

## ReSeqTB Data Platform Now Available to Public

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TUCSON, Ariz., January 17, 2017 —The Rapid Drug Susceptibility Testing Consortium, coordinated by the <a href="Critical Path Institute">Critical Path Institute</a> through the <a href="Critical Path to TB Drug Regimens">CPTR</a>) initiative, announces the public launch of the <a href="Relational Sequencing TB Data Platform">Relational Sequencing TB Data Platform</a> (ReSeqTB). ReSeqTB is a data-sharing platform and analytic visualization tool that can be used to discover, grade, and track key bacterial drug resistance mutations. The tool was created to facilitate the development of new diagnostics capable of rapidly testing drug susceptibility, which could be used to identify effective treatment regimens for better managing patients with drug-resistant TB.

TB is the world's most deadly infectious disease. One of the targets of the United Nations' Sustainable Development Goals for 2030 is to end the TB epidemic, which demands a global effort to tackle the rise of multi-drug-resistant TB (MDR-TB). Management of MDR-TB is lengthy and complex. Approximately 52% of MDR-TB patients are successfully treated, compared to over 80% of patients with drug-susceptible TB (WHO Global TB Report 2016, p.54). In addition to sub-optimal treatment, this is due in large part to the lack of rapid diagnosis and drug susceptibility testing to guide treatment decisions.

Current approaches to test for drug susceptibility require trained technical support and well-resourced laboratories. It can take several months to deliver results especially if the *Mycobacterium tuberculosis* (*M.tb*) bacteria are resistant and require testing against an expanded panel of drugs. ReSeqTB can change this paradigm by enabling clinicians and researchers to simultaneously identify mutations to all drugs.

ReSeqTB provides researchers a user-friendly interface to access whole-genome sequencing data that is standardized, collated, and integrated with culture-based drug susceptibility tests, incorporating clinical outcome data when available. This resource is intended to provide a one-stop location for stakeholders such as healthcare professionals, researchers, and diagnostic developers to identify and categorize *M.tb* mutations associated with drug resistance. Identifying drug resistance mutations using genomic-based diagnostic assays can facilitate quick, well-tailored delivery of patient care. The platform will help overcome confusion about the relevance of mutations and their clinical interpretation. This will be particularly important as new TB treatments are approved and scaled up.

"The ReSeqTB platform provides TB research efforts—specifically for TB surveillance using sequencing technologies—with standardized criteria for grading TB drug resistance conferring mutations through a validated algorithm," said Matteo Zignol, MD, MPH, scientist at the World Health Organization (WHO)

Global TB Programme, TB Monitoring and Evaluation Section.

ReSeqTB is now open to researchers outside of CPTR, who can request access to the data platform via the ReSeqTB website. Expanded access will drive additional research across multiple segments, which can improve treatment practices and increase the efficiency of TB research. To date, more than 2,000 users have visited the ReSeqTB website.

"The goal of opening ReSeqTB more widely is to promote public access to new and contemporary curated data that has been aggregated from different TB studies under a common CDISC [Clinical Data Interchange Standards Consortium] standard," said Marco Schito, PhD, CPTR's scientific director. "A tiered access system will be used to allow individual contributors to define data use and timing of access. This will accelerate the identification and validation of mutations associated with resistance to existing, new, and repurposed drugs, and is in line with funders' requests to ensure publicly funded data are effectively disseminated to promote further collaboration."

The ReSeqTB platform is user-focused. It features a visual browser to aid in the identification and analysis of mutations and their correlation with drug resistance/susceptibility. Downloadable drug resistance reports, along with visualization tools, are available and will be further optimized based on user feedback. More mutations will be validated as data are contributed to the platform. Additional tools and enhancements will be introduced on an ongoing basis.

The continued development of ReSeqTB requires ongoing interaction and dialogue with stakeholders on needs, requirements, and data-sharing challenges. Future iterations of the platform will reflect feedback from clinicians, national TB programs, and patient advocacy groups. Dr. Timothy Rodwell, MD, PhD, at FIND and the University of California San Diego "urges members of the TB research community to explore these tools and provide feedback," in order to advance collective knowledge of TB drug resistance.

ReSeqTB is a joint initiative funded by the <u>Bill & Melinda Gates Foundation</u>, with extensive contributions from several partner organizations, including <u>C-Path</u> and <u>CPTR</u>, <u>FIND</u>, <u>World Health Organization</u>, the <u>Stop TB Partnership's New Diagnostics Working Group</u>, and the <u>US Centers for Disease Control and Prevention</u>.

## **About the organizations:**



Critical Path to TB Drug Regimens (CPTR) 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) 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.



**FIND**, established in 2003 as a global nonprofit, is dedicated to accelerating the development, evaluation and use of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, febrile illnesses and infectious diseases with outbreak potential, such as Ebola. Over the last decade, FIND has partnered in the delivery of 14 new diagnostic tools, including eight for tuberculosis, and has created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility.

FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has over 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, clinical trial sites, and bilateral and multilateral organizations (especially WHO). To learn more, visit <a href="https://www.finddx.org">www.finddx.org</a>.



The World Health Organization (WHO) Global TB Programme guides global action for a world free of TB by advancing universal access to TB prevention, treatment and care; 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.

## **Stop (B)** Partnership

## **New Diagnostics Working Group**

The **New Diagnostics Working Group (NDWG)** is one of the seven working groups of the Stop TB Partnership. Its mission is to foster the development and evaluation of new diagnostics for tuberculosis by serving as a coordination, communication and advocacy platform for all stakeholders in TB diagnostics research and development. The NDWG provides a neutral and overarching platform for coordination at the global level.

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