RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

Hosted by the National Institute of Research in Tuberculosis (NIRT) - ICMR

Key Partners

- Bhagwan Mahavir Medical Research Center (BMMRC)
- Byramjee Jeejeebhoy Government Medical College (BJGMC)
- Boston University/Boston Medical Center (BU/BMC)
- Christian Medical College, Vellore (CMC)
- CRDF Global
- 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)
- PD Hinduja Hospital
- PPD
- RePORT International Coordinating Center (RICC)
- Rutgers University
- University of Cambridge
- University of Massachusetts (UMass)
- University of Texas Health Science Center at Tyler

150 YEARS OF CELEBRATING THE MAHATMA

Department of BioTechnology, Government of India

सत्यमेव जयते

NIH National Institute of Allergy and Infectious Diseases

icmr INDIAN COUNCIL OF MEDICAL RESEARCH | NIRT NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS

Contents prepared February 2019

Contents

This page is intentionally blank

RePORT India Overview

RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank

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). The consortium aims to address the threat of TB to the people of India and across the globe, a disease which also poses an increased risk for persons living with HIV or other immunocompromised conditions. RePORT India is one of 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 in-country data collection, specimen biorepositories, and associated research with the goal of adding additional regional consortia to encourage worldwide TB prevention and treatment research.

RePORT INDIA 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 with an aim of carrying out a wide range of basic and clinical research that can lead to clinically important biomarkers, vaccines, drugs, and diagnostics.

COHORT RESEARCH UNITS (CRUs)

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

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

COMMON PROTOCOL (RePORT INDIA-WIDE OBJECTIVE)

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

The primary objective of the Common Protocol is to collect specimens and make them available to Indian biomarker researchers and collaborators over the next decade to achieve a better understanding of: 1) the prognosis of TB disease; and 2) the pathogenesis of progression from TB exposure to disease.

PARENT PROTOCOLS (CRU-SPECIFIC OBJECTIVES)

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

1. BMMRC and U of Texas, Tyler

- **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
- **US PI:** Dr. Krishna Vankayalapati, University of Texas Health Science Center, Tyler, TX, USA
- **Participating Patient Cohort:** Cohort B

2. BJGMC, NIRT, and JHU

- **Study:** Host and Microbial Factors Associated with Poor Treatment Response and Progression to Active TB (C-TRIUMPH)
- **India PIs:** Drs. Vidya Mave, Shashikala Sangle, Aarti Kinikar and Sanjay Gaikwad, Byramjee Jeejeebhoy Government Medical College (BJGMC), Pune, India and Dr. Padma Chandrasekaran, National Institute for Research in TB (NIRT), Chennai, India
- **US 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 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
- **US 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. Udwadia, Tester F. Ashavaid, and Camilla Rodrigues; PD Hinduja Hospital, Mumbai, India
- **US PI:** Dr. Amita Gupta, Johns Hopkins University, Baltimore, MD, USA
- **Participating Patient Cohorts:** Cohort A (Adult/Adolescent MDR-TB) and Cohort B

5. JIPMER, 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
- **US PI:** Dr. Jerrold Ellner and Dr. Padmini Salgame, Rutgers University, Bridgeton, NJ, USA
- **Participating Patient Cohorts:** Cohort A (Adult Pulmonary TB and Pediatric TB) and Cohort B

6. MVDRC and UMass

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

RePORT INDIA SUBSTUDIES

A complete list of RePORT-related grants and sub studies can be found on page 97 of this booklet.

RePORT INDIA ADMINISTRATION

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

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

The consortium is currently governed by Dr. D.J. Christopher (India Chair), Dr. Vijaya Valluri (India Co-Chair), Dr. Amita Gupta (US Chair), and Dr. Hardy Kornfeld (US Co-Chair). The Executive Committee convenes a monthly teleconference. The consortium has several active working groups including: Operations, Basic Science, Clinical Epidemiology, Behavioral Science, and Data Management. The Common Protocol leadership also convene on a monthly basis. Consortium operations are facilitated by a RePORT India Coordinator located in India in Chennai and a US Secretariat located in the US at Johns Hopkins University.

FUNDING

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

This page is intentionally blank

Data Tables

RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank

PARENT PROTOCOLS: STATUS REPORT
COHORTS A & B | YEARS 2014–2018

Table 1: Sample Size Targets & Enrolments

COHORT A					COHORT B			
Site		Target SS, n	Enrolled, n (%)	Among Enrolled, < 15 years, n (%)	Site	Target SS, n	Enrolled, n (%)	Among Enrolled, < 15 years, n (%)
BJGMC	PTB	400	256 (64%)	NA	BJGMC	700	499 (71%)	164 (33%)
	Ped	100	142 (132%)	142 (100%)				
	EPTB	100	113 (113%)	NA				
NIRT	PTB	400	248 (62%)	NA	NIRT	700	551 (79%)	121 (22%)
	Ped	100	59 (59%)	59 (100%)				
	EPTB	100	88 (88%)	NA				
CMC	PTB	200	110 (55%)	NA	CMC	No Cohort B		
	TBM	200	213 (107%)	NA				
JIPMER	PTB	1100	1159 (100%)	4 (0.3%)	JIPMER	1500	1559 (100%)	314 (19%)
MVDRC	PTB	450	446 (99%)	NA	MVDRC	No Cohort B		
BMMRC	No Cohort A				BMMRC	1500	990 (66%)	63 (6%)
HINDUJA*	MDR-TB	200	56 (28%)	NA	HINDUJA	60	0	0
TOTAL		**3350**	**2890 (86%)**	**205 (7%)**	**TOTAL**	**4460**	**3599 (81%)**	**662 (18%)**

SS=Sample Size; PTB=Pulmonary TB; TBM=TB Meningitis; EPTB= Extra pulmonary TB; Ped=Pediatric; MDR-TB=Multidrug-resistant TB

*Hinduja launched parent protocol in Oct 2017; enrolls PTB and EPTB patients with MDR-TB >15 years old.

COHORTS A & B | YEARS 2014–2018
Table 2: Outcomes

COHORT A | n=2546						
Site		Tx Failure		TB Recurrence		All Cause Death
		Bacteriological	Clinical	Bacteriological	Clinical	
BJGMC	PTB n=256	16 (7%)	7 (3%)	6 (3%)	5 (2%)	21 (9%)
	Ped n=142	2 (1%)	4 (3%)	0	6 (5%)	1(1%)
	EPTB n=113	0	0	3 (3%)	5 (5%)	7 (7%)
NIRT	PTB, n=248	22 (9%)	0	13 (5%)	0	15 (6%)
	Ped n=59	2 (3%)	0	1 (2%)	0	0
	EPTB n=88	4 (5%)	0	2 (2%)	0	3 (3%)
CMC	PTB n= 110	4 (4%)	2 (2%)	2 (2%)	1 (1%)	5 (5%)
	TBM n=213	0	0	0	0	49 (23%)
JIPMER	PTB n=1003	21 (2%)	0	15 (1%)	0	40 (3%)
MVDRC	PTB n=446	18 (5%)	3 (0.6%)	24 (6%)	0	16 (4%)
BMMRC	No Cohort A					
HINDUJA*	MDR-TB n=6	0		0		3 (5%)
Total	PTB	81	12	68	6	97#
	Ped	2	4	1	6	1
	EPTB	4	0	5	5	10 + 39 TBM

COHORT B | n= 3393						
Site	Prevalent TB		Incident TB		Incident LTBI	All Cause Death
	Bacteriological	Clinical	Bacteriological	Clinical		
BJGMC n=499	6 (1%)	15 (3%)	4 (1%)	10 (2%)	61 (12%)	2 (.4%)
NIRT n=551	16 (3%)	0	4 (1%)	0	73 (13%)	4 (.7%)
CMC	No Cohort B					
JIPMER n=1452	6 (0.4%)	0	3 (0.2%)	0	NA	6 (.4%)
MVDRC	No Cohort B					
BMMRC n=891	10# (1%)		18 (1.8%)		66 (7%)	0
HINDUJA n=0	0		0		0	0
Total	**38**	**15**	**29**	**10**	**200**	**12**

TB=Pulmonary TB; TBM=TB Meningitis; Tx=Treatment; LTBI=Latent TB Infection; EPTB=Extrapulmonary TB; Ped=Pediatric; MDR-TB=Multidrug-resistant TB; HHC=Household Contacts
* Hinduja launched parent protocol in Oct 2017, enrols PTB and EPTB patients with MDR-TB >15 years old.
# Reported as prevalent TB infection. ± Doesn't include 3 MDRTB deaths from Hinduja
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.

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW-UP COHORT A | YEARS 2014-2018

Table 3a: Percentage of Subjects Enrolled among Those Screened

COHORT A						
Site		**Total Approached or Screened, n**	**Subjects Enrolled, n (%)**	**BL Smear Positive, n (%)**	**BL Xpert Positive, n (%)**	**BL Culture Positive, n (%)**
BJGMC	PTB*	969	256 (26%)	110 (43%)	173 (68%)	172 (67%)
	Ped	178	142 (80%)	11 (8%)	27 (19%)	24 (17%)
	EPTB	127	113 (89%)	3 (3%)	18 (7%)	10 (9%)
NIRT	PTB*	756	248 (33%)	212 (85%)	169 (68%)	229 (92%)
	Ped	85	59 (69%)	4 (7%)	7 (12%)	12 (20%)
	EPTB	130	88 (68%)	9 (10%)	9 (10%)	17 (19%)
CMC	PTB	113	110 (97%)	94 (85%)	107(97%)	105(95%)
	TBM	239	213 (89%)	CSF – 2 (1%)	CSF – 22 (10%)	CSF – 44 (21%)
JIPMER	PTB	1090	1003 (92%)	1003 (100%)	NA	953 (95%)
MVDRC	PTB	569	446 (79%)	385 (87%)	NA	399 (90%)
HINDUJA	MDR-TB	176	56 (32%)	27 (48%)	42 (75%)	53 (94%)
TOTAL		**4432**	**2734 (62%)**	**1860 (68%)**	**574 (21%)**	**2018 (74%)**

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

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW-UPCOHORT A | YEARS 2014-2018

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=256	30 (15-69)	148 (58%)	31 (12%)	23 (9%)	78 (30%)	23 (9%)	146 (57%)
	Ped n=142	8 (1-14)	64 (45%)	7 (5%)	NA	NA	NA	134 (94%)
	EPTB n=113	30 (15-62)	57 (50%)	15 (13%)	4 (4%)	24 (21%)	5 (4%)	45 (40%)
NIRT	PTB n=248	44 (15-75)	170 (69%)	2 (1%)	38 (15%)	127 (51%)	115 (46%)	150 (60%)
	Ped n=59	10 (2-14)	31 (66%)	0	NA	NA	NA	42 (71%)
	EPTB n=88	29 (15-63)	39 (45%)	4 (5%)	3 (3%)	16 (18%)	8 (9%)	31 (35%)
CMC	PTB n=110	43 (18-79)	74 (67%)	Excluded	24 (22%)	31 (28%)	36 (33%)	70 (64%)
	TBM n=213	39 (18-78)	132 (62%)	28 (13%)	21 (10%)	38(18%)	40 (19)%	42 (20%)
JIPMER	PTB n=1003	45 (13-82)	785 (78%)	6 (<0.1%)	205 (20%)	600 (60%)	262 (26%)	567 (57%)
MVDRC	PTB n=446	48 (25-73)	355 (80%)	Excluded	117 (26%)	189 (42%)	284 (64%)	221 (50%)
HINDUJA	MDR-TB n=56	29 (15-77)	19 (33%)	1 (2%)	3 (5%)	0	7 (13%)	27 (48%)
TOTAL		**—**	**1874 (69%)**	**94 (3%)**	**438 (17%)**	**1103 (44%)**	**780 (31%)**	**1475 (54%)**

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 18 years old and above.

#BMI is approximate for TBM cohort.

†Diabetes defined as self-reported DM or >200 RBS or HbA1c > 6.5% among adults18 years old and above.

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW-UP COHORT A | YEARS 2014-2018

Table 4a: Number of Study Participants on Follow-up among Those Enrolled

COHORT A			
Site		Total Enrolled, n	On active follow up, n (%)
BJGMC	PTB	256	11 (4%)
	Ped	142	43 (30%)
	EPTB	113	22 (20%)
NIRT	PTB	248	60 (24%)
	Ped	59	38 (64%)
	EPTB	88	40 (45%)
CMC	PTB	110	27 (24%)
	TBM	213	39 (18%)
JIPMER	PTB	1003	246 (25%)
MVDRC	PTB	446	53 (12%)
HINDUJA	MDR-TB	56	51 (91%)
TOTAL		**2734**	**630 (23%)**

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

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW UP COHORT A | YEARS 2014-2018

Table 4b: Outcomes among Those Who Have Completed Treatment

COHORT A						
Site		Completed ATT, n	Unfavorable Outcomes, n (%)			
			Tx Failure	Tx Relapse	All-cause mortality	Lost to Follow-up*
BJGMC	PTB	241	23 (10%)	11 (5%)	21 (9%)	33 (14%)
	Ped	140	6 (4%)	6 (5%)	1 (1%)	8 (6%)
	EPTB	108	0	8 (7%)	7 (7%)	17 (16%)
NIRT	PTB	248	22 (9%)	13 (5%)	15 (6%)	15 (6%)
	Ped	59	2 (3%)	1 (2%)	0	2 (3%)
	EPTB	88	4 (5%)	2 (2%)	3 (3%)	5 (6%)
CMC	PTB	55	6 (11%)	3 (5%)	5 (9%)	8 (19%)
	TBM	77	0	0	49 (64%)	12 (24%)
JIPMER	PTB	752	17 (2%)	11 (1%)	34 (5%)	91 (12%)
MVDRC	PTB	317	21 (7%)	24 (8%)	16 (5%)	43 (14%)
HINDUJA	MDR-TB	0	0	0	3 (5%)	2 (3%)
TOTAL		**2085**	**101 (5%)**	**79 (4%)**	**154 (7%)**	**236 (11%)**

PTB=Pulmonary TB; Ped=Pediatric; TBM=TB Meningitis; EPTB=Extrapulmonary TB; ATT=Anti-TB Treatment; Tx=Treatment
*At end of follow-up period only.

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW UP
COHORT B | YEARS 2014-2018

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 (%)**
BJGMC	658	499 (76%)
NIRT	1272	551 (44%)
JIPMER	776	1452 (97%)
BMMRC	1292	990 (77%)
TOTAL	**3998**	**3492 (87%)**

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)**
BJGMC	25 (1-71)	216 (43%)	321 (64%)	27 (5%)	58 (12%)	21 (4%)	197 (40%)
NIRT	27 (1-70)	253 (46%)	416 (76%)	36 (7%)	79 (14%)	49 (14%)	171 (31%)
JIPMER	26 (5-90)	591 (41%)	782 (54%)	105 (7%)	152 (11%)	81 (6%)	485 (34%)
BMMRC	28 (6-73)	465 (47%)	582 (59%)	99 (10%)	109 (11%)	Excluded	238 (24%)
Total	**27 (1 – 90)**	**1525 (43%)**	**2101 (60%)**	**267 (7%)**	**398 (12%)**	**151 (8%)**	**1091 (32%)**

LTBI=Latent TB Infection; BMI=Body Mass Index
*TST or IGRA
**Diabetes defined as self-reported DM or > 200 random blood sugar or HbA1c ≥ 6.5% among adults 18 years old and above

PARENT PROTOCOLS:
PATIENT ENROLMENT, DEMOGRAPHICS & FOLLOW-UP
COHORT B | YEARS 2014-2018

Table 7a: Number of Study Participants on Follow-up among Tthose Enrolled

COHORT B				
Site	**Enrolled, n**	**On follow-up, n (%)**	**Completed follow up, n (%)**	**Lost to follow up, n (%)**
BJGMC	499	30 (6%)	332 (67%)	96* (19%)
NIRT	551	76 (14%)	436 (79%)	39 (7%)
JIPMER	1452	700 (48%)	724 (50%)	28 (2%)
BMMRC	990	116 (12%)	724 (73%)	150 (15%)
TOTAL	**3492**	**922 (26%)**	**2216 (63%)**	**313 (9%)**

Table 7b: Outcomes among Household Contacts

COHORT B					
Site	**Completed follow up, n (%)**	**Unfavorable Outcomes**			
		Lost to follow up* n (%)	**Incident TB****	**Prevalent TB#**	**TB deaths**
BJGMC	332 (67%)	96 (19%)	14 (3%)	21 (4%)	2 (0.4%)
NIRT	436 (79%)	39 (7%)	4 (1%)	16 (3%)	4 **(1%)**
JIPMER	724 (50%)	28 (2%)	3 (0.2%)	6 (0.7%)	1 (0.1%)
BMMRC	724 (73%)	150 (15%)	18 (2%)	10 (1%)	0
TOTAL	**2216**	**313 (14%)**	**39 (2%)**	**53 (2%)**	**7 (0.3%)**

*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 enrolment.

Parent Protocol Banked Specimens
PTB Cohort A

# of Aliquots	Cohort A - Pulmonary TB														Cohort A - Pulmonary TB													
	Baseline (≤14 days)							2 Weeks							1 Month							2 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total
Plasma	2076	1808	680	1004	822		6390								2248	1712					3960	1774	1680			744		4198
Plasma for PK															272	228				666	1166						576	576
PAXgene	214	239	20	2263	296	56	3088								222	228				56	506	215	218		1681	313	46	2473
PBMCs	316	510	55		752		1633								383	489					872	387	432			668		1487
DNA			324			224	548	6						6													184	184
QGIT	2328	828					3156								2085	684					2769	1953	552					2505
Mtb Isolate	114	602		431	490	42	1679	65	384					449	27	213				9	249	16	70				7	93
Urine	2041	924	341			409	3715								1780	914				199	2893	1755	880				166	2801
Hair	302	54					356								122	31					153		7					7
Sputum	247	404				132	783	117	301				56	474	125	287				51	463	122	274				30	426
Sputum Deposit	159						159	95						95	83						83	89						89
G.Aspirate/ Saliva																												
TOTALS	**7797**	**5369**	**1420**	**3698**	**2360**	**863**	**21507**	**283**	**685**				**56**	**1024**	**7347**	**4786**				**981**	**13114**	**6311**	**4113**		**1681**	**1725**	**1009**	**14839**

# of Aliquots	Cohort A - Pulmonary TB													
	5 Month							6 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	Total
Plasma								1585	208			612		2405
Plasma for PK	238	213					451						402	402
PAXgene		1					1	194	26			226	29	475
PBMCs								349	43			492		884
DNA	202	263					465		2				116	118
QGIT								1214	24					1238
Mtb Isolate	4	40					44	3	3					6
Urine								1541	76				112	1729
Hair	102	37					139	93						93
Sputum	111	342					453	105	38				10	153
Sputum Deposit	84						84	71						71
G.Aspirate/ Saliva														
TOTALS	**741**	**896**					**1637**	**5155**	**420**			**1330**	**669**	

Parent Protocol Banked Specimens
PTB Cohort A

# of Aliquots	12 Month							18 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	1711	1552					3263					412		412
Plasma for PK						180	180							
PAXgene	170	202				6	378					205		205
PBMCs	337	365					702					388		388
DNA						24	24							
QGIT	504						504							
Mtb Isolate		1				1	2		15					15
Urine	1350	830				24	2204							
Hair	1						1							
Sputum	13	2					15	123	209					332
Sputum Deposit	3						3	45						45
G.Aspirate/ Saliva														
TOTALS	**4089**	**2952**				**235**	**7276**	**168**	**224**			**1005**		**1397**

# of Aliquots	24 Month							End TB Tx							TB Recurrence- bacteriological						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC*	NIRT*	CMC	JIPMER#	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	1511	1240					2751	180	1512		37			1729	90	208		4			302
Plasma for PK																					
PAXgene	148	169					317	17	182		107			306	9	27		29			65
PBMCs	279	304					583	33	324					357	16	47			42		105
DNA									3					3		1					1
QGIT								75	36					111							
Mtb Isolate									9					9	3	15					18
Urine	1198	616					1814	128	762					890	72	58					130
Hair	40						40	21	27					48	12	2					14
Sputum	1						1	13	211					224	5	33					38
Sputum Deposit								6						6	3						3
G.Aspirate/ Saliva																					
TOTALS	**3177**	**2329**					**5506**	**473**	**3066**		**144**			**3683**	**210**	**391**		**33**	**42**		**676**

Parent Protocol Banked Specimens
PTB Cohort A

# of 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	29						29	240	1		40			281	46						46
Plasma for PK																					
PAXgene	3						3	27	2		58			87	6						6
PBMCs	6						6	37	2					39	11						11
DNA																					
QGIT								120						120	45						45
Mtb Isolate	1						1	16						16	2						2
Urine	31						31	231	15					246	48						48
Hair	5						5	23						23	4						4
Sputum	3						3	16	3					19	4						4
Sputum Deposit	1						1	9						9	1						1
G.Aspirate/ Saliva																					
TOTALS	**79**						**79**	**719**	**23**		**98**			**840**	**167**						**167**

# of Aliquots	Unscheduled							TOTAL						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	512						512	12002	9929	680	1418	2590		**26619**
Plasma for PK	3						3	513	441				1824	**2778**
PAXgene	54						54	1279	1296	20	4138	1040	193	**7966**
PBMCs	109						109	2263	2519	55		2342		**7179**
DNA								208	269	324			548	**1349**
QGIT	95						95	8419	2124					**10543**
Mtb Isolate		34					34	251	1386		431	490	59	**2617**
Urine	413	28					441	10588	5163	341			910	**17002**
Hair	17						17	742	158					**900**
Sputum	4	107					111	1009	2214				279	**3502**
Sputum Deposit	2						2	651						**651**
G.Aspirate/ Saliva													56	**56**
TOTALS	**1209**	**169**					**1378**	**37925**	**25499**	**1420**	**5987**	**6462**	**3869**	**81162**

# of Aliquots	Cohort A TBM
	Baseline (≤14 days)
	CMC
CSF	99
Plasma	165
DNA	75
Urine	129
Total	**468**

Parent Protocol Banked Specimens
Pediatric TB Cohort A

# of Aliquots	Baseline (≤7 days)			2 Weeks			1 Month			2 Month			5 Month			6 month		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	1075	432	1507				1137	448	1585	1188	432	1620		56	56	1079	144	1223
Plasma for PK							183	55	238				171	53	224			
PAXgene	104	56	160				117	56	173	132	55	187		8	8	108	17	125
PBMCs	129	109	238				147	106	253	145	105	250		24	24	132	44	176
DNA													123	199	322		4	4
QGIT	513	36	549				582	36	618	539	36	575				345		345
Mtb Isolate	35	26	61	10	8	18	6	5	11	4	2	6						
Urine	1016	218	1234				1040	224	1264	1039	220	1259		8	8	962	88	1050
Hair	141	32	173				86	29	115				76	32	108	75	1	76
Sputum	126	63	189	62	51	113	70	52	122	72	53	125	75	76	151	66	26	92
Sputum Deposit	78		78	53		53	49		49	45		45	33		33	44		44
Gastric Aspirate	12		12	5		5	3		3	2		2	2		2	1		1
TOTALS	3229	972	4201	130	59	189	3420	1011	4431	3166	903	4069	480	456	936	2812	324	3136

# of Aliquots	12 month			18 Months			24 month			End TB Tx			Tb Recurrence - Bacteriological			Tb Recurrence - Clinical		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	960	304	1264				677	112	789	54	368	422		16	16	27		27
Plasma for PK																		
PAXgene	106	37	143				75	15	90	6	45	51		2	2	3		3
PBMCs	118	81	199				104	27	131	8	105	113		3	3	4		4
DNA											1	1						
QGIT	120		120															
Mtb Isolate																1		1
Urine	846	144	990				598	52	650	47	172	219		4	4	25		25
Hair							8		8	7	21	28				2		2
Sputum	1		1	65	24	89	1		1	5	44	49		2	2	2		2
Sputum Deposit				10		10										3		3
Gastric Aspirate				1		1												
TOTALS	2151	566	2717	76	24	100	1463	206	1669	127	756	883		27	27	67		67

Parent Protocol Banked Specimens
Pediatric TB Cohort A

# of Aliquots	TB Failure - Bacteriological			TB Failure - Clinical			Unscheduled			TOTALS		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	26		26	18		18	62		62	6303	2312	8615
Plasma for PK				2		2	1	1	2	357	109	466
PAXgene	3		3	2		2	6		6	662	291	953
PBMCs	3		3	2		2	8		8	800	604	1404
DNA				2		2				125	204	329
QGIT				15		15				2114	108	2222
Mtb Isolate	2		2	1		1				59	41	100
Urine	19		19	16		16	56		56	5664	1130	6794
Hair	5		5	3		3	4		4	407	115	522
Sputum	1		1	2		2	5	3	8	553	394	947
Sputum Deposit	1		1	2		2	4		4	322		322
Gastric Aspirate										26		26
TOTALS	60		60	65		65	146	4	150	17392	5308	22700

Parent Protocol Banked Specimens
EPTB Cohort A

# of Aliquots	Baseline (<7 days)			2 Weeks			1 Month			2 Month		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	1121	680	1801				1002	592	1594	1045	616	1661
Plasma for PK							143	80	223			
PAXgene	113	85	198				98	78	176	104	84	188
PBMCs	168	143	311				188	140	328	197	138	335
DNA				2		2						
QGIT	620	120	740				483	108	591	525	96	621
Mtb Isolate	14	39	53	8	13	21	4	7	11	1	5	6
Urine	903	334	1237				768	320	1088	823	324	1147
Hair	126	38	164				59	32	91		5	5
Sputum	98	138	236	61	94	155	56	88	144	63	88	151
Sputum Deposit	73		73	43		43	44		44	37		37
Gastric Aspirate	2		2									
TOTALS	3238	1577	4815	114	107	221	2845	1445	4290	2795	1356	4151

# of Aliquots	2 Month			5 Month			6 month			12 month		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	1045	616	1661		48	48	920	160	1080	718	600	1318
Plasma for PK				112	78	190						
PAXgene	104	84	188		6	6	94	23	117	72	75	147
PBMCs	197	138	335		15	15	174	31	205	140	142	282
DNA				84	190	274						
QGIT	525	96	621				285		285	104		104
Mtb Isolate	1	5	6	1	4	5						
Urine	823	324	1147				755	108	863	562	288	850
Hair		5	5	52	32	84	63	1	64			
Sputum	63	88	151	54	129	183	56	29	85			
Sputum Deposit	37		37	31		31	26		26	1		1
Gastric Aspirate												
TOTALS	2795	1356	4151	334	502	836	2373	352	2725	1597	1105	2702

Parent Protocol Banked Specimens
EPTB Cohort A

# of Aliquots	18 Months			24 month			End TB Tx			Tb Recurrence - Bacteriological			Tb Recurrence - Clinical		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma				551	368	919	208	600	808	31		31	50		50
Plasma for PK															
PAXgene				56	45	101	21	75	96	3	1	4	4		4
PBMCs				99	91	190	36	126	162	4	3	7	7		7
DNA															
QGIT							45	60	105						
Mtb Isolate		2	2							1		1			
Urine				448	160	608	168	288	456	21	4	25	35		35
Hair				5		5	22	25	47	4		4	6		6
Sputum	55	55	110				15	78	93	5	1	6	3		3
Sputum Deposit	9		9				3		3				2		2
Gastric Aspirate															
TOTALS	64	57	121	1159	664	1823	518	1252	1770	69	9	78	107		107

# of Aliquots	TB Failure - Bacteriological			TB Failure - Clinical			Unscheduled			TOTALS		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma							110	18	128	5756	3664	9420
Plasma for PK							2		2	257	158	415
PAXgene							11		11	576	472	1048
PBMCs							21		21	1034	829	1863
DNA							1		1	87	190	277
QGIT										2062	384	2446
Mtb Isolate										29	72	101
Urine							80	2	82	4563	1830	6393
Hair							6	4	10	343	133	476
Sputum							1		1	467	712	1179
Sputum Deposit							1	12	13	270		270
Gastric Aspirate										2		2
TOTALS							233	36	269	15446	8444	23890

Parent Protocol Banked Specimens
PTB Cohort A

Specimen \ N	Baseline (≤14 days)							2 Weeks							1 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	256	225	100	998	421		2000								225	213					438
Plasma for PK															221	228				56	505
PAXgene	212	238	346	1119	421	56	2392								222	227				56	505
PBMCs	170	238			295		703								201	227					428
DNA						56	56	6						6							
QGIT	155	69					224								139	57					196
Mtb Isolate	71	220	188	957	404	42	1882	62	194					256	26	130				9	165
Urine	256	229				56	541								225	226				56	507
Hair	257	51	220				528								85	31					116
Sputum	168	229	196			33	626	116	228				15	359	122	224				16	362
Sputum Deposit	114						114	94						94	83						83
TOTALS	**1659**	**1499**	**1050**	**3074**	**1541**	**243**	**9066**	**278**	**422**				**15**	**715**	**1549**	**1563**				**193**	**3305**

Specimen \ N	2 Month							5 Month							6 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	218	210			373		801								187	26			273		486
Plasma for PK						46	46	203	213					416						29	29
PAXgene	215	218		1013	373	46	1865		1					1	187	26			273	29	515
PBMCs	203	225			271		699								176	26			195		397
DNA						46	46	201	205					406		2				29	31
QGIT	131	46					177								78	2					80
Mtb Isolate	15	52				7	74	5	22					27	10	3					13
Urine	221	217				46	484								189	19				29	237
Hair		7					7	82	37					119	82						82
Sputum	122	220				9	351	106	213					319	102	32				2	136
Sputum Deposit	88						88	78						78	68						68
TOTALS	**1213**	**1195**		**1013**	**1017**	**200**	**4638**	**675**	**691**					**1366**	**1079**	**136**			**741**	**118**	

Parent Protocol Banked Specimens
PTB Cohort A

Specimen \ N	12 Month							18 Month							24 Month						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	173	194					367					137		137	153	155					308
Plasma for PK						6	6														
PAXgene	169	202				6	377					137		137	148	169					317
PBMCs	170	208					378					82		82	149	166					315
DNA						6	6														
QGIT	34						34														
Mtb Isolate	1	1				1	3	2	9					11							
Urine	170	204				6	380								150	154					304
Hair	1						1								29						29
Sputum	13	2					15	118	200					318	1						1
Sputum Deposit	3						3	45						45							
TOTALS	**734**	**811**				**25**	**1570**	**165**	**209**			**356**		**730**	**630**	**644**					**1274**

Specimen \ N	End TB Tx							TB Recurrence- bacteriological							TB Recurrence- Clinical						
	BJGMC*	NIRT*	CMC	JIPMER#	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	18	189					207	6	13	2				21	3						3
Plasma for PK																					
PAXgene	17	182		36			235	6	13	6	13			38	3						3
PBMCs	18	186					204	6	13			25		44	3						3
DNA		3					3		1					1							
QGIT	5	3					8														
Mtb Isolate		5					5		11	4				15	1						1
Urine	16	190					206	6	13					19	4						4
Hair	18	27					45	6	2	4				12	3						3
Sputum	13	196					209	2	13	4				19	3						3
Sputum Deposit	6						6	3						3	1						1
TOTALS	**111**	**981**		**36**			**1128**	**35**	**79**	**20**	**13**	**25**		**172**	**21**						21

Parent Protocol Banked Specimens
PTB Cohort A

Specimen \ N	TB Failure- Bacteriological							TB Failure- Clinical							Unscheduled						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	19	1	4				24	6						6	48						48
Plasma for PK																					
PAXgene	19	2	12	33			66	6						6	49						49
PBMCs	17	2					19	6						6	48						48
DNA																					
QGIT	7						7	3						3	7						7
Mtb Isolate	4		4				8	1						1	1	19					20
Urine	19	15					34	6						6	47	7					54
Hair	17		14				31	3						3	14						14
Sputum	14	3	8				25	4						4	4	62					66
Sputum Deposit	9						9	1						1	2						2
TOTALS	**125**	**23**	**42**	**33**			**223**	**36**						36	**220**	**88**					**308**

Specimen \ N	TOTAL						
	BJGMC	NIRT	CMC	JIPMER	MVDRC	Hinduja	**Total**
Plasma	1312	1226	109	998	1204		**4849**
Plasma for PK	424	441				137	**1002**
PAXgene	1253	1278	372	1214	1204	193	**5514**
PBMCs	1167	1291			868		**3326**
DNA	207	211				137	**555**
QGIT	559	177					**736**
Mtb Isolate	199	666	202	957	404	59	**2487**
Urine	1309	1274				193	**2776**
Hair	597	155	244				**996**
Sputum	908	1622	214			75	**2819**
Sputum Deposit	595						**595**
TOTALS	**8530**	**8341**	**1141**	**3169**	**3680**	**794**	**25655**

	Cohort A TBM
Samples	**Baseline (≤14 days)**
	CMC
CSF	185
Plasma	163
DNA	55
Urine	
Total	**403**

Parent Protocol Banked Specimens
Pediatric TB Cohort A

Specimen \ N	Baseline (≤7 days)			2 Weeks			1 Month			2 Month			5 Month			6 month		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	122	54	176				129	56	185	132	53	185		7	7	121	18	139
Plasma for PK							127	55	182				123	53	176			
PAXgene	104	56	160				117	56	173	132	55	187		8	8	108	17	125
PBMCs	87	55	142				111	56	167	112	54	166		9	9	104	17	121
DNA													123	55	178		1	1
QGIT	34	3	37				39	3	42	36	3	39				23		23
Mtb Isolate	12	11	23	8	7	15	6	5	11	4	2	6						
Urine	130	54	184				132	55	187	131	55	186		2	2	122	22	144
Hair	126	32	158				68	29	97				69	31	100	70	1	71
Sputum	77	37	114	62	47	109	70	47	117	70	48	118	75	44	119	64	24	88
Sputum Deposit	57		57	53		53	48		48	45		45	32		32	44		44
Gastric Aspirate	11		11	4		4	3		3	2		2	2		2	1		1
TOTALS	760	302	1062	127	54	181	850	362	1212	664	270	934	424	209	633	657	100	757

Specimen \ N	12 month			18 Months			24 month			End TB Tx			TB Recurrence - Bacteriological			TB Recurrence - Clinical			TB Failure - Bacteriological		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	104	37	141				76	14	90	6	46	52		2	2	3		3	2		2
Plasma for PK																					
PAXgene	103	36	139				75	15	90	6	45	51		2	2	3		3	2		2
PBMCs	91	38	129				74	14	88	5	45	50		2	2	3		3	2		2
DNA											1	1									
QGIT	8		8																		
Mtb Isolate																1		1	2		2
Urine	103	36	139				75	13	88	6	43	49		1	1	3		3	2		2
Hair							5		5	6	21	27				2		2	2		2
Sputum	1		1	64	22	86	1		1	5	42	47		2	2	2		2	1		1
Sputum Deposit				10		10										3		3	1		1
Gastric Aspirate				1		1															
TOTALS	410	147	557	75	22	97	306	56	362	34	243	277		9	9	20		20	14		14

Parent Protocol Banked Specimens
Pediatric TB Cohort A

Specimen \ N	TB Failure - Clinical			Unscheduled			TOTALS		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	2		2	7		7	704	287	991
Plasma for PK	2		2	1	1	2	253	109	362
PAXgene	2		2	6		6	658	290	948
PBMCs	1		1	7		7	597	290	887
DNA	2		2				125	57	182
QGIT	1		1				141	9	150
Mtb Isolate	1		1				34	25	59
Urine	2		2	7		7	713	281	994
Hair	2		2	3		3	353	114	467
Sputum	2		2	5	3	8	499	316	815
Sputum Deposit	2		2	3		3	298		298
Gastric Aspirate							24		24
TOTALS	19		19	39	4	43	4399	1778	6177

Parent Protocol N
EPTB Cohort A

Specimen \ N	Baseline (<7 days)			2 Weeks			1 Month			2 Month			5 Month			6 month		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	112	84	196				100	74	174	105	77	182		4	4	93	20	113
Plasma for PK							99	80	179				86	4	90			
PAXgene	110	84	194				98	78	176	104	84	188		78	78	93	23	116
PBMCs	89	87	176				100	81	181	55	85	140		4	4	93	21	114
DNA				2		2							84	5	89			
QGIT	41	10	51				32	9	41	35	8	43		77	77	19		19
Mtb Isolate	9	19	28	8	8	16	3	5	8	1	5	6						
Urine	112	82	194				97	78	175	103	80	183		3	3	94	26	120
Hair	112	38	150				50	32	82		5	5	48		48	57	1	58
Sputum	69	70	139	60	80	140	55	76	131	61	78	139	53	32	85	56	26	82
Sputum Deposit	49		49	43		43	42		42	37		37	30	73	103	26		26
Gastric Aspirate	2		2															
TOTALS	705	474	1179	113	88	201	676	513	1189	501	422	923	301	280	581	531	117	648

Specimen \ N	12 month			18 Months			24 month			End TB Tx			TB Recurrence - Bacteriologocal		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma	71	73	144				57	45	102	21	72	93	3		3
Plasma for PK															
PAXgene	69	73	142				55	45	100	21	74	95	3	1	4
PBMCs	71	74	145				55	45	100	21	73	94	3	1	4
DNA															
QGIT	7		7							3	5	8			
Mtb Isolate					2	2							2		2
Urine	70	70	140				56	40	96	21	70	91	3	1	4
Hair							4		4	21	25	46	3		3
Sputum				54	53	107				15	71	86	3	1	4
Sputum Deposit	1		1	9		9				3		3			
Gastric Aspirate															
TOTALS	289	290	579	63	55	118	227	175	402	126	390	516	20	4	24

Parent Protocol N
EPTB Cohort A

Specimen \ N	TB Failure - Clinical			Unscheduled			TOTALS		
	BJGMC	NIRT	Total	BJGMC	NIRT	Total	BJGMC	NIRT	Total
Plasma				10		10	575	449	1024
Plasma for PK				1		1	186	158	344
PAXgene				10		10	566	466	1032
PBMCs				10		10	500	472	972
DNA				1		1	87	77	164
QGIT							137	32	169
Mtb Isolate					1	1	23	43	66
Urine				9	1	10	569	448	1017
Hair				3		3	302	133	435
Sputum				1	10	11	431	538	969
Sputum Deposit				1		1	243		243
Gastric Aspirate							2		2
TOTALS				46	12	58	3621	2816	6437

Parent Protocol Banked Specimens

Cohort B | Samples= # of Aliquots

Samples	Baseline (≤14 days)					4 Months					8 Months					12 Months				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma	4471	3920	728	2370	11489	3171	3620		1365	8156				984	984	3034	3247	32	708	7021
Plasma for PK																				
PAXgene	392	523	3122		4037	302	472			774						300	426	69		795
PBMCs	806	1242		1580	3628	628	1050		910	2588				656	656	584	840		472	1896
DNA	456	510		1580	2546	1				1										
QGIT	5315	5352			10667	3913	2316			6229						3774	1116			4890
Mtb Isolate		41			41		23			23										
Urine	3629	2128			5757	2607	1720			4327						2570	1748			4318
Hair	559	3			562	420	3			423						351				351
Sputum	390	696			1086	178	528			706						1				1
Sputum Deposit	286				286	169				169						2				2
Gastric Aspirate	14				14	4				4										
TOTALS	16318	14415	3850	5530	40113	11393	9732		2275	23400				1640	1640	10616	7377	101	1180	19274

Samples	16 Months					20 Months					24 Months				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma				603	603				450	450				633	633
Plasma for PK															
PAXgene															
PBMCs				402	402				300	300				422	422
DNA												1			1
QGIT											3873	801			4674
Mtb Isolate															
Urine												4			4
Hair															
Sputum															
Sputum Deposit															
Gastric Aspirate															
TOTALS				1005	1005				750	750	3873	806		1055	5734

Parent Protocol Banked Specimens

Cohort B | Samples = # of Aliquots

Samples	Prevalent TB- Bacteriological					Prevalent TB- Clinical					Incident TB- Bacteriological					Incident TB- Clinical				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma	64	13	9		86	125				125	40		1		41	93				93
Plasma for PK																				
PAXgene	7	5	18		30	13				13	4		9		13	8				8
PBMCs	9	10			19	21				21	9				9	17				17
DNA	6	4			10	14				14	1				1	1				1
QGIT	84	5			89	176				176	57				57	105				105
Mtb Isolate	2				2						3				3					
Urine	56	5			61	110				110	25				25	72				72
Hair	11				11	21				21	4				4	12				12
Sputum	9	5			14	13				13	3				3	3				3
Sputum Deposit	4				4	12				12						4				4
Gastric Aspirate						4				4										
TOTALS	**252**	**47**	**27**		**326**	**509**				**509**	**146**		**10**		**156**	**315**				**315**

Samples	Unscheduled Visit					TOTALS				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma	832				832	11830	10800	770	7113	**30513**
Plasma for PK										
PAXgene	86		12		98	1112	1426	3230		**5768**
PBMCs	160				160	2234	3142		4742	**10118**
DNA						479	515		1580	**2574**
QGIT	1287				1287	18584	9590			**28174**
Mtb Isolate		4			4	5	68			**73**
Urine	699	56			755	9768	5661			**15429**
Hair	96				96	1474	6			**1480**
Sputum	2	89			91	599	1318			**1917**
Sputum Deposit	7				7	484				**484**
Gastric Aspirate						22				**22**
TOTALS	**3169**	**149**	**12**		**3330**	**46591**	**32526**	**4000**	**13435**	**96552**

Parent Protocol N Cohort B | Samples = N Number of Individuals

Samples	Baseline (≤14 days)					4 Months					8 Months					12 Months					16 Months				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma	469	492	963	891	2815	322	453		306	1081				202	202	315	404		123	842				75	75
Plasma for PK																									
PAXgene	391	521	788		1700	295	470			765						300	425	27		752					
PBMCs	416	521			937	322	476			798						318	444			762					
DNA	456	510		891	1857	1				1															
QGIT	443	515			958	283	233			516						277	118			395					
Mtb Isolate		34			34		16			16															
Urine	461	502			963	320	416			736						321	426			747					
Hair	471	3			474	331	3			334						322				322					
Sputum	280	488			768	174	438			612						1				1					
Sputum Deposit	224				224	166				166						2				2					
Gastric Aspirate	11				11	4				4															
TOTALS	**3622**	**3586**	**1751**	**1782**	**10741**	**2218**	**2505**		**306**	**5029**				**202**	**202**	**1856**	**1817**	**27**	**123**	**3823**				**75**	**75**

Samples	20 Months					24 Months					Prevalent TB- Bacteriological					Prevalent TB- Clinical					Incident TB- Bacteriological				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma				39	39				76	76	6	13			19	14					4				4
Plasma for PK																									
PAXgene											6	5	8		19	13					4		1		5
PBMCs											5	10			15	14					4				4
DNA							1			1	6	4			10	14					1				1
QGIT						285	106			391	6	5			11	14					4				4
Mtb Isolate											2				2						3				3
Urine							1			1	6	5			11	15					4				4
Hair											6				6	15					4				4
Sputum											4	5			9	9					3				3
Sputum Deposit											2				2	6									
Gastric Aspirate																3									
TOTALS				**39**	**39**	**285**	**108**		**76**	**469**	**49**	**47**	**8**		**104**	**117**					**31**		**1**		**32**

Parent Protocol N Cohort B | Samples = N number of Individuals

Samples	Incident TB- Clinical					Unscheduled Visit					TOTALS				
	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total	BJGMC	NIRT	JIPMER	BMMRC	Total
Plasma	10				10	82				82	1222	1362	963	1712	**5259**
Plasma for PK															
PAXgene	8				8	81				81	1098	1421	824		**3343**
PBMCs	10				10	82				82	1171	1451			**2622**
DNA	1				1						479	515		891	**1885**
QGIT	8				8	90				90	1410	977			**2387**
Mtb Isolate							4			4	5	54			**59**
Urine	9				9	84	14			98	1220	1364			**2584**
Hair	9				9	83				83	1241	6			**1247**
Sputum	3				3	2	62			64	476	993			**1469**
Sputum Deposit	4				4	5				5	409				**409**
Gastric Aspirate											18				**18**
TOTALS	**62**				**62**	**509**	**80**			**589**	**8749**	**8143**	**1787**	**2603**	**21282**

RePORT India Common Protocol
1. Enrollment / Disposition (Cohort A)
Data Up to December 2018

Description	RePORT Sites (Site Number)					Total
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	
Number enrolled in Common Protocol (n)	**40**	**200**	**120**	**134**	**216**	**710**
Number previously enrolled in Cohort B	0	1 (0.5%)	0	0	1 (0.46%)	**2 (0.28%)**
Number enrolled in the study other than the Parent Protocol	0	16 (8%)	0	0	0	**16 (2.25%)**
Number completed follow-up (6 months post treatment)	0	25 (12.5%)	4 (3.33%)	22 (16.42%)	48 (22.22%)	**99 (13.94%)**
Reason for NOT completing follow-up through the 6-Month Post-Treatment visit						
Participant was provisionally enrolled but not confirmed to have active pulmonary TB	0	0	0	1 (0.75%)	21 (9.72%)	**22 (3.1%)**
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	0	**0**
HIV test was not completed within seven weeks after enrollment	0	0	0	0	0	**0**
Met one of the following TB outcomes: Treatment Failure, TB Relapse, Emerging Resistance	0	0	2 (1.67%)	9 (6.72%)	8 (3.7%)	**19 (2.68%)**
Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)	0	0	0	3 (2.24%)	0	**3 (0.44%)**
Inadvertent enrollment	0	3 (1.5%)	0	0	0	**3**
Withdrawal by participant	0	2 (1%)	1 (0.83%)	3 (2.24%)	4 (1.85%)	**10 (1.41%)**
Withdrawal by parent/guardian	0	0	0	0	0	**0**
Lost to follow-up	0	0	0	0	1 (0.46%)	**1**
Moved out of area	0	0	0	0	0	**0**

RePORT India Common Protocol
1. Enrollment / Disposition (Cohort A)
Data Up to December 2018

Description	RePORT Sites (Site Number)					Total
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	
Study terminated by funding organization / other government agency	0	0	0	0	0	**0**
Death	0	3 (1.5%)	0	0	4 (1.85%)	**7 (0.99%)**
Other *	1 (2.5%)	16 (8%)	0	0	9 (4.17%)	**26 (3.66%)**

***CMC**	Subject not willing to give sputum and blood sample	**1**
***JIPMER**	**Other**	**16**
	DEFAULTED	**5**
	sputum contaminated	**3**
	scanty	**2**
	MODIFIED REGIMEN	**2**
	PATIENT SHIFTED TO MODIFIED REGIMEN	**1**
	CAT-II	**1**
	CULTURE NEGATIVE	**1**
	UNABLE TO PRODUCE SPUTUM	**1**
***BJGMC**	**Other**	**9**
	ENROLLED IN VPM 1002 STUDY	**4**
	Patient defaulted treatment	**5**

RePORT India Common Protocol
2. Enrollment / Disposition (Cohort B)
Data Up to December 2018

Description	RePORT Sites (Site Number)				Total
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	
Number enrolled in Common Protocol **(n)**	**176**	**223**	**259**	**219**	**777**
Number enrolled in a study other than the parent protocol	30 (17.05%)	0	0	0	30 (3.86%)
Number of completed follow-up (Month 24 visit)	0	0	0	0	0
Reason for not completing follow-up through the Month 24 visit					
Participant developed active TB	0	0	4 (1.54%)	0	4 (0.51%)
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	0	0	0	0
Withdrawal by participant	0	0	2 (0.77%)	0	2 (0.26%)
Withdrawal by parent/guardian	0	0	0	0	0
Lost to follow up	0	1 (0.45%)	1 (0.39%)	0	2 (0.26%)
Moved out of area	0	0	0	0	0
Study terminated by funding organization or other government agency	0	0	0	0	0
Death	0	0	0	0	0
Other*	1 (0.57%)	0	32 (12.36%)	0	33 (4.25%)

***JIPMER**	SAMPLE NOT COLLECTED	**1**
***BJGMC**	Index was terminated from study because B/L cultures were negative.	**32**

RePORT India Common Protocol
3. Final Outcome Status (Cohort A)
Data Up to December 2018

Description	RePORT Sites (Site Number)					Total
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	
Number enrolled in Common Protocol **(n)**	**40**	**200**	**120**	**134**	**216**	**710**
Bacteriologic cure	0	6 (3%)	5 (4.17%)	20 (14.93%)	42 (19.44%)	73 (10.28%)
Bacteriologic status indeterminate (treatment complete)	0	39 (19.5%)	0	0	3 (1.39%)	42 (5.92%)
Bacteriologic failure	0	0	0	6 (4.48%)	2 (0.93%)	8 (1.13%)
Bacteriologic relapse	0	0	0	2 (1.49%)	0	2 (0.28%)
Emerging resistance	0	0	2 (1.67%)	0	0	2 (0.28%)
Clinical response (For participants ≤14 years of age who did not have bacteriologic documentation at baseline)	0	0	0	0	0	0
Clinical failure	0	0	0	0	2 (0.93%)	2 (0.28%)
Clinical relapse	0	0	0	0	0	0
Not Tuberculosis	0	0	0	0	0	0
Death	0	3 (1.5%)	0	0	4 (1.85%)	7 (0.99%)
Treatment incomplete	0	5 (2.5%)	0	3 (2.24%)	5 (2.31%)	13 (1.83%)
Lost to follow-up/unknown	0	14 (7%)	1 (0.83%)	2 (1.49%)	3 (1.39%)	20 (2.82%)

RePORT India Common Protocol
4. Final Outcome Status (Cohort B)
Data Up to December 2018

Description	RePORT Sites (Site Number)				Total
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	
Number enrolled in Common Protocol **(n)**	**176**	**223**	**259**	**219**	**777**
No TB	0	0	2 (0.77%)	0	2 (0.26%)
Definite case	0	0	0	0	0
Probable case	0	0	4 (1.54%)	0	4 (0.51%)
Possible case	0	0	0	0	0
Death	0	0	0	0	0
Lost to follow-up/ unknown	1 (0.57%)	1 (0.45%)	1 (0.39%)	0	3 (0.39%)

RePORT India Common Protocol
5. Demographics
Data Up to December 2018

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
Number enrolled in Common Protocol (n)	40	200	176	120	134	223	216	259	219
Age, Median (Min – Max)	37.5 (18 - 73)	44 (16 - 79)	29.5 (7 - 75)	41.5 (17 - 60)	43 (5 - 69)	34 (0 - 72)	28 (5 - 67)	17 (1 - 67)	30 (9 - 60)
Number of male participants	26 (65%)	160 (80%)	55 (31.2%)	83 (69.17%)	100 (74.63%)	83 (37.22%)	125 (57.87%)	123 (47.49%)	96 (43.65%)
Number of female participants	14 (35%)	40 (20%)	121 (68.7%)	37 (30.83%)	34 (25.37%)	140 (62.78%)	91 (42.13%)	136 (52.51%)	123 (56.3%)
Number of pregnant women	0	0	0	0	0	0	0	1 (0.39%)	0

RePORT India Common Protocol
6. Culture Results
Data Up to December 2018

Description	Study Visits							
	Baseline	Month 1	Month 2	Month 3	Month 6	End of Treatment	Treatment Failure/Relapse/ Withdrawal	TB Activation Eval
Solid Culture Results								
Negative for Mycobacterium Tuberculosis complex	118	290	326	0	0	169	16	5
Positive for Mycobacterium Tuberculosis complex	301	101	20	0	0	4	8	0
Positive for non-tuberculosis mycobacteria (NTM)	6	6	11	0	0	5	0	0
Contaminated	11	12	16	0	0	3	1	0
Liquid Culture Results								
Negative for Mycobacterium Tuberculosis complex	60	181	271	0	0	132	16	6
Positive for Mycobacterium Tuberculosis complex	415	177	37	0	0	9	7	0
Positive for non-tuberculosis mycobacteria (NTM)	6	5	2	0	0	3	0	0
Contaminated	25	57	55	0	0	38	1	0

RePORT India Common Protocol
7. Co-Enrollment Status by Site
(Cohort A and Cohort B)
Data Up to December 2018

Description	RePORT Study 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
Co-Enrolled Study											
Number enrolled in Common Protocol **(n)**	**40**	**200**	**176**	**120**	**134**	**223**	**216**	**259**	**219**	**710**	**777**
Protocol 1 (VPM 1002-IN-3.01 TBR)	0	3	-	2	0	-	7	-	-	12	-
Protocol 2 (Depression Module)							38	26	60	38	26
Protocol 3 (TB Pregnancy)		43								43	0
Protocol 4											
Protocol 5											
Protocol 6											
Protocol 7											
Protocol 8											
Protocol 9											

RePORT India Common Protocol
8. IGRA Testing Results for Cohort B
Data Up to December 2018

At Baseline IGRA Results	RePORT Study Sites (Site Number)				Total
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	
Number enrolled in Common Protocol (n)	176	223	259	219	**777**
IGRA test Expected	176	223	259	219	**777**
IGRA test Performed	166 (94.32%)	206 (92.38%)	256 (98.84%)	173 (78.9%)	**649 (83.53%)**
IGRA test Positive Results	100 (60.24%)	120 (58.25%)	155 (60.55%)	91 (52.6%)	**387 (59.63%)**
IGRA test Negative Results	61 (36.75%)	85 (41.26%)	98 (38.28%)	80 (46.2%)	**253 (38.98%)**
IGRA Indeterminant	5 (3.01%)	1 (0.49%)	4 (1.56%)	2 (1.15%)	**10 (1.54%)**
Month 4-6	**JIPMER (102)**	**NIRT (105)**	**BJGMC (106)**	**BMMRC (107)**	**Total**
IGRA test Expected	9	103	104	80	**323**
IGRA test Performed	2 (22%)	20 (19.42%)	54 (51.92%)	0	**76 (23.53%)**
IGRA test Positive Results	1 (50%)	7 (35%)	12 (22.22%)	0	**20 (26.32%)**
IGRA test Negative Results	1 (50%)	13 (65%)	42 (77.78%)	0	**56 (73.68%)**
IGRA Indeterminant	0	0	0	0	**0**
Month 12	**JIPMER (102)**	**NIRT (105)**	**BJGMC (106)**	**BMMRC (107)**	**Total**
IGRA test expected	6	83	50	0	**139**
IGRA test Performed	0	3 (3.61%)	0	0	**3 (2.16%)**
IGRA test Positive Results	0	2 (66.67%)	0	0	**2 (66.67%)**
IGRA test Negative Results	0	1 (33.33%)	0	0	**01 (33.33%)**
IGRA Indeterminant	0	0	0	0	**0**

RePORT India Common Protocol
9. Demographics for Cohort B
Data Up to December 2018

Description	RePORT 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
	603	**176**	**934**	**223**	**1254**	**259**	**549**	**219**
Children (Age ≤14)		34		32		63		8
Male		55		83		123		96
Female		121		140		136		123
Pregnant		0		0		1		0
HIV		0		0		4		0
Diabetes		0		0		0		0

RePORT India Common Protocol
10. TB Diagnostic Test for Cohort A & Cohort B
Data Up to December 2018

Description	RePORT 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	Cohor B
Smear Test											
Expected*	102	569	9	507	376	1	676	5	0	**2145**	**15**
Performed	101 (99%)	380 (66.78 %)	0	507 (100%)	375 (99.73 %)	1 (100%)	674 (99.7 %)	5 (100%)	0	**1952 (91%)**	**6 (40%)**
Positive Results	34 (34%)	209 (55%)	0	215 (42.41%)	178 (47.47 %)	0	119 (17.66 %)	0	0	**722 (36.99 %)**	**0**
Negative Results	67 (66%)	171 (45%)	0	290 (57.2%)	198 (52.8 %)	1 (100%)	555 (82.34 %)	5 (100%)	0	**1229 (62.96 %)**	**6 (100%)**
LJ culture											
Expected*	102	569	9	507	376	1	676	5	0	**2145**	**15**
Performed	1	0	0	507 (100%)	369 (98.14 %)	1 (100%)	614 (90.83 %)	4 (80%)	0	**1490 (69.46 %)**	**5 (33.33%)**
Positive Results**	1	0	0	188 (37.08%)	87 (23.58 %)	0	159 (25.9 %)	0	0	**434 (29.13 %)**	**0**
Negative Results	0	0	0	268 (52.86%)	218 (59.08 %)	1 (100%)	434 (70.68 %)	4 (100%)	0	**920 (61.74 %)**	**5 (100%)**
Contaminated	0	0	0	23 (4.54%)	0	0	20 (3.26 %)	0	0	**43 (2.89%)**	**0**
MIGIT Cultures											
Expected*	102	569	9	507	376	1	676	5	0	**2145**	**15**
Performed	100 (98%)	467 (82.07 %)	9 (100%)	0	370 (98.4 %)	1 (100%)	634 (93.79 %)	5 (100%)	0	**1487 (69.32 %)**	**15 (100%)**
Positive Results**	44 (44%)	255 (54.6 %)	0	0	159 (42.97 %)	0	231 (36.44 %)	0	0	**645 (43.38 %)**	**0**
Negative Results	56 (56%)	139 (29.76 %)	5 (55.56 %)	0	139 (37.57 %)	1 (100%)	363 (57.26 %)	5 (100%)	0	**655 (44.05 %)**	**11 (73.33%)**
Contaminated	0	73 (15.63 %)	4 (44.44 %)	0	55 (14.86 %)	0	46 (7.26 %)	0	0	**174 (11.7%)**	**4 (26.67%)**

* Number of forms filled for CRF F3.

** Positive for Mycobacterium Tuberculosis complex

RePORT India Consortium
11. Common Protocol Cohort A
Banked Specimens by Visit Type and Totals by CRU
Data Up to December 2018

Specimen Type	Baseline						Month 1					
	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Total	CMC (101)	JIPMER (102)	MVDRC (103)	NIRT (105)	BJGMC (106)	Tota l
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**
Number enrolled in Common Protocol (n)	**40**	**200**	**120**	**134**	**216**	**710**	**40**	**200**	**120**	**134**	**216**	**710**
Number of visits done	**40**	**200**	**120**	**134**	**216**	**710**	**33**	**178**	**99**	**121**	**202**	**633**
Plasma	40	180	92	118	210	**640**	33	141	73	106	182	**535**
PAX gene	40	179	108	111	208	**646**	33	137	88	100	184	**542**
PBMCs	40	181	105	111	214	**651**	33	141	84	99	185	**542**
DNA	40	179	103	119	210	**651**	0	0	0	1	0	**1**
Urine	40	180	76	121	209	**626**	34	137	64	108	183	**526**
Saliva	38	179	72	84	212	**585**	0	0	0	0	0	**0**
Sputum	40	200	200	124	212	**776**	34	131	166	108	178	**617**
Mtb Isolates	4	147	66	82	143	**438**	0	0	0	0	3	**3**
QGIT	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Gastric aspirate	0	0	0	0	0	0	0	0	0	0	0	0

RePORT India Consortium
11. Common Protocol Cohort A
Banked Specimens by Visit Type and Totals by CRU CONTINUED
Data Up to December 2018

Specimen Type	Month 2						Month 3					
	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**
Number enrolled in Common Protocol (n)	**40**	**200**	**120**	**134**	**216**	**710**	**40**	**200**	**120**	**134**	**216**	**710**
Number of visits done	**27**	**159**	**79**	**107**	**186**	**558**	**0**	**0**	**1**	**0**	**0**	**1 u**
Plasma	29	109	66	98	165	**467**	0	0	0	0	0	**0**
PAX gene	29	106	79	96	164	**474**	0	0	0	0	0	**0**
PBMCs	29	107	78	98	171	**483**	0	0	0	0	0	**0**
DNA	29	107	76	91	165	**468**	0	0	0	0	0	**0**
Urine	29	107	60	102	166	**464**	0	0	0	0	0	**0**
Saliva	0	0	0	0	2	**2**	0	0	0	0	0	**0**
Sputum	28	102	148	109	166	**553**	0	0	0	0	0	**0**
Mtb Isolates	0	0	0	0	0	**0**	0	0	0	0	0	**0**
QGIT	NA	NA	NA	NA	NA	**NA**	NA	NA	NA	NA	NA	**NA**
Gastric aspirate	0	0	0	0	0	**0**	0	0	0	0	0	**0**

RePORT India Consortium
11. Common Protocol Cohort A
Banked Specimens by Visit Type and Totals by CRU CONTINUED
Data Up to December 2018

Specimen Type	Month 6						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**
Number enrolled in Common Protocol (n)	**40**	**200**	**120**	**134**	**216**	**710**	**40**	**200**	**120**	**134**	**216**	**710**
Number of visits done	**0**	**0**	**1**	**0**	**0**	**1**	**6**	**90**	**50**	**66**	**95**	**307**
Plasma	0	0	0	0	0	**0**	6	57	41	57	76	**237**
PAX gene	0	0	0	0	0	**0**	6	54	44	58	77	**239**
PBMCs	0	0	0	0	0	**0**	6	57	47	61	79	**250**
DNA	0	0	0	0	0	**0**	6	54	38	61	77	**236**
Urine	0	0	0	0	0	**0**	6	55	32	59	79	**231**
Saliva	0	0	0	0		**0**	6	55	16	60	81	**218**
Sputum	0	0	0	0	0	**0**	0	0	0	0	0	**0**
Mtb Isolates	0	0	0	0	0	**0**	0	0	0	3	0	**3**

RePORT India Consortium
11. Common Protocol Cohort A
Banked Specimens by Visit Type and Totals by CRU CONTINUED
Data Up to December 2018

Specimen Type	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**
Number enrolled in Common Protocol (n)	**40**	**200**	**120**	**134**	**216**	**710**	**40**	**200**	**120**	**134**	**216**	**710**
Number of visits done	**0**	**0**	**0**	**6**	**4**	**10**	**0**	**0**	**0**	**2**	**0**	**2**
Plasma	0	0	0	5	4	**9**	0	0	0	1	0	**1**
PAX gene	0	0	0	4	4	**8**	0	0	0	1	0	**1**
PBMCs	0	0	0	6	4	**10**	0	0	0	1	0	**1**
DNA	0	0	0	5	4	**9**	0	0	0	1	0	**1**
Urine	0	0	0	5	0	**5**	0	0	0	1	0	**1**
Saliva	0	0	0	6	4	**10**	0	0	0	2	0	**2**
Sputum	0	0	0	0	3	**3**	0	0	0	0	0	**0**
Mtb Isolates	0	0	0	1	1	**2**	0	0	0	0	0	**0**

RePORT India Consortium
Common Protocol Cohort B
12. Banked Specimens by Visit Type and Totals by CRU
Data Up to December 2018

Specimen Type	Baseline					Months 4 to 6				
	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**
Number enrolled in Common Protocol (n)	**176**	**223**	**259**	**219**	**777**	**176**	**223**	**259**	**0**	**777**
Number of visits done	**176**	**223**	**259**	**219**	**777**	**22**	**163**	**176**	0	**361**
Plasma	165	202	249	218	**731**	9	18	66	0	**84**
PAX gene	162	186	249	219	**712**	9	18	65	0	**83**
PBMCs	166	192	259	217	**733**	9	20	66	0	**86**
DNA	162	199	252	219	**729**	9	20	60	0	**80**
Urine	165	201	247	218	**728**	9	21	63	0	**84**
Sputum	9	0	0	0	**9**	0	0	0	0	**0**
Mtb Isolates	0	0	0	0	**0**	0	0	0	0	**0**
QGIT	0	27	245	0	**0**	9	4	61	0	**0**
Gastric aspirate	0	0	0	0	**0**	0	0	0	0	**0**
Saliva	162	149	250	219	**780**	9	21	68	0	**98**

RePORT India Consortium
Common Protocol Cohort B
12. Banked Specimens by Visit Type and Totals by CRU CONTINUED
Data Up to December 2018

Specimen Type	Month 12					Month 24				
	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
Number enrolled in Common Protocol (n)	**176**	**223**	**259**	**0**	**777**	**176**	**223**	**259**	**0**	**777**
Number of visits done	**13**	**47**	**78**	0	**138**	**0**	**0**	**0**	0	**0**
Plasma	5	6	16	0	**22**	0	0	0	0	**0**
PAX gene	5	3	16	0	**19**	0	0	0	0	**0**
PBMCs	5	6	17	0	**23**	0	0	0	0	**0**
DNA	5	6	15	0	**21**	0	0	0	0	**0**
Urine	5	5	15	0	**20**	0	0	0	0	**0**
Sputum	0	0	0	0	**0**	0	0	0	0	**0**
Mtb Isolates	0	0	0	0	**0**	0	0	0	0	**0**
QGIT	5	2	16	0	**23**	0	0	0	0	**0**
Gastric aspirate	0	0	0	0	**0**	0	0	0	0	**0**
Saliva	5	11	15	0	**31**	0	0	0	0	**0**

Specimen Type	TB Activation and Evaluation				
	JIPMER (102)	NIRT (105)	BJGMC (106)	BMMRC (107)	Total
E/R **	E/R	E/R	E/R	E/R	E/R
Number enrolled in Common Protocol (n)	**176**	**223**	**259**	**219**	**777**
Number of visits done	**0**	**0**	**8**	**0**	**8**
Plasma	0	0	7	0	**7**
PAX gene	0	0	7	0	**7**
PBMCs	0	0	7	0	**7**
DNA	0	0	7	0	**7**
Urine	0	0	7	0	**7**
Sputum	0	0	5	0	**4**
Mtb Isolates	0	0	0	0	**0**
QGIT	0	0	7	0	**0**
Gastric aspirate	0	0	0	0	**0**
Saliva	0	0	7	0	**0**

Young Investigator Abstracts

RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank

YOUNG INVESTIGATOR ABSTRACTS		
Abstract Number	**Title**	**Presenter/ Submitting Author**
1.	Impact of Standard or Increased Moxifloxacin Dose among MDR-TB Patients in Mumbai with Low-Level Resistance	Jeffrey Tornheim
2.	Host Lipidomic Profile Associated with Adverse Tuberculosis Treatment Outcomes	Rupak Shivakoti
3.	Linezolid Resistance in Mycobacterium tuberculosis Isolates at a Tertiary Care Center in Mumbai, India, by Whole Genome Sequencing	Remya Nambiar
4.	Plasma Drug Concentrations of Isoniazid and Rifampicin in Pulmonary Tuberculosis Patients with Diabetes mellitus	Jedidiah Deva
5.	Simultaneous Rapid Detection of Tubercular Meningitis and Drug Susceptibility Testing Using Pyrosequencing on Uncultured Cerebrospinal Fluid Samples	Kanchan Ajbani
6.	Whole Genome Sequencing of Mycobacterium tuberculosis Directly from Clinical Samples Accurately Identifies Drug Resistance	Priti Kambli
7.	IL-6, TIMP-2 and TGFβ-2 are associated with respiratory impairment during and following successful treatment of pulmonary tuberculosis	Akshay Gupte
8.	Pharmacokinetics of Rifampicin, Isoniazid and Pyrazinamide during Daily and Intermittent Dosing	Deepa Shankar
9.	Altered Circulating Levels of Eicosanoids in Tuberculosis-diabetes Co-morbidity and Reversal upon Standard Tuberculosis Treatment	Nathella Pavan Kumar
10.	Association of Diabetes Mellitus with INH Monoresistance	Basavaradhya Shruthi
11.	Respiratory and Non-respiratory Co-morbidities in TB Patients	Arundhati Chandini Arjun
12.	Mental Health and TB: High Prevalence of Depression among Drug-resistant TB Patients Not Associated with Cycloserine	Shri Vijay Bala Yogendra Shivakumar
13.	Determination of Plasma Clofazimine Levels by Liquid Chromatography-Mass Spectrometry	Prerna K. Chawla
14.	Determination of Serum Linezolid levels by HPLC	Prerna K. Chawla
15.	Effect of Diabetes Prevalence on Circulating Components of Blood, Disease Severity and Drug Susceptibility in Patients with Pulmonary Tuberculosis	Abilasha N
16.	Predictors of Mortality in a TB Meningitis Cohort	Arundhati Chandini Arjun
17.	Role of PET CT Scans in Tuberculous Meningitis	Shona Arlin Christopher

ABSTRACT 1: Impact of Standard or Increased Moxifloxacin Dose Among MDR-Tb Patients in Mumbai with Low-level Resistance

Submitting Author: Jeffrey A Tornheim

Co-authors: Zarir F Udwadia, Sana Porwal, Girija Kishore, Ishita Gajjar, Megha Karane, Shri Vijay Bala Yogendra Shivakumar, Camilla Rodrigues, Amita Gupta

Background and Rationale: Tuberculosis causes more deaths worldwide than any other human infection and reported rates of resistance to both isoniazid and rifampin (multidrug resistant tuberculosis, "MDR-TB") are rising globally. The expansion of shorter, injectable-sparing MDR-TB regimens has reinforced the importance of fluoroquinolone treatment for MDR-TB. Some labs test moxifloxacin at multiple concentrations to identify low-level resistance that could be treated with higher moxifloxacin doses. To assess the impact of high-dose moxifloxacin treatment, we reviewed outcomes of MDR-TB patients with low-level moxifloxacin resistance.

Methods: Records were reviewed from an ongoing prospective observational cohort study of MDR-TB patients at a private referral hospital in Mumbai, India. Participants with isolates resistant to 0.5µg/mL moxifloxacin ("low-level") but susceptible to 2.0µg/mL ("high-level") were selected and analyzed according to treatment with moxifloxacin 400mg or 600mg daily. Final treatment outcomes (completed or cured vs. death, failure, or loss to follow-up), smear and culture conversion, weight gain, radiographic improvement, and treatment-associated side effects were analyzed by moxifloxacin dose. Regression and time-to-event models assessed the relative impact of moxifloxacin dose compared to clinical, microbiological, and radiographic factors and other concomitant treatments.

Results: Out of 551 participants with MDR-TB, 158 had low-level resistance and high-level susceptibility. Of 110 participants with final outcomes, 95 (86%) received moxifloxacin 600mg. No significant differences were found between demographic, clinical, or microbiological characteristics according to moxifloxacin dose. Regression models found that smear grade, x-ray score, cavitary lung disease, cumulative moxifloxacin dose, and lung resections were associated with treatment outcomes, but daily moxifloxacin dose was not. Multivariate and time-to-event analyses did not find moxifloxacin dose to be associated with any outcomes of interest.

Conclusions and Recommendations: In this large single-provider observational cohort in Mumbai's private sector, treatment of MDR-TB patients with low-level moxifloxacin resistance with higher doses of moxifloxacin was not associated with improved outcomes.

ABSTRACT 2: Host Lipidomic Profile Associated with Adverse Tuberculosis Treatment Outcomes

Submitting Author: Rupak Shivakoti

Co-authors: Padmapriyadarsini Chandrasekaran, Luke Elizabeth Hannah, Kannan Thiruvengadam, Natarjan Saravanan, Ramesh Karunaianatham**,** Amita Gupta, Vidya Mave, Nikhil Gupte, Vandana Kulkarni, Neeta Pradhan Akshay Gupte, Mandar Paradkar, Shri Vijay Bala Yogendra Shivakumar**,** Renu Bharadwaj, Anju Kagal, Sanjay Gaikwad, Shashi Sangle**,** Kamil Borkowski, John Newman, Oliver Fiehn, on behalf of CTRIUMPH RePORT India Study team

Background and Rationale: 'Omics' approaches have accelerated the identification of biomarkers for disease outcomes. With a major focus on transcriptomics, these approaches have also started to demonstrate utility in the field of Tuberculosis (TB). Given the significant roles host lipids play in inflammation and disease outcomes, we extended these investigations to assess the host lipidome in individuals with TB and their association with TB treatment outcomes.

Methods: A case-control study (N=289) of adverse TB treatment outcomes was nested within the CTRIUMPH cohort of individuals with active pulmonary TB. Cases (n=104) were defined as adverse TB treatment outcomes, a composite outcome of TB treatment failure (49%), TB recurrence (22%) and death (29%) while age- and gender-matched controls (n=185) were those without the outcomes. We studied the association of baseline (pre-treatment) host plasma lipid profile with development of adverse TB treatment outcomes. Complex lipids were semi-quantified using untargeted approach by liquid chromatography tandem mass spectrometry (LC-MS/MS). Targeted LC-MS/MS approach was used to quantify oxylipins, which include lipid mediators of inflammation, and endocannabinoids. Analysis of variance was used to assess mean difference between designated groups.

Results: Cases and controls were not significantly different based on study characteristics. Levels of twelve baseline lipids were significantly lower ($p<0.05$) in individuals with adverse TB treatment outcomes compared to controls. These included various 18-Carbon metabolites derived from linoleic acid and α-linolenic acid. In addition, baseline levels of linoleic acid, eicosapentaenoic acid, F2-isoprostanes, 5-hydroxyeicosatertaenoic acid (5-HETE) and 5 hydroxyeicosapenta-enoic acid (5-HEPE) were also lower in cases compared to controls.

Conclusions: We identified lipids that were significantly different between cases that developed adverse treatment outcomes compared to controls. These lipids could predict future adverse treatment outcomes and can serve as the basis for future research on their function in parallel with identification of potential therapeutics related to relevant biomarkers.

ABSTRACT 3: Linezolid Resistance in Mycobacterium Tuberculosis Isolates at a Tertiary Care Center in Mumbai, India, by Whole Genome Sequencing

Submitting Author: Remya Nambiar

Co-authors: Jeffrey A Tornheim, Margo Diricks, De Bruyne Katrien, Meeta Sadani, Anjali Shetty, Camilla Rodrigues

Background and Rationale: Linezolid (LZD) is a relatively new anti-tuberculosis (TB) drug, with robust activity against Mycobacterium tuberculosis (MTB). It is being used in TB treatment with increasing frequency. However, LZD resistance has already been reported, which is highly alarming, given its critical therapeutic role. This non-randomized, observational, non-interventional, experimental study aimed to phenotypically and genotypically assess LZD resistance in multidrug-resistant MTB isolates isolated at a tertiary center in Mumbai.

Methods: Laboratory records of all consecutive, culture-positive, pulmonary and extrapulmonary samples submitted to our tertiary center for TB diagnostics from June 2015 to June 2016 were reviewed to identify the number of samples assessed for LZD susceptibility by MGIT DST at a critical concentration of 1 mg/L and identify those that were resistant. Thirty-two consecutive LZD-resistant isolates identified during the same period, representative of the same pool and chosen by convenient sampling, were analyzed by whole genome sequencing (WGS) for LZD resistance.

Results: At our laboratory, the proportion of LZD-resistant isolates was 68 of the 2179 isolates (~3.1%) tested for LZD resistance by MGIT-based susceptibility testing. WGS of 32 representative LZD-resistant isolates identified the presence of the mutations C154R in the rplC gene and G2814T in the rrl gene as the major genomic resistance determinants.

Conclusions and Recommendations: We documented LZD resistance in ~3.1% isolates recovered in our clinical setting, with known mutations being identified as the determinants. LZD resistance poses an important risk to the success of newer treatment regimens, especially those designed for drug-resistant TB. As LZD-containing regimens increase in prominence, it will be important to support clinical decision-making

with a better understanding of the common mutations conferring LZD resistance, their frequency in different settings, and their associated phenotypic inhibitory concentrations.

ABSTRACT 4: Plasma Drug Concentrations of Isoniazid and Rifampicin in Pulmonary Tuberculosis Patients with Diabetes Mellitus

Submitting Author: Jedidiah Deva

Co-authors: Balamugesh Thangakunam, Binu S Mathew, Blessed Winston, DJ Christopher

Background and Rationale: Diabetes mellitus (DM) is a known risk factor for tuberculosis (TB).There is increased severity and poor treatment outcomes in patients with co-existent DM, and multiple factors may be responsible. This study is aimed to assess the influence of DM on the plasma concentrations of Isoniazid (H) and Rifampicin(R) in patients with TB.

Methods: This is a prospective observational study, with calculated sample size of 28 Pulmonary TB (PTB) patients in each of the groups: PTB patients with DM (PTB-DM) and PTB patients without DM (PTB-only) groups. Plasma concentrations of H and R were serially measured over 7 hours after drug ingestion. The maximum drug concentration (Cmax), Area under curve (AUC0-7) and time to reach Cmax (Tmax) were calculated and correlated with treatment outcomes at the end of intensive phase of therapy, which included symptomatic improvement, weight gain, radiological improvement and Sputum conversion rates.

Results: There was no significant difference in Cmax and drug exposure (AUC)of I and R in both the groups. Weight gain at the end of intensive phase was seen in 14(51.9%) of PTB-DM group and 23(82.1%) in PTB-only group which was statistically significant(p=0.017).Linear regression with both the groups combined showed that with one unit increase in baseline BMI, there was 0.28 unit decrease in Cmax of H (CI=-0.50 to-0.06, p=0.013) and 0.43 unit decrease in Cmax of R(CI= -5.55 to 1.49, p=0.037).There was a trend towards lower sputum conversion rates and poor symptomatic improvement in PTB-DM group, which did not achieve statistical significance.

Conclusion and Recommendations: There was no significant difference in pharmacokinetics of H and R between the groups. BMI in both the groups combined had an inverse relationship with maximum drug concentrations of H and R.PTB-DM group showed trend towards poor clinical response, despite adequate plasma concentration. Future studies may address higher ATT drug doses in Diabetics with a hope of improving clinical response.

ABSTRACT 5: Simultaneous Rapid Detection of Tubercular Meningitis and Drug Susceptibility Testing Using Pyrosequencing on Uncultured Cerebrospinal Fluid Samples

Submitting Author: Kanchan Ajbani

Co-authors: Mubin Kazi, Swapna Naik, Rajeev Soman, Anjali Shetty, Camilla Rodrigues

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 and Rationale: Tubercular meningitis (TBM) is a serious form of tuberculosis (TB). Laboratory diagnosis is difficult as culture takes time and is often falsely negative in paucibacillary disease. In high-burden countries, circulating drug resistance confounds empiric treatment for TBM. Pyrosequencing

(PSQ) is a potential tool to detect and characterize TB as multidrug resistant (resistant to isoniazid and rifampin, "MDR") or extensively drug resistant (MDR plus fluoroquinolone and second-line injectable drug resistance, "XDR") directly from cerebrospinal fluid (CSF).

Methods: Sixty-seven consecutive CSF samples were included from patients who requested CSF pyrosequencing due to history, clinical findings, and routine CSF studies suggestive of TBM. CSF DNA was extracted using the Qiagen spin column protocol. PCR was performed for the rpoB, katG, inhA, gyrase A, eis, and rrs genes. PCR products were then pyrosequenced using the pyromark Q96. Results were compared to those obtained from CSF MGIT culture and drug susceptibility testing (DST) and CSF Xpert MTB/RIF.

Results: Of 67 CSF samples, 46 (68.7%) detected TB by PSQ. Of those, 13 were MDR-TB (28.3%), 2 were XDR-TB (4.3%), 3 were isoniazid monoresistant (6.5%), and the remaining 28 were susceptible to all XDR-defining drugs (60.9%). Of the 17 culture-positive samples 88% (15 of 17) concordance was observed between PSQ and phenotypic DST. In two samples PSQ failed to detect resistance to INH and RIF. Xpert MTB/RIF was positive in 21 of 67 (31.3%) samples that were also PSQ positive. Of those 21 samples, 8 were rifampin resistant (38.1%) and 13 were susceptible (61.9%). Patients were initiated on treatment based on PSQ reports.

Conclusions and Recommendations: In vital paucibacillary samples like CSF, PSQ can improve timely detection of TB and provide drug resistance information to guide early initiation of appropriate therapy while awaiting phenotypic DST.

ABSTRACT 6: Whole Genome Sequencing of Mycobacterium Tuberculosis Directly from Clinical Samples Accurately Identifies Drug Resistance

Submitting Author: Priti Kambli

Co-authors: Jeffrey A Tornheim, Lakshmi Soundararajan, Sushri Priyadarshini, Ravi Gupta, V.L. Ramprasad, Amita Gupta, Camilla Rodrigues

Background and Rationale: Culture-based identification of Mycobacterium tuberculosis (Mtb), the bacterium that causes tuberculosis and standard drug susceptibility testing (DST) are cumbersome processes that require several weeks for results. This delays diagnosis, effective treatment, and may worsen outcomes. Whole genome sequencing (WGS) is a promising tool for simultaneous identification of Mtb and DST, but culture-free WGS has not yet demonstrated consistent results at high depth.

Methods: We present a custom Mtb-specific enrichment assay for WGS from uncultured sputum samples. We sequenced 46 samples to identify Mtb and resistance-associated mutations. Mutations identified by WGS were compared to results obtained from both LPA and phenotypic DST performed on the same samples.

Results: This enrichment method significantly improved recovery of Mtb DNA, with proportion of reads mapping to Mtb increasing from 3% from unenriched samples to 65.5% from enriched samples. Our method increased median Mtb genome coverage from 49.1% obtained using unenriched samples to ~100% among the enriched samples. Using MPT64 gene coverage for species identification, we detected Mtb with 100% accuracy. Among Mtb samples, 97% of the genome achieved a depth of ≥100x. Assessment of resistance-associated mutations found 96.8% sensitivity, 98.5% and 98.3% accuracy compared to LPA. Average MICs and ranges were identified for mutations associated with resistance to XDR-TB drugs for these isolates.

Conclusions and Recommendations: This novel custom tiling probe allows successful WGS of Mtb at high depth and with high accuracy of DST results compared LPA, and phenotypic DST. Sequencing whole genome accurately will help in exploring regions that are not yet known for drug resistance and will enable discovery of new drug resistance mutations.

ABSTRACT 7: IL-6, TIMP-2 and TGFβ-2 are Associated with respiratory Impairment During and Following Successful Treatment of Pulmonary Tuberculosis

Submitting Author: Akshay Gupte

Co-authors: Mandar Paradkar, Sriram Selvaraju, Pavan Kumar, Rahul Lokhande, Vandana Kulkarni, Luke Hanna, Kannan Thiruvengadam, Krithikaa Sekar, Ayesha Momin, Sri Vijay Bala Yogendra, Nikhil Gupte, Subash Babu, Sundeep Salvi, Jonathan Golub, William Checkley, Robert Bollinger, Bruno Andrade, Vidya Mave, Padmapriyadarsini Chandrasekaran, Amita Gupta

Background and Rationale:
Pulmonary tuberculosis (PTB) is increasingly being recognized as an independent risk factor for chronic lung diseases. However, inflammatory pathways associated with respiratory impairment in PTB are unclear; preventing the identification of prognostic and therapeutic targets for risk-stratification and host-directed therapies to limit lung injury.

Methods: New adult (>18 years) drug-sensitive PTB cases were enrolled within 1 week of treatment initiation and, prospectively evaluated at 2 months and 6 months for plasma concentrations of cytokines associated with the host immune response in PTB (INF-γ, TNF-α, IL-1β, IL-4, IL-6, IL-10, CXCL-10, IL-12, IL-13, IL-17), matrix destruction (MMP-1, MMP-3, MMP-7, TIMP-1, TIMP-2, TIMP-3, TIMP-4) and fibrosis (TGFβ-1, TGFβ-2, TGFβ-3). Respiratory impairment was assessed from the patient's perspective by the Saint George's Respiratory Questionnaire (SGRQ) administered during treatment, and objectively by post-bronchodilator spirometry conducted during a 6-monthinterval following successful treatment completion. P-values were adjusted for multiple comparisons using the Benjamini-Hochberg procedure and considered significant at $\alpha<0.05$.

Results: Of the 30 participants enrolled, 20 (74%) were male, 9 (31%) ever-smoked, 2 (7%) had HIV coinfection and 7 (26%) had diabetes. The median (IQR) age and body mass index (BMI) was 36 (28-50) years and 18.1 (16.0-20.0) kg/m2, respectively. Higher levels of IL-6were associated with higher SGRQ scores during treatment (5-points per log-higher IL-6, 95%CI 2 to 8, $p<0.001$).A greater decline in TIMP-2 levels during the first 2 months of treatment was associated with higher percent-predicted FEV1 ($r=0.70$, $p=0.005$) and FVC ($r=0.67$, $p=0.008$), while a greater decline in TGFβ-2 during the first 2 months of treatment was associated with higher percent-predicted FEV1 ($r=0.55$, $p=0.03$) and FEV1/FVC ratio ($r=0.58$, $p=0.03$) following successful treatment.

Conclusion: Lower levels of IL-6 and greater resolution of TIMP-2 and TGFβ-2 during early treatment was associated with better respiratory health status and lung function in successfully treated PTB.

ABSTRACT 8: Pharmacokinetics of Rifampicin, Isoniazid and Pyrazinamide during Daily and Intermittent Dosing

Submitting Author: Deepa Shankar

Co-authors: DJ Christopher, AK Hemanth Kumar, Balamugesh Thangakunam, T Kannan, Geetha Ramachandran

Background: Tuberculosis (TB) is a readily curable disease when adequate anti-TB treatment (ATT) is properly administered. Despite of standard RNTCP short course regimen, treatment failure, relapse and drug

resistant remain unexplained. Sub-therapeutic drug concentration as risk factors for unfavourable outcome has been reported. Recently, there was a transition in tuberculosis (TB) treatment from thrice-weekly to daily regimens in India. The aim of the study is to compare the pharmacokinetics (PK) of rifampicin (RMP), isoniazid (INH) and pyrazinamide (PZA) between TB patients undergoing daily and thrice-weekly ATT.

Methods: This prospective observational PK study was undertaken in 49 newly diagnosed adult patients with pulmonary/extra-pulmonary TB receiving either daily ATT (n = 22) or thrice-weekly ATT(n = 27). Patients fulfilling the criteria of HIV-Seronegative, ATT for minimum of 2 weeks and HBA1c less than 7% were included in the study. The anti-TB drugs were administered under fasting conditions and drug administration was observed by an investigator. Blood samples were obtained before (0) and at 2, 4, 6 & 8 hours after drug ingestion. Plasma RMP, INH and PZA were estimated by HPLC.

Results: Peak concentration (Cmax) of RMP was significantly higher (RMP: 8.5µg/mlvs 5.5µg/ml; p = 0.003) and Cmax of INH was significantly lower (INH: 4.8µg/ml vs10.9µg/ml; p < 0.001) during daily than thrice-weekly ATT. Cmax of drugs and doses were significantly correlated. A higher proportion of patients had sub-therapeutic RMP Cmax (8.0µg/ml) during thrice-weekly than daily ATT (78% vs 36%; p = 0.004). Multiple linear regression analysis showed that RMP Cmax was significantly influenced by dosing rhythm and pulmonary TB, and Cmax of INH and PZA by mg/kg doses.

Conclusions: During daily ATT, drug doses used produced adequate RMP concentrations, but INH doses may have to be increased. More studies are required using higher INH doses with monitoring for occurrence of adverse drug reactions.

ABSTRACT 9: Altered Circulating Levels of Eicosanoids in Tuberculosis-diabetes Co-morbidity and Reversal upon Standard Tuberculosis Treatment

Submitting Author: Nathella Pavan Kumar

Co-authors: Kadar Moideen, Vijay Viswanathan, Basavaradhya S Shruthi, Shanmugam Sivakumar, Mohan Natarajan, Hardy Kornfeld, Subash Babu

Background and Rationale: Host eicosanoids are lipid mediators of inflammation that are increasingly recognized as important modulators of the host immune response in Mycobacterium tuberculosis infection (TB). Published studies have reported that leukotriene B4 (LTB4) and prostaglandin E2 (PGE2) play a host protective role by mediating bacterial clearance, while lipoxin A4 (LXA4) and 15-epi-lipoxin A4 (15-epi-LXA4) play a pathogenic role by hampering the host inflammatory response in TB. However, a detailed examination of the association of eicosanoids in tuberculosis-diabetes comorbidity (TB-DM) and relationship to disease pathology or bacterial burdens has not been studied.

Methods: To study this, we examined the systemic levels of LTB4, PGE2, LXA4 and 15-epi-LXA4 in individuals with either TB-DM, TB, diabetes mellitus (DM) or healthy controls (HC).

Results: Circulating levels of LXA4, 15-epi-LXA4 and PGE2 were significantly increased while the levels of LTB4 were significantly decreased in TB-DM and TB group compared to DM and HC. Moreover, the levels of LXA4 and15-epi-LXA4 were significantly higher in TB-DM individuals with bilateral and cavitary disease and these markers also exhibited a significant positive relationship with bacterial burden. Thus, both disease severity and bacterial burden in TB-DM is associated with elevated systemic levels of circulating eicosanoids. In addition, LXA4, 15-epi-LXA4 and PGE2exhibited a positive correlation with HbA1c, whereas LTB4 exhibited a negative correlation with HbA1c indicating an association of these factors with poor diabetic control. Finally, the end of anti-tuberculosis therapy resulted in significantly diminished levels of LXA4, 15-epi-LXA4 and PGE2 in TB-DM and TB group and enhanced levels of LTB4 in only the TB group compared to pre-treatment.

Conclusions and Recommendations: Our data on eicosanoids suggest that modulation and upregulation of eicosanoids are typical characteristics of TB-DM co-morbidity. Finally, our study highlights the complex network interlinking the pathogenesis of TB-DM in terms of host physiological interference.

ABSTRACT 10: Association of Diabetes Mellitus with INH Monoresistance

Submitting Author: Basavaradhya Shruthi

Co-authors: Shanmugam Sivakumar, Arutselvi, Nathella Pavan Kumar, Subash Babu, Pradeep A. Menon, Mohan Natarajan, Sathyavani K, Hardy Kornfeld, Vijay Viswanathan

Background: Tuberculosis (TB) remains a public health problem worldwide and diabetes mellitus (DM) is considered as one of the major risk factors for both drug susceptible and drug resistant TB. Drug-resistant TB has high rates of morbidity and mortality globally and presents a formidable obstacle to TB elimination. Isoniazid (INH) and rifampicin are the most important drugs for treating drug-susceptible TB. Isoniazid mono-resistance (IMR) is the most common form of mono-resistance; its world prevalence is estimated to range between 0.0 to 9.5% globally. Although several studies have determined IMR is not associated with poor outcomes, others have found associations with higher rates of treatment failure and progression to multidrug-resistant TB. Concurrent DM and TB is associated with adverse outcomes including delayed time to sputum conversion, treatment failure, and TB recurrence after curative treatment completion.

Aim of the Study: To determine the association of DM with INH mono resistance and its association with adverse outcomes in subjects with TB DM.

Methodology: 282 newly diagnosed pulmonary TB participants from the EDOTS cohort were included in the study. Drug sensitivity testing was applied to baseline sputum culture isolates. All the participants were evaluated for glycaemic status by oral glucose tolerance test and measurement of haemoglobin A1c. They were grouped as TB with DM (TB/DM) and TB without DM (TB/non-DM). Prevalence of IMR in both the groups was compared using Chi Square test and risk ratio.

Results and Conclusion: Amongst 282 subjects, 177 were TB/DM and 105 were TB/non-DM. a total of 86 participants (30.5%) showed resistance to at least one anti-TB drug, out of which isoniazid mono-resistance was the highest [32 out of 86 (37.2%)], followed by streptomycin 30(34.8%), ethambutol 18(20.9%), and rifampicin 6(6.9%). There was a non-significant trend (risk ratio 1.1) for higher IMR in the TB/DM group 22(12.42%) compared with TB/non-DM 10(9.5%). Amongst 32 IMR subjects, 20 (62.5%) subjects showed adverse treatment outcome (failure or relapse or death). Our findings are in accordance with results reported by Saldana et al. 2from a cohort in Southern Mexico but differ from those reported by Baghaei et al. 3 who found significantly increased odds of mono-resistance to at least one first-line drug in TB/DM. There are many potential explanation for these differences including regional host and microbe genetics and differing co-prevalence of host factors that increase TB disease and/or transmission risk. Further studies with larger number of subjects are necessary to clarify the reasons of primary resistance in TB patients with and without DM. Considering the increased unfavourable outcomes in IMR subjects, the present study suggests a need for intensified, tailored TB treatment in order to achieve favourable outcomes in TB patients with DM and IMR

ABSTRACT 11: Respiratory and Non-respiratory Co-morbidities in TB Patients

Submitting Author: Arundhati Chandini Arjun
Co-authors: DJ Christopher, Balamugesh Thangakunam, Deepa Shankar

Background and Rationale: Tuberculosis is a debilitating disease with devastating consequences unless detected and treated early. Co-morbidities such as DM, HIV, and malnutrition are well established risk factors for the reactivation of TB. However TB patients could have several respiratory and non-respiratory co-morbidities, some of which may contribute to reactivation and have a bearing on the morbidity, course of disease and mortality. These have not been well studied in published literature. The aim of the study was to assess the prevalence of respiratory and non-respiratory co-morbidities in consecutive TB patients who presented to the Christian Medical College, Vellore a tertiary care teaching hospital.

Methods: This was a retrospective study of newly diagnosed cases of pulmonary and extra-pulmonary tuberculosis presenting to the Department of Pulmonary Medicine from January to June 2018. The subjects were identified from the departmental TB database. They were included if they had disease either microbiologically confirmed by smear microscopy, Gene Xpert, culture, or by histopathology with consistent clinical picture. A detailed evaluation of the hospital records was carried out to identify respiratory co-morbidities such as ILD, sarcoidosis, COPD, bronchial asthma, lung malignancy, and bronchiectasis. Non-respiratory co-morbidities included haematological, oncological, cardiovascular (ischemic heart disease, cerebrovascular accident, hypertension etc.), endocrinological, rheumatologic and autoimmune disorders, HIV and diabetes mellitus.

Results: We diagnosed and treated 229 patients with tuberculosis during the study period-179 pulmonary (PT) and 50 extra-pulmonary (EPTB). Out of 229, 173(75.5%) patients had at least one co-morbidity. Eighty-one (35.3%) had 1, 60(26.2%) had 2 and 32(14%) had 3 or more co-morbidities. The most common co-morbidities were Anemia in 39.7%, Diabetes in 34.49%, Hypertension in 13.1%, Asthma in5.6%and COPD in 4.8% and HIV in 4(1.75%) patients. Low BMI (<18.5%) was present in 42.1%, however it was not recorded in all the patients. Among the 179 PT patients, 16.75% had respiratory co-morbidities and 68.71% had non-respiratory co-morbidities.

Conclusion: Three quarters of the TB patients had co-morbidities, the commonest being Low BMI, Diabetes and Anemia. HIV prevalence was low. Among PT subjects, respiratory co-morbidities were found in 16.75%. The study makes a case for careful screening for co-morbidities in TB patients.

ABSTRACT 12: Mental Health and TB: High Prevalence of Depression among Drug-resistant TB Patients Not Associated with Cycloserine

Submitting Author: Shri Vijay Bala Yogendra Shivakumar

Co-authors: Jeffrey Tornheim, Ishita Gajjar, Sana Porwal, Girija Kishore, Megha Karane, Samrin Sayed, Prerna Chawla, Camilla Rodrigues, Tester Ashavaid, Amita Gupta, Zarir F. Udwadia

Background and Rationale: Depression often coexists with TB, and is often associated with poor treatment adherence and higher mortality. Drug-resistant TB(DR-TB) patients often receive cycloserine, a bacteriostatic drug with partial NMDA-receptor activity that is associated with neuropsychiatric side effects. We evaluated Patient Health Questionnaire-9 (PHQ-9)scores among DR-TB patients undergoing treatment with and without cycloserine.

Methods: Participants in an ongoing prospective cohort of newly-diagnosed DR-TB patients(≥15yearsof age)at a private referral hospital in Mumbai completed PHQ-9questionnaire at enrolment and after 2weeks, 1, 2, 3, 4, 5, and 6 months of treatment. PHQ-9 scores between 1-4, 5-9, 10-14, 15-19 & ≥20 were defined as minimal, mild, moderate, moderate-severe and severe depression.

Results: Of 55 DR-TB patients, 67% were female, 93% culture-confirmed, 9% diabetic, and 1 HIV-infected. Of 52 patients with PHQ-9 scores, 10% (5/52) were severely, 21% (11/52) moderately, 29% (15/52) mildly and 38% (20/52) minimally depressed at baseline with scores ≥10 reported by 60% (31/52)of patients during treatment. Of 55 DR-TB patients, 44 received cycloserine. Mean PHQ-9 scores were similar among patients treated with and without cycloserine at entry (7.4 vs. 7.1), week 2 (5.3 vs. 5.4), month 1 (8.0 vs. 7.3), month 2 (7.1 vs. 7.0), month 3 (7.6 vs. 8.6), month 4 (6.9 vs. 8.1), month 5 (9.8 vs. 6.6) and month 6 (8.1 vs. 7.9). No significant difference was found between groups at any time point.

Conclusions and Recommendations: Depression as measured by PHQ-9 scores is very common during DR-TB treatment. The depression experienced during MDR-TB treatment was not significantly impacted by concomitant cycloserine treatment. More attention should be paid to the mental health of DR-TB patients during treatment. Active screening and development of blood based biomarkers to assess mental health could help triage high risk patients for early intervention.

ABSTRACT 13: Determination of Plasma Clofazimine Levels by Liquid Chromatography-Mass Spectrometry

Submitting Author: Prerna K. Chawla

Co-authors: Rohan V. Lokhande, Prasad R. Naik, Alpa J. Dherai, Zarir F. Udwadia, Ashok A. Mahashur, Lancelot Pinto, Rajeev Soman,Camilla Rodrigues, Amita Gupta, Jeffrey A Tornheim, Neil Martinson, Ebrahim Variava, Lubbe Wiesner, Anton Joubert, Tester F. Ashavaid

Background and Rationale: Clofazimine (CFZ) is used as a second line drug for multidrug resistant tuberculosis (MDR-TB) treatment. It exerts slow bactericidal effect on mycobacteria by binding to DNA, leading to cell cycle disruption. Efficient in vitro and in vivo activity against drug resistant strains and low rates of CFZ resistance has promoted its use in MDR-TB therapy. CFZ is well-absorbed orally with food but has a very long half-life and its pharmacokinetics are not well understood, especially among MDR-TB patients. Therefore, the present study aimed to establish and validate an assay to quantitate CFZ levels in the plasma of MDR-TB patients.

Methods: CFZ quantitation was standardized and validated with a tandem mass spectrometry approach using liquid chromatography mass spectrometry (LC-MS). LC-MS grade solvents were used along with pure CFZ powder and an internal standard (IS). Chromatography was carried out using the reverse phase column with an isocratic elution technique. Plasma samples were deproteinized with organic solvents and analysed on LC-MS from a calibration range of 0.0313-4mg/L.

Results: The method was validated for linearity, accuracy, precision, recovery, and limit of quantitation. The stability analyses are on-going. A consistent ratio of area count of CFZ/area count of IS was observed with recovery ranging from 80-120%. Inter-day and intra-day accuracy and precision passed the %coefficient of variance (CV)of<20%for standards and controls. Therapeutic range of plasma CFZ is 0.5–2mg/l. CFZ levels have been quantitated for 32 samples (2-hr post dose) so far, and the remaining collected samples are under process. The drug levels observed will be correlated with factors affecting plasma drug levels.

Conclusion and Recommendations: The method is validated as per the Bioanalytical Guidelines for method validation, FDA 2018. The developed method is a simple and robust method to estimate plasma Clofazimine levels.

ABSTRACT 14: Determination of Serum Linezolid levels by HPLC

Submitting Author: Prerna K. Chawla

Co-authors: Prasad R. Naik, Rohan V. Lokhande, Alpa I. Dherai1, Zarir F. Udwadia, Ashok A. Mahashur, Lancelot Pinto, Rajeev Soman, Camilla Rodrigues, Amita Gupta, Jeffrey A. Tornheim, Tester F. Ashavaid

Background and Rationale: Linezolid is widely used as a second line drug for anti-tuberculosis treatment. It binds to the ribosomal subunit, inhibiting formation of the initiation complex and preventing translation and protein synthesis. Linezolid is well absorbed orally but its pharmacokinetics is known to exhibit wide inter individual variability warranting the need for therapeutic drug monitoring. The present study aimed to develop a validated assay to quantitate serum linezolid levels for patients on ongoing linezolid therapy.

Methods: A high performance liquid chromatographic (HPLC) method with UV detection for quantitative estimation of linezolid in serum was developed. Chromatography was carried out using reverse phase technique with a mobile phase composed of phosphate buffer and acetonitrile. Serum samples were deproteinized with organic solvents and analyzed on HPLC. The assay is calibrated from 2-100mg/L calibration range with a lower limit of detection of 1mg/L.

Results: The method has been validated for linearity, recovery, accuracy, precision, robustness, limit of detection and limit of quantitation. The retention time of linezolid was found to be 8.01min. The recovery of linezolid was close to 100% and ranged from 80%to 120% as per guidelines. Inter-day and intra-day accuracy and precision passed the % coefficient of variance (CV) of< 20%. Therapeutic range of serum linezolid levels is 12 –26 mg/l. Drug level estimation in patients on ongoing linezolid therapy is initiated with about 10 samples processed so far. The remaining collected samples will be processed and correlated with factors affecting serum drug levels. Conclusion and Recommendations: The method is validated as per the Bioanalytical Guidelines for method validation, FDA 2018. The developed method is a simple & robust method to estimate linezolid levels in plasma samples.

ABSTRACT 15: Effect of Diabetes Prevalence on Circulating Components of Blood, Disease Severity and Drug Susceptibility in Patients with Pulmonary Tuberculosis

Submitting Author: Abilasha N

Co-authors: Bharath B, Jasemine Priyanga R, Senbagavalli P, Roy G, Sarkar S, Subitha L, Muthuraj M, Vinod K, Noyal J, Hochberg NS

Background: Diabetes mellitus (DM) is a known co-morbid condition for tuberculosis (TB) and also a major risk factor in the development of active TB.

Aim: To study peripheral blood components, disease severity and susceptibility to anti-TB drugs in active pulmonary TB patients with and without the co-existence of DM.

Methodology: The data is obtained from RePORT India cohort, JIPMER CRU. The study population comprises of 21 healthy community controls (HCC) and 184 active pulmonary TB patients, of which 99 (58%) were TB+DM+ and 72 (42%) had only TB+. Patients with TB were further sub-grouped as 1+, 2+ and 3+ based on sputum smear results. Complete blood count (CBC), chest X-ray (% of lung affected and cavitation) and MGIT drug susceptibility (DST) were the parameters analysed.

Results: Whole blood parameters including WBC, Haemoglobin, Platelets, Neutrophils, Neutrophil Lymphocyte ratio, Eosinophil Lymphocyte Ratio (ELR) and Platelet Lymphocyte ratio were significantly higher

(p<0.05) in TB+ and TB+DM+ groups compared to HCC. Hb and HCT were the only parameters significantly different (P<0.01) between TB+ and TB+DM+ groups. Interestingly, eosinophils and ELR were showing significant inverse trend when compared between males and females with TB severity. The percentage of 2+ TB severity was significantly higher in TB+DM+ group (41.41%) in comparison to TB alone group (30.99)and the effect on lung damage was also analysed. DST results showed 3% of TB+DM+ patients being resistant to INH and Ethambutol, whereas5% and 2.5%of TB alone group were resistant to INH and ethambutol respectively.

Conclusion: DM seem to have varied effects on cellular levels, disease severity and drug susceptibility and it warrants detailed studies to explore the underlying mechanisms which might help to improve TB control in TB-diabetic co-prevalent countries.

ABSTRACT 16: Predictors of Mortality in a TB Meningitis Cohort

Submitting Author: Arundhati Chandini Arjun

Co-authors: Balamugesh Thangakunam, Thambu David, Soumya Satheyendra, Ramya I, OC Abraham, Alice Mathuram, DJ Christopher

Background and Rationale: TB Meningitis is a frightening disease with high mortality rates. DBT and NIAID (USA) through CRDF global have jointly funded an observational cohort of TBM and pulmonary TB patients to study the genetic variants of determinants of immune response in Indian patients with TBM and PTB, and its effects on TB severity and outcomes. We aimed to compare the baseline & disease severity characteristics of this cohort of patients who successfully completed anti-tuberculous treatment against those who succumbed to the disease.

Methods: All patients who underwent hospitalization & treatment for TB Meningitis in CMC, Vellore were recruited from September 2014 to August 2018. After obtaining consent, patients underwent detailed screening of symptoms, examination and standardised anti-TB treatment (ATT) for 12 -18 months, along with corticosteroids for 8 weeks, with extension based on response. We extracted from the CRF the baseline demographics such as age and gender; BMI, Diabetic &HIV status and disease severity indices such as Glasgow Coma Scale, Karnofsky and MRC grading; and compared those who succumbed with those who completed treatment. Patients who needed prolonged ATT (beyond 18 months) or steroid regimen (beyond 9 weeks) deemed to have received extended treatment and they were compared with those who received treatment of the standard duration.

Results: A total of 239 patients were recruited during the study duration. Of these 77(32.21%) successfully completed treatment, 49(20.5%) succumbed to the disease and treatment is ongoing for 39(16.32%) patients. Those that successfully completed treatment and those that succumbed were included and the comparison was done between these groups. Those who succumbed were significantly older (51.4 VS years, p <0.001), of male gender (p= 0.008), had a higher BMI (p =0.028), were more likely to be in MRC grade 2 or 3 (p<0.001), to be diabetic (p= 0.001).Of the patients who completed treatment successfully, the patients who required a prolonged course of steroids had a lower GCS (p= 0.047) compared to those who received treatment of standard duration.

Conclusion: TB Meningitis is a gruesome disease with a fatal outcome in 20.5% of the patients. Older patients, male sex, higher BMI, diabetes and those with MRC grades 2 & 3 were found to be predictors or mortality and those with lower GCS scale were more likely to have extension of ATT.

ABSTRACT 17: Role of PET CT Scans in Tuberculous Meningitis

Submitting Author: Shona Arlin Christopher

Co-authors: DJ Christopher, Balamugesh Thangakunam, Julie Hephzibah, Alice Mathuram, Thambu David, Soumya Satheyendra, OC Abraham, Ramya I, Deepa Shankar

Background: Tuberculous meningitis (TBM) is the most severe form of TB and has the highest mortality and morbidity rate compared to other forms of TB. TBM accounts for about 1% of all cases of tuberculosis (TB) and 5% of EPTB in immuno-competent individuals. The case fatality ratio remains relatively high (15-40%) despite effective treatment. Early diagnosis is challenging due to the non-specific symptoms of TBM and the low number of tubercle bacilli in cerebrospinal fluid (CSF). Until now, there is no established diagnostic method that can rapidly detect M. tuberculosis. So the diagnosis is often on the basis of prediction scores and consensus criteria. The aim of this study is to assess the role of 18F-FDG PET-CT in detecting the extra cranial involvement in patients with TBM. This improves the probability of TBM, thus improves confidence in diagnosis and also may reveal more accessible sites to obtain samples for confirming diagnosis and drug susceptibility patterns with appropriate microbiologic & pathology tests.

Methods: This is a prospective sub-study of a RePORT-Parent protocol TBM cohort. Patients presenting with TBM symptoms were included from all Medicine Units (1 to 5) of Christian Medical College, Vellore. Out of 32patients who consented for whole body 18F-FDG PET-CT, 22 were eligible and underwent PET CT scan successfully. Extra-cranial FDG uptake was positive in 16(73%) and negative in 6(27%) patients. Of the positive PET scans, 14 FDG avid lesions were picked up related to TB (64%)-in lymph nodes, lungs, bones, spine, pleura and blood vessel (Aorta). There were 2 non-significant avid lesions not related to TB (1-Thyroid nodule, 1-Bone marrow secondary to steroid treatment)

Results: TBM patients were classified as Definite, Probable and Possible as per Consensus Criteria. When PET CT positive results were included for scoring, in 3 patients, TBM classification changed from possible to probable. Out of 14 positive PET CT scan, pleural biopsy was performed in 1 patient, which was Xpert positive and the diagnosis changed from possible to probable TBM in this patient.

Conclusion: 18F-FDG PET-CT is a promising modality in the evaluation of suspected TBM and has an important role in detecting extra cranial involvement, thus improving diagnostic probability and provides an opportunity for obtaining for specific diagnosis.

This page is intentionally blank

Publications

PARENT & COMMON PROTOCOLS

RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank

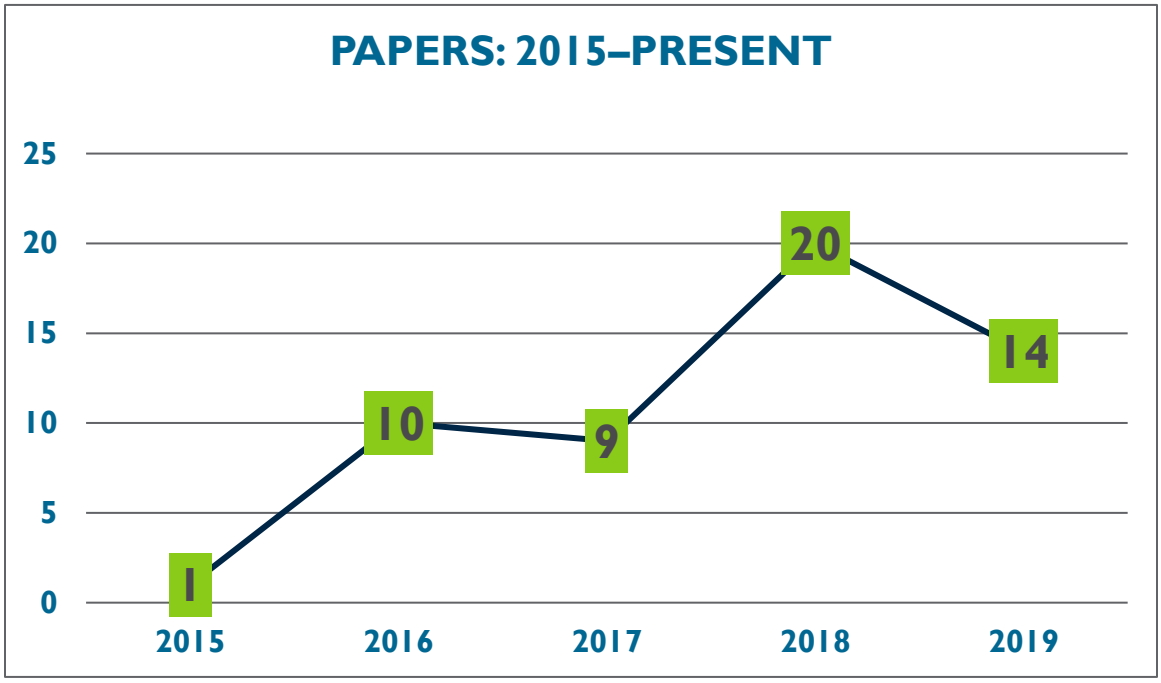


*Figure for 2019 reflects manuscripts that have been published and are in process as of January 23, 2019.

RePORT India Consortium

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.
PubMed: http://www.ncbi.nlm.nih.gov/pubmed/26409277

Collaborating Organizations:

- Scientific Affairs, Global Health, Population and Nutrition, FHI 360
- Department of Medicine, Division of Infectious Diseases, Duke University School of Medicine, Durham, NC, USA
- Indian Council of Medical Research and Department of Health Research, Government of India
- Pulmonary Medicine, Christian Medical College, Vellore, India
- School of Medicine, Boston University, MA, USA
- School of Medicine, Johns Hopkins University, Baltimore, MD, USA
- Department of Medicine, Division of Infectious Diseases, Vanderbilt University School of Medicine, Nashville, TN, USA
- National Institute of Infectious Diseases Evandro Chagas-Fiocruz, Rio de Janeiro, Brazil
- Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health
- Collaborative Clinical Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health
- The National Institute of Research and Development, Indonesia Ministry of Health, Jakarta, Indonesia
- Collaborative Clinical Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health
- Health Studies Sector, Westat, Rockville, MD, USA

Bhagwan Mahavir Medical Research Centre/University of Texas Health Science Center at Tyler (CRU 107)

1. **Young household contacts of tuberculosis (TB) patients with reduced T4 and IL-1α 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. *(Journal of Clinical Investigation; under review*)

2. **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, Vankaylapati R, Valluri VL. Cytokine. 2018;110: 213-221.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29778672

3. **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 Infectious Diseases. 2018;18:321.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29996789

4. **Alcohol enhances type I interferon-αproduction 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;14(8): e1007174.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30071107

5. **IL-21 regulates NK cell responses during Mycobacterium tuberculosis infection**
   Paidipally P, Tripathi D, Van A, Radhakrishnan R, Dhiman R, Venkatasubramanian S, Devalraju K, Tvinnereim A, Valluri V, Vankayalapati R. J Infect Dis. 2018 Mar 28;217(8):1323-1333.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29390153

6. **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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27982034

   Collaborating Organizations:
   - Department of Pulmonary Immunology, Center for Biomedical Research, University of Texas Health Science Center at Tyler, Tyler, Texas, USA

7. **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. 2016 Dec 7. doi: 10.1038/mi.2016.105
   PubMed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5462891/

   Collaborating Organizations:
   - Department of Pulmonary Immunology, Center for Biomedical Research, University of Texas Health Science Center at Tyler, Tyler, Texas, USA
   - Department of Immunology, M. D. Anderson Cancer Center, Houston, Texas, USA

8. **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.

PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27783671

Collaborating Organizations:

- Department of Pulmonary Immunology, Center for Biomedical Research, University of Texas Health Science Center at Tyler, Tyler, Texas, USA
- National Institutes of Health, International Center for Excellence in Research, Chennai, India
- Department of Cellular and Molecular Biology, Center for Biomedical Research, University of Texas Health Science Center at Tyler, Tyler, Texas, USA
- Blue Peter Research Center, LEPRA Society, Cherlapally, Hyderabad, India,
- Department of Medicine, University of Massachusetts Medical School, Worcester, MA, USA

Byramjee Jeejeebhoy Medical College (BJGMC)/ National Institute for Research in Tuberculosis (NIRT)/ Johns Hopkins University (JHU) (CRU 106 & 105)

1. **Smoking, alcohol use disorder and TB treatment outcomes: A dual co-mobidity 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 for the CTRIUMPH- RePORT India Study. (*Submitted: PLOS ONE; January 2018*)

2. **Age-specific burden of tuberculosis infection in household contacts in an endemic setting: Time for prophylaxis?**
   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. (*Submitted: International Journal of Tuberculosis and Lung Disease; January 2018*)

3. **Sub-therapeutic rifampicin concentration is associated with unfavourable tuberculosis treatment outcomes**
   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 C-TRIUMPh team. (*Submitted: Clinical Infectious Diseases; January 2019*)

4. **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. (*Submitted: PLOS ONE; December 2018*)

5. **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, Valvi C, Hanna LE, Andrade B, Chandrasekaran P, Mave V, Pandey A, Gupta A for the CTRIUMPh RePORT India Study Team. (*Submitted: Journal of Infectious Diseases; December 2018*)

6. **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. (*Submitted: International Journal of Tuberculosis and Lung Disease*)

7. **Assessment of lung function in successfully treated tuberculosis reveals high burden of ventilatory defects and COPD**
Gupte A; Paradkar A; 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; Chandrasekaran P; Gupta A. (*Under review; December 2018*)

8. **Respiratory health status is associated with treatment outcomes in pulmonary tuberculosis**
Gupte, A; Selvaraju S; Paradkar M; Dhanasekaran K; Shivakumar SVBY; Thiruvenkadam K; Dolla CK; Sivaramakrishnan GN; 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 JE; Bollinger R; Chandrasekaran P; Mave V; Gupta A. (*Accepted: International Journal of Tuberculosis and Lung Disease; September 2018*)

9. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30236186

Collaborating Organizations:
- Byramjee Jeejeebhoy Government Medical College/Sassoon General Hospital, Pune.
- Department of Community Medicine, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi.
- Byramjee Jeejeebhoy Government Medical College/Johns Hopkins Clinical Trials Unit, Pune, India.
- Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.
- Byramjee Jeejeebhoy Government Medical College/Johns Hopkins Clinical Trials Unit, Pune, India, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.

10. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30067752

Collaborating Organizations:
- Department of Clinical Research, National Institute for Research in Tuberculosis, Chennai, India.
- Johns Hopkins University School of Medicine, Baltimore, United States of America.
- Byramjee- Jeejeebhoy Government Medical College- Johns Hopkins University Clinical Research Site, Pune, India.
- Johns Hopkins University-India office, Pune, India.
- Department of Medicine, Byramjee Jeejeebhoy Government Medical College, Pune, India.
- Johns Hopkins Bloomberg School of Public Health, Baltimore, United States of America.
- Department of Chest Medicine, Government Headquarters Hospital, Thiruvallur, India.
- Indian Council of Medical Research, New Delhi, India.

11. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30041729

Collaborating Organizations:
- Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

- Johns Hopkins University School of Medicine, Baltimore, MD, USA
- Johns Hopkins Clinical Trials Unit, Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Dr D Y Patil Medical College, Pune, India

12. **Addressing knowledge gaps and prevention for tuberculosis-infected Indian adults: a vital part of elimination**
Deluca A, Dhumal 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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29720095

Collaborating Organizations:
- Johns Hopkins Bloomberg School of Public Health, International Health, Baltimore, MD, USA
- Byramjee-Jeejeebhoy Government Medical College-Johns Hopkins University Clinical Trials Unit, Pune, India.
- Division of Infectious Diseases, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA.
- Byramjee-Jeejeebhoy Government Medical College, Pune, India.
- Department of Community Medicine, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.
- Johns Hopkins Bloomberg School of Public Health, International Health, Baltimore, MD, USA.

13. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30514497

Collaborating Organizations:
- RePORT International

14. **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; 22(6): 686-694. Doi: 10.5588/ijtld.17.0598.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29862955

Collaborating Organizations:
- Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
- Johns Hopkins University School of Medicine, Baltimore, MD, USA
- National Institute for Research in Tuberculosis, Chennai, Tamil Nadu, India
- Johns Hopkins Clinical Trials Unit, Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Indian Council of Medical Research, New Delhi, India
- International Union for TB and Lung Diseases, Paris

15. **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, Breysse 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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29789668

16. **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, Breysse PN, Gupta A, Golub JE. Pediatrics. 2018 Jan; 141 (Suppl 1): S118-S129. doi: 10.1542/peds.2017-1026O.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29292312

Collaborating Organizations:

- Division of Infectious Disease, School of Medicine, Johns Hopkins School of Medicine, Baltimore, MD, USA
- Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative, Washington, DC, USA
- Department of Pediatrics, Sassoon General Hospital and Byramjee Jeejeebhoy Medical College, Pune, India
- Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA

17. **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.
PubMed:https://www.ncbi.nlm.nih.gov/pubmed/29216273

Collaborating Organizations:

- Byramjee-Jeejeebhoy Government Medical College-Johns Hopkins University Clinical Research Site, Pune, India.
- Johns Hopkins University School of Medicine, Baltimore, Maryland, USA
- Byramjee-Jeejeebhoy Government Medical College, Pune, India
- University of California San Francisco, San Francisco, USA
- National Institute of Research in Tuberculosis, Chennai, India

18. **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
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29297449

Collaborating Organizations:

- Byramjee-Jeejeebhoy Medical College-Johns Hopkins University Clinical Research Site, Pune, India
- Johns Hopkins University School of Medicine, Baltimore, MD, USA
- Dr D Y Patil Medical College, Pune, India
- Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

19. **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
PubMed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4889729/

Collaborating Organizations:
- Byramjee-Jeejeebhoy Medical College Clinical Trials Unit, Pune, India
- Johns Hopkins University School of Medicine, Baltimore, MD, USA
- University of California, San Francisco, CA, USA
- National Institute of Research in Tuberculosis, Chennai, India

20. **Cohort for Tuberculosis Research by the Indo-US 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.
PubMed: http://www.ncbi.nlm.nih.gov/pubmed/26916698

Collaborating Organizations:
- Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
- Johns Hopkins University School of Medicine, Baltimore, MD, USA
- National Institute for Research in Tuberculosis, Chennai, Tamil Nadu, India
- Johns Hopkins Clinical Trials Unit, Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Byramjee Jeejeebhoy Government Medical College, Pune, Maharashtra, India
- Indian Council of Medical Research, New Delhi, India

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. (*Submitted for publication*)

2. **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 for publication*)

3. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29486527

Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER)/Boston Medical Center (BMC) (CRU 102)

1. **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, JJRoy G, Horsburgh CR Jr, Hochberg NS (*Submitted: PLoS One*)

2. **Additive and multiplicative interactions between body mass index and diabetes mellitus in latent tuberculosis infection and active tuberculosis disease in south India**
   Kubiak R, Sarkar S, Horsburgh CR Jr, Roy G, Kratz M, Reshma, Knudsen S, Salgame P, Ellner JJ, Drain PK, Hochberg NS. (*Submitted: Am Journal of Epidemiology*)

3. **Crystal ball: the yesterday and tomorrow of tuberculosis**
   Sinha P, Hochberg NS. Environ Microbiol Rep. 2018 Dec 25. doi: 10.1111/1758-2229.12726. [Epub ahead of print]
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30585431

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. 2018 Nov 22. doi: 10.1093/infdis/jiy675. [Epub ahead of print]
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30476125

5. **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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29562981

6. **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, Lakshminarayanan S, 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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29559120

   Collaborating Organizations:
   - Centre for Emerging Pathogens, Department of Medicine, Rutgers-New Jersey Medical School, Newark, NJ, USA
   - Division of Computational Biomedicine and Bioinformatics Program, Boston University, Boston, MA, USA
   - Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India
   - Boston Medical Centre, Boston, MA, USA
   - Boston University, School of Public Health, Boston, MA, USA
   - Department of Biostatistics, Boston University, Boston, MA, USA

7. **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;12(8): e0183195.
   PubMed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5568341

   Collaborating Organizations:
   - Boston University School of Medicine, Boston, MA, USA
   - Boston University School of Public Health, Boston, MA, USA
   - Boston Medical Center, Boston, MA, USA
   - Government Chest Clinic, Puducherry, India
   - Rutgers University, Newark, New Jersey, USA

8. **Predictors of delay to accessing care among tuberculosis patients in southern India. (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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28806911

Collaborating Organizations:
- Boston University Department of Biostatistics, Boston, MA, USA
- Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry, India
- Boston Medical Center, Boston, MA, USA
- Boston University School of Medicine, Boston, MA, USA
- Boston University School of Public Health, Boston, MA, USA

9. **Advances in basic and translational tuberculosis research proceedings of the first meeting of RePORT international**
Geadas C, Stoszek SK, Sherman D, Andrade BB, Srinivasan S, Hamilton CD, Ellner J. Tuberculosis. 2016. doi: 10.1016/j.tube.2016.11.006
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28061953

Collaborating Organizations:
- Boston Medical Center and Boston University School of Medicine, Department of Internal Medicine, Section of Infectious Diseases, Boston, MA, USA
- Health Studies Sector, Westat, Rockville, MD, USA
- Center for Infectious Disease Research, Seattle, Washington, USA
- Unidade de Medicina Investigativa, Laboratório Integrado de Microbiologia e Imunorregulação, Instituto Gonçalo Moniz, Fundação Oswaldo Cruz, Salvador, Brazil
- Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA
- Scientific Affairs, Global Health, Population and Nutrition, FHI 360
- Department of Medicine, Division of Infectious Diseases, Duke University, School of Medicine, Durham, North Carolina, USA

MV Diabetes Research Centre – NIRT-NIH-ICER /University of Massachusetts (CRU 103)

1. **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.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28910369

Collaborating Organizations:
- National Institutes of Health-NIRT-International Center for Excellence in Research, Chennai, India
- Prof. M. Viswanathan Diabetes Research Center, Chennai, India
- National Institute for Research in Tuberculosis, Chennai, India
- University of Massachusetts Medical School, Worcester, MA, USA
- LPD, NIAID, NIH, Bethesda, MA, USA

2. **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. doi: 10.1038/s41598-017-01767-4.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28515464

Collaborating Organizations:
- Department of Pathophysiology and Toxicology, School of Pharmaceutical Sciences, University of São Paulo, São Paulo, Brazil
- Laboratório de Imunoparasitologia, Instituto Gonçalo Moniz, Fundação Oswaldo Cruz, Salvador, Brazil
- National Institutes of Health- NIRT - International Center for Excellence in Research, Chennai, India
- Unidade de Medicina Investigativa, Laboratório Integrado de Microbiologia e Imunorregulação, Instituto Gonçalo Moniz, Fundação Oswaldo Cruz, Salvador, Brazil
- Multinational Organization Network Sponsoring Translational and Epidemiological Research, Instituto Brasileiro para a Investigação da Tuberculose, Fundação José Silveira, Salvador, Brazil
- Curso de Medicina, Faculdade de Tecnologia e Ciências, Salvador, Brazil
- Department of Medicine, University of Massachusetts Medical School, Worcester, MA, USA
- National Institute for Research in Tuberculosis, Chennai, India
- Prof. M. Viswanathan Diabetes Research Center, Chennai, India
- Universidade Salvador (UNIFACS), Laureate Universities, Salvador, Brazil
- Division of Infectious Diseases, Department of Medicine, Vanderbilt University School of Medicine, Nashville, TN, USA

3. **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. doi: 10.1016/j.chest.2017.02.032. Epub 2017 Apr 20.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28434937

Collaborating Organizations:
- Mater Research Institute-The University of Queensland, Translational Research Institute,
- Woolloongabba, Queensland, Australia
- Department of Science and Technology/National Research Foundation Centre of Excellence for Biomedical TB Research/Medical Research Council Centre for Molecular and Cellular Biology, Division of Molecular Biology and Human Genetics, Faculty of Medicine and Health Sciences, Stellenbosch University, Tygerberg, South Africa
- Department of Internal Medicine, Radbourd University Medical Center, Nijmegen, the Netherlands
- Population Health Research Institute, St George's, University of London, UK
- Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, USA
- Department of Microbial Infection & Immunity, The Ohio State University, Ohio, USA
- World Diabetes Foundation, Copenhagen, Denmark
- Department of Microbiology, Immunology and Pathology, Colorado State University, Colorado, USA
- Department of Medicine, University of Massachusetts Medical School, USA
- University of Texas Health Science Center Houston, School of Public Health, Brownsville Campus, Texas, USA

4. **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. doi: 10.1016/j.chest.2017.04.155. Epub 2017 Apr 20.
PubMed: https://www.ncbi.nlm.nih.gov/pubmed/28434936

Collaborating Organizations:
- Population Health Research Institute, St George's, University of London, UK

- University of Texas Health Science Center Houston, School of Public Health, Brownsville
- Campus, Texas, USA
- Mater Research Institute – The University of Queensland, Translational Research Institute, Woolloongabba, Queensland, Australia
- World Diabetes Foundation, Copenhagen, Denmark
- Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, USA
- Department of Microbial Infection & Immunity, The Ohio State University, Ohio, USA
- Department of Microbiology, Immunology and Pathology, Colorado State University, Colorado, USA
- Department of Medicine, University of Massachusetts Medical School, USA
- Department of Internal Medicine, Radbourd University Medical Center, Nijmegen, the Netherlands

5. **Tuberculosis-diabetes co-morbidity is characterized by heightened systemic levels of circulating angiogenic factors**
   Kumar NP, Moideen K, SivakumarS, Menon PA, Viswanathan V, Kornfeld H, Babu S.J Infect. 2017 Jan;74(1):10-21. doi: 10.1016/j.jinf.2016.08.021. Epub 2016 Oct 4.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27717783

   Collaborating Organizations:
   - National Institutes of Health-NIRT-International Center for Excellence in Research, Chennai, India
   - Prof. M. Viswanathan Diabetes Research Center, Chennai, India
   - University of Massachusetts Medical School, Worcester, MA, USA
   - LPD, NIAID, NIH, MD, USA

6. **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. doi: 10.1016/j.tube.2016.10.004. Epub 2016 Oct 11.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27865391

   Collaborating Organizations:
   - National Institutes of HealthNIRTInternational Center for Excellence in Research, Chennai, India
   - Prof. M. Viswanathan Diabetes Research Center, Chennai, India
   - National Institute for Research in Tuberculosis, Chennai, India
   - University of Massachusetts Medical School, Worcester, MA, USA
   - LPD, NIAID, NIH, MD, USA

7. **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. doi: 10.1111/imm.12632. Epub 2016 Jul 26.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27289086

   Collaborating Organizations:
   - National Institutes of Health - NIRT - International Centre for Excellence in Research, Chennai, India
   - Prof. M. Viswanathan Diabetes Research Centre, Chennai, India
   - University of Massachusetts Medical School, Worcester, MA, USA
   - Laboratory of Parasitic Diseases, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, MD, USA

8. **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. doi: 10.1016/j.chest.2016.02.675. Epub 2016 Mar 10.
   PubMed: http://www.ncbi.nlm.nih.gov/pubmed/26973015

Collaborating Organizations:

- University of Massachusetts Medical School, Worcester, MA, USA
- Prof. M. Viswanathan Diabetes Research Center, Royapuram, India

P.D. Hinduja National Hospital and Medical Research Center/ Johns Hopkins University (JHU) (CRU 108)

1. **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. (*Accepted: BMC Infectious Diseases; 2019*)

2. **Utility of pyrosequencing for rapid detection of tubercular meningitis (TBM) and associated susceptibility directly from CSF specimens**
   Ajbani 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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/30029915

3. **Pyrosequencing to resolve discrepant Xpert MTB/RIF and Mycobacterial Growth Indicator Tube 960**
   Ajbani 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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29487256

4. **Evaluation of pyrosequencing for extensive drug resistance-defining anti-tuberculosis drugs for use in public healthcare**
   Nambiar R, Shah D, Ajbani 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.
   PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29779779

Lectures & Presentations

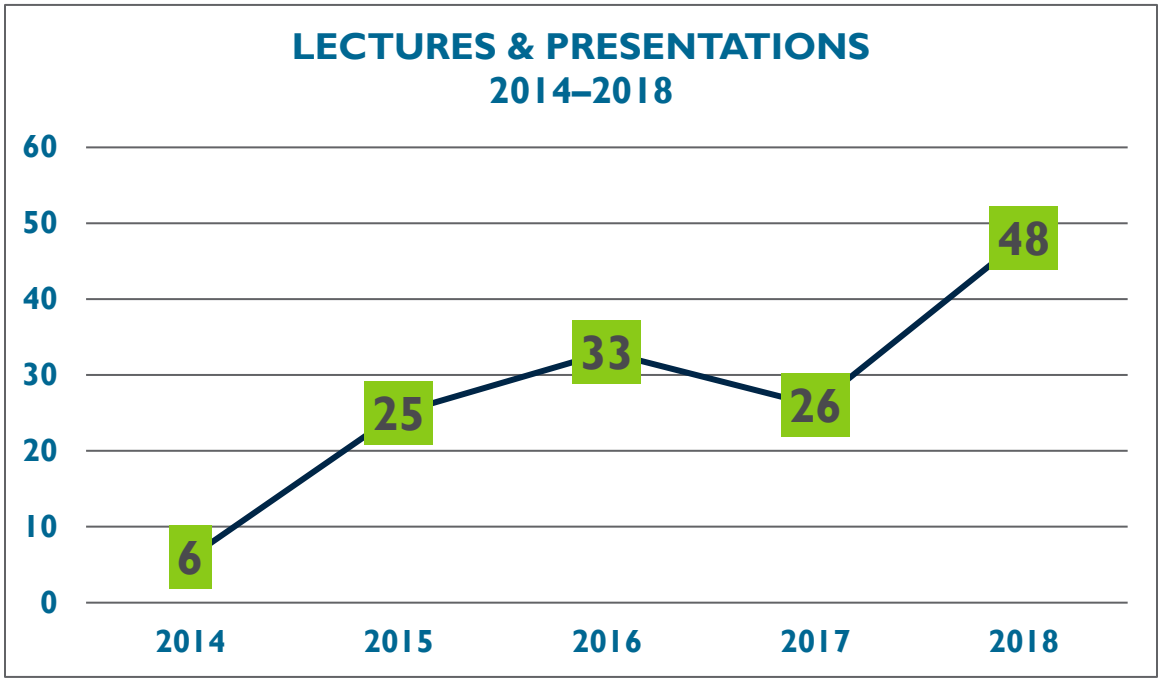
RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank



Category Definitions

LECTURE: Individual presentation on a topic of field of expertise

PRESENTATION: Multiple authors, includes poster and oral discussions

RePORT India Consortium

LECTURE

- Gupta A. An Overview of the RePORT India Consortium. Presented at: Annual IeDEA Meeting; National Institutes of Health; June 22, 2016; Rockville, MD, USA.

PRESENTATION/ABSTRACT

- 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: 45thUnion World Conference on Lung Health of the International Union Against TB and Lung Disease; October 28-November 1, 2014; Barcelona, Spain.

Bhagwan Mahavir Medical Research Centre (BMMRC)/ University of Texas Health Science Center at Tyler

PRESENTATIONS/ABSTRACTS

- 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 the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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 the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- Devalraju KP. **Identify Potential Biomarkers for Development of Latent Tuberculosis Infection (LTBI) by Longitudinal Follow-Up of HHC's of TB Patients**. Presented at:RePORT International 2016 Meeting; July 14-15, 2016.
- 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); February 28-March 3, 2016; Keystone, CO, USA.
- 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; May 8-12, 2015; New Orleans, LA, USA.
- 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 Immunologist Meeting; May 8-12, 2015; New Orleans, LA, USA.
- 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 1 Diabetic Mice**. Presented at: American Association of Immunologist Meeting; May 8-12, 2015; New Orleans, LA, USA.
- 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 1 Diabetic Mice**. Presented at: American Association of Immunologist Meeting; May 8-12, 2015; New Orleans, LA, USA.
- 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 Immunologist Meeting; May 8-12, 2015; New Orleans, LA, USA.
- 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—15thMeeting of the Society for Natural Immunity; May 2-6, 2015; Montebello, Canada.

Byramjee Jeejeebhoy Medical College (BJMC)/National Institute for Research in Tuberculosis (NIRT)/Johns Hopkins University (JHU) – Lectures/ Abstracts/ Posters/ Presentations

LECTURES

- Gupta A. **RePORT India Symposium.** Convener and Moderator, 49th Union World Conference on Lung Health. October 25, 2018; The Hague, The Netherlands.
- Kinikar A . **Update on RICC Pediatric Transcriptomic Study-India component**. RePORT International Annual Meeting. September 12-14, 2018; Szouchou, China.
- Gupta A. **RePORT India Overview.** Presented at: CFAR RePORT International Meeting; July 2, 2018; Rockville, MD.
- Gupta A. **Global Health Diplomacy: Why It Really Matters!** Keynote Address. AAAS Science & Technology, May 31, 2018. Washington, DC (RePORT India described)
- Gupta, A. **The Challenge of Eliminating TB in India.** Keynote Address. University of Washington TB Symposium. May 18, 2018; Seattle, WA.
- Chandrasekaran P, **TB Research in India**. Presented at: 1st BRICS TB Research Network Meeting. September 14-15, 2017; Rio de Janeiro, Brazil.
- 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). August 31-September 1, 2017; Seoul, Republic of Korea.
- Gupta, A. **Conducting HIV and TB Research in India: Challenges and Opportunities.** August 27, 2015; Emory University, Atlanta, GA.
- Gupta, A. **Conducting HIV and TB Research in India: Challenges and Opportunities.** June 23, 2016; University of Texas Health Science Center, Tyler, TX.
- Gupta A. **TB in Pregnancy**. Presented at: RePORT India meeting: Advancing TB Research; February 2, 2016; CMC Vellore, India.
- Gupta A. **TB in Pregnancy**. Presented at: RePORT India TB Workshop; March 5, 2015; Mumbai, India.
- Gupta A. Panelist. **Leveraging Collective Impact to Promote India's Development: The Role of the Indian Diaspora in the Fight Against Tuberculosis**. Diaspora TB Event, Georgetown University. November 9, 2017; Washington, DC.
- Mave V. **RePORT India: Objectives and Future Directions.** Presented at: TB Vaccine 4thGlobal Forum; 2015; Shanghai, China.
- Mave V. **Therapeutic Drug Monitoring (TDM) of TB in Young Children: The Role of Hair Assays.** Presented at: IMPAACT Annual Meeting; June 2015; Washington DC, USA.

PRESENTATIONS/ABSTRACTS:

- 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.** Submitted at 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting – "Biomarkers and Beyond" February 4-6, 2019, Chennai, India
- 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. Submitted at 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting – "Biomarkers and Beyond" February 4-6, 2019, Chennai, India

- 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.
- 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.
- Gupte N, Gupte A, Sivaramakrishnan GN, Pradhan N, Shivakumar SVBY, Gupta A, Mave V, Chandrasekaran P for the CTRIUMPh 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 24-47, 2018.
- Thomas B, Kannan T, Rani V, Gupte N, Gupta A, Deluca A, Suryavanshi N, Kohli R, Chandrasekaran P for the CTRIUMPH 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.
- 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 C-TRIUMPh team. **Sub-therapeutic Rifampicin concentration among thrice weekly treated PTB patients with unfavourable treatment outcomes.** 49th Annual Union World Conference on Lung Health. The Hague, The Netherlands. October 24-27, 2018.
- 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 Lung Function Impairment in Treated Pulmonary Tuberculosis.** RePORT International Young Investigator Abstract Presentation for the RePORT International Annual Meeting, September 12-14, 2018, Suzhou, China.
- 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 CTRIUMPh Study Team. **Incidence of *Mycobacterium tuberculosis* Infection among Household Contacts of Adult Pulmonary Tuberculosis Cases in India.** RePORT International Young Investigator Abstract Presentation for the RePORT International Annual Meeting, September 12-14, 2018, Suzhou, China
- Dolla CK, Paradkar M, Gupte A, Thiruvenkadam K, Gupte N, Kukarni V, Balasubranian 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?** Accepted for poster presentation at: 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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 C-TRIUMPh Study Team. **Risk Factors Associated with Unfavorable Outcomes in a Cohort of Pulmonary TB Patients.** Presented at the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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 CTRIUMPh Study Team. **Incidence of *Mycobacterium tuberculosis* Infection among Household Contacts of Adult**

Pulmonary Tuberculosis Cases in India. Abstract Presented at the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.

- Selvaraju S, Thiruvenkadam 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, Kukarni V, Ayyanu S, Kohli R, Shivakumar SVBY, Swaminathan S, Mave V, Gupta A, Chandrasekaran[P] for the CTRIUMPh Study Team. **Incidence of Tuberculosis Disease among the Household Contacts of Adult Pulmonary TB Patients in India**—A Multicentric Cohort Study. Accepted for poster presentation at: 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- Mave V, Chandrasekaran P, Paradkar M, Gupte A, Pradhan N, Sivaramakrishnan GN, Thiruvenkadam 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**.Accepted for poster presentation at: 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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**. Accepted for oral presentation at: 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- Gupte A. **Interleukin-6, Interleukin-13 and Interferon-γ as Potential Biomarkers for Treatment Failure in Pulmonary Tuberculosis.** Abstract Presented at the RePORT India meeting, February, 2018; New Delhi, India.
- Dhamal G. **Poor Understanding of TB Infection among At-risk Tuberculin Skin-test Positive Household Contacts of Pulmonary TB Cases in Pune, India**. Abstract Presented at the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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**. Abstract Presented at the 5th Global Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- Tornheim JA, Madugundu AK, Pradhan N, Bharadwaj R, Mave V, Goloub J, Pandey A, Gupta A. **Drug Susceptibility of Rifampin-resistant Tuberculosis using Whole Genome Sequencing to Identify Genes of Interest in Pune, India**. Abstract Presented at the 5thGlobal Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- 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; October 13, 2017; Guadalajara, Mexico.
- 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, October 13, 2017; Guadalajara, Mexico.
- 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 Meeting; September 13; 2017; Rio de Janeiro, Brazil.
- 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.** Presented at: RePORT International Meeting; September 13; 2017; Rio de Janeiro, Brazil.
- Shivakumar SVBY, Chandrasekaran P, Paradkar M, Danasekaran K, Kumar AMV, Ramachandran G, Thomas B, Suryavarshini 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?** Presented at: RePORT International Meeting September 13, 2017; Rio de Janeiro, Brazil.

- Tornheim J. Paradkar M. **CTRIUMPh Pediatric Biomarker Substudy**. Session: The Future of MDR-TB Treatment in Children. Invited Presentation. 2017 IMPAACT Annual Meeting; May 30, 2017; Washington, DC, USA.

- Mathad J, Alexander M, Bhosale R, Naik S, Shivakoti R, Mave V, Suryavanshi N, Gupte N, Kulkarni V, Pradan N, Patil N, Gupta A. **Impact of Immune Changes of Pregnancy and HIV Infection on Tuberculosis.** Poster Presentation. 6th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership Meeting; February 3, 2017; Hyderabad, India.

- 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 Annual Meeting; February 3, 2017; Hyderabad, India.

- 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: 6th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership Meeting; February 3, 2017. Hyderabad, India.

- Paradkar M, Kavitha D, Shiva Kumar 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 CTRIUMPH Study Team. **Descriptive Baseline Characteristics, Treatment Outcomes and Biorepository of Pediatric TB Cases in CTRIUMPh-RePORT India Prospective Cohort**. Presented at: 6th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership Meeting; February 3, 2017. Hyderabad, India.

- John S, DeLuca A, Paradkar M, Nayagam R, Shivakumar SVBY, Gupte A, Gupte N, Thomas B, Suryavanshi N, Kolhi 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 CTRIUMPH India Cohort.** Presented at: 6th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership Meeting; February 3, 2017. Hyderabad, India.

- 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; October 27, 2016; Liverpool, UK.

- 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; October 27, 2016; Liverpool, UK.

- 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: 2016 IDSA Conference; October 27, 2016; New Orleans, LA, USA.

- Chandrasekaran P, Mave V, Tiruvengadam 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: 2016 IDSA Conference; October 27, 2016; New Orleans, LA, USA.

- 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: 2016 IDSA Conference; October 27, 2016; New Orleans, LA, USA

- Elf JL, Kinikar A, Khadse S, Mave V, Gupte N, Kulkarni V, Patekar S, Raichur P, Breysse 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; July 14, 2016; Durban, South Africa.

- 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; July 14, 2016; Durban, South Africa.

- 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.** Poster presented at: 46th World Conference on Lung Health of the International Union Against TB and Lung Disease; December 1-5, 2015; Cape Town, South Africa.
- Elf JL, Kinikar A, Khadse S, Mave V, Gupte N, Kulkarni V, Patekar S, Raichur P, Breysse 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; May 1, 2015; Denver, CO, USA.

Christian Medical College, Vellore (CMC-Vellore)/University of Cambridge-University of Washington

LECTURES

- Christopher DJ. **Is India's Endeavor to End TB by 2025 Achievable?** Presented at: 36th AP Tuberculosis & Chest Diseases Conference. 10-11 November 2018, Madanapally, Andhra Pradesh, India.
- Christopher DJ. **Addressing Diagnostic Challenges for TB Meningitis—From Clinical Staging to Pet Scanning.** Presented at: The 49th Union World Conference on Lung Health. 24-27 October 2018, The Hague, The Netherlands.
- Christopher DJ. **Is India's Endeavor to End TB by 2025 Achievable? How can RePORT Align with This?** Presented at: RePORT 4th Annual International meeting. 12-14th September 2018, Suzhou, China.
- Christopher DJ. **Determination of Efficacy of expert PCR Ultra and Transcriptional Signatures in the Diagnosis of Pleural Tuberculosis.** Presented at: RePORT 4th Annual International meeting. 12-14th September 2018, Suzhou, China.
- Christopher DJ. **Health Care Personnel TB—Fact of Life in High Burden Countries.** Presented at: RePORT 4th Annual International meeting. 12-14th September 2018, Suzhou, China.
- Christopher DJ. **Point of Care Diagnostics & Need for Triage Test in a High Prevalence Setting.** Presented at: Understanding the Resources and gaps in DIADS funded TB Research Investigators Meeting. July 2-3, 2018; NIAID Conference Center; Rockville MD, US.
- Christopher DJ. **Battling the White Plague (TB) in Our Campuses.** Presented at: The Quality Circle, Christian Medical College. 14th April 2018, Vellore, India.
- Christopher DJ. **State of TB Control in India.** Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- 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 7th Annual Joint Leadership Meeting. Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- Christopher DJ. **Targeted LTBI Testing.** Presented at: LTBI Knowledge Seminar. January 11, 2018; Hyderabad, India.
- Christopher DJ. **LTBI Screening in High TB Prevalence Setting.** Presented at: Qiagen Knowledge Seminar. November 2, 2017; Bangalore, India.
- Christopher DJ. **LTBI Screening: A Clinician's Perspective.** Presented at: CME organized by Qiagen. April 5, 2017; New Delhi, India.
- Christopher DJ. **LTBI: To Screen or Not to Screen.** Presented at The Three T's of TB Prevention: Test, Treat and Track Symposium. Asia Pacific Regional Conference; International Union against Tuberculosis. March 23, 2017; Tokyo, Japan.
- 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). December 21, 2016; Manipal, India.

- Christopher DJ. **Healthcare Worker TB: A Panel Discussion.** Presented at: TB Symposium. Convened by Krishna Medical College in collaboration with McGill University (Canada). December 21, 2016; Manipal, India.
- Christopher DJ. **Evolution of Drug Resistant TB in India.** Presented at: Annual Update in Tuberculosis. Convened by CMC Vellore. November 19, 2016; Vellore, India.
- Christopher DJ. **Screening for LTBI in Healthcare Personnel to Assess TB Risk—Lessons from India.** Presented at: 5th Meeting of Asian Experts Community. August 26-28, 2016; Taipei, Taiwan.
- Christopher DJ. **TB Risk in Health Care Workers: Myth or Reality?** Presented at: RePORT International Meeting. July 14-15, 2016; Durban, South Africa.
- 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). March 23-24, 2016; Mumbai, India.
- Christopher DJ. **Lessons from Healthcare—TB Research in India.** Presented at: CMC Winter Symposium and the 5th RePORT Leadership Group Meeting. February 12-13, 2016; Vellore, India.
- Christopher DJ. **Pleural Tuberculosis.** Presented at: Association of Physicians of India Meeting. January 29-31, 2016; Hyderabad, India.
- Christopher DJ. **TB in Healthcare Workers.** Presented at: National Update in Respiratory Medicine. Convened by PD Hinduja Hospital. November 27-29, 2015; Mumbai, India.
- Christopher DJ. **Road for TB Elimination in India.** Presented at: 4th Meeting of Asian Experts Community. August 7-9, 2015; Bali, Indonesia.
- Christopher DJ. **Newer Diagnostics in TB.** Presented at: Institute of Thoracic Medicine, MMC, CME Program for the PG Students of Southern States. September 2014; Chennai, India.
- Christopher DJ. **Relevance of TST and IGRA in Current Day Practice.** Presented at: ASHRAICON Conference 2014. July 27, 2014; Ahmedabad, India.

PRESENTATIONS/ABSTRACTS

- 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 7th Annual Joint Leadership Meeting. February 15-17, 2018; Delhi, India.
- 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 7th Annual Joint Leadership Meeting. February 15-17, 2018; Delhi, India.
- 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 7th Annual Joint Leadership Meeting. February 15-17, 2018; Delhi, India.
- 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. March 2-4, 2017; CMC, Vellore, India.
- Christopher DJ , Balamugesh T, Dhabi 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: Winter Symposium RePORT Leadership Group Meeting. February 12-14, 2016; Vellore, India.
- 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: Winter Symposium RePORT Leadership Group Meeting. February 12-14, 2016; Vellore, India.

- 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 Annual Union World Conference on Lung Health. October 28-Nov 1, 2014; Barcelona, Spain.
- 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 Annual Union World Conference on Lung Health. October 28–Nov 1, 2014; Barcelona, Spain.

Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER)/ Boston Medical Center (BMC)

LECTURES

- Hochberg, NS. **Indo-US TB Cohort: Study Design and Preliminary Results**. Presented at: TB Research Unit (TBRU) Investigators Meeting. September 2017; Boston, MA, USA.
- Hochberg, NS. **Updates in Tuberculosis: The Era of Sea Changes**. Medicine Grand Rounds. Presented at: Carney Hospital. March 2017.
- Hochberg, NS. **Indo-US TB Cohort: Study Design and Preliminary Results**. Invited speaker, JIPMER. February 8, 2017; Puducherry, India.
- Hochberg, NS. **Malnutrition and TB in India: Intersection and Implications.** Presented at: Northeastern World TB Day Symposium.
- 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.

PRESENTATIONS/ABSTRACTS

- 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. May 18-23, 2018; San Diego, CA, USA.
- 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 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination; February 15, 2018; Delhi, India.
- 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 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- Reddy D. **Wood Fuel Usage Is Associated with a Higher Leukocyte Count in Pulmonary Tuberculosis Patients.** Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- Forsyth M. **Alcohol Use and Clinical Presentation of Tuberculosis at Time of Diagnosis in Puducherry and Tamil Nadu, India**. Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- 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: American Society of Tropical Medicine & Hygiene Meeting. November 2016; Atlanta, GA, USA.
- **Stigma as a Barrier to Tuberculosis Care: A Literature Review.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. October 2016; Boston, MA, USA.

- 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.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. October 2016; Boston, MA, USA.
- 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. October 2016; Boston, MA, USA.
- **Conversion among Pulmonary Tuberculosis Cases in India.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. October 2016; Boston, MA, USA.
- **Predictors of 2 Month Sputum Conversion among Tuberculosis Patients in India.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. October 2016; Boston, MA, USA.
- **Prolonged Cough among Tuberculosis Patients In Tamil Nadu and Pondicherry, India.** Poster presented at: Evans Department of Medicine Research Days, Boston University School of Medicine. October 2016; Boston, MA, USA.
- 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.** Poster presented at: American Thoracic Society Conference. May 2016; San Francisco, CA, USA.
- 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.** Poster presented at: 46th Union World Conference on Lung Health of the International Union Against TB and Lung Disease. December 1-5, 2015; Cape Town, South Africa.
- 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.** Poster presented at: 46th Union World Conference on Lung Health of the International Union Against TB and Lung Disease. December 1-5, 2015; Cape Town, South Africa.
- 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. December 1-5, 2015; Cape Town, South Africa.

MV Diabetes Research Centre (MVDRC)/University of Massachusetts

LECTURES

- Kornfeld H. **Sugar, Fat and Consumption**. Invited seminar: Boston University School of Medicine. January 16, 2016; Boston, MA, USA.
- Kornfeld H. **Tuberculosis: The Rise of Comorbidities**. Medical Grand Rounds, University of Massachusetts Medical School. June 4, 2015; Worcester, MA, USA.
- Kornfeld H. **TB and Diabetes**. Invited seminar: Singapore Immunology Network. February 27, 2015; Singapore.
- Kornfeld H. **TB and Diabetes**. Keystone Symposium on Granulomas in Infectious and Non-Infectious Disease. January 22-27, 2015; Santa Fe, NM, USA.
- Kornfeld H. **The Effects of Diabetes on TB Susceptibility**. Invited seminar: No.4 People's Hospital of Nanning. January 12, 2015; Nanning, China.
- Kornfeld H. **Sugar, Fat, and Consumption**. Invited seminar: University of Texas, Health Science Center at Tyler. August 22, 2014; Tyler, TX, USA.
- Kornfeld H. **Determinants of TB Severity**. Invited seminar: Shenzhen-Hong Kong Institute of Infectious Diseases. Shenzhen, China.

PRESENTATIONS/ABSTRACTS

- 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 Co-morbidity**. Accepted for poster presentation at: Keystone Symposia -Tuberculosis: Translating Scientific Findings for Clinical and Public Health Impact. April 15-19, 2018; Whistler, BC, Canada.
- 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 Co-morbidity.** Accepted for poster presentation at: 5th Global Forum on TB Vaccines. February 20-23, 2018; New Delhi, India.
- 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 Co-morbidity and Changes Following Treatment. Accepted for poster presentation at: 5th Global Forum on TB Vaccines; February 20-23, 2018; New Delhi, India.
- Moideen K. **Effect of Anti-tuberculosis Treatment on the Systemic Levels of Tissue Inhibitors of Metalloproteinases in Tuberculosis–Diabetes Co-morbidity**. Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination; February 15, 2018; Delhi, India.
- Kumar P. **Effect of Standard Tuberculosis Treatment on Circulating Levels of Monocyte Activation Markers and RAGE Ligands in Tuberculosis–Diabetes Co-morbidity**. Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- Shruthi BS. **Impact of Metformin Use on TB Severity in Diabetes.** Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.

PD Hinduja Hospital/Johns Hopkins University (JHU)

PRESENTATIONS/ABSTRACTS

- Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwadia ZF, Mahashur AA, Pinto L, Soman R, Rodrigues C, Gupta A, Tornheim JA, Martinson N, Variava E, Weisner L, Joubert A, Ashavaid TF. **Determination of Plasma Clofazimine Levels by Liquid Chromatography-Mass Spectrometry.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwadia ZF, Mahashur AA, Pinto L, Soman R, Rodrigues C, Gupta A, Tornheim JA, Ashavaid TF. **Determination of Serum Linezolid levels by HPLC.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- Tornheim JA, Udwadia 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.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- Gajjar IN, Tornheim JA, Udwadia 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.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- Shivakumar SVBY, Tornheim JA, Gajjar I, Porwal S, Kishore G, Karane M, Chawla P, Rodrigues C, Ashavaid T, Gupta A, Udwadia ZF. **Mental Health and TB: High prevalence of depression among drug-resistant TB patients not associated with cycloserine.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- 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. 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.

- 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.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- 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.** 8th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership meeting—Biomarkers and Beyond. February 4-6, 2019, Chennai, India.
- Tornheim J, Ganatra S, Deluca A, Banka R, Rodrigues C, Gupta A, Udwadia Z. **Linezolid Experience among MDRTB Patients in Mumbai.** Presented at: RePORT India 7th Annual Joint Leadership Meeting: Catalyzing Discoveries toward TB Elimination. February 15, 2018; Delhi, India.
- Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwadia ZF, Mahashur AA, Soman R, Patel J, Ashavaid TF. **Therapeutic Drug Monitoring of Rifampicin & Isoniazid and Implications of Acetylator Genotype on Plasma Levels.** Presented at: 15thInternational Congress on Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT). September 27, 2017; Kyoto, Japan.
- Tornheim J, DeLuca A, Ganatra S, Radhika B, Gupta A, Udwadia 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. May 21, 2017; Washington, DC, USA.
- Tornheim JA, Ganatra S, DeLuca A, Banka R, Gupta A, Udwadia 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: 6th Annual Regional Prospective Observational Research for Tuberculosis (RePORT) India Joint Leadership Meeting. February 3, 2017. Hyderabad, India.
- Udwadia 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: 2016 IDSA Conference. October 27, 2016; New Orleans, LA, USA.
- Chawla PK, Lokhande RV, Naik PR, Dherai AJ, Udwadia ZF, Rodrigues CR, Mahashur AA, Soman R, Patel J, Ashavaid TF. **Implication of Acetylator Genotype of Plasma Rifampcin and Isoniazid.** Oral Presentation at: 31st Annual Research Day meeting. March 3, 2018. (Awarded 1st Prize for Best Laboratory paper)
- Chawla PK, Lokhande RV, Naik PR, Singh S, Dherai AJ, Udwadia ZF, Pinto L, Soman R, Rodrigues C, Patel J, Ashavaid TF. **Implications of Acetylator Genotype on Plasma Rifampicin and Isoniazid Levels in TB Patients.** Poster presentation at 45th National Conference of Association of Clinical Biochemists of India (ACBICON 2018). 25-27th October 2018; Goa, India.

Grants & Substudies

RePORT India

8TH ANNUAL JOINT LEADERSHIP MEETING

BIOMARKERS & BEYOND

CHENNAI | 4–6 FEB 2019

This page is intentionally blank

RePORT INTERNATIONAL SUPPLEMENTAL FUNDED PROJECTS | AWARDED							
	Title	**Partners & IRB Status**	**CRDF #**	**Start Date**	**Investigators**	**Progress/ Challenges**	**CRDF Updates (Feb 2018)**
1.	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	24 patients enrolled (15 HIV only and 9 HIV-TB) and ongoing at BJMC	BJMC award active October 10. Fiocruz pending IRB approval.
2.	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	MSTDI Transcriptomics – Sample testing at Medgenome complete and results are being analysed. MSTDI – Metabalomics: Sample shipment to UCD is on hold awaiting DBT approval for BJMC & sample shipment for NIRT is in progress.	PO's in place with both Medgenome and UC Davis vendors. BJGMC agreement signed. Fully executed agreement to be sent back week of 2/5/18. Pending review and signature by NIRT, and MVDRC to be sent back to CRDF.
3.	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	Two batches of Sample shipment from BJMC to US complete. 3rd Shipment from NIRT is in process. Data generation in process.	Emory Active July 17, Jipmer active Aug 17th: Collecting receipts, reimbursement upon submission

RePORT INTERNATIONAL SUPPLEMENTAL FUNDED PROJECTS | AWARDED							
	Title	**Partners & IRB Status**	**CRDF #**	**Start Date**	**Investigators**	**Progress/ Challenges**	**CRDF Updates (Feb 2018)**
4.	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	WGS for 79 pairs of MTB isolates complete at Medgenome. Data review, variables finalization and data analysis yet to begin.	JHU active August 17, NIRT active August 24, BJMC active October 17: Collecting receipts, reimbursement upon submission
5.	Host RNA expression for diagnosis and monitoring of pediatric TB in Africa and India	NIRT, BJMC, JHU, Univ. Cape Town, Imperial college, London	DAA3-18-64080-1	2018	Kinikar A, Paradkar M, Hissar S, Workman L	Award Active. IRB approved & DBT NOC awaiting at BJMC, IRB submission in progress at NIRT. MTA & CRF finalization ongoing.	-
6.	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	5 patients enrolled at NIRT and on enrolment pause.	BJGMC Active October 17, JIPMER active September 17, NIRT, BMC Active Jan. 11, 2018.
7.	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	CMC agreement signed and active-09/24/17 Received IRB clearance from IIT Delhi .CMC building up database of images(Cases and Controls) and Software under Development	Agreement active September 24: collecting receipts, reimbursement in process

RePORT INTERNATIONAL SUPPLEMENTAL FUNDED PROJECTS | AWARDED							
	Title	**Partners & IRB Status**	**CRDF #**	**Start Date**	**Investigators**	**Progress/ Challenges**	**CRDF Updates (Feb 2018)**
8.	Extracranial Involvement as Detected by Positron Emission Tomography Scan in Patients with Tubercular Meningitis	Approved: CMC	23721	2016	**Thangakunam B,** Christopher DJ	Patient recruitment initiated (24 recruited).	Award Active September 25: Collecting receipts, reimbursement upon submission
9.	Inflammatory Biomarkers as a Triage Test for Screening Symptomatic TB	Approved: JIPMER Rutgers BMC	23732	2016	**Ellner J,** Salgame P, Sarkar S, Pleskunas J	Award is active, approvals received, project initiated	BMC Active August 24, JIPMER Active October 23: Collecting receipts, reimbursement upon submission
10.	Characterization of Monocyte Responses in Pulmonary TB Patients with or without Type 2 Diabetes	Approved: NIRT-NIH – ICER MVDRC	23722	2016	**Kumar P**	Award is active. All the ordered reagents for the study have been received. Currently cell culture and flow cytometry experiments ongoing.	Award Active June 17: PO's signed by vendors, submission of invoices will be paid 50% up front, and 50% upon delivery of supplies/reagents.
11.	Effect of Malnutrition on Latent TB	Approved: JIPMER Rutgers BMC	23719	2016	**Hochberg NS,** Negi VS, Mahalakshmy T, Johnson WE, Salgame P, Pleskunas J	Approved; awaiting funding to arrive at MedGenome so that samples can be processed/analyzed.	Award Active August 21st: Collecting Receipts, reimbursement upon submission.
12.	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	Final documents awaiting final approvals at JIPMER; submit translations to BMC, then ready	Award Pending: amendment being translated at JIPMER. No new updates, as of last EC call.

RePORT INTERNATIONAL SUPPLEMENTAL FUNDED PROJECTS | AWARDED							
	Title	Partners & IRB Status	CRDF #	Start Date	Investigators	Progress/ Challenges	CRDF Updates (Feb 2018)
13.	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, Vankayalapati K	Award is active. Study initiated since October 2017.	Award Active June 17: reallocation of funds, signed new agreement. DNA isomation being done.
14.	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	Award active. 328 Health care workers enrolled. Tubersol successfully received from Sanofi. Coding and blindiing reagents is in process.	Collection Receipts, reimbursement upon submission.

GRANTS & SUBSTUDIES | AWARDED					
	Title	Partners	Grant Source	Start Date/ Duration	Investigators
1.	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	**Tornheim JA, Paradkar M,** Dutta N, Bader J, Kulkarni V, Balasubramanian U, Bharadwaj R, Raja R, Sreenivasmurthy S, Karakousis P, Mave V, Pandey A, Gupta A
2.	The Role of Innate Immunity in the Acquisition of Sterile Protection Against TB Infection	U Colorado, JHU, BJMC	NIH R21	2017	**Weinberg A,** Segano Z, Mave V, Gupte N, Paradkar M, Suryavanshi N, Kulkarni V, Balasubramanian U, Bharadwaj R, Gupta A

GRANTS & SUBSTUDIES | AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
3.	Association of Lipid Mediators of Inflammation with TB Treatment Outcomes	JHU, NIRT, BJGMC	CTRIUMPH and Gilead Foundation	2017	**Shivakoti R, Chandrasekaran P,** Mave V, Kulkarni V, Gupte A, Gupte N, Shivakumar SVBY, Nimkar S, Dalli J, Natarajan, S, Karunaianantham R, Gupta A
4.	Measuring TB Drugs in Hair as a Tool to Monitor Adherence, Exposure and Response	BJGMC NIRT JHU	NIH/NIAID: R21	2016-2018	**Mave V**, Dooley K, Ramachandran G, Gupta A, Bacchetti, Sushant M, Gupte N, Gandhi M
5.	Impact of Immune Changes of HIV and Stages of Pregnancy on TB	BJGMC NIRT JHU	NIH/NICHD: R01	2015-2019	**Gupta A**, **Mathad J**, Bhosale R, Alexander M, Mave V, Gupte N, Padhan N, Kulkarni V, Hannah LE, Babu S
6.	Residual Respiratory Impairment Following Pulmonary Tuberculosis: The Lung Health Sub-Study	BJGMC NIRT JHU	UJALA/ Gilead Foundation/ RePORT India	2015-2017	**Gupte A,** Gupta A, Meshram S, Kadam D, Mandar, Gupte N, Chandrasekaran P, Salvi S, Golub J, Selvaraju S
7.	Targeting Mycobacterium Tuberculosis Persisters By Enhancing Stringent Response-Specific Cellular Immunity	JHU, BJMC	NIH R21	2015	**Karakousis P**, Gupta A, Mave V, Kulkarni V, Dutta N
8.	Understanding of Tuberculosis Infection and Preventive Therapy Among Skin-Test Positive Household Contacts of Tuberculosis Cases	BJGMC NIRT JHU	NIH CFAR and D43	2015	**Deluca A**, Suryavanshi N, Mave V, Kadam D,Chandrasekaran P, Shivakumar SVBY, Pardeshi G, Thomas B, Kolhi R, Gupta A
9.	Validating a Th17 Switch as a Novel Correlate of Protective Immunity to TB	NIRT, BJMC, IISc, Bangalore, JHU	DBT/ IISc	2018	**Vyakarnam A**, Chandrasekaran P, Gupta A, Mave V
10.	Immune Responses and Effect of Disulfiram on MTB Infected PBMCs as a Potential Host Directed Therapy	NIRT, BJMC, THSTI, JHU	THSTI	2018	**Singh R**, Singhal A, Gupta A, Hannah LE, Chandrasekaran P

GRANTS & SUBSTUDIES | AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
11.	Characterization of Genomics and Metabolomics among Individuals (TB-GWAS)	Emory JHU BJGMC NIRT PHRU McGill	NIH R01	2018	**Gandhi N,** Shah S, Brust J, Gupta A, Mave V, Bharadwaj R, Chandrasekaran P, Hanna LE, Martinson N, Sun Y, Gwinn M, Schurr E, Jones D
12.	IFN-γ Independent Inhibition of MTB Growth in Human Macrophages	BMMRC UT	NIH/NIAID: R01AI123310-01A1	2017	**Vankayalapati K**, Valluri V and others
13.	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	**Vankayalapati K,** Valluri V, and others
14.	D4GDI-mediated Immune Responses in LTBI+HIV+ Individuals	BMMRC UT	NIH: R21AI120257-01 Indo-US Vaccine Program, RePORT India	2015-2017	**Vankayalapati K,** Valluri V and others
15.	T-regs Mediated Immune Responses in LTBI+HIV+ Individuals	BMMRC UT	UT	2015	**Vankayalapati K,** Valluri V and others
16.	Validation Study of TruNAT-MTB-Rif in EPTB	CMC/NIRT/Hinduja/ AIIMS	ICMR	2017	**Christopher DJ**, Singh M, Gomathi, Rodrigues C, Singh U
17.	Validation Study of TruNAT-MTB-Rif in Pediatric TB	CMC/NIRT/Hinduja/ AIIMS	ICMR	2017	**Christopher DJ,** Singh M, Gomathi, Rodrigues C, Singh U
18.	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	**Christopher DJ**, Chatterjee S, Balamugesh T

GRANTS & SUBSTUDIES | AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
19.	Role of Iron Deficiency in Resistance of Women of Child-Bearing Age to Tuberculosis	JIPMER BMC	NIH	2016-2017	**Ellner J,** Salgame P, Sarkar S, Pleskunas J, Amsaveni, Hochberg NS
20.	Impact of Pregnancy on Tuberculosis	JIPMER BMC	NIH/NIAID R01	2015-2018	**Ellner J,** Sarkar S, Hochberg N, Horsburgh CR, Salgame P, Savic R, Dartois V, Joseph NM, Jacob SE, Jayalakshmy R, Plakkal N, Ramachandran G, Sasirekha R, White LF
21.	Tuberculosis: Learning the Impact of Nutrition (TB LION)	JIPMER BMC Rutgers Tufts NIRT	Warren Alpert Foundation	2018-2023	**Hochberg NS,Parija S, Chandrasekaran P,** Ellner JJ, Johnson WE, Wanke C, Sarkar S, Negi VS, Joseph N, Rajkumari N, Mahalakshmy T, Reddy D, Saravanan N, Harisankar, Tripathy S
22.	Impact of Personal Exposure to Black Carbon on Pulmonary Tuberculosis Severity	JIPMER BMC	Potts Memorial Foundation	2014-2018	**Hochberg NS,** Reddy D, Sahu S, Sarkar S
23.	Compare Drug Levels in Newly Diagnosed or Relapsed PTB/ EPTB Following Daily ATT vs DOTS Regimen	CMC	Internal fluid research grant	2015	**Christopher DJ**, Balamugesh T
24.	Yield of TB using GeneXpert (Xpert MTB-Rif) by Induced Sputum Compared to Standard Sputum Samples	CMC	Internal fluid research grant	2014	**Christopher DJ,**Balamugesh T
25.	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	**RePORT India PIs**

GRANTS & SUBSTUDIES | AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
26.	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	**Ashavaid TF**, Variava E, Rodrigues C, Udwadia ZF, Gupta A, Martinson N
27.	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	**Horsburgh R**, **Sterling TR,**Pelloquin C, Alland D, Ciegelski P, Collins J, Chandrasekharan P, Ellner J, Gupta A, Mave V, Rolla V, Kritski A, Sarkar S
28.	MDR-TB Free: Monitoring Adverse Effects, Utilizing Resources Optimally, Knowing Resistance Patterns, and Treatment Strategy (MDR TB – MUKT)	Hinduja JHU	Hinduja	2017	**Udwadia ZF**, Rodrigues C, Ashavaid TF, Tornheim JA, Gupta A
29.	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	**Tornheim JA,** Rodrigues C, Udwadia ZF, Ashavaid TF, Gupta A

GRANTS & SUBSTUDIES | NOT AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
1.	RePORT India TB Transmission Training Program (RITP)	RePORT India Consortium	NIH Fogarty D43	2017	Gupta A, Christopher DJ, Bollinger R, Deluca A, Golub J

GRANTS & SUBSTUDIES | NOT AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
2.	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, Walzl G, Hamilton C, Duffy D, Gillette M
3.	Research and Interventions for HIV, Alcohol, Tobacco and Tuberculosis in India and South Africa (The HATT Consortium)	BJGMC NIRT JHU	NIH/NIAAA: R01	2017	Gupta A, Chander G, Heidi H, Thomas B, Kadam D, Suryavanshi N, Chandrasekaran P, Mave V, Gupte N
4.	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
5.	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
6.	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
7.	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
8.	Impact of Malnutrition on Latent Tuberculosis Infection	JIPMER BMC Rutgers OHSU Tufts	NIH/R01	2016	Hochberg NS, Salgame P, Wanke C, Johnson WE, Ellner JJ, Parija S, Negi VS, Joseph NM, Rajkumari N, Mahalakshmy T, White LF, Lewinsohn D

GRANTS & SUBSTUDIES | NOT AWARDED					
	Title	**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
9.	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
10.	Determining Barriers to TB Care	JIPMER BMC	BU SPH Pilot	2016	Fernandes P, Sabin L, Sarkar S, Pleskunas J, Amsaveni, Hochberg NS
11.	Novel Serum Based Biomarkers for Diagnosis of TB and Treatment Monitoring in HIV-infected and Uninfected Children	BJGMC NIRT DTTC, Capetown 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, Thiruvenkadam K
12.	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
13.	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
14.	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
15.	Memory-like NK Cells and Household Contacts of TB Patients	BMMRC UT	NIH: 1R21AI112717 7-01		Vankayalapati K, Valluri V and others
16.	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

GRANTS & SUBSTUDIES | NOT AWARDED					
Title		**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
17.	Radiological Treatment Response in Pulmonary Tuberculosis	CMC	RePORT India Supplemental Funding	2016	Balamugesh T, Christopher DJ

GRANTS & SUBSTUDIES | PENDING					
Title		**Partners**	**Grant Source**	**Start Date/ Duration**	**Investigators**
1.	Effect of Helminths on Tuberculosis Severity	JIPMER BMC Rutgers NIRT NIH	NIH R21	2018	**Hochberg NS,** Salgame P, Babu S, Ellner JJ, Johnson WE, Joseph NM, Mahalakshmy T, Nutman T, Rajkumari N, Parija S
2.	Innate Immune Responses in Household Contacts	BMMRC/LEPRA BJMC NIRT JHU UT	NIH/NIAID : R01	2017	**Vankayalapati K**, Valluri V, Gupta A, Mave V, Kadam D, Bharadwaj R,Hanna LE,Shivakumar SVBY, Prudhula, Chandrasekaran P, Gupte N
3.	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 JIPMER NIRT PHRU UWITS	Indo-South Africa	2016	**Valluri VL**, Martinson N, Christopher DJ, Variava E, Sarkar S, Priyadarsini P, Bhavna G, Ziyaad W, Melissa C, Prudhula DK, Sanjeev NV