CRITICAL PATH INSTITUTE 20 YEARS

TWO DECADES OF IMPACT

& A PROMISING FUTURE

2025 ANNUAL REPORT

Our Mission

"C-Path leads collaborations that accelerate drug development, advancing better treatments for people worldwide."

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A Letter from Our Leadership

Dear Friends and C-Path Supporters,

In the spirit of year-end lists and as we close the door on 2025 and C-Path's 20th anniversary year, we reflect on the momentum behind a more hopeful future for medical innovation. While we have numerous achievements from the past 12 months to celebrate, these selected highlights inspire hope and progress for the coming year:

Unprecedented global collaboration

This year, C-Path convened our most well-attended event (our 2024 Global Impact Conference in Washington, D.C.), with expert regulators, industry leaders, scientists, clinicians, and patient advocates from around the world to collaborate, break down silos, and solve drug development challenges together.

Data working smarter

We dramatically expanded our data platform, integrating diverse datasets from rare disease registries and hospitals into our Rare Disease Cures Accelerator–Data and Analytics Platform (RDCA-DAP®). By uniting insights from groups like Sanford CoRDS and The Champ Foundation, and partnering with platforms such as Vivli, we're turning previously siloed data into a powerhouse that can support unprecedented innovation to accelerate drug development.

Funding innovation at critical moments

Through our Translational Therapeutics Accelerator (TRxA), C-Path provided vital support to early-stage drug development collaborations in academia. We provided guidance and grants of varied amounts, including a landmark $1 million award in type 1 diabetes research to major funding for first-in-class treatments in prostate cancer, ALS, pediatric brain tumors and more, ensuring that promising therapies are supported with expert guidance and resources to continue moving forward.

CEO Klaus Romero brings his signature harmony to both leadership and the stage.

Faster, smarter clinical trials

C-Path consortia introduced cutting-edge tools to streamline medical research, drug development, and regulatory decision-making. Our Type 1 Diabetes Consortium released a simulation tool to optimize new-onset diabetes trial design, while the Duchenne and Parkinson's teams advanced digital measures to monitor patients in real time. These innovations mean clinical trials can be designed more efficiently, with endpoints and biomarkers that truly matter.

Big steps for rare diseases

We launched targeted initiatives to dismantle roadblocks in often-overlooked diseases. This year, we started a new task force for Limb-Girdle muscular dystrophies and a global collaboration to address neonatal brain injury. We also deepened our role in the rare disease space in Europe through C-Path Europe and alliances such as the European Rare Disease Research Alliance, while welcoming new partners, including biopharma leaders Kamada and Sanofi, to our alpha-1 antitrypsin deficiency program to accelerate progress for conditions that desperately need treatments.

Breakthrough science with real-world impact

C-Path and our collaborators continued to publish peer-reviewed game-changing research. In one highlight, our teams advanced a novel kidney injury biomarker that could vastly improve early detection of drug toxicity. We also co-authored a Nature Reviews Drug Discovery paper outlining how to maximize the regulatory impact of consortia-driven science. Every publication like this adds a new tool or insight to improve patient safety and therapeutic development.

A stronger C-Path leading the charge

We bolstered our own leadership and capacity to deliver on our mission. This year, we welcomed Jennifer Kendra as Vice President of Strategic Partnerships and Paul Edmeier as Chief Financial Officer. We also promoted Dr. Diane Stephenson to Vice President of Neurology and onboarded seasoned experts to our Board of Directors, including Steven Spector, James King, Ron Bartek, Dr. Aoife Brennan, and Colin Hill. Board member Dr. Karen Bernstein also stepped into the role of Vice Chair. These leaders bring fresh energy and expertise, ensuring C-Path is well-positioned for the road ahead.

Recognition of our impact

C-Path's two decades of work has not gone unnoticed. We are honored to receive the Reagan-Udall Foundation's Innovation Award for regulatory science in 2025, a testament to the measurable public health impact of our programs. Additionally, our President and COO, Kristen Swingle, was named one of the "Women Leading the Region" by BizTUCSON, reflecting the talent and dedication of the people behind C-Path. This recognition belongs to our entire community of partners and supporters who drive us forward.

A 20-year milestone … and momentum for the future

In September, C-Path marked its 20th anniversary with a gathering of global stakeholders at Washington, D.C.'s historic Andrew Mellon Auditorium. Nearly 200 early adopters, partners and supporters joined us, generating a shared sense of purpose and inspiring concrete commitments that underscored one resounding message: our future is positioned to be the most impactful yet.

A united, engaged, and energized community: it's YOU!

Every achievement above was made possible because of you. Because patients and families shared their data and stories. Because researchers, innovators, and clinicians lent their expertise. Because regulators provided guidance and open dialogue. Because advocates and donors believed in our mission. You remind us why we do this work. United by a shared purpose, we are an unstoppable force for good. When we're united, as C-Path supporters, partners, and friends, there's nothing we can't achieve for those with unmet medical needs.

Thank you for making this another remarkable year. Together, we've transformed challenges into progress and cultivated the seeds of future cures. Here's to the next 20 years of innovation and hope!

With deepest gratitude,

Klaus Romero, MD, MS, FCP
Chief Executive Officer
Critical Path Institute


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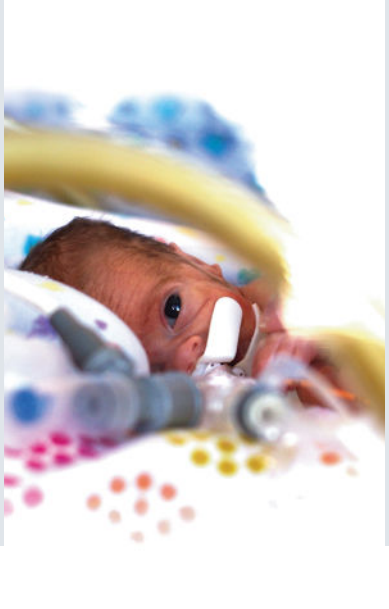
CRITICAL PATH INSTITUTE
20 YEARS

Our Impact



Drug development still takes too long and costs too much.

This is why C-Path brings competitors and regulators to our unique neutral table, builds shared tools, and sets common standards to help cut months, even years, from the drug development process. Over the past 20 years, our consortia have helped clear the path for real advances. The world has seen the first new tuberculosis treatment in half a century, disease-modifying therapies in areas such as Alzheimer's, polycystic kidney disease, and Friedreich's ataxia, and the first therapy shown to delay the onset of type 1 diabetes. Our role is to build the conditions that make breakthroughs repeatable and recurrent.

We have delivered the first regulatory-endorsed clinical trial simulators, new drug safety and disease biomarkers, and patient-centric endpoints that reflect what matters in daily life. We have also built some of the world's most comprehensive integrated databases, rare and common diseases alike, now covering more than 700,000 individual records across multiple conditions and data sources. These are practical tools and resources that help sponsors design smarter studies and help regulators see evidence with less ambiguity, all while honoring the time and trust of the participants.

The work ahead is clear and inspiring. We are developing resources across more than twenty-six therapeutic areas. Each voice in our community matters: patients, caregivers, researchers, clinicians, regulators, and partners. Your effort and your stories fuel our commitment.

This is what drives every scientist, every partner, and every advocate at C-Path. Together, we turn individual hopes into concrete gains, one well-designed solution after another.

FY25
Year in Review

As C-Path marked its 20-year anniversary, we are proud to report that fiscal year 2025 saw us surpass the bold goals we set for ourselves. From July 2024 through June 2025, we witnessed significant growth in funding and a flourishing expansion of our programs and consortia. New partners joined our ever-growing network of collaborators, and our unique model continued to unite industry leaders, scientists, academic researchers, regulatory bodies, and patient groups in neutral, creative collaboration. These alliances propelled essential advances in regulatory science and medical innovation, accelerating the development of therapies for people with unmet medical needs.

Key achievements this year include:

Rare Disease Platform Expanded with New Data and Partnerships

C-Path's Rare Disease Cures Accelerator–Data and Analytics Platform (RDCA-DAP®) continued its rapid growth. We entered a landmark agreement with Sanford Health's CoRDS registry to aggregate diverse rare disease datasets. We also forged a strategic partnership with Vivli to enhance data sharing for rare diseases on RDCA-DAP. New patient-driven data contributions, for example, from The Champ Foundation's mitochondrial disease registry, were integrated, enriching an ever-growing repository that is streamlining research and enabling breakthroughs in rare disease.

Translational Therapeutics Accelerator Fueled Multiple New Therapies

C-Path's TRxA program had a record year in catalyzing drug development projects. In partnership with funders, TRxA awarded an unprecedented $1 million grant to a type 1 diabetes project, as well as major grants of $815,000 for advanced prostate cancer research and $250,000 to combat antibiotic-resistant infections. Additional six-figure awards targeted ALS, hereditary spastic paraplegia, and pediatric brain tumors. In total, TRxA provided approximately $2.5 million in 2025 to academic innovators, marking a record level of support for early-stage therapies across cancer, infectious disease, neurology, immunology and beyond.

New Collaborations Accelerating Data-Driven Research

C-Path entered a groundbreaking partnership with Citizen Health to harness real-world patient data for neuromuscular disorders. Over 10 years of medical records from patients with limb-girdle muscular dystrophy, Charcot-Marie-Tooth, and other neuromuscular diseases will be collected and securely hosted on RDCA-DAP. This patient-consented, de-identified dataset will help characterize disease progression and validate meaningful endpoints, providing powerful new tools to accelerate therapy development for these conditions.

Advances in Neurodegenerative Disease Initiatives

We expanded our leadership in neurological disorders through the launch of Global Evidence in Medicine for Parkinson's Disease, an initiative to integrate worldwide data and address gaps in access to clinical trials and meaningful representation in research. At the same time, our Alzheimer's team published a seminal methodology for standardizing tau imaging in trials, enabling consistent comparisons of this crucial biomarker across studies. These efforts are paving the way for more robust, efficient trials in Alzheimer's, Parkinson's, and related diseases.

Neonatal Program Expanded Real-World Data

Our International Neonatal Consortium made great strides in addressing the needs of vulnerable newborns. In collaboration with the Institute for Advanced Clinical Trials for Children, the Neonatal Real-World Data project underwent a significant expansion, adding new datasets from major medical centers and bringing the total to approximately 386,000 neonatal cases worldwide. This trove of real-world evidence is shaping how we approach treatments and outcomes for infants in intensive care, informing everything from dosing to long-term safety monitoring.

C-Path's Disease Modeling Coalition Begins Global Work from European Hub

C-Path's European office is beginning its fifth year with a strong team, while launching a multi-stakeholder, public-private initiative to develop regulatory-grade, quantitative disease progression and care models to accelerate and better inform drug development and evaluations for pediatric Crohn's disease and ulcerative colitis. This project serves as a proof-of-concept for the broader disease modeling coalition platform. Following successful pilots, the coalition will expand to support multi-indication portfolios, with an evolving structure designed to ensure sustainability, regulatory impact, and patient relevance. C-Path Europe also contributed to the European Rare Diseases Research Alliance, a European partnership uniting over 170 public and private organizations across 37 countries and the RealiseD IHI project to advance innovative methods in rare diseases. We are also continuing efforts to support the WHO Global Accelerator for Pediatric Formulations as co-lead of the Clinical Research Working Group.

Regulatory Science Milestones

C-Path consortia delivered concrete tools to support regulatory decisions. Predictive Safety Testing Consortium published breakthrough findings that a blood enzyme can serve as a sensitive and specific biomarker for detecting drug-induced liver injury. These achievements will help regulators and sponsors alike in evaluating new therapies with greater confidence and speed.

Consortium for Alpha-1 Antitrypsin Deficiency Gained Momentum

The Critical Path for Alpha-1 Antitrypsin Deficiency (CPA-1) consortium hit key milestones in FY25. We welcomed new members Kamada and Sanofi as consortium supporters, broadening the expertise focused on this rare genetic disease. In addition, CPA-1 received its first major data transfer from Takeda, contributing invaluable clinical data to accelerate development of much-needed treatments for alpha-1-related liver and lung disease.

Task Forces Driving Rare Disease Progress

In our mission to leave no disease behind, C-Path led targeted task forces to jump-start therapy development for challenging conditions. This year we coordinated efforts addressing neonatal hypoxic-ischemic encephalopathy — joining global calls to action to accelerate neonatal drug development for brain injury. These focused initiatives bring hope to patients and families in areas with few or no existing treatments.

Modernizing Drug Development in Practice

C-Path's influence was evident in the broader ecosystem as well. At our 2024 Annual Neuroscience Public-Private Partnership Meeting, we worked with FDA, academia, and industry to advance cutting-edge topics like neuroimaging and digital biomarkers. In November 2024, our Type 1 Diabetes Consortium published landmark trial results showing immune therapies improved outcomes in new-onset type 1 diabetes, bolstering support for using C-peptide as a regulatory endpoint. Across dozens of publications, workshops, and regulatory submissions, C-Path continued to set new standards for how therapies are developed, tested, and approved — always with an eye on what will most benefit patients.

Taken together, these achievements (and many other significant accomplishments throughout the year) demonstrate the power of collaboration to advance medical innovation. With our partners, C-Path turned bold ideas into concrete results in FY25 and prepared a strong foundation for the decades ahead.

20 Years of Impact

Celebrating C-Path's 20th Anniversary

In 2025, Critical Path Institute proudly celebrated 20 years of advancing drug development through innovation and collaboration. We are very proud to see that what began in 2005 as a small team of just six visionaries in Tucson, Arizona, has grown into the globally recognized leader in regulatory science. C-Path has played a pivotal role in accelerating the development of safe and effective treatments for the benefit of individuals and their families. We were founded as a public-private partnership on the reality that no single entity can solve the complex challenges of drug and medical product development alone. Twenty years later, that idea has become our lived reality, and the compass for our future.

Our Journey

From supporting the FDA's Critical Path Initiative in the early days, to launching the first multi-stakeholder consortia, to achieving the first-ever FDA and EMA qualification of drug development tools (like safety biomarkers and disease models), C-Path has been at the forefront of regulatory innovation. We have now obtained 41 formal regulatory endorsements for tools that aid drug development, more than any other organization in the world. Our collaborations have facilitated pivotal drug approvals by providing novel trial designs, endpoints, and data evidence in areas ranging from tuberculosis to neurodegenerative diseases. Notably, C-Path was responsible for the first-ever FDA qualification (seven kidney safety biomarkers) and the first-ever FDA-endorsed clinical trial simulator (in Alzheimer's disease), as well as numerous endorsed clinical outcome assessment tools, biomarkers, and quantitative solutions now used to accelerate drug development for those in need.

Growth and Impact

Today, C-Path's consortia and initiatives span nearly 30 drug development areas, uniting more than 1,600 scientists and representatives from government, academia, patient organizations, and the biopharmaceutical industry. We have amassed over 700,000 standardized patient records across a multitude of indications and data sources to drive modeling and data analysis. Importantly, what was once a local effort has become truly global: C-Path now has team members and partners on almost every continent, with a thriving branch in Amsterdam, as well as global collaborations reaching multiple continents (North America, Europe, Asia, and Africa). Our growth has always been in service of our mission — every new partnership, every new dataset, and every new tool directly contributes to faster, safer, and more efficient development of new medicines and therapies.

20th Anniversary Events

To mark this milestone year, C-Path hosted two special gatherings celebrating our roots and our growing global reach.

On February 10, 2025, members of C-Path's leadership, staff, board members, and global partners gathered in Tucson, Arizona, where the organization was founded, for a 20th anniversary celebration. The program highlighted two decades of progress, as well as the urgent need to embrace the future of collaborations to further accelerate drug development. One of the most moving moments came from Sarah Zenner-Dolan, a woman who has lived with young-onset Parkinson's disease for about 20 years. Sarah shared her personal mission and journey and spoke about staying strong in the face of this challenging condition: "My personal mission of living my best today is buoyed by the trust I have in the behind-the-scenes work of the brilliant teams at Critical Path Institute. I thank you for all you are doing to efficiently and effectively integrate the research, regulatory, clinical, industry, and advocacy communities to bring us the breakthroughs that we so desperately need. I am looking forward to a very bright future." Another powerful moment came from C-Path project manager Hailey Davenport, who has lived with type 1 diabetes for 16 years. Hailey described the real progress she has seen in both treatment and disease understanding, showing in very concrete terms why our work cannot slow down.

In September, C-Path hosted **"20 Years of Impact: Honoring the Journey. Shaping What's Next."** at the Andrew Mellon Auditorium in Washington, D.C. The evening celebrated the enduring collaborations, as well as the visionary contributions that will continue to advance our mission into the future. A fireside chat led by CEO Klaus Romero, with Kathryn Bryant Knudson (The Speak Foundation), Board member Ron Bartek (Friedreich's Ataxia Research Alliance), and Dr. Anita Goel (Nanobiosym Education & Research Institute), explored how data sharing, patient advocacy, and scientific innovation can work together to transform drug development. We were honored to celebrate C-Path's founder, Dr. Raymond Woosley, and to welcome several of the original visionary leaders in attendance. A special gala dinner recognized their contributions and the unwavering support of partners including the FDA, as well as other global regulatory agencies, academia, patient advocacy groups, and industry pioneers who have been with us since the beginning. The event honored the leaders and partners who helped build C-Path and set a clear intention for the future: deepen collaboration, share data more effectively, and bring better treatments to patients faster.

Looking Ahead

Our 20th anniversary year has been both a celebration and a call to action. It reminds us of the value of C-Path's unique approach (neutral collaboration, data-driven science, and patient-focused innovation). It has saved time, resources, and lives over the last two decades. Now, as we enter our next decades, we do so with renewed optimism and transformative goals. We will continue uniting stakeholders in new ways, embracing cutting-edge technologies, and keeping the needs of patients at the center of everything we do. The gala and events in 2025 each closed with a clear message: when we work together, the possibilities are endless.

By the Numbers

Collaborative Programs

26 active consortia and therapeutic area programs spanning conditions from Alzheimer's to tuberculosis.

Years of Innovation

20 years since C-Path's founding in 2005, transforming drug development through collaboration.

Global Network

1,600+ scientists, regulators, clinicians, and patient representatives participating in C-Path collaborations worldwide.

Publications & Impact

Thousands of scientific publications, tool submissions, and regulatory approvals facilitated, including multiple "firsts" (first trial simulator, first qualified biomarkers, first prevention therapy for type 1 diabetes) that have opened new pathways for treatment development.

Regulatory Endorsements

41 drug development tools formally endorsed by FDA, EMA, and other regulators, leading the world in regulatory science impact.

Committed Team of Experts

160+ C-Path staff across the U.S. and Europe, growing from just six employees in 2005.

Integrated Data

700,000+ standardized, patient-level records aggregated in C-Path databases, powering innovative research and models.

(For a full interactive timeline of C-Path's 20 years of milestones, visit our 20th Anniversary page at **c-path.org/20-years-of-impact**.)

Core Excellence

C-Path's commitment to accelerating drug development is built on expertise and excellence in five core areas. By sharing data and knowledge in a neutral environment, we have achieved distinction in these competencies:

Data Management and Standards

Developing and implementing cutting-edge data management practices and universal data standards to ensure quality and consistency across global projects.

Biomarker Research

Identifying, developing, and qualifying biomarkers that improve disease understanding and enable more efficient drug development. These efforts help detect diseases earlier, predict drug efficacy or toxicity, and shorten clinical trials.

Modeling and Analytics

Utilizing state-of-the-art modeling techniques and analytical tools, such as clinical trial simulators and quantitative disease models, to predict outcomes, optimize trial designs, and inform regulatory decisions with evidence-based insights.

Clinical Outcome Assessments

Crafting and refining patient-centric clinical outcome assessment tools that measure what truly matters to patients. From symptom scales to functional endpoints, these tools are developed and validated to reliably capture treatment benefits in trials.

Regulatory Science

Advancing the field of regulatory science by creating new frameworks and toolsets that streamline the medical product review and approval process. By working closely with regulatory agencies, C-Path ensures that innovative methods (like model-informed drug development and real-world evidence use) gain acceptance, ultimately accelerating the delivery of therapies to patients.

These core areas form the foundation of C-Path's model. By excelling in data collaboration, biomarkers, modeling, COAs, and regulatory science, C-Path provides the pharmaceutical and biomedical community with the tools and evidence needed to make informed decisions in drug development and regulatory review. Our focus spans numerous domains: neuroscience, immunology and inflammation, infectious diseases, pediatrics, and rare/orphan diseases, and in each, our core competencies are driving innovation. Together with our partners, we are de-risking and demystifying the drug development process, so that effective and safe new treatments can reach those in need faster than ever before.

Financials

ASSETS

Cash and Cash Equivalents	$	24,760,244
Investments	$	7,939,830
Accounts Receivable	$	4,313,023
Property and Equipment, Net	$	1,868
Other	$	1,346,701
Total Assets	**$**	**38,361,666**

LIABILITIES AND NET ASSETS

LIABILITIES

Accounts Payable	$	1,038,098
Accrued Expenses	$	2,034,002
Deferred Revenue*	$	7,751,209
Operating lease obligations	$	1,273,260
Total Liabilities	**$**	**12,096,569**

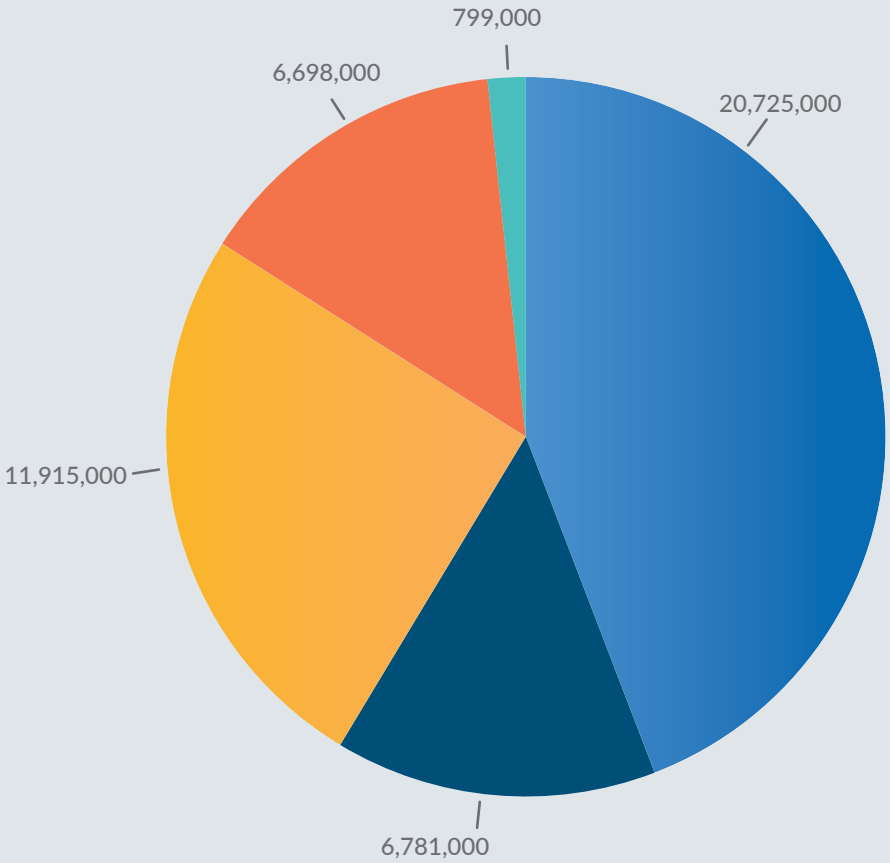
NET ASSETS

Undesignated	$	7,887,736
Board Designated**	$	6,653,025
Coordinating committee designated	$	1,965,129
Property and Equipment	$	1,868
Donor Restricted	$	9,757,339
Total Net Assets	**$**	**26,265,097**
Total Liabilities and Net Assets	**$**	**38,361,666**

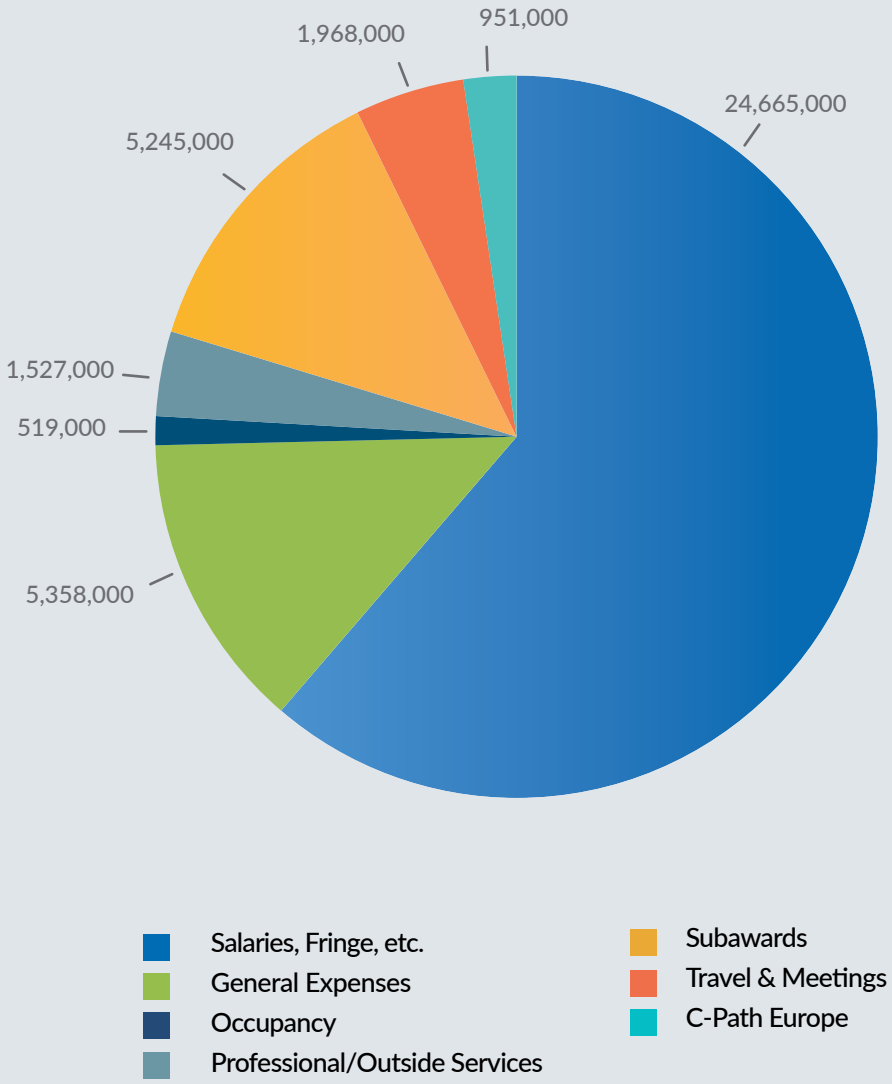
* Pre-awarded funds received for grants and consortia

** Consortia fees managed by C-Path to support consortia activities

C-PATH 2025 FISCAL YEAR REVENUE: $ 46,918,000



C-PATH 2025 FISCAL YEAR EXPENSES: $ 40,233,000



Our Collaborators

C-Path relies on insights from the experiences of people living with different conditions, as well as caregivers and advocacy groups that support them around the world. With their help, we make the process of developing cures, therapies, and medical products more efficient.

Regulatory Agencies

Agencies like the FDA, EMA, PMDA, and others around the globe play a critical role as stewards of public health. In C-Path's collaborative model, regulators share valuable non-competitive insights at every stage. Their expertise helps ensure that the novel methods and trial designs emerging from our programs meet the highest standards for patient safety and efficacy. This partnership accelerates regulatory review without compromising rigor.

Scientists (Academia & Industry)

By addressing overarching process inefficiencies, C-Path allows academic and industry scientists to focus on what they do best: innovating and developing therapies to improve human health. We provide the data, tools, and regulatory pathways that empower researchers to translate discoveries into treatments more efficiently.

Medical Product Developers (Biotech & Pharma)

C-Path's neutral ground allows pharmaceutical and biotech companies to pre-competitively collaborate, share data, expertise, and even resources to solve common problems. By increasing process efficiencies (like creating drug development tools that everyone can use), C-Path helps industry stakeholders focus on their own goals and pipeline milestones. Partners can advance their programs faster, de-risk development decisions, and ultimately deliver new products to patients sooner.

Patients and Advocacy Groups

Patients are at the heart of everything we do. C-Path relies on insights from patients living with diseases, their care partners, and the advocacy organizations that represent them. These voices guide the selection of meaningful endpoints, the design of patient-friendly trials, and the prioritization of which challenges to tackle first. By incorporating the lived experience of patients, we make sure that the therapies and tools developed truly address the needs that matter most.

Philanthropy and Public/Private Funders

The support of foundations, donors, and funding agencies is vital to C-Path's work. Philanthropic investment in our programs yields outsized returns in public health impact. Donors enable us to pursue bold, disruptive and cutting-edge ideas without the shackles of traditional funding. Likewise, public-private partnerships (including government grants) provide crucial support to build shared infrastructure, like data platforms and consortia, that benefit the entire ecosystem. Simply put, C-Path's mission to accelerate cures for people with unmet medical needs would not be possible without the generous support of the philanthropic community and forward-thinking funders.

(For a full list of the hundreds of organizations and individuals who collaborate with C-Path, please visit **c-path.org/c-path-collaborators**.)

Board & Advisors

Board of Directors

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James W. Newman, C.P.A.

Advisors to the Board

Janet Woodcock, M.D. – FDA Advisor

The Honorable James C. Greenwood – Senior Advisor

Peter B. Corr, Ph.D. – Senior Advisor

ShaAvhrée Buckman-Garner, M.D., Ph.D. – FDA Advisor

Emeritus Leadership (Former CEOs and Founders)

Martha A. Brumfield, Ph.D. – President & CEO (emeritus); Senior Advisor

Daniel M. Jorgensen, M.D., M.P.H., M.B.A. – CEO (emeritus); Special Advisor

Joseph Scheeren, Pharm.D. – President & CEO (emeritus); Special Advisor

Raymond Woosley, M.D., Ph.D. – Founder and President & CEO (emeritus); Senior Advisor

C-Path gratefully acknowledges the guidance and dedication of its Board of Directors, Advisors, and Emeritus leaders. Their expertise and stewardship have been instrumental to C-Path's success.

Forward Focus 2026

As we turn the page on an incredible 20th anniversary year, everyone at C-Path is energized by the road ahead. The accomplishments of 2025 have set the stage for an even more impactful 2026. In the coming year, we plan to push the boundaries of innovation as only C-Path can, by uniting diverse partners and embracing cutting-edge science to solve the toughest challenges in drug development.

Several transformative goals guide our focus for 2026. First, we will expand our global data collaboration efforts into new frontiers. This means not only growing our RDCA-DAP platform to include more diseases and international datasets, but also harnessing emerging technologies like artificial intelligence and machine learning to extract actionable insights that were never before possible. We envision a future where clinical trials can be simulated with high fidelity on a computer, where patient subpopulations can be identified via digital biomarkers, and where real-world data routinely complements clinical trial data in regulatory submissions. Achieving this future will require bold steps, and C-Path is prepared to lead the charge.

Second, we will continue to champion our core philosophy of patient-centric drug development. In 2026, C-Path will launch new initiatives to incorporate patient-reported outcomes and wearable device data more directly into drug approvals. We heard the call at our Global Impact Conference: patients worldwide are asking for outcomes that reflect their real lives, and faster access to treatments. Our job is to make sure their voices shape every tool and every trial going forward. Whether through developing novel clinical outcome assessments for rare diseases or creating frameworks for the FDA to utilize patient preference data, C-Path will ensure that the patient perspective remains front and center.

Third, we recognize that diseases do not have borders, and neither should solutions. Building on our strengthened European presence, C-Path will pursue even deeper international partnerships. In the year ahead, we aim to further enhance our global collaborations to advance pediatric inflammatory bowel disease drug development and promote health equity in clinical research. By sharing data and expertise across borders, we can address worldwide health challenges more effectively. C-Path's neutral, trusted platform is an ideal convener for these global efforts.

Finally (and perhaps most importantly) we remain driven by a sense of urgency. Every innovative project we undertake in 2026 will tie back to speeding up the development timeline or de-risking steps in the process. We are exploring ambitious ideas like "master protocol" clinical trials that test multiple therapies at once, and regulatory-ready disease progression models by year's end. These are in no way small undertakings, but C-Path's history has shown that with the right collaboration, even the most ambitious goals can be met if not exceeded. After all, as we often remind ourselves, the true measure of success is getting effective treatments to patients faster.

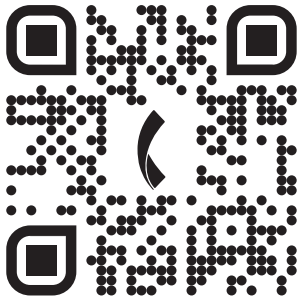
Looking forward to 2026, the possibilities before us are breathtaking. We have two decades of experience and a community more united than ever. Our toolkit, from advanced analytics to global data networks, has never been more powerful. And our resolve has never been stronger. We know the work ahead won't be easy, but fueled by the progress we've made and the partnerships we've forged, C-Path is leading the way into a new era of medical and healthcare innovation.

On behalf of our entire team, thank you for your continued support. Whether you are a donor, a collaborator, a scientist, or a patient advocate, you are the driving force behind our mission. Together, let's make 2026 a year of unprecedented achievement, a year in which we turn more hopes into cures, and move ever closer to a world where every patient has the safe and effective treatment they need.

Stay curious. Stay relentless. Let's forge the critical path ahead, together.

— The C-Path Leadership Team

Advancing Drug Development. Improving Lives. Together.



c-path.org

1840 E River Rd, Suite 100, Tucson, AZ 85718

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