

## **RePORT International Newsletter**

October 2024

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#### HIGHLIGHTING RePORT KOREA

#### Message from Jerry Ellner

In a short period (LOI signed 2022), REPORT Korea has become a regular participant in RePORT activities both in providing funding for studies in RePORT Philippines and in developing plans for integration and alignment of Korean TB research initiatives with RePORT. We look forward to closer collaboration especially in the area of biomarker discovery.

# RePORT Korea: Advancing Tuberculosis Research and Collaboration in the Global Fight Against TB

RePORT Korea is affiliated with the National Institute of Infectious Disease (NIID) of the Korean National Institute of Health (NIH), Korea Disease Control and Agency (KDCA). These agencies conduct tuberculosis (TB) research and provide funding for research project to TB researchers and institutes in Korea. In that, they are similar to the intramural and extramural programs at the US NIH.

The signing of a Letter of Intent (LOI) on April 27, 2022, between the U.S. National Institute of Allergy and Infectious Diseases and NIH-NIID paved the way for RePORT Korea to join the RePORT Consortium. This agreement focused on fostering research collaboration for developing vaccines and treatments against infectious diseases, with a particular emphasis on tuberculosis. Around the same time, KDCA launched the 3rd National Strategic plan for TB Control in Republic of Korea (2023–2027), aiming to reduce Korea's new tuberculosis incidence rate to fewer than 20 cases per 100,000 people by 2027. In step with this, the Korea NIH-NIID created a new R&D roadmap for END-TB, focused on innovations in prevention, diagnosis, and treatment technologies. RePORT Korea has made it a priority to develop new technologies and provide support to shorten the duration of tuberculosis treatment and enhance its effectiveness.

Tuberculosis remains a global threat, and we fully understand the importance of international cooperation in sharing strategies and support for TB elimination. Our participation in RePORT gives us a great opportunity to share our research achievements and work more closely together moving forward.

## **Project Descriptions**

COSMOTB (Cohort Study of Pulmonary Tuberculosis), their observational cohort study on active tuberculosis patients in Korea, is in the process of being integrated with RePORT Korea's activities. Led by Principal Investigator Dr. Jin-Soo Min from Seoul St. Mary's Hospital, the COSMOTB research network spans 20 general hospitals across Korea. Launched in 2019, COSMOTB focuses on adult active TB patients aged 19 and above, with the primary goal of identifying biological markers that can predict poor treatment outcomes. The study's timeline is as follows: 2019-2021: Enrolled 1,200 patients; 2019-2023: Continued follow-up to study predictive pathogen- and/or host-based biomarkers for treatment outcomes in drug-sensitive TB patients; 2022-2024: plans are to enroll an additional 1,000 patients to study side effects of isoniazid monoresistant treatment, risk factors for non-adherence to treatment, and the relationship between treatment modalities and side effects. To support this extensive study, they have implemented an electronic case report system (eCRF) and a comprehensive data management system. This study also engages with the RePORT International Data Harmonization Working Group to discuss data sharing and technical processes.

Since 2022, RePORT Korea also has been collaborating with the De La Salle Medical and Health Science Institute (DLSMHSI) in the Philippines on an international study called K-BOP. This study aims to identify factors that predict TB onset among close contacts of active TB patients. In K-BOP, cohorts A and B, formed by RePORT Philippines have been followed up to assess biomarker candidates for TB onset by analyzing cytokines and mRNA in the blood of 34 patients who developed active TB after close contact with a patient with TB. Additionally, they are planning to analyze the metabolites from TB patients in cohort B and compare them with biomarker candidates which have been studied in Korea. This partnership is set to continue through 2024.





**Highlights - New Projects** 

RePORT Korea is gearing up for the next five years, aligning our activities with the Korean national TB management plan and R&D strategy which is focused on reducing TB incidence and developing strategies to address the growing number of elderly TB cases, as Korea's population continues to age. In response, RePORT Korea has planned research projects to develop next-generation diagnostic technologies and treatments that will shorten the treatment duration, improve treatment adherence, and reduce side effects.

In the area of diagnostic technology, RePORT Korea will support projects aimed at

developing biomarkers to predict TB onset in high-risk groups and biomarkers to assess the effectiveness and prognosis of treatments early on. This will help reduce side effects and shorten treatment duration through personalized treatment approaches.

Additionally, the team is working on a multinational, multi-institutional study to evaluate the performance of diagnostic kits that use genetic testing methods to rapidly diagnose multidrug-resistant TB. Alongside this, clinical trials will assess the effectiveness of shortened treatment regimens for multidrug-resistant TB and study the side effects and factors hindering treatment adherence in patients with latent TB and renal disease. Additionally, RePORT Korea aims to harness extensive datasets from two key sources: Korea's national health insurance service (NHS) and the tuberculosis integrated management system (TBIS). By analyzing this big data, the organization intends to assess the effectiveness of policies promoting early TB screening, evaluate the cost-efficiency of recently implemented shortened treatment regimens, and investigate the long-term effects of TB treatment on patients. This data-driven approach will provide valuable insights to inform future TB management strategies in Korea. Through this research, they hope to provide scientific evidence for strategies to reduce the socioeconomic burden of TB, shorten treatment duration through early diagnosis, and develop a strategy to address TB in the elderly population.

RePORT Korea is close to securing funding for these research projects over the next five years, with new projects expected to kick off in 2025. They will also support joint collaborative research projects between Korean and international researchers including RePORT colleagues.

### Strengths

RePORT Korea has a solid foundation for collaboration with the 20 hospitals participating in the COSMOTB research network. And the NIH, KDCA, one of their key institutions, is a major funder for TB research in Korea, and it leads the research component of the Korea national TB management policy. The TB patient registration database (TBIS) and the National Health Insurance Service (NHS), managed by the KDCA and the Ministry of Health and Welfare, can be linked to conduct large-scale retrospective studies using big data in collaboration with both public and private researchers.

The specimens and bacterial isolates, along with clinical research data collected through RePORT Korea's projects, are periodically transported, stored and managed using the central biorepository systems managed by Korea NIH. The Human Biobank Information System (HUBIS) manages samples from TB patients (e.g., sputum, blood, urine) through stable storage facilities (high pressure and liquid nitrogen or ultimate low temperature storage).

## Challenges

Over the past decade, Korea has seen great success in reducing the incidence of TB through international collaboration on policy. However, this success has led to a sharp reduction in resources for research activities and has created limitations in forming contact cohorts. While the number of researchers in Korea has increased significantly, there is still a lack of opportunities and support for international collaborative research. The various biorepositories available to RePORT Korea were originally designed as independent systems for domestic use, so to share these resources with international researchers within the RePORT Consortium, new legal and administrative frameworks,

as well as efficient research methods, need to be developed.

#### Conclusion

Based on feedback collected at the 2023 RePORT International Annual Meeting in Goa, India, participating countries and researchers suggested key focus areas for RePORT Korea's research. The survey highlighted three main priorities: investigating subclinical tuberculosis, advancing biomarker research, and improving resource and data sharing practices. Moving forward, they will continue to share updates on RePORT Korea's research activities and push forward with projects that contribute to the shared goals of the RePORT Consortium. Korea welcomes and encourages active interest and participation of all researchers involved in the consortium.

#### **RePORT INTERNATIONAL & JOHNS HOPKINS UNIVERSITY**



#### A Foundational Member of RePORT International

Johns Hopkins University (JHU) has been a partner in RePORT International's efforts since the network's inception in 2014, having served as a foundational member of both RICC and of RePORT India, one of RICC's first and most robust country-level research efforts.

"Our team at JHU was involved in the consortium early on," said Dr. Amita Gupta, who is a RePORT International

EC Co-Chair, the US EC Chair of RePORT India, Florence Sabin Professor of Infectious Diseases, and Chief of the Division of Infectious Diseases at the Johns Hopkins University School of Medicine.

Alongside JIPMER (Puducherry, India), JHU serves as Co-Hub for the RePORT India consortium, which comprises 9 India-based research sites and 7 U.S. academic research institutions. The consortium's mission is to advance TB science, strengthen TB research, capacity, and infrastructure, and foster scientific collaboration. Leveraging 10 years of specimen and data collection, research infrastructure, and scientific partnerships established by RePORT India in Phase I, the consortium is completing the science in Phase II, and shifting to Phase 2b, where the focus is publishing scientific findings and highlighting local Indian scientists and partnering organizations.





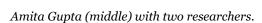
Vidya Mave (left) and Robert Bollinger (right) at the RePORT International meeting in Goa.

## **Existing Research Partnerships Afforded Early Impact**

"We have decades-long partnerships with medical research institutions in India with existing research infrastructure and clinical research personnel on the ground in Pune, expertly led by JHU India team Drs. Vidya Mave, Nishi Suryavanshi, Mandar Paradkar, and Nikhil Gupte, and in Chennai, led by Shri Vijay Bala Yogendra Shivakumar," Gupta explained. "In Phase 1, we were able to hit the ground running because we were not starting from scratch. We have an amazing cadre of world-class tuberculosis researchers at JHU with existing ties to world-class TB researchers in India. And this allowed us to start RePORT research relatively quickly, and to grow capacity, collaborate with other partners across India and at other U.S. research institutions, provide meaningful research opportunities that have launched careers among junior investigators, and foster collaborations with colleagues in Brazil and South Africa to work on multi-country efforts."

While JHU's collaborations with BJGMC, India's National Institute for TB Research, and PD Hinduja Hospital and Medical Research Center have been impactful on many fronts, the work on TB epidemiology and biomarker research has been impressive. More than 50 peer-reviewed papers have been published by the three collaborations since 2016, and JHU investigators have collaborated on others as well. Currently the JHU team is conducting eight RICC funded studies involving RePORT India data and samples that are focused on inflammasome genetics, validation of transcriptional signatures in advanced HIV, innovative modelling for predicting TB treatment outcomes, and pediatric TB biomarkers.







The PD Hinduja team.

## Research Capacity Strengthening Is Expanded Focus in Phase 2b

With Phase 2, JHU has expanded its focus with a dedicated effort on capacity strengthening for RePORT International. Dr. Robert Bollinger—Raj and Kamla Gupta Professor of Infectious Diseases at the JHU School of Medicine, former Fogarty International Research Program Director and a renowned researcher and global health educator—was tapped to serve as Director of RICC's Research Capacity Strengthening Program and Mary Talalay is the Research Capacity Strengthening Manager. "The Capacity Strengthening Program is not only critical for existing TB researchers," said Bollinger, "it's intended to expand the cadre of experts working in TB research."

The new Capacity Strengthening Working Group, led by Bollinger, is charged with developing and evaluating two courses each year for RePORT International faculty and staff and for other TB researchers around the world. In the first year, two hybrid courses, *Epidemiology for Tuberculosis* and *Professional Development for Researchers*, were offered and then later reformatted as asynchronistic offerings to allow for broader reach. Plans are currently underway for Year 2 courses. As Bollinger explained, "the more people that are trained to confront the challenges of TB, the better our odds are for identifying regionalized challenges, and developing solutions that

move us toward global change."

Additionally, a two-year, faculty mentored RICC Post-doctoral Fellowship Program has been established, and four fellows were selected: BeatrizBarreto (RePORT Brazil), Mandar Paradkar (RePORT India), Felipe Ridolfi (RePORT Brazil), and Sumedha Sharma(RePORT India, due to a recent job change, Dr. Sharma has discontinued the fellowship). Fellows have been immersed in course offerings and attended the annual RePORT International meeting in Brazil in August 2024.



Amita Gupta, Vidya Mave, and Robert Bollinger with the BJGMC team.

#### Additional JHU Tuberculosis Focus

In addition to Johns Hopkins' efforts with RePORT International, the team is working with the USAID-supported SMART4TB program and has developed and shared its ESI Training Program coursework, as well as researcher resources. The synergy between these two programs has added value for all members.

#### JHU Team:

Amita Gupta Robert Bollinger Derek Armstrong Matt Robinson Jonathan Golub Jeffrey Tornheim Sonya Krishnan Samyra Cox Mary Talalay Benji Riggan Colter Billings Molly Bowen

#### JHU India Team:

Vidya Mave Nishi Suryavanshi Nikhil Gupte Mandar Paradkar Shri Vijay Bala Yogendra Shivakumar Vandana Kulkarni Neeta Pradhan

## **RESOURCES**



The Union World Conference on Lung Health 2024

When: November 12 - 16, 2024

Location: Bali, Indonesia

Will you be attending the #UnionConf2024 this year? Sign up below and let us know!

Established in 1920, the International Union Against Tuberculosis and Lung Disease is committed to creating a healthier world for all, free of tuberculosis and lung disease. The conference brings together thousands of experts, including researchers, scientists, health professionals, doctors, nurses, and government officials to discuss tuberculosis and the challenges faced by low- and lower-middle income populations.

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#### **FUNDING OPPORTUNITIES**

## Pulmonary Outcomes and Sequelae after Treatment-TB (POST-TB)

(Ro1 Clinical Trial Optional)

This Notice of Funding Opportunity supports applications for epidemiological and observational research projects on the long-term cardiopulmonary sequelae following treatment for tuberculosis (TB). Investigators should propose additional testing and data collection in existing cohorts of adult and/or pediatric TB participants to better characterize and understand adverse outcomes and

## Global Infectious Disease Research Training Program

(D43 Clinical Trial Optional)

This Funding Opportunity Announcement (FOA) encourages joint applications for the Global Infectious Disease Research Training programs from low- and middle-income country (LMIC) and U.S. institutions. The application should propose a collaborative training program that will strengthen the capacity of a LMIC institution to conduct infectious disease research (not including

morbidity associated with TB disease post treatment in individuals with and without HIV infection.

HIV/AIDS).

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#### International Research in Infectious Diseases

(Ro1 Clinical Trial Not Allowed)

This FOA supports applications for high-priority, regionally relevant infectious diseases research by international investigators in resource-constrained countries. Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies by <a href="World Bank Classification">World Bank Classification</a>). Applicant organizations headquartered in low- and lower-middle income economy countries are particularly encouraged to apply.

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## Dissemination and Implementation Research in Health

(Ro1 & R21 Clinical Trial Optional)

These FOAs support studies that will identify, develop, and/or test strategies for overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, practices, programs, tools, treatments, guidelines, and policies. Studies that promote equitable dissemination and implementation of evidence-based interventions among underrepresented communities are encouraged.

Ro1 OPTION R<sub>21</sub> INFO

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