New TB clinical trial data-sharing platform available for researchers

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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, respectively, by TB Alliance, St. George's, University of London, and TDR. 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. "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."

More information: c-path.org/programs/tb-pacts/

Provided by The Critical Path Institute (C-Path)

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