

RESIST-TB

Research Excellence to Stop TB Resistance

RESIST-TB ANNUAL REPORT FOR 2018

RESIST-TB is an organization of concerned patients, physicians, research scientists and stakeholders. Its mission is to promote and conduct 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 in 2018 were sponsored by the World Health Organization, 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 2018 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, developing consensus guidelines on molecular TB diagnostics;

and

(2) Increasing public policy and awareness by gathering data on DR-TB treatments globally through the creation, deployment, and analysis of an online survey;

Details about these activities are provided below.

SCIENTIFIC ADVOCACY

RESIST-TB WEBSITE AND eNEWSLETTER

The RESIST-TB website (www.resisttb.org) remains active and updated often in order to accurately reflect advances in DR-TB clinical trials and disseminate news, developments and publications. Our website is updated weekly and our newsletter is received by 398 subscribers. In our the monthly eNewsletter, we highlight information about new DR-TB related publications, news updates, and events. Topics covered in our news articles included DR-TB trial status updates, announcements of publications, symposia, and webinars of interest in addition to global headlines related to DR-TB.

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ADVOCACY PUBLICATIONS

In 2018, a number of RESIST-TB affiliated articles were published:

- “Has compassionate use ever sunk a drug?” – RESIST-TB members S. McAnaw, C. Mitnick and C.R. Horsburgh. *The International Journal of Tuberculosis and Lung Disease*, 22(2), 119-120, 2018
- “Pan-tuberculosis regimens: an argument against” – RESIST-TB members C.R. Horsburgh and C. Lange.
- *The Lancet Respiratory Medicine*, 6(4), 240-242, 2018
- “Insights into drug-resistant tuberculosis treatment: results of The Union DR-TB Working Group Survey, 2017” – RESIST-TB members Sarah McAnaw, C-Y. Chiang, C.R. Horsburgh. *Public health action*, 8(3), 141-144, 2018

CLINICAL TRIALS PROGRESS REPORT

RESIST-TB continues to be a critical source for up-to-date information on clinical trials for MDR-TB. The Clinical Trials Progress Report gathers information on clinical trials underway and in development, including study names, description, status, study enrollment size, and links to more information on all MDR-TB trials planned or in progress. There are currently 21 clinical trials regularly updated on our website. Of the 21 listed on the Clinical Trials Progress Report, approximately 14% are in Phase 1, 43% are in Phase 2, and 43% are in Phase 3. Roughly 57% of trials listed are currently enrolling participants and approximately 43% have completed enrollment and follow up or data analysis is ongoing. This resource is updated monthly with downloadable versions available in PDF, PowerPoint, and Word Document formats.

WEBINAR AND CONFERENCE CALL SERIES

In 2015 we initiated a webinar series in collaboration with the CDC TBTC MDR/XDR-TB Working Group. This webinar series serves as a forum for updates on pressing issues in the field of MDR-TB and presentations on recent publications. This webinar series helps fill a critical and otherwise unmet role in disseminating newly identified but unpublished advances in MDR-TB care and treatment, as well as providing a forum for authors to discuss newly published findings. The Webinars that took place during 2018 are listed below:

- **MDR-TB Clinical Trials Capacity Building (TREAT-TB)**, presented by Dr. Jan Komrska – July 10, 7:00 – 10:00 EDT (13:00 -16:00 CET)
- **Preliminary Results from the endTB observational cohort study**, presented by Dr. Cathy Hewison and Dr. Lorenzo Guglielmetti – April 5, 9:30 – 11:00 EDT (15:30-17:00 CET)

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- **Adequate and Well-Controlled Studies in TB Regimen Development: An FDA Perspective**, presented by Carole Mitnick and Karen Higgins - September 6, 2018 - 8:30 – 9:30am EST
- **Results of DR-TB Working Group Surveys, 2017 and 2018**, presented by Robert Horsburgh, Chen-Yuen Chiang, and Arnaud Trebucq - June 7

A collection of previous webinars hosted/sponsored by RESIST-TB can be found on our website [here](#).

STATE-OF-THE-ART SERIES ON MDR-TB

In 2018, RESIST-TB finished compiling the State-of-the-Art Series on MDR-TB for the IJTLD. An editorial written by Steering Committee members, and guest editors of the IJTLD, Robert Horsburgh, Carole Mitnick and Christoph Lange will accompany the series. The series consists of the following seven articles:

1. Healthcare inequalities and the global burden of drug-resistant TB (under review),
2. Reducing MDR-TB Transmission (under review)
3. Rapid and equitable integration of innovations in DR-TB diagnosis and treatment (submitted)
4. Precision medicine for DR-TB treatment (submitted)
5. Management of DR-TB in low-resource, high burden settings (submitted)
6. Palliative care for patients with incurable DR-TB (submitted)
7. Elimination of DR-TB: what will it really take? (submitted)

Publication of a supplement in the IJTLD: Pediatric MDR-TB Clinical Trials Landscape Meeting

In order to summarize what is known about pediatric MDR-TB, to highlight current research in this area and to outline an agenda for future research, RESIST-TB and IMPAACT convened the Pediatric MDR-TB Clinical Trials Landscape Meeting on 14 June 2016. This supplement summarizes the presentations from that meeting and provides a primer of current directions in the field. Robert Horsburgh and Carole Mitnick of RESIST-TB served as guest editors of this supplement.

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PUBLIC POLICY AND AWARENESS

UNION WORLD CONFERENCE ON LUNG HEALTH

RESIST-TB continues to strive to ensure that drug-resistant tuberculosis remains a focus at scientific meetings and conferences. RESIST TB sponsored two symposia at the Union Meeting at the Hague in the Netherlands (October, 2018) entitled *Clinical Trials Capacity Building and Toward Zero Hearing Loss: Access to New TB Drugs and the Human Right to Enjoy the Benefits of Scientific Progress* with the following speakers/topics:

- *Clinical Trials Capacity Building*
 - Multidrug-resistant tuberculosis clinical trial landscape overview – Robert Horsburgh
 - Ethics and regularity – Abraham Aseffa
 - Challenges, efforts in strengthening site pharmacies and pharmacists in the STREAM Trial – Jan Komrska
 - Mycobacteriology laboratory capacity building for tuberculosis clinical trials – Gomathi N.S.
- *Toward Zero Hearing Loss: Access to New TB Drugs and the Human Right to Enjoy the Benefits of Scientific Progress*
 - Deaf or dead: where is the choice here? – Nandita Venkatesan
 - The human right to science and new treatments for drug-resistant tuberculosis – Michael Frick
 - Clinical considerations and consequences of DR-TB treatment, hearing loss and access to new drugs – Jonathan Stillo
 - Strategies for changing clinical practice – Jennifer Furin

In addition, RESIST-TB sponsors the Drug-Resistant Tuberculosis Working Group (DR-TB WG) within the IUATLD; the WG is currently chaired by Bob Horsburgh, Arnaud Trebucq and C-Y Chiang. The group met for their third Annual Meeting at the 49th Union World Conference on Lung Health held in Hague, Netherlands, 24-27 October, 2018. At the Annual meeting, the WG reviewed annual progress in diagnosis, treatment and prevention of MDR-TB; collaborated with DR-STAT to review the current progress in roll-out of new drugs and regimens for MDR-TB; and identified best practices and research gaps in MDR-TB prevention, diagnosis and treatment. In order to assess MDR-TB treatment options available in working group countries in 2017 and 2018, an internet-based survey was designed and implemented and the results were presented and discussed in a webinar in June, 2018.

Results of 2018 SURVEY of Roll-out of the 9-month regimen, Bedaquiline and Delamanid: RESIST-TB, in collaboration with the WG, created a nine-question survey using the online survey software and questionnaire, SurveyMonkey. All members of the

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IUATLD registered in the Tuberculosis Section were invited to participate. A total of 158 DR-TB working group members responded to all or part of the survey. These respondents represented 45 countries across 6 continents and included health professionals from a variety of roles. Responses were received from 62 respondents from the African Region; 6 from the Eastern Mediterranean Region; 25 from the European Region; 21 from the Region of the Americas; 32 from the South-East Asian Region; and 12 from the Western Pacific Region. These results indicate that roll-out of new drugs and regimens is variable but most regions are making substantial progress. Full results of the survey can be found on the RESIST-TB website [here](#).

RESIST-TB is in the process of submitting a manuscript based on the survey results to Public Health Action. In partnership with The IUATLD DR-TB WG, we plan to perform a repeat survey in 2019 to determine if continued progress in the roll-out of these treatments can be detected.

LEADERSHIP

The leadership of RESIST-TB remains stable. Susan van den Hof stepped down from her position on the Steering Committee in 2018. We would like to extend our sincere thanks to Dr. van den Hof for her valuable contributions to RESIST-TB and the organization's cause.

RESIST-TB GOALS FOR 2019 AND BEYOND

RESIST-TB continues its strategic plan, updated in 2017, focusing on accelerating the identification and update 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. These strategic goals are posted on the RESIST-TB website [here](#).

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 for the upcoming year include:

- Implementing and analyzing results from a second survey on the global roll-out of the 9-month regimen, bedaquiline and delamanid for MDR-TB treatment.
- Continuation of the bi-monthly webinar series. Webinar topics scheduled for the beginning of 2019 include an introduction to managing MDR-TB treatment side effects.

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- Continuing to provide up-to date information about MDR-TB clinical trials through the RESIST-TB eNewsletter and Clinical Trials Progress Report
- Completing and publishing the State-of-the-Art series on MDR-TB in *The International Journal of Tuberculosis and Lung Disease*.

RESIST-TB continues to fill 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 needed research. We also undertake important research projects that are not currently being addressed by the global TB community. Moreover, focusing on development and demonstration of efficacy of scalable regimens will facilitate rapid translation of these advances into practice. The successful continuation of these activities is recognized as critical to continued improvement in treatment and prevention of MDR-TB and XDR-TB.