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### *Critical Path Institute Receives Grant to Accelerate Development of Tuberculosis Treatments*

*Multi-year grant brings together non-profits, government, academia and the pharmaceutical industry to study pressing public health challenge*

Tucson, AZ, 4 February, 2014 — The [Critical Path Institute](#), an independent, non-profit that catalyzes innovative ideas that accelerate the speed of drug and medical product development, today announced it has received a three-year grant from the [Bill & Melinda Gates Foundation](#). The grant will be used to develop quantitative mathematical models to optimize the design of clinical trials and tackle challenges facing the development of effective tuberculosis (TB) treatments.

The grant work, which is focused on advancing the science behind TB drug treatments, will be implemented through the [Critical Path to TB Drug Regimens Initiative](#) (CPTR). Co-founded by the Critical Path Institute, the Bill & Melinda Gates Foundation, and the Global Alliance for TB Drug Development, the CPTR initiative has multiple, related projects. Projects include developing physiologically-based pharmacokinetic models, which enable improved understanding of the absorption and distribution of TB drugs through the lungs, and a population-based pharmacodynamic model to help determine effective treatment doses. Additionally, the project will enable promising drug combinations to be tested and developed together to create entirely new multi-drug treatments.

“TB is a pressing global public health issue and stopping its spread requires new treatment options,” said Martha Brumfield, Ph.D, president and chief executive officer of the Critical Path Institute. “This grant and the collaborative work of CPTR will reduce the time and uncertainty in developing innovative regimens from decades to years.”

TB is a disease caused by *Mycobacterium tuberculosis*, a bacterium that attacks the body, most frequently the lungs, kidney, spine or brain. According to the Centers for Disease Control and Prevention, a total of 9,945 TB cases were reported in the United States in 2012.<sup>1</sup> Worldwide, TB remains a major global health problem, particularly in developing countries. In 2012, an estimated 8.6 million people developed TB and the World Health Organization reported 1.3 million fatalities.<sup>2</sup> India represented approximately two to three million people with TB infections, helping to prompt the United Nations to incorporate “halting and reversing the TB epidemic by 2015” as one of its Millennium Development Goals.<sup>3</sup>

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<sup>1</sup> “Trends in Tuberculosis, 2012.” Centers for Disease Control & Prevention. Accessed December 10, 2013. <http://www.cdc.gov/tb/publications/factsheets/statistics/TBTrends.htm>

<sup>2</sup> “Global Tuberculosis Report 2013.” World Health Organization. Accessed December 11, 2013. [http://www.who.int/tb/publications/global\\_report/en/index.html](http://www.who.int/tb/publications/global_report/en/index.html)

<sup>3</sup> “We Can End Poverty. Millennium Development Goals and Beyond 2015. Accessed December 12, 2013. <http://www.un.org/millenniumgoals/aids.shtml>

### ***Fostering Innovation through Public-Private Collaborations***

In support of the CPTR project, Janssen Research & Development, a subsidiary of Johnson & Johnson, will provide data from its clinical trials of Sirturo (bedaquiline) to CPTR's Regulatory Science Consortium. The approval of Sirturo in December 2012 ended a 50 year drought in new treatment options for TB, widely acknowledged as a neglected disease.<sup>4</sup> CPTR's Regulatory Science Consortium is focused on developing and integrating data standards, developing quantitative disease progression and response metrics, as well as facilitating new pharmacokinetic measures for drug interactions.

A significant portion of the efforts to expedite availability of TB treatments is advancing understanding and decreasing risk and failure often associated with late stage clinical trials for TB. CPTR's unprecedented collaboration with pharmaceutical companies and strong commitments from public and private partners around the world are enabling the design of models that make clinical trials for TB more efficient and speed development of TB treatments from early clinical testing.

"We are proud to actively contribute to CPTR and foster new ways to tackle the challenge of TB," stated Wim Parys, M.D., Head R&D Global Public Health, Janssen Pharmaceuticals, Inc. "Through our collaborations with the CPTR Initiative we look forward to continuing to provide safe, efficacious and faster-acting TB regimens for individuals impacted by this terrible disease."

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

[The Critical Path to Drug TB Regimens Initiative](#) (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 is committed to improving health and saving lives by accelerating the development of safe, effective medicines. An international leader in forming collaborations around this mission, C-Path has established global, public-private partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty-five major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit [www.c-path.org](http://www.c-path.org).

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<sup>4</sup> "First New TB Drug in Fifty Years Risks Being Squandered Without Better Research and Pricing Strategies." Doctors without Borders. October 13, 2013. Accessed on December 11, 2013.

<http://www.doctorswithoutborders.org/press/release.cfm?id=7132&cat=press-release>.