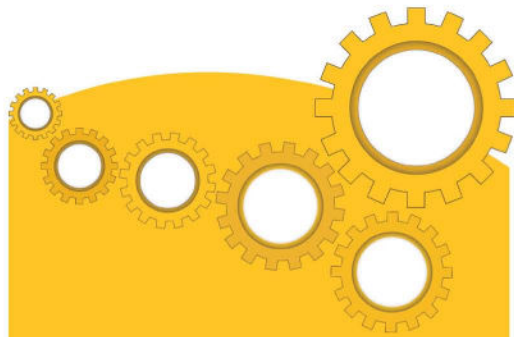


2011
ANNUAL REPORT



CRITICAL PATH
INSTITUTE

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science · therapies · standards · safety · innovation ·
health · milestones · knowledge · accelerate · neutral
· educate · consensus · global · effective · biomarkers
· collaborative · excellence · data · community ·
dedication · research · facilitate · science · therapies ·
standards · patients · safety · innovation · health ·

DEAR FRIENDS AND SUPPORTERS:



Raymond L. Woosley, MD, PhD

It is with great pride, and a bit of nostalgia, that I join Dr. Carolyn Compton to send you this fiscal year annual report, my last as President and CEO of Critical Path Institute (C-Path). We opened our doors in 2005 with five employees, a unique idea, and overwhelming community support.

I am proud to pass the torch of leadership to Dr. Carolyn Compton. She inherits a world class organization with 52 staff

physicians, scientists, project managers, and directors who participate in six international consortia, as well as a global network of over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, 7 clinical trial support providers and 34 major pharmaceutical companies - all working together to improve the path for medical therapies to reach patients in need.

C-Path has been able to achieve many significant milestones over the past six years due to the extraordinary support of our community and the over \$30 million in federal and state research grants awarded to the organization. These grants have funded our work on global projects related to drug safety, biomarkers for use in drug development, mathematical models of disease progression, and innovative measures of patient-reported outcomes. Major progress is being made on developing new testing methods to accelerate development of drugs for Alzheimer's and Parkinson's diseases, polycystic kidney disease, asthma, depression, cancer, arthritis, and tuberculosis.

I will be eternally grateful to the Arizona community for the support that made it possible to launch the Critical Path Institute. I am also thankful to the many talented individuals who joined C-Path and dedicated their careers to creating a truly unique "trusted third party" for the FDA. Although based in Tucson, C-Path is a global enterprise that is connecting patients, care providers, and scientists dedicated to improving health and reducing the burden of diseases. Dr. Compton and her team are perfectly positioned to lead C-Path to even greater successes. Please join me in continuing to support C-Path as it demonstrates to the nation, and the world, the power of collaboration.

Sincerely,

A handwritten signature in blue ink that reads "Raymond L. Woosley". The signature is fluid and cursive.

Raymond L. Woosley, MD, PhD
Founder and President Emeritus



Carolyn Compton, MD, PhD

As C-Path's new President and CEO, it is my honor to co-present our 2011 Annual Report with Dr. Raymond L. Woosley, the organization's visionary founder. When Ray retired earlier this year, it became my honor to lead C-Path's extraordinary staff and work with our dedicated collaborators to change the world for patients.

Despite weathering tough economic times over the last several years, C-Path has persevered in its mission

and continued to realize the successful development of tools and methods to accelerate the development of safe, effective medical therapies. Among other significant milestones, C-Path consortia are developing 53 potential biomarkers, disease models, and patient-reported outcomes instruments that are currently in various stages of review by the FDA. Our global collaborations have continued to grow, and today, we remain committed to advancing scientific innovations that improve human health worldwide.

My aim is to bring new stakeholder connections, scientific approaches and conceptual innovation to C-Path that we can incorporate into the strategic plan for our next phase of growth and development. I am committed to furthering the initiatives that will unite scientists across the country and around the world, as we continue to develop previously non-existent standards and best practices for the research that translates scientific discovery into new medical products that are effective, safe and affordable. These standards and practices will create the opportunity to more accurately identify characteristics (biomarkers) of patients likely to respond to precisely targeted therapies, thus enabling patient-centered diagnosis and treatment.

In doing this, we will continue to work closely with the U.S. Food and Drug Administration (FDA) and its regulatory counterparts around the world to streamline and modernize the processes that help patients get the medicines they need more quickly and efficiently.

Please remember that the financial and in-kind support we receive allows C-Path to continue its global efforts to improve health and save lives. I am proud to be joining all of you in this brilliant effort, and expect 2012 to be a remarkable year for us.

Sincerely,

A handwritten signature in blue ink that reads "Carolyn Compton MD PhD". The signature is fluid and cursive.

Carolyn Compton, MD, PhD
President and CEO

Establish standards

for diagnostic tests and clinical research enabling the development of personalized medicine.

Accelerate development of therapies

for Alzheimer's and Parkinson's disease.

Create new tools

that assess drug safety.

Quicken the pace

of clinical research and new therapeutic approaches for major diseases.

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Design new paradigm for drug development

focused on novel multi-drug regimens for tuberculosis.

Partner with leading experts

to establish common data standards needed in clinical research and medical product development.

Capture the patient's perspective

when testing a medicine or therapy for diseases such as asthma, cancer, depression, and others.



STRATEGIC DIRECTION

Critical Path Institute's (C-Path) mission is to transform and accelerate the medical products development process to ensure that new life-saving drugs, diagnostics, and devices reach the patients who need them faster, safer, and less expensively.

C-Path leads global collaborations that include the biopharmaceutical industry, the biomedical technology industry, academia, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and other key Federal and international governmental agencies. These collaborations share data and develop data-driven standards, scientific tools, and testing methodologies for use in product development. These standards then assist the FDA and European Medicines Agency (EMA) in making regulatory decisions and issuing guidelines.

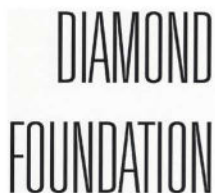
C-Path's ultimate goal is to improve and accelerate medical product development and the regulatory approval process to benefit patients worldwide.

2011 DONORS

Joseph Assenzo
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Honorable James T. Kolbe
Walter H. Moos
Richard T. and Judy Myers
Pfizer Foundation Matching Gifts Program
Tim and Jane Reckart
Ethel & Jerry Timan Family Fund
Tucson Pharma Ventures, LLC
Raymond L. and Julianne Woosley



Critical Path Foundation is working to build on Critical Path Institute's success and to increase philanthropic support in Arizona and throughout the U.S. The Foundation is deeply grateful to its dedicated donors who recognize the importance of C-Path's mission and continue to provide support with their philanthropic gifts. Together we are creating meaningful and lasting change to develop safe, effective medicines to improve public health and save lives. The acknowledgements below represent gifts made in fiscal year 2010-2011.



FINANCIAL STATUS

FISCAL YEAR ENDING JUNE 30, 2011

Critical Path Institute (C-Path) started in 2005 with a five-year commitment of almost \$12 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) and other global regulatory agencies to accelerate the development of safe, effective medical therapies.

The first legislation sponsored by Arizona Congresswoman Gabrielle Giffords created Critical Path public-private partnerships. C-Path applied for a partnership grant and received a five-year award of \$7.5 million. Other grants, including awards from Science Foundation Arizona and \$2.1 million from the Bill & Melinda Gates Foundation, are enabling C-Path to fundamentally change drug development.

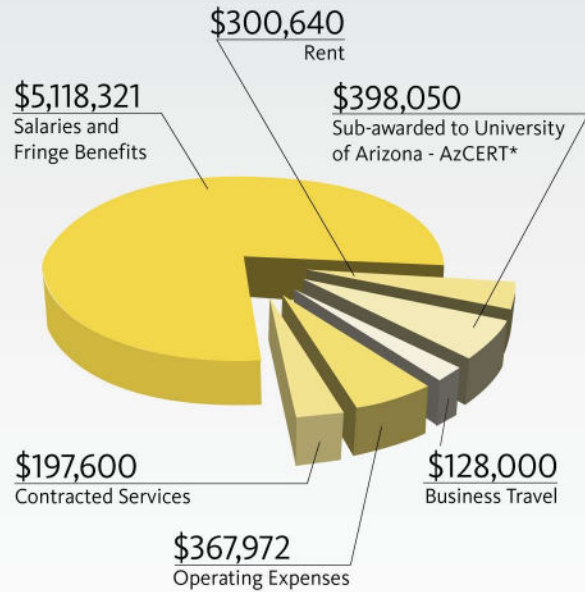
Fully 98.5% of all revenues go to support our people and programs. On the job creation front, C-Path opened its doors with five employees and ended FY'11 with 52 employees. In addition, C-Path and its team of scientists have helped launch four new biotechnology companies in Arizona.

The steadfast support of our community, the passion and dedication of our scientists and staff, and the trust of our stakeholders continue to enable C-Path to fulfill its mission of improving health and saving lives.



FY11 BUDGET

\$6,510,583



*Supported by federal grant

ASSETS

Cash and cash equivalents	\$3,512,846
Government Contract receivables	\$319,648
Other receivables	\$533,167
Other Assets	\$37,137
Restricted funds, invested	\$3,346,595
Property and equipment, net	\$460,501
TOTAL ASSETS	\$8,209,894

LIABILITIES & NET ASSETS

Accounts payable	\$476,090
Deferred revenue**	\$3,909,643
Deferred rent	\$54,684
TOTAL LIABILITIES	\$4,440,417

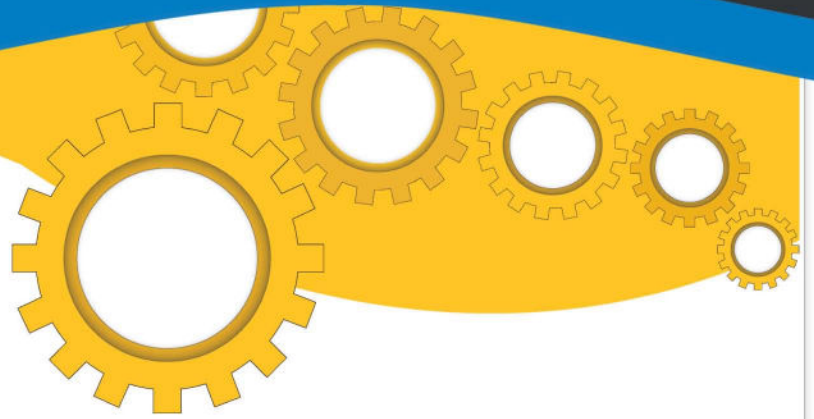
Unrestricted:

Undesignated funds	\$733,455
Board Designated funds***	\$2,383,789
Invested in property and equipment	\$460,501
Temporarily Restricted	\$191,732
TOTAL NET ASSETS	\$3,769,477

TOTAL LIABILITIES & NET ASSETS **\$8,209,894**

**Pre-awarded funds received for grants

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



C-PATH CONSORTIA

Coalition Against Major Diseases (CAMD)

Critical Path to TB Drug Regimens (CPTR)

Electronic Patient-Reported Outcome (ePRO) Consortium

Patient-Reported Outcome (PRO) Consortium

Polycystic Kidney Disease (PKD) Consortium

Predictive Safety Testing Consortium (PSTC)

OUR SUCCESSES*

- 1 6 global consortia, 1,000+ scientists and 41 companies
- 2 7 safety biomarkers qualified by FDA, EMA, and PMDA (the Japanese counterpart) and in use by industry
- 3 53 biomarkers, disease models, and PRO instruments under evaluation
- 4 34 safety biomarkers in review at FDA
- 5 **The first data standards set for Alzheimer's disease** developed with Clinical Data Interchange Standards Consortium (Parkinson's, TB, and Polycystic Kidney Disease in progress)
- 6 **Largest database of aggregated Alzheimer's Disease clinical trial data** (6,100 patients and 22 clinical trials) - publicly available to qualified researchers
- 7 **First imaging biomarker qualification by the EMA** to enrich Alzheimer's disease clinical trials
- 8 **First Alzheimer's disease progression model and simulation platform** in review by FDA
- 9 **First imaging and Cerebral Spinal Fluid (CSF) biomarkers** in consultation with the FDA

*As of December 31, 2011



We want to thank the Food and Drug Administration and Science Foundation Arizona for their significant funding of our work.

CONSORTIA MEMBERS



RESEARCH PARTNERS





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F 301.762.7722

www.c-path.org

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.

CHARITABLE CONTRIBUTIONS

The financial support Critical Path Institute receives from philanthropy enables global collaborations that advance scientific innovations to improve public health. Please contact the Critical Path Foundation to make a gift in support of C-Path's mission.

science · therapies · standards · safety · innovation ·
health · milestones · knowledge · accelerate · neutral
· educate · consensus · global · effective · biomarkers
· collaborative · excellence · data · community ·
dedication · research · facilitate · science · therapies ·
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