To improve health and save lives by accelerating the development of safe, effective medicines
Over the past year, Critical Path Institute (C-Path) has continued to gain recognition as the global leader in forming successful collaborations and programs focused on accelerating the development of safe, effective medical products.

Despite tremendous scientific breakthroughs and medical advances, hundreds of thousands of people still suffer needlessly and die early deaths. Many lives would be improved or saved if needed therapies could be developed more quickly and reliably.

In attempting to cut through the red tape of medical product development, C-Path facilitates a neutral, collaborative environment that includes pharmaceutical companies, regulatory agencies, academic scientists, and patient advocates. These alliances advance scientific innovations that improve human health.

In our fifth full year of operation, C-Path sustained extraordinary programmatic and operational growth coupled with groundbreaking scientific results. C-Path’s first-of-its-kind partnerships now include over 1,000 scientists from international government regulatory agencies, academia, patient advocacy organizations, and 35 major pharmaceutical companies.

As an independent non-profit organization, the financial and in-kind support we receive from grants and philanthropy allows us to lead global efforts to improve health and save lives. We encourage our supporters and collaborators to take pride in what you have created at C-Path, and we invite others to learn more about our work and join our efforts.

Sincerely,

Raymond L. Woosley, MD, PhD
President and CEO

DID YOU KNOW…?

- It takes an average of 15 years for a new drug to navigate the “path” from idea to market.

- The “path” for successfully developing just one new drug can cost more than $1 billion.

- After millions are spent on laboratory research, 95% of new drugs that enter human testing fail to reach patients who need them.
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CRITICAL PATH INSTITUTE

collaborate . innovate . accelerate
It's essential that patients take medicines safely. C-Path and the University of Arizona College of Pharmacy created the federally-funded Arizona Center for Education and Research on Therapeutics (AzCERT) to promote improved therapeutic outcomes by educating and informing healthcare providers and the public about how to reduce adverse events caused by drug interactions.

C-Path's global, public-private consortia structured around major diseases and drug safety testing methods which include 1,000+ scientists from 35 major pharmaceutical companies, the National Institutes of Health, academic institutions, patient advocacy organizations, and international regulatory agencies including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and the Japanese Pharmaceutical and Medical Devices Agency (PMDA).

Innovative initiatives like C-Path's Arizona Biosignatures Laboratory have united scientists across our state in establishing a national resource to develop previously non-existent standards and best practices for new diagnostic tests and clinical research that translates science into healthcare. These standards will make it possible to more accurately identify characteristics (biomarkers) of patients likely to respond to precisely targeted therapies, thus enabling patient-centered diagnosis and treatment.

The amount awarded by federal and state research grants for the funding of major C-Path projects related to drug safety, biomarkers for use in drug development, disease models, and measures of patient-reported outcomes.

Partnerships with key organizations like Clinical Data Interchange Standards Consortium (CDISC) to establish and implement common data standards needed in clinical research and medical product development. The FDA has cited this as a critical component in allowing them to review new drug applications more efficiently.

C-Path has produced groundbreaking scientific outcomes including the world's largest, standardized database of Alzheimer's clinical trial data from eleven industry-sponsored trials. This is the first database of combined clinical trials to be openly shared by pharmaceutical companies and made available to qualified researchers around the world. This type of database will be replicated for other major diseases, and will ultimately serve as a tool to help promote earlier diagnosis, more effective measurements of disease progression, and more efficient trial designs.

The FDA formalized its process for submitting biomarkers and other tools to be “qualified” for specific uses in supporting drug development by releasing a draft guidance document for public review. The progress of our consortia will now be measured by the number of submissions that are approved by the FDA, adding greater predictability to the medical product development process. C-Path's consortia were instrumental in helping the FDA define and develop the qualification process outlined in this guidance.

Growing Arizona’s Bioscience Sector

C-Path is playing a vital role in building and contributing to the growth of the State’s economy and ability to compete nationally in this arena.

In 2010, the FDA formalized its process for submitting biomarkers and other tools to be “qualified” for specific uses in supporting drug development by releasing a draft guidance document for public review. The progress of our consortia will now be measured by the number of submissions that are approved by the FDA, adding greater predictability to the medical product development process. C-Path's consortia were instrumental in helping the FDA define and develop the qualification process outlined in this guidance.
We gratefully acknowledge the following donors who have given support to Critical Path Institute and Critical Path Foundation

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Critical Path Institute (C-Path) started in 2005 with a five-year commitment of more than $11 million in pledges from the Arizona community. Even through difficult financial times, more than 98% of these pledges have been honored. In addition, Science Foundation Arizona (SFAz) has awarded C-Path over $14 million to build upon the community’s initial investment, making it possible for C-Path to create public-private partnerships that enable the biopharmaceutical industry to work closely with the U.S. Food and Drug Administration (FDA). The first legislation sponsored by Arizona Congresswoman Gabrielle Giffords enabled the FDA to fund Critical Path public-private partnerships and, because of this, C-Path applied for and received a five-year award of $8.5 million. Other grants, including a recent award of $2.1 million from the Bill & Melinda Gates Foundation, are part of the return on Arizona’s investment. In exchange, our promise was to fundamentally change drug development and replace the original financial commitments over time with long-term sources of funding.

C-Path is also expected to help grow the number of high-paying jobs in Arizona’s biosciences sector. Fully 98.5% of all revenues go to support our people and programs. C-Path has competed successfully for a number of multimillion-dollar federal and foundation grants that will provide $8.5 million in funding over the next several years. For every dollar of public funding we received in FY’10, eight dollars in private and federal funding were brought into the local economy. On the job creation front, Critical Path Institute opened its doors with five employees and ended FY’10 with 36 employees. In addition, C-Path and its team of scientists have helped launch four new biotechnology companies in Arizona.

When C-Path began, we had no idea that we would have to survive one of the most severe economic downturns in our nation’s history. However, the steadfast support of the community, the passion and dedication of our scientists and staff, and the trust of our stakeholders have enabled C-Path to become an internationally respected organization that is fulfilling its mission of improving health and saving lives.

*Supported by federal grant

**Consortia fees accounts managed by C-Path to support only consortia activities.
C-PATH CONSORTIA AND PROGRAMS

Arizona Biosignatures Laboratory (ABL)

Arizona Center for Education and Research on Therapeutics (AzCERT)

Coalition Against Major Diseases (CAMD)

Critical Path to TB Drug Regimens (CPTR)

Patient-Reported Outcome (PRO) Consortium

Polycystic Kidney Disease (PKD) Consortium

Predictive Safety Testing Consortium (PSTC)
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Raymond L. Woosley, MD, PhD
President & Chief Executive Officer
MISSION
To improve health and save lives by accelerating the development of safe, effective medicines.

VISION
To be the global leader in creating collaborations that advance scientific innovations to improve human health.

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