New TB Clinical Trial Data-Sharing Platform Available for Researchers

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TUCSON, Ariz., April 18, 2016 — The Critical Path Institute (C-Path), the Special Programme for Research and Training in Tropical Diseases (TDR), TB Alliance, and St. George's, University of London, are pleased to announce the launch of the TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS).

"TB-PACTS is a valuable tool in the fight against the world's leading infectious killer," says Dr. Martha Brumfield, President and CEO of C-Path. "By combining C-Path's core strengths in data aggregation, standardization, and curation with a wealth of clinical trial data from TDR, TB Alliance, St. George's, University of London, and other organizations, we strive to enable more efficient and effective drug development for TB. We envision TB-PACTS as a prime example of how a collaborative, data-sharing approach leads to a knowledge base greater than the sum of its parts."

TB-PACTS is designed to catalyze and accelerate TB research by curating and standardizing Phase III tuberculosis (TB) clinical trial data and making this data available to the research community. Data can be accessed and analyzed in aggregate, or filtered and viewed as individual records. Types of data available include demographic information, concomitant medications information, dose/concentration information, outcomes data, and relevant covariates of interest. Having these data curated, validated, and easily accessible under one platform helps inform recommendations for policymaking as well as informing the development of novel drug and drug regimens, which would ultimately benefit TB patients.

"By making this data collectively available, we achieve what no single organization could. The entire field is advanced—allowing researchers to potentially extract new information from clinical trials that could pave the way to more rapid and meaningful progress," says Dr. Mel Spigelman, President and CEO of TB Alliance. "In a field like tuberculosis, where there is no financial incentive, this partnership provides real value to the donor and scientific community alike."

Researchers can review and analyze patient-level data from the REMoxTB, RIFAQUIN, and OFLOTUB clinical trials. These large trials were sponsored by TB Alliance (REMoxTB) and St. George's, University of London (RIFAQUIN). The OFLOTUB trial was co-sponsored by TDR and IRD (Institut de Recherche pour

le Developpement, France). Their funding was trial specific.

“We are very delighted to know that this investment has the potential to give us an even greater return through trial data sharing,” says Dr. Michael Makanga, Executive Director of the European & Developing Countries Clinical Trials Partnership (EDCTP), a main funder of the REMoxTB and RIFAQUIN trials.

The data have been combined into a single dataset. In this aggregated form, it may be possible to detect patterns not otherwise apparent in individual datasets. Data from the individual studies can be separated if needed. TB-PACTS is equipped to host additional trial data as well as data from additional studies in the future.

Data sharing is a means to improve knowledge and better inform both policy decisions and the design of future research. While this principle is generally promoted, however, it has been implemented infrequently. Now, three institutions that have sponsored large trials of TB treatments are taking additional steps to make the data broadly accessible, to help answer critical research and programmatic questions.

“This is an extremely important initiative, of which St. George’s is a founding member,” said Dr. Amina Jindani, who leads the International Consortium for Trials of Chemotherapeutic Agents in Tuberculosis (INTERTB) at St. George’s, University of London. “Data sharing will prevent the duplication of clinical research and facilitate the funding of trials critical to the eventual elimination of tuberculosis. INTERTB has much to contribute to TB-PACTS, both from past and future clinical trials of tuberculosis.”

“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. “We’re excited to have been able to work with partners to set up a secure, efficient, and equitable system to store and protect data integrity, and to allow access under conditions that promote the generation and further dissemination of knowledge. We also look forward to others joining this initiative in the future.”

Researchers applying for access must agree to the *Terms and Conditions for Use of the TB-PACTS data platform* and submit an online application form to request access to the data platform. Visit https://c-path.org//programs/tb-pacts/ for more information.

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 1,300 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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TDR, the Special Programme for Research and Training in Tropical Diseases, is a global program 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. For more information, visit 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, Indonesia Health 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 US Food and Drug Administration. For more information please visit www.tballiance.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

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