

Critical Path Institute Receives Third Grant To Accelerate Tuberculosis Diagnostics



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Multi-Year Grant to Fund Innovative Global Data Platform Designed To Streamline Tuberculosis Diagnosis and Treatment

TUCSON, Ariz., December 8, 2014 – Critical Path Institute (C-Path), an Arizona-based non-profit organization dedicated to fostering collaborative initiatives to improve the quality and efficiency of the drug development process, has received a new multi-year grant from the Bill & Melinda Gates Foundation. This grant will fund the creation and implementation of the Rapid Drug Susceptibility Test Data Platform. The platform will catalog a vast amount of tuberculosis genomic data of worldwide tuberculosis strains. Tuberculosis is the second leading cause of death (after HIV) from a single infectious agent.

The database will inform correlations between mutations and clinically relevant resistance. This will advance the development of rapid drug susceptibility tests for tuberculosis that can be used to speed up the selection of effective treatment. The longer-term vision of the database is to directly enable sequencing data interpretation and patient care.

"To create the kinds of tests essential to the effective deployment of novel tuberculosis treatments," explains Martha Brumfield, Ph.D., President and CEO of C-Path, "we need a singular data resource that encompasses global resistance trends and markers for resistance that come directly from patients with tuberculosis and their caregivers."

C-Path is uniquely qualified to work on this initiative, given their successful history of forging partnerships and developing new tools to shorten the drug development cycle time. C-Path's Critical Path to Drug TB Regimens (CPTR) program, which focuses on the efficient and effective development of new TB regimens, will partner with FIND, New Diagnostics Working Group (NDWG), the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) to compile the international tuberculosis data relevant to developing the ability to very rapidly diagnose the specific type of resistant TB present in a patient, and in turn, help define the most effective TB treatment regimen for each patient. Standard tuberculosis therapies are now almost fifty years old, and tuberculosis has become resistant to many treatments. Having this data at the fingertips of researchers will allow for the development of personalized treatment regimens that take into account resistance trends in the patient's specific locale. "There are a great many different strains of tuberculosis, and diagnosing the specific strain and developing a treatment regimen is currently a time-consuming undertaking," says Mario Raviglione, director of the WHO's Global Tuberculosis Programme. "With this global partnership in place, a great need is being addressed by putting existing data from around the world to work in developing the fastest and best diagnostic tools to help the patients suffering from the scourge of tuberculosis – which remains an urgent public health threat that kills 1.5 million people each year."

About the Critical Path to Drug TB Regimens (CPTR) Initiative

The Critical Path to Drug TB Regimens (CPTR) Initiative, launched in 2010, is a broad collaboration of industry, civil society, government and regulatory officials working together to develop regulatory science that can be used to identify, develop and put through formal regulatory review new methods and tools with a specific application in the development of promising tuberculosis (TB) drug candidate combinations. CPTR was formally launched on March 18, 2010, in Washington, D.C., with a keynote address by U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg. Its mission is to address an urgent public health need — with the goal of saving millions of lives.

About the Critical Path Institute

The Critical Path Institute (C-Path) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona and the U.S. Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established seven global, public-private partnerships that currently include over 1,000 scientists from government and regulatory agencies, academia, patient advocacy organizations and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit <u>http://www.c-path.org</u>.

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