Research Excellence to Stop TB Resistance

### **RESIST-TB ANNUAL REPORT FOR 2022**

RESIST-TB is an organization of concerned patients, physicians, research scientists and stakeholders. Its mission is to facilitate and promote clinical research to cure and prevent drug-resistant tuberculosis. RESIST-TB is committed to addressing the substantial existing gaps in knowledge and to helping provide access to effective curative and preventive treatment for drug-resistant tuberculosis (DR-TB). Efforts were supported by the Stop TB Partnership, the International Union Against Tuberculosis and Lung Disease, Treatment Action Group, Partners In Health, the U. S. Centers for Disease Control & Prevention, Vital Strategies and Médecins Sans Frontières.

Our 2022 activities centered on:

(1) DR-TB scientific advocacy through dissemination of information through our website, including promoting and arranging a series of webinars and an eNewsletter, publicizing weekly news articles, participating in the World Conference on Lung Health and contributing to published literature on DR-TB testing and treatment.

And

(2) Driving public policy change by publicizing data on DR-TB diagnosis and susceptibility testing globally and disseminating new developments and best practices in DR-TB treatment.

Details about these activities are provided below.

#### SCIENTIFIC ADVOCACY

#### **RESIST-TB WEBSITE AND eNEWSLETTER**

The RESIST-TB website (www.resisttb.org) remains active to share advances in DR-TB clinical trials and disseminate news, developments, and publications. Our website is updated weekly and our newsletter is distributed to 549 subscribers. In our monthly eNewsletter, we highlight information about new DR-TB related publications, provide news updates, and inform readers about upcoming events. Topics covered in our news articles included DR-TB clinical trial status updates, developments in the use of drugs and susceptibility testing, publication announcements, symposia, and webinars of interest in addition to global headlines related to DR-TB.

#### CLINICAL TRIALS PROGRESS REPORT

RESIST-TB continues to be a critical source for up-to-date information on clinical trials for DR-TB. The Clinical Trials Progress Report gathers and maintains updated information on clinical trials that are underway and/or in development, including study names, description, status, study enrollment size, and links to more information. There are currently 33 clinical trials being

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routinely monitored on our website. Of the 33 trials included in the Clinical Trials Progress Report, 9% are Phase 1, 36% are Phase 2, 33% are Phase 3, and 9% are Phase 4; 6% are not yet recruiting, 51% are currently enrolling participants, and 12% have completed enrollment and follow up, or data analysis is ongoing, and 30% have been completed with results. This resource is updated on a monthly basis with downloadable versions available in PDF Microsoft Powerpoint of a joint RESIST-TB/Union effort to describe distribution and capacity of this important tool to inform care for DR-TB and research on new treatments.

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format <u>here</u>. The Clinical Trials Progress Report page is the most visited page on RESIST-TB's website, aside from the homepage.

In November of 2022, RESIST-TB co-sponsored the Symposium "Mobilising Communities Against TB" at The Union's annual World Conference on Lung Health. This Symposium discussed the importance of engaging community leaders, reducing stigma, generating momentum for eliminating TB from the communiuty, and devising strategies for finding and treating community members affected by TB.

## **INCREASING AWARENESS TO CHANGE PUBLIC POLICY**

In 2022, RESIST-TB partnered with TB Net to prepare an update to our 2016 Consensus Statement article, expected to be published in early 2023

Clinical implications of molecular drug resistance testing for Mycobacterium tuberculosis: a TBnet/RESIST-TB consensus statement. J. Domínguez1, M. Boeree, E. Cambau, D. Chesov, F. Conradie, V. Cox, K. Dheda, A. Dudnyk, M. Farhat, S. Gagneux, M. P. Grobusch, M. Groeschel, L. Guglielmetti, I. Kontsevaya, B. Lange, Fv. Leth, C. Lienhardt, A. Mandalakas, F. Maurer, M. Merker, P. Miotto, B. Molina-Moya1, S. Niemann, F. Morel, N. Veziris, A. Whitelaw, D. Willemse, C.R. Horsburgh\*, C. Lange\*, for the TBnet and RESIST-TB networks. The Lancet Infectious Disease (in press).

In 2022, a report jointly-authored by RESIST-TB and The Union was published in efforts to describe the distribution and capacity of susceptibility testing to inform care for DR-TB and research on new treatments: This is part of a joint RESIST-TB/Union initiative to describe distribution and capacity of this important tool to facilitate optimal care for DR-TB and stimulate further research on new treatments. **Global availability of susceptibility testing for second-line anti-tuberculosis agents.** Lazarchik A, Nyaruhirira AU, Chiang CY, Wares F, Horsburgh CR. Int J Tuberc Lung Dis. 2022 Jun 1;26(6):524-528. Doi: 10.5588/ijtld.21.0420. PMID: <u>35650708</u>

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### WEBINAR SERIES

Since 2015, RESIST-TB has hosted a webinar series on recent developments in DR-TB. This webinar series serves as a forum for updates on pressing issues in the field of MDR-TB through presentations on recent publications. The webinar series also helps fill a critical and otherwise unmet gap in disseminating new, unpublished advances in MDR-TB care and treatment. Webinars hosted as part of this series during 2022 are listed below:

 <u>Pediatric PK for the New and Repurposed TB Drugs – Where Are They Now?</u>, Presentations by Dr. Ronelle Moodliar, Dr. Tony Garcia-Prats, Dr. Jerry Nedelmen, and Dr. Tomohiro Sasaki on January 26<sup>th</sup>, 2022

*Description*: This webinar offered updates on the latest developments in pediatric PK of bedaquiline, linezolid, delamanid, and pretomanid.

 Discussion of 6-Month MDR-TB Treatment, Presentations by Dr. Salah Foraida and Dr. Catherine Berry on April 14<sup>th</sup>, 2022

*Description*: This comprehensive webinar included presentations on multiple recent studies of pretomanid-containing regimens, ZeNiX (Nix-TB) and TB-PRACTECAL.

 Treatment of Pediatric MDR-TB – Lessons from the Field, Presentations by Dr. Cathy Hewison, Dr. Aung Aung from MSF Tajikistan, Dr. Vijay Chavan from MSF Mumbai and Dr. Anthony Garcia-Prats on May 4<sup>th</sup>, 2022

*Description*: Presenters discussed the latest WHO guidelines and treatment regimens for pediatric MDR-TB regimens, and experience with their implementation

 <u>Choosing TB Regimens to Advance to Late-Stage Clinical Trials</u>, Presentation by Suzanne Dufault, PhD on October 24<sup>th</sup>, 2022

*Description*: Dr. Dufault presented a novel approach, using Bayesian analysis of interim endpoints, to select TB regimens with strong potential for success in late-stage clinical trials.

#### **RESIST-TB LEADERSHIP**

In 2022, Andy Vernon rotated off the Steering Committee for RESIST-TB. We thank him for his many years of service to RESIST-TB and his dedication to the goal of eliminating all forms of TB. Wendy Carr has now joined the Steering Committee to continue the CDC's invaluable institutional contribution to RESIST-TB. We are delighted to have Dr. Carr on the Steering Committee and look forward to her many contributions in the near future.

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### **RESIST-TB GOALS FOR 2023 – AND BEYOND**

RESIST-TB continues to implement our strategic plan, updated in 2017, focused on accelerating the identification and uptake of effective, scalable regimens for MDR-TB; advocating for clinical trials of preventive therapy for MDR-TB; and optimizing communication between stakeholders in the MDR-TB community.

In the coming year, RESIST-TB will continue to provide leadership in scientific advocacy, MDR-TB clinical trials design and preparation, and public policy development. Activities planned for 2023 include:

- RESIST-TB will continue its webinar series. The first 2023 webinar, <u>"STREAM Stage 2</u> <u>Efficacy, Safety, and Site Perspective Results."</u>, was presented by Ruth Goodall, Dr. Golopan Naranden, and Sarah on January 19<sup>th</sup>. The <u>second 2023 webinar</u>, featuring Leena Menghaney and Christophe Perrin from Médecins Sans Frontières, presented on their "Drugs Under The Microscope" report which discussed DR-TB drug pricing and access policies, including recommendations for governments, policymakers and healthcare providers to improve access to these lifesaving treatments.
- RESIST-TB is currently organizing a survey to assess the centralized approval of treatment for MDR-TB globally. This survey is planned to be conducted in 2023.
- RESIST-TB will continue to provide up-to-date information about MDR-TB clinical trials through the RESIST-TB eNewsletter and Clinical Trials Progress Report posted to our website.

RESIST-TB fills an important unmet need for innovation, information dissemination and advocacy. By addressing research and implementation gaps in the treatment and prevention of MDR-TB, we draw attention to areas still in need of research. We also undertake important research projects that are not currently being addressed by the global TB community. Our focus remains the development and demonstration of efficacy of scalable, nontoxic regimens and facilitation of rapid translation of these advances into practice. The successful continuation of these activities is critical to continued improvement in treatment and prevention of MDR-TB and XDR-TB.