

C-Path Selected as Host For New TB Clinical Trial Data-Sharing Platform

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TUCSON, Ariz., May 4, 2015 — The non-profit [Critical Path Institute](#) has been selected to host a new tuberculosis (TB) clinical trial data sharing platform. The initiative will start by creating a common database from three Phase III clinical trials earlier supported by the [Special Programme for Research and Training in Tropical Diseases \(TDR\)](#), the [TB Alliance](#) and [St. George's, University of London](#).

“This is the first time trial sponsors have come together to make clinical trial data collectively available,” says Piero Olliaro, head of Intervention and Implementation Research at TDR. “Choosing the hosting organization is the first step. In the next few months we will be working together to format the data so that they can be accessed and used for further analysis.”

Randomized, controlled TB clinical trials are lengthy and costly, but this platform is designed to speed up data analysis through this sharing. To start, researchers will be able to mine patient-level data from the OFLOTUB, REMoxTB and RIFAQUIN clinical trials. Other trials are expected to be added in the future.

“For research in areas like tuberculosis, where there is no financial incentive, we must work together to advance the field,” says Mel Spigelman, MD, President and CEO of TB Alliance. “This collaboration and data platform will enable donors’ investment to go further in helping to tackle the TB epidemic and bringing researchers from around the globe together to solve one of the world’s most intractable public health problems.”

C-Path was selected through a competitive proposal submission process. It is a non-profit institute and recognized expert in database development, data standards development, secure management of patient-level data, individual privacy, database security and controlled access methods. In this role, C-Path will host, curate and make key Phase III TB clinical trial data sets available to qualified researchers. C-Path has 10 years of experience with the design and implementation of global data platforms in nine major disease areas, representing data from more than 30,000 patients.

“This is a welcome extension of one of C-Path’s core competencies,” says C-Path CEO, Martha Brumfield, PhD, “and with this collaboration, we are positioned to further enable meaningful learning from clinical trials in TB. Ongoing collaboration and data sharing across multiple organizations is critically important if we are to develop the necessary new regimens to fight this deadly disease.”

The groups expect to make the platform open to interested research groups by the end of the year.

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TDR, the Special Programme for Research and Training in Tropical Diseases, is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. It is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO.

www.who.int/tdr

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TB Alliance (Global Alliance for TB Drug Development) is a not-for-profit organization dedicated to finding faster-acting and affordable drug regimens to fight tuberculosis (TB). Through innovative science and with partners around the globe, we aim to ensure equitable access to faster, better TB cures that will advance global health and prosperity. TB Alliance operates with support from Australia's Department of Foreign Affairs and Trade, Bill & Melinda Gates Foundation, European Commission, Global Health Innovative Technology Fund, Irish Aid, National Institute of Allergy and Infectious Disease, UNITAID, United Kingdom Department for International Development, United States Agency for International Development, and the United States Food and Drug Administration. For more information please visit

www.tballiance.org.



C-Path (Critical Path Institute) 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 eight 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 www.c-path.org.

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St. George's, University of London, is a Medical School and is a constituent college of the University of London. St George's offers foundation and undergraduate degrees in medical, biomedical and healthcare sciences. Its Institute for Infection and Immunity aims to have a significant beneficial impact on human health by developing a better understanding of pathogen biology and human immune responses. The Institute sustains a range of international research interests, supporting efforts to control globally important infectious disease. Within the Institute for Infection and Immunity, Amina Jindani, MD, FRCP and Professor Denny Mitchison are conducting international Phase III clinical trials to refine the complex treatment of tuberculosis. www.sgul.ac.uk