

RePORT INDIA

BACKGROUND

RePORT India (Regional Prospective Observational Research for Tuberculosis (TB)) is a bilateral, multi-organizational, collaborative effort established in 2013 under the Indo-US Vaccine Action Program (VAP). The consortium aims to address the threat of TB to the people of India and across the globe, a disease which also poses an increased risk for persons living with HIV or other immunocompromised conditions. RePORT India is one of the six regional consortia — China, Brazil, Indonesia, Philippines, and South Africa are also undertaking multi-organizational TB research efforts (<https://www.reportinternational.org/>). Each RePORT consortium is designed to support in-country data collection, specimen bio-repositories, and associated research with the goal of adding additional regional consortia to encourage worldwide TB treatment and prevention research.

RePORT INDIA MISSION

RePORT India is charged with:

1. Advancing regional TB science in India;
2. Strengthening TB research capacity and infrastructure; and
3. Fostering research collaboration within India and with other countries with an aim of carrying out a wide range of basic and clinical research that can lead to clinically important biomarkers, vaccines, drugs, and diagnostics.

COHORT RESEARCH UNITS (CRUs)

RePORT India consists of six distinct TB Cohort Research Units (CRUs) at seven Indian clinical sites located in Western and Southern India. Each CRU is partnered with a US-based Principal Investigator (PI) and an academic institution. CRUs consist of one or more clinical sites where participants are enrolled and where data and samples are collected for research. There are two prospective observational cohorts of participants from whom specimens are collected:

- **Cohort A:** Participants who have active pulmonary TB. Studies involving this cohort of patients focus on TB diagnosis and treatment outcomes.
- **Cohort B:** Participants who are household contacts (HHCs) of an active case of TB. Studies involving this cohort of patients focus on risk of infection and TB disease after exposure.

COMMON PROTOCOL (RePORT INDIA-WIDE OBJECTIVE)

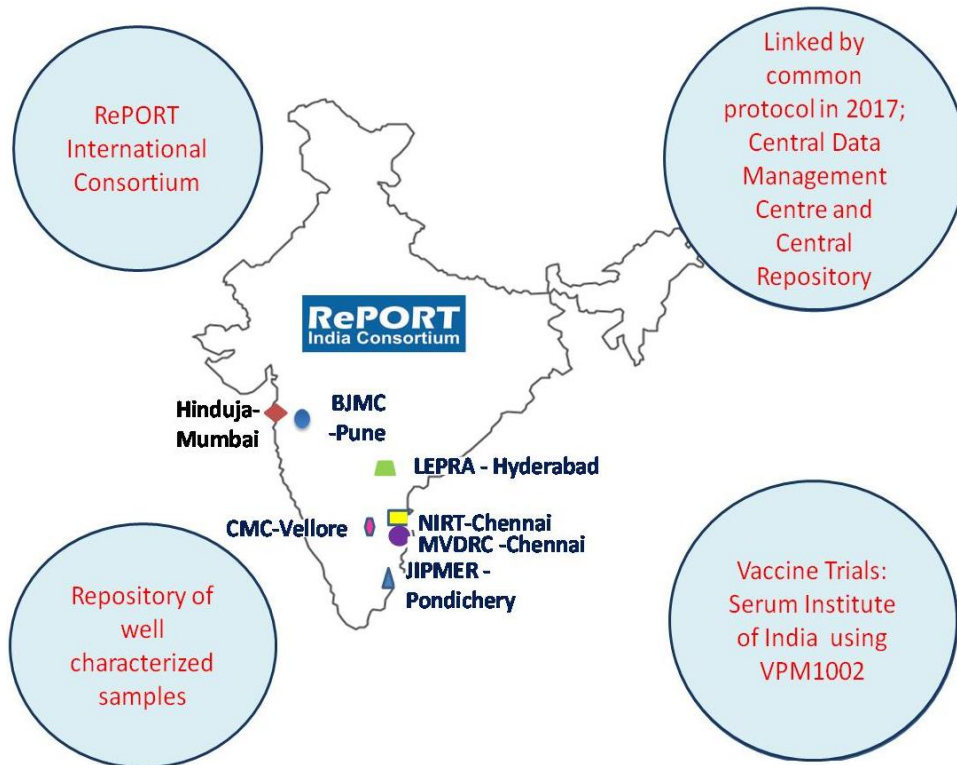
All CRUs collaborate to implement a RePORT India Common Protocol to establish an Indian bio-repository of well-characterized and standardized specimens with associated clinical data for future TB research. The Common Protocol was launched in April 2017. The central repository for specimen storage is located at the National Institute of Research in Tuberculosis (NIRT) in Chennai. A statistical and data management center is housed at the Society for Applied Studies (SAS)-Centre for Health Research and Development (CHRD) in New Delhi, and US coordination and support center is located at PPD.

The primary objective of the Common Protocol is to collect specimens and make them available to Indian biomarker researchers and collaborators over the next decade to achieve a

better understanding of: 1) the prognosis of TB disease; and 2) the pathogenesis of progression from TB exposure to disease.

PARENT PROTOCOLS (CRU – SPECIFIC OBJECTIVES)

Prior to commencing the Common Protocol, and as early as 2014, CRUs began implementing individual “Parent Protocols” with distinct research objectives. Each CRU is connected to one or more laboratories where samples are processed for storage and specified for both protocol and future testing. The CRUs house their Parent Protocol data and samples at their respective India-based institutions. Below are the CRUs and their Parent Protocols:



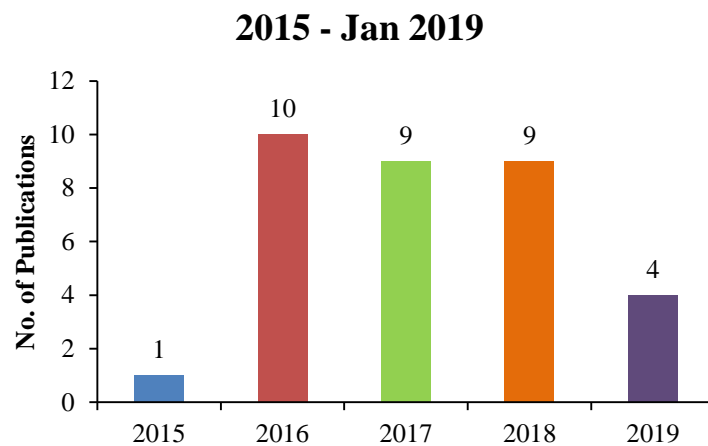
1. **Bhagawan Mahavir Medical Research Centre, Hyderabad and University of Texas, Tyler:** Immunologic Markers of Persons at Highest Risk of Progression of Latent TB Infection to TB – PI: Dr. Vijaya Valluri (BMMRC) and Dr. Krishna Vankayalapati (University of Texas)
2. **Byramjee Jeejeebhoy Government Medical College, Pune, National Institute for Research in Tuberculosis, Chennai, and John Hopkins University, Baltimore:** Host and Microbial Factors Associated with Poor Treatment Response and Progression to Active TB (C-TRIUMPH) – Drs. Vidya Mave, Shashikala Sangle, and Sanjay Gaikwad (BJGMC), Dr. Padma Chandrasekaran (NIRT), and Dr. Amita Gupta (JHU)
3. **Christain Medical College, Vellore and University of Washington/University of Cambridge:** Host Determinants in the Eicosanoid Pathway that Modulate the Inflammatory Response, Disease Outcome, and Treatment Responsiveness in TB - Dr. DJ Christopher, CMC, Vellore and Dr. Lalitha Ramakrishnan, University of Washington/University of Cambridge, UK
4. **PD Hinduja Hospital, Mumbai and John Hopkins University, Baltimore:** MDR-TB Treatment Outcomes, Adverse Effects, *Mtb* Genotyping, and Pharmacokinetic Testing -

Drs. Zarir F. Udwardia, Tester F. Ashavaid, and Camilla Rodrigues; PD Hinduja Hospital and Dr. Amita Gupta, JHU.

5. **Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, Boston Medical Center, Boston and Rutgers University, Bridgeton:** Biomarkers for Risk of TB and for TB Treatment Failure and Relapse – Drs. Subhash Parija, Gautam Roy, and Sonali Sarkar, JIPMER, Dr. Jerrold Ellner, BMC, and Dr. Padmini Salgame, Rutgers University.
6. **M. Viswanathan Diabetes Research Centre, Chennai and University of Massachusetts Medical School, Boston:** Effects of Diabetes and Prediabetes on TB Severity – Dr. Vijay Viswanathan, MVDRC and Dr. Hardy Kornfeld, UMass.

RePORT Sites Achievements:

A total of 33 articles have been published in peer-reviewed journals from the studies carried out at the RePORT India sites.



RePORT India consortium is collaborating with the Serum Institute of India Pvt. Ltd. and Vakzine Projekt Management GmbH, for a phase III trial evaluating the efficacy of a novel recombinant BCG vaccine, VPM1002, in the prevention of TB recurrence in adults treated successfully for pulmonary TB.

RePORT INDIA ADMINISTRATION

The RePORT India Consortium's primary governance body is the Executive Committee, whose mission is to:

- Set research priorities for the consortium and guide scientific activities;
- Ensure coordination of TB research; and
- Provide administrative and logistics support.

The consortium is currently chaired by Dr. D.J. Christopher (India) and Dr. Amita Gupta (US) and co-chaired by Dr. Vijaya Valluri (India) and Dr. Hardy Kornfeld (US). The Executive Committee convenes a monthly teleconference. The consortium has several active working groups including Operations, Basic Science, Clinical Epidemiology, Behavioral Science, and Data Management. The Common Protocol leadership also convenes on a monthly basis.

Consortium operations are facilitated by a RePORT India Coordinator located in Chennai, India and a US Secretariat located at Johns Hopkins University, USA.

FUNDING

The RePORT Indian Consortium is supported with funding from the Government of India's (GOI) Department of Biotechnology (DBT) as the primary GOI sponsor and the US National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS), and Office of AIDS Research (OAR). CRDF Global administers and oversees the funding from the US government. Supplemental funding through RePORT has been made available in 2016-2017 with additional awards forthcoming in 2018.