

# RePORT India

**9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING**  
**NEXT GEN RePORT**  
**MUMBAI | 10-12 FEB 2020**

**Hosted by the P.D. Hinduja Hospital and Medical Research Center**

# PARTICIPATING INSTITUTIONS

- Bhagwan Mahavir Medical Research Center (BMMRC)
- Byramjee Jeejeebhoy Government Medical College (BJGMC)
- Boston University/Boston Medical Center (BU/BMC)
- Christian Medical College, Vellore (CMC)
- Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)
- Johns Hopkins University (JHU)
- M. Viswanathan Diabetes Research Center (MVDRC)
- National Institute for Research In Tuberculosis (NIRT)
- North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS)
- P.D. Hinduja Hospital
- Postgraduate Institute of Medical Education and Research (PGI), Chandigarh
- Rutgers University
- University of Massachusetts (UMass)
- University of Texas Health Science Center at Tyler (UTT)

# COLLABORATORS

- Indian Institute of Technology Bombay, Mumbai
- Indian Institute of Science, Bangalore
- theraCUES, Bangalore
- Emory University
- National Institute for Research in Tuberculosis–International Centers for Excellence in Research (NIRT–ICER)
- MedGenome
- Translational Health Science and Technology Institute (THSTI)
- University of California—San Francisco (UCSF)

# SUPPORTING ORGANIZATIONS

- CRDF Global
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Contents prepared February 2020

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# Overview

## RePORT India

9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING

NEXT GEN RePORT

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RePORT India 2019 Joint Leadership Meeting. Chennai, India

## BACKGROUND

RePORT India (Regional Prospective Observational Research for Tuberculosis (TB)) is a bilateral, multi-organizational, collaborative research effort established in 2013 under the Indo-US Vaccine Action Program (VAP). RePORT India is now the largest of six regional consortia—China, Brazil, Indonesia, Philippines, and South Africa are also undertaking multi-organizational TB research efforts. Each RePORT consortium is designed to support local, in-country, TB-specific data and specimen biorepositories and associated research. Taken together, the anticipated results include greater global clinical research capacity in high-burden settings and increased local access to quality data and specimens for members of each consortia and their domestic and international collaborators.

## MISSION

RePORT India is charged with:

1. Advancing regional TB science in India, towards fulfilling the TB strategic goals of the country;
2. Strengthening TB research capacity and infrastructure; and
3. Fostering research collaboration within India and with other countries focused on research that can lead to clinically important biomarkers, vaccines, drugs, and diagnostics.

## PHASE I

Phase I (2013–18) commenced with six Clinical Research Sites (CRSs) in Western and Southern India that were partnered with five U.S. academic institutions. P.D. Hinduja Hospital and Medical Research Centre was subsequently added as the seventh Indian site. Initially, each site had its own “Parent Protocol” with distinct research topics. In 2017, RePORT India launched the “Common Protocol” with standardized data elements and harmonized procedures for enrollment. Under the Parent and Common Protocols, CRSs established prospective observational cohorts of participants from whom specimens were collected:

- **Cohort A:** Participants who have active TB disease. 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 risk and progression to TB disease after exposure.

## PARENT PROTOCOLS (CRS-SPECIFIC OBJECTIVES)

Each CRS is connected to one or more laboratories where samples are processed for storage and specified for both protocol and future testing. The CRSs house their Parent Protocol data and samples at their respective India-based institutions. Below are the CRSs and their Parent Protocols:

### 1. BMMRC and U of Texas, Tyler

- **Topic of Study:** Immunologic Markers of Persons at Highest Risk of Progression of Latent TB Infection to TB
- **India PI:** Dr. Vijaya Valluri, Bhagawan Mahavir Medical Research Centre (BMMRC), Hyderabad, India
- **U.S. PI:** Dr. Krishna Vankyalapati, University of Texas Health Science Center, Tyler, TX, USA
- **Participating Patient Cohort:** Cohort B

### 2. BJGMC, NIRT, and JHU

- **Topic of Study:** Host and Microbial Factors Associated with Poor Treatment Response and Progression to Active TB (C-TRIUMPH)
- **India PIs:** Drs. Sanjay Gaikwad, Aarti Kinikar and Shashikala Sangle, Byramjee Jeejeebhoy Government Medical College (BJGMC), Pune, India; Dr. Vidya Mave, JHU-BJGMC Clinical Research Site; Drs. Padma Chandrasekaran and Bhavani PK, National Institute for Research in TB (NIRT), Chennai, India
- **U.S. PI:** Dr. Amita Gupta, Johns Hopkins University, Baltimore, MD, USA
- **Participating Patient Cohorts:** Cohort A (Adult Pulmonary TB, Pediatric TB, and Extrapulmonary TB) and Cohort B

### 3. CMC Vellore and U of Wash/U of Cambridge

- **Topic of Study:** Host Determinants in the Eicosanoid Pathway that Modulate the Inflammatory Response, Disease Outcome, and Treatment Responsiveness in TB
- **India PI:** Dr. DJ Christopher, Christian Medical College (CMC), Vellore, India
- **U.S. PI:** Dr. Lalitha Ramakrishnan, University of Washington/University of Cambridge, UK
- **Participating Patient Cohort:** Cohort A (Adult Pulmonary TB and TB Meningitis)

### 4. Hinduja and JHU

- **Topic of Study:** MDR-TB Treatment Outcomes, Adverse Effects, Mtb Genotyping, and Pharmacokinetic Testing
- **India PIs:** Drs. Zarir F. Udawadia, Tester F. Ashavaid, and Camilla Rodrigues; PD Hinduja Hospital, Mumbai, India
- **U.S. PIs:** Drs. Amita Gupta and Jeffrey Tornheim, Johns Hopkins University, Baltimore, MD, USA
- **Participating Patient Cohorts:** Cohort A (Adult/Adolescent MDR-TB) and Cohort B

### 5. JIPMER, BU/BMC, and Rutgers

- **Topic of Study:** Biomarkers for Risk of TB and for TB Treatment Failure and Relapse
- **India PIs:** Drs. Gautam Roy and Sonali Sarkar, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India
- **U.S. PIs:** Drs. Jerrold Ellner and Padmini Salgame, Rutgers University, Newark, NJ, USA; Dr. Robert Horsburgh, Boston University, Boston, MA, USA; Dr. Natasha Hochberg, Boston Medical College, Boston, MA, USA
- **Participating Patient Cohorts:** Cohort A (Adult Pulmonary TB and Pediatric TB) and Cohort B

### 6. MVDRC, NIRT-ICER and UMass

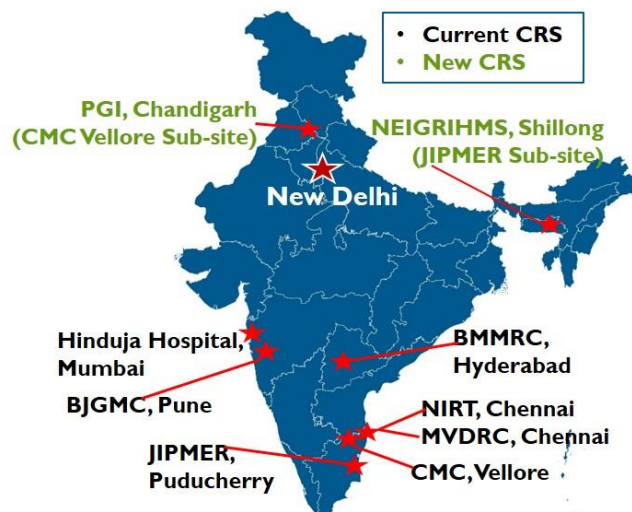
- **Topic of Study:** Effects of Diabetes and Prediabetes on TB Severity
- **India PIs:** Dr. Vijay Viswanathan, MV Diabetes Research Centre (MVDRC), Chennai, India; Dr. Subash Babu, NIRT-ICER, Chennai, India
- **U.S. PI:** Dr. Hardy Kornfeld, University of Massachusetts Medical School, Boston, USA
- **Participating Patient Cohort:** Cohort A (Adult Pulmonary TB)

## COMMON PROTOCOL (REPORT INDIA-WIDE OBJECTIVE)

The primary objective of the Common Protocol is to provide data and specimens to Indian biomarker researchers and collaborators to better understand: (1) prognosis of TB disease; and (2) pathogenesis of progression from TB exposure to disease. A RePORT India central biorepository was established at the National Institute of Research in Tuberculosis (NIRT) in Chennai. In addition, a statistical/data management center was established at the Society for Applied Studies (SAS)-Centre for Health Research and Development (CHRD) in New Delhi, and Pharmaceutical Product Development, LLC (PPD) was contracted to provide Common Protocol technical support.

## REPORT INDIA PHASE 2

Leveraging the data, specimens, infrastructure, and scientific partnerships established by RePORT India in Phase 1, the consortium is now launching Phase 2. We will pursue five specific scientific aims under a Phase 2 Common Protocol including the following cohorts: Diagnostic (New TB suspects), Cohort A (Active TB disease), and, Cohort B (HHCs). The consortium has now been expanded to include two new CRSs in Northern India:





## North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS)

- **Location:** Shillong, India
- **PI:** Dr. Himashree Bhattacharyya
- **Linked to:** JIPMER

## Postgraduate Institute of Medical Education and Research (PGI)

- **Location:** Chandigarh, India
- **PI:** Dr. Ashutosh Aggarwal
- **Linked to:** CMC Vellore

## SUBSTUDIES

The complete list of RePORT-related grants and sub studies begins on page 105.

## ADMINISTRATION

RePORT India has established a collaborative governance structure composed of: 1) an Executive Committee led by two Chairs and two Co-chairs from India and the U.S.; 2) an Indo-U.S. Coordinating Hub; 3) three Scientific Working Groups (Basic Science, Clinical Epidemiology, Behavioral Science); and 4) four Operational Working Groups (Common Protocol Leadership, Site Operations, Laboratory Management, and Data Management). The EC's mission is to set research priorities, guide scientific activities, and offer administration and logistics in support of research priorities.

The consortium is currently led by:

- Chairs: Sonali Sarkar (JIPMER, Clinical Epi) and Amita Gupta (JHU, Clinical Epi)
- Co-Chairs: Vijaya Valluri (BMMRC, Basic Science) and Padmini Salgame (Rutgers, Basic Science)

## FUNDING

The RePORT Indian Consortium is supported with bilateral funding from the Government of India's (GOI) Department of Biotechnology (DBT) and the U.S. National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS), and Office of AIDS Research (OAR). The initiative is also supported by the Indian Council of Medical Research (ICMR) from the Indian side. CRDF Global administers and oversees the funding from the U.S. government.

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## RePORT PHASE 2 STRATEGIC ADVISORY COMMITTEE

### ANURAG BHARGAVA, MD, MSc

Anurag Bhargava is Professor of Medicine at Yenepoya Medical College, Mangalore and Adjunct Professor in the Department of Medicine at McGill University. He is a member of the National Technical Working Group on TB and Comorbidities, and a member of WHO's Strategic Advisory Group of Experts on In-Vitro Diagnostics (SAGE-IVD) 2019-20. Currently, he is Principal Investigator of the RATIONS study, a large cluster-randomized, controlled trial of nutritional support in TB affected households in central Indian state of Jharkhand.



Dr. Bhargava has 29 years of clinical experience working at all levels of healthcare in India. His research interests include tuberculosis, nutrition, and acute febrile illnesses. He has documented the nutritional status in a large cohort of rural patients with TB, and its impact on mortality, he has estimated the proportion of TB incidence in India attributable to adult undernutrition, and he has reanalyzed the socio-medical experiment in TB control at the Papworth village settlement (1918-43). Dr. Bhargava led the development of the *Guidance Document on Nutritional Care and Support for Patients with TB in India*.

## APURVA SARIN, PhD

Professor Apurva Sarin is Director and Dean of Faculty at Institute for Stem Cell Science & Regenerative Medicine (inStem). Her laboratory at NCBS explored the cross-talk between cell death and survival signaling during cell-fate decisions in cells of the mammalian immune system, and her laboratory focuses on metabolite regulation underlying cell fate decisions.



She received her master's degree in zoology from the University of Delhi and her PhD from Jawaharlal Nehru University, New Delhi, India. She began her independent career—following postdoctoral training at the Exptl. Immunol. Branch, National Cancer Institute, NIH, USA—in 1989 at the National Centre for Biological Sciences (NCBS), Bangalore India. In 2005, she was awarded the National Bioscience Award for Career Development for her contributions to biosciences. Presented by the Department of Biotechnology, Government of India, this award is one of the most prestigious Indian science awards. Her research has attracted funding from the Wellcome Trust UK (Senior Research Fellowship 2012-2017); the Department of Science & Technology (Swarnajayanti Fellowship in Biology, 2013-2018); Department of Biotechnology, Centre of Excellence Award (2016-2021) amongst other grants. She is a Fellow of the Indian Science Academy, Bangalore and represents India on the Board of Trustees, Human Frontiers Science Program.

## ROBERT MODLIN, MD

Robert Modlin is the Klein Professor of Dermatology, Professor of Microbiology, Immunology, and Molecular Genetics at UCLA. He is also Chief of the Division of Dermatology and Vice Chair for cutaneous medicine and dermatologic research in the Department of Medicine.



Dr. Modlin's interest in leprosy began during his dermatology residency at the Los Angeles County/ University of Southern California Medical Center. The research in the Modlin lab is centered on the study of leprosy and tuberculosis as models to learn about mechanisms of host defense in humans. As such, Dr. Modlin's laboratory has made fundamental insights into T cell subsets, cytokine patterns, antigen presentation, innate immunity and antimicrobial mechanisms in the human immune response to infection. Key discoveries include the role of Th1/Th2 cytokines in disease outcomes in humans, identification of structurally defined nonpeptide antigens presented by CD1 to T cells, identification of granulysin as mediating CD8+ T cell antimicrobial activity, identification of the first ligands for Toll-like receptor 2, and elucidating the role for vitamin D in human antimicrobial responses.

Dr. Modlin has published more than 200 articles, including 14 papers in *Science* and *Nature*, and 6 in *Nature Medicine*. He completed his undergraduate studies at Johns Hopkins University, received his medical degree at the New York University School of Medicine, was a pediatrics intern at NYU, and a dermatology resident at Los Angeles County/University of Southern California School of Medicine.

## **SUSAN SWINDELLS, MBBS, MD**

Susan Swindells is Professor of Internal Medicine in the Section of Infectious Diseases at the University of Nebraska Medical Center, USA. A native of England, Dr. Swindells earned her medical degree from University College London in 1977, with postgraduate training in England and at the University of Washington in Seattle.



She has been involved in HIV care since 1984. A clinician and active researcher, Dr. Swindells has many years of experience in translational and clinical research in the field of HIV/AIDS, with a special interest in tuberculosis co-infection. Dr. Swindells is on the leadership of the AIDS Clinical Trials Group of the National Institutes of Health, and is a member of the U.S. Department of Health & Human Services Panel on Antiretroviral Guidelines.





RePORT India 2018 Joint Leadership Meeting. Delhi, India

# Data Tables

## RePORT India

9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING

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**PARENT PROTOCOLS: STATUS REPORT | COHORTS A & B**  
**TABLE I: SAMPLE SIZE TARGETS & ENROLLMENTS | YEARS 2014–2018**

COHORT A				COHORT B		
n (%)				n (%)		
	Site	Target SS	Enrolled	Target SS	Enrolled	Among Enrolled, <15 years
BJGMC*	PTB	300	261 (87%)	700	499 (71%)	165 (33%)
	Ped	100	142 (142%)			
	EPTB	100	108 (108%)			
NIRT*	PTB	300	252 (84%)	700	553 (79%)	121 (22%)
	Ped	100	59 (59%)			
	EPTB	100	84 (84%)			
CMC	PTB	200	142 (71%)	No Cohort B		
	TBM	200	269 (135%)			
JIPMER	PTB†	1100	1241 (113%)	1500	1603 (107%)	315 (20%)
MVDRC	PTB	450	446 (99%)	No Cohort B		
BMRC	No Cohort A			1500	990 (66%)	70 (7%)
HINDUJA	MDR‡	200	97 (49%)	60	16 (27%)	4 (25%)
<b>TOTAL</b>		<b>3150</b>	<b>3101 (98%)</b>	<b>4460</b>	<b>3661 (82%)</b>	<b>675 (18%)</b>

Source: Parent Protocol data was provided by individual sites and aggregated by the RePORT India Coordinating Hub. SS=Sample Size; PTB=Pulmonary TB; TBM=TB Meningitis; EPTB=Extrapulmonary TB; Ped=Pediatric TB (<15 years); MDR=Multidrug-resistant TB

\* BJGMC and NIRT jointly implemented a parent protocol. Together, BJGMC and NIRT enrolled 86% of the PTB target, 101% of the Ped target, and 96% of the EPTB target for Cohort A.

† Of 1241 PTB participants at JIPMER, 4 (0.3%) were <15 years old.

‡ Hinduja protocol launched in Oct 2017; enrolls PTB and EPTB patients with MDR-TB>15 years old. Of 97 MDR-TB enrolled, 61 PTB and 36 EPTB.



**PARENT PROTOCOLS: STATUS REPORT | COHORTS A & B**  
**TABLE 2: OUTCOMES | YEARS 2014–2018**

\* For proportion of participants who failed treatment, denominator is total number of participants who completed treatment (see Table 4B).  
 † For proportion of participants who died, denominator is total number of participants enrolled (see Table 1).  
 ‡ Hinduja protocol launched in Oct 2017; enrolls PTB and EPTB patients with MDR-TB>15 years old. Of 97 MDR-TB enrolled, 61 PTB and 36 EPTB.  
 § Reported as prevalent TB infection.  
**Tx Failure:** TB patients enrolled in the parent protocol and declared failure while on treatment between month five and end of treatment.  
**Tx Recurrence:** Patients diagnosed as TB after being declared as cured or treatment complete.  
**Incident LTBI:** LTBI negative at baseline by either TST or IGRA and became positive by either TST or IGRA at follow-up visits among HHCs

COHORT A   N = 3101										COHORT B   N = 3661					
Site	TX Failure*			TB Recurrence*			All Cause Death†	Prevalent TB			Incident TB			All Cause Death	
	Bacteriological	Clinical	Bacteriological	Bacteriological	Clinical	Clinical		Bacteriological	Clinical	Bacteriological	Clinical	Bacteriological	Clinical		Incident LTBI
BjGMC	PTB	17 (9%)	5 (3%)	8 (4%)	7 (4%)	24 (9%)	6 (1%)	16 (3%)	4 (1%)	11 (2%)	61 (12%)	2 (0.4%)			
	Ped	2 (2%)	2 (2%)	1 (1%)	5 (4%)	2 (1%)									
	EPTB	0 (0%)	2 (2%)	1 (1%)	5 (6%)	5 (5%)									
NIRT	PTB	23 (12%)	4 (2%)	8 (4%)	3 (2%)	15 (6%)	22 (4%)	1 (0.2%)	7 (1%)	1 (0.2%)	161 (29%)	4 (1%)			
	Ped	0 (0%)	0 (0%)	1 (2%)	0 (0%)	1 (2%)									
	EPTB	0 (0%)	0 (0%)	1 (1%)	1 (1%)	4 (5%)									
CMC	PTB	3 (4%)	2 (3%)	3 (4%)	1 (1%)	6 (4%)	<b>No Cohort B</b>								
	TBM	0 (0%)	0 (0%)	0 (0%)	0 (0%)	55 (20%)	<b>No Cohort B</b>								
JIPMER	PTB	0 (0%)	11 (1%)	3 (0.4%)	13 (2%)	42 (3%)	7 (0.4%)	0 (0%)	3 (0.2%)	0 (0%)	0 (0%)	2 (0.1%)			
	PTB	24 (8%)	—	15 (5%)	—	16 (4%)	<b>No Cohort B</b>								
BMRC	<b>No Cohort A</b>						<b>No Cohort B</b>								
	MDR‡	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (7%)	13§ (1%)	0 (0%)	21 (2%)	0 (0%)	102 (10%)	0 (0%)			
HINDUJA	MDR‡	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)			
	PTB	67 (4%)	22 (1%)	37 (2%)	24 (2%)	110 (5%)	48 (1%)	17 (0.5%)	35 (1%)	12 (0.3%)	324 (9%)	8 (0.2%)			
	PED	2 (1%)	2 (1%)	2 (1%)	4 (3%)	3 (1%)									
	EPTB/TBM	0 (0%)	2 (1%)	2 (1%)	6 (2%)	64 (13%)									
TOTAL	<b>No Cohort A</b>						<b>No Cohort B</b>								

TB=Pulmonary TB; TBM=TB Meningitis; Tx=Treatment; LTBI=Latent TB Infection; EPTB=Extrapulmonary TB; Ped=Pediatric; MDR=Multidrug-resistant TB; HHC=Household Contacts



**PARENT PROTOCOLS | COHORT A | PATIENT ENROLLMENT, DEMOGRAPHICS & FOLLOW-UP | YEARS 2014-2019**

**TABLE 3A: PERCENTAGE OF SUBJECTS ENROLLED AMONG THOSE SCREENED**

<b>COHORT A</b>						
	<b>Site</b>	<b>Total Approached or Screened, n</b>	<b>Subjects Enrolled, n (%)</b>	<b>BL Smear Positive, n (%)</b>	<b>BL Xpert Positive, n (%)</b>	<b>BL Culture Positive, n (%)</b>
<b>BJGMC</b>	PTB*	969	261 (27%)	150 (57%)	195 (76%)	205 (79%)
	Ped	178	142 (80%)	19 (14%)	27 (20%)	31 (23%)
	EPTB	127	108 (85%)	4 (4%)	14 (13%)	16 (15%)
<b>NIRT</b>	PTB*	756	252 (33%)	215 (85%)	169 (68%) <sup>†</sup>	232 (92%)
	Ped	85	59 (69%)	4 (7%)	7 (12%)	12 (20%)
	EPTB	130	84 (65%)	7 (8%)	7 (8%)	16 (19%)
<b>CMC</b>	PTB	150	142 (95%)	123 (87%)	140 (99%)	138 (97%)
	TBM	302	269 (89%)	CSF – 3 (1%)	CSF – 34 (13%)	CSF – 59 (22%)
<b>JIPMER</b>	PTB	1622	1241 (92%)	1110 (89%)	NA	1179 (95%)
<b>MVDRC</b>	PTB	569	446 (79%)	385 (87%)	NA	403 (90%)
<b>HINDUJA</b>	MDR	176	97 (55%)	45 (46%)	75 (77%)	91 (94%)
<b>TOTAL</b>		<b>5064</b>	<b>3101 (61%)</b>	<b>1860 (68%)</b>	<b>574 (21%)</b>	<b>2018 (74%)</b>

BL=Baseline; ATT=Anti-TB Treatment; PTB=Pulmonary TB; TBM=TB Meningitis; Ped=Pediatric; EPTB=Extrapulmonary TB; CSF=Cerebrospinal Fluid; MDR =Multidrug-resistant TB

\*Approached or screened any patient who was started on ATT in the study area including new and re-treatment cases for adult PTB, EPTB and Pediatric TB. Smear negative TB patients and clinically diagnosed TB patients were included.

<sup>†</sup> Xpert not performed for all participants.

**PARENT PROTOCOLS | COHORT A | PATIENT ENROLLMENT, DEMOGRAPHICS & FOLLOW-UP | YEARS 2014-2019**

**TABLE 3B: DEMOGRAPHICS AMONG THOSE ENROLLED**

COHORT A   CHARACTERISTICS, n (%)								
Site	Age, median (min-max)	Male n (%)	HIV Positive n (%)	Current Smoker* n (%)	Current Drinker* n (%)	Diabetes*† n (%)	Low BMI‡ (<18.5) n (%)	
BJGMC	PTB n=261	30 (15-70)	150 (57%)	32 (12%)	23 (10%)	78 (34%)	29 (11%)	149 (57%)
	Ped n=142	9 (1-14)	64 (45%)	9 (6%)	NA	NA	NA	134 (94%)
	EPTB n=108	30 (15-62)	55 (51%)	19 (18%)	4 (4%)	24 (24%)	5 (5%)	43 (39%)
NIRT	PTB n=252	44 (15-75)	170 (68%)	2 (1%)	38 (15%)	127 (51%)	115 (46%)	150 (60%)
	Ped n=59	10 (2-14)	34 (58%)	0	NA	NA	NA	42 (71%)
	EPTB n=84	29 (15-63)	37 (44%)	4 (5%)	3 (4%)	16 (19%)	8 (10%)	30 (36%)
CMC	PTB n=142	44 (18-79)	97 (68%)	Excluded	25 (18%)	43 (30%)	44 (31%)	73 (51%)
	TBM n=269	36 (18-78)	162 (60%)	38 (14%)	25 (9%)	21 (8%)	44 (18%)	55 (20%)
JIPMER	PTB n=1241	48 (13-82)	956 (77%)	7 (<0.1%)	295 (23%)	717 (57%)	309 (24%)	88 (7%)
MVDRC	PTB n=446	45 (25-73)	355 (80%)	Excluded	117 (26%)	189 (42%)	284 (64%)	217 (49%)
HINDUJA	MDR n=97	26 (15-77)	31 (32%)	1 (1%)	7 (7%)	9 (9%)	16 (16%)	32 (33%)
<b>TOTAL</b>	—	<b>2133 (69%)</b>	<b>112 (4%)</b>	<b>537 (17%)</b>	<b>1224 (39%)</b>	<b>858 (28%)</b>	<b>1013 (33%)</b>	

PTB=Pulmonary TB; TBM=TB Meningitis; Ped=Pediatric; MDR-TB=Multidrug-resistant TB; EPTB=Extrapulmonary TB; CSF=Cerebrospinal Fluid

\* Smoking, drinking, diabetes only assessed among patients 15 years old and above.

† Diabetes defined as self-reported DM or >200 RBS or HbA1c > 6.5% among adults 18 years old and above.

‡ BMI is approximate for TBM cohort.

**PARENT PROTOCOLS | COHORT A | PATIENT ENROLLMENT, DEMOGRAPHICS & FOLLOW-UP | YEARS 2014-2019**

**TABLE 4A: NUMBER OF STUDY PARTICIPANTS ON FOLLOW-UP AMONG THOSE ENROLLED**

<b>COHORT A</b>			
	<b>Site</b>	<b>Total Enrolled, n</b>	<b>On active follow up, n (%)</b>
<b>BJGMC</b>	PTB	261	0 (0%)
	Ped	142	4 (3%)
	EPTB	108	0 (0%)
<b>NIRT</b>	PTB	252	0 (0%)
	Ped	59	10 (17%)
	EPTB	88	7 (8%)
<b>CMC</b>	PTB	142	29 (20%)
	TBM	269	62 (23%)
<b>JIPMER</b>	PTB	1241	0 (0%)
<b>MVDRC</b>	PTB	446	2 (<1%)
<b>HINDUJA</b>	MDR	97	84 (87%)
<b>TOTAL</b>		<b>3101</b>	<b>197 (6%)</b>

PTB=Pulmonary TB; Ped=Pediatric; TBM=TB Meningitis; EPTB=Extrapulmonary TB; MDR =Multidrug-resistant TB

**TABLE 4B: OUTCOMES AMONG THOSE WHO HAVE COMPLETED TREATMENT**

COHORT A						
Site	Treatment Complete/ Cured, n	Unfavorable Outcomes, n (%)				
		Tx Failure*	Tx Recurrence*	All-cause Mortality†	Lost to Follow-up‡	
BJGMC	PTB	188 (72%)	22 (12%)	15 (8%)	24 (9%)	36 (14%)
	Ped	125 (88%)	4 (3%)	6 (5%)	2 (1%)	13 (9%)
	EPTB	88 (81%)	0	6 (7%)	5 (5%)	20 (19%)
NIRT	PTB	198 (79%)	27 (14%)	11 (6%)	15 (6%)	20 (8%)
	Ped	56 (95%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)
	EPTB	78 (93%)	4 (5%)	2 (3%)	4 (5%)	6 (7%)
CMC	PTB	71 (50%)	5 (7%)	4 (6%)	6 (4%)	15 (11%)
	TBM	101 (38%)	0	0	55 (20%)	29 (11%)
JIPMER	PTB	824 (66%)	11 (1%)	16 (2%)	42 (3%)	147 (12%)
MVDRC	PTB	307(69%)	24 (8%)	15 (5%)	16 (4%)	72(16%)
HINDUJA	MDR	5 (5%)	0	0	7 (7%)	3 (3%)
<b>TOTAL</b>		<b>2041 (66%)</b>	<b>95 (5%)</b>	<b>76 (4%)</b>	<b>177 (4%)</b>	<b>365 (12%)</b>

PTB=Pulmonary TB; Ped=Pediatric; TBM=TB Meningitis; EPTB=Extrapulmonary TB; MDR=Multi-drug resistant TB; Tx=Treatment

\* For proportion of participants who failed treatment, denominator is total number of participants who completed treatment

† For proportion of participants who died, denominator is total number of participants enrolled (see page 11).

‡ At end of follow-up period only.

**TABLE 5: NUMBER OF HOUSEHOLD CONTACTS (HHC) ENROLLED AMONG THOSE REPORTED BY INDEX CASES**

COHORT B		
Site	HHCs Reported by Index Case, N	Enrolled, N (%)
<b>BJGMC</b>	658	499 (76%)
<b>NIRT</b>	730	553 (76%)
<b>JIPMER</b>	1750	1603 (92%)
<b>BMMRC</b>	1292	990 (77%)
<b>HINDUJA</b>	21	16 (76%)
<b>TOTAL</b>	<b>4451</b>	<b>3659 (82%)</b>

**TABLE 6: BASELINE DEMOGRAPHICS AMONG THOSE ENROLLED**

COHORT B   CHARACTERISTICS, n (%)							
Site	Age, median (min-max)	Male	LTBI Positive*	Current Smoker	Current Drinker	Diabetes†	Low BMI (<18.5)
<b>BJGMC</b>	25 (1-71)	216 (43%)	319 (64%)	27 (5%)	58 (12%)	21 (4%)	198 (40%)
<b>NIRT</b>	26 (1-70)	254 (46%)	416 (75%)	36 (7%)	79 (14%)	81 (15%)	191 (35%)
<b>JIPMER</b>	48 (5-90)	626 (39%)	438 (27%)	85 (5%)	161 (10%)	81 (6%)	258 (16%)
<b>BMMRC</b>	28 (6-73)	497 (50%)	505 (51%)	75 (8%)	120 (12%)	Excluded	159 (16%)
<b>HINDUJA</b>	33 (4-59%)	5 (32%)	8 (50%)	2 (13%)	2 (13%)	1 (6%)	5 (31%)
<b>TOTAL</b>	<b>32 (1-90)</b>	<b>1598 (44%)</b>	<b>1686 (46%)</b>	<b>225/2984 (8%)</b>	<b>420 (14%)</b>	<b>184 (6%)</b>	<b>811 (22%)</b>

LTBI=Latent TB Infection; BMI=Body Mass Index

\*LTBI Positive by TST or IGRA. BJGMC, NIRT, and Hinduja used both IGRA and TST. JIPMER used TST only. BMMRC used in-house ELISPOT.

† Diabetes defined as self-reported DM or > 200 random blood sugar or HbA1c ≥ 6.5% among adults 18 years old and above

**TABLE 7A: NUMBER OF STUDY PARTICIPANTS ON FOLLOW-UP AMONG THOSE ENROLLED**

<b>COHORT B</b>				
<b>Site</b>	<b>Enrolled, n</b>	<b>On Follow Up, n (%)</b>	<b>Completed Follow Up, n (%)</b>	<b>Lost to Follow Up, n (%)</b>
<b>BJGMC</b>	499	0	347 (70%)	98* (20%)
<b>NIRT</b>	553	0	496 (90%)	44 (8%)
<b>JIPMER</b>	1603	0	1577 (98%)	24 (1%)
<b>BMMRC</b>	990	15 (2%)	825 (83%)	150 (15%)
<b>HINDUJA</b>	16	16 (100%)	0 (0%)	0 (0%)
<b>TOTAL</b>	<b>3661</b>	<b>31 (1%)</b>	<b>3245 (89%)</b>	<b>316 (9%)</b>

**TABLE 7B: OUTCOMES AMONG HOUSEHOLD CONTACTS**

<b>COHORT B</b>					
<b>Site</b>	<b>Completed follow up, n (%)</b>	<b>Unfavorable Outcomes</b>			
		<b>Lost to Follow Up* n (%)</b>	<b>Incident TB†</b>	<b>Prevalent TB‡</b>	<b>TB Deaths</b>
<b>BJGMC</b>	347 (70%)	98* (20%)	15 (3%)	22 (4%)	2 (0.4%)
<b>NIRT</b>	496 (90%)	44 (8%)	8 (1%)	23 (4%)	4 (1%)
<b>JIPMER</b>	1577 (98%)	24 (1%)	3 (0.2%)	7 (0.4%)	2 (0.1%)
<b>BMMRC</b>	825 (83%)	150 (15%)	21 (2%)	13 (1%)	0
<b>HINDUJA</b>	0	0	0	0	0
<b>TOTAL</b>	<b>3245 (89%)</b>	<b>316 (9%)</b>	<b>47 (1%)</b>	<b>65 (2%)</b>	<b>8 (0.02%)</b>

\* Only includes patients who have completed their follow up study period per the site's definition.

† Not Prevalent TB and diagnosed with TB either bacteriologically or clinically, four or more weeks from the time of enrolment.

‡ Diagnosed as TB at site bacteriologically or clinically, at the time of screening or within 4 weeks since the time of enrollment.

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PULMONARY TB  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

PTB Enrolled, n		BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total
		261	248	142	1247	446	61	2405

Specimen \ N	Baseline (≤14 days)										2 Weeks			1 Month			2 Months												
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total								
	Plasma	261	225	138	1025	336	24	2009		225	213			24	462	217	210	8			307	27	769						
Serum													57	57								55	55						
Plasma for PK									220	228			57	505								55	55						
PAXgene	215	238	28	1222	265	61	2029		221	227			57	505	213	218	8	961	307	55	55	1762							
PBMCs	175	212	13		270		670		201	225				426	202	216	3		245			666							
DNA			131			61	192	6						6			8				55	63							
QGIT	156	69					225		140	57				197	132	46						178							
Mtb Isolate (LJ/7H9/TE)	181	220	92	809	404	52	1758	85	194				279	35	130						15	180	21	52	84				
Urine	261	229	127			59	676		225	226			57	508	223	217	1					24	465						
Hair	259	51					310		41	31				72		7							7						
Sputum	183	229	117			52	581	122	228			30	380	124	224						23	371	126	220	18	364			
Sputum Deposit	128						128	94					94	89									89	90					
TOTALS	1819	1473	646	3056	1275	309	8578	307	422			30	759	1521	1561						290	3372	1224	1186	28	961	859	300	4558

Specimen \ N	5 Months										6 Months			9 Months			12 Months											
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total							
	Plasma								198	26	3		224	26	477								169	194				25
Serum													44	44													29	29
Plasma for PK	194	213					407																			29	29	
PAXgene		1					1	198	26	3		224	44	495								167	202			29	398	
PBMCs								185	26			200		411								168	208			29	376	
DNA	192	205					397	2	3			40	45												29	29		
QGIT								85	2				87									34					34	
Mtb Isolate (LJ/7H9/TE)	1	22			2	25	6	3					2	11							2			1			1	
Urine								199	19				44	262								169	204			29	402	
Hair	17	37					54	28					28									1					1	
Sputum	105	213			1	319	106	32					2	140								11	2				13	
Sputum Deposit	80						80	77						77								2					2	
TOTALS	589	691			3	1283	1082	136	9			648	202	2077							2	721	811			170	1702	





**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PULMONARY TB  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF  
VISIT | CONTINUED**

Specimen \ N	Unscheduled							TOTAL						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total
<b>Plasma</b>	47					1	<b>48</b>	1320	1226	158	1101	1117	146	<b>5068</b>
<b>Serum</b>						1	<b>1</b>						186	<b>186</b>
<b>Plasma for PK</b>	2					1	<b>3</b>	416	441				142	<b>999</b>
<b>PAXgene</b>	48					1	<b>49</b>	1261	1278	39	2260	1046	266	<b>6150</b>
<b>PBMCs</b>	47						<b>47</b>	1164	1244	16		907		<b>3331</b>
<b>DNA</b>						1	<b>1</b>	198	211	240			187	<b>836</b>
<b>QGIT</b>	7						<b>7</b>	564	177					<b>741</b>
<b>Mtb Isolate (LJ/7H9/TE)</b>	3	21					<b>24</b>	344	668	98	809	404	84	<b>2407</b>
<b>Urine</b>	46	7					<b>53</b>	1326	1274	137			232	<b>2969</b>
<b>Hair</b>	9						<b>9</b>	420	155					<b>575</b>
<b>Sputum</b>	4	64					<b>68</b>	943	1624	126			127	<b>2820</b>
<b>Sputum Deposit</b>	3						<b>3</b>	622						<b>622</b>
<b>TOTALS</b>	<b>216</b>	<b>92</b>				<b>5</b>	<b>313</b>	<b>8578</b>	<b>8298</b>	<b>814</b>	<b>4170</b>	<b>3474</b>	<b>1370</b>	<b>26704</b>

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PULMONARY TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT**

PTB Enrolled, n	BJGMC	NIRT	CMC	JIPMER	MVDRCH	Hinduja	Total
256	248	142	1247	446	61	2400	

# of Aliquots	Baseline (<14 days)							2 Weeks			1 Month			2 Months			Total										
	BJGMC	NIRT	CMC	JIPMER	MVDRCH	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRCH	Hinduja	Total	BJGMC	NIRT		CMC	JIPMER	MVDRCH	Hinduja	Total					
	Plasma	2062	1611	443	1585	588	192	6481						192	4142	1732		1678	21		514	216	4161				
Serum													543	543							618	618					
Plasma for PK													1022	1523							1234	1234					
PAXgene	206	239	28	2247	265	61	3046						57	495	203	218	8	1681	307	55	2472						
PBMCs	321	426	27	540			1314						382	838	386	401	6		490		1283						
DNA			262			242	504	6						6			16			220	236						
QGIT	2343	828					3171						2085	2769	1953	552					2505						
Mtb Isolate	258	602	368	809	490	412	2939	88	384				92	341	21	70				64	155						
Urine	2057	924	252			229	3462						1775	2910	1771	880				212	2863						
Hair	259	54					313						41	72		7					7						
Sputum	256	404	287			193	1140	122	301				70	483	126	274				59	459						
Sputum Deposit	164						164	95						89	91						91						
Gastric Aspirate						121	121																				
<b>TOTALS</b>	<b>7926</b>	<b>5088</b>	<b>1667</b>	<b>4641</b>	<b>1883</b>	<b>1450</b>	<b>22655</b>	<b>311</b>	<b>685</b>	<b>0</b>	<b>0</b>	<b>103</b>	<b>1099</b>	<b>7255</b>	<b>4753</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2197</b>	<b>14205</b>	<b>6283</b>	<b>4080</b>	<b>51</b>	<b>1681</b>	<b>1311</b>	<b>2678</b>	<b>16084</b>

# of Aliquots	5 Months							6 Months			9 Months			12 Months			Total					
	BJGMC	NIRT	CMC	JIPMER	MVDRCH	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRCH	Hinduja	Total	BJGMC	NIRT		CMC	JIPMER	MVDRCH	Hinduja	Total
	Plasma							1587	208	5	348	208	2356			1689		1552				200
Serum											408	408								288	288	
Plasma for PK	226	213					439				825	825								588	588	
PAXgene		1		198	25	3	1	355	38	224	44	494			168	202			29	399		
PBMCs										400		793			333	365					698	
DNA	192	263					455	2	6		160	168								116	116	
QGIT							1274	24				1298			506						506	
Mtb Isolate	5	40				30	75	10	3		6	19			1	1				12	14	
Urine							1571	76			176	1823			1345	830				116	2291	
Hair	17	37					54	28				28			1						1	
Sputum	109	342					451	106	38		10	154			11	2					13	
Sputum Deposit	86						86	77				77			2						2	
Gastric Aspirate																						
<b>TOTALS</b>	<b>635</b>	<b>896</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>30</b>	<b>1561</b>	<b>5206</b>	<b>414</b>	<b>14</b>	<b>972</b>	<b>1837</b>	<b>8443</b>	<b>12</b>	<b>12</b>	<b>4056</b>	<b>2952</b>	<b>0</b>	<b>0</b>	<b>1349</b>	<b>8357</b>	





**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PULMONARY TB**  
**# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

# of Aliquots	Unscheduled								TOTAL						
	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total
Plasma	45	500						500	12011	9729	503	1733	2590	1160	27726
Serum							10	10						1867	1867
Plasma for PK		3					20	23	502	441				3689	4632
PAXgene	3	53					1	54	1257	1293	39	4123	1040	266	8018
PBMCs	7	106						106	2267	2341	33		2342		6983
DNA	4						4	4	198	269	298			746	1511
QGIT	10	95						95	8401	2124					10525
Mtb Isolate	4	3	36					39	439	1388	392	809	490	628	4146
Urine	43	405	28					433	10709	5148	270			1030	17157
Hair	3	9						9	441	158					599
Sputum	9	4	109					113	1041	2213	318			439	4011
Sputum Deposit		3						3	672						672
Gastric Aspirate														121	121
<b>TOTALS</b>	<b>128</b>	<b>1181</b>	<b>173</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>35</b>	<b>1389</b>	<b>37938</b>	<b>25104</b>	<b>1853</b>	<b>6665</b>	<b>6462</b>	<b>9946</b>	<b>87968</b>

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A EXTRA PULMONARY TB**  
**# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

Specimen \ N	Baseline (<7 days)				2 Weeks				1 Month				2 Months			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma	111	84	15	210					96	70	13	179	102	73	31	206
Serum											35	35			31	31
Plasma for PK		84		84					95	76	35	206			0	
PAXgene	110	87	36	233					95	75	35	205	101	80	31	212
PBMCs	88		0	88					96	77	0	173	101	81	0	182
DNA		9	36	45	2			2							31	31
QGIT	40	19	0	59		6		6	32	8	0	40	35	8	0	43
Mtb Isolate	9	80	26	115	7		0	7	3	5	0	8	1	5	0	6
Urine	112	37	34	183					94	76	35	205	100	78	32	210
Hair	111	70	0	181		80		80	31	31	0	62		5	0	5
Sputum	68		15	83	58		5	63	52	76	4	132	30	78	2	110
Sputum Deposit	61		0	61	41			41	43		0	43	37			37
Gastric Aspirate	2		35	37												
<b>TOTALS</b>	<b>712</b>	<b>470</b>	<b>197</b>	<b>1379</b>	<b>108</b>	<b>86</b>	<b>5</b>	<b>199</b>	<b>637</b>	<b>494</b>	<b>157</b>	<b>1288</b>	<b>507</b>	<b>408</b>	<b>158</b>	<b>1073</b>

<b>EPTB</b>	BJGMC	NIRT	Hinduja	Total
<b>Enrolled, n</b>	108	88	36	232

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A EXTRA PULMONARY TB  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT |  
CONTINUED**

Specimen \ N	5 Months				6 Months				12 Months			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma		4		4	89	20	17	126	70	73	19	162
Serum							29	29			20	20
Plasma for PK	84	74		158			29	29			20	20
PAXgene		4		4	89	23	29	141	69	73	20	162
PBMCs		5		5	89	21	0	110	70	74	0	144
DNA	82	77		159			24	24			20	20
QGIT					19		0	19	7		0	7
Mtb Isolate	1	2		3							0	
Urine					90	26	28	144	70	68	20	158
Hair	17	31		48	25	1	0	26				
Sputum	53	73		126	58	26	0	84				
Sputum Deposit	30			30	26			26	1			1
Gastric Aspirate												
<b>TOTALS</b>	<b>267</b>	<b>270</b>	<b>0</b>	<b>537</b>	<b>485</b>	<b>117</b>	<b>156</b>	<b>758</b>	<b>287</b>	<b>288</b>	<b>119</b>	<b>694</b>

Specimen \ N	18 Months				24 Months				End TB Tx				TB Recurrence—Bacteriological				TB Recurrence—Clinical			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma			11	11	72	45	2	119	21	70	0	91	1		0	1	4			4
Serum			0				0													
Plasma for PK			0				0													
PAXgene			11	11	70	45	2	117	21	70	0	91	1	1	0	2	4			4
PBMCs			0		55	45	0	100	20	69	0	89	1	1	0	2	4			4
DNA			0				0													
QGIT			0				0		3	5	0	8								
Mtb Isolate		2	0	2			0													
Urine			10	10	72	38	2	112	21	67	0	88	1	1	0	2	5			5
Hair			0		4		0	4	21	24	0	45	1		0	1	5			5
Sputum	68	53	0	121			0		9	71	0	80	1	1	0	2	4			4
Sputum Deposit	9		0	9			0		3			3					1			1
Gastric Aspirate			0				0													
<b>TOTALS</b>	<b>77</b>	<b>55</b>	<b>32</b>	<b>164</b>	<b>273</b>	<b>173</b>	<b>6</b>	<b>452</b>	<b>119</b>	<b>376</b>	<b>0</b>	<b>495</b>	<b>6</b>	<b>4</b>	<b>0</b>	<b>10</b>	<b>27</b>	<b>0</b>	<b>0</b>	<b>27</b>

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A EXTRA PULMONARY TB  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT |  
CONTINUED**

Specimen \ N	TB Failure—Bacteriological				TB Failure—Clinical				Unscheduled				TOTALS			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma					2			2	10			10	578	439	108	1125
Serum													0	0	115	115
Plasma for PK									1			1	180	150	84	414
PAXgene					2			2	10			10	572	455	164	1191
PBMCs					2			2	10			10	536	460	0	996
DNA									1			1	85	77	111	273
QGIT													136	30	0	166
Mtb Isolate													21	39	26	86
Urine					2			2	9	1		10	576	435	161	1172
Hair					1			1	3			3	219	129	0	348
Sputum					1			1	1	10		11	403	538	27	968
Sputum Deposit					1			1	1			1	254	0	0	254
Gastric Aspirate													2	0	35	37
<b>TOTALS</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>11</b>	<b>0</b>	<b>0</b>	<b>11</b>	<b>46</b>	<b>11</b>	<b>0</b>	<b>57</b>	<b>3562</b>	<b>2752</b>	<b>831</b>	<b>7145</b>

Cohort A TBM	
SPECIMEN / #	Baseline (≤14 days)
ALIQUOTS	CMC
CSF	190
Plasma	780
DNA	409
Urine	384
Total	1763
TBM Enrolled, n	CMC 269

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A EXTRA PULMONARY TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT**

SPECIMEN / # ALIQUOTS	Baseline ( $<7$ days)				2 Weeks				1 Month				2 Months			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma	1121	612	120	1853					1002	560	112	1674	1045	584	96	1725
Serum											306	306			378	378
Plasma for PK									143	76	605	824			769	769
PAXgene	113	81	36	230					98	75	35	208	104	80	31	215
PBMCs	168	123	0	291					188	131	0	319	197	133	0	330
DNA			144	144	2			2							124	124
QGIT	620	108	0	728					483	96	0	579	525	96	0	621
Mtb Isolate	14	32	199	245	8	7	0	15	4	6	6	16	1	5	0	6
Urine	903	318	131	1352					768	304	138	1210	823	312	123	1258
Hair	126	37	0	163					59	31	0	90		5	0	5
Sputum	98	130	40	268	61	88	13	162	56	85	9	150	63	84	8	155
Sputum Deposit	73		0	73	43		0	43	44		0	44	37			37
Gastric Aspirate	2		75	77												
<b>TOTALS</b>	<b>3238</b>	<b>1441</b>	<b>745</b>	<b>5424</b>	<b>114</b>	<b>95</b>	<b>13</b>	<b>222</b>	<b>2845</b>	<b>1364</b>	<b>1211</b>	<b>5420</b>	<b>2795</b>	<b>1299</b>	<b>1529</b>	<b>5623</b>

SPECIMEN / # ALIQUOTS	5 Months				6 Months				12 Months			
	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total	BJGMC	NIRT	Hinduja	Total
Plasma		48		48	920	160	136	1216	718	600	144	1462
Serum							272	272			200	200
Plasma for PK	112	74		186			544	544			398	398
PAXgene		6		6	94	23	29	146	72	75	20	167
PBMCs		15		15	174	31	0	205	140	142	0	282
DNA	84	187		271			96	96			80	80
QGIT					285		0	285	104		0	104
Mtb Isolate	1	3		4								
Urine					755	108	112	975	562	288	80	930
Hair	52	31		83	63	1		64				
Sputum	54	123		177	56	28		84				
Sputum Deposit	31			31	26			26	1			1
Gastric Aspirate												
<b>TOTALS</b>	<b>334</b>	<b>487</b>	<b>0</b>	<b>821</b>	<b>2373</b>	<b>351</b>	<b>1189</b>	<b>3913</b>	<b>1597</b>	<b>1105</b>	<b>922</b>	<b>3624</b>

<b>EPTB</b>	BJGMC	NIRT	Hinduja	Total
<b>Enrolled, n</b>	113	88	36	237



**PARENT PROTOCOL BANKED SPECIMENS | COHORT A EXTRA PULMONARY TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

SPECIMEN / # ALIQUOTS	18 Months			24 Months			End TB Tx			TB Recurrence—Bacteriologic			TB Recurrence—Clinical				
	BjGMC	NIRT	Hinduja	Total	BjGMC	NIRT	Hinduja	Total	BjGMC	NIRT	Hinduja	Total	BjGMC	NIRT	Hinduja	Total	
Plasma			88	88	551	368	16	935	208	560	0	768	31		0	50	50
Serum																	
Plasma for PK																	
PAXgene			11	11	56	45	2	103	21	70	0	91	3	1	0	4	4
PBMCs					99	91	0	190	36	116	0	152	4	3	0	7	7
DNA																	
QGIT									45	60	0	105					
Mtb Isolate		2	0	2									1		0	1	
Urine			40	40	448	160	8	616	168	268	0	436	21	4	0	25	35
Hair					5			5	22	24	0	46	4		0	4	6
Sputum	55	55		110					15	74	0	89	5	1	0	6	3
Sputum Deposit	9			9					3			3					2
Gastric Aspirate																	
<b>TOTALS</b>	<b>64</b>	<b>57</b>	<b>139</b>	<b>260</b>	<b>1159</b>	<b>664</b>	<b>26</b>	<b>1849</b>	<b>518</b>	<b>1172</b>	<b>0</b>	<b>1690</b>	<b>69</b>	<b>9</b>	<b>0</b>	<b>78</b>	<b>107</b>

SPECIMEN / # ALIQUOTS	TB Failure—Bacteriological			TB Failure—Clinical			Unscheduled			TOTALS						
	BjGMC	NIRT	Hinduja	Total	BjGMC	NIRT	Hinduja	Total	BjGMC	NIRT	Hinduja	Total				
Plasma	0	0	0	0			0		110		0	110	5756	3492	712	9960
Serum															1156	1156
Plasma for PK									2			2	257	150	2316	2723
PAXgene	0	0	0	0	0	0	0	0	11	0	0	11	576	456	164	1196
PBMCs	0	0	0	0	0	0	0	0	21	0	0	21	1034	785	0	1819
DNA									1	0	0	1	87	187	444	718
QGIT													2062	360	0	2422
Mtb Isolate													29	55	205	289
Urine	0	0	0	0	0	0	0	4	80	4	0	84	4563	1766	632	6961
Hair	0	0	0	0	0	0	0	0	6		0	6	343	129	0	472
Sputum	0	0	0	0	0	0	0	0	1	10	0	11	467	678	72	1217
Sputum Deposit	0	0	0	0	0	0	0	0	1			1	270		0	270
Gastric Aspirate													2		75	77
<b>TOTALS</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>233</b>	<b>14</b>	<b>0</b>	<b>247</b>	<b>15446</b>	<b>8058</b>	<b>5776</b>	<b>29280</b>

SPECIMEN / # ALIQUOTS	Cohort A TBM	
	Baseline (≤14 days)	
CSF	CMC	
	190	
Plasma	CMC	
	780	
DNA	CMC	
	409	
Urine	CMC	
	384	
Total	CMC	
	1763	
TBM Enrolled, n	CMC	
	269	
PTB Enrolled, n	BjGMC	NIRT
	256	248
	142	1247
	446	61
	2400	



**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PEDIATRIC TB**  
**# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

Specimen \ N	Baseline (≤7 days)			2 Weeks			1 Month			2 Months		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	127	54	181				134	56	190	137	53	190
Plasma for PK							133	55	188			
PAXgene	108	56	164				121	56	177	137	55	192
PBMCs	88	55	143				115	56	171	116	54	170
DNA												
QGIT	34	3	37				39	3	42	36	3	39
Mtb Isolate	23	11	34	10	7	17	6	5	11	4	2	6
Urine	136	54	190				137	55	192	136	55	191
Hair	132	32	164				42	29	71			
Sputum	87	37	124	66	47	113	76	47	123	79	48	127
Sputum Deposit	67		67	56		56	49		49	48		48
Gastric Aspirate	15		15	5		5	3		3	3		3
<b>TOTALS</b>	<b>817</b>	<b>302</b>	<b>1119</b>	<b>137</b>	<b>54</b>	<b>191</b>	<b>855</b>	<b>362</b>	<b>1217</b>	<b>696</b>	<b>270</b>	<b>966</b>

Specimen \ N	5 Months			6 Months			12 Months		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma		7	7	127	18	145	116	37	153
Plasma for PK	129	53	182						
PAXgene		8	8	114	17	131	115	36	151
PBMCs		9	9	108	17	125	95	38	133
DNA	130	55	185		1	1			
QGIT				24		24	8		8
Mtb Isolate				1		1			
Urine		2	2	128	22	150	115	36	151
Hair	36	31	67	35	1	36			
Sputum	85	44	129	78	24	102	1		1
Sputum Deposit	38		38	44		44			
Gastric Aspirate	3		3	1		1	1		1
<b>TOTALS</b>	<b>421</b>	<b>209</b>	<b>630</b>	<b>660</b>	<b>100</b>	<b>760</b>	<b>451</b>	<b>147</b>	<b>598</b>

Pediatric TB	BJGMC	NIRT	Total
Enrolled, n	142	59	201

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PEDIATRIC TB  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT |  
CONTINUED**

Specimen \ N	18 Months			24 Months			End TB Tx			TB Recurrence—Bacteriological		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma				105	14	119	7	46	53		2	2
Plasma for PK												
PAXgene				103	15	118	7	45	52		2	2
PBMCs				82	14	96	6	45	51		2	2
DNA								1	1			
QGIT												
Mtb Isolate	1		1							1		1
Urine				104	13	117	7	43	50		1	1
Hair				5		5	7	21	28			
Sputum	85	22	107	1		1	2	42	44	1	2	3
Sputum Deposit	13		13									
Gastric Aspirate	1		1									
<b>TOTALS</b>	<b>100</b>	<b>22</b>	<b>122</b>	<b>400</b>	<b>56</b>	<b>456</b>	<b>36</b>	<b>243</b>	<b>279</b>	<b>2</b>	<b>9</b>	<b>11</b>

Specimen \ N	TB Recurrence—Clinical			TB Failure—Bacteriological			TB Failure—Clinical			Unscheduled			TOTALS		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	5		5	2		2	2		2	8		8	770	287	1057
Plasma for PK										1	1	2	263	109	372
PAXgene	5		5	3		3	2		2	7		7	722	290	1012
PBMCs	5		5	2		2	2		2	8		8	627	290	917
DNA													130	57	187
QGIT													141	9	150
Mtb Isolate				2		2							48	25	73
Urine	5		5	2		2	2		2	8		8	780	281	1061
Hair	5		5	3		3	2		2	3		3	270	114	384
Sputum	3		3	2		2	1		1	7	3	10	574	316	890
Sputum Deposit	2		2	1		1	1		1	3		3	322		322
Gastric Aspirate													32		32
<b>TOTALS</b>	<b>30</b>		<b>30</b>	<b>17</b>		<b>17</b>	<b>12</b>		<b>12</b>	<b>45</b>	<b>4</b>	<b>49</b>	<b>4679</b>	<b>1778</b>	<b>6457</b>

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PEDIATRIC TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT**

SPECIMEN / # ALIQUOTS	Baseline (≤7 days)			2 Weeks			1 Month			2 Months		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	1131	430	1561				1185	448	1633	1237	432	1669
Plasma for PK							189	55	244			
PAXgene	107	55	162				119	56	175	136	55	191
PBMCs	129	107	236				154	106	260	151	105	256
DNA												
QGIT	513	36	549				582	36	618	539	36	575
Mtb Isolate	34	26	60	11	8	19	6	5	11	4	2	6
Urine	1072	218	1290				1080	224	1304	1079	220	1299
Hair	133	32	165				42	29	71			
Sputum	133	63	196	66	51	117	76	52	128	81	53	134
Sputum Deposit	85		85	56		56	50		50	48		48
Gastric Aspirate	16		16	6		6	3		3	3		3
<b>TOTALS</b>	<b>3353</b>	<b>967</b>	<b>4320</b>	<b>139</b>	<b>59</b>	<b>198</b>	<b>3486</b>	<b>1011</b>	<b>4497</b>	<b>3278</b>	<b>903</b>	<b>4181</b>

SPECIMEN / # ALIQUOTS	5 Months			6 Months			12 Months		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma		56	56	1136	144	1280	1065	304	1369
Plasma for PK	177	53	230						
PAXgene		8	8	114	17	131	117	37	154
PBMCs		24	24	139	44	183	122	81	203
DNA	130	199	329		4	4			
QGIT				360		360	120		120
Mtb Isolate				1		1			
Urine		8	8	1010	88	1098	929	144	1073
Hair	36	32	68	35	1	36			
Sputum	85	76	161	79	26	105	1		1
Sputum Deposit	38		38	44		44			
Gastric Aspirate	3		3	1		1	1		1
<b>TOTALS</b>	<b>469</b>	<b>456</b>	<b>925</b>	<b>2919</b>	<b>324</b>	<b>3243</b>	<b>2355</b>	<b>566</b>	<b>2921</b>

Pediatric TB	BJGMC	NIRT	Total
Enrolled, n	142	59	201

**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PEDIATRIC TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

SPECIMEN / # ALIQUOTS	18 Months			24 Months			End TB Tx			TB Recurrence—Bacteriological		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma				953	112	1065	64	368	432		16	16
Plasma for PK												
PAXgene				103	15	118	7	45	52		2	2
PBMCs				120	27	147	10	105	115		3	3
DNA								1	1			
QGIT												
Mtb Isolate	1		1							1		1
Urine				830	52	882	55	172	227		4	4
Hair				5		5	7	21	28			
Sputum	86	24	110	1		1	2	44	46	2	2	4
Sputum Deposit	13		13									
Gastric Aspirate	1		1									
<b>TOTALS</b>	<b>101</b>	<b>24</b>	<b>125</b>	<b>2012</b>	<b>206</b>	<b>2218</b>	<b>145</b>	<b>756</b>	<b>901</b>	<b>3</b>	<b>27</b>	<b>30</b>



**PARENT PROTOCOL BANKED SPECIMENS | COHORT A PEDIATRIC TB  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

SPECIMEN / # ALIQUOTS	TB Recurrence- Clinical						TB Failure- Bacteriological						TB Failure- Clinical									
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	
Plasma	80		4				84	227	8	14	54			303	40		5					45
Serum																						
Plasma for PK																						
PAXgene	8						8	24	2		73			99	3							3
PBMCs	15						15	39	3					42	7							7
DNA			2				2			2				2			4					4
QGIT								75						75	10							10
Mtb Isolate								12		12				24			4					4
Urine	64		2				66	204	60	6				270	39		4					43
Hair	7						7	23						23	3							3
Sputum	5		2				7	22	3	11				36	4		5					9
Sputum Deposit	2						2	7						7								
Gastric Aspirate																						
<b>TOTALS</b>	<b>181</b>	<b>0</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>191</b>	<b>633</b>	<b>76</b>	<b>45</b>	<b>127</b>	<b>0</b>	<b>0</b>	<b>881</b>	<b>106</b>	<b>0</b>	<b>22</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>128</b>

SPECIMEN / # ALIQUOTS	TB Recurrence—Clinical						TB Failure—Bacteriological						TB Failure—Clinical						Totals						
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	
Plasma	45		45	26		26	17		17	72		72			6931	2310	9241								
Plasma for PK																									
PAXgene	5		5	3		3	2		2	7		7			367	109	476								
PBMCs	6		6	3		3	3		3	11		11			720	290	1010								
DNA															848	602	1450								
QGIT															130	204	334								
Mtb Isolate				2		2									2114	108	2222								
Urine	40		40	19		19	16		16	64		64			6194	1130	7324								
Hair	5		5	3		3	2		2	3		3			271	115	386								
Sputum	3		3	2		2	1		1	7		7			625	394	1019								
Sputum Deposit	2		2	1		1	1		1	4		4			342		342								
Gastric Aspirate															34		34								
<b>TOTALS</b>	<b>106</b>		<b>106</b>	<b>59</b>		<b>59</b>	<b>42</b>		<b>42</b>	<b>169</b>		<b>173</b>		<b>4</b>	<b>18636</b>	<b>5303</b>	<b>23939</b>								

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B HOUSEHOLD CONTACTS ALL AGES  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

Specimen \ N	Baseline (≤14 days)						4 Months				8 Months				12 Months			
	BjGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BjGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BjGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
Plasma	467	492	1218	790	16	2983	321	453		357		1131	319	404	31	141		895
Plasma for PK																		
PAXgene	390	521	1525		16	2452	294	470				764	301	425	31			757
PBMCs	337	498		742		1577	257	476		339		1072	257	444		130		831
DNA	457	510		729		1696	1					1						
QGIT	446	515			16	977	295	233				528	282	118				400
Mtb Isolate	3	34	1			38		14			14							
Urine	462	502			16	980	326	416			742		322	426				748
Hair	470	3				473	331	3			334		323					323
Sputum	282	488			3	773	172	438			610		2					2
Sputum Deposit	237					237	175				175		2					2
Gastric Aspirate/ Saliva (adults)	12				16	28	5				5							
<b>TOTALS</b>	<b>3563</b>	<b>3563</b>	<b>2744</b>	<b>2261</b>	<b>83</b>	<b>12214</b>	<b>2177</b>	<b>2503</b>		<b>696</b>	<b>5376</b>	<b>445</b>	<b>1808</b>	<b>1817</b>	<b>62</b>	<b>271</b>		<b>3958</b>

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B HOUSEHOLD CONTACTS ALL AGES  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

Specimen \ N	16 Months		20 Months		24 Months					Prevalent TB—Bacteriological					Prevalent TB—Clinical								
	BMMRC	Total	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	
	Plasma	110	110	75	75			142			142	6	7	4			17	15			13		
Plasma for PK																							
PAXgene											6	7	4			17	14						14
PBMCs	100	100	66	66			123			123	5	6				11	15						15
DNA						1				1	6	7				13	15						15
QGIT						106				417	6	7				13	15						15
Mtb Isolate											1					1							
Urine						1				1	6	7				13	16						16
Hair											6					6	16						16
Sputum											5	7				12	9						9
Sputum Deposit											1					1	7						7
Gastric Aspirate/ Saliva (adults)																	3						3
<b>TOTALS</b>	<b>210</b>	<b>210</b>	<b>141</b>	<b>141</b>	<b>311</b>	<b>108</b>	<b>265</b>	<b>684</b>	<b>684</b>	<b>48</b>	<b>48</b>	<b>8</b>	<b>104</b>	<b>104</b>	<b>125</b>	<b>138</b>	<b>138</b>	<b>13</b>	<b>13</b>	<b>13</b>	<b>13</b>	<b>13</b>	<b>138</b>

See Table 7b for number of Cohort B participants with Prevalent TB and Incident TB.

HHCs Enrolled, n	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
Total (all ages)	499	553	1603	990	16	3661
<15 years	165	121	315	70	4	675
>=15 years	334	432	1288	920	12	2986

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B HOUSEHOLD CONTACTS ALL AGES  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

Specimen \ N	Incident TB—Bacteriological						Incident TB—Clinical						Unscheduled Visit						TOTALS					
	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
Plasma	4		5			9	11				11	82						82	1225	1356	1258	1860	16	5715
Plasma for PK																								
PAXgene	3		6			9	9				9	81						81	1098	1423	1566		16	4103
PBMCs	4					4	11				11	70						70	956	1424		990		3370
DNA	1					1													480	518		990		1988
QGIT	4					4	9				9	92						92	1460	979			16	2455
Mtb Isolate	2					2								4				4	6	58	1			65
Urine	4					4	11				11	84		14				98	1231	1366		16		2613
Hair	3					3	11				11	83						83	1243	6				1249
Sputum	3					3	5				5	3		62				65	481	995			3	1479
Sputum Deposit							3				3	5						5	430					430
Gastric Aspirate/ Saliva (adults)							1				1								21				16	37
<b>TOTALS</b>	<b>28</b>		<b>11</b>			<b>39</b>	<b>71</b>				<b>71</b>	<b>500</b>	<b>80</b>				<b>580</b>	<b>8631</b>	<b>8125</b>	<b>2825</b>	<b>3840</b>	<b>83</b>	<b>23504</b>	



**PARENT PROTOCOL BANKED SPECIMENS | COHORT B PEDIATRIC HHCS (<15 YEARS)**  
**# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

Specimen \ N	Baseline (≤14 days)										4 Months				8 Months			12 Months				Total
	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total				
	145	104	199	21	4	473	93	97	18	18	208	13	13	100	88	8	12	208				
Plasma																						
Plasma for PK																						
PAXgene	111	107	278		4	500	70	97			167			85	96	8		189				
PBMCs	102	103		15		220	82	99	12		193	8	8	90	98		10	198				
DNA	139	101		21		261																
QGIT	139	103			4	246	85	49			134			88	33			121				
Mtb Isolate	2	8				10																
Urine	143	104			4	251	94	88			182			101	96			197				
Hair	146					146	94				94			101				101				
Sputum	81	124				205	46	106			152			1				1				
Sputum Deposit	56					56	51				51			1				1				
Gastric Aspirate/ Saliva (adults)	12				4	16	5				5											
<b>TOTALS</b>	<b>1076</b>	<b>754</b>	<b>477</b>	<b>57</b>	<b>20</b>	<b>2384</b>	<b>620</b>	<b>536</b>	<b>30</b>	<b>1186</b>	<b>21</b>	<b>21</b>	<b>567</b>	<b>411</b>	<b>16</b>	<b>22</b>	<b>1016</b>					

HHCs Enrolled, n	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total
Total (all ages)	499	553	1603	990	16	3661
<15 years	165	121	315	70	4	675
>=15 years	334	432	1288	920	12	2986

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B PEDIATRIC HHCS (<15 YEARS)**  
**# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

Specimen \ N	16 Months		20 Months		24 Months				Prevalent TB—Bacteriological				Prevalent TB—Clinical				
	Total		Total		Total		Total		Total		Total		Total		Total		
	BMMRC	Total	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	
Plasma	10	10	8	8			10			10	2	2				4	13
Plasma for PK											2	2				4	
PAXgene																	
PBMCs	8	8	6	6			9			9	1	1				2	13
DNA											2	2				4	13
QGIT						54			153	2	2					4	13
Mtb Isolate																	
Urine										2	2					4	14
Hair										2						2	14
Sputum										1	3					4	8
Sputum Deposit										1						1	6
Gastric Aspirate/ Saliva (adults)																3	3
<b>TOTALS</b>	18	18	14	14	99	54	19		172	15	14					29	110

Specimen \ N	Incident TB—Bacteriological				Incident TB—Clinical				Unscheduled Visit				TOTALS					
	Total		Total		Total		Total		Total		Total		Total		Total			
	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
Plasma	4		5			9	11					11	82					82
Plasma for PK																		
PAXgene	3		6			9	9					9	81					81
PBMCs	4					4	11					11	70					70
DNA	1					1												
QGIT	4					4	9					9	92					92
Mtb Isolate	2					2								4				4
Urine	4					4	11					11	84	14				98
Hair	3					3	11					11	83					83
Sputum	3					3	5					5	3	62				65
Sputum Deposit							3					3	5					5
Gastric Aspirate/ Saliva (adults)							1					1						
<b>TOTALS</b>	28		11			39	71					71	500	80				580
													8631	8125	2825	3840	83	23504

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B ADULT HHCS (>=15 YEARS)  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT**

Specimen \ N	Baseline (≤14 days)										4 Months				8 Months				12 Months					
	BJGMC		NIRT		JIPMER		BMMRC		Hinduja		Total		BJGMC		NIRT		JIPMER		BMMRC		Hinduja		Total	
Plasma	322	388	1019	769	12	2510	228	356			339	923	219	219	316	23	129						687	
Plasma for PK																								
PAXgene	279	414	1247		12	1952	224	373				597			329	23							568	
PBMCs	235	395		742		1372	175	377		339		891	213	213	346		130						643	
DNA	318	409		729		1456	1					1												
QGIT	307	412			12	731	210	184				394			85								279	
Mtb Isolate	1	26	1			28		14				14												
Urine	319	398			12	729	232	328				560			330								551	
Hair	324	3				327	237	3				240											222	
Sputum	201	364			3	568	126	332				458			1								1	
Sputum Deposit	181					181	124					124			1								1	
Gastric Aspirate/ Saliva (adults)					12	12																		
<b>TOTALS</b>	<b>2487</b>	<b>2809</b>	<b>2267</b>	<b>2240</b>	<b>63</b>	<b>9866</b>	<b>1557</b>	<b>1967</b>		<b>678</b>		<b>4202</b>	<b>432</b>	<b>432</b>	<b>1241</b>	<b>1406</b>	<b>46</b>	<b>259</b>					<b>2952</b>	

HHCs Enrolled, n		BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
Total (all ages)		499	553	1603	990	16	3661
<15 years		165	121	315	70	4	675
>=15 years		334	432	1288	920	12	2986

**PARENT PROTOCOL BANKED SPECIMENS | COHORT B ADULT HHCS (>=15 YEARS)  
# OF PARTICIPANTS WITH STORED SPECIMENS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

Specimen \ N	16 Months		20 Months		24 Months					Prevalent TB- Bacteriological					Prevalent TB- Clinical								
	BMMRC	Total	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	
	Plasma	100	100	67	67				132		132	4	5	4			13	2			13		
Plasma for PK																							
PAXgene													4	5	4	13	1						1
PBMCs	100	100	66	66				123		123	4	5	5			9	2						2
DNA						1				1	4	5				9	2						2
QGIT					212	52				264	4	5				9	2						2
Mtb Isolate											1	4				5							
Urine						1				1	4	5				9	2						2
Hair											4					4	2						2
Sputum											4	4				8	1						1
Sputum Deposit																							1
Gastric Aspirate/ Saliva (adults)																							
<b>TOTALS</b>	<b>200</b>	<b>200</b>	<b>133</b>	<b>133</b>	<b>212</b>	<b>54</b>	<b>255</b>	<b>521</b>	<b>33</b>	<b>38</b>	<b>8</b>	<b>79</b>	<b>15</b>	<b>13</b>	<b>28</b>								

Specimen \ N	Incident TB- Bacteriological				Incident TB- Clinical				Unscheduled Visit				TOTALS				
	BJGMC	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total
	Plasma	4		4		8	3					3	55				
Plasma for PK																	
PAXgene	3		5		8	3					3	55					55
PBMCs	4				4	3					3	45					45
DNA	1				1												
QGIT	4				4	2					2	63					63
Mtb Isolate	2				2								4				4
Urine	4				4	3					3	56	13				69
Hair	3				3	3					3	56					56
Sputum	3				3	1					1	2	48				50
Sputum Deposit						1					1	3					3
Gastric Aspirate/ Saliva (adults)																	
<b>TOTALS</b>	<b>28</b>	<b>9</b>	<b>37</b>	<b>19</b>	<b>400</b>	<b>65</b>	<b>19</b>	<b>335</b>	<b>639</b>	<b>4210</b>	<b>63</b>	<b>5927</b>	<b>2330</b>	<b>4110</b>	<b>63</b>	<b>18869</b>	





**PARENT PROTOCOL BANKED SPECIMENS | COHORT B HHCS (ALL AGES)**  
**# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

SPECIMEN / # ALIQUOTS	Incident TB—Bacteriological					Incident TB—Clinical					Unscheduled Visit					TOTALS								
	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total
Plasma	40		10	21		71	102				102	832						832	11795	10823	2516	1881	128	27143
Plasma for PK																								
PAXgene	3					3	9				9	86		12				98	1111	1427	3151		16	5705
PBMCs	5					5	14				14	134						134	1723	3068		1781		6572
DNA	1					1													480	518		750		1748
QGIT	57					57	117				117	1302						1302	19069	9657			192	28918
Mtb Isolate	2					2								4				4	7	77				84
Urine	25					25	88				88	699	56					755	9835	5684			64	15583
Hair	3					3	11				11	88						88	1259	6				1265
Sputum	3					3	5				5	3	89					92	599	1323			3	1925
Sputum Deposit							3				3	7						7	504					504
Gastric Aspirate							1				1								25					61
<b>TOTALS</b>	<b>139</b>		<b>10</b>	<b>21</b>		<b>170</b>	<b>350</b>				<b>350</b>	<b>3151</b>	<b>149</b>	<b>12</b>			<b>3312</b>	<b>46407</b>	<b>32583</b>	<b>5667</b>	<b>4412</b>	<b>439</b>	<b>89508</b>	



**PARENT PROTOCOL BANKED SPECIMENS | COHORT B PEDIATRIC HHCS (<15 YEARS)**  
**# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT**

SPECIMEN / # ALIQUOTS	Baseline (≤14 days)										4 Months				8 Months				12 Months					
	BJGMC		NIRT		JIPMER		BMMRC		HinduJa		Total		BJGMC		NIRT		JIPMER		BMMRC		HinduJa		Total	
Plasma	1257		824	398	21	32	2552	825	772	18	1615	825	772	18	1615	825	772	18	1615	825	772	18	1615	
Plasma for PK																								
PAXgene	111		107	559		4	781	72	97		169	72	97		169	72	97		169	72	97		169	
PBMCs	154		281		15		450	120	264	12	396	120	264	12	396	120	264	12	396	120	264	12	396	
DNA	139		101		21		261	1061	428		1489	1061	428		1489	1061	428		1489	1061	428		1489	
QGIT	1665		1104			48	2817	742	352		1094	742	352		1094	742	352		1094	742	352		1094	
Mtb Isolate	2		11			13	13	1	3		4	1	3		4	1	3		4	1	3		4	
Urine	1116		416			16	1548	95	106		95	95	106		153	95	106		153	95	106		153	
Hair	147						147	47	106		153	47	106		153	47	106		153	47	106		153	
Sputum	116		124				240	51			51	51			51	51			51	51			51	
Sputum Deposit	73					12	73	5			5	5			5	5			5	5			5	
Gastric Aspirate	15						15																	
<b>TOTALS</b>	<b>4795</b>		<b>2968</b>	<b>957</b>	<b>57</b>	<b>112</b>	<b>8889</b>	<b>3019</b>	<b>2022</b>	<b>30</b>	<b>5071</b>	<b>3019</b>	<b>2022</b>	<b>30</b>	<b>5071</b>	<b>3019</b>	<b>2022</b>	<b>30</b>	<b>5071</b>	<b>3019</b>	<b>2022</b>	<b>30</b>	<b>5071</b>	

SPECIMEN / # ALIQUOTS	16 Months				20 Months				24 Months				Prevalent TB—Bacteriological				Prevalent TB—Clinical											
	BMMRC		Total		BMMRC		Total		BJGMC		NIRT		JIPMER		HinduJa		Total		BJGMC		NIRT		JIPMER		HinduJa		Total	
Plasma	10		10	8	8					10	16	17	16							115							115	
Plasma for PK																												
PAXgene												2	2	3						13							13	
PBMCs	8		8	6	6			9			3	1	3							18							18	
DNA											2	2	2							13							13	
QGIT										1467	24	24	48							156							156	
Mtb Isolate											2																	
Urine											16	8								106							106	
Hair											2									14							14	
Sputum											2	3								11							11	
Sputum Deposit											2									11							11	
Gastric Aspirate																				4							4	
<b>TOTALS</b>	<b>18</b>		<b>18</b>	<b>14</b>	<b>14</b>			<b>19</b>	<b>1486</b>	<b>60</b>	<b>68</b>	<b>131</b>	<b>461</b>	<b>3</b>	<b>3</b>	<b>131</b>	<b>461</b>	<b>3</b>	<b>461</b>	<b>131</b>	<b>461</b>	<b>3</b>	<b>3</b>	<b>131</b>	<b>461</b>	<b>461</b>		

HHCs Enrolled, n	BJGMC	NIRT	JIPMER	BMMRC	HinduJa	Total
Total (all ages)	499	553	1603	990	16	3661
<15 years	165	121	315	70	4	675
>=15 years	334	432	1288	920	12	2986





**PARENT PROTOCOL BANKED SPECIMENS | COHORT B ADULT HHCS (>=15 YEARS)  
# OF ALIQUOTS AVAILABLE, BY TYPE OF VISIT | CONTINUED**

SPECIMEN / # ALIQUOTS	Incident TB—Bacteriological				Incident TB—Clinical				Unscheduled Visit				TOTALS												
	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total	BJGMC	NIRT	JIPMER	BMMRC	Hinduja	Total							
Plasma	40		8	20		68	30				30	562							562						
Plasma for PK																									
PAXgene	3		13			16	3				3	57		12				12	69						
PBMCs	5					5	4				4	95							95						
DNA	1					1																			
QGIT	57					57	27				27	903							903						
Mtb Isolate	2					2							4						4						
Urine	25					25	24				24	456	52						508						
Hair	3					3	3				3	58							58						
Sputum	3					3	1				1	2	75						77						
Sputum Deposit							1				1	5							5						
Gastric Aspirate																									
<b>TOTALS</b>	<b>139</b>		<b>21</b>	<b>20</b>		<b>180</b>	<b>93</b>				<b>93</b>	<b>2138</b>	<b>131</b>	<b>12</b>				<b>2281</b>	<b>32391</b>	<b>25630</b>	<b>4670</b>	<b>4230</b>	<b>327</b>	<b>24</b>	<b>67248</b>



**COMMON PROTOCOL | COHORT A ENROLLMENT / DISPOSITION  
DATA UP TO DECEMBER 2019**

DESCRIPTION	REPORT SITES (SITE NUMBER)					TOTAL
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	
Number enrolled in Common Protocol (n)	40	214	120	134	216	724
Number previously enrolled in Cohort B	0	1 (0.47%)	0	0	0	1 (0.14%)
Number enrolled in the study other than the Parent Protocol	0	16 (7%)	0	0	0	16 (2%)
Number completed follow-up (6 months post treatment)	19 (48%)	128 (60%)	65 (54%)	88 (66%)	122 (56%)	422 (58%)
<b>Reason for NOT completing follow-up through the 6-Month Post Treatment Visit</b>						
Participant was provisionally enrolled but not confirmed to have active pulmonary TB	0	1 (0.47%)	3 (3%)	4 (3%)	26 (12%)	34 (5%)
Participant was provisionally enrolled but was confirmed by a culture that was conducted on respiratory secretions obtained by bronchoalveolar lavage or bronchial wash	0	0	0	0	0	0
More than 1 week of anti-TB therapy was received before the required baseline specimens for storage were collected	0	0	0	0	0	0
The required baseline biorepository specimens for storage were not collected	0	0	0	0	1 (0.46%)	1 (0.14%)
HIV test was not completed within seven weeks after enrollment	0	0	0	0	0	0
Met one of the following TB outcomes: <ul style="list-style-type: none"> <li>• Treatment Failure</li> <li>• TB Relapse</li> <li>• Emerging Resistance</li> </ul>	0	5 (2%)	14 (12%)	12 (9%)	11 (5%)	42 (6%)
Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)	0	0	0	3 (2%)	0	3 (0.41%)
Inadvertent enrollment	0	0	0	0	0	0
Withdrawal by participant	2 (5%)	4 (2%)	4 (3%)	9 (7%)	5 (2%)	24 (3%)
Withdrawal by parent/guardian	0	0	0	0	0	0
Lost to follow-up	3 (8%)	4 (2%)	6 (5%)	2 (1%)	3 (1%)	18 (2%)
Moved out of area	0	1 (0.47%)	1 (0.83%)	0	0	2 (0.28%)
Study terminated by funding org./other government agency	0	0	0	0	0	0
Death	0	4 (2%)	2 (2%)	2 (1%)	5 (2%)	13 (2%)
Other *	3 (8%)	21 (10%)	3 (3%)	0	22 (10%)	49 (7%)
	<b>Other</b>					<b>3</b>
<b>*CMC</b>	Baseline Culture Negative					2
	Treatment Incomplete					1
	<b>Other</b>					<b>21</b>
	Defaulted					2
	Sputum Contaminated					6
	Scanty					2
<b>*JIPMER</b>	Culture Negative					2
	Modified Regimen					6
	TB Stigma					1
	Unable to Contact					1
	Unable to Produce Sputum					1
	<b>Other</b>					<b>3</b>
<b>*MVDRC</b>	Enrolled in VPM 1002 Study					2
	Default					1
	<b>Other</b>					<b>22</b>
	Enrolled in VPM 1002 Study					11
<b>*BJGMC</b>	Participant defaulted treatment. Hence as per discussion with CP central team participant is terminated from the study as treatment incomplete.					9
	Participant diagnosed to have MDR TB and started on MDR treatment and hence terminated.					2

Source: Common Protocol data was transferred by individual sites to SAS-CHRD for aggregation and generation of tables.

**COMMON PROTOCOL | COHORT B ENROLLMENT / DISPOSITION**  
**DATA UP TO DECEMBER 2019**

DESCRIPTION	REPORT SITES (SITE NUMBER)				TOTAL
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	
Number enrolled in Common Protocol (n)	191	229	259	219	898
Number enrolled in a study other than the parent protocol	8 (4%)	0	0	0	8 (0.89%)
Number of completed follow-up (Month 24 visit)	0	32 (14%)	48 (19%)	0	80 (9%)
<b>Reason for not completing follow-up through the month 24 visit</b>					
Participant developed active TB	0	1 (0.44%)	8 (3%)	2 (0.91%)	11 (1%)
Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)	0	0	0	0	0
Inadvertent enrollment	0	5 (2%)	0	0	5 (0.56%)
Withdrawal by participant	1 (0.52%)	0	2 (0.77%)	0	3 (0.33%)
Withdrawal by parent/guardian	0	0	0	0	0
Lost to follow up	0	3 (1%)	3 (1%)	0	6 (0.67%)
Moved out of area	0	4 (2%)		0	4 (0.45%)
Study terminated by funding organization or other government agency	0	0	0	0	0
Death	0	0	0	0	0
Other*	2 (1%)	0	35 (14%)	15 (7%)	52 (6%)
	<b>*JIPMER</b>	<b>Other</b>			
		Sample not collected			
		Unable to collect the blood SA			
	<b>*BJGMC</b>	Cohort A baseline culture negative			
	<b>*BMMC</b>	<b>Other</b>			
		Does not agree to collection of samples			
		Moved away from area			
		Not interested			



**COMMON PROTOCOL | COHORT A FINAL OUTCOME STATUS  
DATA UP TO DECEMBER 2019**

DESCRIPTION	REPORT SITES (SITE NUMBER)					TOTAL
	CMC (101)	JIPMER (102)	MVDRRC (103)	NIRT (105)	BJGMC (106)	
Number enrolled in Common Protocol (n)	<b>40</b>	<b>214</b>	<b>120</b>	<b>134</b>	<b>216</b>	<b>724</b>
Bacteriologic cure	19 (48%)	127 (59%)	65 (54%)	87 (65%)	108 (50%)	<b>406 (56%)</b>
Bacteriologic status indeterminate (treatment complete)	0	12 (6%)	0	1 (0.75%)	9 (4%)	<b>55 (8%)</b>
Bacteriologic failure	0	5 (2%)	3 (3%)	9 (7%)	5 (2%)	<b>21 (3%)</b>
Bacteriologic relapse	0	0	6 (5%)	2 (1%)	2 (0.93%)	<b>10 (1%)</b>
Emerging resistance	0	0	5 (4%)	0	0	<b>5 (0.69%)</b>
Clinical response (For participants ≤14 years of age who did not have bacteriologic documentation at baseline)	0	0	0	0	1 (0.46%)	<b>1 (0.14%)</b>
Clinical failure	0	0	0	0	4 (2%)	<b>4 (0.55%)</b>
Clinical relapse	0	0	0	0	1 (0.46%)	<b>1 (0.14%)</b>
Not tuberculosis	0	0	0	3 (2%)	0	<b>3 (0.41%)</b>
Death	0	4 (2%)	0	2 (1%)	5 (2%)	<b>11 (2%)</b>
Treatment incomplete	1 (3%)	4 (2%)	1 (0.83%)	6 (4%)	9 (4%)	<b>24 (3%)</b>
Lost to follow-up/unknown	3 (8%)	24 (11%)	3 (3%)	5 (4%)	9 (4%)	<b>44 (6%)</b>

**COMMON PROTOCOL | COHORT B FINAL OUTCOME STATUS  
DATA UP TO DECEMBER 2019**

DESCRIPTION	REPORT SITES (SITE NUMBER)				TOTAL
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	
Number enrolled in Common Protocol (n)	<b>191</b>	<b>229</b>	<b>259</b>	<b>219</b>	<b>898</b>
No TB	0	42 (18%)	49 (19%)	0	<b>91 (10%)</b>
Definite case	0	1 (0.44%)	3 (1%)	2 (0.91%)	<b>5 (0.56%)</b>
Probable case	0	0	5 (2%)	0	<b>5 (0.56%)</b>
Possible case	0	0	0	0	<b>0</b>
Death	0	0	0	0	<b>0</b>
Lost to follow-up/ unknown	3 (2%)	1 (0.44%)	5 (2%)	15 (7%)	<b>24 (3%)</b>

**COMMON PROTOCOL | DEMOGRAPHICS  
DATA UP TO DECEMBER 2019**

Description	RePORT Sites (Site Number)								
	CMC (101)	JIPMER (102)		MVDRC (103)	NIRT (105)		BJGMC (106)		BMMRC (107)
	Cohort A	Cohort A	Cohort B	Cohort A	Cohort A	Cohort B	Cohort A	Cohort B	Cohort B
Enrolled in Common Protocol (n)	40	214	191	120	134	229	216	259	219
Age, Median (Min – Max)	37.5 (18-73)	44 (16-79)	28 (7-75)	41.5 (17-60)	43 (15-69)	33 (0-72)	28 (5-67)	27 (1-67)	28 (9-60)
Male participants	26 (65%)	160 (79%)	62 (32%)	83 (69%)	101 (75%)	85 (37%)	125 (58%)	123 (47%)	99 (45%)
Female participants	14 (35%)	40 (20%)	129 (68%)	37 (31%)	33 (25%)	144 (63%)	91 (42%)	136 (53%)	120 (55%)
Pregnant women	0	0	0	0	0	0	0	1 (0.39%)	0

**COMMON PROTOCOL | COHORT A CULTURE RESULTS  
DATA UP TO DECEMBER 2019**

DESCRIPTION	STUDY VISITS							
	BASELINE	MONTH 1	MONTH 2	MONTH 3	MONTH 6	END OF TREATMENT	TREATMENT FAILURE/ RELAPSE/ WITHDRAWAL	TB ACTIVATION EVAL
<b>Solid Culture Results</b>								
Negative for Mycobacterium tuberculosis complex	144	340	393	0	0	294	29	11
Positive for Mycobacterium tuberculosis complex	393	114	24	0	0	6	17	1
Positive for non-tuberculosis mycobacteria (NTM)	9	14	14	0	0	16	0	0
Contaminated	28	39	51	0	0	53	5	1
<b>Liquid Culture Results</b>								
Negative for Mycobacterium tuberculosis complex	68	252	383	0	0	317	26	11
Positive for Mycobacterium tuberculosis complex	524	217	46	0	0	22	18	1
Positive for non-tuberculosis mycobacteria (NTM)	7	7	4	0	0	7	0	0
Contaminated	31	73	68	0	0	66	2	2

**COMMON PROTOCOL | COHORTS A & B CO-ENROLLMENT STATUS  
DATA UP TO DECEMBER 2019**

DESCRIPTION	SITES									TOTAL	
	CMC (101)	JIPMER(102)		MVDRC (103)	NIRT (105)		BJGMC (106)		BMMRC (107)		
	Cohort A	Cohort A	Cohort B	Cohort A	Cohort A	Cohort B	Cohort A	Cohort B	Cohort B	Cohort A	Cohort B
<b>Co-Enrolled Study</b>											
Enrolled in Common Protocol (n)	40	214	191	120	134	229	216	259	219	724	898
Protocol 1 (VPM 1002-IN-3.01 TBR)							11			11	—
Protocol 2 (Depression Module)	2						38	26	33	40	59
Protocol 3 (TB Pregnancy)		16								16	
Protocol 4 (vaccine protocol trial)				2						2	
Protocol 5											
Protocol 6											
Protocol 7											
Protocol 8											
Protocol 9											

**COMMON PROTOCOL | COHORT B IGRA TESTING RESULTS  
DATA UP TO DECEMBER 2019**

BASELINE	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	TOTAL
<b>Enrolled in Common Protocol</b>	<b>191</b>	<b>229</b>	<b>259</b>	<b>219</b>	<b>898</b>
IGRA expected	191	229	259	219	898
IGRA performed	188 (98%)	228 (100%)	257 (99%)	219 (100%)	892 (99%)
IGRA positive results	109 (58%)	134 (59%)	155 (60%)	104 (47%)	502 (56%)
IGRA negative results	73 (39%)	93 (41%)	98 (38%)	114 (52%)	378 (42%)
IGRA indeterminate	6 (3%)	1 (0.44%)	4 (2%)	1 (0.46%)	12 (1%)
<b>MONTH 4-6</b>	<b>JIPMER (102)</b>	<b>NIRT (105)</b>	<b>BJGMC (106)</b>	<b>BMMRC* (107)</b>	<b>TOTAL</b>
IGRA expected	79	94	102	0	275
IGRA performed	23 (29%)	31 (33%)	79 (77%)	0	133 (48%)
IGRA positive results	2 (9%)	7 (23%)	15 (19%)	0	24 (18%)
IGRA negative results	20 (87%)	24 (77%)	60 (76%)	0	104 (78%)
IGRA indeterminate	1 (4%)	0	4 (5%)	0	5 (4%)
<b>MONTH 12</b>	<b>JIPMER (102)</b>	<b>NIRT (105)</b>	<b>BJGMC (106)</b>	<b>BMMRC (107)</b>	<b>TOTAL</b>
Complete IGRA expected (M12 follow up)	56	63	23	115	257
IGRA expected (Includes # to be retested, and M12 pending follow up)	77	87	87	115	366
IGRA performed	34 (44%)	14 (16%)	30 (34%)	50 (43%)	128 (35%)
IGRA positive results	0	6 (43%)	2 (7%)	10 (9%)	18 (14%)
IGRA negative results	28 (82%)	7 (50%)	28 (93%)	36 (31%)	99 (77%)
IGRA indeterminate	6 (18%)	0	0	4 (3%)	10 (8%)
IGRA negative at M4-6 Retest expected at M12	21	24	64	0	109
IGRA negative at M4-6 Retest complete at M12	18	0	15	0	33
IGRA negative at M4-6, positive at M12	0	0	0	0	0
IGRA negative at M4-6, negative at M12	18	0	15	0	33
IGRA indeterminate	0	0	0	0	0

## COMMON PROTOCOL | COHORT B DEMOGRAPHICS

DESCRIPTION	STUDY SITES (SITE NUMBER)							
	JIPMER (102)		NIRT (105)		BJGMC (106)		BMMRC (107)	
	Household Members	Actual Enrolled	Household Members	Actual Enrolled	Household Members	Actual Enrolled	Household Members	Actual Enrolled
	671	191	961	229	1254	259	1225	219
Children ( Age ≤15)		37		32		63		8
Male		62		85		123		99
Female		129		144		136		120
Pregnant		0		0		1		0
HIV		0		0		4		0
Diabetes		0		0		0		0

## COMMON PROTOCOL | COHORTS A & B TB DIAGNOSTIC TEST

DESCRIPTION	STUDY SITES (SITE NUMBER)									TOTAL	
	CMC (101)	JIPMER (102)		MVDRC (103)	NIRT (105)		BJGMC (106)		BMMRC (107)		
	Cohort A	Cohort A	Cohort B	Cohort A	Cohort A	Cohort B	Cohort A	Cohort B	Cohort B	Cohort A	Cohort B
<b>SMEAR TEST</b>											
Expected*	153	815	11	701	514	2	781	12	0	2964	25
Performed	144 (94%)	698 (86%)	0	701 (100%)	512 (100%)	2 (100%)	781 (100%)	12 (100%)	0	2836 (96%)	14 (56%)
Positive Results	42 (29%)	254 (36%)	0	276 (39%)	228 (45%)	1 (50%)	133 (17%)	4 (33%)	0	933 (33%)	5 (36%)
Negative Results	102 (71%)	444 (64%)	0	425 (61%)	284 (55%)	1 (50%)	648 (83%)	8 (67%)	0	1903 (67%)	9 (64%)
<b>LJ CULTURES</b>											
Expected*	153	815	11	701	514	2	781	12	0	2964	25
Performed	1 (1%)	0	0	701 (100%)	512 (100%)	2 (100%)	781 (100%)	12 (100%)	0	1995 (67%)	14 (56%)
Positive Results**	1 (100%)	0	0	256 (37%)	109 (21%)	0	188 (24%)	1 (8%)	0	554 (28%)	1 (7%)
Negative Results	0	0	0	369 (53%)	268 (52%)	1 (50%)	567 (73%)	10 (83%)	0	1204 (60%)	11 (79%)
Contaminated	0	0	0	40 (6%)	117 (23%)	0	20 (3%)	1 (8%)	0	177 (9%)	1 (7%)
<b>MIGIT CULTURES</b>											
Expected*	153	815	11	701	514	2	781	12	0	2964	25
Performed	143 (93%)	698 (86%)	11 (100%)	0	512 (100%)	2 (100%)	781 (100%)	12 (100%)	0	2134 (72%)	25 (100%)
Positive Results**	53 (37%)	301 (43%)	0	0	208 (41%)	0	267 (34%)	1 (8%)	0	829 (39%)	1 (4%)
Negative Results	90 (63%)	291 (42%)	6 (55%)	0	195 (38%)	1 (50%)	468 (60%)	10 (83%)	0	1044 (49%)	17 (68%)
Contaminated	0	106 (15%)	5 (45%)	0	85 (17%)	1 (50%)	47 (6.02%)	1 (8%)	0	238 (11.15%)	7 (28%)

## COMMON PROTOCOL | COHORT A # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE

DESCRIPTION	BASELINE						I M					
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	TOTAL	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	TOTAL
E/R**	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	40	214	120	134	216	724	40	214	120	134	216	724
Number of visits done	40	214	120	134	216	724	39	189	111	128	194	661
Plasma	40	214	120	131	215	720	37	189	107	128	192	653
PAX gene	40	213	119	134	214	720	37	189	105	128	191	650
PBMCs	40	213	119	134	214	720	37	189	107	128	190	651
DNA	40	213	120	134	215	722	0	0	0	0	0	0
Urine	40	213	120	134	215	722	38	189	107	128	192	654
Saliva	38	212	119	134	215	718	0	0	0	2	0	2
Sputum	40	213	120	132	215	720	38	189	108	120	194	649
Mtb isolates	31	205	103	104	175	618	0	0	0	0	0	0
QGIT	0	0	0	0	0	0	0	0	0	0	0	0
Gastric aspirate	0	0	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT A # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	2 M						3 M					
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	TOTAL	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	TOTAL
E/R**	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	40	214	120	134	216	724	40	214	120	134	216	724
Number of visits done	35	161	105	126	185	612	0	0	1	0	0	1
Plasma	35	161	103	126	185	610	0	0	0	0	0	0
PAX gene	35	161	103	125	184	608	0	0	0	0	0	0
PBMCs	35	160	103	126	184	608	0	0	0	0	0	0
DNA	35	161	103	115	185	599	0	0	0	0	0	0
Urine	35	161	104	125	184	609	0	0	0	0	0	0
Saliva	0	0	0	0	0	0	0	0	0	0	0	0
Sputum	35	159	105	118	185	602	0	0	0	0	0	0
Mtb isolates	0	0	0	0	0	0	0	0	0	0	0	0
QGIT	0	0	0	0	0	0	0	0	0	0	0	0
Gastric aspirate	0	0	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT A # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	6 M						END OF TREATMENT					
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Total	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Total
E/R**	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	40	214	120	134	216	724	40	214	120	134	216	724
Number of visits done	0	0	0	0	0	0	33	142	93	109	140	517
Plasma	0	0	0	0	0	0	33	141	92	102	129	497
PAX gene	0	0	0	0	0	0	33	141	92	90	129	485
PBMCs	0	0	0	0	0	0	33	141	91	109	129	503
DNA	0	0	0	0	0	0	33	141	92	92	129	487
Urine	0	0	0	0	0	0	33	142	93	95	131	494
Saliva	0	0	0	0	0	0	33	140	93	102	131	499
Sputum	0	0	0	0	0	0	0	0	0	0	0	0
Mtb Isolates	0	0	0	0	0	0	0	0	0	7	0	7
QGIT**	0	0	0	0	0	0	0	0	0	0	0	0
Gastric aspirate**	0	0	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT A # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	TREATMENT FAILURE						RELAPSE					
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Total	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Total
E/R**	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	40	214	120	134	216	724	40	214	120	134	216	724
Number of visits done	0	5	3	9	9	26	0	0	4	2	3	9
Plasma	0	5	3	6	9	23	0	0	4	2	3	9
PAX gene	0	5	3	6	9	23	0	0	4	2	3	9
PBMCs	0	5	3	9	9	26	0	0	4	1	3	8
DNA	0	5	3	6	9	23	0	0	4	2	3	9
Urine	0	5	3	6	9	23	0	0	4	2	3	9
Saliva	0	5	3	7	9	24	0	0	4	2	3	9
Sputum	0	5	3	0	9	17	0	0	2	0	3	5
Mtb isolates	0	1	1	4	5	11	0	0	0	0	1	1
QGIT	0	0	0	0	0	0	0	0	0	0	0	0
Gastric aspirate	0	0	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT B # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019**

DESCRIPTION	BASELINE					4 -6 M				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
E/R **	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	191	229	259	219	898	191	229	259	219	898
Number of visits done	191	229	259	219	898	86	223	217	219	745
Plasma	187	229	259	219	894	14	45	82	0	141
PAX gene	187	225	257	219	888	14	42	82	0	138
PBMCs	187	225	255	219	886	14	44	83	0	141
DNA	187	226	256	219	888	14	45	82	0	141
Urine	188	227	257	219	891	14	45	83	0	142
Saliva	188	234	257	219	898	14	46	83	0	143
Sputum	9	0	0	0	9	0	0	0	0	0
Mtb isolates	0	0	0	0	0	0	0	0	0	0
QGIT	188	234	258	219	899	14	30	82	0	126
Gastric aspirate	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT B # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	12 M					24 M				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
E/R **	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	191	229	259	219	898	191	229	259	219	898
Number of visits done	142	196	198	141	677	0	32	50	0	82
Plasma	21	25	25	55	126	0	0	2	0	2
PAX gene	21	25	25	55	126	0	0	2	0	2
PBMCs	21	29	26	55	131	0	0	3	0	3
DNA	21	26	25	55	127	0	0	2	0	2
Urine	21	25	26	55	127	0	0	2	0	2
Saliva	21	26	24	55	126	0	0	2	0	2
Sputum	0	0	0	0	0	0	0	0	0	0
Mtb isolates	0	0	0	0	0	0	0	0	0	0
QGIT	21	30	23	55	129	0	0	2	0	2
Gastric aspirate	0	0	0	0	0	0	0	0	0	0

**COMMON PROTOCOL | COHORT B # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	12 M					24 M				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
E/R **	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R	E/R
Enrolled in Common Protocol (n)	191	229	259	219	898	191	229	259	219	898
Number of visits done	142	196	198	141	677	0	32	50	0	82
Plasma	21	25	25	55	126	0	0	2	0	2
PAX gene	21	25	25	55	126	0	0	2	0	2
PBMCs	21	29	26	55	131	0	0	3	0	3
DNA	21	26	25	55	127	0	0	2	0	2
Urine	21	25	26	55	127	0	0	2	0	2
Saliva	21	26	24	55	126	0	0	2	0	2
Sputum	0	0	0	0	0	0	0	0	0	0
Mtb isolates	0	0	0	0	0	0	0	0	0	0
QGIT	21	30	23	55	129	0	0	2	0	2
Gastric aspirate	0	0	0	0	0	0	0	0	0	0



**COMMON PROTOCOL | COHORT B # PARTICIPANTS WITH STORED SPECIMENS AVAILABLE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	TB ACTIVATION & EVALUATION				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
<b>E/R **</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>
Enrolled in Common Protocol (n)	191	229	259	219	898
Number of visits done	0	1	12	2	15
Plasma	0	0	10	2	12
PAX gene	0	0	10	2	12
PBMCs	0	0	10	2	12
DNA	0	0	10	2	12
Urine	0	0	11	2	13
Saliva	0	0	11	0	11
Sputum	0	0	13	0	13
Mtb isolates	0	0	1	0	1
QGIT	0	0	10	0	10
Gastric aspirate	0	0	0	0	0

**COMMON PROTOCOL | COHORT B BANKED SPECIMENS BY VISIT TYPE | DATA UP TO DECEMBER 2019 CONTINUED**

DESCRIPTION	TB ACTIVATION & EVALUATION				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
<b>E/R **</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>	<b>E/R</b>
Enrolled in Common Protocol (n)	191	229	259	219	898
Number of visits done	0	1	12	2	15
Plasma	0	0	10	2	12
PAX gene	0	0	10	2	12
PBMCs	0	0	10	2	12
DNA	0	0	10	2	12
Urine	0	0	11	2	13
Saliva	0	0	11	0	11
Sputum	0	0	13	0	13
Mtb isolates	0	0	1	0	1
QGIT	0	0	10	0	10
Gastric aspirate	0	0	0	0	0

**COMMON PROTOCOL | COHORTS A & B OUTCOMES PER CRU DATA UP TO DECEMBER 2019**

COHORT A OUTCOMES	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	BMMRC (107)	TOTAL
Enrolled in Common Protocol (n)	40	214	120	134	216		724
TB Tx failure	8	27	17	29	34		115
TB recurrence	0	0	0	0	5		5
TB death	0	4	0	2	5		11
MDR TB cases**							
COHORT B OUTCOMES	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	BMMRC (107)	TOTAL
Enrolled in Common Protocol (n)		191		229	259	219	898
TB incidence		0		0	5	0	5



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# Young Investigator Abstracts

**RePORT India**

**9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING**

**NEXT GEN RePORT**

**MUMBAI | 10-12 FEB 2020**

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## YOUNG INVESTIGATOR ABSTRACTS

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## **ABSTRACT 1: Metformin use is associated with diminished plasma cytokines/ chemokines and acute phase proteins in incident tuberculosis with known diabetes mellitus**

**Submitting Author:** Arul Nancy

**Co-authors:** Nathella Pavan Kumar, Kadar Moideen, Vijay Viswanathan, Mythili Dhanasekaran, Shanmugam Sivakumar, Syed Hissar, Hardy Kornfeld, Subash Babu

**Background & Rationale:** Metformin use is associated with decreased risk of tuberculosis (TB) and decreased risk of mortality during TB treatment in diabetic individuals. However, very little is known about the underlying cytokine/chemokine and acute phase protein responses associated with metformin use in TB-diabetes co-morbidity.

**Methods:** To study the association of metformin use and plasma cytokines/ chemokines, and acute phase proteins, we measured the levels of a panel of cytokines/ chemokines and acute phase proteins in Type 2 diabetes mellitus (DM) individuals with newly diagnosed pulmonary TB either with (n=50) or without (n=48) history of prior metformin use.

**Results:** Metformin users were not significantly different from non-metformin users in terms of demographics, including age and gender, BMI, duration of known diabetes nor in terms of clinical presentation of TB, including smear or culture grade and radiological extent of disease or cavitation. Prior metformin use was also not associated with any differences in biochemical parameters including fasting blood glucose, HbA1c levels or lipid profiles (Table 1). However, plasma levels of IFN $\gamma$ , TNF $\alpha$ , IL-2, IL-17A, IL-1 $\alpha$ , IL-1 $\beta$ , IL-6, IL-12 and IL-10 were significantly lower in metformin users compared to non-metformin users. Similarly, plasma levels of CCL4, CXCL1, CXCL2, CXCL10 and CXCL11 were significantly lower in metformin users compared to non-metformin users. In addition, the plasma levels of acute phase proteins – CRP and  $\alpha$ 2 macroglobulin but not haptoglobin or serum amyloid P were significantly lower in metformin users compared to non-metformin users. Finally, PCA analysis using the parameters of IFN $\gamma$ , IL-2, IL-17A, IL-1 $\alpha$ , IL-1 $\beta$ , IL-6, IL-12 and CRP showed clearly discrimination between metformin users and non-users.

**Conclusions & Recommendations:** Our data demonstrate that systemic inflammatory markers, including pro-inflammatory cytokines/chemokines and acute phase proteins are significantly down-modulated in metformin users with TB-DM co-morbidity, a finding that could have potential implications in pathogenesis.

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## **ABSTRACT 2: Dried plasma spots as a replacement for conventional plasma rifampicin concentration for use in resource limited settings**

**Submitting Author:** Samuel Santhosh

**Co-authors:** Blessed Winston, Devasahayam J Christopher, Ratna Prabha, Sumith Mathew, Deepa Shankar, Binu Susan Mathew

**Background & Rationale:** Rifampicin, the cornerstone of Anti-Tubercular therapy(ATT), is known to have high inter-individual variability in plasma levels achieved. The expected therapeutic range for Rifampicin plasma concentration (C<sub>max</sub>) is 8-24 ug/ml. However in one of our previous studies in a pediatric population it was not achieved in 77% using the recommended doses under the National control programme (RNTCP) I

Peripheral clinics which treat TB, do not have the infrastructure or access for monitoring plasma Rifampicin concentrations. Thus, we planned to study the role of Dried Plasma Spots (DPS) for the measurement of Rifampicin concentration, since it has the advantage of easier storage and transport, and reduced biohazard risk, without the need of cold chain. It opens up the possibility of testing programme patients at remotely located reference labs.

**Methods:** Patients diagnosed with Pulmonary or Extra pulmonary Tuberculosis and have completed one month of ATT, were recruited in to the study, after obtaining written informed consent. On the day of the test, 2 ml of blood was withdrawn two hours after the administration of Rifampicin, and the plasma was separated and stored at -80°C and 40 ul was spotted on the Whatman™ filter paper (DPS). The rifampicin concentration was

measured in the plasma samples by HPLC method. The benefit of using plasma was that it avoided the influence of haematocrit on the accuracy of this assay. A newly developed and validated HPLC method was used to measure DPS rifampicin concentration. The correlation between plasma and DPS rifampicin concentrations was estimated.

**Results:** A total of 46 patients were recruited. The sample from the 26 patients were used to develop an equation to predict the plasma rifampicin concentrations from the Dried Plasma Concentration (Predicted Plasma Concentration =  $0.96 + 1.15 \text{ (DPS)}$ ) with an Intraclass correlation coefficient (ICC) consistency of 0.97 (CI 0.93-0.98). This equation was validated on the samples from the subsequent 20 patients, with ICC agreement of 0.96 (CI 0.89 – 0.98). A Bland Altman plot showed 90% of the values from the predicted plasma concentration were within 2 standard deviation.

**Conclusion:** We have shown that DPS could be an effective alternative to plasma rifampicin concentration. This has tremendous potential for use in the RePORT sites and for implementation in the National Control Programme.

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### **ABSTRACT 3: Total lung and diffusing capacity in treated pulmonary tuberculosis patients**

**Submitting Author:** Dhivya Roy

**Co-authors:** Deepa Shankar, Balamugesh Thangakunam, Devasahayam J Christopher

**Background & Rationale:** In many patients with Pulmonary TB (PTB) even after attaining microbiological cure residual lung scarring leads to functional impairment. The few studies that have evaluated the physiological impact of TB on lung function have confined themselves to spirometric measurements. Advanced lung function parameters – Total lung capacity (TLC) & Diffusing lung capacity for carbon monoxide (DLco) have not been used in studies. This study aims to assess the DLco and TLC in PTB patients during and after completion of ATT.

**Methods:** This is a prospective cohort study conducted at the department of pulmonary medicine, CMC Vellore, a tertiary care center. Eighty four consecutive newly diagnosed PTB patients, with no previous history of PTB or underlying chronic lung disease & who fulfilled other entry criteria were recruited. Spirometry was performed at baseline and at 2 and 6 months post treatment initiation, DLco and TLC were performed in addition to Spirometry.

**Results:** The mean age was 41 years and BMI was 19kg/m<sup>2</sup>, 65 % were males. Post treatment completion 44% had restrictive ventilatory abnormality and 28 % had impaired diffusing capacity. The mean TLC at 2nd month was 74.16 % of predicted, which improved to 78.48 (p =0.03) and the corresponding DLco change was from 7.15 to 7.22(p=0.38). Those with cavity had lower mean TLC (3.42 Vs 4.66) & DLco (7.15Vs7.22) at 6 months. Restriction as assessed by spirometry over diagnosed restrictive impairment in 5(6%).

**Conclusions:**

- A substantial number of patients had residual Restrictive abnormality and impaired DLco.
- With treatment TLC and not DLco improved.
- Spirometry alone over diagnosed restrictive impairment.

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### **ABSTRACT 4: A study on lung function impairment in patients with pulmonary tuberculosis and changes with treatment**

**Submitting Author:** Dhivya Roy

**Co-authors:** Devasahayam J Christopher, Balamugesh Thangakunam

**Background and Rationale:** In many patients microbiological cure after Pulmonary TB (PTB) treatment may not be complete cure, and the morbidity may continue as a result of residual lung scarring. Lung function

changes at baseline and the impact of anti-TB treatment on lung function recovery has not been adequately assessed. Our study was designed to assess the change in lung function through the course of disease, characterize the ventilatory defects and correlate impairment with chest x-ray (CXR) scores and quality of life (QOL) as assessed through SGRQ scores.

**Methods:** This is a prospective cohort study conducted in the department of pulmonary medicine at Christian Medical College, Vellore. Eighty four consecutive patients with newly diagnosed PTB with no previous history of PTB or underlying chronic lung disease were recruited. Demographic & clinical information was captured. Spirometry was performed at baseline and 2 and 6 months post treatment initiation. The spirometric indices were compared with radiology and SGRQ scores.

**Results:** At baseline 63% of patients had ventilatory impairment of which 54 % had restrictive defect and 9% obstructive defect. Both FEV1 & FVC improved with treatment, and this was statistically significant. After treatment completion ventilatory defect persisted in 53%, restrictive defect in 44% and obstructive in 9%. There was significant correlation of lung function impairment with baseline CXR scores & SGRQ scores.

**Conclusion and Recommendations:**

- Despite improvement of lung function with treatment more than half were left with residual lung function impairment.
- The predominant ventilatory defect was Restrictive not Obstructive as per popular belief.
- It appears imperative that Spirometry should be performed on all patients completing ATT to assess residual lung function impairment.

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**ABSTRACT 5: Memory like NK cells and monocytes as immunological markers for protection in household contacts of tuberculosis patients**

**Submitting Author:** Sanjeev Kumar

**Co-authors:** Venkata Sanjeev Kumar Neela, Kamakshi Prudhula Devalraju, Mohammad Soheb Ansari, Ramakrishna Vankayalapati, Vijaya Lakshmi Valluri

**Background:** Evaluating incident tuberculosis infection (TBI) in household contacts (HHC) of tuberculosis (TB) cases in high burden settings such as India is vital for TB biomarker and vaccine development.

**Background & Rationale:** Mycobacterium tuberculosis (M.tb) causes almost 1.4 million deaths annually. House hold contacts (HHCs) of TB patients are at a higher risk of developing latent or active TB due to definitive exposure. NK cells play a key role in immune response against M.tb by controlling the infection due to their cytotoxic activity. Monocytes (CD14+CD16+ cells) were found to secrete pro-inflammatory cytokines for arresting M.tb growth and activation of T cells. Not all HHCs exposed to M.tb develop active TB disease. We determined if these cell populations can identify resistors of TB infection among house hold contacts of TB patients.

**Methods:** PBMCs (Peripheral Blood Mononuclear Cells) were isolated from blood (20 mL) collected from HHCs of TB patients. Immunophenotyping of memory like NK cells, monocytes and T regulatory cells was performed by flow cytometry. Remaining PBMC were cultured with ESAT6 and CFP-10 for 96 hours. IFN- $\gamma$  levels were measured in culture supernatants by ELISA. These experiments were repeated after every 4 months for 2 years.

**Results:** In response to M.tb antigens (CFP-10 and ESAT-6) PBMC from LTBI- HHCs who remained LTBI- expressed steady levels of IFN- $\gamma$  at baseline and consecutive follow ups. At baseline the percentages of CD3-CD56+CD27+CCR7+ and CD14+CD16+ cells however, were high ( $p < 0.05$ ) in LTBI- who remained LTBI- compared to those who converted to LTBI+.

**Conclusion & Recommendations:** High CD3-CD56+CCR7+CD27+ and CD14+CD16+ cells in LTBI- who remained LTBI- indicate robust innate immune responses and can be used as an immune correlate of protection against TB. Further studies determining the underlying mechanisms of the cell expansion would help in better understanding of host pathogen interactions and interventions.

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## **ABSTRACT 6: BCG vaccination reduces the mortality of Mycobacterium tuberculosis-infected type 2 diabetes mellitus (T2DM) mice**

**Submitting Author:** Rajesh Kumar Radhakrishnan

**Co-authors:** Ramya Sivangala Thandi, Deepak Tripathi, Padmaja Paidipally, Madeline Kay McAllister, Sachin Mulik, Buka Samten, Ramakrishna Vankayalapati

**Background & Rationale:** Type 2 diabetes mellitus (T2DM) alters host innate and adaptive immune responses against tuberculosis (TB) and making the host more susceptible to develop active TB disease. There is no information available about vaccine induced protective immune responses against TB in T2DM host. In several developing countries BCG is given upon birth and developing nations are epicenters of diabetes. In the current study, we investigated the effects of prior BCG vaccination on the immune responses and survival of T2DM mice infected with Mycobacterium tuberculosis (Mtb).

**Methods:** C57BL/6 mice were vaccinated with BCG subcutaneously or treated with PBS. Three months later some mice were induced with T2DM using streptozotocin and nicotinamide. One month after the induction of T2DM fifty percent of all groups of mice were challenged with Mtb. One and four-months post Mtb infection, we determined immunopathology, cytokines/chemokines levels by multiplex ELISA and immunophenotyping by flow cytometry, qPCR and confocal microscopy.

**Results:** We found that at 6-7 months post-Mtb infection, 90% of the Mtb infected T2DM mice died, whereas only 50% of BCG-vaccinated T2DM-Mtb-infected mice died. Moreover, 40% of the PBS-treated uninfected T2DM mice and 30% of the uninfected BCG-vaccinated T2DM mice died, whereas all uninfected and infected nondiabetic mice survived. BCG vaccination was less effective in reducing the lung bacterial burden of Mtb infected T2DM mice compared to Mtb-infected nondiabetic mice. BCG vaccination significantly reduced lung inflammation in Mtb-infected T2DM mice compared to that of unvaccinated T2DM mice infected with Mtb. Furthermore, reduced mortality of BCG vaccinated Mtb infected T2DM mice is associated with expansion of IL-13 producing CXCR3+ T-regulatory cells in the lungs of Mtb-infected T2DM mice. Recombinant IL-13 and T-regulatory cells from BCG vaccinated Mtb-infected T2DM mice converted pro-inflammatory M1 macrophages to anti-inflammatory M2 macrophages.

**Conclusions & Recommendations:** In conclusion, we found that BCG vaccination of Mtb-infected T2DM mice enhanced survival and reduced inflammation. The enhanced survival of BCG-vaccinated T2DM mice infected with Mtb was associated with the expansion of a subset of CXCR3-expressing and IL-13-producing T-regulatory cells. Further understanding of this BCG mediated immunosuppressive mechanisms will help to develop an adequate prophylactic or therapeutic agent to prevent inflammation and mortality of the T2DM host infected with Mtb.

We are planning to determine BCG induced protective immune responses of T2DM household contacts of TB patients using RePORT-India cohort samples.

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## **ABSTRACT 7: Elevated unstimulated and TB antigen stimulated levels of IL-36 isoforms in tuberculosis-diabetes comorbidity**

**Submitting Author:** Nathella Pavan Kumar

**Co-authors:** Arul Nancy, Kadar Moideen, Vijay Viswanathan, Mythili Dhanasekaran, Shanmugam Sivakumar, Syed Hissar, Hardy Kornfeld, Subash Babu

**Background & Rationale:** The IL-36 subfamily comprises the proinflammatory molecules IL-36 $\alpha$ , IL-36 $\beta$  and IL-36 $\gamma$  and the putative IL-36 receptor antagonist (IL-36Ra). The signaling through a specific IL-36 receptor (IL-36R) induces type I immune responses, which are critical for control of intracellular bacterial pathogens like Mycobacterium tuberculosis (M.tb). Published studies have reported that IL-36 production is triggered by M.tb

infection, and that IL-36 plays a critical role in limiting bacterial growth. However a detailed examination of the association of IL-36 family in active and latent tuberculosis-diabetes comorbidity (TB-DM) remains elusive.

**Methods:** To study this, we examined the unstimulated as well as TB-antigen and mitogen stimulated levels of IL-36 isoforms in active TB with (TB-DM) or without (TB) diabetes and also those with latent TB with (LTB-DM) or without (LTB) diabetes.

**Results:** Active TB individuals exhibited a significantly increased net cytokine levels of IL-36 $\beta$  and IL-36 $\gamma$  upon TB antigen stimulation in comparison to LTB individuals. TB-DM individuals are characterized by significantly elevated – unstimulated levels and TB antigen stimulated net cytokine levels of IL-36 $\alpha$ , IL-36 $\beta$ , and IL-36 $\gamma$  in comparison to TB. However upon TB antigen stimulation, IL-36Ra was significantly diminished in TB-DM. Similarly, LTB-DM is also characterized by the elevated unstimulated levels of IL-36 $\beta$  and elevated TB antigen stimulated net cytokine levels of IL-36 $\alpha$ , IL-36 $\beta$  and IL-36 $\gamma$  in comparison to LTB. Moreover, there was a significant positive correlation of IL-36 $\alpha$ , IL-36 $\beta$ , and IL-36 $\gamma$  levels with hemoglobin A1C (HbA1c) levels in both PTB and/or LTB individuals with and without DM.

**Conclusions & Recommendations:** Our data on IL-36 isoforms suggest that upregulation of IL-36 $\alpha$ , IL-36 $\beta$  and IL-36 $\gamma$  are typical characteristics of TB-DM co-morbidity. Thus, the IL-36 family of cytokines might play an important role in pathogenesis of TB-DM.

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## ABSTRACT 8: Is smear microscopy obsolete in the era of Xpert MTB/Rif?

**Submitting Author:** Vedantam Rajasekar

**Co-authors:** Devasahayam J Christopher, Balamugesh Thangakunam

**Background:** Xpert MTB/RIF (Xpert), a cartridge based test has been a game changer in TB diagnosis with sensitivity of 97% in smear positive Pulmonary TB (PTB) and 74% in smear negative PTB, with a high specificity. It can also detect Rifampicin resistance. AFB smear microscopy (Smear) is an old technology, which has been the bedrock of PTB diagnosis in programmatic conditions. However its role has diminished with the advent of Xpert. The aim of this study is to assess the role of Smear, if Xpert is used as the first diagnostic test alongside smear.

**Methods:** We reviewed the results of all patients evaluated by the department of Pulmonary medicine, CMC, Vellore from 1 Jan 2018 to 31 Dec 2018, on whom sputum tests were ordered for the diagnosis of PTB. The following details were obtained from the electronic medical records of the hospital: clinical details, radiological features, results of Smear, Xpert, and Mycobacteria Culture (Culture).

**Results:** In all 11,673 sputum samples of 5609 patients were tested. The tests performed were 8766 smears, 2485 Xpert and 422 cultures. A total of 2043 patients had Xpert test and at least 2 Smears. Both tests were positive in 190, Xpert alone in 199 and Smear alone in only 4(2 were non tuberculous mycobacterial infection and 2 lost to follow up).

In 409 patients who had Xpert and Culture of which 287 grew Mycobacterium Tuberculosis (MTB), the sensitivity of Xpert with culture as gold standard (GS) was 94% (271/287). A total of 421 patients had 2 Smears and Culture of which 302 grew MTB, sensitivity of Smear with Culture as GS was only 55% (168/302).

**Conclusion:** Xpert yield was significantly higher than Smear, which did not add to yield. Xpert as the first diagnostic test could render Smear obsolete.

## **ABSTRACT 9: Innate immune mechanisms of protection against Mycobacterium tuberculosis infection**

**Submitting Author:** Vaishnavi Kaipilyawar

**Co-authors:** Sheetal Verma, Lorenzo Lyrio Stringari, Jerrold J. Ellner, David Alland, Reynaldo Dietze, Rodrigo Ribeiro-Rodrigues, Padmini Salgame

**Background & Rationale:** “Infection resistant” (IR) individuals are defined as individuals who despite significant exposure to Mycobacterium tuberculosis remain asymptomatic and persistently unreactive to the Tuberculin Skin Test (TST) and Interferon Gamma Release Assay (IGRA) detection assays, suggesting that they remain uninfected or rapidly clear their infection early on following exposure. Currently, it is unclear why these ‘infection resistant’ individuals remain uninfected despite repeated exposure to M. tuberculosis. Aim 4 of the Phase II RePORT India application proposes to characterize host factors underlying mycobacterial infection resistance and we present here our preliminary data that form the basis of these proposed studies.

**Methods:** A household contact (HHC) study conducted in Vitória, Brazil between 2008 and 2013 evaluated TB patients and their HHCs and identified them as ‘infection susceptible’ (IS) and ‘infection resistant’ (IR) based on serial TST and IGRA testing. PBMC from HHCs were infected ex-vivo with M. tuberculosis Beijing-HN878 and RNA-sequencing was conducted. Ingenuity Pathway Analysis (IPA) was applied to the gene expression data to identify differentially expressed genes and pathways in IR and IS PBMC following in vitro infection with M. tuberculosis.

**Methods:** A household contact (HHC) study conducted in Vitória, Brazil between 2008 and 2013 evaluated TB patients and their HHCs and identified them as ‘infection susceptible’ (IS) and ‘infection resistant’ (IR) based on serial TST and IGRA testing. PBMC from HHCs were infected ex-vivo with M. tuberculosis Beijing-HN878 and RNA-sequencing was conducted. Ingenuity Pathway Analysis (IPA) was applied to the gene expression data to identify differentially expressed genes and pathways in IR and IS PBMC following in vitro infection with M. tuberculosis.

**Results:** IPA pointed to upregulation of anti-mycobacterial innate immune response genes including IL-1 and IL-17 family cytokines and the differential regulation of cytokine production in macrophages and T helper cells as the dominant pathways activated in PBMCs from IR HHC. In contrast, PBMC from IS HHC demonstrated an upregulation of pro-inflammatory cytokine genes and upregulation of Th1/Th2 adaptive immune response pathways.

**Conclusions:** Our findings suggest that distinct protective immune pathways are activated in IR HHC and serve as the basis for studies proposed in Aim 4 of the Phase II RePORT India application. In particular, our studies focus on delineating the mechanistic basis of IL-1 and IL-17-mediated protective immune mechanisms that lead to the establishment of mycobacterial infection resistance.

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## **ABSTRACT 10: Monitoring household contacts of drug resistant tuberculosis patients for incident infection from the private sector in Mumbai: An ongoing study**

**Submitting Author:** Nisha Kharat

**Co-authors:** Ishita Gajjar, Jeffrey A. Tornheim, Namrata Sawant, Heeral Pandya, Shri Vijay Bala Yogendra Shivakumar, Prerna Chawla, Camilla Rodrigues, Tester Ashavaid, Amita Gupta, Zarir F Udawadia

**Background & Rationale:** Household contacts (HHCs) of active multi drug resistant tuberculosis (MDRTB) patients show variable response to exposure to tuberculosis. Some contacts remain uninfected while a few develop incident latent tuberculosis infection (LTBI), and others who develop active tuberculosis disease. Contact investigation involves the systematic evaluation of the contacts of known tuberculosis patients to identify active disease or LTBI. WHO has currently recommended contact investigation in two high-risk populations: children aged <5 years and people living with HIV infection.



**Methods:** The present study enrolls household contacts of pulmonary MDRTB patients exposed within 3 months of diagnosis. The HHC evaluation includes tuberculin skin test (TST), interferon gamma release assay (QGIT), chest X-ray, sputum to rule out active tuberculosis among HHCs. Psychosocial parameters assessed include residence in crowded urban setting, socioeconomic status, environmental, demographic, clinical, and psychosocial characteristics (e.g. age, sex, co-morbidities, tobacco, alcohol, malnutrition, depression).

**Results:** A total of 16 HHCs are enrolled so far, including 4 male and 12 females age 4 to 59 years. 12 HHCs are adults, whereas 4 are below 15 years. Of the 16 participants, 63% had a positive TST including 3 out of 4 children. The pediatric cases were referred further for evaluation. None of the HHCs showed any clinical signs or symptoms of tuberculosis, and none had chest X-ray findings concerning for tuberculosis. The samples are currently preserved for IGRA testing.

**Conclusions & Recommendations:** The high rate of TST positive results in this study suggest that HHCs are at a high risk to be infected with MDRTB. There is an important need to create awareness towards the risk of spread of disease among the family members of tuberculosis patients.

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## **ABSTRACT II: A case report on cycloserine induced late onset of psychosis and linezolid induced peripheral neuropathy in an adolescent with drug resistant tuberculosis from the private sector in Mumbai**

**Submitting Author:** Ishita N. Gajjar

**Co-authors:** Nisha Kharat, Jeffrey A Tornheim, Namrata Sawant, Heeral Pandya, Girija Kishore, Perna Chawla, Megha Karane, Samrin Sayed, Camilla Rodrigues, Tester Ashavaid, Amita Gupta, Zarir F Udwadia

**Background & Rationale:** Adverse events inevitably accompany all drug resistant tuberculosis treatment. Cycloserine is a bacteriostatic second-line anti-tuberculosis drug associated with neurological and psychiatric disturbances and causes side effects like dizziness, depression, anxiety, hallucinations and coma. Linezolid is also commonly used anti-tubercular with known side effects like anemia and peripheral neuropathy.

**Methods:** A case report of a 17-year old male patient diagnosed with drug resistant tuberculosis affecting both the lung and mediastinal lymph nodes in December 2017.

**Results:** The patient was started on multidrug-resistant tuberculosis treatment as per drug susceptibility testing that included linezolid 600mg once daily and cycloserine 250mg twice daily with kanamycin, moxifloxacin, clofazimine and para-aminosalicylic acid (PAS). The patient's initial weight was 57 kg, and his presenting vital signs, audiometry, electrocardiogram, complete blood count, creatinine, and liver function were normal. The patient complained about numbness and a burning sensation in both lower limbs after 6th months of treatment. He screened positive for neuropathy by 128 Hz vibration and monofilament sensation. Consequently linezolid was stopped in June 2018 (treatment month 6) due to neuropathy. The patient was continued with cycloserine, PAS, moxifloxacin and clofazimine. A few months after withdrawing linezolid the neuropathy was reversed, but he later complained of symptoms of depression and mild psychosis. The patient was counselled, but the symptoms did not subside, following which cycloserine was discontinued in May 2019 (treatment month 16). Eventually after discontinuing cycloserine, the symptoms subsided after starting the patient on anti-psychotic medicines. Samples have been preserved for pharmacokinetic-pharmacodynamic evaluation and their results may help understand the impact of drug concentration on his symptoms.

**Conclusions & Recommendations:** This was an interesting case where the importance of awareness about the psychiatric adverse drug event was observed. Early diagnosis of adverse event and timely treatment modification can improve the patient compliance and outcomes.

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## **ABSTRACT 12: Impact of cycloserine treatment on depression among patients treated for multidrug-resistant tuberculosis in the private sector in Mumbai**

**Submitting Author:** Ishita N Gajjar

**Co-authors:** Jeffrey A. Tornheim, Nisha Kharat, Girija Kishore, Shri Vijay Bala Yogendra Shivakumar, Prerna Chawla, Camilla Rodrigues, Tester Ashavaid, Amita Gupta, Zarir F Udawadia

**Background & Rationale:** Multidrug resistant tuberculosis (MDR-TB) and depression act synergistically to magnify the burden of disease. Cycloserine, while useful for MDR-TB treatment, is associated with psychiatric side effects including depression, insomnia, and psychosis. We assessed the impact of cycloserine treatment on symptoms of depression among MDR-TB patients in an ongoing cohort study in Mumbai.

**Methods:** Newly diagnosed adult and adolescents with MDR-TB were enrolled in an ongoing cohort study at a private hospital in Mumbai. Each participant completes a Patient Health Questionnaire-9 (PHQ-9) to assess depression at baseline, 2 weeks, 1, 2, 3, 4, 5, 6, 12, 18 and 24 months of treatment. PHQ-9 scores >9 were defined as “moderate or severe depression.” Generalized estimating equations were constructed to assess the association between moderate or severe depression at each visit and cycloserine prescription since the previous visit, controlling for dose and each participant’s previous PHQ-9 score.

**Results:** In total, 94 participants completed PHQ-9 scores during 476 visits. Of these, 65 (69.1%) were women with a median age of 26 years. Most had pulmonary disease (N=84, 89.4%), 9 (9.6%) had diabetes, and only 1 (1.1%) had HIV. 83 participants (88.3%) received cycloserine. Depression at enrolment was common, affecting 28 participants (29.8%), though median initial PHQ-9 scores were not different by cycloserine prescription (4 vs. 6,  $p=0.675$ ). Odds of depression were associated with higher cycloserine doses (odds ratio (OR)=1.64 for each 250mg daily,  $p=0.35$ ) but not with cycloserine prescription alone (OR=0.89,  $p=0.737$ ) or total cycloserine (OR=1.47,  $p=0.317$ ). Odds of moderate or severe depression were also associated with insomnia (OR=3.33,  $p=0.005$ ) and psychosis (OR=5.81,  $p=0.075$ ), though results were not significant.

**Conclusions & Recommendations:** In this ongoing cohort study, dose of cycloserine was significantly associated with moderate or severe depression. PHQ-9 screening can be useful to identify those MDR-TB patients who may benefit from additional support during treatment.

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## **ABSTRACT 13: Causes and timing of death among patients treated for tuberculosis in Pune and Chennai, India**

**Submitting Author:** Samyra R. Cox

**Co-authors:** Padmapriyadarsini Chandrasekaran, Sanjay Gaikwad, Aarti Kinikar, Shri Vijay Bala Yogendra Shivakumar, Mandar Paradkar, Krithikaa Sekar, Akshay Gupte, Bhavna Seth, Kannan Thiruvengadam, Swapnil Raskar, Neeta Pradhan, Vandana Kulkarni, Luke Elizabeth Hanna, Nikhil Gupte, Robert C. Bollinger, Vidya Mave, Amita Gupta, for the CTRIUMPH-RePORT India Study Team

**Background & Rationale:** 1.5 million people die of tuberculosis (TB) annually and India carries the highest burden of TB-related deaths worldwide. Even after completing treatment, evidence suggests that TB patients are at higher risk of death than the general population. We sought to characterize causes and timing of death among TB patients to better understand how to prevent premature mortality.

**Methods:** From 2014 to 2018, we enrolled newly diagnosed drug-sensitive pulmonary TB (PTB) or extrapulmonary TB patients from Pune and Chennai, India. Participants were followed for up to 24 months. To ascertain cause of death, study clinicians reviewed clinical records and death certificates, collected death narratives from contacts and treating clinicians, and used ICD-10 codes. Deaths with unknown causes were re-evaluated by an additional study clinician.

**Results:** Of 906 TB patients enrolled, 705 (78%) were adults (>15 years), 513 (57%) male, 68 (8%) HIV-infected, and 626 (69%) had PTB (Table 1). 49 (5%) participants died within a median follow-up of 12.7 months (IQR 5.0-18.1). 3 (6%) deaths occurred during intensive treatment, 10 (20%) during continuation, and 36 (73%) post-

treatment. 22 (61%) post-treatment deaths were TB-related (Figure 1). Among the deceased, 47 (96%) were adults, 39 (80%) male, 10 (20%) HIV-infected, and 38 (78%) had PTB. Of 29 (59%) TB-related deaths, 12 were patients who failed treatment and 3 had TB recurrence. Other causes were ischemic heart disease (3), other pulmonary disease (1), COPD (3), diabetes mellitus (1), suicide (1), malignancy (2), accident (2), and alcohol poisoning (1), and unknown (8).

**Conclusions & Recommendations:** Patients treated for TB are at high risk for premature death. The majority of deaths in this cohort were TB-related and occurred after treatment. All TB patients should be followed up on after treatment, with more intensive care for patients who fail treatment or have recurrent TB.

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#### **ABSTRACT 14: A sensitive PCR - Restriction Fragment Length Polymorphism (RFLP) method for the detection of leukotriene A4 hydrolase (LTA4H) rs17525495 genotyping**

**Submitting Author:** Raja Solomon

**Co-authors:** Christhunesa S. Christudass, Deepa Shankar, Balamugesh Thangakunam, Devasahayam J Christopher

**Background & Rationale:** Tuberculosis (TB), caused by mycobacterium tuberculosis (MTB), remains a world-wide health concern, especially so in developing countries. Arachidonic acid metabolic pathway plays an essential role in the balance of TB and immune system. Leukotriene A4 hydrolase (LTA4H) is a key enzyme in the pathway which catalyzes the generation of factor leukotriene B4 (LTB4), and the genetic variation of LTA4H affects the balance between pro-inflammatory and anti-inflammatory responses in the body. Many researchers confirmed that rs17525495 genotype affects LTA4H transcription and interferes with therapeutic outcomes of TB meningitis and extra-pulmonary tuberculosis. But till now studying this genotype is not easy except in a laboratory with infrastructure for either sequencing or real time PCR facilities. To overcome this problem, we have developed a sensitive PCR-RFLP method which can be performed even in laboratories without the aforementioned technology, using normal PCR.

**Methods:** Genomic DNA was isolated from the peripheral blood samples collected from 25 participants, using the QiaAmp Blood mini kit (Qiagen). Genotyping for LTA4H rs17525495 (C/T) polymorphism was carried out by PCR-RFLP method using the primers 5'-TTAAGAACTTCCTTTCCCGGC-3' and 5'-CCAACGAACAGGTATCCACTAT-3' and HpyAV restriction enzyme. The 175bp PCR product on digestion with HpyAV resulted in two fragments of 103bp and 72bp in the presence of T allele. Representative samples from CC, CT, and TT genotypes were further confirmed by sequencing the PCR product.

**Results:** We could identify CC genotype (175bp) in 12 samples, CT (175, 103 and 72bp) in 10 samples and TT (103 and 72bp) in 3 samples accurately on digestion with 2.5 units of enzyme [Figure 1] and they matched with the sequencing data.

**Conclusions & Recommendations:** We conclude that this PCR-RFLP method is sensitive, accurate and ideal for small laboratories and could pave the way for use in patient care.

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#### **ABSTRACT 15: Targeted next generation sequencing (tNGS) for detection of drug resistant mutations in TB**

**Submitting Author:** Priti Kambli

**Co-authors:** Kanchan Ajbani, Meeta Sadani, Mubin Kazi, Archana Khillari, Anjali Shetty, Jeffrey A Tornheim, Camilla Rodrigues

**Background & Rationale:** The Deeplex®-MycTB is an all-in-one targeted next generation sequencing (tNGS)-based *in vitro* diagnostics of *Mycobacterium tuberculosis* complex (MTBC) strains, directly applicable on clinical samples

**Methods:** To validate the Deeplex®-MycTB tNGS assay (GenoScreen, Lille, France) directly from clinical samples, we prospectively collected a convenience sample of 40 consecutive smear- and Xpert MTB/RIF-positive expectorated sputum samples at Hinduja Hospital in Mumbai, India. DNA extraction, sequencing, and secured cloud-based analysis were performed using the Deeplex®-MycTB platform. To validate tNGS results, the same samples were processed by Hain line probe assay (LPA), pyrosequencing (PSQ), and whole genome sequencing (WGS). Isolates grown from 39 samples completed phenotypic drug susceptibility testing (DST) in Mycobacteria Growth Indicator Tubes (MGIT). Resistance interpretation results were compared by method for each drug using the Fisher exact test.

**Results:** Of 39 participant samples analysed, 22 were obtained from female participants (56%). Median participant age was 35 years (interquartile range 18-62). All samples were obtained from HIV-negative participants with pulmonary tuberculosis. Results obtained by tNGS were not significantly different from Xpert MTB/RIF, LPA, PSQ, or MGIT results for rifampin, isoniazid, fluoroquinolones, amikacin, capreomycin, clofazimine, pyrazinamide, ethambutol, or linezolid. WGS analysis is ongoing.

DRUG	Resistant by tNGS	Resistant by Xpert MTB/RIF		Resistant by LPA		Resistant by PSQ		Resistant by MGIT	
	N (%)	N (%)	p-value vs. tNGS	N (%)	p-value vs. tNGS	N (%)	p-value vs. tNGS	N (%)	p-value vs. tNGS
RIF	30 (76.9%)	29 (74.4%)	1.000	27 (69.2%)	0.793	29 (74.4%)	1.000	29 (74.4%)	1.000
INH	28 (71.8%)	NA	NA	27 (69.2%)	1.000	27 (69.2%)	1.000	30 (76.9%)	0.796
FQ	21 (53.8%)	NA	NA	17 (43.6%)	0.450	19 (48.7%)	0.821	16 (41.0%)	0.365
KAN	6 (15.4%)	NA	NA	0 (0.0%)	0.025	3 (7.7%)	0.481	2 (5.1%)	0.263
AMI	2 (5.1%)	NA	NA	0 (0.0%)	0.494	1 (2.6%)	1.000	1 (2.6%)	1.000
CAP	3 (7.7%)	NA	NA	0 (0.0%)	0.240	1 (2.6%)	0.615	1 (2.6%)	0.615
ETH	9 (23.1%)	NA	NA	NA	NA	NA	NA	20 (51.3%)	0.018
CFZ	2 (5.1%)	NA	NA	NA	NA	NA	NA	0 (0.0%)	0.494
PZA	18 (46.2%)	NA	NA	NA	NA	NA	NA	25 (64.1%)	0.172
EMB	26 (66.7%)	NA	NA	NA	NA	NA	NA	27 (69.2%)	1.000
LZ	1 (2.6%)	NA	NA	NA	NA	NA	NA	1 (2.6%)	1.000
SM	25 (64.1%)	NA	NA	NA	NA	NA	NA	NA	NA
BDQ	2 (5.1%)	NA	NA	NA	NA	NA	NA	NA	NA

**Conclusions & Recommendations:** Deeplex®-MycTB provided similar results to those obtained by exiting technologies, with high-depth detection of resistance-associated mutations, including mixed infections. The comprehensive, rapid DST obtained through such platforms could reduce the need for phenotypic DST, especially for drugs for which phenotypic methods are often unreliable or unavailable, such as pyrazinamide and bedaquiline.

## ABSTRACT 16: Moxifloxacin levels in Indian MDR-TB patients

**Submitting Author:** Prasad Naik

**Co-authors:** Perna K. Chawla, Rohan V. Lokhande, Alpa J. Dherai, Zarir F. Udawadia, Ashok A. Mahashur, Lancelot Pinto, Mullerpattan Jai, Ayesha Sunavala, Rajeev Soman, Camilla Rodrigues, Amita Gupta, Jeffrey A Tornheim, Martinson Neil, Variava Ebrahim, Wiesner Lubbe, Joubert Anton, Tester F. Ashavaid

**Background & Rationale:** Multidrug resistant tuberculosis (MDR-TB) is one of the major health concerns in India. Moxifloxacin (Mfx) is a broad spectrum fluoroquinolone widely used in the treatment of MDR-TB. It is well absorbed from the gastrointestinal tract however it exhibits wide inter-individual variability and drug-drug interactions. There is limited literature on the pharmacokinetics of Mfx especially in MDR-TB patients where treatment monitoring and adherence play a vital role.

**Methods:** Mfx quantification was standardized and validated using liquid chromatography tandem mass spectrometry. Plasma levels (pre-dose and 2 hours post dose) were quantitated from 76 treatment-naive MDR-

TB patients being followed up at months 1(M1), 2(M2), 6(M6), and 12 (M12) of treatment. The therapeutic range for Mfx was defined as 3-5mg/L.

**Results:** Mfx levels were assessed in 76 patients with a median age of 25 years (range 15-77), 33% men and 67% women with a median weight of 54.8 kg (range 35-91). At M1, 22% of the study group had sub-therapeutic Mfx levels which reduced to 16% by M2 of treatment. However, around 43% of the study group had toxic levels at M1 and M2 of treatment. A wide inter- as well as intra-individual variability was observed with 4 patients having sub-therapeutic levels at M1 who showed toxic levels at M2 while 2 patients with toxic levels at M1 showed sub-therapeutic levels at M2 of treatments despite being on the same dosage regimens. Median Mfx levels observed at M1 and M2 were 4.5 (0.164-8.7mg/L) and 4.67 mg/L (0.183-8.78mg/L) respectively. Significant differences in pre-dose and 2 hour levels were observed ( $p=0.001$ ) at both M1 and M2. The Mfx levels for M6 and M12 are in process.

**Conclusion & Recommendations:** Wide inter-individual and intra-individual variability is observed between MFX levels at month 1 and month 2 of treatment. Monitoring drug levels will be essential to provide patients the most advantageous treatment possible.

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### **ABSTRACT 17: Glycaemic status in screen detected versus known cases of DM TB patients and its effect on treatment outcomes: EDOTS Study from South India**

**Submitting Author:** Arutselvi Devarajan

**Co-authors:** Satyavani Kumpatla, Mythili Dhanasekaran, Shruthi Basavaradhya Sahukar, Subash Babu, Hardy Kornfeld, Vijay Viswanathan

**Background & Rationale:** DM increases risk of poor treatment outcomes in TB. No recent literature available on TB treatment outcomes among screened detected(SDM) versus known cases of DM TB. Aim was to compare the glycaemic control and its effect on TB treatment outcomes among SDM and known DM(KDM).

**Methods:** A total of 569 PTB patients were enrolled from tuberculosis units in North Chennai, South India between 2014 to 2018. Out of 569, 179 had previous history of diabetes and remaining 390 underwent OGTT. 293 with normoglycaemia, pre-diabetes and those with culture negative results and unwilling were excluded and KDM patients ( $n=164$ ) and SDM ( $n=97$ ) by OGTT were included. Subjects were classified as diabetes based on WHO criteria. HbA1c was measured by HPLC method. HbA1c was repeated after 3, 6, 12 and 18 months. Treatment outcomes were assessed at the end of TB treatment.

**Results:** SDM had mean HbA1c of (8.6%) at baseline and showed greater reduction at 3rd month (7.3%) compared to 10.5% in KDM which reduced to 9.9% (mean difference  $1.4\pm 1.9$  Vs.  $0.62\pm 2.4$ ,  $p=0.01$ ). The proportion of subjects with better glycaemic control ( $HbA1c < 7.0\%$ ) at 3rd month in KDM was only 15.9% compared to 51.3% in SDM ( $p < 0.0001$ ) and at the end of TB treatment, it was 13.5 Vs. 54.1% respectively. This trend was observed throughout the follow up period in both the groups. The cure rate was higher in KDM (84.8%) compared to 72.2% in SDM ( $p=0.013$ ). KDM Vs. SDM (Treatment failure: 3 Vs. 6.2%,  $p=0.22$ ), (death rate: 1.2 VS. 4.1,  $p=0.54$ ). At the end of intensive phase, 21.2% were sputum smear positive in KDM compared to 25% in SDM ( $p=0.49$ ).

**Conclusion:** Treatment outcomes did not differ between screened versus known cases of DM except cure rate. Cure rate was higher among KDM compared to SDM.

## **ABSTRACT 18: Defective expansion and function of memory like natural killer cells in HIV+ individuals with latent tuberculosis infection**

**Submitting Author:** Kamakshi Prudhula Devalraju

**Co-authors:** Venkata Sanjeev Kumar Neela, Anvesh Kumar Bogam, Vara Lakshmi Mallidi

**Background & Rationale:** HIV infection markedly increases the likelihood of latent tuberculosis infection progressing to active TB. Identification of HIV+ individuals with LTBI who are at greatly increased risk of development of TB would allow treating only high-risk individuals, facilitating completion of therapy for LTBI and preventing future development of TB.

**Methods:** In this study we compared the expansion and function of memory like NK cells of HIV-LTBI+ and HIV+LTBI+ individuals in response to Mtb antigens ESAT-6 and CFP-10 before any treatment. In freshly isolated PBMC, the percentages of CD3-CD56+ cells were similar in HIV+LTBI+ patients and healthy HIV-LTBI+ individuals. In contrast, the percentages of CD3-CD56+CD16+ cells were higher in healthy HIV-LTBI+ individuals compared to healthy HIV+LTBI+ patients.

**Results & Inference:** HIV infection inhibited the expansion of memory like NK cells and IL-32 $\alpha$  and IFN- $\gamma$  production in response to Mtb antigens in LTBI+ individuals. We found that suboptimal NK cell and monocyte interactions in HIV+LTBI+ individuals leads to reduced IL-15, IFN- $\gamma$  and granzyme B and increased CCL5 production in HIV+LTBI+ patients. Our study for the first time demonstrates that HIV infection in LTBI+ individuals inhibits the expansion and function of memory like NK cells.





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# Publications

## PARENT & COMMON PROTOCOLS

### RePORT India

9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING

NEXT GEN RePORT

MUMBAI | 10-12 FEB 2020

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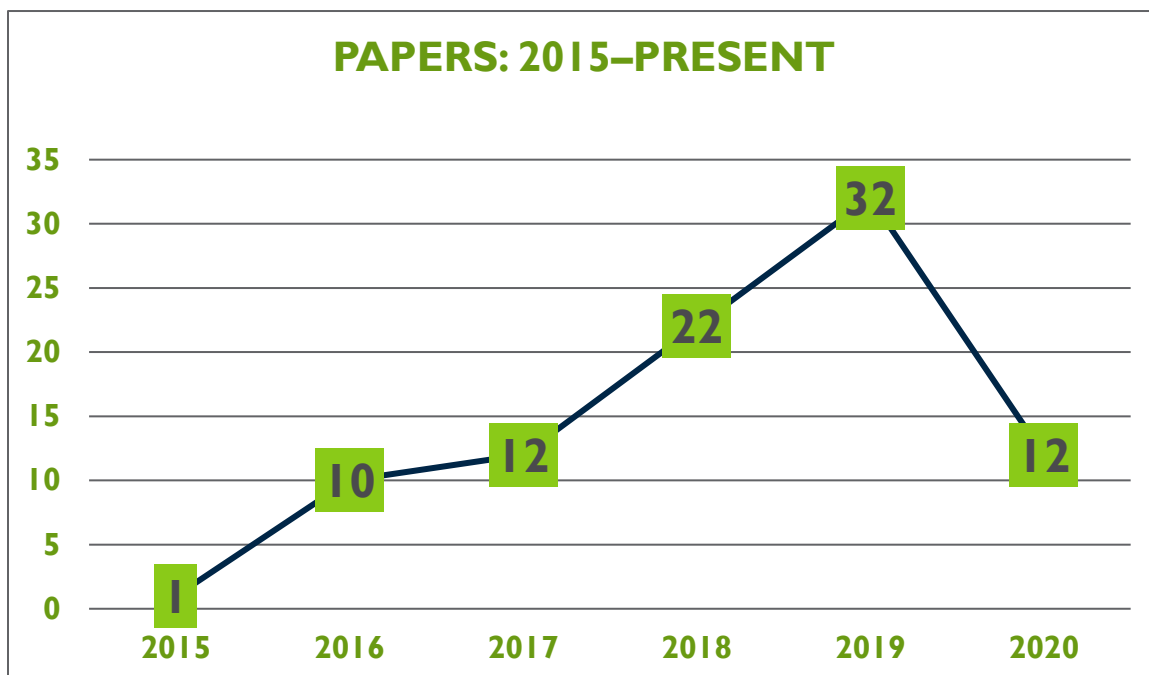


Figure for 2020 reflects manuscripts that have been published and are in process as of January 23, 2020.

## RePORT INDIA CONSORTIUM

### 1. Building capacity for advances in tuberculosis research; proceedings of the third RePORT International meeting

Van der Heijden YF, Abdullah F, Andrade BB, Andrews JR, Christopher DJ, Croda J, Ewing H, Haas DW, Hatherill M, Horsburgh CR Jr, Mave V, Nakaya HI, Rolla V, Srinivasan S, Sugiyono RI, Ugarte-Gil C, Hamilton C. *Tuberculosis (Edinb)*. 2018;113: 153-162. PMID: 30514497; PMCID: PMC6349374.

### 2. RePORT International: Advancing Tuberculosis Biomarker Research through Global Collaboration

Hamilton CD, Swaminathan S, Christopher DJ, Ellner J, Gupta A, Sterling TR, Rolla V, Srinivasan S, Karyana M, Siddiqui S, Stoszek SK, Kim P. *Clinical Infectious Diseases (CID)*. 2015 October 15; 61(Suppl 3): S155–S159. PMID: 26409277; PMCID: PMC4583572.

## **BHAGWAN MAHAVIR MEDICAL RESEARCH CENTRE/UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER (CRU 107)**

- 1. Ornithine-A urea cycle metabolite enhances autophagy and controls Mycobacterium tuberculosis infection**  
Sivangala Thandi R, Radhakrishnan RK, Tripathi D, Paidipally P, Azad AK, Schlesinger LS, Samten B, Mulik S, Vankayalapati R. (*In press: Nature Communications*)
- 2. BCG vaccination reduces the mortality of Mycobacterium tuberculosis-infected type 2 diabetes mellitus (T2DM) mice through the induction of CXCR3+ T-regulatory cells**  
Radhakrishnan RK, Sivangala Thandi R, Tripathi D, Paidipally P, McAllister MK, Mulik S, Samten B and Vankayalapati R. *JCI insight (Accepted for publication)*
- 3. Young household contacts of tuberculosis (TB) patients with reduced T4 and IL-1 $\alpha$  production are at a highest risk for developing active TB disease**  
Devalraju KP, Tripathi D, Neela VSK, Paidipally P, Bogam AK, Mallidi V, Sykam A, Singh KP, Ansari MS, Vankayalapati R, Valluri VL. (*Submitted to Journal of Clinical Investigation*)
- 4. Toll-like receptor 2 polymorphisms and their effect on the immune response to ESAT-6, Pam3CSK4 TLR2 agonist in pulmonary tuberculosis patients and household contacts**  
Mandala JP, Ahmad S, Pullagurla A, Thada S, Joshi L, Ansari MSS, Valluri VL, Gaddam SL. *Cytokine*. 2020 Feb;126:154897. doi: 10.1016/j.cyto.2019.154897. Epub 2019 Oct 31. PMID: 31678868.
- 5. IL-22 produced by type 3 innate lymphoid cells (ILC3s) reduces the mortality of type 2 diabetes mellitus (T2DM) mice infected with Mycobacterium tuberculosis**  
Tripathi D, Radhakrishnan RK, Sivangala Thandi R, Paidipally P, Devalraju KP, Neela VSK, McAllister MK, Samten B, Valluri VL, Vankayalapati R. *PLoS Pathog*. 2019 Dec 6;15(12):e1008140. PMID: 31809521.
- 6. Down regulation of RANTES in pleural site is associated with inhibition of antigen specific response in tuberculosis**  
Pydi SS, Ghousunnissa S, Devalraju KP, Ramaseri SS, Gaddam R, Auzumeedi SK, Vankayalapati R, Valluri VL. *Tuberculosis (Edinb)*. 2019 May;116S:S123-S130. PMID: 31103419.
- 7. Alcohol enhances type I interferon- $\alpha$  production and mortality of young mice infected with Mycobacterium tuberculosis**  
Tripathi D, Welch E, Cheekatla SS, Radhakrishnan R, Venkatasubramanian S, Paidipally P, Van A, Samten B, Devalraju P, Neela V, Valluri V, Mason C, Nelson S and Vankayalapati R. *PLoS Pathog*. 2018 Aug 2;14(8):e1007174. doi: 10.1371/journal.ppat.1007174. eCollection 2018 Aug. PMID: 30071107; PMCID: PMC6072099.
- 8. IL-17 and IL-22 production in HIV+ individuals with latent and active tuberculosis**  
Devalraju KP, Neela VSK, Ramaseri SS, Van A, Chaudhury A, Krovvidi SS, Vankayalapati R, Valluri VL. *BMC Infect Dis*. 2018 Jul 11;18(1):321. doi: 10.1186/s12879-018-3236-0. PMID: 29996789; PMCID: PMC6042451.
- 9. Defective MyD88 and IRAK4 but not TLR-2 expression in HIV+ individuals with latent tuberculosis infection**  
Devalraju KP, Neela VSK, Gaddam R, Chaudhury A, Van A, Krovvidi SS, Vankayalapati R, Valluri VL. *Cytokine*. 2018 Oct;110:213-221. doi: 10.1016/j.cyto.2018.05.005. Epub 2018 May 17. PMID: 29778672; PMCID: PMC6103807.
- 10. Interleukin-21 regulates Natural Killer cell responses during mycobacterium tuberculosis infection**

Paidipally P, Tripathi D, Van A, Radhakrishnan RK, Dhiman R, Venkatasubramanian S, Devalraju KP, Tvinnereim AR, Valluri VL, Vankayalapati R. *J Infect Dis.* 2018 Mar 28;217(8):1323-1333. doi: 10.1093/infdis/jiy034. PMID: 29390153; PMCID: PMC6018723.

- 11. Association of TNF- $\alpha$ , IL-10 and IL-6 promoter polymorphisms in pulmonary tuberculosis patients and their household contacts of younger age group**  
Joshi L, Chelluri LK, Valluri V, Gaddam S. *Comp Immunol Microbiol Infect Dis.* 2018 Feb;56:20-26. doi: 10.1016/j.cimid.2017.12.001. Epub 2017 Dec 26. PMID: 29406278.
- 12. IL-6 and IL-18 cytokine gene variants of pulmonary tuberculosis patients with co-morbid diabetes mellitus and their household contacts in Hyderabad**  
Ponnana M, Sivangala R, Joshi L, Valluri V, Gaddam S. *Gene.* 2017 Sep 5;627:298-306. doi: 10.1016/j.gene.2017.06.046. Epub 2017 Jun 23. PMID: 28652186
- 13. IL-21-dependent expansion of memory-like NK cells enhances protective immune responses against *Mycobacterium tuberculosis***  
Venkatasubramanian S, Cheekatla S, Paidipally P, Tripathi D, Welch E, Tvinnereim AR, Nurieva R, Vankayalapati R. *Mucosal Immunol.* 2017 Jul;10(4):1031-1042. doi: 10.1038/mi.2016.105. Epub 2016 Dec 7. PMID: 27924822; PMCID: PMC5462891.
- 14. A TLR9 agonist promotes IL-22-dependent pancreatic islet allograft survival in type 1 diabetic mice**  
Tripathi D, Venkatasubramanian S, Cheekatla SS, Paidipally P, Welch E, Tvinnereim AR, Vankayalapati R. *Nat Commun.* 2016 Dec 16;7:13896. doi: 10.1038/ncomms13896. PMID: 27982034; PMCID: PMC5171644.
- 15. NK-CD11c+ cell crosstalk in diabetes enhances IL-6-mediated inflammation during *Mycobacterium tuberculosis* infection**  
Cheekatla SS, Tripathi D, Venkatasubramanian S, Nathella PK, Paidipally P, Ishibashi M, Welch E, Tvinnereim AR, Ikebe M, Valluri VL, Babu S, Kornfeld H, Vankayalapati R. *PLoS Pathog.* 2016 Oct 26;12(10):e1005972. doi: 10.1371/journal.ppat.1005972. eCollection 2016. PMID: 27783671; PMCID: PMC5082658.
- 16. Cytokine production and mRNA expression in pulmonary tuberculosis patients and their household contacts of younger age group**  
Joshi L, Ponnana M, Sivangala R, Chelluri LK, Nallari P, Valluri VL, Gaddam S. *J Immunol Methods.* 2016 May;432:65-71. doi: 10.1016/j.jim.2016.02.012. Epub 2016 Feb 12. PMID: 26876300
- 17. Polymorphisms of IFN- $\gamma$  (+874A/T) and IL-12 (+1188A/C) in tuberculosis patients and their household contacts in Hyderabad, India**  
Thada S, Ponnana M, Sivangala R, Joshi L, Alasandagutti M, Ansari MS, Schumann RR, Valluri V, Gaddam S. *Hum Immunol.* 2016 Jul;77(7):559-65. doi: 10.1016/j.humimm.2016.04.016. Epub 2016 Apr 22. PMID: 27108964

## **BYRAMJEE JEEJEBHOY MEDICAL COLLEGE (BJGMC)/ NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS (NIRT)/ JOHNS HOPKINS UNIVERSITY (JHU) (CRU 106 & 105)**

- 1. Lack of association between TIRAP variants and disease severity among the active tuberculosis patients from South India**  
Rajagopalan S, Pattabiraman S, Thiruvengadam K, Selvachithiram M, Shivakumar SVBY, Sivaramakrishnan GN, Dhanasekaran K, Paradkar M, Puvaneshwari R, Muthuramalingam K, Madheswaran A, Pradhan N, Kulkarni V, Gupte AN, Gupte N, Mave V, Gupta A, Chandrasekaran P, Hanna LE for the C-TRIUMPh Study Team.



Infect Genet Evol. 2020 Jan;77:104093. doi: 10.1016/j.meegid.2019.104093. Epub 2019 Oct 31. PMID: 31678649.

**2. MAL adaptor (TIRAP) S180L polymorphism and severity of disease among tuberculosis patients**

Saranathan R, Sathyamurthi P, Thiruvengadam K, Murugesan S, Shivakumar SVBY, NS Gomathi, Kavitha D, Paradkar M, Puvaneshwari R, Kannan M, Madheswaran A, Pradhan N, Kulkarni V, Gupte AN, Gupte N, Mave V, Bollinger RC, Gupta A, Chandrasekaran P, Hanna LE. *Infection, Genetics, and Evolution*. 2020 Jan(44). Epub ahead of print 2019 Oct 31. PMID: 31678649.

**3. Transcriptomic profiles of confirmed pediatric tuberculosis patients and exposed household contacts identifies tuberculosis disease, infection, and response to treatment among Indian patients**

Tornheim JA, Madugundu A, Paradkar M, Gupte N, Fukutani KF, Gupte AN, Kinikar A, Kulkarni V, Balasubramanian U, Sreenivasamurthy S, Raja R, Pradhan N, Shivakumar SVBY, Vali C, Hanna LE, Andrade B, Chandrasekaran P, Mave V, Pandey A, Gupta A for the CTRIUMPH RePORT India Study Team. *J Infect Dis*. 2019 Dec 4. pii: jiz639. doi: 10.1093/infdis/jiz639. [Epub ahead of print]. PMID: 31796955.

**4. Lipid mediators of inflammation and resolution in individuals with tuberculosis and tuberculosis-diabetes**

Shivakoti R, Dalli J, Kadam D, Gaikwad S, Barthwal M, Colas RA, Mazzacuva F, Lokhande R, Dharmshale S, Bharadwaj R, Kagal A, Pradhan N, Deshmukh S, Atre S, Sahasrabudhe T, Kakrani A, Kulkarni V, Raskar S, Suryavanshi N, Chon S, Gupte A, Gupta A, Gupte N, Arriaga MB, Fukutani KF, Andrade BB, Golub JE, Mave V. *Prostaglandins Other Lipid Mediat*. 2019 Nov 11;147:106398. doi: 10.1016/j.prostaglandins.2019.106398. [Epub ahead of print] PMID: 31726221.

**5. Age-specific prevalence of TB infection among household contacts of pulmonary tuberculosis: Is it time for TB preventive therapy?**

Dolla CK, Chandrasekaran P, Thiruvengadam K, Lokhande R, Kinikar A, Paradkar M, Gupte A, Gaikwad S, Pradhan N, Kulkarni V, Shivakumar SVBY, Suryavanshi N, Gupte N, Pattabiraman S, Kagal A, Shrinivas BM, Murali L, Bharath TK, Pirthivi M, Kumaran P, Mave V, Gupta A. *Trans R Soc Trop Med Hyg*. 2019 Oct 11;113(10):632-640. doi: 10.1093/trstmh/trz049. PMID: 31225622; PMCID: PMC6792162.

**6. Delays and barriers to early treatment initiation for childhood tuberculosis in India**

Vali C, Chandanwale A, Khadse S, Kulkarni R, Kadam D, Kinikar A, Joshi S, Lokhande R, Garg P, Gupte N, Jain D, Suryavanshi N, Golub J, Shankar A, Gupta A, Dhumal G, DeLuca A, Bollinger RC. *Int J Tuberc Lung Dis*. 2019 Oct 1;23(10):1090-1099. doi: 10.5588/ijtld.18.0439. PMID: 31627774.

**7. Smoking, alcohol use disorder and TB treatment outcomes: A dual co-morbidity burden that cannot be ignored**

Thomas B, Thiruvengadam K, Rani S, Ovung S, Sivakumar S, Shivakumar SVBY, Paradkar M, Gupte N, Suryavanshi N, Akshay GN, Kohli R, Pradhan N, Sivaramakrishnan GN, Gaikwad S, Kagal A, Dhanasekaran K, DeLuca A, Golub JE, Mave V, Chandrasekaran P, Gupta A, CTRIUMPH-RePORT India Study. *PLoS One*. 2019 Jul 31;14(7):e0220507. doi: 10.1371/journal.pone.0220507. eCollection 2019. PMID: 31365583; PMCID: PMC6668833.

**8. Infection free “resisters” among household contacts of adult pulmonary tuberculosis**

Mave V; Chandrasekaran P; Chavan A; Shivakumar SVBY; Danasekaran K; Paradkar M; Thiruvengadam K, Kinikar A; Murali L; Gaikwad S; Hannah LE; Kulkarni V; Pattabiraman S; Suryavanshi N; Thomas B; Kohli R; Sivaramakrishnan GN; Pradhan N; Banu B; Kagal A; Golub J; Gupte A; Gupte N; Swaminathan S; Gupta A. *PLoS One*. 2019;14(7):e0218034. Published 2019 Jul 18. doi:10.1371/journal.pone.0218034. PMID: 31318864; PMCID: PMC6638997.

- 9. Mobile phone access and comfort: Implications for HIV and tuberculosis care in India and South Africa**  
Cox SN, Elf JL, Lokhande R, Ogale YP, DiAndreth L, Dupuis E, Milovanovic M, Mpongose N, Mave V, Suryavanshi N, Gupta A, Martinson N, Golub JE, Mathad JS. *Int J Tuberc Lung Dis.* 2019 Jul 1;23(7):865-872. doi: 10.5588/ijtld.18.0542. PMID: 31439120.
- 10. Assessment of lung function in successfully treated tuberculosis reveals high burden of ventilatory defects and COPD**  
Gupte AN, Paradkar M, Selvaraju S, Thiruvengadam K, Shivakumar SVBY, Sekar K, Marinaik S, Momin A, Gaikwad A, Natrajan P, Prithivi M, Shivaramakrishnan G, Pradhan N, Kohli R, Raskar S, Jain D, Velu R, Karthavarayan B, Lokhande R, Suryavanshi N, Gupte N, Murali L, Salvi S, Checkley W, Golub J, Bollinger R, Mave V, Padmapriyadarasini C, Gupta A. *PLoS One.* 2019 May 23;14(5):e0217289. doi: 10.1371/journal.pone.0217289. eCollection 2019. PMID: 31120971; PMCID: PMC6532904.
- 11. Sub-therapeutic rifampicin concentration is associated with unfavourable tuberculosis treatment outcomes**  
Ramachandran G, Padmapriyadarsini C, Gaikwad S, Kumar AKH, Kannan T, Gupte N, Paradkar M, Danasekaran K, Gomathi NS, Kagal A, Thomas B, Pradhan N, Kadam D, Hanna LE, Balasubramanian U, Kulkarni V, Murali L, Golub J, Gupte A, Shivakumar SVBY, Swaminathan S, Dooley KE, Gupta A, Mave V for the C-TRIUMPh team. *Clin Infect Dis.* 2019 May 10. pii: ciz380. doi: 10.1093/cid/ciz380. [Epub ahead of print]. PMID: 31075166.
- 12. Respiratory health status is associated with treatment outcomes in pulmonary tuberculosis**  
Gupte AN, Selvaraju S, Paradkar M, Danasekaran K, Shivakumar SVB, Thiruvengadam K, Dolla C, Shivaramakrishnan G, Pradhan N, Kohli R, John S, Raskar S, Jain D, Momin A, Subramanian B, Gaikwad A, Lokhande R, Suryavanshi N, Gupte N, Salvi S, Murali L, Checkley W, Golub J, Bollinger R, Chandrasekaran P, Mave V, Gupta A. *International Journal of Tuberculosis and Lung Disease* April 2019 1; 23(4): 450-457. *Int J Tuberc Lung Dis.* 2019 Apr 1;23(4):450-457. doi: 10.5588/ijtld.18.0551. PMID: 31064624.
- 13. Effect of diabetes mellitus on the pharmacokinetics and pharmacodynamics of tuberculosis treatment**  
Alfarisi O, Mave V, Gaikwad S, Sahasrabudhe T, Ramachandran G, Kumar H, Gupte N, Kulkarni V, Deshmukh S, Atre S, Raskar S, Lokhande R, Barthwal M, Kakrani A, Chon S, Gupta A, Golub JE, Dooley KE. *Antimicrob Agents Chemother.* 2018 Oct 24;62(11). pii: e01383-18. doi: 10.1128/AAC.01383-18. Print 2018 Nov. PMID: 30126955; Central PMCID: PMC6201087.
- 14. Barriers to screening and isoniazid preventive treatment for child contacts tuberculosis patients**  
Belgaumkar V, Chandanwale A, Valvi C, Pardeshi G, Lokhande R, Kadam D, Joshi S, Gupta N, Jain D, Dhumal G, Deluca A, Golub J, Shankar A, Gupta A, Kinikar A, Bollinger RC. *Int J Tuberc Lung Dis.* 2018 Oct 1;22(10):1179-1187. doi: 10.5588/ijtld.17.0848. PMID: 30236186.
- 15. Tuberculin skin test and QuantiFERON-Gold In tube assay for diagnosis of latent TB infection among household contacts of pulmonary TB patients in a high TB burden setting**  
Chandrasekaran P, Mave V, Thiruvengadam K, Gupte N, Shivakumar SVBY, Hanna LE, Kulkarni V, Kadam D, Dhanasekaran K, Paradkar M, Thomas B, Kohli R, Dolla C, Bharadwaj R, Sivaramakrishnan GN, Pradhan N, Gupte A, Murali L, Valvi C, Swaminathan S, Gupta A; CTRIUMPH Study Team. *PLoS One.* 2018 Aug 1;13(8):e0199360. doi: 10.1371/journal.pone.0199360. eCollection 2018. PMID: 30067752; PMCID: PMC6070176.
- 16. Trends in HbA1c levels and implications for diabetes screening in tuberculosis cases undergoing treatment in India**  
Gupte AN, Mave V, Meshram S, Lokhande R, Kadam D, Dharmshale S, Bharadwaj R, Kagal A, Pradhan N, Deshmukh S, Atre S, Sahasrabudhe T, Barthwal M, Meshram S, Kakrani A, Kulkarni V, Raskar S, Suryavanshi

S, Shivakoti S, Chon S, Selvin E, Gupte N, Gupta A, Golub JE. *Int J Tuberc Lung Dis*. 2018 Jul 1;22(7):800-806. doi: 10.5588/ijtld.18.0026. PMID: 30041729; PMCID: PMC6198328.

**17. Diabetes and prediabetes among household contacts of TB patients in India: Is it time to screen them all?**

Shivakumar SVBY, Chandrasekaran P, Kumar AMV, Paradkar M, Dhanasekaran K, Suryavarshini N, Thomas B, Kohli R, Thiruvengadam K, Kulkarni V, Hannah LE, Gomathy NS, Pradhan N, Dolla C, Gupte A, Ramachandran G, DeLuca A, Meshram S, Bhardawaj R, Bollinger RC, Golub J, Selvaraj K, Gupte N, Swaminathan S, Mave V, Gupta A for the CTRIUMPH- RePORT India Study Team. *Int J Tuberc Lung Dis*. 2018 Jun 1; 22(6): 686-694. Doi: 10.5588/ijtld.17.0598. PMID: 29862955.

**18. Sources of household air pollution and their association with fine particulate matter in low-income urban homes in India**

Elf JL, Kinikar A, Khadse S, Mave V, Suryavanshi N, Gupte N, Kulkarni V, Patekar P, Raichur P, Breyse P, Gupta A, Golub JE. *J Expo Sci Environ Epidemiol*. 2018 Jun;28(4):400-410. Doi: 10.1038/s41370-018-0024-2. Epub 2018 May 23. PMID: 29789668; PMCID: PMC6013356.

**19. Addressing knowledge gaps and prevention for tuberculosis-infected Indian adults: A vital part of elimination**

Deluca A, Dhupal G, Paradkar M, Suryavanshi N, Mave V, Kohli R, Shivakumar SVBY, Hulyolkar V, Gaikwad A, Nangude A, Pardeshi G, Kadam D, Gupta A. Published in *BMC Infectious Diseases*, May 2018. *BMC Infect Dis*. 2018 May 2;18(1):202. doi: 10.1186/s12879-018-3116-7. PMID: 29720095; PMCID: PMC5932769.

**20. Second hand smoke exposure and validity of self-report in low-income women and children in India**

Elf J, Kinikar A, Khadse S, Mave V, Gupte N, Kulkarni V, Patekar V, Raichur P, Cohen J, Breyse PN, Gupta A, Golub JE. *Pediatrics*. 2018 Jan; 141 (Suppl 1): S118-S129. doi: 10.1542/peds.2017-1026O. PMID: 29292312; PMCID: PMC5745676.

**21. Isoniazid concentrations in hair and plasma area-under-the-curve exposure among children with tuberculosis**

Mave V, Kinikar A, Kagal A, Nimkar S, Koli H, Khwaja S, Bharadwaj R, Gerona R, Wen A, Ramachandran G, Kumar H, Bacchetti P, Dooley KE, Gupte N, Gupta A, Gandhi M. *PLoS One*. 2017 Dec 7;12(12):e0189101. doi: 10.1371/journal.pone.0189101. PMID: 29216273; PMCID: PMC5720757.

**22. Prevalence of dysglycemia and clinical presentation of pulmonary tuberculosis in Western India**

Mave V, Meshram S, Lokhande R, Kadam D, Dharmshale S, Bharadwaj R, Kagal A, Pradhan N, Deshmukh S, Atre S, Sahasrabudhe T, Barhwal M, Meshram S, Kakrani A, Kulkarni V, Raskar S, Suryavanshi N, Shivakoti R, Chon S, Selvin E, Gupte A, Gupta A, Gupte N, Golub J. *Int J Tuberc Lung Dis*. 2017 Dec 1;21(12):1280-1287. doi: 10.5588/ijtld.17.0474. PMID: 29297449; PMCID: PMC6203962.

**23. The association of household fine particulate matter and kerosene with tuberculosis in women and children in Pune, India.**

Elf JL, Kinikar A, Khadse S, Mave V, Suryavanshi N, Gupte N, Kulkarni V, Patekar S, Raichur P, Paradkar M, Kulkarni V, Pradhan N, Breyse PN, Gupta A, Golub JE. *Occup Environ Med*. 2018 Sep 7. pii: oemed-2018-105122. doi: 10.1136/oemed-2018-105122. [Epub ahead of print]. PMID: 30194271.

**24. Isoniazid hair concentrations in children with tuberculosis: A proof of concept study**

Mave V, Chandanwale A, Kinikar A, Khadse S, Kagal A, Gupte N, Suryavanshi N, Nimkar S, Koli H, Khwaja S, Bharadwaj R, Joshi S, Horng H, Benet LZ, Ramachandran G, Dooley KE, Gupta A, Gandhi M. *Int J Tuberc Lung Dis*. 2016 Jun; 20(6): 844-847. doi: 10.5588/ijtld.15.0882. PMID: 27155191; PMCID: PMC4889729.

**25. Cohort for Tuberculosis Research by the Indo-U.S. Medical Partnership (CTRIUMPH): Protocol for a multicentric prospective observational study**

Gupte A, Padmapriyadarsini C, Mave V, Kadam D, Suryavanshi N, Shivakumar SVBY, Kohli R, Gupte N, Thiruvengadam K, Kagal A, Meshram S, Bharadwaj R, Khadse S, Ramachandran G, Hanna LE, Pradhan N, Gomathy NS, DeLuca A, Gupta A, Swaminathan S; CTRIUMPH Study Team. *BMJ Open* 2016 Feb 25;6(2):e010542. PMID: 26916698; PMCID: PMC4769396.

**CHRISTIAN MEDICAL COLLEGE, VELLORE (CMC-VELLORE)  
/UNIVERSITY OF CAMBRIDGE-UNIVERSITY OF WASHINGTON (CRU  
101)**

- 1. Burden of diabetes among patients with tuberculosis: 10 year experience from a tertiary care referral teaching hospital in South India**  
Christopher DJ, Jeyaseelan L, Yadav B, Balaji V, Michael JS, Gupta M, Manipadam MT, Sudarsanam TD. *(Accepted by Lung India)*
- 2. Profile of Indian patients with tubercular meningitis in the CMC, Vellore cohort**  
Balamugesh T, Thambu D, Alice M, Soumya S, Ramya, Samuel G H, Lalitha R, Christopher D J. *(Submitted to Indian Journal of Medical Research)*
- 3. Pharmacokinetics of rifampicin, isoniazid and pyrazinamide during daily and intermittent dosing**  
Ramachandran G, Hemanth Kumar AK, Kannan T, Thangakunam B, Shankar D, Christopher DJ *(Submitted for publication)*
- 4. Prevalence of active TB disease and latent TB infection in patients with type 2 diabetes mellitus in tertiary care hospital of India**  
Christopher DJ, Dabhi P, Naik D, Nihal T, Prince J, Thangakunam B, Gupta R. *(Submitted to PLoS ONE)*
- 5. Thoracoscopic pleural biopsy improves yield of Xpert MTB/RIF for diagnosis of pleural tuberculosis**  
Christopher DJ, Dinakaran S, Gupta R, James P, Isaac B, Thangakunam B. *Respirology*. 2018 Jul;23(7):714-717. doi: 10.1111/resp.13275. Epub 2018 Feb 27. PMID: 29486527.

**JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL  
EDUCATION & RESEARCH (JIPMER)/BOSTON MEDICAL CENTER  
(BMC) (CRU 102)**

- 1. Interaction of nutritional status and diabetes on active and latent tuberculosis: a cross-sectional analysis**  
Kubiak R, Sarkar S, Horsburgh CR Jr, Roy G, Kratz M, Reshma, Knudsen S, Salgame P, Ellner JJ, Drain PK, Hochberg NS. *BMC Infect Dis*. 2019 Jul 16;19(1):627. doi: 10.1186/s12879-019-4244-4. PMID: 31311495; PMCID: PMC6636094.
- 2. Effect of malnutrition on radiographic findings and mycobacterial burden in pulmonary tuberculosis**  
Hoyt K, Sarkar S, White LF, Joseph NM, Salgame P, Lakshminarayanan S, Muthaiah M, Kumar SV, Ellner, JJ, Roy G, Horsburgh CR Jr, Hochberg NS. *PLoS ONE*. 2019 Mar 27; 14(3). doi: 10.1371/journal.pone.0214011. PMID: 30917170; PMCID: PMC6436704.

3. **Food for thought: The role of undernutrition and diabetes in India's TB epidemic**  
Sinha P, Hochberg NS. *International Journal of Medicine and Public Health* 2019;9(1):1-3.
4. **Undernutrition and tuberculosis: Public health implications**  
Sinha P, Davis J, Saag L, Wanke C, Salgame P, Mesick J, Horsburgh CR Jr, Hochberg NS. *J Infect Dis.* 2019 Apr 16;219(9):1356-1363. doi: 10.1093/infdis/jiy675. PMID: 30476125; PMCID: PMC6941617.
5. **Crystal ball: The yesterday and tomorrow of tuberculosis**  
Sinha P, Hochberg NS. *Environ Microbiol Rep.* 2019 Feb;11(1):41-44. doi: 10.1111/1758-2229.12726. Epub 2018 Dec 25. PMID: 30585431.
6. **Low BMI and latent tuberculosis infection: A systematic review and meta-analysis**  
Saag LA, LaValley MP, Hochberg NS, Cegielski P, Pleskunas JA, Linas B, Horsburgh CR. *Int J Tuberc Lung Dis.* 2018 Apr 1;22(4):358-365. doi: 10.5588/ijtld.17.0558. PMID: 29562981.
7. **Existing blood transcriptional classifiers accurately discriminate active tuberculosis from latent infection in individuals from South India**  
Leong, S, Yue Zhao, Joseph NM, Hochberg NS, Sarkar S, Pleskunas J, HomD, LakshminarayananS, Horsburgh Jr, CR, Roy G, Ellner JJ, Johnson WE, Salgame, P. *Tuberculosis (Edinb).* 2018 Mar;109:41-51. doi: 10.1016/j.tube.2018.01.002. Epub 2018 Jan 31. PMID: 29559120.
8. **Comorbidities in pulmonary tuberculosis cases in Puducherry and Tamil Nadu, India: Opportunities for intervention**  
Hochberg NS, Sarkar S, Horsburgh, Jr, CR, Knudsen S, Pleskunas J, Sahu S, Kubiak RW, Govindarajan S, Salgame P, Lakshminarayanan S, Sivaprakasam A, White LF, Joseph NM, Ellner JJ, Roy G. *PLoS One.* 2017 Aug 23;12(8):e0183195. doi: 10.1371/journal.pone.0183195. eCollection 2017. PMID: 28832615; PMCID: PMC5568341.
9. **Predictors of delayed care seeking for tuberculosis in Southern India: An observational study**  
Van Ness SE, Chandra A, Sarkar S, Pleskunas J, Ellner JJ, Roy G, Lakshminarayanan S, Sahu S, Horsburgh Jr CR, Jenkins HE, Hochberg NS. *BMC Infect Dis.* 2017 Aug 15;17(1):567. doi: 10.1186/s12879-017-2629-9. PMID: 28806911; PMCID: PMC5557420.

## **MV DIABETES RESEARCH CENTRE – NIRT-NIH-ICER /UNIVERSITY OF MASSACHUSETTS (CRU 103)**

1. **Impact of diabetes and low body mass index on tuberculosis treatment outcomes**  
Kornfeld H, Sahukar BS, Procter-Gray E, Kumar NP, West K, Kane K, Natarajan M, Li W, Babu S, Viswanathan V. *Clin Infect Dis.* 2020 Jan 19. pii: c1aa054. doi: 10.1093/cid/c1aa054. [Epub ahead of print]. PMID: 31955202.
2. **Heterogeneity in the cytokine profile of tuberculosis-diabetes co-morbidity**  
Kumar NP, Moideen K, Nancy A, Viswanathan V, Shruthi BS, Sivakumar S, Natarajan M, Kornfeld H, Babu S. *Cytokine* 2020 Jan;125:154824. PMID: 31472402.
3. **Systemic RAGE ligands are upregulated in tuberculosis individuals with diabetes co-morbidity and modulated by anti-tuberculosis treatment and metformin therapy**  
Kumar NP, Moideen K, Nancy A, Viswanathan V, Shruthi BS, Sivakumar S, Hissar S, Kornfeld H, Babu S. *BMC Infect Dis* 2019 Dec 9;19(1):1039. PMID: 31818258; PMCID: PMC6902343.
4. **Plasma chemokines are biomarkers of disease severity, higher bacterial burden and delayed sputum culture conversion in pulmonary tuberculosis**  
Kumar NP, Moideen K, Nancy A, Viswanathan V, Shruthi BS, Sivakumar S, Natarajan M, Kornfeld H, Babu S. *Sci Rep* 2019 Dec 3;9(1):18217. PMID: 31796883; PMCID: PMC6890773.

- 5. Plasma eicosanoid levels in tuberculosis and tuberculosis-diabetes co-morbidity are associated with lung pathology and bacterial burden**  
 Kumar NP, Moideen K, Nancy A, Viswanathan V, Shruthi BS, Shanmugam S, Hissar S, Kornfeld H, Babu S. *Front Cell Infect Microbiol* 2019 Oct 1;9:335. PMID: 31632923; PMCID: PMC6779700.
- 6. Persistent inflammation during anti-tuberculosis treatment with diabetes comorbidity**  
 Kumar NP, Fukutani KF, Shruthi BS, Alves T, Silveira-Mattos PS, Rocha MS, West K, Natarajan M, Viswanathan V, Babu S, Andrade BB, Kornfeld H. *eLife*. 2019 Jul 4;8. pii: e46477. PMID: 31271354; PMCID: PMC6660216.
- 7. Elevated circulating levels of monocyte activation markers among tuberculosis patients with diabetes co-morbidity**  
 Kumar NP, Moideen K, Viswanathan V, Sivakumar S, Natarajan M, Kornfeld H, Babu S. *Immunology*. 2019 Mar;156(3):249-258. PMID: 30427060; PMCID: PMC6376263.
- 8. Elevated levels of matrix metalloproteinases reflect severity and extent of disease in tuberculosis-diabetes co-morbidity and are predominantly reversed following standard anti-tuberculosis or metformin treatment**  
 Kumar NP, Moideen K, Viswanathan V, Sivakumar S, Menon PA, Kornfeld H, Babu S. *BMC Infect Dis*. 2018 Jul 25;18(1):345. PMID: 30045688; PMCID: PMC6060542.
- 9. Heightened circulating levels of antimicrobial peptides in tuberculosis-diabetes co-morbidity and reversal upon treatment**  
 Kumar NP, Moideen K, Viswanathan V, Sivakumar S, Menon PA, Kornfeld H, Babu S. *PLoS One*. 2017 Sep 14;12(9):e0184753. doi: 10.1371/journal.pone.0184753. eCollection 2017. PMID: 28910369; PMCID: PMC5599016.
- 10. Systems immunology of diabetes tuberculosis comorbidity reveals signatures of disease complications**  
 Prada-Medina CA, Fukutani KF, Kumar NP, GilSantana L, Babu S, Lichtenstein F, West K, Sivakumar S, Menon PA, Viswanathan V, Andrade BB, Nakaya HI, Kornfeld H. *Sci Rep*. 2017 May 17;7(1):1999. PMID: 28515464; PMCID: PMC5435727.
- 11. Defining a research agenda to address the converging epidemics of tuberculosis and diabetes. Part 2: Underlying biological mechanisms**  
 Ronacher K, van Crevel R, Critchley J, Bremer A, Schlesinger LS, Kapur A, Basaraba R, Kornfeld H, Restrepo BI. *Chest*. 2017 Jul;152(1):174-180. PMID: 28434937; PMCID: PMC5577357.
- 12. Defining a research agenda to address the converging epidemics of tuberculosis and diabetes. Part 1: Epidemiology and clinical management**  
 Critchley JA, Restrepo BI, Ronacher K, Kapur A, Bremer AA, Schlesinger LS, Basaraba R, Kornfeld H, van Crevel R. *Chest*. 2017 Jul;152(1):165-173. PMID: 28434936; PMCID: PMC5989639.
- 13. Tuberculosis-diabetes co-morbidity is characterized by heightened systemic levels of circulating angiogenic factors**  
 Kumar NP, Moideen K, Sivakumar S, Menon PA, Viswanathan V, Kornfeld H, Babu S. *J Infect*. 2017 Jan;74(1):10-21. PMID: 27717783; PMCID: PMC5164955.
- 14. Modulation of dendritic cell and monocyte subsets in tuberculosis-diabetes co-morbidity upon standard tuberculosis treatment**  
 Kumar NP, Moideen K, Sivakumar S, Menon PA, Viswanathan V, Kornfeld H, Babu S. *Tuberculosis (Edinb)*. 2016 Dec;101:191-200. PMID: 27865391; PMCID: PMC5127284.
- 15. Effect of standard tuberculosis treatment on naive, memory and regulatory T-cell homeostasis in tuberculosis-diabetes co-morbidity**



Kumar NP, Moideen K, Viswanathan V, Kornfeld H, Babu S. Immunology. 2016 Sep;149(1):87-97. PMID: 27289086; PMCID: PMC4981606.

**16. Glucose metabolism disorder is associated with pulmonary tuberculosis in individuals with respiratory symptoms from Brazil**

Almeida-Junior JL, Gil-Santana L, Oliveira CA, Castro S, Cafezeiro AS, Daltro C, Netto EM, Kornfeld H, Andrade BB. PLoS One. 2016 Apr 14;11(4):e0153590. PMID: 27078026; PMCID: PMC4831681.

**17. High prevalence and heterogeneity of diabetes in patients with TB in South India: A report from the Effects of Diabetes on Tuberculosis Severity (EDOTS) Study**

Kornfeld H, West K, Kane K, Kumpatla S, Zacharias RR, Martinez-Balzano C, Li W, Viswanathan V. Chest. 2016 Jun;149(6):1501-8. PMID: 26973015; PMCID: PMC4944775.

## **P.D. HINDUJA NATIONAL HOSPITAL & MEDICAL RESEARCH CENTER/ JOHNS HOPKINS UNIVERSITY (JHU) (CRU 108)**

**1. Recent advances in infectious diseases and tuberculosis**

Shah A, Tiwari K, Camilla Rodrigues C. (Accepted by Association Physicians India)

**2. Interpreting very low MTB detected on Xpert MTB/ RIF**

Ajbani K, Naik S, Kazi M, Shetty A, Rodrigues C. Lung India. 2019 Nov-Dec;36(6):555-557. doi: 10.4103/lungindia.lungindia\_463\_18. PMID: 31670308; PMCID: PMC6852221.

**3. Guidance for studies evaluating the accuracy of rapid tuberculosis drug-susceptibility tests**

Georghiou SB, Schumacher SG, Rodwell TC, Colman RE, Miotto P, Gilpin C, Ismail N, Rodrigues C, Warren R, Weyer K, Zignol M, Arafah S, Cirillo DM, Denkinger CM. J Infect Dis. 2019 Oct 8;220(Supplement\_3):S126-S135. doi: 10.1093/infdis/jiz106. PMID: 31593599.

**4. Delamanid central nervous system pharmacokinetics in tuberculous meningitis in rabbits and humans**

Tucker EW, Pieterse L, Zimmerman MD, Udawadia ZF, Peloquin CA, Gler MT, Ganatra S, Tornheim JA, Chawla P, Caoili JC, Ritchie B, Jain SK, Dartois V, Dooley KE. Antimicrob Agents Chemother. 2019 Sep 23;63(10). pii: e00913-19. doi: 10.1128/AAC.00913-19. Print 2019 Oct. PMID: 31383662; PMCID: PMC6761520.

**5. Management of drug-resistant tuberculosis**

Lange C, Dheda K, Chesov D, Mandalakas AM, Udawadia Z, Horsburgh CR Jr. Lancet. 2019 Sep 14;394(10202):953-966. doi: 10.1016/S0140-6736(19)31882-3. PMID: 31526739.

**6. A shorter regimen for rifampin-resistant tuberculosis**

Tornheim JA, Udawadia ZF, Gupta A. N Engl J Med. 2019 Sep 12;381(11):e22. doi: 10.1056/NEJMc1905782. PMID: 31509687.

**7. Multi-centre study to establish interpretive criteria for clofazimine drug susceptibility testing**

Ismael N, Said HM, Rodrigues C, Omar SV, Ajbani K, Sukhadia N, Kohl TA, Niemann S, Kranzer K, Diels M, Rigouts L, Rüscher-Gerdese S, Siddiqi S. Int J Tuberc Lung Dis. 2019 May 1;23(5):594-599. doi: 10.5588/ijtld.18.0417. PMID: 31097068.

**8. Making a positive diagnosis of intestinal tuberculosis with the aid of new biologic and histologic features: How far have we reached?**

Mehta V, Desai D, Abraham P, Rodrigues C. Intestinal Diseases. Inflamm Intest Dis. 2019 Apr;3(4):155-160. doi: 10.1159/000496482. Epub 2019 Mar 15. PMID: 31111030; PMCID: PMC6501547.

- 9. For drug resistance (DR) TB is there any strength in the old warriors yet?**  
Soman R, Singhal T, Shetty A, Rodrigues C. Indian J Tuberc. 2019 Oct;66(4):496-498. doi: 10.1016/j.ijtb.2019.03.002. Epub 2019 Mar 26. PMID: 31813438.
- 10. Performance of bioMérieux Lowenstein-Jensen slopes in plastic tube packaging, compared to existing phenotypic methods, for efficient recovery of Mycobacterium tuberculosis (MTB) complex**  
Nambiar R, Bereksi N, Gonzalez R, Anthony de Cozar, Loubet M, Shetty A, Alex van Belkum, Rodrigues C. J Med Microbiol. 2019 Mar;68(3):398-401. doi: 10.1099/jmm.0.000930. Epub 2019 Feb 6. PMID: 30724723.
- 11. Few eligible for the newly recommended short course MDR-TB regimen at a large Mumbai private clinic**  
Udwadia ZF, Tornheim JA, Ganatra S, DeLuca A, Rodrigues CS, Gupta A. BMC Infectious Diseases 2019 Jan 28; 19:94, <https://doi.org/10.1186/s12879-019-3726-8>. PMID: 30691407; PMCID: PMC6350313.
- 12. Unified variant analysis: Integrating standardized whole genome sequence analysis with a global Mycobacterium tuberculosis antibiotic resistance knowledgebase**  
Ezewudo M, Borens A, Álvaro Chiner-Oms, Miotto P, Chindelevitch L, Starks AM, Hanna D, Liwski R, Zignol M, Gilpin C, Niemann S, Kohl T, Warren RM, Crook D, Gagneux S, Hoffner S, Rodrigues C, Comas I, Engelthaler DM, Alland D, Rigouts L, Lange C, Dheda K, Hasan R, McNerney R, Cirillo DM, Schito M, Rodwell TC, Posey J. Sci Rep. 2018 Oct 18;8(1):15382. doi: 10.1038/s41598-018-33731-1. PMID: 30337678; PMCID: PMC6194142.
- 13. Utility of pyrosequencing for rapid detection of tubercular meningitis (TBM) and associated susceptibility directly from CSF specimens**  
Ajvani K, Kazi M, Naik S, Soman R, Shetty A, Rodrigues C. Tuberculosis (Edinb). 2018 Jul;111:54-56. doi: 10.1016/j.tube.2018.05.009. Epub 2018 May 19. PMID: 30029915
- 14. Evaluation of pyrosequencing for extensive drug resistance-defining anti-tuberculosis drugs for use in public healthcare**  
Nambiar R, Shah D, Ajvani K, Kazi M, Sadani M, Shetty A, Keskar P, Kamble S, van Belkum A, Rodrigues C. Tuberculosis (Edinb). 2018 May;110:86-90. doi: 10.1016/j.tube.2018.03.006. Epub 2018 Mar 26. PMID: 29779779
- 15. Pyrosequencing to resolve discrepant Xpert MTB/RIF and Mycobacterial Growth Indicator Tube 960**  
Ajvani K, Kazi M, Tornheim J, Naik S, Soman R, Shetty A, Rodrigues C. Lung India. 2018 Mar-Apr;35(2):168-170. doi: 10.4103/lungindia.lungindia\_71\_17. PMID: 29487256; PMCID: PMC5846270.



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# Lectures & Presentations

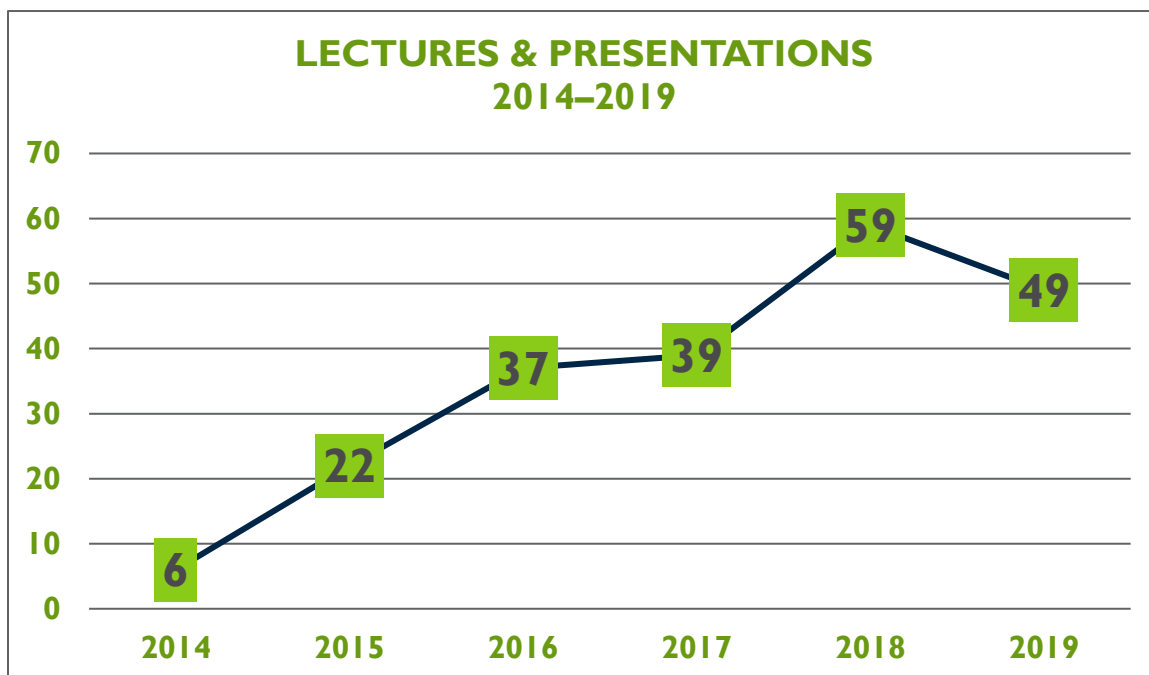
## RePORT India

9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING

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#### Definitions

**LECTURE:** Individual presentation on a topic of field of expertise

**PRESENTATION | ABSTRACT:** Multiple authors, includes poster and oral discussions

## RePORT INDIA CONSORTIUM

### LECTURES

1. Christopher DJ. **State of the RePORT India Consortium.** Presented at: RePORT India 8th Annual Joint Leadership Meeting. Chennai, India; February 4–6, 2019.
2. Gupta A, Rodrigues C, Christopher DJ, Kornfeld H, Ellner J, Mave V, Devalraju KP. **RePORT India Symposium: Biomarkers, diagnostics, and comorbidities.** 49<sup>th</sup> Union World Conference on Lung Health. The Hague, The Netherlands; October 25, 2018.
3. Gupta A. **RePORT India overview.** Presented at: CFAR RePORT International Meeting. Rockville, MD; July 2, 2018.
4. Gupta A. **Keynote Address: Global health diplomacy: Why it really matters!** (RePORT India described) AAAS Science & Technology. Washington, DC; May 31, 2018.
5. Gupta, A. **Keynote Address: The challenge of eliminating TB in India.** (RePORT India described) University of Washington TB Symposium. Seattle, WA; May 18, 2018;
6. Gupta A. **An Overview of the RePORT India Consortium.** Presented at: Annual leDEA Meeting; National Institutes of Health. June 22, 2016; Rockville, MD, USA.
7. Mave V. **RePORT India: Objectives and future directions.** Presented at: TB Vaccine 4<sup>th</sup> Global Forum. Shanghai, China; 2015.

### ABSTRACT

1. Hamilton CD, Ellner J, Swaminathan S, Christopher D, Gupta A, Sterling T, Rolla VC, Stoszek S. **Regional Prospective Observational Research for Tuberculosis (RePORT) Consortia using a common protocol to collect specimens for biomarker research.** Poster presented at: 45<sup>th</sup> Union World



## **BHAGWAN MAHAVIR MEDICAL RESEARCH CENTRE (BMMRC) UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER**

### **PRESENTATIONS | ABSTRACTS**

1. Valluri V. **Vaccines and immunological markers for TB prevention.** Presented at: 50th Annual Union World Conference on Lung Health. Hyderabad, India; October 30–Nov 2, 2019.
2. Kumar NV. **T Cell subsets and cytokines in HIV+ individuals with latent and active tuberculosis.** Poster presented at: 50th Annual Union World Conference on Lung Health. Hyderabad, India; October 30–Nov 2, 2019.
3. Prudhula DK. **Defective monocyte signalling pathway in HIV+ individuals with latent tuberculosis infection.** Poster presented at: 50th Annual Union World Conference on Lung Health. Hyderabad, India; October 30–Nov 2, 2019.
4. Devalraju KP, Neela VSK, Chaudhury A, Vankayalapati R, Valluri VL. **NK cells and memory-like NK cells as immunological markers of protection against latent TB conversion in household contacts of TB patients.** Abstract presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
5. Neela VSK, Devalraju KP, Sumnalatha G, Chowdary A, Ansari MS, Vankayalapati R, Valluri VL. **CD14+ CD16+ cells as immunological marker for protection in household contacts with latent tuberculosis infection.** Abstract presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
6. Devalraju KP. **Identify potential biomarkers for development of latent tuberculosis infection (LTBI) by longitudinal follow-up of HHCs of TB patients.** Presented at: Presented at: RePORT International 2016 Annual Meeting. Durban, South Africa; July 14–15, 2016.
7. Cheekatla SS, Tripathi D, Venkatasubramanian S, Nathella PK, Paidipally P, Ishibashi M, Welch E, Tvinnereim AR, Mitsuo I, Babu S, Kornfeld H, Vankayalapati R. **NK-DC crosstalk in diabetes enhances IL-6 mediated inflammation during tuberculosis infection.** Poster presented at: Keystone Symposium on Tuberculosis Co-Morbidities and Immunopathogenesis (B6). Keystone, CO, USA; February 28–March 3, 2016.
8. Cheekatla SS, Venkatasubramanian S, Tripathi D, Paidipally P, Welch E, Tvinnereim AR, Vankayalapati R. **IL-21 is essential for the optimal control of Mycobacterium tuberculosis infection.** Presented at: American Association of Immunologist Meeting. New Orleans, LA, USA. May 8–12, 2015.
9. Cheekatla SS, Tripathi D, Venkatasubramanian S, Paidipally P, Welch E, Tvinnereim AR, Kornfeld H, Vankayalapati R. **IL-6 regulates pro- and anti-inflammatory cytokine production and mortality of Mycobacterium tuberculosis infected Type 2 diabetic mice.** Presented at: American Association of Immunologists Meeting. New Orleans, LA, USA. May 8–12, 2015.
10. Tripathi D, Venkatasubramanian S, Cheekatla SS, Paidipally P, Welch E, Tvinnereim AR, Vankayalapati R. **CD4+CD25+Foxp3+ cells from JNK-/- mice prolong pancreatic allograft survival in type I diabetic Mice.** Presented at: American Association of Immunologist Meeting. New Orleans, LA, USA. May 8–12, 2015.
11. Tripathi D, Venkatasubramanian S, Cheekatla SS, Paidipally P, Welch E, Tvinnereim AR, Vankayalapati R. **Liver NK1.1 cells and IL-22 promote pancreatic islets allograft survival in type I diabetic mice.** Presented at: American Association of Immunologists Meeting New Orleans, LA, USA. May 8–12, 2015.
12. Venkatasubramanian S, Dhiman R, Paidipally P, Cheekatla SS, Tripathi D, Welch E, Tvinnereim AR, Brenda Jones B, Theodorescu D, Barnes PF, Vankayalapati R. **A rho GDP dissociation inhibitor produced by**

**apoptotic T-cells inhibits growth of Mycobacterium tuberculosis.** Presented at: American Association of Immunologists Meeting. New Orleans, LA, USA. May 8–12, 2015.

13. Venkatasubramanian S, Paidipally P, Cheekatla SS, Welch E, Raghunath A, Tvinnereim AR, Nurieva R, Barnes PF, Vankayalapati R. **IL-21 dependent expansion of memory-like NK cells enhances protective immune responses against Mycobacterium tuberculosis.** Presented at: NK 2015—15<sup>th</sup> Meeting of the Society for Natural Immunity. Montebello, Canada; May 2-6, 2015.

## **BYRAMJEE JEEJEBHOY MEDICAL COLLEGE (BJMC) NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS (NIRT) JOHNS HOPKINS UNIVERSITY (JHU)**

### **LECTURES**

1. Gupta A. Panelist. **Leveraging collective impact to promote India's development: The role of the Indian diaspora in the fight against tuberculosis.** The Role of the Indian Diaspora in the Fight Against Tuberculosis. Georgetown University. Washington, DC, USA; October 2, 2018.
2. Kinikar A. **Update on RICC pediatric transcriptomic study—India component.** RePORT International Annual Meeting. Szouchou, China; September 12–14, 2018.
3. Chandrasekaran P. **TB research in India.** Presented at: 1<sup>st</sup> BRICS TB Research Network Meeting. Rio de Janeiro, Brazil; September 14–15, 2017.
4. Chandrasekaran P. **Ongoing research and research priorities for India on LTBI.** Presented at: WHO Global TB Programme Technical Consultation Meeting on Programmatic Management of Latent Tuberculosis Infection (LTBI). Seoul, Republic of Korea; August 31–September 1, 2017.
5. Gupta, A. **Conducting HIV and TB research in India: Challenges and opportunities.** University of Texas Health Science Center. Tyler, TX, USA; June 23, 2016.
6. Gupta A. **TB in pregnancy.** Presented at: RePORT India 2016 Joint Leadership Meeting: Advancing TB Research. February 2, 2016; CMC Vellore, India.
7. Gupta A. **TB in pregnancy.** Presented at: RePORT India TB Workshop. March 5, 2015; Mumbai, India.
8. Gupta, A. **Conducting HIV and TB research in India: Challenges and opportunities.** Emory University. Atlanta, GA, USA; August 27, 2015.
9. Mave V. **Therapeutic drug monitoring (TDM) of TB in young children: The role of hair assays.** Presented at: IMPAACT Network Annual Meeting. Washington DC, USA; June 2015.

### **ABSTRACTS | POSTERS | PRESENTATIONS**

1. Alexander M, Bhosale R, Mathad J, Naik S, Divya A, Gupte N, Patil N, Gupta A. **Inappropriate postpartum weight loss may predict development of active TB.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
2. Baliashvili D, Gandhi NR, Kim S, Gupta A, Churchyard G, Swindells S, Hesselting A, Hughes M, Shah S for the ACTG 5300/IMPAACT I2003 PHOENIX Feasibility study team. **Resistance to Mycobacterium tuberculosis infection among household contacts of MDR TB patients.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
3. Bhosale R, Graham H, Alexander M, Kinikar A, Khwaja S, Patil N, Gupta A, Mathad J, Shivakoti R. **Association of latent TB infection in pregnancy with maternal and infant health outcomes in an Indian cohort.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.

4. Graham H, Bhosale R, Kinikar A, Alexander M, Patil N, Khwaja, Gupta A, Mathad J, Shivakoti R. **Association of HIV infection with perinatal health outcomes among Indian women with and without latent TB infection.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
5. Kim S, Wu X, Hughes M, Mendoza-Ticona A, Churchyard G, Swindells S, Shah NS, Gupta A, Hesselning A for the A5300/I2003 PHOENIX Feasibility Study Team. **High prevalence of tuberculosis infection in children living in households of MDR-TB patients.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
6. Kulkarni V, Bhosale R, Jain D, Deshpande P, Alexander M, Patil N, Gupte N, Gupta A, Mathad J. **Performance of QuantiFERON-TB Gold In Tube (QFT-GIT) and QuantiFERON-TB Gold Plus (QFT-Plus) for detection of Mycobacterium tuberculosis infection in pregnant women in India** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
7. Mehta S, Murrill M, Suryavanshi N, Bhosale R, Patil N, Gupta A, Mathad J, Shivakoti R, Alexander M. **Assessing TB-related knowledge and stigma and associated risk factors among pregnant women in low resource settings of Pune, India.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
8. Naik SN, Chandanwale A, Kadam D, Sambarey PW, Dhumal G, DeLuca A, Jain D, Gupta A, Mave V, Bollinger R. **Does treatment of infertile women with probable genital tuberculosis improve fertility outcome?** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
9. Pradhan N, Kagal A, Gupte N, Gaikwad S, Barthwal M, Gupta A, Golub JE, Mave V. **Six-week culture conversion predicts tuberculosis treatment outcomes.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
10. Suryavanshi N, Sane M, Gaikwad S, Paradkar M, Mave V, Chandrasekaran P, Shivakumar SVBY, Gupta A, Gupte N, Thomas B for CTRIUMPH RePORT India study. **Female tuberculosis (TB) patients with stigma are at increased risk of persistent depression: Time to integrate mental health screening in TB care.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 20–November 2, 2019.
11. Gupte AN, Paradkar M, Selvaraju S, Kumar P, Lokhande R, Kulkarni V, Hanna LE, Thiruvengadam K, Sekar K, Momin A, Shivakumar SVBY, Gupte N, Babu S, Salvi S, Golub J, Checkley W, Bollinger B, Andrade B, Mave V, Chandrasekaran P, Gupta A. **IL-6, TIMP-2 and TGFβ-2 are associated with respiratory impairment during and following successful treatment of pulmonary tuberculosis.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, India; February 4–6, 2019.
12. Shivakoti R, Chandrasekaran P, Hannah LE, Thiruvengadam K, Natarjan S, Karunaianatham R, Mave V, Gupte N, Kulkarni V, Pradhan N, Gupte A, Paradkar M, Shivakumar SVBY, Bharadwaj R, Kagal A, Gaikwad S, Sangle S, Borkowski K, Newman J, Fiehn O, Gupta A for CTRIUMPH RePORT India Study team. **Host lipidomic profile associated with adverse tuberculosis treatment outcomes.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, India; February 4–6, 2019.
13. DeLuca A, Thomas B, Suryavanshi N, Jain D, Paradkar M, Gupte A, Chandrasekaran P, Gupta A for the CTRIUMPH RePORT India Study Team. **Alcohol use disorder, drinking patterns, and tuberculosis treatment failure in Indian patients.** 49th Annual Union World Conference on Lung Health. The Hague, The Netherlands. October 24–27, 2018.
14. Gupte A, Kumar P, Kulkarni V, Bharadwaj R, Andrade B, Mave V, Chandrasekaran P, Gupta A. **Interleukin-6, interleukin-13 and interferon-γ as potential biomarkers for treatment failure in pulmonary tuberculosis.** 49th Annual Union World Conference on Lung Health. The Hague, The Netherlands; October 24–27, 2018.
15. Gupte N, Gupte A, Sivaramakrishnan GN, Pradhan N, Shivakumar SVBY, Gupta A, Mave V, Chandrasekaran P for the C-TRIUMPH RePORT India team. **Time to culture conversion, identifying independent**

- modifiable risk factors in Indian patients.** Presented at 49th Union World Conference on Lung Health. The Hague, The Netherlands; October 24–27, 2018.
16. Thomas B, Kannan T, Rani V, Gupte N, Gupta A, Deluca A, Suryavanshi N, Kohli R, Chandrasekaran P for the C-TRIUMPH RePORT India Study Team. **Does smoking have an impact on TB treatment outcomes? A prospective cohort study from India.** Session: Tobacco Use in Various Populations: Implications for Policy and Practice. 49th Annual Union World Conference on Lung Health. The Hague, The Netherlands; October 24–27, 2018.
  17. Ramachandran G, Chandrasekaran P, Gaikwad S, Kumar AKH, Thiruvengadam K, Gupte N, Paradkar M, Dhanasekaran K, Sivaramakrishnan GN, Kagal A, Thomas B, Pradhan N, Kadam D, Hanna LE, Balasubramanian U, Kulkarni V, Murali L, Golub J, Gupte A, Shivakumar SVBY, Swaminathan S, Dooley KE, Gupta A, Mave V for the C-TRIUMPH Study Team. **Sub-therapeutic rifampicin concentration among thrice weekly treated PTB patients with unfavorable treatment outcomes.** 49th Annual Union World Conference on Lung Health. The Hague, The Netherlands; October 24–27, 2018.
  18. Gupte A, Paradkar M, Selvaraju S, Shivakumar SVBY, Kohli R, Momin A, Gaikwad S, Jain D, Raskar S, Suryavanshi N, Thiruvengadam K, Sekar K, Kumar B, Yashoda R, Lokhande R, Gupte N, Golub J, Chandrasekaran P, Mave V, Gupta A. **Hyperglycemia and impairment in treated pulmonary tuberculosis.** RePORT International Young Investigator Abstract Presentation at: RePORT International 2018 Annual Meeting. Suzhou, China; September 12–14, 2018.
  19. Paradkar M, Chandrasekaran P, Shivakumar SVBY, Jain D, Thiruvengadam K, Gupte A, Thomas B, Kinikar A, Bharadwaj R, Gaikwad S, Lokhande R, Dolla CK, Selvaraju S, Murali L, Rajagopal S, Kulkarni V, Pradhan N, Hannah LE, Pattabiraman S, Kohli R, Nayagam R, Suryavanshi N, Cox S, Gupte N, Mave V, Gupta A for the C-TRIUMPH Study Team. **Incidence of Mycobacterium tuberculosis infection among household contacts of adult pulmonary Tuberculosis cases in India.** RePORT International Young Investigator Abstract Presentation at: RePORT International 2018 Annual Meeting. Suzhou, China; September 12–14, 2018.
  20. Dolla CK, Paradkar M, Gupte A, Thiruvengadam K, Gupte N, Kulkarni V, Balasubramanian U, Hannah LE, Dhanasekaran K, Bharadwaj R, Shivakumar SVBY, Gaikwad S, Meshram S, Kohli R, Lokhande R, Thomas B, Kinikar A, Swaminathan S, Mave V, Gupta A, Chandrasekaran P. **TB infection among household contacts: Preventive therapy for all?** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  21. Dhanasekaran K, Chandrasekaran P, Paradkar M, Marinaik SB, Gupte A, Dolla CK, Joseph B, Subramanyam B, Sivaramakrishnan GN, Thiruvengadam K, Gupte N, Rajagopal S, Pradhan N, Selvaraju S, Kulkarni V, Hannah LE, Nayakam R, Suryavanshi N, Shivakumar SVBY, Mave V, Thomas B, Bharadwaj R, Gaikwad S, Meshram S, Lokhande R, Kinikar A, Daware R, Murali L, Swaminathan S, Gupta A for the C-TRIUMPH Study Team. **Risk factors associated with unfavorable outcomes in a cohort of pulmonary TB patients.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  22. Paradkar M, Dhanasekaran K, Kinikar A, Kulkarni R, Bharadwaj R, Gaikwad S, Lokhande R, Meshram S, Dolla CK, Selvaraju S, Murali L, Thiruvengadam K, Jain D, Rajagopal S, Kulkarni V, Pradhan N, Shalini J, Kohli R, Nayagam R, Shivakumar SVBY, Suryavanshi N, Gupte A, Gupte N, Chandrasekaran P, Mave V, Gupta A for the C-TRIUMPH Study Team. **Incidence of Mycobacterium tuberculosis infection among household contacts of adult pulmonary tuberculosis cases in India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  23. Selvaraju S, Thiruvengadam K, Paradkar M, Marinaik SB, Bharadwaj R, Rajagopalan S, Gaikwad S, Pattabiraman S, Kinikar A, Sivaramakrishnan GN, Meshram S, Hanna LE, Lokhande R, Dhanasekaran K, Gupte A, John S, Gupte N, Thomas B, Kulkarni V, Ayyanu S, Kohli R, Shivakumar SVBY, Swaminathan S, Mave V, Gupta A, Chandrasekaran for the CTRIUMPH Study Team. **Incidence of Mycobacterium tuberculosis infection among household contacts of adult pulmonary tuberculosis cases in India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  24. Mave V, Chandrasekaran P, Paradkar M, Gupte A, Pradhan N, Sivaramakrishnan GN, Thiruvengadam K, Shivakumar SVBY, Kulkarni V, Dhanasekaran K, Subramanyam B, Selvaraju S, Murali L, Bharadwaj R, Gaikwad

- S, Meshram S, Kinikar A, Hanna LE, Swaminathan S, Gupte N, Gupta A. **Infection free “resistors” among household contacts of culture-confirmed adult pulmonary TB cases.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
25. Tornheim JA, Paradkar M, Valvi C, Gupte N, Madugundu A, Kulkarni V, Sreenivasamurthy S, Raja R, Pradhan N, Shivakumar SVBY, Kohli R, Gupte A, Chandrasekaran P, Mave V, Pandey A, Gupta A. **Gene expression profiles of pediatric tuberculosis patients and exposed controls from India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  26. Dhumal G. **Poor understanding of TB infection among at-risk tuberculin skin-test positive household contacts of pulmonary TB cases in Pune, India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  27. Mathad J, Alexander A, Bhosale R, Naik S, Suryavanshi N, Mave V, Deshpande P, Balasubramanian U, Kulkarni V, Kumar P, Babu S, Gupte N, Nevrekar N, Patil S, Chandanwale A, Gupta A. **The effect of HIV on the immune response to Myobacterium tuberculosis in pregnant women from Pune, India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  28. Tornheim JA, Madugundu AK, Pradhan N, Bharadwaj R, Mave V, Golub J, Pandey A, Gupta A. **Drug susceptibility of rifampin-resistant tuberculosis using whole genome sequencing to identify genes of interest in Pune, India.** Presented at: 5<sup>th</sup>Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
  29. Belgaumkar V. **Barriers to contact screening and isoniazid preventive therapy among pediatric contacts of adults with smear-positive tuberculosis.** Presented at: 48th Union World Conference on Lung Health. Guadalajara, Mexico; October 13, 2017.
  30. DeLuca A, Dhumal G, Paradkar M, Suryavanshi N, Mave V, Kohli R, Shivakumar SVBY, Gupta A. **Lack of TB knowledge among TST-positive household contacts of pulmonary cases: A missed opportunity.** Presented at: 48th Union World Conference on Lung Health. Guadalajara, Mexico; October 13, 2017.
  31. Tornheim J, Paradkar M, Valvi C, Gupte N, Madugundu A, Kulkarni V, Sreenivasamurthy S, Raja R, Pradhan N, Shivakumar SVBY, Kohli R, Chandrasekaran P, Pandey A, Mave V, Gupta A. **Gene expression profiles of pediatric tuberculosis patients and exposed controls from India.** Presented at: RePORT International 2017 Annual Meeting. Rio de Janeiro, Brazil; September 13; 2017.
  32. Gupte A, Mave V, Meshram S, Lokhande R, Kadam D, Dharmshale S, Bharadwaj R, Kagal A, Pradhan N, Deshmukh S, Atre S, Sahasrabudhe T, Barthwal M, Meshram S, Kakrani A, Kulkarni V, Raskar S, Suryavanshi N, Shivakoti R, Chon S, Selvin E, Gupte N, Gupta A, Golub J. **Trends in glycated hemoglobin levels and implications for diabetes screening among pulmonary tuberculosis cases undergoing treatment in India.** RePORT International 2017 Annual Meeting. Rio de Janeiro, Brazil; September 13; 2017.
  33. Shivakumar SVBY, Chandrasekaran P, Paradkar M, Danasekaran K, Kumar AMV, Ramachandran G, Thomas B, Suryavanshi N, Kohli R, Thiruvengadam K, Gupte N, Kulkarni V, Hannah LE, Gomathy NS, Pradhan N, Dolla CK, Gupte A, DeLuca A, Meshram S, Kagal AD, Golub J, Selvaraj K, Murali L, Swaminathan S, Mave V, Gupta A. **High burden of dysglycemia among contacts of tuberculosis patients in India: Is it time to screen them all?** RePORT International 2017 Annual Meeting. Rio de Janeiro, Brazil; September 13; 2017.
  34. Tornheim J, Paradkar M. **C-TRIUMPH pediatric biomarker substudy.** Invited Presentation. Session: The Future of MDR-TB Treatment in Children. 2017 IMPAACT Network Annual Meeting. Washington, DC, USA; May 30, 2017.
  35. Mathad J, Alexander M, Bhosale R, Naik S, Shivakoti R, Mave V, Suryavanshi N, Gupte N, Kulkarni V, Pradhan N, Patil N, Gupta A. **Impact of immune changes of pregnancy and HIV infection on tuberculosis.** Presented at: RePORT India 2017 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.

36. Gupte A, Meshram S, Selvaraju S, Gupte N, Shivakumar SVBY, Paradkar M, Kohli R, Thiruvengadam K, Suryavanshi N, Chandrasekaran P, Mave V, Swaminathan S, Gupta A, Golub J, Checkley W. **Host factors associated with poor respiratory health-related quality of life in pulmonary tuberculosis.** Presented at: RePORT India 2017 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.
37. Chandrasekaran P, Thiruvengadam K, Gupte N, Luck EH, Mave V, Gupte A, Gupta A, Swaminathan S. **Household contact tracing of adult pulmonary TB patients in India: Prevalence of TB disease and infection.** Presented at: RePORT India 2017 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.
38. Paradkar M, Kavitha D, Shivakumar SVBY, Khadse S, Khwaja S, Hari K, Rani N, Thiruvengadam K, Gupte N, Raskar S, Jain D, Suryavanshi S, Kohli R, Kulkarni V, Pradhan N, Sathyamurthi B, Tornheim J, Gupte A, DeLuca A, Mave V, Chandrasekaran P, Gupta A for the C-TRIUMPH Study Team. **Descriptive baseline characteristics, treatment outcomes, and biorepository of pediatric TB cases in C-TRIUMPH-RePORT India prospective cohort.** Presented at: RePORT India 2017 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.
39. John S, DeLuca A, Paradkar M, Nayagam R, Shivakumar SVBY, Gupte A, Gupte N, Thomas B, Suryavanshi N, Kohli R, Golub J, Kulkarni V, Pradhan N, Mave V, Chandrasekaran P, Gupta A. **Alcohol use among adult pulmonary and extra-pulmonary TB cases in the C-TRIUMPH India cohort.** Presented at: RePORT India 2017 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.
40. Mave V, Pradhan R, Kagal A, Bharadwaj R, Gupte N, Gupta A, Meshram S, Golub J. **Third anti-TB drug in continuation phase for TB patients: Is it the need of the hour for India?** Presented at: 47th Union World Conference on Lung Health. Liverpool, UK; October 27, 2016.
41. Mave V, Gupte N, Meshram S, Kagal A, Gupta A, Bharadwaj R, Pradhan R, Golub J. **Xpert® MTB/RIF assay for pulmonary tuberculosis diagnosis in patients with pre-diabetes mellitus and diabetes mellitus.** Presented at: 47th Union World Conference on Lung Health. Liverpool, UK; October 27, 2016.
42. Gupte A, Meshram S, Selvaraju S, Gupte N, Shivakumar SVBY, Paradkar M, Kohli R, Thiruvengadam K, Suryavanshi N, Chandrasekaran P, Mave V, Swaminathan S, Gupta A, Golub J, Checkley W. **Host factors associated with poor respiratory health-related quality of life in pulmonary tuberculosis.** Presented at: IDWeek 2016. New Orleans, LA, USA; October 27, 2016.
43. Chandrasekaran P, Mave V, Thiruvengadam K, Gupte N, Hannah LE, Meshram S, Swaminathan S, Gupta A. **Household contact tracing of adult pulmonary TB patients in India: Prevalence of TB disease.** Presented at: IDWeek 2016. New Orleans, LA, USA; October 27, 2016.
44. Shivakumar SVBY, Thiruvengadam K, Gupte N, Chandrasekaran P, Mave V, Hannah LE, Kulkarni V, Gupte A, DeLuca A, Pattabiraman S, Sharma GN, Pradhan N, Subramaniyan B, Chandrakumar D, Thomas B, Suryavanshi B, Paradkar M, Meshram S, Kagal A, Kohli R, Golub J, Ramachandran G, Swaminathan S, Gupta A. **TB infection prevalence, incidence, and risk factors among child and adult household contacts of adult TB cases in India.** Presented at: IDWeek 2016. New Orleans, LA, USA; October 27, 2016.
45. Elf JL, Kinikar A, Khadse S, Mave V, Gupte N, Kulkarni V, Patekar S, Raichur P, Breyse P, Gupta A, Golub J. **The association of exposure to air pollution from biomass fuels, kerosene, and secondhand tobacco smoke with TB in adult women and children in Pune, India.** Presented at: RePORT International 2016 Annual Meeting. Durban, South Africa; July 14, 2016.
46. Gupte A, Meshram S, Selvaraju S, Gupte N, Shivakumar SVBY, Paradkar M, Kohli R, Thiruvengadam K, Suryavanshi N, Chandrasekaran P, Mave V, Swaminathan S, Gupta A, Golub J, Checkley W. **Host factors associated with poor respiratory health-related quality of life in pulmonary tuberculosis.** Presented at: RePORT International 2016 Annual Meeting. Durban, South Africa; July 14, 2016.
47. Ogale YP, Elf JL, Lokhande R, Mave V, Roy S, Gupta A, Golub JE, Mathad J. **Characteristics associated with mobile phone access among TB patients in Pune, India.** Presented at: 46th World Conference on Lung Health. Cape Town, South Africa; December 1–5, 2015.



48. Elf JL, Kinikar A, Khadse S, Mave V, Gupte N, Kulkarni V, Patekar S, Raichur P, Breyse P, Gupta A, Golub J. **The association of exposure to air pollution from biomass fuels, kerosene, and secondhand tobacco smoke with TB in adult women and children in Pune, India.** Presented at: American Thoracic Society International Conference. Denver, CO, USA; May 1, 2015.

## **CHRISTIAN MEDICAL COLLEGE, VELLORE (CMC-VELLORE) UNIVERSITY OF CAMBRIDGE–UNIVERSITY OF WASHINGTON**

### **LECTURES**

1. Christopher DJ, **Post TB bronchiectasis.** Presented at: Nexlore Bronchiectasis Conclave. Candolim, Goa, India; December 14, 2019.
2. Christopher DJ. **Experiences with LTBI screening of healthcare workers in an Indian referral hospital.** Presented at: 50th Annual Union World Conference on Lung Health. Hyderabad, India; October 30–November 2, 2019.
3. Christopher DJ. **TB-diabetes link.** Presented at: Prof. Dr. M. Viswanathan Oration at the Research Society for the study of Diabetes in India, Annual Conference. Dindigul, Tamil Nadu, India; August 10, 2019.
4. Christopher DJ. **PET scan in TB meningitis.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
5. Christopher DJ. **Xpert PCR ultra and transcriptional signatures in pleural tuberculosis.** RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
6. Christopher DJ. **Is India's endeavor to end TB by 2025 achievable?** Presented at: 36th AP Tuberculosis & Chest Diseases Conference. Madanapally, Andhra Pradesh, India; November 10–11, 2018.
7. Christopher DJ. **Addressing diagnostic challenges for TB meningitis—From clinical staging to PET Scanning.** Presented at: 49th Union World Conference on Lung Health. The Hague, The Netherlands; October 24–27, 2018.
8. Christopher DJ. **Is India's endeavor to end TB by 2025 achievable? How can RePORT align with this?** Presented at: RePORT International 2018 Annual Meeting. Suzhou, China; September 12–14, 2018.
9. Christopher DJ. **Determination of efficacy of expert PCR ultra and transcriptional signatures in the diagnosis of pleural tuberculosis.** Presented at: RePORT International 2018 Annual Meeting. Suzhou, China; September 12–14, 2018.
10. Christopher DJ. **Healthcare personnel TB—Fact of life in high burden countries.** Presented at: RePORT International 2018 Annual Meeting. Suzhou, China; September 12–14, 2018.
11. Christopher DJ. **Point of care diagnostics and need for triage test in a high prevalence setting.** Presented at: Investigators Meeting: Understanding the Resources and Gaps in DAIDS funded TB Research. NIAID Conference Center. Rockville, MD, USA; July 2–3, 2018.
12. Christopher DJ. **Battling the white plague (TB) in our campuses.** Presented at: The Quality Circle, Christian Medical College. Vellore, India; April 14, 2018.
13. Christopher DJ. **State of TB control in India.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
14. Christopher DJ. **Prevalence of latent TB infection (LTBI) among undergraduate nursing trainees in a rural secondary care hospital in Southern India.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
15. Christopher DJ. **Targeted LTBI testing.** Presented at: LTBI Knowledge Seminar. Hyderabad, India; January 11, 2018.

16. Christopher DJ. **LTBI screening in high TB prevalence setting.** Presented at: Qiagen Knowledge Seminar. Bangalore, India; November 2, 2017.
17. Christopher DJ. **LTBI Screening: A clinician's perspective.** Presented at: CME organized by Qiagen. New Delhi; India. April 5, 2017.
18. Christopher DJ. **LTBI: To screen or not to screen.** Presented at: Three T's of TB Prevention: Test, Treat, and Track Symposium. Asia Pacific Regional Conference; International Union against Tuberculosis. Tokyo, Japan; March 23, 2017.
19. Christopher DJ. **Advances in the management of drug resistant TB.** Presented at: TB Symposium. Convened by Krishna Medical College in collaboration with McGill University (Canada). Manipal, India; December 21, 2016.
20. Christopher DJ. **Healthcare worker TB: A Panel Discussion.** Presented at: TB Symposium. Convened by Krishna Medical College in collaboration with McGill University (Canada). Manipal, India; December 21, 2016.
21. Christopher DJ. **Evolution of drug resistant TB in India.** Presented at: Annual Update in Tuberculosis. Convened by CMC Vellore. Vellore, India; November 19, 2016.
22. Christopher DJ. **Screening for LTBI in healthcare personnel to assess TB risk—Lessons from India.** Presented at: 5th Meeting of Asian Experts Community. Taipei, Taiwan; August 26–28, 2016.
23. Christopher DJ. **TB risk in healthcare workers: Myth or reality?** Presented at: RePORT International 2016 Meeting. Durban, South Africa; July 14–15, 2016.
24. Christopher DJ. **From lab to clinic: Optimizing the importance of new diagnostics.** Presented at: Advancing TB Research—An Exploration of Opportunities. Convened by PD Hinduja Hospital and NIH (USA). Mumbai, India; March 23–24, 2016.
25. Christopher DJ. **Lessons from healthcare—TB research in India.** Presented at: CMC Winter Symposium and the RePORT India 2016 Joint Leadership Group Meeting. Vellore, India; February 12–13, 2016.
26. Christopher DJ. **Pleural tuberculosis.** Presented at: Association of Physicians of India Meeting. Hyderabad, India; January 29–31, 2016.
27. Christopher DJ. **TB in healthcare workers.** Presented at: National Update in Respiratory Medicine. Convened by PD Hinduja Hospital. Mumbai, India; November 27–29, 2015.
28. Christopher DJ. **Road for TB elimination in India.** Presented at: 4th Meeting of Asian Experts Community. Bali, Indonesia; August 7–9, 2015.
29. Christopher DJ. **Newer diagnostics in TB.** Presented at: Institute of Thoracic Medicine, MMC, CME Program for the PG Students of Southern States. Chennai, India; September 2014.
30. Christopher DJ. **Relevance of TST and IGRA in current day practice.** Presented at: ASHRAICON Conference 2014. Ahmedabad, India; July 27, 2014.

## PRESENTATIONS | ABSTRACTS

1. Christopher DJ, Kuruvilla L, Sarangi PK, Irodi A, Chacko B, Leena RV, Shankar D, Thangakunam B. **Comparison of chest radiographic pattern in diabetic and non-diabetic patients with pulmonary tuberculosis.** Presented at: 29<sup>th</sup> ERS International Congress, IFEMA. Madrid, Spain; September 28–October 2, 2019.
2. Christopher DJ, Deva J, Thangakunam B, Mathew BS, Winston B. **Anti-tubercular drug concentrations in pulmonary tuberculosis patients—Diabetics vs non-diabetics.** Presented at: 29<sup>th</sup> ERS International Congress, IFEMA. Madrid, Spain; September 28–October 2, 2019.

3. Christopher DJ. **Experiences with LTBI screening of healthcare workers in an Indian referral hospital.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India; October 30–Nov 2, 2019.
4. Christopher DJ, Christopher SA, Balamugesh. T, Hephzibah J, David T, Sathyendra S, Abraham OC, Ramya I, Mathuram A. **Role of PET CT scans in tuberculous meningitis.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, Tamil Nadu, India; February 4–6, 2019.
5. Christopher DJ, Deva J, Thangakunam B, Mathew BS, Winston B. **Plasma drug concentrations of isoniazid and rifampicin in pulmonary tuberculosis patients with diabetes.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, Tamil Nadu, India; February 4–6, 2019.
6. Christopher DJ, Shankar D, Hemanth Kumar AK, Thangakunam B, Kannan T, Ramachandran G. **Pharmacokinetics of rifampicin, isoniazid and pyrazinamide during daily and intermittent dosing.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, Tamil Nadu, India; February 4–6, 2019.
7. Christopher DJ, Arjun AC, Balamugesh T, David T, Sathyendra S, Ramya I, Abraham OC, Mathuram A, Ramakrishnan L. **Predictors of mortality in a TB meningitis cohort.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, Tamil Nadu, India; February 4–6, 2019.
8. Christopher DJ, Arjun AC, Balamugesh T, Shankar D. **Respiratory and non-respiratory comorbidities in tuberculosis.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, Tamil Nadu, India; February 4–6, 2019.
9. Christopher DJ, Thangakunam B, Shankar D, Samuvel S, Oliver A, Deepak A. **Empirical treatment of smear negative ‘supposedly’ pulmonary tuberculosis patients—Is it right?** Presented at: RePORT India 2018 Joint Leadership Meeting. Delhi, India; February 15–17, 2018.
10. Christopher DJ, Thangakunam B, Samuvel S, Deepak A, Shankar D, Mathuram A, David T, Sathyendra S, Abraham OC, Ramya I, Ramakrishnan L. **Comparison of profile of Indian patients with tubercular meningitis in the CMC, Vellore, cohort with other cohorts.** Presented at: RePORT India 2018 Joint Leadership Meeting. Delhi, India; February 15–17, 2018.
11. Christopher DJ, Shankar D, Micheal JS, Thangakunam B, Ramakrishnan L. **Factors affecting time to sputum smear and culture conversion in adults with pulmonary tuberculosis: A prospective cohort study from CMC RePORT data.** Presented at: RePORT India 2018 Joint Leadership Meeting. Delhi, India; February 15–17, 2018.
12. Christopher DJ, Dinakaran S, Gupta R, Prince J, Isaac B, Thangakunam B. **Large thoracoscopic pleural biopsy improves yield of Xpert MTB/RIF for diagnosis of pleural tuberculosis.** Presented at: BRONCOCON, CMC Vellore. Vellore, India; March 2–4, 2017.
13. Christopher DJ, Balamugesh T, Dhobi P. **The prevalence of active and latent tuberculosis infection in patients with type 2 diabetes mellitus in a tertiary care hospital of South India.** Presented at: RePORT India 2016 Joint Leadership Meeting. Vellore, India; February 12–14, 2016.
14. Christopher DJ, Balamugesh T, Rohit KO, James P, Gupta R. **Diagnostic yield of various microbiologic and histopathologic tests in TB pleural effusion diagnosed with thoracoscopy and outcomes of such patients on 6 months follow up.** Presented at: RePORT India 2016 Joint Leadership Meeting. Vellore, India; February 12–14, 2016.
15. Christopher DJ, Mitra S, Saroini JS, Balaji V, Gupta M, Therese M, Yadav B, Jeyaseelan L. **Burden of diabetes among patients with tuberculosis: Ten-year experience from an Indian tertiary care teaching hospital.** Presented at: 45<sup>th</sup> Union World Conference on Lung Health. Barcelona, Spain; October 28–November 1, 2014.
16. Christopher DJ, Denkinger C, Thangakunam B, Sarojini JS, Pai M, Schumacher S. **Point-of-care implementation of Xpert: Evaluating the impact of product and process innovation in TB diagnosis.** Presented at: 45<sup>th</sup> Union World Conference on Lung Health. Barcelona, Spain; October 28–November 1, 2014.

# JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH (JIPMER) BOSTON MEDICAL CENTER (BMC)

## LECTURES

1. Hochberg, NS. **Tuberculosis: The fundamentals and the sea changes.** Presented at: MPH Course: Global Health Priorities & Approaches. Tufts University School of Medicine. Boston, MA, USA; 2019.
2. Hochberg, NS. **Malnutrition and tuberculosis.** World TB Day, National Regional Conference, Albany, NY, USA; 2019.
3. Hochberg, NS. **Malnutrition and tuberculosis.** Providence/Boston CFAR TB/HIV Scientific Working Group TB Interest Group Round Table. Boston, MA, USA; 2019
4. Hochberg, NS. **The skinny on tuberculosis: Why malnutrition matters.** Infectious Diseases Grand Rounds. Presented at: Boston Medical Center. Boston MA, USA; 2019.
5. Hochberg NS. **Indo-U.S. TB cohort: Study design and preliminary results.** Presented at: TB Research Unit (TBRU) Investigators Meeting. Boston, MA, USA; September 2017.
6. Hochberg NS. **Updates in tuberculosis: The era of sea changes.** Medicine Grand Rounds. Presented at: Carney Hospital. Dorchester, MA. USA; March 2017.
7. Hochberg NS. **Indo-U.S. TB Cohort: Study design and preliminary results.** Invited speaker, JIPMER. February 8, 2017; Puducherry, India.
8. Hochberg NS. **Malnutrition and TB in India: Intersection and implications.** Presented at: Northeastern World TB Day Symposium. Boston, MA, USA. March 6–7, 2017.

## PRESENTATIONS | ABSTRACTS

1. Abilasha N, Bharath B, Priyanga J, Senbagavalli P, Prakash B, Vinod K, Subitha L, Roy G, Salgame P, Muthuraj M, Roy G, Sarkar S, Hochberg NS, Noyal J. **Effect of diabetes prevalence on circulating components of blood, disease severity and drug susceptibility in patients with pulmonary tuberculosis.** Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 30–November 2, 2019.
2. Chua A, Mowry WB, Sahu S, Roy G, Ellner JJ, Horsburgh Jr CR, Pleskunas J, Sarkar S, Hochberg NS, Reddy D. **Does the form of tobacco product used by smokers influence pulmonary tuberculosis severity?** Presented at: ATS 2018. San Diego, CA, USA; May 18–23, 2018.
3. Abilasha N, Bharath B, Priyanga J, Senbagavalli P, Prakash B, Vinod K, Subitha L, Roy G, Salgame P, Muthuraj M, Roy G, Sarkar S, Hochberg NS, Noyal J. **Effect of diabetes prevalence on circulating components of blood, disease severity and drug susceptibility in patients with pulmonary tuberculosis.** Presented at: RePORT India 2018 Joint Leadership Meeting. Chennai, India; February 14-16, 2018.
4. Schenk NM, Sahu S, Roy G, Ellner JJ, Horsburgh Jr CR, Pleskunas J, Sarkar S, Hochberg NS, Reddy D. **Influence of type of tobacco product on chest X-ray findings in pulmonary tuberculosis patients in India.** Presented at: RePORT India 2018 Joint Leadership Meeting. Chennai, India; February 14-16, 2018.
5. Hoyt K, White L, Sarkar S, Pleskunas J, Zhou T, Noyal J, Muthuraj M, Vinod K, Roy G, Ellner JJ, Horsburgh Jr CR, Hochberg NS. **Effect of malnutrition on tuberculosis mycobacterial burden and chest radiographic findings.** Presented at: RePORT India 2018 Joint Leadership Meeting. Chennai, India; February 14-16, 2018.
6. Reddy D. **Wood fuel usage is associated with a higher leukocyte count in pulmonary tuberculosis patients.** Presented at: RePORT India 2018 Joint Leadership Meeting. Chennai, India; February 14-16, 2018.

7. Forsyth M. **Alcohol use and clinical presentation of tuberculosis at time of diagnosis in Puducherry and Tamil Nadu, India.** Presented at: RePORT India 2018 Joint Leadership Meeting. Chennai, India; February 14-16, 2018.
8. Johnson WE, Knudsen S, Hochberg N, Joseph N, Roy G, Sarkar S, Ellner J, Salgame P. **Optimizing parsimonious gene signatures defining the spectrum of tuberculosis infection.** Presented at: 48<sup>th</sup> Union World Conference on Lung Health. Hyderabad, India; October 2017.
9. Johnson WE. **Parsimonious gene signatures for TB outcomes.** Presented at: JIPMER. Pondicherry, India; November 2017.
10. Johnson WE. **Addressing unwanted heterogeneity in genomic data: Applications in RNA-sequencing and prediction.** Presented at: Department of Statistics, University of Connecticut. Storrs, CT, USA; November 2017.
11. Svadzian A, Sahu A, Pleskunas JA, Sarkar S, Roy G, Ellner JJ, Hochberg NS, Reddy D. **Association between wood fuel usage and disease severity among pulmonary tuberculosis cases.** Presented at: American Society of Tropical Medicine & Hygiene Meeting. Atlanta, GA, USA; November 2016.
12. **Stigma as a barrier to tuberculosis care: A literature review.** Presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
13. Roy G, Sivaprakasam A, Kubiak R, Govindarajan S, Salgame P, Ellner J, Hochberg N, Sarkar S. **Description of new pulmonary tuberculosis cases in Southern India.** Presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
14. Svadzian A, Sahu A, Pleskunas JA, Sarkar S, Roy G, Ellner JJ, Hochberg NS, Reddy D. **Association between wood fuel usage and disease severity among pulmonary tuberculosis cases.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
15. **Conversion among pulmonary tuberculosis cases in India.** Presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
16. **Predictors of 2 month sputum conversion among tuberculosis patients in India.** Presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
17. **Prolonged cough among tuberculosis patients in Tamil Nadu and Pondicherry, India.** Presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. Boston, MA, USA; October 2016.
18. Reddy D, Sahu S, Roy G, Ellner JJ, Horsburgh Jr CR, Pleskunas JA, Sarkar S, Hochberg NS. **Association between biomass fuel, tobacco use and two-month sputum smear conversion among pulmonary tuberculosis cases in India.** Presented at: American Thoracic Society Conference. San Francisco, CA, USA; May 2016.
19. Roy G, Sivaprakasam A, Kubiak R, Govindarajan S, Salgame P, Ellner J, Hochberg N, Sarkar S. **Description of new pulmonary tuberculosis cases in Southern India.** Presented at: 46th Union World Conference on Lung Health. Cape Town, South Africa; December 1–5, 2015.
20. Sarkar S, Fernandes P, Lakshminarayanan S, Kubiak R, Horsburgh CR, Ravikumar T, Ellner J, Hochberg N. **Age and gender distribution of latent tuberculosis infection cases in a household contact study, India.** Presented at: 46th Union World Conference on Lung Health. Cape Town, South Africa; December 1–5, 2015.
21. Reddy, D, Sahu S, McIntosh A, Kubiak R, Roy G, Ellner J, Sarkar S, Hochberg N. **Association between latent tuberculosis infection and indoor air pollution among household contacts of pulmonary tuberculosis cases.** Poster presented at: 46th Union World Conference on Lung Health of the International Union Against TB and Lung Disease. Cape Town, South Africa; December 1–5, 2015.

## MV DIABETES RESEARCH CENTRE (MVDRC) UNIVERSITY OF MASSACHUSETTS

### LECTURES

1. **TB and diabetes from bench to bedside and back.** Presented at: 2<sup>nd</sup> International Symposium on Frontiers in Biomedical Science of Infection Control Convergence Medical Research Center, MMRC. Chungnam National University. Daejeon, Korea; October 15, 2019.
2. Shruthi BS, Sivakumar S, Arutselvi D, Kumar NP, Babu S, Menon PA, Natarajan M, Sathyavani K, Kornfeld H, Viswanathan V. **Association of diabetes mellitus with INH monoresistance.** Presented at: RePORT India 2019 Joint Leadership Meeting. Chennai, India; February 4–6, 2019.
3. Kumar NP, Moideen K, Sivakumar S, Menon P, Viswanathan V, Kornfeld H, Babu S. **Altered circulating levels of eicosanoids in tuberculosis-diabetes co-morbidity and reversal upon standard tuberculosis treatment.** Presented at: Keystone Symposia -Tuberculosis: Mechanisms, Pathogenesis and Treatment. Banff, Alberta, Canada; January 17–21, 2019.
4. Kumar NP, Moideen K, Sivakumar S, Menon P, Viswanathan V, Kornfeld H, Babu S. **Elevated circulating levels of monocyte activation markers among tuberculosis patients with diabetes co-morbidity** Presented at: IMMUNOCON 2018 45th Annual Meeting of Indian Immunology Society. TSHTI, Faridabad, India; November 1–3, 2018.
5. Kornfeld H. **AMP kinase activation as host-directed therapy for tuberculosis.** 49<sup>th</sup> Union World Conference on Lung Health. The Hague, Netherlands; October 23–26, 2018.
6. Kumar NP, Moideen K, Sivakumar S, Menon P, Viswanathan V, Kornfeld H, Babu S. **Effect of standard tuberculosis treatment on circulating levels of pro-inflammatory cytokines in tuberculosis-diabetes comorbidity.** Presented at Keystone Symposia -Tuberculosis: Translating Scientific Findings for Clinical and Public Health Impact. Whistler, BC, Canada; April 15–19, 2018.
7. Kornfeld H. **TB and diabetes from bench to bedside and back.** Presented at: American Thoracic Society International Conference ATS San Diego, CA, USA; March 22, 2018.
8. Kornfeld H. **Diabetic immunopathy and TB.** Presented at: TB Conference. The Union-North American Region, Chicago, IL, USA; March 3, 2018.
9. Kumar NP, Moideen K, Sivakumar S, Menon P, Viswanathan V, Kornfeld H, Babu S. **Effect of anti-tuberculosis treatment on the systemic levels of matrix metalloproteinases and tissue inhibitors of MMP in tuberculosis–diabetes comorbidity.** Presented at: 5th Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
10. Moideen K, Kumar NP, Bethunaickan R, Sivakumar S, Menon PA, Viswanathan V, Shruthi BS, Kornfeld H, Babu S. **Altered systemic levels of neutrophil and mast cell granular proteins in tuberculosis-diabetes comorbidity and changes following treatment.** Presented at: 5th Global Forum on TB Vaccines. New Delhi, India; February 20–23, 2018.
11. Shruthi BS. **Impact of metformin use on TB severity in diabetes.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
12. Moideen K. **Effect of anti-tuberculosis treatment on the systemic levels of matrix metalloproteinases and tissue inhibitors of MMP in tuberculosis–diabetes comorbidity.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
13. Kumar NP. **Effect of standard tuberculosis treatment on circulating levels of monocyte activation markers and RAGE ligands in tuberculosis–diabetes comorbidity.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.



14. Shruthi BS. **Impact of metformin use on TB severity in diabetes.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
15. Kornfeld H. **TB and diabetes from bench to bedside and back.** Presented at: Division of Infectious Disease, Boston University School of Medicine. Boston, MA, USA; January 25, 2018.
16. Kornfeld H. **TB and diabetes from bench to bedside and back.** Presented at: Division of Endocrinology, University of Massachusetts School of Medicine. Worcester, MA, USA; January 9, 2018.
17. Kornfeld H. **Clinical and immunological findings from the Effect of Diabetes on TB (EDOTS) study in India.** Presented at: 48<sup>th</sup> Union World Conference on Lung Health. Guadalajara, Mexico; October 11–14, 2017.
18. Kornfeld H. **Impact of diabetes and hyperlipidemia on host defense.** Presented at: 48<sup>th</sup> Union World Conference on Lung Health. Guadalajara, Mexico; October 11–14, 2017.
19. Kornfeld H. **Sugar, fat, and consumption.** Presented at: Infectious Diseases Grand Rounds, Perelman School of Medicine, University of Pennsylvania. Philadelphia, PA, USA; September 28, 2017.
20. Kornfeld H. **Intersection between TB & diabetes.** Presented at: New England TB Clinicians' Conference, University of Massachusetts Medical School. Worcester, MA, USA; May 11, 2017.
21. Kornfeld H. **Diabetic immunopathy and TB.** Presented at: Rollins School of Public Health, Emory University. Atlanta, GA, USA; April 20, 2017.
22. Kornfeld H. **Diabetic immunopathy & TB.** Presented at: Meakins-Christie Laboratories, McGill University. Montreal, Canada; April 10, 2017.
23. Kornfeld H. **Diabetic immunopathy and TB.** Presented at: National TB Conference. Atlanta, GA, USA; 21 April 2017.
24. Kornfeld H. **Tuberculosis and diabetes: From bench to bedside and back.** Presented at: Workshop on Integrated Care and Research for Tuberculosis, Diabetes, and HIV/AIDS: Challenges, Strategies, and Clinical Solutions. NIAID, International Union for Tuberculosis and Lung Disease, Bill and Melinda Gates Foundation. Liverpool, UK.; October 24, 2016.
25. Kornfeld H. **Diabetic immunopathy.** Presented at: Boston University School of Medicine Inflammation Symposium. Boston, MA, USA; May 23, 2016.
26. Kornfeld H. **Developing a comprehensive therapeutic research strategy for the converging epidemics of TB, T2DM, and HIV.** Co-Organizer and Speaker. NIAID Workshop. Rockville, MD, USA; May 10–11, 2016.
27. Kornfeld H. **Workshop on advancing TB research: TB, diabetes, and host-directed therapies.** Presented at: P.D. Hinduja Hospital. Mumbai, India; April 23–24, 2016.
28. Kornfeld H. **The impact of Mycobacterium tuberculosis immune evasion on protective immunity: Implications for TB vaccine design.** Co-Organizer, NIAID TB Workshop. Rockville, MD, USA; March 7–8, 2016.
29. Kornfeld H. **Symposium on Tuberculosis Co-Morbidities & Immunopathogenesis.** Organizer and Speaker, Keystone, CO, USA; February 28–March 2, 2016.
30. Kornfeld H. **Sugar, fat, and consumption.** Presented at: Pulmonary Center, Boston University School of Medicine. Boston, MA, USA; January 16, 2016.
31. Kornfeld H. **Environmental epigenetics—Diabetes and tuberculosis.** Presented at: Joint Retreat for the Centres for Biodiscovery & Molecular Development of Therapeutics and Biosecurity and Tropical Infectious Diseases (Australian Institute of Tropical Health & Medicine). Port Townsend, Australia; September 22, 2015.
32. Kornfeld H. **Determinants of TB severity.** Presented at: Shenzhen-Hong Kong Institute of Infectious Diseases. Shenzhen, China; November 20, 2015.

33. Kornfeld H. **Tuberculosis: The rise of comorbidities**. Presented at: Medical Grand Rounds. University of Massachusetts Medical School. Worcester, MA, USA; June 4, 2015.
34. Kornfeld H. **TB and diabetes**. Presented at: Singapore Immunology Network. Singapore; February 27, 2015.
35. Kornfeld H. **Keystone Symposium on Granulomas in Infectious and Non-Infectious Disease: TB and Diabetes**. Invited speaker, Santa Fe, NM, USA; January 22–27, 2015.
36. Kornfeld H. **The effects of diabetes on tb susceptibility**. Presented at: No.4 People's Hospital of Nanning. Nanning, China; January 12, 2015.
37. Kornfeld H. **Sugar, fat, and consumption**. Presented at: University of Texas, Health Science Center at Tyler. Tyler, TX, USA; August 22, 2014.

## PD HINDUJA HOSPITAL/JOHNS HOPKINS UNIVERSITY (JHU)

### PRESENTATIONS | ABSTRACTS

1. Chawla PK, Naik P, Lokhande R, Dherai AJ, Udwardia ZF, Mahashur AA, Pinto L, Mullerpattan J, Sunavala A, Soman R, Rodrigues C, Gupta A, Tornheim JA, Martinson N, Variava E, Wiesner L, Joubert A, Ashavaid TF. **Therapeutic drug monitoring of moxifloxacin in Indian MDR-TB patients**. Presented at: Association of Clinical Biochemists of India. 15th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) Congress. Jaipur, India; November 17–20, 2019.
2. Tornheim JA, Gajjar I, Shivakumar SVBY, Gupte AN, Kishore G, Karane M, Rodrigues C, Gupta A, Udwardia ZF. **Increased moxifloxacin dosing among MDR-TB patients with low-level resistance to moxifloxacin did not improve treatment outcomes in a tertiary care centre in Mumbai, India**. Presented at: 50th Union World Conference on Lung Health. Hyderabad, India. October 30–November 2, 2019.
3. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Pinto L, Soman R, Rodrigues C, Gupta A, Tornheim JA, Martinson N, Variava E, Wiesner L, Joubert A, Ashavaid TF. **Therapeutic drug monitoring of clofazimine in Indian MDR-TB patients**. Presented at: MSACL 2019 EU. Salzburg, Austria; September 22–26, 2019.
4. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Soman R, Rodrigues C, Gupta A, Tornheim JA, Martinson N, Variava E, Wiesner L, Joubert A, Ashavaid TF. **Determination of plasma clofazimine levels by liquid chromatography-mass spectrometry**. Presented at: 32<sup>nd</sup> Annual Research Day, P.D. Hinduja Hospital and MRC. Mumbai, India; March 2, 2019.
5. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Soman R, Rodrigues C, Gupta A, Tornheim JA, Ashavaid TF. **Determination of serum linezolid levels by HPLC**. Presented at: 32<sup>nd</sup> Annual Research Day, P.D. Hinduja Hospital and MRC. Mumbai, India; March 2, 2019. (Awarded 2<sup>nd</sup> Prize for Best Laboratory paper)
6. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Pinto L, Soman R, Rodrigues C, Gupta A, Tornheim JA, Martinson N, Variava E, Wiesner L, Joubert A, Ashavaid TF. **Determination of plasma clofazimine levels by liquid chromatography-mass spectrometry**. Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
7. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Pinto L, Soman R, Rodrigues C, Gupta A, Tornheim JA, Ashavaid TF. **Determination of serum linezolid levels by HPLC**. Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
8. Tornheim JA, Udwardia ZF, Porwal S, Kishore G, Gajjar I, Karane M, Shivakumar SVBY, Rodrigues C, Gupta A. **Impact of standard or increased moxifloxacin dose among MDR-TB patients in Mumbai with low-level resistance**. Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.

9. Gajjar IN, Tornheim JA, Udwardia ZF, Kishore G, Karane M, Sayed S, Chawla P, Rodrigues C, Ashavaid T, Shivakumar SVBY, Gupta A. **Quality of life among MDR-TB patients from the public sector in Mumbai.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
10. Shivakumar SVBY, Tornheim JA, Gajjar I, Porwal S, Kishore G, Karane M, Chawla P, Rodrigues C, Ashavaid T, Gupta A, Udwardia ZF. **Mental health and TB: High prevalence of depression among drug-resistant TB patients not associated with cycloserine.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
11. Kambli P, Tornheim JA, Soundararajan L, Priyadarshini S, Gupta R, Ramprasad VL, Gupta A, Rodrigues C. **Whole genome sequencing of Mycobacterium tuberculosis directly from clinical samples accurately identifies drug resistance.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
12. Ajbani K, Kazi M, Naik S, Soman R, Shetty A, Rodrigues C. **Simultaneous rapid detection of tubercular meningitis and drug susceptibility testing using pyrosequencing on uncultured cerebrospinal fluid samples.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
13. Nambiar R, Tornheim JA, Diricks M, Katrien DB, Sadani M, Shetty A, Rodrigues C. **Linezolid resistance in Mycobacterium tuberculosis isolates at a tertiary care center in Mumbai, India, by whole genome sequencing.** Presented at: RePORT India 2019 Joint Leadership Meeting: Biomarkers and Beyond. Chennai, India; February 4–6, 2019.
14. Chawla PK, Lokhande RV, Naik PR, Singh S, Dherai AJ, Udwardia ZF, Pinto L, Soman R, Rodrigues C, Patel J, Ashavaid TF. **Implications of acetylase genotype on plasma rifampicin and isoniazid levels in TB patients.** Presented at: 45<sup>th</sup> National Conference of Association of Clinical Biochemists of India (ACBICON 2018). Goa, India; October 25–27, 2018.
15. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Rodrigues CR, Mahashur AA, Soman R, Patel J, Ashavaid TF. **Implication of acetylase genotype of plasma rifampicin and isoniazid.** Oral Presentation at: 31<sup>st</sup> Annual Research Day. (Awarded 1st Prize for Best Laboratory paper) P.D. Hinduja Hospital and MRC. Mumbai, India; March 3, 2018.
16. Tornheim J, Ganatra S, DeLuca A, Banka R, Rodrigues C, Gupta A, Udwardia Z. **Linezolid experience among MDRTB patients in Mumbai.** Presented at: RePORT India 2018 Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. Delhi, India; February 15, 2018.
17. Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwardia ZF, Mahashur AA, Soman R, Patel J, Ashavaid TF. **Therapeutic drug monitoring of rifampicin and isoniazid and implications of acetylase genotype on plasma levels.** Presented at: 15<sup>th</sup> International Congress on Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT). Kyoto, Japan; September 27, 2017.
18. Tornheim J, DeLuca A, Ganatra S, Radhika B, Gupta A, Udwardia Z. **It simply won't work here: Few eligible for the newly recommended short course MDR-TB regimen in a Mumbai private clinic.** Presented at: American Thoracic Society 2017 International Conference. Washington, DC, USA; May 21, 2017.
19. Tornheim JA, Ganatra S, DeLuca A, Banka R, Gupta A, Udwardia ZF. **Impact of drug susceptibility testing on drug choice in a tuberculosis cohort with high rates of drug resistance from the private sector in Mumbai.** Presented at: RePORT India 2016 Joint Leadership Meeting. Hyderabad, India; February 3, 2017.
20. Udwardia ZF, Tornheim JA, Ganatra S, DeLuca A, Banka R, Gupta A. **Impact of drug susceptibility testing on drug choice in a tuberculosis cohort with high rates of drug resistance from the private sector in Mumbai.** Presented at: IDWeek 2016. New Orleans, LA, USA; October 27, 2016.



# Grants & Substudies

## RePORT India

9<sup>TH</sup> ANNUAL JOINT LEADERSHIP MEETING

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**REPORT INTERNATIONAL & CFAR SUPPLEMENTAL FUNDED PROJECTS | AWARDED**

	TITLE	PARTNERS & IRB STATUS	CRDF #	START DATE	INVESTIGATORS
1.	Hybrid trial for Alcohol reduction among people with TB and HIV in India (HATHI)	JHU, BJGMC, London School of Hygiene and Medicine, DY Patil	NIH	Submitted 2019 - Pending	Chander G, Gupta A, Mave V, Gupte N, Dowdy D, Golub J, Hutton H, Kane J, Sangle SA, Atre S
2.	T Cell Biomarkers And T-Regulatory Responses To Pediatric TB	Emory, JHU (approved), BJMC (approved), NIRT	65373	2019	RengarajanJ, Mave V, Kinikar A, Kagal A, Chandrasekaran P, Hanna L, Paradkar M
3.	Pregnancy Associated Immune Responses to TB and HIV in India and South Africa (PARTHISA study)	JHU (approved), BJMC (approved), Wits Health Consortium, Cornell	65344	2019	Gupta A, Martinson N, Mathad J, Bhosale R
4.	Pharmacokinetic Assessment of MDR-TB Drugs in the Treatment of TB Meningitis	JHU, PD Hinduja, Beijing Chest Hospital, BJMC, Wits Health	65351	2019	Tornheim J, Ashavaid T, Rodrigues C, Duan H, Sangle S, Varaiava E, Dooley K
5.	Inflammasome Genetics and TB Treatment Outcomes	UPenn, JHU (approved), UMass, NIRT, MVDRC, BJMC (approved)	65375	2019	Bisson G, Gupta A, Gupte A, Kornfeld H, Hanna L, Babu S, Andrade B
6.	Host RNA Expression for Diagnosis and Monitoring of Pediatric TB in Africa and India	NIRT, BJMC (approved), JHU (approved), Univ. Cape Town, Imperial College, London	64080	2019	Kinikar A, Paradkar M, Hissar S, Workman L
7.	Validation of Transcriptional Signature to Predict Active TB Disease among Advanced HIV Patients	RePORT Brazil Approved: BMC, BJGMC, JHU	RICC	2017	Mave V, Rolla V, Salgame P, Kadam D, Andrade B, Gupta A, Meshram S, Kulkarni V, Ellner J
8.	Molecular Signatures of Tuberculosis-Diabetes Interaction (MSTDI) Study	Approved: JHU, UMass, BJGMC, NIRT, MVDRC	RICC	2017	Kornfeld H, P Chandrasekaran, Gupte A, Mave V, Bharadwaj R, Golub J, Andrade B, Paradkar M, Luke H, Kulkarni V, Gupte N, Shivakumar SVBY, Gupta A
9.	Biomarkers for TB Diagnosis and Treatment Response	Approved: BJGMC, NIRT, Emory, JHU	23737	2016	Rengarajan J, Hanna LE, Mave V, Chandrasekaran P, Thiruvengadam K, Toidi A, Gupte N, Kulkarni V, Gupta A and CTRIUMPH team
10.	Impact of HIV and Diabetes Mellitus on TB Drug Resistance and Recurrence	Approved: BJGMC, NIRT, JHU, MVDRC, UMass, Rutgers	23738	2016	Mave V, Devi U, Chandrasekaran P, Mathema B, Vishwanathan V, Kornfeld H, Kreiswirth B, Golub J, Gupte N, Shivakumar SVBY, Gupta A
11.	MDR-TB and HIV at RePORT Sites India	Approved: BJGMC, NIRT, JIPMER, JHU, BMC	23723	2016	Horsburg R, Chandrasekaran P, Mave V, Gupta A, Sarkar S
12.	Validation and Fine Tuning of the Computer Aided Diagnosis of Pulmonary Tuberculosis Model for the Indian Subcontinent	Approved: CMC	23734	2016	Christopher DJ, Thangakunam B, Lal B, Agrawal A
13.	Extracranial Involvement as Detected by Positron Emission Tomography Scan in Patients with Tubercular Meningitis	Approved: CMC	23721	2016	Thangakunam B, Christopher DJ
14.	Inflammatory Biomarkers as a Triage Test for Screening Symptomatic TB	Approved: JIPMER, Rutgers, BMC	23732	2016	Ellner J, Salgame P, Sarkar S, Pleskunas J
15.	Characterization of Monocyte Responses in Pulmonary TB Patients with or without Type 2 Diabetes	Approved: NIRT-NIH – ICER, MVDRC	23722	2016	Kumar P
16.	Effect of Malnutrition on Latent TB	Approved: JIPMER, Rutgers, BMC	23719	2016	Hochberg NS, Negi VS, Mahalakshmy T, Johnson WE, Salgame P, Pleskunas J
17.	Determining Barriers to TB Care	Approved: JIPMER Pending: BMC/BU (Submitted to BMC in Aug 2017)	23730	2016	Sabin L, Sarkar S, Hochberg NS, Fernandes P, Pleskunas J, Amsaveni
18.	TH17 Cell Subsets as Potential Risk Markers of Latency and Active TB Infection in Household Contacts	Approved: BMMRC UT	23725	2016	Devalraju KP, Neela VSK, Valluri VL, Vankyalapati K
19.	Comparison of Available Purified-Protein Derivative (PPD) Tuberculin Skin Test (TST) Antigen Solutions in Detecting Latent Tuberculosis Infection in India	Approved: CMC, BJGMC, JIPMER, BMMRC, NIRT, JHU, BMC	61783	2015	Christopher DJ, DeLuca A, Ellner J, Gupta A, Horsburgh B, Kadam D, Kulkarni V, Lakshmi V, Amsaveni, Chandrasekaran P, Mave V, Jones F, Hochberg N



## GRANTS & SUBSTUDIES | AWARDED

	TITLE	PARTNERS	GRANT SOURCE	START DATE
1.	Immune Responses and Effect of Disulfiram on MTB Infected PBMCs as a Potential Host Directed Therapy	BJGMC, NIRT, JHU, THSTI	Funding from Translational Health Sciences and Technology (THSTI)	2019
2.	Whole Genome Sequencing of Drug Resistant Tuberculosis in India: Genotype-Phenotype Correlation, Clinical Impact of Resistance, and Sequencing Directly from Sputum	Hinduja, JHU	NIH - 1K23AI135102-01A1	2018
3.	Validating a Th17 Switch as a Novel Correlate of Protective Immunity to TB	NIRT, BJMC, IISc, Bangalore, JHU	DBT/ IISc	2018
4.	Characterization of Genomics and Metabolomics among Individuals (TB-GWAS)	Emory, JHU, BJGMC, NIRT, PHRU, McGill	NIH R01	2018
5.	Tuberculosis: Learning the Impact of Nutrition (TB LION)	JIPMER, BMC, Rutgers, Tufts, NIRT	Warren Alpert Foundation	2018-2023
6.	Transcriptomic and Metabolomic Analysis of Microbiologically Confirmed Pediatric Tuberculosis Patients and Uninfected Household Contacts	BJGMC, JHU	Ujala Foundation Wyncote Foundation BWI-CTU C-TRIUMPH	2017
7.	Multicenter Phase II/III Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of VPM1002 in the Prevention of TB Recurrence in Pulmonary TB Patients after Successful TB Treatment in India.	RePORT India Sites	Serum Institute	2017-2020
8.	Therapeutic Outcomes with Second-Line Drug Exposures in a Cohort of South African and Indian Patients with Drug Resistant TB: A Pharmacokinetic-Pharmacodynamic Assessment	Hinduja, PHRU, JHU	DBT/South Africa MRC	2017
9.	Association of Lipid Mediators of Inflammation with TB Treatment Outcomes	JHU, NIRT, BJGMC	CTRIUMPH and Gilead Foundation	2017
10.	The Role of Innate Immunity in the Acquisition of Sterile Protection Against TB Infection	U Colorado, JHU, BJMC	NIH R21	2017
11.	IFN- $\gamma$ Independent Inhibition of MTB Growth in Human Macrophages	BMMRC, UT	NIH/NIAID: R01AI123310-01A1	2017
12.	Predictors of Resistance Emergence Evaluation in MDR-TB Patients on Treatment - (PREEMPT)	JIPMER, NIRT, BJGMC, Brazil, Vanderbilt, Rutgers, CDC, JHU, BMC, Hinduja	NIH/NIAID: R01	7/1/2017-6/30/2022
13.	MDR-TB Free: Monitoring Adverse Effects, Utilizing Resources Optimally, Knowing Resistance Patterns, and Treatment Strategy (MDR TB – MUKT)	Hinduja, JHU	Hinduja	2017
14.	The Role of Monocyte Subpopulation in HIV+LTB+ Individuals and Development of Active TB	BMMRC, UT	NIH: R21AI127178-01 Indo-US Vaccine Program, RePORT India Cohort	2016-2018
15.	Studying T cell Memory Responses for Understanding Protective Immune Response in Tuberculosis (TB)	CMC, NIRT, Saint Louis U	American Society of Tropical Medicine and Hygiene/ Burroughs Wellcome Fund)	2016
16.	Role of Iron Deficiency in Resistance of Women of Child-Bearing Age to Tuberculosis	JIPMER, BMC	NIH	2016-2017
17.	Measuring TB Drugs in Hair as a Tool to Monitor Adherence, Exposure and Response	BJGMC, NIRT, JHU	NIH/NIAID: R21	2016-2018
18.	Impact of Immune Changes of HIV and Stages of Pregnancy on TB	BJGMC, NIRT, JHU	NIH/NICHD: R01	2015-2020
19.	Residual Respiratory Impairment Following Pulmonary Tuberculosis: The Lung Health Sub-Study	BJGMC, NIRT, JHU	UJALA/ Gilead Foundation/ RePORT India	2015-2017
20.	Understanding of Tuberculosis Infection and Preventive Therapy Among Skin-Test Positive Household Contacts of Tuberculosis Cases	BJGMC, NIRT, JHU	NIH CFAR and D43	2015
21.	D4GDI-mediated Immune Responses in LTBI+HIV+ Individuals	BMMRC, UT	NIH: R21AI120257-01 Indo-US Vaccine Program, RePORT India	2015-2017

22.	T-regs Mediated Immune Responses in LTBI+HIV+ Individuals	BMMRC, UT	UT	2015
23.	Impact of Pregnancy on Tuberculosis	JIPMER, BMC	NIH/NIAID R01	2015-2018
24.	Compare Drug Levels in Newly Diagnosed or Relapsed PTB/ EPTB Following Daily ATT vs DOTS Regimen	CMC	Internal fluid research grant	2015
25.	Impact of Personal Exposure to Black Carbon on Pulmonary Tuberculosis Severity	JIPMER BMC	Potts Memorial Foundation	2014-2018
26.	Yield of TB using GeneXpert (Xpert MTB-Rif) by Induced Sputum Compared to Standard Sputum Samples	CMC	Internal fluid research grant	2014
27.	Dried Plasma Spots as a Simple Sampling Strategy to Measure Rifampicin Concentration to Facilitate this Service In Resource Limited Settings	CMC	Internal fluid research grant	2019
28.	Prevalence of Latent Tuberculosis in Rheumatoid Arthritis and Ankylosing Spondylitis	CMC	Internal fluid research grant	2018
29.	The Effect of Appropriate Anti Tuberculous Treatment on Recovery of Pulmonary And Pleural Tuberculosis and the Impact of Tuberculosis on Lung Function and Quality of Life in Newly Diagnosed Patients	CMC	Internal fluid research grant	2018
30.	Validation of Indigenously Developed Technology (TruNat MTB) for Diagnosis of Extra-pulmonary Tuberculosis: Multi-centric Validation	CMC, Hinduja, NIRT, AIIMS	ICMR	2018

**GRANTS & SUBSTUDIES | NOT AWARDED**

	TITLE	PARTNERS & IRB STATUS	GRANT SOURCE	START DATE/ DURATION	INVESTIGATORS
1.	Analysis and consequences of humoral responses during Mycobacterium tuberculosis infection	Rockefeller, JHU, Emory, BJGMC	NIAID P01	2019	Ravetch J, Ahmed R, Gupta A, Gandhi NR, Chandele A, Amara R
2.	Protective Immune Responses and Effective Vaccines to End TB (PREVEN-TB) (IMPAcT-TB)	Emory, JHU, Tulane, RePORT Brazil, RePORT India	NIH	2018	Rengarajan J, Sterling T, Gupta A, Bollinger RC, Gaikwad S
3.	Sex And TB Immunity (SATI) (IMPAcT-TB)	Rutgers, JHU, Stanford, Saint Louis, Tulane, Emory	NIH	2018	Gennaro ML, et al.
4.	Analysis of IgG-FcR interactions in TB	Rockefeller, JHU, Emory, BJGMC	Bill & Melinda Gates Foundation	2018	Ravetch J, Ahmed R, Gandhi NR, Gupta A, Mave V, Gupte N
5.	RePORT India Tuberculosis Research Training Program (D43)	RePORT India	Fogarty	2017/2018	Gupta A, Kornfeld H, Bollinger RC, Christopher DJ, Rodrigues C, Tripathy S, Mehendale S
6.	RePORT India TB Transmission Training Program (RITP)	RePORT India Consortium	NIH Fogarty: D43	2017	Gupta A, Christopher DJ, Bollinger R, Deluca A, Golub J
7.	Developing a Rapid Point-of-Care TB Diagnostic	RePORT International	NIH/NIAID: R01	2017	Walt D (Tufts PI), Rushdy A (Broad Institute co-PI), Rolla V, Santos M, Kristi A, Sterling T, Li Y, Mave V, Cristopher DJ, Gupta A, Pim A, Walz G, Hamilton C, Duffy D, Gillette M
8.	Research and Interventions for HIV, Alcohol, Tobacco and Tuberculosis in India and South Africa (The HATT Consortium)	BJGMC, NIRT, JHU	NIH/NIAAAA: R01	2017	Gupta A, Chander G, Heidi H, Thomas B, Kadam D, Suryavanshi N, Chandrasekaran P, Mave V, Gupte N
9.	Bio-markers for Risks of Development of LTBI and TB Disease in a Cohort of Childhood Contacts of Sputum Positive TB Patients	CMC	RePORT India Supplemental Funding	2017	Christopher DJ, Rose W
10.	Impact of Air Pollution on Inflammation and Anti TB Immunity	BJGMC, NIRT, JHU	RePORT India Supplemental Funding	2016-2017	Shivakoti R, Gupta A, Chandrasekaran P, Chandrakumar D, Golub J, Mave V, Babu S, Elf J, Hannah LE, Kulkarni V, Gupte N
11.	Characterizing the Host Inflammatory Response, and its Association with Treatment Outcomes and Lung Health in Adult Pulmonary TB Patients Undergoing Treatment in India	BJGMC, NIRT, JHU	RePORT India Supplemental Funding	2016-2017	Gupte A, Chandrasekaran P, Gupta A, Babu S, Mave V, Gupte N, Kornfeld H
12.	Association of Recent Active Tuberculosis Disease with Significant Coronary Artery Disease at JIPMER, Puducherry: A Hospital-based Case Control Study	JIPMER, BMC	RePORT India Supplemental Funding	2016	Kar S, Sarkar S, Ellner JJ, Santhosh Satheesh
13.	Novel Serum Based Biomarkers for Diagnosis of TB and Treatment Monitoring in HIV-infected and Uninfected Children	BJGMC, NIRT, DTTC, Cape Town, JHU	India SA RFA	2016	Valvi C, Hesseling AC, Chandanwale A, Kulkarni R, Paradkar M, Mave V, Gupte N, Chandrasekaran P, Shivakumar SVBY, Danasekaran K, Thiruvengadam S
14.	Pediatric TB Biomarkers for Diagnosis and Treatment Response	BJGMC, NIRT, JHU	NIH/NIAID: R01	2016	Karakousis P, Paradkar M, Tornheim JA, Gupta A, Chandrasekaran P, Bader J, Mave V, Gupte N, Kulkarni V, Bharadwaj R, Valvi C, Shivakumar SVBY, Hannah LE, Pandey A
15.	Biomarkers for Treatment Response and Disease Recurrence in Pulmonary and Extrapulmonary Tuberculosis Disease	IGIB, BJGMC, SA, NIRT, JHU	India SA RFA	2016	Gokhale R, Kana B, Swaminathan S, Chandrasekaran P, Mave V, Gupta A, Shivakumar SVBY
16.	Novel Blood Biomarker to Predict Progression to Active TB Disease Among Recently Exposed Adult and Pediatric Household Contacts of TB Patients in India and South Africa	BJGMC, NIRT, SA, JHU	India SA RFA	2016	Chandrasekaran P, Scriba T, Mave V, Paradkar M, Shivakumar SVBY, Gupte N, Gupta A, Danasekaran K, Khan S, Thiruvengadam S, Tripathy S, Prasad K
17.	Memory-like NK Cells and Household Contacts of TB Patients	BMMRC, UT	NIH: IR21AI127177-01		Vankayalapati K, Valluri V and others

## GRANTS & SUBSTUDIES | NOT AWARDED

	TITLE	PARTNERS & IRB STATUS	GRANT SOURCE	START DATE/ DURATION	INVESTIGATORS
18.	Annual Screening of Healthcare Personnel Using TST & QGFT and Identification of Bio-markers & the Role of Pet Scan	CMC	RePORT India Supplemental Funding	2016	Christopher DJ, Balamugesh T
19.	Radiological Treatment Response in Pulmonary Tuberculosis	CMC	RePORT India Supplemental Funding	2016	Balamugesh T, Christopher DJ
20.	Does Tubercular Infection Adversely Affect Cardiovascular Risk?	JIPMER, BMC	RePORT India Supplemental Funding	2016	Kar S, Sarkar Si, Negi VS, Prasanna MD, Roy G, Premarajan KC, Hochberg N, Lakshminarayanan S
21.	Geographical and Genotypic Distribution of TB Cases Under RePORT India – Tools for Understanding Epidemiology	JIPMER, BMC, BU	RePORT India Supplemental Funding	2016	Sarkar S, Roy G, Mahalakshmy T, Lakshminaraya S, Joseph NM, Jenkins H, Amsaveni, Hochberg NS

## GRANTS & SUBSTUDIES | PENDING

	TITLE	PARTNERS	GRANT SOURCE	START DATE/ DURATION	INVESTIGATORS
1.	A Nanopore Biosensor for Leveling Mtb Antigens in Blood	JHU, BJGMC Tulane University	NIH R01	2020	Hu T, Bollinger B, Gupta A, Gupte N, Bhardwaj R
2.	Effect of Helminths on Tuberculosis Severity	JIPMER, BMC, Rutgers, NIRT, NIH	NIH R21	2018	Hochberg NS, Salgame P, Babu S, Ellner JJ, Johnson WE, Parija S, Sarkar S, Mahalakshmy T, Joseph N, Rajkumari N
3.	Innate Immune Responses in Household Contacts	BMMRC/LEPRA, BJGMC, NIRT, JHU, UT	NIH/NIAD: R01	2017	Vankayalapati K, Valluri V, Gupta A, Mave V, Kadam D, Bharadwaj R, HannaLE, Shivakumar SVBY, Prudhula, Chandrasekaran P, Gupte N
4.	Progression of Tuberculosis Infection to Disease Among HIV-Infected and HIV Seronegative Individuals: A Prospective Cohort Study in South India and South Africa	CMC, BMMRC/LEPRA, NIRT, PHRU, UWITS, JIPMER	Indo-South Africa	2016	Valluri VL, Martinson N, Christopher DJ, Variava E, Priyadarsini P, Bhavna G, Ziyaad W, Melissa C, Prudhula DK, Sanjeev NV

