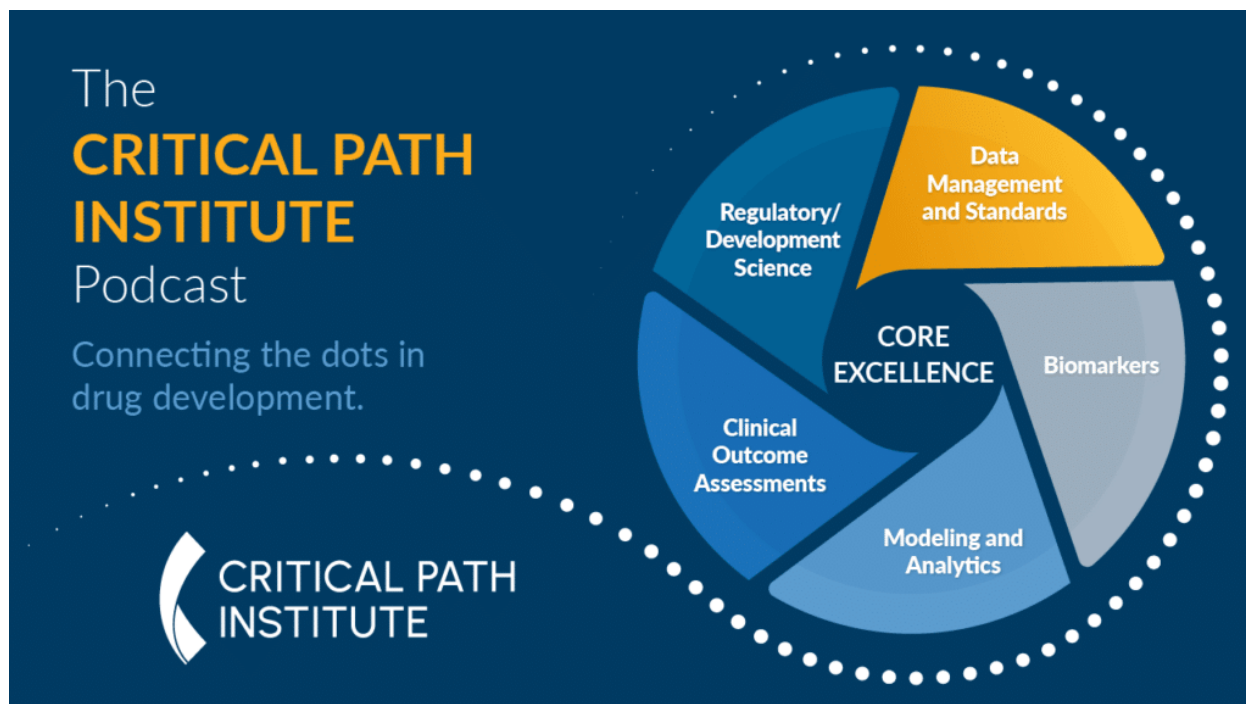
With small and heterogeneous patient populations, the ability to generate and share high-quality data is critical. Discussions highlighted how data sharing can strengthen disease progression modeling, endpoint selection, clinical trial design, and safety monitoring—ultimately improving outcomes for patients.

C-Path contributed across the program, with Klaus Romero moderating a session on key components and stakeholders in data sharing; Collin Hovinga sharing real-world examples; and Ramona Belfiore-Oshan alongside Ron Bartek discussing infrastructure and tools to support scalable approaches.

This work reflects C-Path's leadership in advancing collaborative, data-driven models, an effort closely aligned with the One to Millions initiative, which aims to transform how data is generated, shared, and leveraged to accelerate therapies from individuals to broader patient populations.

Learn more about the workshop, [here](#).

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!

Episode 11: [The Critical Path Institute Podcast: Connecting the Dots Between T1D and CKD.](#)

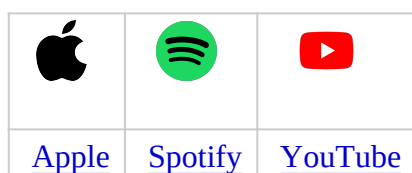
Episode 10: [The Critical Path Institute Podcast: Connecting the Dots in Rare and Pediatric Diseases with VP Collin Hovinga.](#)

Episode 9: [The Critical Path Institute Podcast: Electronic Clinical Outcome Assessments in Oncology Research.](#)

Episode 8: [20 Years of Innovation: Reflecting on C-Path's Legacy and Looking Ahead, Pt. 2.](#)

Episode 7: [The Critical Path Institute Podcast: 20 Years of Impact Reflect on C-Path's Legacy and a Look Ahead, Pt. 1.](#)

Listen and subscribe here:



Impact Stories

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 experience to be a part of drug development. Whether you are an individual or a family affected by a condition, an advocate, or partner, these stories will inspire and reinforce the importance of what C-Path does.

ICYMI, here are our two most recent impact stories shared during Kidney Awareness Month in March and Rare Disease Awareness Month in February.

[Turning Adversity into Advocacy, Innovation, and Hope for Those Living with ARPKD.](#)



For Monica Patton, life and autosomal recessive polycystic kidney disease (ARPKD) go hand in hand. Diagnosed at just six months old after doctors noticed abdominal swelling and discomfort, Monica doesn't have the experience of living without an ARPKD diagnosis. From her first memories and conversations, she entered a world where survival was far from guaranteed. At the time of this diagnosis nearly four decades ago, ARPKD was widely considered fatal in early childhood.

Read the full story, [here](#).

[Redefining Endpoints Through Lived Experience: Jon Hagstrom's Story of Patient Advocacy in Alpha-1 Antitrypsin Deficiency.](#)



Jon Hagstrom's journey with Alpha-1 underscores why patient voices matter so deeply. Diagnosed with Alpha-1 at age 39, after years of unexplained shortness of breath that persisted even after he quit smoking, he sought care from a pulmonologist in New York City, his symptoms initially resembled more common respiratory conditions, but his young age and severely diminished lung function raised red flags.

Read the full story, [here](#).

Recognizing Rare Disease Awareness Month

February marked Rare Disease Awareness Month, a time to elevate understanding, advocacy, and action for the millions of individuals and families affected by rare diseases worldwide. It is an especially meaningful moment for the Critical Path Institute community, as we work alongside partners to help advance therapies for patients with significant unmet needs.

Throughout the month, we were proud to share a range of new content across our channels, including a podcast, Jon's impact story, and the four blogs below, highlighting the experiences of patients and the collaborative efforts driving progress in rare disease drug development. Each piece reflected our shared commitment to improving access to diagnosis, advancing research, and accelerating the development of new therapies.

We thank our partners, collaborators, and community for helping amplify these efforts and for their continued dedication to making a difference in the lives of those affected by rare diseases.

Rare Disease Awareness Month Blogs:

- [Turning the Impossible into the POSSIBLE.](#)
 - [Building the Infostructure of Hope.](#)
 - [What Collaboration Makes Possible.](#)
 - [Listening As a Form of Precision Medicine.](#)
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Latest News & Events

[Critical Path Institute and Collaborators Honored with Society of Toxicology Science Paper of the Year Award](#)

[PBC Ireland Partners with C-Path's Rare Disease Data Platform, Advancing Research Efforts for Primary Biliary Cholangitis](#)

[New Study on Early Parkinson's Disease Progression Highlights Vital Role of Patient Focused Drug Development and Real-World Impacts](#)

[Critical Path Institute's Translational Therapeutics Accelerator Awards Grant to Support Development of Novel Nonopioid Pain Therapeutics](#)

[C-Path's Translational Therapeutics Accelerator Announces 2026 Request for Proposals from Academic Investigators](#)

[C-Path's New Clinical Pharmacology & Therapeutics Publication Highlights Real-World Impact of FDA-Qualified Urine Biomarkers for Earlier Detection of Drug-Induced Kidney Injury](#)

Find more press releases and news, [here](#).

Register now for these upcoming events:

- **April 8:** [Scalable Approaches to Patient-Centered Benefit–Risk: Defining Patient-Focused Drug Development in Precision Medicine.](#)
- **April 9:** [Hope on the Horizon for ADTKD Patients.](#)
- **April 16-17:** [2026 Clinical Outcome Assessment Annual Meeting.](#)

On Demand Webinars:

[Transforming Drug Development for Precision Medicines: A Practical Path from Evidence Generation to Reimbursement](#)

[C-Path’s Translational Therapeutics Accelerator Award Funding Opportunities 2026](#)

[C-Path’s 2025 Rare & Orphan Disease Program Webinars](#)