TB-ReFLECT: A Collaborative Effort to Enhance TB Clinical Research

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TUCSON, Ariz., October 25, 2016 — The Critical Path Institute's Critical Path to TB Drug Regimens (CPTR) initiative and the Global TB Programme of the World Health Organization (WHO) have partnered with researchers from the University of California, San Francisco (UCSF), to develop leading-edge quantitative analyses of data from the TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS) database. This collaboration, called TB-ReFLECT, will extract from these analyses key lessons from the TB-PACTS platform, and then package such lessons as tools for future TB trial design.

TB-PACTS, which is now available to researchers across the world, is an integrated and standardized patient-level database comprising data from three leading contemporary, Phase III studies (OFLOTUB, REMox, and RIFAQUIN trials) that were the first to evaluate the treatment-shortening potential of quinolone-containing regimens in a systematic and controlled way. TB-PACTS is hosted by C-Path, in partnership with the WHO Special Programme for Research and Training in Tropical Diseases (TDR), the TB Alliance, and St. George's, University of London. The database has been accessible since April 2016. So far, the TB-PACTS scientific committee has received 23 applications; 16 have been granted access within a mean of eight days.

"TB-PACTS has already elicited a lot of interest; within the first six months of the database being available, 16 requests have been granted access to the data. And TB ReFLECT has already produced results, showing the value of data-sharing and maximizing the utility of shared trial data," says Piero Olliaro, head of Intervention and Implementation Research at TDR.

TB-ReFLECT will evaluate endpoints of treatment outcome for the selection of new regimens to be tested in Phase III clinical trials, as well as optimizing statistical methods for comparing results between regimens. This will lead to an improved understanding of the factors responsible for the variability in a patient's response to treatment. As part of this effort, researchers will develop a framework with clinically relevant endpoints that links the response of the bacteria to treatment.

“These Phase III trials represent over 4500 patients, decades of effort, and millions of dollars of investment,” says Debra Hanna, PhD, Executive Director of CPTR. “The analysis of these aggregated data will provide critical new insights to the TB drug development community and help to shape increasingly informed TB clinical trial approaches.”

On October 27, CPTR and WHO will co-host a symposium at the 2016 Union Conference on Lung Health in Liverpool, UK, to update the TB research community on the progress of the TB-ReFLECT partnership. Presentations and panel discussions will highlight initial results, publicly accessible tools, data standards, and the TB-PACTS data sharing platform.

“The outcomes of this collaboration will provide vital guidance to the research and development community on their quest for shorter and optimal TB treatments,” says Dr. Christian Lienhardt, Senior Research Adviser at the WHO Global TB Programme. “This will be crucial in saving lives, and easing the immense burden of suffering on the millions of people who combat TB each year.”

About the organizations:

Critical Path to TB Drug Regimens

CPTR (Critical Path to TB Drug Regimens) is an initiative that aims to speed the development of new and markedly improved drug regimens for tuberculosis. This partnership brings together the world’s leading pharmaceutical and other drug developers, global regulatory agencies, and civil society organizations to support advances in regulatory science, the development of infrastructure, and other progress needed to facilitate the development and availability of new TB drug treatments. Co-founded by the Bill & Melinda Gates Foundation, the Critical Path Institute, and the TB Alliance, and launched in March 2010, CPTR is working with stakeholders around the world to advance a new paradigm that dramatically speeds new TB drug regimens to patients.

CRITICAL PATH INSTITUTE

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US 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 12 global, public-private partnerships that currently include over 1,450 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 www.c-path.org.

The World Health Organization (WHO) Global TB Programme guides global action for a world free of TB by advancing universal access to TB prevention, care and control; framing the response to threats through norms, standards and strategy; technically supporting Member States; monitoring the burden and response; and promoting innovation. WHO is the directing and coordinating authority for health within the United Nations system.

C-Path Contact:
Kissy Black
+1.615.298.1144
kissyblack@lotosnile.com