INDIAN COUNCIL OF MEDICAL RESEARCH

NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS

ANNUAL REPORT

2025-2026

WHO Collaborating Centre for Tuberculosis Research & Training

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PREFACE

It gives me great pleasure to present the Annual Report 2025–2026 of the ICMR–National Institute for Research in Tuberculosis (ICMR–NIRT), one of the premier tuberculosis research institutions in the country and a WHO Collaborating Centre for Tuberculosis Research and Training.

I would like to place on record my sincere gratitude for the wholehearted support and guidance extended by Dr. Rajiv Bahl, Secretary, Department of Health Research and Director General, ICMR; Dr. Sanghamitra Pati, Additional Director General, ICMR; and Dr. Nivedita Gupta, Head, Communicable Diseases Division, ICMR, along with her team. I also gratefully acknowledge the support of the Central TB Division, Ministry of Health and Family Welfare, Government of India. I am equally thankful to all the members of the Scientific Advisory Committee, Institutional Ethics Committee, and Community Advisory Board for their valuable guidance.

I would also like thank the Principal Secretary to Govt. (Dept. of Health & Family Welfare), Government of Tamil Nadu; the Mission Director, National Health Mission (NHM), Government of Tamil Nadu; the State TB Officer; all District TB Officers; the Deans of partner medical colleges across Tamil Nadu; and the health officials of the Greater Chennai Corporation. Their continued encouragement, guidance, and wholehearted support have been instrumental in advancing the Institute's research and programmatic contributions.

Tuberculosis continues to remain a major public health challenge in India and globally. At ICMR–NIRT, we remain steadfast in our commitment to generating high-quality evidence to inform policy, strengthen programme implementation, and accelerate progress towards TB elimination. Over the past year, the Institute has further expanded its research portfolio across the continuum of TB care—from basic science and diagnostics to clinical trials, implementation research, and health systems strengthening.

This report highlights several important advancements. During 2025-2026, 68 projects were being implemented, 24 projects have been completed, 124 scientific articles have been published in peer reviewed scientific journals. We are also tracking the impact of our past research studies on policy and practice. Our work in molecular diagnostics, including the development and evaluation of rapid assays and next-generation sequencing approaches, is contributing to faster and more accurate detection of TB and drug resistance. Studies on host-directed therapies, pharmacodynamics, and non-replicating persisters are providing deeper insights into treatment response and relapse. At the same time, multicentric clinical trials and operational research studies are generating critical evidence to improve patient outcomes and inform national guidelines.

The Institute continues to actively advance TB research through strategic collaborations with national and international partners. Our sustained focus on

innovations—including the development of indigenously produced point-of-care diagnostics, shorter and safer anti-TB regimens, TB prevention through vaccines and other emerging modalities, and integrated approaches addressing TB and its co-morbidities—along with efforts to demonstrate scalable implementation models for the rapid reduction of TB incidence and mortality, reflects our commitment to remaining at the forefront of scientific and programmatic advancements.

None of these achievements would have been possible without the dedication and hard work of our scientists, administrative, financial, and technical staff, collaborators, and partners.

As we move forward, the challenge before us is clear—India's goal of TB elimination demands not only scientific excellence, but also speed, scale, and seamless translation of evidence into action. We must continue to innovate, rigorously evaluate, and rapidly deploy solutions that reach the last mile. ICMR–NIRT will remain committed to leading this effort—bridging science, policy, and implementation—to ensure that our research translates into measurable impact for individuals, communities, and the nation.

- Dr. Srinath Satyanarayana MD, PhD
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ABBREVIATIONS

2-DG	2-Deoxy-D-glucose
3HP	3-month weekly regimen of Isoniazid and Rifapentine
6MWT	Six-Minute Walk Test
AAS	Atomic Absorption Spectrometry
AB PM-JAY	Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana
ACF	Active Case Finding
ADRs	Adverse Drug Reactions
AI	Artificial Intelligence
AIIMS	All India Institute of Medical Sciences
Alf	Acute Liver Failure
ANKRD22	Ankyrin Repeat Domain 22
ART	Antiretroviral Therapy
ASHA	Accredited Social Health Activist
ASP	Anti-Sense Protein
ATT	Anti-Tuberculosis Treatment
AUC	Area Under Curve
BACTEC	Bacterial Culture Detection System
BCG	Bacillus Calmette-Guérin
BCoV	Bovine Coronavirus
BDI/TDI	Baseline/Transition Dyspnea Index (BDI/TDI)
BDQ	Bedaquiline
BSL3	Biosafety Level 3
bNAb	Broadly Neutralizing Antibody
bTB	Bovine Tuberculosis
CAD	Computer Aided Detection
CARPD17	Caspase Recruitment Domain Family Member 17
Cas	CRISPR-associated protein (e.g., Cas13)
CBNAAT	Cartridge-Based Nucleic Acid Amplification Test
CBR	Central Biorepository
ccfDNA	Circulating Cell-Free DNA
CD	Cluster of Differentiation
CD4	Cluster of Differentiation 4 (T-helper cell marker)
CD8	Cluster of Differentiation 8 (Cytotoxic T-cell marker)
C-DAC	Centre for Development of Advanced Computing
cDNA	Complementary Deoxyribo Nucleic Acid
ccfDNA	Circulating Cell Free DNA
CFP-10	Culture Filtrate Protein-10
CFU	Colony Forming Unit
CI	Confidence Interval
CHSI	Costing of Health Services in India
CKD	Chronic Kidney Disease
CLIA	Chemiluminescence Immunoassay
CM/AS	Common Mycobacteria / Additional Species
CMC	Christian Medical College
COPD	Chronic Obstructive Pulmonary Disease

COPD-C	COPD due to Smoking
COVID-19	Coronavirus Disease 2019
CP	Continuation Phase
CRF	Case Report Form
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRP	C-Reactive Protein
CTD	Central Tuberculosis Division
CXR	Chest X-ray
Cy-TB	Cytokine release TB test
DBS	Dried Blood Spots
DBT	Department of Biotechnology
ddPCR	digital droplet PCR
DHR	Department of Health Research
DNA	Deoxyribonucleic Acid
DOTS	Directly Observed Treatment, Short-course
DPH	Directorate of Public health
DRP-118, DRP-148, DRP-155, and DRP-263	Mutations in HIV Drug Resistance Associated Proteins
DR-TB	Drug-Resistant Tuberculosis
DST	Drug Sensitivity Testing
DS-TB	Drug-Sensitive Tuberculosis
DTA	Diagnostic Test Accuracy
DTG	Dolutegravir
DTO	District Tuberculosis Officer
E	Ethambutol
EHI	Early HIV Infected Individuals
EID	Early Infant Diagnosis
ELISA	Enzyme-Linked Immunosorbent Assay
EMB	Ethambutol
EPTB	Extra Pulmonary Tuberculosis
ESAT-6	6 kDa Early Secretory Antigenic Target
EQA	External Quality Assurance
EQAPOL QC	External Quality Assurance Program Oversight Laboratory - Quality Control
FDC	Fixed Dose Combination
FGD	Focus Group Discussion
FCGR1B	Fc Fragment of IgG Receptor Ib
FCGBP	IgG Fc-binding protein
FOT	Forced Oscillation Technique
FLQ	Fluroquinolone
GCC	Greater Chennai Corporation
GCLP	Good Clinical Laboratory Practice
GDP	Gross Domestic Product
GDM	Gestational Diabetes Mellitus
gDST	Genotypic Drug Susceptibility Testing
GFP	Green Fluorescent Protein
GH	Government Hospital

GHTM	Government Hospital of Thoracic Medicine
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
GTHTM	Government Thiruvatteeswarar Hospital of Thoracic Medicine
GWAS	Genome Wide Association Study
H	Isoniazid
HbA1c	Glycated Hemoglobin
HBP	Health Benefit Package
HC	Healthy Control
HDAC	Histone Deacetylase
HDT	Host-Directed Therapy
HHC	Household Contact
HI	Health Inspector
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HLA	Human Leukocyte Antigen
HPLC	High-Performance Liquid Chromatography
HPLC-UV	High-Performance Liquid Chromatography with Ultraviolet detection
HRCT	High-Resolution Computed Tomography
HTA	Health Technology Assessment
HTAIn	Health Technology Assessment in India
IAVI	International AIDS Vaccine Initiative
IAVI IIR Call	International AIDS Vaccine Initiative - Investigator-Initiated Research Call
ICAM-1	Intercellular Adhesion Molecule-1
ICER	Incremental Cost-Effectiveness Ratio
ICH	Institute of Child Health
ICMR	Indian Council of Medical Research
ICP-MS	Inductively *coupled plasma mass spectrometry*
ICT	Immunochromatography
IEC	Information, Education, and Communication
IEDB	Immune Epitope Database
i-FABP	Intestinal Fatty Acid-Binding Protein
IFN	Interferon
IFNITM3	Interferon-induced transmembrane protein 3
Ig	Immunoglobulin
IGRA	Interferon Gamma Release Assay
IIT	Indian institute of Technology
IL	Interleukin
INH	Isoniazid
INMB	Incremental Net Monetary Benefit
iNOS	Inducible Nitric Oxide Synthase
INSHORT	Intensified Short Course Regimen for TB Meningitis Trial
INSTI	Integrase Strand Transfer Inhibitor
IP	Intensive Phase
IPT	Isoniazid Preventive Therapy
IQR	Inter Quartile Range

IRL	Intermediate Reference Laboratory
IS6110 and IS1081	Insertion Sequences
ISG	Interferon-Stimulated Genes
IT	Information technology
ITM	Institute of Thoracic Medicine
JE	Japanese Encephalitis
JIPMER	Jawaharlal Institute of Postgraduate Medical Education and Research
KGMU	King George's Medical University
KLF12	Krüppel-like factor 12
LAM	Lipoarabinomannan
LBP	LPS-Binding Protein
LC-MS	Liquid chromatography–mass spectrometry
LJ	Lowenstein-Jensen (medium)
LIMS	Laboratory Information Management System
LPA	Line Probe Assay
LPC	lysophosphatidylcholine
LPE	lysophosphatidylethanolamine
LPS	Lipopolysaccharide
LRAC	Local Research Advisory Committee
LTBI	Latent Tuberculosis Infection
LZD	Linezolid
M	Moxifloxacin
MCP-1	Monocyte Chemoattractant Protein-1
META	Methods and Evidence in Test Accuracy
MBL	Mannose Binding Lectin
MDR	Multi Drug Resistance
MDR/RR	Multidrug-Resistant And Rifampicin-Resistant
MDR-TB	Multidrug-Resistant Tuberculosis
MDSC	Myeloid-derived suppressor cells
MGIA	Mycobacterial Growth Inhibition Assay
MGIT	Mycobacteria Growth Indicator Tube
MIC	Minimum Inhibitory Concentration
MIP-1α	Macrophage Inflammatory Protein-1 alpha
miRNA	Micro RNA
MLHP	Multi-Purpose Health care Provider
MMC	Madras Medical College
MPT64	24 kDa protein antigen secreted by the Mycobacterium tuberculosis (MTB) complex
MRHRU	Model Rural Health Research unit
mRNA	Messenger Ribo Nucleic Acid
M.tb	*Mycobacterium tuberculosis*
MTB	*Mycobacterium tuberculosis*
MTBC	Mycobacterium tuberculosis Complex
mTOR	Mechanistic Target of Rapamycin
NAAT	Nucleic Acid Amplification Test
NACO	National AIDS Control Organization
NEIGRIHMS	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences

NETs	Neutrophil Extracellular Traps
NGS	Next Generation Sequencing
NIAID	National Institute of Allergy and Infectious Diseases (NIAID)
NICPR	National Institute of Cancer Prevention and Research
NIE	National Institute of Epidemiology
NIH	National Institutes of Health
NIIRNCD	National Institute for Implementation Research on Non-Communicable Diseases
NIN	National Institute of Nutrition
NIOH	National Institute of Occupational Health
NIRBI	ICMR-National Institute of Cholera and Enteric Diseases
NIRT	National Institute for Research in Tuberculosis
NIRTH	National Institute for Research in Tribal Health
NITRD	National Institute of Tuberculosis and Respiratory Diseases
NITVAR	National Institute for Translational Virology and Antiviral Research
NIV	National Institute of Virology
NJILOMD	National JALMA Institute for Leprosy and Other Mycobacterial Diseases
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRP	Non-Replicating Persisters
NRL	National Reference Laboratory
NRT	Nicotine replacement therapy
NS1	Non-Structural Protein 1
NTEP	National Tuberculosis Elimination Programme
NTM	Nontuberculous Mycobacteria
NTM-DR	Nontuberculous Mycobacteria – Drug Resistant
ONT	Oxford Nanopore Technology
OOP	Out-of-Pocket
OP	Outpatient
OR	Odds Ratio
PANTA	Polymyxin B, Amphotericin B, Nalidixic Acid, Trimethoprim, and Azlocillin
PBMC	Peripheral Blood Mononuclear Cell
PCOS	Polycystic ovary syndrome
PCR	Polymerase Chain Reaction
PD	Pharmacodynamics
pDST	Phenotypic Drug Susceptibility Testing
P-FAB	Plasmonic Fiber Optic Absorbance Biosensor
PFT	Pulmonary Function Test
PGIMER	Postgraduate Institute of Medical Education and Research
PI	Principal Investigator
PI	Protease Inhibitor
PK	Pharmacokinetics
PM-ABHIM	Pradhan Mantri – Ayushman Bharat Health Infrastructure Mission
PMN	Poly Morpho Nuclear Cells

POC	Point-of-Care
POCOS	Prevalence of cardiopulmonary perfusion defects and vascular damage among Post COVID-19 patients using Q-SPECT/CT hybrid imaging and correlation with biomarkers for prognostication – a longitudinal study
PP	Per Protocol
PPD	Purified Protein Derivative
PR	Protease
PR	Pulmonary Rehabilitation
Pre-XDR	Pre-Extensively Drug-Resistant
PRNT	Plaque Reduction Neutralization Test
PT program	Proficiency Testing
PTB	Pulmonary Tuberculosis
PTLD	Post-Tuberculosis Lung Disease
PTLFU	Pre-treatment loss to follow-up
PZA	Pyrazinamide
QALY	Quality Adjusted Life Years
QMS	Quality Management System
Q-SPECT/CT	Quantitative Single-Photon Emission Computed Tomography/Computed Tomography
R	Rifampicin
RANTES	Regulated upon Activation, Normal T-cell Expressed and Secreted
RePORT	Regional Prospective Observational Research for Tuberculosis
RFLP	Restriction Fragment Length Polymorphism
RGGGH	Rajiv Gandhi Government General Hospital
RIF	Rifampicin
RMP	Rifampicin
RMRC	Regional Medical Research Centre
RMRIMS	Rajendra Memorial Research Institute of Medical Sciences
RNA	Ribonucleic Acid
RNA-Seq	RNA sequencing
ROC curve	Receiver Operating Characteristic curve
RPF	Resuscitation Promoting Factor
RSV	Respiratory Syncytial Virus
RT-LAMP	Reverse Transcription Loop-mediated Isothermal Amplification
RT-PCR	Real Time- Polymerase Chain Reaction
RT-qPCR	Real Time- Quantitative Polymerase Chain Reaction
SAM	Severe Acute Malnutrition
SARANSH	Systematic Reviews and Networking Support in Health
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SD	Standard Deviation
SGRQ	St. George's Respiratory Questionnaire
SNP	Single Nucleotide Polymorphism
SOP	Standard Operating Procedure
SR	Sustained Release
SRIHER	Sri Ramachandra Institute of Higher Education and Research
STLS	Senior Tuberculosis Laboratory Supervisor
STO	State Tuberculosis Officer

STS	Senior Treatment Supervisor
T2DM	Type 2 Diabetes Mellitus
TAC	Technical Appraisal Committee
TANUVAS	Tamil Nadu Veterinary and Animal Sciences University
TBM	Tuberculous Meningitis
TBVIL	TB Vaccine Immunology Laboratory
TCID	Tissue Culture Infectious Dose
TCR	T Cell Receptor
Tfh	T Follicular Helper (Cells)
THP-1	Human monocytic cell line derived from an acute monocytic leukemia patient
TLR	Toll Like Receptor
TNF- α	Tumor Necrosis Factor- α
TNFAIP6	TNF- α -induced protein 6
TPT	Tuberculosis Preventive Treatment
TNA	Total Nucleic Acid
tNGS	Targeted Next-Generation Sequencing
TOPD	TB-Associated COPD
TRC	Technical Resource Centre
TST	Tuberculin Skin Test
TU	Tuberculosis Unit
UPF	Unani Pharmacopeial Formulation
VA	Verbal Autopsy
VCAM-1	Vascular Cell Adhesion Molecule-1
VDR	Vitamin D Receptor
VIT	Vellore Institute of Technology
VRDL	Virus Research and Diagnostic Laboratory
WGS	Whole Genome Sequencing
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis
YP	Yellow Phospherous
Z	Pyrazinamide
ZO-1	Zonula Occludens-1
zTB	Zoonotic Tuberculosis

RESEARCH ACTIVITIES
2025-2026

STUDIES IN PROGRESS

1. Comparative evaluation of intensified short course regimen and standard regimen for adults TB meningitis: an open-label randomized controlled trial (INSHORT trial)

Principal Investigator	:	Dr Leeberk Raja. I
Participating Institutes	:	ICMR- NIRT, MMC- Chennai, CMC- Vellore, AIIMS-Jodhpur, JIPMER-Puducherry, NEIGRIHMS- Shillong, KGMU- Lucknow, Madurai Medical College- Madurai, Govt. Medical College, Omandurar
Source of funding	:	ICMR- Intramural
Study period	:	2024 - 2027
Pillar	:	Treat
Category	:	Development

Background / Objectives:

Tuberculous meningitis (TBM) continues to be a burning issue with a higher mortality despite variation in drug dosages, duration and existing guidelines governing management. It is extremely important to generate evidence by conducting a robust, multicentric randomized control trial. We aim to compare the intensified short course Anti-Tuberculosis Treatment (ATT) with standard ATT regimen in reducing composite outcome (mortality and disability) and to compare pharmacokinetic parameters between two groups.

Methods:

An open label randomized controlled trial is being conducted to achieve a sample size of 372 participants across 6 sites in India. Eligible participants will be randomly allocated in 1:1:1 ratio into either one of the two intervention arms or the control arm. Participants in the intervention arms will receive high dose rifampicin (R) (25mg/kg), moxifloxacin (M) with or without aspirin along with Isoniazid (H), Pyrazinamide (Z) during Intensive Phase (IP) which will be followed by 4HRZ in the Continuation Phase (CP). Modified intention to treat and a Per Protocol (PP) analysis will be conducted at 12 months and 24 months after the treatment initiation.

Study progress:

The trial began the recruitment on 30th August 2024.

Recruitment status is enlisted in the table below :

Site	Pre-Screening	Screening	Enrolled
MMC	370	31	20
NEIGRIHMS	207	21	19
CMC	196	25	16
JIPMER	147	21	19
AIIMS	210	24	18
KGMU	60	55	46
GRH, Madurai	02	0	01
OMC	01	02	00
TOTAL	1193	173	139

Translational value:

The INSHORT trial holds immense translational potential as the largest multi-centric clinical trial ever conducted in India among patients with TB meningitis. Given the current TBM regimen's several drawbacks, if the study regimen proves beneficial, it will have policy implications for both national and global TBM treatment.proves beneficial, it will have policy implications for both national and global TBM treatment.

2. Role of artificial intelligence using X-ray CAD software in detection and differentiation of TB using a phased approach

Principal Investigator : Dr.G.Narendran

Participating Institutes : ICMR-NIRT CDAC, GHTM, ITM, MMC Chennai

Source of funding : Requested for stage 2

Study period : Jan 2024 – ongoing

Pillar : Detect

Category : Development

Background / Objectives:

Chest X-ray screening serves as a very useful tool in pulmonary TB (PTB) diagnosis especially during surveys. In Tamil Nadu, 36% of the TB cases found during the state prevalence survey were eligible for sputum examination based only on X-ray abnormality and most of them were asymptomatic. Artificial Intelligence (AI) can serve as a boon in plugging various lacunae in such scenarios, increasing accuracy as well. Secondly, the intra and inter-observer difference in interpretation could be minimised largely. These are only point of care tests, differentiating normal from abnormal X-rays with greatest accuracy, very efficiently chalking out extent of lesions, can unearth hidden lesions and smaller opacities invisible to the naked eye through heat mapping and quantification. Early admission and triaging using these tools could substantially prevent TB complications and reduce TB mortality overall. Our objective is to develop a computer-aided detection (CAD) system for detecting TB and advancing the

findings to detect and differentiate TB from other diseases using chest x-ray characteristics, as a clinical decision support system for TB care.

Methods:

Study Design: Phased, prospective observational validation study conducted by ICMR-NIRT, C-DAC Chennai, ITM, and GHTM Tambaram, collaborating medical colleges.

Study population: Chest X-rays from TB surveys, clinical trials, and patients with TB and non-TB lung diseases used for 3 stages as mentioned below.

Study progress:

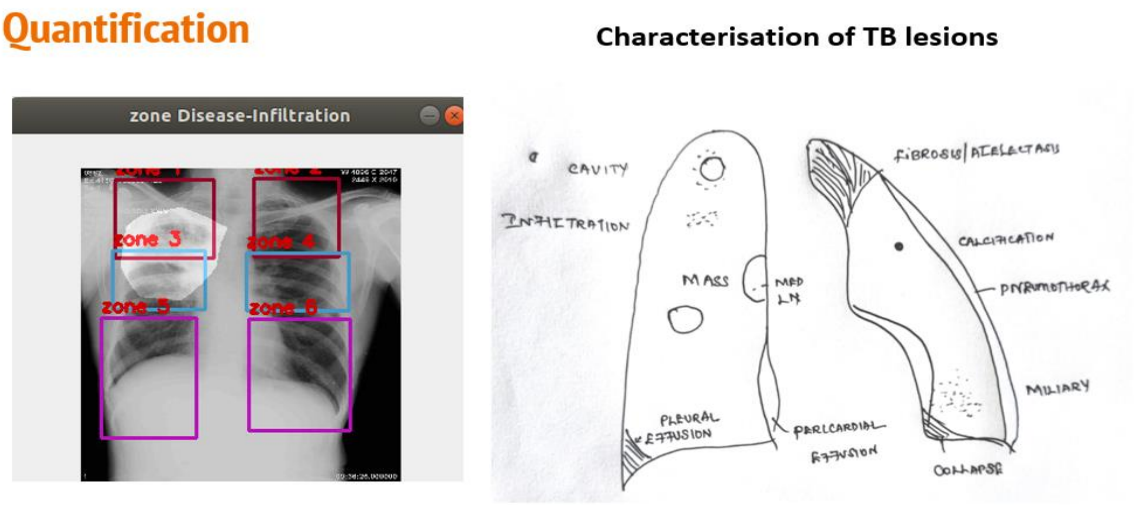
For the Stage 1: X-rays from the National tuberculosis prevalence survey from NIRT had been used to differentiate normal from abnormal x-rays –completed.

For Stage 2 (ongoing): X-rays from well characterized cohort of sputum culture positive TB from clinical trials conducted in ICMR-NIRT would be used for TB diagnosis and surveillance of TB progression. In these cohorts, follow up x-rays are available on a periodic basis from pre-treatment to almost 18 months after treatment initiation. This gives a better experience for not only diagnosing TB but also making the software understand the improvement or deterioration – by looping or integrating the various radiological manifestations.

For stage 3: X-ray images from Non-TB pathology would be obtained from medical colleges and would be used if stage 2 is successful.

The study is unique as the software developed by CDAC –ICMR NIRT has been refined not only to diagnose pulmonary lesions suggestive of TB, but also to compare x-rays of the same patient and help in gauging progress and also for triaging which would be useful in reducing TB mortality.

Figure 1 and 2: Zonal distribution and quantification along with characteristics abnormalities



IOU for Disease Infiltration and zone 1 = 34.86% for Disease Infiltration and zone 3 = 38.82%

3. Prevalence of cardiopulmonary perfusion defects and vascular damage among Post COVID-19 patients using Q-SPECT/CT hybrid imaging and correlation with biomarkers for prognostication – a longitudinal study (POCOS)

Principal Investigator	:	Dr.G.Narendran
Participating Institutes	:	ICMR-NIRT, Omandurar Government multispecialty hospital, MMC
Source of funding	:	Covid call for proposals – Extramural grant
Study period	:	2022-2026
Pillar	:	Detect
Category	:	Description

Abstract:

The prevalence of cardiopulmonary vascular defects in the post Covid period was studied using the radionuclide imaging – 99 Tech SESTIMBI for the cardiac micro and macro circulation while the 99 tech MAA was used for the pulmonary circulation. We prospectively followed these patients to find out if they would progress to overt ischemic syndromes including sudden death. Immunological parameters were also studied and correlated with the perfusion defects.

Background / Objectives:

To estimate the prevalence of vascular defects among Coronavirus Disease- 2019 (COVID-19) patients with minimal and advanced diseases and follow them for a year to determine if these defects translate into overt clinical vascular insufficiency syndromes subsequently.

Methods:

Using a longitudinal observational cohort of post-COVID-19 patients (6-28 weeks from their illness) segregated into minimal and advanced disease, evaluation of clinical, cardio-pulmonary evaluation including Quantitative Single-Photon Emission Computed Tomography/ Computed Tomography (Q-SPECT/CT) hybrid will be performed supplemented by immunological profile for finding potential vascular defects in the cardiopulmonary tree with close follow- up for one-year duration after consenting to see the progression.

Study progress: 133 participants had been followed up for 2 years post enrolment. Manuscript on cardiac perfusion has been submitted to Nature Scientific reports and is under review while the lung perfusion defects is being written up

Translational value / contribution to national programme:

The study provides much needed relief that Post Covid status per se did not progress to any overt ischemic syndromes unless driven by comorbidity or cardiac injury during acute covid illness that remains unrecognised. This finding might be helpful in avoiding routine use of higher investigations in the general population

4. Impact of Xpert MTB/XDR in early diagnosis and treatment and 6-month mortality in patients with drug-resistant tuberculosis: a pragmatic quasi-experimental study

Principal Investigator	:	Dr Leeberk Raja.I
Participating Institutes	:	ICMR-NIRT, District TB Office, Chennai
Source of funding	:	ICMR- Ignition grant
Study period	:	2025-2027
Pillar	:	Detect
Category	:	Delivery

Background / Objectives:

The rapid diagnosis and appropriate treatment of drug-resistant tuberculosis (DR-TB) is essential to prevent higher morbidity, mortality, and further transmission of tuberculosis. The newer Xpert MTB/XDR has the ability to detect resistance to isoniazid, fluoroquinolones and aminoglycosides in a few hours. Though Xpert MTB/XDR has an excellent sensitivity and specificity, it has not been used widely in the TB program and impact of patient outcomes with this test has also not been studied. We aim to determine the reduction in time to diagnosis and time to treatment for DR-TB with the implementation of Xpert MTB/XDR (intervention) compared to current standard diagnostic algorithm in National Tuberculosis Elimination Programme (NTEP) (control).

Methods:

We proposed a quasi-experimental study among 756 individuals in five NTEP districts of Chennai. Three districts would be offered Xpert MTB/XDR for all the patients with presumptive DR-TB and the remaining two districts will follow the routine NTEP diagnostic algorithm. We will record time to diagnosis and treatment in both the arms and evaluate mortality at 3 and 6 months. Independent sample ‘t’ test or Mann-Whitney U test will be used to compare the outcomes between intervention and control districts depending on the distribution of the data. Sensitivity and specificity will be calculated comparing Xpert MTB/XDR results with Phenotypic Drug Susceptibility Testing (pDST).

Study progress:

The study was initiated in March 2025, and as of March 2026, a total of 329 participants had been enrolled, with 173 in the intervention arm and 156 in the control arm.

Translational value:

The study will demonstrate the effectiveness of Xpert MTB/XDR in reducing the diagnostic delay in patients with resistance to INH and FLQ, which is currently detected in Line Probe Assay (LPA). If fluoroquinolone resistance is found based on Xpert MTB/XDR, it will also help to modify the treatment regimen appropriately. Subsequently, this will enable quick decision and reduce the treatment delay. Overall, reducing the diagnostic delay and treatment initiation will improve patient outcomes, increase the proportion of patients with favorable outcomes, and reduce mortality due to DR-TB. The study will also indirectly give diagnostic accuracy of Xpert MTB/XDR and strengthen the cause of utilizing this molecular test in the routine diagnostic algorithm in NTEP.

5. Feasibility of implementation of Out-patient (OP) Screen TB initiative for pulmonary TB case detection in Primary Health Care settings

Principal Investigator	:	Dr V.V. Banu Rekha Scientist F
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-NIRT Grant-in-Aid
Study period	:	2025-2026
Pillar	:	Detect
Category	:	Delivery

Background / Objectives

It is essential to identify the missing TB cases to prevent ongoing TB transmission which is crucial in the pathway to TB elimination. *'OP Screen TB'* is an initiative to ensure screening for TB of all out-patients (OP) attending the Primary Health Care centres and that sputum examination is done for all the identified presumptive PTB individuals. We propose to study the feasibility and usefulness of this initiative in TB case notification.

Methods

All adult patients (age ≥18 years) attending the primary health care facility (n=6) in Chennai and Madurai district are screened by using a TB symptom screen checklist by the Health Care Worker of the facility for a period of 3 months. Chest x-ray is offered based on feasibility for all out-patients at risk for TB/those with symptoms. Patients with symptoms and or abnormal chest x-ray are actively pursued for sputum examination. In-depth interview of health care workers in the study centres is planned to identify the barriers and facilitators.

Study progress

The study was initiated in June 2025 and is ongoing. A total of 20330 out-patients were approached. OP Screen TB initiative attempts to incorporate Intensive TB case finding by symptom screening and chest-ray in health care settings for TB case detection using OP Screen TB checklist seal in OP slip in out-patient primary health care settings. This could be adopted in health care settings if found useful.

6. Accelerating Efforts to END TB in India

Principal Investigator	:	Dr. R. Balaji
Participating Institutes	:	ICMR-NIRT, State TB office, District TB offices
Source of funding	:	ICMR-NHRP
Study period	:	2023-2027
Pillar	:	Prevent / Detect / Treat / Build
Category	:	Delivery

Background:

In 2023, the estimated 10.8 million of TB cases were noted worldwide. There exists an estimated global gap of 2.7 million cases in 2023 between estimated incident TB cases and notified Tb cases. Thus, this study focus to build a unique model of state specific implementation. The uniqueness of this study is the amplified implementation approach where all the key stakeholders collaborate to complete the cycle of identification and treatment completion along with follow-up and contact tracing.

Methods:

ICMR and ICMR-NIRT implement the study in collaboration with Central TB Division (CTD). ICMR institutes across India implement the study in population designated as vulnerable to TB as per NTEP guidelines. Sites make detailed micro plans to screen, diagnose and treat the population by active case finding along with contact tracing enhanced by IEC activities, socio-behavioral counselling and nutritional supplementation. The primary outcome of the study is to measure proportional improvement in the yield compared to current indicators such as TB notification rate, treatment initiated, treatment completion, TB preventive therapy (TPT) initiation among contacts with intensified case-finding activities and follow up.

Progress:

Till date, around 25 lakh population has been screened and being followed up under this project. This model has served as a deliverable model for states to plan ACF activities to identify the missed TB cases and the NTEP program has been implementing the Hundred Day campaign in similar lines.

ACF- Screening by WHV's

X-Ray testing by using Hand-held X-Ray Machine

7. Identifying gaps and challenges in Continuum of TB care among labourers working in quarries in Madurai district

Principal Investigator	:	Dr. R. Balaji
Participating Institutes	:	ICMR-NIRT, Madurai district quarries
Source of funding	:	ICMR Ignition grant
Study period	:	2025-2027
Pillar	:	Detect
Category	:	Delivery

Background:

Periodic screening of labourers especially migrants for chest symptoms, in order to detect TB disease and provide treatment remains a challenge in TB control program globally. A regular screening system along with early case detection and management through NTEP program among labourers including migrants is required for marching towards ending TB in India. Objectives: The present study is planned for identifying the gaps and challenges in the continuum of TB care for the vulnerable population of labourers working in quarries to achieve early diagnosis and management.

Methods:

This is a cohort study where screening of labourers including migrants for TB disease is done once in 6 months. All the participants undergo symptom screening and upfront chest x ray. Those who are symptomatic or with abnormal chest X-ray findings undergo sputum testing by molecular diagnostic tests. Persons diagnosed with TB are treated under program and contacts of persons with TB are initiated on TPT and treatment compliance is monitored. Post treatment follow-up is done for early identification of recurrence and appropriate management. Gaps and challenges identified in the continuum of TB care is addressed to strengthen the continuum of TB care. Health care seeking is assessed among the TB symptomatic.

Expected outcomes:

The study will estimate the burden of TB disease among the labourers including migrants working in quarries. It will address the difficulties and challenges in achieving the continuum of TB care among this vulnerable population, both at the community level and at the program level.

8. Patient outcomes associated with Tuberculosis Obstructive Pulmonary Disease in India: A prospective single arm study

Principal Investigator	:	Dr. Newtonraj A
Participating Institutes	:	ICMR- NIRT
Source of funding	:	ICMR Intramural
Study period	:	2025-2027
Pillar	:	Treat
Category	:	Delivery

Background / Objectives:

This study was done in the adults diagnosed newly with PTB initiated on six months daily regimen under NTEP. The primary objective is to determine the prevalence, pattern and progression of Post TB lung disease (PTLD) during and after two years of successful treatment completion. The secondary objectives: To identify the risk factors of PTLD; To understand the circulating immune markers at baseline and longitudinal assessment of PTLD; To understand the psychosocial and economic challenges faced by the persons with PTLD at the end of treatment.

Methods:

The calculated sample size was 177. Eligible participants (persons with PTB initiated on 6 months NTEP daily regimen) for the study will be prospectively recruited from the study sites in selected TUs. Consecutive sampling will be done. Data collection includes demographic, clinical information, pulmonary function test (PFT), 6 minute walk test (6MWT), X-ray chest, HRCT chest, forced oscillation technique (FOT) and St. John's Respiratory Questionnaire (SGRQ) assessment, which will be collected in a case report forms (CRF). Peripheral Blood Mononuclear Cells (PBMCs), serum and plasma will be stored at prescribed visits for biochemical and immunological assessments. The CRFs will be checked for completeness by study team at every time. Those who are diagnosed with PTLD will be treated as per standard of care. The study outcomes would be prevalence of patients with PTLD at various time points, pattern of PTLD in each time point (clinical, anatomical and functional), course of PTLD in two years (clinical, anatomical and functional outcomes) and risk factors of PTLD such as demographic, co-exposure, co-morbidity, host immune responses . Treatment and post treatment outcomes (proportion of successfully treated PTB individuals without TB, died, TB recurrence, lost at 2 years post-treatment) will also be calculated as proportions with 95% CI. Qualitative and thematic representation of psychosocial and economic challenges faced by the PTLD patients in two years will also be assessed.

Study Progress:

The study recruitment has been completed in all the sites (NIRT Chennai and Madurai). Study is ongoing as per protocol. PFT and FOT are done from 3rd month of post treatment. Progress of the lung function is noted. Most of the study participants have completed the treatment and are currently in the first year of post treatment follow-up.

9. Impact of the m-Health counselling support on adherence and treatment outcome among newly diagnosed DS-TB patients under programmatic setting in India: An implementation research study (Mixed Method - RCT).

Principal Investigator	:	Dr. Newtonraj A
Participating Institutes	:	ICMR- NIRT
Source of funding	:	ICMR Intramural
Study period	:	2025-2026
Pillar	:	Treat
Category	:	Delivery

Background and objectives:

Recent studies have shown that the adherence among the newly diagnosed drug DS-TB on six months daily regimen was relatively low. This may be because of the shift from Directly Observed Therapy Short Course (DOTS) to family DOTS, with drugs supplied on a monthly basis. This reduces the contact of the patient with the health care system. Our study aimed to bridge this gap and to show improvement in the treatment adherence and treatment outcome in a programme setting by providing regular counselling support to the participants through phone calls (m-Health).

Methods:

This will be an open label cluster randomized control trial, where tuberculosis units (TU) within the selected districts will be divided in to control and intervention arm. Four high burden districts as per Tamil Nadu TB prevalence survey were selected for the study. Persons with DS-TB in the control TUs will receive the standard of care for TB treatment adherence. Counselling by a qualified counsellor will be given over phone call weekly during IP and fortnightly during CP for the persons with DS-TB in the intervention TUs. Adherence will be checked objectively by analysing urine for drug metabolites using a High Performance Liquid Chromatography (HPLC) or an equivalent standard testing along with a subjective questionnaire. Post treatment outcomes (cured, treatment completed / failure, death, loss to follow-up) will be noted at the end of treatment completion. Qualitative interviews will be conducted among the participants and health care workers to understand the perception regarding intervention. Sample size calculated was 914 participants (457 in each arm).

Study Progress:

After getting all due approvals, study was initiated in four districts (Theni, Dindigul, Perambalur and Thiruvallur) from August 2025. Study is successfully ongoing. Participant recruitment was completed in all sites by March 2026. Project is expected to reach completion by October 2026.

10. Predictors of unfavorable treatment outcomes and emerging drug resistance among patients started on drug regimen for Isoniazid (INH) mono-resistant Pulmonary Tuberculosis under NTEP in Tamil Nadu and Kerala: a prospective cohort study

Principal Investigator	:	Dr Leeberk Raja.I
Participating Institutes	:	ICMR-NIRT, State TB cell and NTEP
Source of funding	:	Intramural
Study period	:	2023-2026
Pillar	:	Treat
Category	:	Description

Background / Objectives:

Isoniazid mono-resistance is the most common type of prevailing drug-resistance in TB. It reduces the treatment success and increases the risk of acquiring additional drug resistance such as rifampicin and fluroquinolones. Studies across the globe have reported unfavourable outcome rates of 7-44% among these patients treated with first line drugs. This study aims to identify predictors for unfavorable treatment outcomes among patients with PTB patients.

Methods:

All newly diagnosed PTB patients initiated on treatment for INH mono resistance were recruited. Patients with additional resistance for rifampicin or fluroquinolones were excluded. Demographic details and sputum sample were collected at the baseline. Subsequently, sputum samples were collected during the treatment and post-treatment for smear microscopy, first and second line LPA, culture and DST. During the follow up, details regarding change of regimen, adverse events and TB recurrence were also collected.

Study progress:

We screened 1053 individuals with INH mono-resistant PTB and enrolled 847 participants across 11 districts in Tamil Nadu. The median age was 49 years (IQR-39 to 58) and majority were men (78.2%). More than of the study participants were malnourished (50.8%) and more than one third were diabetic (39%). Of the participants whose Chest X-ray (527/847, 62.2%) was available, 39.3% had cavities. At the baseline, 68.8% samples were culture positive, 1.9% were resistant to fluoroquinolone, and 10.6% were resistant to pyrazinamide. The follow-up is ongoing and final results will be available by May 2026.

Translational value:

The factors contributing for the unfavourable treatment outcomes and drug resistance pattern among these patients will give the researchers, clinicians and program managers' crucial insights on planning newer interventions and devise strategies for the future. This study will also help us to understand the effectiveness of drug regimen currently used for these patients, thus contributing to overall goal of TB elimination.

11. Technical Resource Cenrte, Centre for Evidence-based guidelines, DHR

Principal Investigator	:	Dr Leeberk Raja.I
Participating Institutes	:	ICMR- NIRT
Source of funding	:	DHR
Study period	:	2024-27
Pillar	:	Build
Category	:	Development

Background:

The Technical Resource Centre at ICMR-NIRT has been established by Dept. Health Research to systematically synthesize and evaluate evidence, develop and promote evidence-based guidelines and enhance the adoption-based practice in Health care. The objective of this centre as follows,

1. Conduct systematic reviews and meta-analyses to generate high-quality evidence for the development of clinical guidelines, utilizing the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach.

2. Organize training programs and workshops to disseminate best practices in evidence synthesis and the application of the GRADE methodology, supporting effective and rigorous guideline development

Specific activities:

During 2025-26, the TRC at ICMR-NIRT undertook the following activities:

- Completed two systematic reviews on community-acquired pneumonia, the findings of which will inform national antibiotic guidelines.
- Initiated three ongoing systematic reviews to support guideline development for Polycystic Ovarian Disease.
- Organized SARANSH (Systematic Reviews and Networking Support in Health), week-long workshop held in November 2025. This META (Methods and Evidence in Test Accuracy) programme followed a mentor–mentee model and strengthened national capacity in diagnostic test accuracy reviews.
- Organized one-day workshop on meta-analysis for intervention reviews on 4 July 2025.
- Organized a one-day introductory workshop on systematic reviews on 27 June 2025.
- Conducted a pre-conference workshop on systematic reviews of diagnostic accuracy as part of the Cochrane Conclave on 30 November 2025 at AIIMS, New Delhi.
- Conducted a three-day workshop on systematic reviews of diagnostic accuracy in collaboration with the TRC at AIIMS, Jodhpur, from 27 to 30 January 2026.
- Conducted a one-day workshop as part of the Indian Association of Public Health Annual Conference on 12 March 2026 in Guntur.

- TRC faculty members also contributed as resource persons in various capacity-building programmes conducted at SRIHER Chennai, SRM Medical College Chennai, and CMC, Vellore.

Group Photograph Taken During SARANSH

12. Effect of Pulmonary rehabilitation on the exercise tolerance in sputum positive TB patients

Principal Investigator	:	Dr.N.Poorana Ganga Devi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Intramural
Study period	:	2024-2027
Pillar	:	Prevent
Category	:	Discovery

Introduction:

Treatment of PTB leads to reduced exercise tolerance and diminished quality of life along with long-term pulmonary impairment even after microbiological cure. Evidence for pulmonary rehabilitation (PR) with respiratory physiotherapy among patients with PTB is limited. Our study assesses the effect of a 16 week pulmonary rehabilitation programme with respiratory physiotherapy during the CP of tuberculosis treatment among patients with sputum positive PTB.

Methods and Analysis:

This is an open-label, parallel-arm, cluster controlled clinical trial enrolling sputum-positive PTB patients who become smear-negative at the end of IP of treatment. A total of 240 participants as eight clusters will be allocated equally to either (i) chemotherapy and PR or (ii) chemotherapy alone during their CP of ATT. The clusters will be followed up for a period of 18-months post chemotherapy treatment completion. A change in walking distance measured by the 6MWT will be the measure to assess the exercise tolerance. Secondary outcome measures include measuring change in lung function testing, dyspnoea assessment using Baseline/Transition Dyspnea Index (BDI/TDI) scale and respiratory health-related quality of life measure using SGRQ.

Translational value / contribution to national programme:

The findings of this study will help to generate evidence regarding the long term impact of TB and plan appropriate interventions. Addressing the issues relevant to the quality of life and considering measures for pulmonary rehabilitation will provide added value to the programme.

13. Scaling up short course TB preventive regimen containing Isoniazid and Rifapentine given once-weekly for three months (3HP) among household contacts of sputum positive Pulmonary TB patients in India: A demonstration project

Principal Investigator	:	Dr S Ramesh Kumar
Participating Institutes	:	ICMR-NIRT, ICMR – RMRC, Bhubaneswar NITRD, New Delhi NTEP of Gujarat, Pondicherry, Karnataka and Tamil Nadu
Source of funding	:	ICMR Extramural
Study period	:	2022-2025 (Extension)
Pillar	:	Prevent
Category	:	Discovery

Background / Objectives

Various studies provide evidence that 3HP regimen is non-inferior and perhaps superior to the 6- or 9-month Isoniazid preventive treatment in terms of effectiveness for TB prevention, and is well tolerated with better adherence rates. The primary objective of the study is to determine the feasibility of providing the 3HP preventive therapy to household contacts of bacteriologically positive PTB patients under program settings. The study also aimed to describe the pattern of adverse drug reactions, understand the barriers and facilitators and estimate the proportion of household contacts developing TB over a 2 year follow up period.

Methods: Multi-centric prospective demonstration study among household contacts of adults with PTB. Focus group discussions (FGD) will be conducted among participants and health care workers to understand the barriers and facilitators for 3HP implementation.

Study progress: Stakeholder meetings with the State TB Officers of Tamil Nadu, Karnataka and Gujarat followed by study initiation, training, and recruitment of 3HP recipients were done. The 3HP provision for the HHC was based on the "Test and treat" or "Treat all" policy of the concerned State. Data are collected through Redcap for Tamil Nadu & Pondicherry, New Delhi and Orissa. A total of 2466 were screened and 765 eligible received 3HP. Data from Karnataka and Gujarat are being extracted from the program data as provided by the concerned STOs. A total of 2937 and 2477 were 3HP recipients from Karnataka and Gujarat State respectively. The 24 Months follow up of 3HP recipients has been completed. FGDs were conducted among household contacts of sputum positive PTB patients who received 3HP and health care providers who delivered 3HP in five districts of Chennai, Pondicherry, Madurai, Thoothukudi of Tamil Nadu and Tumkur, Karnataka. The manuscript based on the FGDs conducted was accepted for publication. New FGDs conducted as suggested by Expert Committee among 3HP recipients who were 100% compliant to understand the facilitators for the compliance in Madurai, Thoothukudi, Chennai, Bhubaneshwar and New Delhi sites is also completed. Data cleaning, analysis of the data collected and write up is being done.

14. Smoking Cessation among TB patients in Madurai district Corporation centres: aiding TB free Madurai

Principal Investigator	:	Dr S Ramesh Kumar
Participating Institutes	:	ICMR-NIRT, DTO, NTEP, Madurai, Govt Rajaji Hospital, Tobacco Cessation Clinic of Cancer Institute Adyar, Chennai & Madurai branch, Distrct Health Officer, Madurai
Source of funding	:	Partly ICMR intramural and partly office of District Health Officer, Madurai
Study period	:	2023 to 2026
Pillar	:	Treat
Category	:	Delivery

Background / Objectives:

Smoking cessation in TB patients improves TB outcome. Smoking cessation strategy study among TB patients established the effectiveness of smoking cessation interventions namely Bupropion sustained release (SR) or enhanced counselling at THE field level. We proposed to deliver these smoking cessation strategies to TB patients attending NTEP centres and estimate the quit rate and assess the TB outcomes with and without quitting at Madurai district.

Methods:

To estimate the quit rate when the smoking cessation interventions namely enhanced counselling is offered to TB patients who are smokers and to assess whether that aids in improving TB free indicators in Madurai district. All persons diagnosed with TB and attending for TB treatment in NTEP Centres of Madurai district will be screened for history of current smoking. TB patients who are current smokers are to be offered Enhanced counselling strategy to enable them in smoking cessation. The intervention will be delivered by the Health Inspector (HI)/ Multi-Purpose Health care Provider (MLHP) for Enhanced counselling strategy. Quitting smoking will be assessed at 2nd month and at the end of treatment (6^{th} month) and follow up at 9th month and.at one year.

Study progress:

The study has two phase 1. Training Phase, where in the health care workers will be trained for delivering smoking cessation interventions 2. Study participants recruitment phase where in the recruitment of persons on TB treatment and smoking will take place and the trained health care workers will deliver the Smoking Cessation Intervention Strategy. So far recruited about 35 TB patients with current smoking and the enhanced counselling has been delivered by the trained health care workers and follow-up is being done.

Translational value:

A policy brief mentioning suggesting for implementation of the NIRT Smoking cessation strategy namely Enhanced counselling is in place at the ICMR website. As the Govt. of Tamil Nadu was interested in the implementation of the strategy, a cost effectiveness analysis study in collaboration with Tamil Nadu State officials was done and it have shown that proposed strategies are cost effective than those currently implemented in the program, the findings published in 2025.

15. DLSS: Sentinel Surveillance for Tuberculosis Burden in India 2023-2024" under the project Strengthening and Monitoring of Tuberculosis Elimination in India

Principal Investigators	:	Dr.Mukesh Kumar Sathya Narayanan / Dr.Sriram Selvaraju
Participating Institutes	:	ICMR-NIRT, ICMR-NJILOMD Agra, ICMR-RMRC Gorakhpur, ICMR-RMRIMS Patna, ICMR-RMRC Bhubaneshwar, ICMR-NIN Hyderabad, ICMR-NITVAR, Pune, ICMR-RMRC, Dibrugarh, ICMR-NICPR, Noida ICMR-NIRTH, Jabalpur ICMR-NIRBI, Kolkata, NTI, Bengaluru ICMR-NIIRNCD, Jodhpur ICMR-RMRC, Dibrugarh
Source of funding	:	Global Fund
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Description

Objectives:
Primary Objective:

1. To develop a national curve TB fitting mathematical model for incidence, estimation on an annual basis, using a community-based sentinel survey.

Secondary objectives:

1. To monitor national trends of TB prevalence, TB infection, health-seeking behavior, and the prevalence-to-notification ratio at the national level
2. To estimate the prevalence of TB infection in India
3. To monitor the TB mortality rate at the National Level in India among the surveyed population using verbal autopsy.
4. To explore the feasibility of using AI tools for the improvement of existing AI tools in sentinel surveys.

Methods:

We conducted a population-based cross-sectional survey across 300 clusters in 50 districts of India, excluding Andaman and Nicobar Islands and Lakshadweep, among individuals aged ≥10 years selected through probability proportional to size sampling. After consent, data on demographics, respiratory symptoms, healthcare-seeking behaviour, and anthropometry were collected. Chest X-ray, sputum testing including CBNAAT, smear, culture and DST, Cy-TB skin testing, and point-of-care glucose and haemoglobin assessments were performed. Tuberculosis mortality was assessed using the World Health Organization (WHO) 2022 verbal autopsy tool.

Study progress:

Field work has been completed in 300 clusters, while culture results for the collected samples are pending. Conducted 573 VA interviews for 606 enumerated deaths, and 23,537 participants screened for TB infection, by Cy-Tb test.

Translational value/contribution to national programme:

The study generated robust estimates of bacteriologically confirmed PTB prevalence, infection prevalence, and prevalence-to-notification ratio, identifying high-risk groups. Findings provided critical evidence to assess progress under the National Strategic Plan and to inform policy refinement and programme strengthening under NTEP.

16. An integrated psycho-social intervention to improve self- efficacy towards treatment uptake and infection prevention among patients and family caregivers – A multi- centric implementation research study

Principal Investigator	:	Dr. N. Karikalan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2024-2025
Pillar	:	Build
Category	:	Delivery

Background:

Psycho-social interventions to improve the treatment self-efficacy and self-management skills to address the multi-dimensional challenges faced by TB patients need to be integrated into the present TB care system.

Objectives:

To adopt a self-efficacy-driven intervention for improving the treatment self-efficacy of TB patients and family caregivers under the NTEP and to evaluate its efficacy in comparison to the standard of care on primary outcomes: i) improved TB treatment self-efficacy, ii) improved medication adherence, iii) decreased TB stigma, iv) improved infection control self-management practices.

Method:

A multi-centric Hybrid I mixed-method implementation design to adapt and evaluate the implementation feasibility and efficacy of delivering a self-efficacy-driven intervention using an implementation research approach.

Study progress:

Participant recruitment is completed, a total of 825 patients has been screened, of which 520 patients, along with their caregivers, have been enrolled in the study across the three districts. For the qualitative component a total of 48 Focus Group Discussions (FGDs) has been conducted at two time points: 24 FGDs at the time of treatment initiation and 24 FGDs at the end of treatment completion across the study sites. Data management

and analysis for both quantitative and qualitative components are currently underway. This self-efficacy–based psychosocial intervention could be integrated into NTEP to strengthen patient-centred TB care, improve treatment adherence, and support patient and caregiver self-management. The study will generate evidence for a scalable psychosocial intervention to improve TB treatment outcomes.

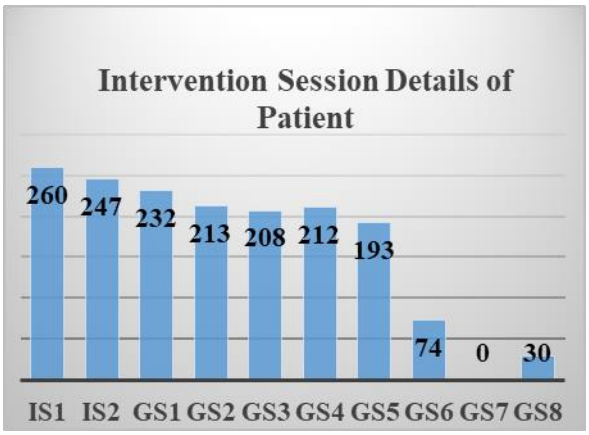


Figure 1: Self efficacy intervention coverage

17. Reducing pre-treatment loss to follow-up among individuals diagnosed with TB through behavioural nudging intervention - A multi-centric mixed methods implementation study

Principal Investigator	:	Dr. N. Karikalan
Participating Institutes	:	ICMR-NIRT, ICMR-RMRC, ICMR- NJIL& OMD, ICMR-NIOH
Source of funding	:	Intramural
Study period	:	2024-2026
Pillar	:	Delivery
Category	:	Build

Background:

Pre-treatment loss to follow-up (PTLFU) and treatment imitation delays remain major gaps in the TB patient cascade of care in India. PTLFU patients (who are diagnosed but have not initiated TB treatment immediately) remain infectious, experience poor treatment outcomes, and suffer high mortality rates. As of 2020 about 6% of the notified patients have not initiated treatment for TB subsequently in India. There is a need for developing behaviour change interventions that could address patient-level barriers and gaps that lead to PTLFU.

Objectives:

To assess gaps in the patient referral process and treatment initiation gaps among newly diagnosed DS-TB patients.

To evaluate the incremental effectiveness of a patient behavioural nudging intervention in reducing PTLFU rates as compared to the standard of care among newly diagnosed DS-TB patients.

Evaluate the implementation process of a behavioral nudging intervention from the perspective of patients, caregivers, and healthcare providers.

Methods:

Employing a hybrid two-arm cluster intervention design to evaluate the incremental effectiveness and implementation aspects of delivering a patient behavioral nudging intervention using an implementation research PRODCUES (Problem, Objective, and Design, (end-) Users, Co-creators, Evaluation, and Scalability) framework.

Study Progress:

Patient recruitment is completed. (Table 1) As part of qualitative data collection, a total of seven FGDs among health care providers, thirty IDIs and thirty Feedback interviews among study participants were conducted. Data analysis is ongoing.

Table 1: Sitewise Patient Recruitment

S.no.	Study sites	Intervention	Control
1	Agra	316	318
2	Bhubaneshwar	193	204
3	Mayurbhanj	197	190
	Total	706	712

Translational Value:

The study will help generate evidence on simple behavioural change nudges for reducing PTLFU rates and reducing early dropouts which further could be scaled up in NTEP settings where PTFLU rates are high.

18. Unmet needs and coping strategies of family caregivers of persons with TB– an exploratory mixed method study – an exploratory mixed method study

Principal Investigator : B. Priscilla Rebecca
Participating Institutes : ICMR-NIRT
Source of funding : Non-funded
Study period : 2026
Pillar : Description
Category : Treat

Background:

Family carers are a part of the healthcare system; therefore, the assistance they give improves the quality of life for those receiving care while saving costs for the healthcare system.

Methods:

This study is a mixed methods research design, allowing for an in-depth exploration of the subjective experiences and perspectives of family caregivers and quantitative assessment for measuring, and valuing care.

Objectives:

(1) To understand the experiences, psycho-social challenges, and barriers faced by family caregivers in fulfilling their caregiving responsibilities for persons with TB (DR & DS TB). (2) To identify the coping mechanisms, strategies, and support systems that family caregivers employ to navigate their caregiving roles for persons with TB. (3) To measure and value the level of family care provided by the caregivers on a day-to-day basis.

Study progress:

Participant recruitment is completed with 120 participants for the quantitative measure enrolled. A total of 40 longitudinal semi-structured interviews were conducted with family caregivers and the patients at two key points along the TB care cascade: at the end of the IP and at the end of the CP of treatment. Data cleaning, management, and analysis of both quantitative and qualitative data are currently in progress.

Total caregiving time at three treatment time points

Variable	N	Minimum (hrs)	Maximum (hrs)	Mean (hrs)	Std. Deviation (hrs)
Baseline	106	0.75	38.50	17.12	11.25
Midline	106	0.00	32.92	8.25	7.83
Endline	106	0.67	25.00	4.51	3.28

Translational Value:

The study will generate evidence on caregiver burden and psychosocial needs of TB-affected families, informing caregiver-focused support strategies within NTEP.

19. Evaluating urine isoniazid testing for tuberculosis disease in India to detect medication nonadherence and improve treatment outcomes

Principal Investigator : Dr. N. Karikalan
Participating Institutes : ICMR-NIRT
Source of funding : NIH - NIAID, USA
Study period : 2026-2031
Pillar : Detect
Category : Delivery

Background:

Nonadherence to TB medications is associated with increased death TB recurrence and drug resistance. Specifically, missing >10% of doses is associated with 6 times greater risk of poor TB outcomes and detecting nonadherence in routine care is challenging. Early and accurate identification of nonadherence may serve as an entry point for providing differentiated care for TB.

Objectives:

Aim 1: To assess the agreement between urine test results collected at scheduled

clinic in comparison to unannounced home visits.

Aim 2: To assess the relationship between nonadherence by urine testing and subsequent TB outcomes.

Aim 3: To identify reasons for nonadherence across the TB treatment course.

Aim 4: To identify implementation factors that will inform integrating urine testing into routine care.

Aim 5: To understand the sensitivity and specificity of urine isoniazid testing for detecting nonadherence with a small validation study.

Methods:

We will be employing a Mixed Method with Longitudinal Cohort Design & Qualitative Interviews as research methods. The overall study schema is given in Figure 1.

Study Progress:

Preliminary work for the study is currently underway. The selection of TUs in the study sites of Chennai and Thanjavur is in progress and the field visits are ongoing.

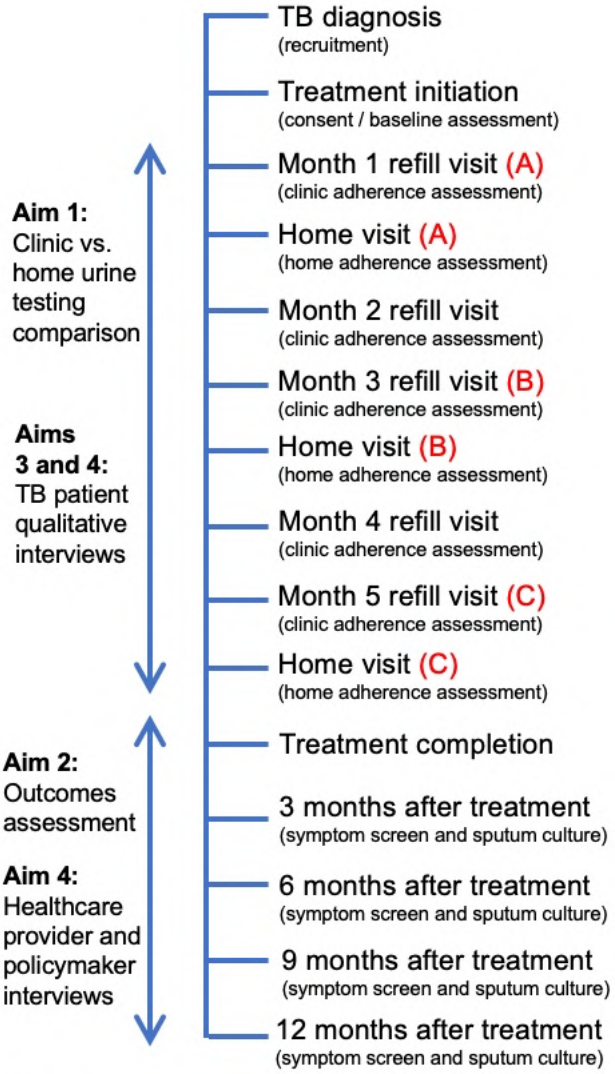


Figure 1. Study schema and integration of aims

20. Transportation workers lead intervention to improve TB literacy among co-workers and demand generation in the community - A quasi-experimental study

Principal Investigator	:	Mrs Chandra Suresh
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2026
Pillar	:	Build
Category	:	Prevent

Background:

Public transportation serves as a potential pathway for TB transmission due to overcrowding and poor ventilation. Thus, there is an unmet need for transportation workers who are at increased risk of airway transmission of infection to increase awareness and knowledge about TB. On the other hand, public transportation is also used by people from different socioeconomic, demographic, and geographical backgrounds and provides an opportunity for engaging with a large volume of the population. This opportunity for public transportation workers to engage with lakhs of passengers every day could be utilized for demand generation for TB-related information among the public.

Objectives:

1. To assess the outcomes of transport ambassador-led lead community engagement strategy in improving TB literacy among co-transportation workers in Chennai.
2. To assess the outcomes of transport ambassador-led community engagement strategy in increasing the demand for TB literacy among passengers in Chennai.

Methods:

Study design: Quasi-experimental design with pre and post-tests to assess the impact of the intervention. (TB-IEC tickets).

Study sites: Fifteen zones of Greater Chennai Corporation with 31 Metropolitan Transport Corporation (MTC) Limited bus depots.

Study population: Conductors and Drivers of MTC workers and public transport passengers of Chennai corporation buses.

Study progress:

Phase 1: Formative phase - Data analysis is completed Phase 2: Intervention & Phase 3: Evaluation of Intervention to be initiated. The study is ongoing.

21. Culture Free detection of tuberculosis drug resistance testing using targeted next generation sequencing

Principal Investigator	:	Dr S Siva Kumar
Participating Institutes	:	ICMR-NIRT, IRLs and NRLs
Source of funding	:	ICMR-Intramural
Study period	:	2023 to 2026
Pillar	:	Detect
Category	:	Discovery

Background / Objectives:

Timely drug resistance detection is essential for global TB management. Phenotypic DST takes 6-8 weeks. This limitation can be overcome by whole-genome sequencing (WGS). However, the direct sequencing of sputum samples is challenging due to low amounts of *Mycobacterium tuberculosis* (*M.tb*) DNA. To overcome this difficulty, an all-in-one targeted deep-sequencing assay has been developed. The study uses DNA samples generated as part of other molecular tests in the NTEP without the need for a separate DNA extraction protocol, and wherever possible without using a biosafety level 3 (BSL3) containment facility. This study appraises the use of Targeted Next Generation Sequencing (tNGS)-based rapid DR and lineage prediction of *M. tb* on compact, low-cost Oxford Nanopore Technologies (ONT).

Objectives:

A. To develop in-house primers to perform a TB tNGS assay kit for lineage and drug resistance prediction for first-line, second-line, and newer anti-tuberculosis drugs.

B. Capacity building to perform TB tNGS assay at a National Reference laboratory and an Intermediate Reference laboratory

Methods:

Sputum samples/ *M.tb* isolates from bacteriologically confirmed TB patients were used in the study. An in-house primer set was used for species-level identification, genotyping, and antibiotic resistance prediction of *M.tb*. Library preparation was performed using a rapid barcoding kit from ONT, and the run was performed on a MiniON Mk1C (ONT). A bioinformatics pipeline was developed in-house for lineage and drug resistance prediction using tNGS data at ICMR-NIRT as part of this study.

Study progress:

LJ cultures gave 93.80% successful runs, while direct sputum gave 60.58%. The distribution of single nucleotide polymorphisms (SNPs) and depth of reads among all the runs done using MinION, ONT, was comparable to previous studies when evaluated with our in-house bioinformatic pipeline. With the in-house pipeline, the highest depth was obtained for inhA (1160.11), while rrl (89.52) had the lowest depth comparable to a few previously published results. tNGS showed 99-100% concordance to WGS and pDST for the first line, second line, and newer/repurposed drugs.

Currently, 400 samples are being tested at the National reference Laboratories (NRLs) and culture and Drug Sensitivity testing (DST) laboratories. Analysis is ongoing and will be reported once results are available. Total of three labs under NTEP have been trained and performing tNGS as part of the project.

22. Development of RT-PCR assay for MTB detection, drug resistance testing and treatment monitoring

Principal Investigator	:	Dr S Siva Kumar
Participating Institutes	:	ICMR-NIRT, IRLs and NRLs
Source of funding	:	ICMR-Intramural
Study period	:	2023 to 2026
Pillar	:	Detect
Category	:	Discovery

Objectives:

1. To develop a Real Time- Polymerase Chain Reaction (RT-PCR) assay for MTB and drug-resistant gene detection and validate it compared to an MGIT culture to detect resistance.
2. To develop a RT-PCR assay to differentiate nontuberculous mycobacteria (NTM) and MTB complex.
3. To develop a RT-PCR assay to detect live MTB using RNA from the stored *M.tb* isolates

Methods:

Phase 1 involves designing and development of the assay for all parameters in the objectives. Out of the proposed objectives, designing and development of RT-PCR for MTB detection is accomplished.

Phase 2 will be the validation of the finalized protocol from phase 1 and will be carried out this year.

Study progress:

A RT-PCR kit for MTB detection has been developed and validated as given in Table 1.

Table 1 : Statistics of newly developed RT-PCR kit for MTB detection.

Statistic	Value	95% CI
Sensitivity	84.32%	79.04% to 88.71%
Specificity	100.00%	98.12% to 100.00%
Positive Predictive Value	100.00%	98.16% to 100.00%
Negative Predictive Value	99.18%	98.90% to 99.39%
Accuracy	99.22%	97.85% to 99.82%

Design and development of RT-PCR assay to detect NTM and live MTB is ongoing.

23. Manipulation of Autophagy for host directed therapy in Tuberculosis

Principal Investigator	:	Dr S Siva Kumar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-Intramural
Study period	:	2024 to 2027
Pillar	:	Detect
Category	:	Discovery

Background / Objectives:

Autophagy is the most prominent cell intrinsic biological pathway. This autophagic pathway is of principal interest due to its critical role in bacterial clearance. Increasing level of multi-drug resistance has raised concerns and shorter regimens are urgently required to control TB. This could be addressed by the development of host-directed therapy (HDT) which is a novel concept that aims at increasing host immune response using drugs/compounds. The rationale of the proposed work is to understand the effect of autophagy induction on intracellular killing of *M.tb*. Therefore, the present study is focused on intracellular killing of *M.tb* strains via induction of autophagy. Secondly, the genetic bacterial factors (Genes) of the *M.tb* strains involved in autophagy regulation (inhibition or stimulation) will be examined using bacterial genome wide association study (GWAS).

Objectives:

- To determine the extent of autophagy markers and *M.tb* co-localisation in diverse population of *M.tb* strains (drug sensitive and drug resistance) by using established THP1 reporter cell lines for autophagy.
- To define the genetic determinants regulating autophagy induction and resistance among *M.tb* strains by GWAS.
- To study the potential of host directed therapeutic autophagy inducers on different clinical *M.tb* strains.

Methods:

This retrospective laboratory study involves a cohort of 50 multi drug resistant (MDR), 100 drug sensitive (DS) and 50 treatment failure/relapse *M.tb* strains stored at the institute. These strains along with 500 *M.tb* strains from the Institutional repository will be utilized for the study.

The *M.tb* strains will be used in an in vitro assay to determine the co-localisation ability of the strains with autophagy using Modified THP1 reporter cell line expressing fluorescent tagged autophagy. All the sequenced *M.tb* strains from the repository including the failure and relapse strains will be used to identify clinically relevant mutations contributing to resistance to host autophagic killing by bacterial genome wide association study (GWAS).

Study progress:

Objective 1:
The infection model has been established and presently infection with clinical strains

is ongoing to establish autophagy induction by each strain.

Objective 2:
The sequencing of *M.tb* strains has been completed and stored, to put them into two baskets of autophagy enhancers and autophagy inhibitors. Once the data is available from objective 1 we will be able to perform GWAS and short list the genes.

Objective 3:
Three compounds (Trimipramine, Carbamazepine, and R848) were tested for their autophagy inducing property and found to exhibit a significant inhibitory effect on the growth of *M.tb* at specific concentrations. This inhibitory action suggests their potential application in host-directed therapy for tuberculosis.

24. Clinical Performance Evaluation of Molecular Tests for Diagnosis of Tuberculosis (TB) and Drug Resistant TB

Principal Investigator	:	Dr S Siva Kumar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR
Study period	:	2025-2028
Pillar	:	Detect
Category	:	Discovery

Background / Objectives:

A proof-of-concept study protocol for evaluating diagnostic performance of newly developed MTB and MDR-TB detection kits in comparison with MGIT culture and GeneXpert/TrueNat for detection of TB with drug resistance from stored Sputum/DNA/*M.tb* isolates is proposed. The protocol includes evaluation algorithm, required sample size, laboratory procedures and quality control measures. Based on results of this proof-of-concept study, a multicentric clinical diagnostic validation study will be conducted as next phase. The aim of this study is to carry out analytical validation of MTB detection kits.

Objectives:

- To determine the analytical sensitivity, analytical specificity, accuracy, precision and limit of detection of diagnostic assays in the early development or pre-validation stage
- To determine the diagnostic accuracy of new Nucleic Acid Amplification Test (NAAT) test against Mycobacteria Growth Indicator Tube (MGIT) culture in detecting pulmonary MTB and NTM among the individuals with presumptive TB.
- To determine the diagnostic accuracy of new MDR NAAT test against culture based DST in detecting first line drug resistance ((Rifampicin (RIF), Isoniazid (INH)) among the microbiologically confirmed TB patients (positive by smear or NAAT test).
- To determine the diagnostic accuracy of new NAAT test against culture-based drug sensitivity testing (DST) in detecting fluroquinolone (FLQ) drug

resistance among MDR-TB/ RR-TB pulmonary tuberculosis patients

Study progress:

A total of 3 kits were evaluated as part of the study:

A. Quantiplus® assay (Huwel Diagnostics)

Of the 644 samples analysed, the sensitivity and specificity of the Quantiplus® assay, relative to MGIT culture, were 86 percent (95% CI 81–90) and 96 percent (95% CI 94–98), respectively, at Ct ≤ 38. The performance of the Quantiplus® assay (v2.0) was comparable to XpertMTB/RIF® (κ=0.83, SE=0.02) at Ct ≤ 38.

B. "UniAMP MTB/T Card"

The sensitivity and specificity of tongue swab UniAMP MTB/T card test are 68.3 % (95% CI 62 to 75 %) and 95% (95% CI 92 to 96 %) respectively with reference to sputum MGIT culture. When sputum NAAT test Xpert MTB/RIF is used as the reference standard, the sensitivity and specificity of tongue swab UniAMP test are 70.6 (95% CI 64 to 77 %) and 95.2 % (95% CI 93 to 97 %) respectively.

C. ERBA-MX8 TB RT-PCR assay

The analytical sensitivity of ERBA MX-08 was determined to be 100 IU/ml based on the 95% probit analysis. Diagnostic sensitivity and specificity were determined to be 93.75% and 96.12% respectively.

25. Role of Pharmacodynamics and non-replicating persisters in successful elimination of tubercle bacilli

Principal Investigator	:	Dr. V. N. Azger Dusthackeer
Participating Institutes	:	ICMR-NIRT, Tambaram sanatorium
Source of funding	:	ICMR Intramural
Study period	:	2024-2026
Pillar	:	Detect
Category	:	Discovery

Abstract:

Poor Pharmacodynamics (PD) and/or inadequate treatment strategies to eliminate the persisters are the main reasons behind treatment failures and relapse. Hence we hypothesize that sub-therapeutic PD and/or the role played by the persisters could be the crucial factors for treatment success. Correlating clinical outcomes with pharmacodynamic indices (using the Pharmacokinetic (PK) levels in each of the patient and the Minimum Inhibitory Concentration (MIC) of the infecting pathogen) among DS-TB and DR-TB patients with the presence of the Non-Replicating Persisters (NRPs) will be the novel component of this study.

Methods:

For enumerating NRPs, sputum samples of TB patients will be treated with the resuscitation promoting factor (RPF) protein that will activate the NRPs and cause them to replicate. The number of colonies will be counted and correlated with treatment outcome. Further, a PK/PD

analysis will be performed on this group of TB patients by sampling plasma concentrations of the anti-TB drugs at 2, 4, 6 and 8 hours and estimating PK variables such as peak concentration (C_{max}), time to attain C_{max} (T_{max}), exposure (AUC_{0-8}& $AUC_{0-\infty}$), clearance (Cl) and half-life ($t_{½}$).will be calculated using a non-compartmental model, and plasma drug levels will be correlated with the frequency of NRPs. This analysis will throw light on the significance of NRPs and their utility as prognostic markers for predicting treatment outcome, besides having policy implications.

Study progress:

Total screened population:
DS-TB patients: 96
MDR-TB patients: 40

Till date 70 DS-TB and 36 MDR-TB patients were admitted for the PK blood draws after one month of their treatment. Blood samples were collected at 7 time points from 0^{th} hour, 1^{st}, 2^{nd}, 4^{th}, 6^{th}, 8^{th} and 12^{th} hour after administration of the drugs.

Presence of RPF dependent and RPF independent tubercle bacillary population were enumerated in a total of 60 and 24 DS-TB and MDR-TB patients prospectively till date. The preliminary data demonstrated the presence of RPF dependent populations among 17 DS-TB and 3 MDR-TB patients indicating the presence of NRPs getting expectorated in sputum of these patients. In two of the patients there were increased bacillary load of NRPs at the end of IP of treatment in DS patients indicating the higher fitness cost of survival of NRPs in these patients.

Translational value:

This analysis will throw light on the significance of NRPs and their utility as prognostic markers for predicting treatment outcome, besides having policy implications.

26. Characterisation of M. abscessus, M. kansasii, M. avium-intracellulare Complex - the most common NTM species isolated from presumptive TB patients

Principal Investigator	:	Dr. R. Priya
Participating Institutes	:	ICMR -NIRT
Source of funding	:	Intramural
Study period	:	2024 -2027
Pillar	:	Detect
Category	:	Description

Background:

Non-tuberculous mycobacteria (NTM) are increasingly recognized as causative agents of opportunistic infection in humans. In general, MTB and NTM infections have identical clinical symptoms, leading to misdiagnosis of the disease. Most of the NTM are resistant to antibiotics and anti-tuberculosis therapy (ATT). Hence patients infected with NTM don't respond to treatment but instances of them being identified as multidrug-resistant TB are common. Appropriate identification methods for the differential diagnosis of NTM and MTB are needed. In

this study, we aim to identify NTM isolated from presumptive TB patients and further characterize them by genotypic and phenotypic methods.

Objectives:

Primary objective:

To identify the pathogenic non-tuberculous mycobacteria causing symptomatic pulmonary disease

Secondary objectives:

1. To further characterize the most common species, M. abscessus, M. kansasii, and M. avium-intracellulare complex isolates using different molecular methods
2. To determine the drug resistance pattern of the isolates using different phenotypic and genotypic methods

Methodology

Currently, under the NTEP and as part of patient management, sputum samples of the Presumptive TB population from all the NTEP centres of Tamil Nadu and other hospitals are sent to ICMR- NIRT for culture and identification. Details of the sputum growing Acid Fast Bacilli but not suggestive of MTB complex in culture will be informed to the concerned treating hospital / medical officer/ laboratory for further treatment, and these isolates will be used for further characterisation at NIRT for this study.

In brief, the positive MGIT/Löwenstein–Jensen (LJ) cultures will be tested with Immunochromatography (ICT) test involving MPT64Ag to differentiate MTB and NTM. DNA from NTM cultures will be extracted by Genolyse Extraction kit. Speciation of growth from two positive cultures per patient will be done using Genotype Mycobacterium Common Mycobacteria / Additional Species (CM/AS) kit. In addition, PCR-RFLP (Polymerase Chain Reaction- Restriction Fragment Length Polymorphism) will be carried out on the species for further subtyping. Genotypic and phenotypic drug resistance testing will be carried out by the NTM-DR kit and broth microdilution method, respectively.

Study progress

A total of 200 isolates has been subjected to characterization methods, and 85 have been sent to sequencing so far.

27. Evaluation of AfuPEPLISA kits for diagnosis of Aspergillosis in presumptive TB patients

Principal Investigator	:	Dr. R. Priya
Participating Institutes	:	ICMR -NIRT
Source of funding	:	Intramural
Study period	:	2025-2027
Pillar	:	Detect
Category	:	Description

Background:

People recovering from tuberculosis are prone to pulmonary fungal coinfections and are mostly misdiagnosed as cases of relapsed PTB. There is an increase in misdiagnosis of patients with invasive fungal infections as tuberculosis and vice versa, due to similar clinical presentation leading to wrong or delayed treatment of the patients. Chronic pulmonary

aspergillosis is a progressively destructive lung disease caused by Aspergillus species, mainly A. fumigatus. Progress of the disease and prolonged treatment with antibiotics or immunosuppressive agents makes tuberculosis patients immunocompromised and hence become susceptible to Aspergillus infections. Hence simultaneous diagnosis of TB and Aspergillosis is important to incorporate appropriate regimen. With the given limitations of compromised sensitivity, specificity and reproducibility for serodiagnosis and cost issues of ImmunoCAP assay, an indirect Enzyme Linked Immuno Sorbent Assay (ELISA)-AfuPEPLISA was developed for detection of specific IgE and IgG antibodies using synthetic peptide epitope of Asp f1.The current study aims to evaluate the usefulness of this indigenously developed AfuPEPLISA for detection of A. fumigatus specific IgE and IgG antibodies in TB patients visiting NTEP centres, in comparison with the ImmunoCAP assay.

Objectives:

Primary Objectives: a) Evaluation of specific IgG and IgE antibodies in the study participants using AfuPEPLISA. b) Comparative evaluation of results obtained through AfuPEPLISA with ImmunoCAP assay

Secondary Objective(s): a) To determine the level of coinfection of Aspergillosis and Tuberculosis in TB patients started on ATT (Microbiologically confirmed TB)

b. To determine the level of misdiagnosis of Aspergillosis as Tuberculosis (Clinically confirmed TB)

Methods:

Investigations for Tuberculosis (Sputum)

Smear microscopy, Xpert testing, Culture and identification

Investigations for Aspergillosis:

a. **Blood:** Serum will be separated from the blood sample and shall be evaluated for presence of specific IgG and IgE antibodies using the AfuPEPLISA kits. The study participants shall also be evaluated for specific IgE antibodies in the serum using ImmunoCAP assay. Sensitivity and serodiagnostic efficiency of AfuPEPLISA for detection of *A. fumigatus* specific antibodies in the serum samples shall be compared with that of ImmunoCAP assay.

b. **Sputum:** DNA extraction and Aspergillus PCR (CheX ASPERGILLUS RT PCR) will be carried out. In addition, a multiplex PCR targeting other fungal pathogens (Histoplasma, Cryptococcus, Pneumocystis) will be performed to determine other fungal pathogens grown.

Study progress

A total of 20 patients has been recruited. Phase I validation of ELISA kits has been completed.

28. Point of care estimation of Vitamin D and C-Reactive Protein for tuberculosis screening in household contacts of active pulmonary tuberculosis patients in Tamil Nadu, India.

Principal Investigator	:	Dr. N Saravanan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-Extramural
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Development

Background / Objectives:

The delayed diagnosis of active TB leads to increased transmission, higher risk of deaths, suffering, longer duration of infectiousness and unexpected economic burdens. To achieve optimal elimination of TB, WHO stressed the importance of 'active screening' among high-risk populations such as HHCs of index cases to detect TB early. The primary objective of the study is to compare the diagnostic accuracy (sensitivity and specificity) and the predictive value (negative and positive predictive value) of point-of-care (POC) estimation of C-reactive protein (CRP) and Vitamin D with WHO symptom-based screening for active TB in HHCs of PTB patients.

Methods:

In this prospective cross-sectional cohort study HHCs of newly diagnosed PTB patients recruited for clinical studies at ICMR-NIRT and any contacts of new PTB patients in Chennai and parts of Tamil Nadu were included (children > 12 years of age and adults, with no IPT and ATT at the time of enrollment). The sputum samples were examined for the presence of M.tb using smear, culture and molecular assays. The blood samples were assayed for vitamin D and CRP using POC and clinical chemistry analyzer. 5 mL of blood was collected from participants and fractions were prepared for biochemical investigations.

Study Progress:

We have recruited 1029 HHCs (n = 1600), the bacteriological and biochemical tests have been completed. Presently aggressive participant recruitment is in progress and we will be able to analyze the data only after the completion of the study.

Basic details of study participants*.

Variables	Overall (n=882)	NON-TB (n=852)	TB (n=30**)
Age (in years) (Mean ± SD)	39.0±15.0	38.9 ±14.8	36.9 ±15.0
Gender: n (%) Male, Female	331(37.5), 551(62.5)	315(37.0), 537(63.4)	16(53.3), 14(46.7)
Vitamin D (ng/mL), Median (range)	12.9 (10.5-15.9)	13.0(10.4-16.0)	12.6(10.7-15.1)
CRP (mg/L) Median (range)	4.7 (3.2 – 7.5)	4.7(3.2-7.5)	4.6(3.6-8.0)
X-Ray, n (%)			
Normal	823(93.3)	799(93.8)	24(80.0)
Abnormal	50(5.7)	44(5.2)	6(20.0)

*As on 28-03-2026, 1029 study participants were enrolled. 882 study participants were subjected for basic data analysis. **Based on preliminary data; confirmation report awaited

Translational potential:

The study would provide information on the predictive value of CRP and vitamin D for the active TB. As the analysis is simple to perform it can be employed anywhere in the country to other high-risk populations such as tribal populations, people living with Human Immunodeficiency Virus (HIV) etc., as a prerequisite for the costlier confirmatory diagnostic techniques such as Xpert MTB/RIF.

29. Assessment of Intestinal barrier integrity in Tuberculosis and its association with anti-TB drug levels

Principal Investigator	:	Dr. Souparnika. S
Participating Institutes	:	ICMR-NIRT, GHTM, Saveetha Institute of Medical and Technical Sciences
Source of funding	:	ICMR- Ignition grant
Study period	:	2026-2028
Pillar	:	Detect
Category	:	Development

Background:

Intestinal barrier is a functional entity separating the gut lumen from the inner host and consists of mechanical, immunological, muscular and neurological elements. Several factors can lead to damage in intestinal barrier integrity thereby altering the intestinal permeability. Prolonged antibiotic regimen and/or dysbiosis of gut microbiome inTB can compromise the barrier integrity which in turn can cause reduced drug bioavailability. Studies on intestinal permeability in TB patients are scarce worldwide, especially in India.

Primary Objective:

To compare the intestinal barrier integrity and the biomarkers of intestinal barrier integrity of PTB patients with healthy controls.

Secondary Objective:

To correlate the intestinal barrier integrity with blood anti-TB drug levels in PTB patients

Methods:

This study will be conducted as a prospective observational study at the Government Hospital of Thoracic Medicine (GHTM), Tambaram. The study population includes newly diagnosed PTB patients aged ≥18 years and age- and sex-matched healthy controls. A total of 132 participants will be enrolled, including 66 TB patients (33 DS-TB and 33 DR-TB) and 66 healthy controls. Screening and enrolment will be carried out using a structured questionnaire and written informed consent. Intestinal permeability will be assessed using the lactulose–mannitol sugar permeability test**.** TB cases will be evaluated before treatment initiation and after two months of therapy, while controls will be assessed once. Blood and urine samples will be collected to measure biomarkers of intestinal barrier integrity including LPS, LBP, i-FABP, ZO-1, sCD14, citrulline and Claudin-3 using ELISA, and anti-tuberculosis drug levels will be measured two hours after drug administration using LC-MS. A brief socio-behavioural assessment will capture

selected dietary, lifestyle, and stress-related factors that may influence intestinal permeability and drug absorption.

Study progress:

The study protocol is currently under review by the Institutional Ethics Committee. Recruitment of participants will begin following approval.

Translational value :

If a direct link between intestinal barrier dysfunction and reduced anti-TB drug absorption is established, targeted interventions to restore barrier integrity may improve drug bioavailability and reduce the risk of sub-therapeutic levels, drug resistance, and prolonged treatment.

30. Bioavailability of fixed dose combination of first line anti-TB drugs in patients with pulmonary tuberculosis

Principal Investigator	:	S.M.Jeyakumar
Participating Institutes	:	ICMR-NIRT, GHTM and ICH, Chennai
Source of funding	:	Intramural grant
Study period	:	2021-2024 (Extension)
Pillar	:	Treat
Category	:	Description

Background:

Fixed dose combination (FDC) of drugs is one of the methods to improve compliance and reduce errors. The rationale of FDC is that the presence of all these drugs combined in one tablet can facilitate dosage calculation, prevent prescribing errors, increases patient's acceptance and decreases pill burden. In India, FDC's are recommended for TB patients under the NTEP during daily treatment both in IP and CP. There are four weight bands for adult TB patients receiving INH, RMP, PZA and EMB (75/150/400/275mg) and 6 weight bands for children receiving dispersible FDC's (50/75/150/100) in addition to streptomycin for 2 months in the IP. No study to date has assessed the combined use of the three drugs (FDC's) for TB treatment in different weight bands, both in adults and children, which is of great clinical relevance.

Objectives:

To assess the bioavailability of RMP, INH and PZA when administered as FDC in adults and children with PTB treated in the NTEP in India.

Methods:

This study is an observational and bioavailability study, carried out at the Institute for Child Health, Egmore for children and at Government Hospital for Thoracic Medicine, Tambaram for adults. As per the sample size, 12 patients each receiving treatment under 5 different weight bands in adults and while 6 different weight bands in pediatric population, receiving ATT will be included according to the inclusion criteria, i) newly diagnosed PTB patients (both adult and children) as per the NTEP guidelines, ii) willing for blood draws and iii) adult patients or parent/guardian of pediatric patients willing to give written informed consent. On the day for PK evaluation, eligible patients will be requested to report at the hospital in the morning under fasting condition. A sample of blood (2.5ml) will be collected in a heparinised vacutainer tube, followed by

administration of anti-TB medications. The time of drug administration will be noted in the lab reception form. Blood samples (2.5 ml equivalent to half teaspoon) will be collected at 2, 4, 6, 8 and 12 hours in heparinised vacutainer tubes after drug administration. Plasma RMP, INH and PZA levels will be measured by validated HPLC methods.

Study progress:

Plasma anti-TB drug (PK) analysis of adult weight-band category is complete and the statistical analysis of PK parameters is being initiated

Recruitment is in progress for pediatric population and so far, we have recruited a total of 42 in different weight-band categories. Plasma drug measurement is yet to be initiated for this group.

A manuscript entitled "Development and validation of a HPLC-UV method for measuring ethambutol in human plasma following a derivatization procedure" is under review; J Chromatographic Science (JCS-25-063).

31. Pharmacokinetics of linezolid when administered with other second line anti-TB drugs in MDR-TB/Pre-XDR-TB Patients

Principal Investigator	:	S.M. Jeyakumar
Participating Institutes	:	ICMR-NIRT, GHTM
Source of funding	:	Intramural grant
Study period	:	2021-2024 (Extension)
Pillar	:	Treat
Category	:	Description

Background:

Drug-resistant TB (DR-TB) is more difficult to treat than drug-sensitive form and treatment options are very limited. Addition of linezolid (LZD) in the treatment regimen of DR-TB has been associated with improved treatment outcome with reduction of mortality among MDR-TB and Pre-XDR-TB patients. However, limited information is available on the pharmacokinetics of second-line drugs used in the treatment regimen of MDR-TB and Pre-XDR-TB, particularly in the Indian context. Therefore, here we plan to undertake a pharmacokinetic study of LZD and other second-line anti-TB drugs used in the treatment of MDR-TB and Pre-XDR TB.

Objectives:

1. To develop and validate methods for the estimation of linezolid (LZD) in plasma and saliva by HPLC.
2. To study the pharmacokinetics of LZD and other second-line anti-TB drugs in adult patients with MDR-TB and pre-XDR-TB patients.

Methods:

It is a prospective study, which will be carried out at GHTM, Tambaram, Chennai. The study population will be adult MDR-TB and pre-XDR-TB patients (>18y) being treated at GHTM based on the following inclusion and exclusion criteria.

Inclusion criteria: i) Bacteriologically confirmed adult MDR-TB & pre-XDR-TB

patients, ii) Treatment regimen containing LZD along with other second line drugs for minimum period of 15 days, iii) Willing for hospitalization for the purpose of the study & willing to give informed written consent.

Exclusion criteria: Patients with HIV-seropositivity, moribund, pregnant & breastfeeding women, chronic diarrhoea, liver and renal abnormalities.

On the day for PK evaluation, study participants will be requested to report at the hospital in the morning under fasting condition. A sample of blood (5mL) will be collected in a heparinised vacutainer tube, followed by administration of anti-TB medications. The time of drug administration will be noted in the lab reception form. Blood samples (5mL) will be collected at 2, 4, 6, 8 and 12 hours in heparinised vacutainer tubes after drug administration. Saliva (5 ml) will be collected from these patients at each time point of blood collection.

Study progress:

Recruitment is ongoing and 70 patients have been recruited for the PK evaluation. We completed the development and validation of a simple HPLC-UV method to quantify linezolid and other second-line anti-TB drugs both in plasma and saliva for pharmacokinetic studies. A manuscript entitled "Development and validation of a simple high-performance liquid chromatography-ultraviolet (HPLC-UV) detection method for simultaneous quantification of levofloxacin, ethionamide, moxifloxacin and linezolid in human plasma" is under review; Indian Journal of Tuberculosis (IJTB-D-25-00432).

32. Cost comparison of UniAMP sputum swab and Tongue swab UniAMP MTB for Tuberculosis in India

Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	DHR
Study period	:	2025 to 2026
Pillar	:	Detect
Category	:	Description

Background / Objective:

India carries one of the highest burdens of tuberculosis (TB) globally, necessitating rapid and affordable diagnostic technologies to improve early detection. This Health Technology Assessment (HTA) aimed to evaluate the diagnostic performance and cost implications of the UniAMP point-of-care molecular test using sputum and tongue swab samples compared with Truenat for the detection of PTB among adults in India.

Methods:

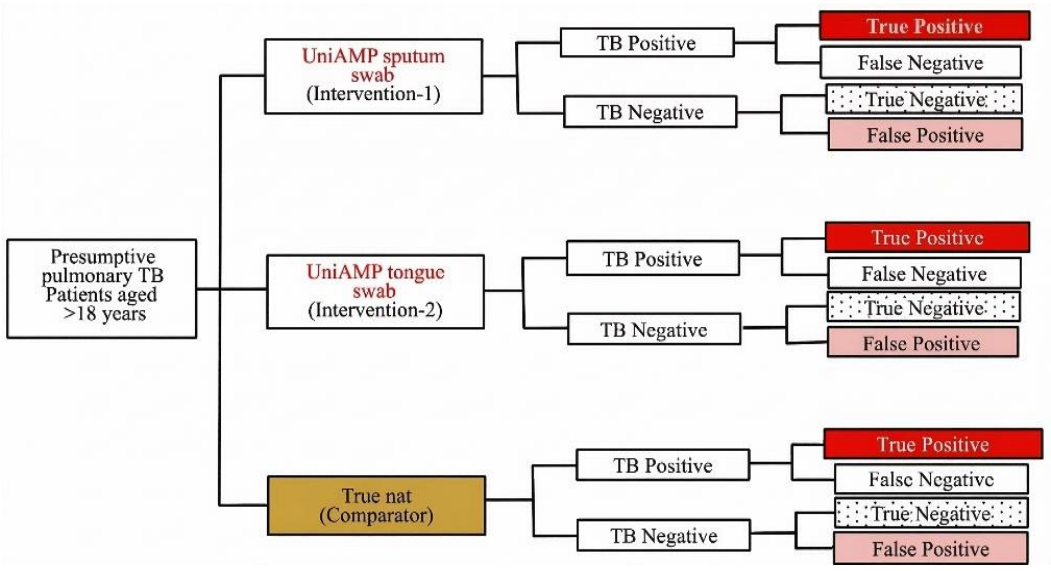
A decision-tree model was developed to compare UniAMP (sputum swab and tongue swab) with Truenat for diagnosing PTB among adults (>18 years) presenting with presumptive TB at public health facilities. The analysis was conducted from a health-system perspective, including direct diagnostic costs such as equipment, consumables, cartridges and human resource time. Diagnostic accuracy parameters (sensitivity and specificity) were obtained from published studies and

ICMR validation reports, using MGIT culture as the reference standard. A resource-based micro-costing approach estimated per-test costs under different testing volumes, with 50 tests per day used as the primary reference scenario. Model outcomes included diagnostic accuracy, number of true and missed TB cases, total costs, cost per TB case detected and incremental cost-effectiveness ratio (ICER) comparing UniAMP strategies with Truenat.

Study progress:

The preliminary HTA report has been presented at the HTA Technical Appraisal Committee (TAC) meeting. Feedback and recommendations from the committee have been received and the report is currently being revised accordingly. The study provides evidence on the potential translational value of UniAMP as a decentralized molecular diagnostic option for the National TB Elimination Programme (NTEP), particularly due to its rapid turnaround time, lower per-test cost and feasibility of using easily collected oral samples such as tongue swabs

Figure: Decision tree for UniAMP diagnostic tool



33. Cost comparison of MERINAT diagnostic platforms for tuberculosis in India

Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	DHR
Study period	:	2026
Pillar	:	Detect
Category	:	Description

Background / Objectives:

Tuberculosis remains a major public health challenge in India, necessitating rapid, accurate and affordable diagnostic technologies for early detection. Molecular diagnostic platforms have improved TB diagnosis but often involve substantial costs for large-scale programme implementation. This HTA study evaluates the cost and diagnostic performance of the MERINAT and Quantiplus molecular platforms in comparison with Truenat for TB detection in India. The objectives were to estimate and compare the per-test costs of MERINAT, Quantiplus and Truenat; assess the incremental cost and incremental diagnostic effect measured as additional TB cases detected; and examine the influence of testing volume (throughput scenarios) on per-test costs across platforms.

Methods:

This study represents a partial economic evaluation within an HTA framework focusing on resource-based costing and comparison of diagnostic costs. Facility-level resource utilisation and cost data were used, supplemented by information from published literature and manufacturer-provided sources. A resource-based micro-costing approach was applied to estimate and compare the per-test costs of the selected molecular diagnostic platforms under different testing volume scenarios. Diagnostic performance parameters were obtained from published studies using MGIT culture as the reference standard. In addition, a deterministic decision-tree model was developed using TreeAge software to compare diagnostic accuracy and associated costs across testing strategies.

Study progress:

Preliminary results indicate comparable diagnostic accuracy across platforms within WHO-recommended performance ranges. At a testing volume of 50 samples per day, the estimated per-test costs were ₹245 for Quantiplus, ₹342 for MERINAT and ₹834 for Truenat. Base-case analysis for 1,000 presumptive TB cases suggests substantial cost savings with MERINAT and Quantiplus compared with Truenat. The modelling analysis estimated total costs incurred and the number of true positive and true negative TB cases detected across strategies. The findings provide evidence to inform diagnostic procurement and potential adoption of cost-efficient molecular platforms within the National TB Elimination Programme

Table: Cost per test with a volume testing of about 50 patients/day

Test kit	Consumable including kit (₹)	All other costs (₹)	Cost per test (₹)
MERINAT	286	56	342
Quantiplus	189	56	245
Truenat	770	64	834
GeneXpert	1292	95	1387

34. Cost effectiveness of Nicotine replacement therapy, Bupropion and Varenicline vs Placebo for smoking cessation in people who smoke tobacco

Site Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	DHR
Study period	:	2025 to 2026
Pillar	:	Treat
Category	:	Description

Background / Objectives:

Tobacco smoking remains a major cause of preventable morbidity, mortality, and economic burden in India. Although tobacco control policies and cessation services exist, sustained quit rates remain low and there is limited context-specific economic evidence to guide public investment in pharmacological smoking cessation therapies. Nicotine replacement therapy (NRT), bupropion SR, and varenicline are evidence-based pharmacotherapies recommended internationally; however, their cost-effectiveness within the Indian public health system has not been formally evaluated. This HTA aims to evaluate the cost-effectiveness of NRT, bupropion SR, and varenicline compared with placebo or usual care for smoking cessation among people who smoke tobacco in India, measured as incremental cost per quality-adjusted life year (QALY) gained from a health-system perspective. A secondary objective is to estimate the budget impact of scaling up pharmacological smoking cessation therapies within public sector health services in India over a five-year horizon.

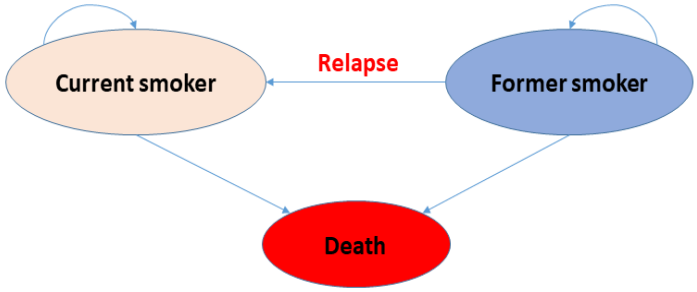
Methods:

The analysis will be conducted from a public payer perspective using a lifetime time horizon, with health outcomes expressed in QALYs. A hybrid decision-analytic modelling framework will be used, comprising a short-term decision tree capturing treatment initiation, adherence, and smoking cessation outcomes during the first year, followed by a long-term Markov model projecting lifetime costs and health outcomes according to smoking status (current smoker versus former smoker). The ICERs and incremental net monetary benefit (INMB) will be estimated and assessed against a willingness-to-pay threshold of one-time GDP per capita.

Study progress:

A hybrid decision-analytic model integrating a decision tree and Markov structure has been developed. Clinical effectiveness parameters will be derived from systematic reviews and network meta-analyses, while cost inputs will be sourced from Indian costing databases and published literature. The study will generate an HTA report and policy brief to inform decisions on integrating pharmacological smoking cessation therapies into national tobacco control programmes.

Figure: Markov model



35. Costing of Health Services in India (CHSI) 2.0: Collection of Hospital-wise and Speciality-wise Claims Data from PM-JAY Empanelled Private Hospitals in Chennai and Thiruvallur Districts, Tamil Nadu CHSI 2.0

Site Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT, & PGIMER
Source of funding	:	DHR
Study period	:	Jan to July 2026
Pillar	:	Treat
Category	:	Delivery

Background / Objectives:

Reliable cost data are essential for strategic purchasing and price setting under publicly financed health insurance schemes in India such as Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB PM-JAY). The earlier Costing of Health Services in India (CHSI 1.0) study generated unit cost estimates for selected services but did not cover several important specialties and diagnostic services. CHSI 2.0 aims to address these gaps by estimating the cost of delivering medical and surgical procedures across ten high-priority specialties, as well as radiological and laboratory diagnostic tests, in public and private hospitals across India. The study also aims to update Health Benefit Package (HBP) costs from CHSI 1.0 by incorporating the actual cost of diagnostics, assess variations in costs based on patient-level characteristics, and examine differences between estimated costs and current bundled package prices under AB PM-JAY. Additionally, the study will explore private provider perspectives on the adequacy of current reimbursement rates.

Methods:

A comprehensive costing study will be conducted in secondary and tertiary public hospitals and private healthcare facilities across fourteen Indian states to ensure geographic and health system diversity. A standardized mixed-method costing approach combining top-down and bottom-up methods will be used to estimate unit costs of services, procedures, and diagnostic tests. Data will be collected on resource utilization, capital and recurrent costs, and patient-level characteristics. Updated estimates of health benefit package costs will be generated by incorporating diagnostic costs and adjusting capital and variable

costs for inflation and technological changes.

Study progress:

The training for data collection was completed. We have requested state government and hospitals for data collection, after the approvals, the data collection will be initiated. The findings will contribute directly to revising package prices under AB PM-JAY, strengthening the National Health System Cost Database, and supporting evidence-based tariff setting and health financing policies.

Table: District-wise list of selected hospitals & specialities for CHSI 2.0 in Tamil Nadu

District	Hospitals/ Speciality	Gastroenterology	Nephrology	Neurology/ Neurosurgery	Medical Oncology	Radiation Oncology	Surgical Oncology
Chennai	Cancer Institute (WIA), Adyar			✓	✓	✓	✓
Chennai	Voluntary Health Services (VHS) Hospital,		✓	✓	✓		✓
Chennai	Billroth Hospitals, Shenoy Nagar	✓	✓		✓	✓	
Chennai	Kauvery Hospital, Alwarpet	✓	✓	✓		✓	
Tiruvallur	ACS Medical College and Hospital		✓				✓

36. Cost-effectiveness of plasma exchange (PLEX) treatment for rodenticide poisoning cases (Yellow Phosphorous) with severe liver injury in Tamil Nadu

Site Principal Investigator : Dr. M. Muniyandi
Participating Institutes : ICMR-NIRT, ICMR-NITVAR, Pune
Source of funding : DHR
Study period : 2025 to 2026
Pillar : Treat
Category : Description

Background / Objectives:

Rodenticide poisoning is a significant public health concern in India and is associated with high mortality, prolonged hospitalisation and substantial treatment costs. Among the commonly used rodenticides, yellow phosphorus (YP) compounds are a major cause of acute hepatotoxicity and acute liver failure (ALF). Management is largely supportive, and severe cases often require intensive care. PLEX has been proposed as an adjunctive therapy to reduce systemic toxicity and improve survival in patients with severe poisoning. This HTA aims to evaluate the cost-effectiveness of PLEX as an adjunct to standard medical treatment (SMT) compared with SMT alone in the management of YP rodenticide poisoning in India. The study also aims to assess the cost-effectiveness of PLEX among patients with severe liver injury in Tamil Nadu and estimate the additional budget required for the potential implementation of PLEX.

Methods:

A deterministic decision-analytic model was developed to compare PLEX plus standard medical treatment with standard

medical treatment alone over the defined analytical time horizon. The model incorporated direct medical costs and health outcomes expressed as mortality and QALYs. Cost inputs were derived from hospital-based resource utilisation and published literature. ICERs were estimated using cost per QALY gained and cost per death averted as outcome measures.

Study progress:

In the base-case analysis, PLEX was associated with improved health outcomes but higher overall costs compared with SMT alone. The intervention resulted in an incremental gain of 3.77 QALYs and 0.179 deaths averted, with an additional cost of ₹3,004.53 per patient. The estimated ICERs were ₹797 per QALY gained and ₹16,785 per death averted, indicating favourable cost-effectiveness. The study has been completed and the outcome report was presented at the Technical Appraisal Committee meeting. Recommendations from the committee have been incorporated, and the revised report has been submitted

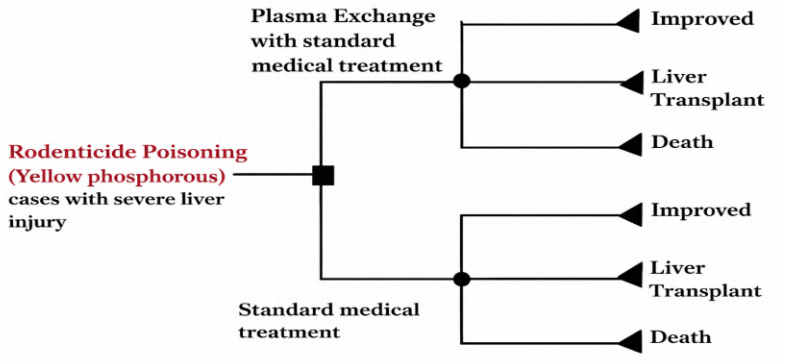


Figure: Decision tree model of plasma exchange treatment for rodenticide poisoning

37. Lifestyle Interventions to Prevent or Delay the Onset of Polycystic Ovary Syndrome among Adolescent Girls: A Systematic Review and Meta-analysis

Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT, Technical Resource Centre, New Delhi
Source of funding	:	NA
Study period	:	2025 to 2026
Pillar	:	Treat
Category	:	Development

Background / Objectives:

Polycystic ovary syndrome (PCOS) is a common endocrine disorder among women of reproductive age and is associated with metabolic disturbances, infertility risk, and long-term health complications. Evidence indicates that many cases originate or become clinically apparent during adolescence, a critical period for prevention. In India, the prevalence of PCOS among adolescents is substantial and coincides with a rising burden of overweight and obesity, increasing future metabolic risk. Although lifestyle modification is recommended as

first-line management for PCOS, evidence on its role in **the** primary prevention or delay of PCOS onset among adolescents remains limited. This systematic review aims to evaluate the effectiveness of lifestyle interventions in preventing or delaying the onset of PCOS among adolescent girls aged 10-19 years. Secondary objectives include assessing the impact of different intervention types (dietary, physical activity, behavioural or multi-component), examining differences between general adolescents and those at risk of PCOS, and evaluating changes in metabolic and reproductive risk markers.

Methods:

A systematic review and meta-analysis will be conducted using a predefined protocol. The population includes adolescent girls aged 10-19 years, including both general populations and those at risk of PCOS. Interventions include dietary, physical activity, behavioural, or multi-component lifestyle programmes. Comparators include usual care, minimal intervention, or no intervention. Outcomes include incidence or delayed diagnosis of PCOS, metabolic risk indicators (BMI, insulin resistance, lipid profile), and gynaecological outcomes such as menstrual irregularities and ovulatory dysfunction. Eligible studies will be identified through comprehensive database searches and synthesised using meta-analytic techniques where appropriate.

Study progress:

Database searching and title-abstract screening has been completed. Data extraction is currently ongoing. The review will generate evidence on the preventive role of lifestyle interventions during adolescence and may inform school health programmes, adolescent health strategies, and clinical guidance for early PCOS risk reduction in India.

38. Effects of Bariatric Surgery on Reproductive, Metabolic, and Gynaecological Outcomes in Women with Polycystic Ovary Syndrome: A Systematic Review and Meta-analysis

Principal Investigator	:	Dr. M. Muniyandi
Participating Institutes	:	ICMR-NIRT, Technical Resource Centre, New Delhi
Source of funding	:	NA
Study period	:	2025 to 2026
Pillar	:	Treat
Category	:	Development

Background / Objectives:

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder among women of reproductive age and is frequently associated with obesity, insulin resistance, metabolic disturbances, and adverse reproductive outcomes. Bariatric surgery has emerged as an effective intervention for sustained weight loss and may improve reproductive, metabolic, and gynaecological outcomes in women with PCOS. However, existing evidence is heterogeneous and dispersed across different surgical procedures and study designs. This systematic review and meta-analysis aims to evaluate the effects of

bariatric surgery on reproductive, metabolic, and gynaecological outcomes in women with PCOS compared with non-surgical management. Secondary objectives include comparing outcomes across different bariatric procedures, assessing fertility-related outcomes (ovulation, conception, live birth, miscarriage), evaluating metabolic improvements (weight loss, glycaemic control, lipid profile, insulin resistance), examining changes in menstrual regularity and hyperandrogenism, and identifying adverse events associated with bariatric surgery.

Methods:

A systematic review and meta-analysis will be conducted following a predefined protocol. Studies involving women diagnosed with PCOS undergoing bariatric surgery will be included. Comparators include lifestyle interventions and medical management such as anti-obesity medications. Outcomes of interest include reproductive outcomes (ovulation, conception, live birth, miscarriage), gynaecological outcomes (menstrual regularity, hyperandrogenism, hormonal profiles), and metabolic outcomes (weight loss, insulin resistance, glycaemic control, lipid profile). Studies across BMI categories (≥35-<40 kg/m², ≥40 kg/m², and mixed BMI groups) will be considered. Eligible studies will be identified through comprehensive database searches, and data will be synthesised using meta-analytic methods where appropriate.

Study progress:

The database search has been completed and screening of titles and abstracts is currently ongoing using the Rayyan platform. The study will generate consolidated evidence on the effectiveness and safety of bariatric surgery in women with PCOS. The findings will support evidence-based clinical decision-making and may inform clinical guidelines and policy discussions related to obesity management and reproductive health in India.

39. Decoding Bedaquiline Resistance: Mutational Profiling in Tuberculosis

Principal Investigator	:	Dr. K.R. Uma Devi
Participating Institutes	:	ICMR-NIRT; Pandit MM Malviya Shatabdi Hospital, Mumbai; IRL, Sikkim; STDC/IRL, Chennai; ICMR-RMRC, Bhubaneswar; ICMR-NIOH, Ahmedabad
Source of funding	:	ICMR -Intramural
Study period	:	2025–2028
Pillar	:	Detect
Category	:	Discovery

Background & Objectives:

Current discrepancies between phenotypic (pDST) and genotypic (gDST) drug susceptibility testing for Bedaquiline are creating diagnostic uncertainties in NTEP implementation. This knowledge gap potentially compromises treatment decisions for MDR/RR-TB patients receiving BDQ-inclusive regimens. This study aims to (1) to identify and characterize pre-treatment Bedaquiline resistance at baseline in TB patients before initiating Bedaquiline-containing regimens; (2) To identify emerging/ acquired Bedaquiline resistance in TB

patients who will receive a BDQ-inclusive regimen; (3) to establish a comprehensive genomic database for Bedaquiline resistance and its association with Minimum Inhibitory Concentration pattern and analyze its association with treatment outcomes.

Methods:

A total of 1,616 culture-positive MDR/RR-TB isolates from patients aged over 15 years receiving Bedaquiline are being collected as baseline samples. Follow-up samples will be obtained from patients remaining culture-positive beyond 3 months or during relapse between 18-24 months of treatment initiation. All isolates will undergo Minimum Inhibitory Concentration (MIC) testing against 13 anti-TB drugs, including Bedaquiline, Pretomanid, Isoniazid, Rifampicin, Moxifloxacin, Ethionamide, Linezolid, Clofazimine, Para-aminosalicylic acid, Cycloserine, Ethambutol, Levofloxacin, and Amikacin. MIC values will be systematically correlated with whole-genome sequencing data. A brief overview of the project workflow is provided in figure 1.

Study Progress:

Baseline collection, pDST and gDST (WGS) are actively underway with CRF documentation ongoing at all sites.

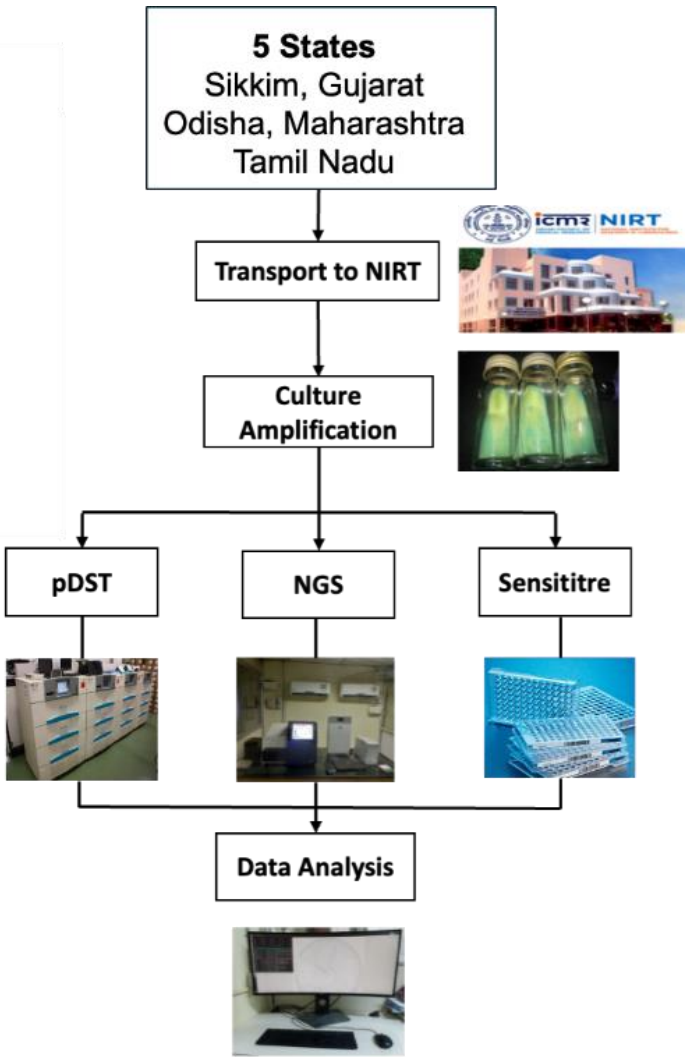


Figure 1: Project Workflow

Translational Values:

(i) Proportion of patients with baseline and acquired BDQ resistance during treatment; (ii) a catalogue of mutations associated with drugs used in BDQ-inclusive regimens; and (iii) a comprehensive genomic and phenotypic database of drug-resistant *M. tb* mutations at ICMR-NIRT.

40. Establishing TB Vaccine Immunology Laboratory (TBVIL) with International Standards and Accreditation

Principal Investigator	:	Dr. K.R. Uma Devi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Bill and Melinda Gates foundation
Study period	:	2025 - 2027
Pillar	:	Build
Category	:	Development

Background:

The aim of this proposed study is to establish a specialized facility equipped with advanced technologies and analytical tools that will essentially lead to test the efficacy and immunogenicity of TB vaccines. The initiative includes identifying and outfitting a designated area with necessary equipment, furniture, and appropriate biosafety measures to support these critical activities effectively.

Objectives:

- To establish a centralized TB Vaccinology Laboratory that aims to conduct comprehensive immune assays under one roof, advancing TB vaccine research in India.

Methods:

Phase I

- Training and development of the laboratory personnel
- Good Clinical Laboratory Practice (GCLP) certification
- Knowledge Exchange Lab Visit

Phase II

- Development of a state-of-the-art infrastructure for TBVIL
- Developing SOPs for all the proposed assays
- Validation of Regulatory and Exploratory Assays
- Development of a Laboratory Information Management System (LIMS) for data management

Study Progress:

All key milestones are in Progress. HMSC and Ethics approvals obtained and initial funding has been received. All Staff achieved GCLP certification in advanced Intracellular staining and PBMC isolation. Technical partner site visits and documentation are in progress. Ongoing efforts include SOP review, QMS development, equipment procurement and recruitment, security system establishment, sample storage setup along with upcoming assay validation, accreditation, and transition to fully operational laboratory for global clinical trials.

Translational value:

The TBVIL, a dedicated facility with cutting-edge capabilities, accelerate the validation and deployment of safe and effective TB vaccines, ultimately contributing to national and global efforts to control and eradicate tuberculosis.

41. Vitamin D regulatory *Cyp24A1* gene polymorphisms in pulmonary tuberculosis

Principal Investigators	:	Dr. Ramalingam B, & Dr. Harishankar M
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Intramural
Study period	:	2026–2028
Pillar	:	Prevent
Category	:	Description

Background & Objectives:

CYP24A1 (on chromosome 20q13.2) encodes vitamin D 24-hydroxylase, which is involved in the inactivation of vitamin D metabolites. *CYP24A1* gene variants, impact the enzyme 24-hydroxylase and potentially reducing available levels for immune response. This gene single nucleotide polymorphisms (SNPs) are associated with higher risk of vitamin D deficiency and altered metabolism, which may prone to susceptibility to tuberculosis (TB). The gene variants impact the enzyme 24-hydroxylase and potentially reducing available levels for immune response. This study aims to (1) To find out allele and genotype frequencies of Cyp27A1 in 100 healthy controls (HCs) and 100 PTB patients, (2) To correlate the association of gene variants with anti-microbial mRNA gene expressions from with and without vitamin D treated whole blood cultures.

Methods:

Genomic DNA was isolated from whole blood by a simple salting out procedure. Genotyping was performed by polymerase chain reaction followed by restriction fragment length polymorphism (PCR-RFLP) method from isolated genomic DNA of HCs and PTB patients. Allele and genotype frequencies will be calculated using SNP stats online software, to find out the protective/susceptible associations with TB. Whole blood cultures were carried out in the presence and absence of vitamin D for 48hrs and mRNA was isolated and converted into cDNA for anti-microbial gene expressions to correlate with gene variants.

Study Progress:

Genotyping and whole blood culture method optimization carried out in few samples. So far, the mRNA was isolated and converted into cDNA from 10 individuals in each group. Genotyping will be carried out from genomic DNA.

Translational Values:

(i) This study will explore susceptible/ protective genetic markers for TB protection/susceptibility and its regulation on host anti-microbial response to TB

(ii) The identified markers will be helpful for better treatment management to overcome the disease.

42. Effect of Micronutrients and Trace elements towards influencing host immune response to unfavourable treatment outcomes in tuberculosis

Principal Investigator	:	Dr. Ramalingam B.
Participating Institutes	:	ICMR-NIRT, ICMR-NIN
Source of funding	:	DBT
Study period	:	2022 to 2027
Pillar	:	Treat
Category	:	Discovery

Background

This study aims to evaluate the impact of micronutrients and trace elements towards determining treatment outcomes in PTB by comparing unfavourable TB cases with cured controls. Vitamin D is known to play an important immunomodulatory role in host defence against *Mycobacterium tuberculosis*, primarily by enhancing macrophage activity. Deficiency of Vitamin D has been associated with poor immune response and adverse TB outcomes, yet its role in unfavourable cases remains insufficiently explored.

Objectives:

The primary objective is to estimate plasma 25-hydroxy Vitamin D [25(OH) D] levels in unfavourable TB cases and cured individuals. Secondary objectives include evaluating the expression of Vitamin D-related metabolic genes such as *VDR*, *CYP27B1*, DBP, *TLR2*, and *TLR4*, and assessing their role in maintenance of serum Vitamin D levels and treatment outcomes.

Methods:

This case-control study includes PTB patients categorized as unfavourable cases (treatment failure, relapse, or death) and cured controls. Plasma samples were used for Vitamin D estimation (Cases n= 36; Cured Controls n= 47) and Tempus RNA tubes (Cases N= 25; Cured Controls N= 25) for gene expression analysis. Vitamin D levels were measured using Chemiluminescence Immunoassay (CLIA-iFLASH YHLO 1800) whereas Gene expression analysis will be performed using real-time PCR (QuantStudio 5-Applied Biosystem) following RNA extraction and cDNA synthesis, with relative quantification by the ΔΔCt method.

Study progress:

Currently, Vitamin D estimation has been completed and statistically analyzed using GraphPad Prism. Gene expression analysis is in process. The study is expected to identify associations between Vitamin D deficiency, altered gene expression, and unfavourable TB outcomes, thereby contributing to prognostic biomarker development. The trace elements will be measured through Inductively coupled plasma mass spectrometry, *(*ICP-MS) and Atomic Absorption Spectrometry (AAS).

Translational value:

The study findings can generate enough evidences to provide Vitamin D as a supplement for the TB patients and to understand the mechanism behind the vitamin D metabolism towards immune protection for TB, thereby improving patient outcomes and reducing disease burden.

43. Molecular Profiling of Inflammatory markers among individuals with Latent TB infection

Principal Investigator	:	Dr. B. Ramalingam
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR -Intramural
Study period	:	2024–2027
Pillar	:	Detect
Category	:	Discovery

Background & Objectives:

Latent Tuberculosis Infection (LTBI) is an asymptomatic state marked by immune containment of *M.tb* but may involve persistent low-grade inflammation. Interferon-gamma release assay (IGRA) widely used for LTBI diagnosis, cannot distinguish latent infection from active disease and do not reflect inflammatory or immune activation status. Therefore, identification of complementary biomarkers is needed to better characterize immune responses in LTBI. The study therefore aims: 1) To profile the inflammatory molecules among individuals with latent TB infection. 2) To evaluate the levels of trace elements and micronutrients associated with inflammation in Latent TB. 3) To analyze the miRNAs that are differentially expressed between LTBI+ and LTBI- group.

Methods:

A total of 84 participants are recruited and are categorized into two groups (LTBI+ & LTBI−) based on IGRA. For each participant, detailed demographics, vital parameters, and medical history are obtained through a structured questionnaire, and they are followed over time. At each time point, heparinized blood is collected from the study participants, PBMCs and plasma are isolated. Classical biochemical and hematological parameters are also estimated for every individual. Followed by miRNA isolation, miRNA expression profiles are analyzed using NanoString technology. Nutritional biomarkers such as serum Zn, Fe, Se, and Mg are also being estimated for all samples.

Study Progress:

We have successfully completed baseline participant enrolment and baseline demographic and clinical data have been collected in accordance with the approved protocol. Scheduled follow up at 6^{th}, 12^{th} and 18^{th} month time points are currently ongoing. At baseline, hematological parameters and biochemical parameters like CRP, albumin and total protein were analysed between the study groups. Circulating proteins like Complement C3, RBP-4, Haptoglobin, MBL, α1 Acid glycoprotein, α2 macroglobulin, VCAM-1, ICAM-1, procalcitonin, L-selectin and chemokines (Eotaxin, GRO-α, IP-10, IL-8, MCP-1, MIP-1α, MIP-1β, RANTES) were quantified using ELISA and multiplex assays to characterize the immunological profile of the LTBI. We have found a significant difference in the levels of Complement C3 protein and α2 macroglobulin between the study groups. During follow up, a subset of participants was found to have reverted to LTBI- status. Data from these individuals are particularly valuable as they provide

insight into dynamic changes in immune markers over time. Comprehensive statistical analysis will be undertaken once all follow-up data are available. Conclusion will be drawn upon completion of all follow-up visits.

Translational Values:

(i) By identifying differential expression of circulating proteins such as complement components and acute-phase reactants, the study contributes to the discovery of potential biomarkers for LTBI stratification. (ii) The longitudinal design, with follow-up at 6, 12, and 18 months, enables the identification of dynamic immune changes, especially in individuals who revert from LTBI-positive to LTBI-negative status.

44. Estimation of Risk Associated with Zoonotic Tuberculosis in South India (ERAzTB)

Principal Investigator	:	Dr. P.Kannan
Participating Institutes	:	ICMR-NIRT, Penn state University USA, CMC Vellore, TANUVAS, CisGEn, Chennai
Source of funding	:	NIH, USA
Study period	:	2025 to 2029
Pillar	:	Prevent
Category	:	Description

Background / Objectives:

Zoonotic tuberculosis (zTB), caused by animal-adapted members of the *Mycobacterium tuberculosis* complex (MTBC), has been recognized as a potential contributor to human TB In India. As close human–animal, interactions are common and bovine tuberculosis (bTB) is endemic in certain livestock systems, understanding the epidemiologic relevance of animal–human MTBC transmission remains an important One Health priority.

Methods:

Case–control study to identify risk factors associated with zTB among humans**.**

Study progress:

Cattle from households of consenting TB cases and controls were screened for bTB using a commercial interferon-gamma release assay (IGRA) (BOVIGAM™, Prionics). This in vitro blood assay quantifies IFN-γ production following stimulation with bovine purified protein derivative (PPD).

Translational value:

The project will generate robust evidence on key risk factors—such as livestock exposure, occupational practices, and consumption of unpasteurized dairy products—thereby supporting targeted public health interventions and behavior change strategies.

45. Characterisation of Immune Responses in Tuberculosis Associated Chronic Obstructive Pulmonary Disease

Principal Investigator	:	Dr. N. Pavan Kumar
Participating Institutes	:	ICMR-NIRT, ITM Chennai, RGGGH Chennai
Source of funding	:	ICMR Intramural
Study period	:	2025 to 2026
Pillar	:	Prevent
Category	:	Description

Background / Objectives:

Pulmonary tuberculosis is a risk factor for COPD, resulting in persistent airflow limitation and impaired lung function. Post-TB COPD follows a similar pathological pathway, with many patients experiencing severe lung function impairment. Our study aims to to characterize circulating immune biomarkers and TB antigen–specific innate and adaptive immune responses in TB-associated COPD (TOPD) and compare them with smoking-associated COPD (COPD-C) and healthy controls

Methods:

The study team enrolls consecutive patients from respiratory clinics meeting inclusion criteria for TOPD, COPD-C, and controls. TOPD includes patients with prior PTB who later develop COPD, while COPD-C includes smokers diagnosed with COPD. Inflammatory and immune activation markers in blood samples are measured using multiplex ELISA and flow cytometry.

Study progress:

To date, we have enrolled 97 participants in the study, comprising COPD-C (n=35), TOPD (n=47), and healthy controls (n=14). We have completed ex vivo immunophenotyping of memory T cells, monocyte subsets, and dendritic cells, and have also quantified circulating levels of inflammatory and lung-associated markers to assess immune and pulmonary function.

Translational value:

This study has significant public health relevance due to the impact of post-TB sequelae, and a better understanding of the immunological links between TB and COPD may help develop therapies to reduce disease burden and improve quality of life.

46. Metabolites, Inflammation, Type 2 Diabetes Mellitus and Tuberculosis Patients

Principal Investigator	:	Dr. N. Pavan Kumar
Participating Institutes	:	ICMR-NIRT, Saint Louis University School Medicine, USA
Source of funding	:	RePORT International Consortium, NIH-NIAID, CRDF Global
Study period	:	2025 to 2027
Pillar	:	Prevent
Category	:	Description

Background / Objectives:

Limited information exists on immune responses to *M.tb* infection in individuals with type 2 Diabetes Mellitus (T2DM). T2DM increases susceptibility to TB and is associated with more severe disease and poorer outcomes, including mortality. This study aims to investigate how hyperglycemia-driven metabolic changes promote necroptosis and related inflammatory responses in TB patients with and without T2DM.

Methods:

The study will utilize pre-collected PBMCs and plasma from TB patients with and without T2DM prior to treatment to compare immune responses. Conducted in India under the RePORT consortium, it leverages well-characterized cohorts of TB cases and HHCs, along with existing epidemiological and preliminary data, to achieve the study objectives.

Study progress:

We have received plasma, PBMC, and whole blood samples (PAXgene tubes) from the ICMR-NIRT central biorepository. Using these samples, we have characterized immune responses, including monocyte-associated cytokines, activation markers, and the expression of TNF receptors and ligands. Additionally, we have assessed inflammatory immune responses and performed untargeted metabolomics profiling.

Translational value:

The proposed studies will identify factors driving macrophage necroptosis and inflammation in T2DM patients with TB; however, a deeper understanding of necroptosis-mediated immune pathology is crucial for developing effective preventive and therapeutic strategies.

47. An affordable and easy-to-use optical biosensor for mannosylated lipoarabinomannan M.tb LAM in urine for TB diagnosis

Principal Investigator	:	Dr. N. Pavan Kumar
Participating Institutes	:	ICMR-NIRT, IIT-Madras
Source of funding	:	Intramural
Study period	:	2025 to 2026
Pillar	:	Detect
Category	:	Discovery

Background / Objectives:

While diagnosis of PTB is relatively easier on the basis of symptoms and several diagnostic kits based on sputum analysis, Extrapulmonary TB (EPTB) diagnosis is of a big concern due to several reasons including the lack of established biomarkers in serum or urine that can confirm the infection and a lack of sensitive diagnostic kits. It is anticipated that LAM cannot be detected in urine samples of HIV negative TB patients because of its low abundance, possibly due to formation of complexes with host antibodies. This study aims to evaluate a plasmonic fiber optic absorbance biosensor (P-FAB) using urine samples from

suspected TB patients, with M. tuberculosis culture as the gold standard.

Methods:

A cross-sectional pilot study to determine the test accuracy (sensitivity and specificity) of the P-FAB test for TB detection in patients with microbiology confirmed PTB in comparison to the conventional reference standard. A total of n=100 samples will used for this pilot study which includes n=50 TB samples and n=50 healthy community controls samples

Study progress:

The device validation process is currently underway. Upon successful completion of validation, clinical urine samples from suspected TB patients will be systematically analyzed using the P-FAB device to assess its diagnostic performance and reliability.

Translational value:

This study will evaluate the effectiveness of a urine-based P-FAB assay for tuberculosis diagnosis, providing a non-invasive diagnostic approach. The findings may help improve the TB diagnostic care cascade and support better patient management and early detection.

48. Immunometabolomics in the quest for comprehending protection and pathogenesis in tuberculosis

Principal Investigator	:	Dr. M. Madhan Kumar
Participating Institutes	:	ICMR- NIRT, Vellore institute of technology (VIT), Vellore
Source of funding	:	ICMR extramural
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Discovery

Background & Objectives:

Metabolic activity shapes immune cell fate, and its disruption compromises immune function, highlighting the importance of immunometabolism in pathogen clearance. No studies have comprehensively addressed glycolysis, TCA cycle, oxidative phosphorylation, and fatty acid metabolism in TB and their associated signaling and immune responses. This study aims to: (i) Compare metabolic patterns in CD4+ cells, CD8+ cells, and monocytes with/without metabolic inhibitors between PTB and latent TB (LTBI). (ii) Analyze altered molecular signaling pathways in these cells under metabolic inhibition in PTB and LTBI (iii) Evaluate metabolic/signaling-dependent immune alterations in these cells in PTB vs. LTBI.

Methodology:

To examine metabolic regulation, purified CD4+, CD8+, and monocytes (via MACS from study subject PBMCs) were treated with metabolic inhibitors (2-DG, Oligomycin, Etomoxir, C75) to analyze metabolite changes via LC-ESI-MS untargeted metabolomics. Simultaneously, PBMC subsets (n=3/group) were studied by flow cytometry to evaluate cytokines,

proliferation, and Treg populations following inhibitor treatment. To assess the impact on killing Mycobacterium smegmatis, THP-1 cell lines and infected monocyte-derived macrophages (MDM, from NHS, PTB, LTBI groups) were treated with inhibitors, followed by CFU quantification. Finally, signaling mechanisms were investigated through western blot analysis of metabolism-related proteins (Sirtuin-1, Akt, mTOR, FOXO) and RNA expression studies were done on inhibitor-treated purified CD4+. CD8+ cells.

Study progress:

Metabolites from 2DG/Oligomycin-treated CD4+ cells (HC) and untreated PTB cells were analyzed. Inhibitor treatment increased metabolites (LPC, LPE, Arginine, DL-Norleucine) related to glycerophospholipid, amino acid, and fatty acid oxidation, which are known to be toxic to *M.tb* or enhancement of immune response. Ongoing studies with PTB and LTBI samples are investigating this metabolic reprogramming. Western blots showed 2DG and Oligomycin downregulate FOXO-1, suggesting reduced immune suppression and increased inflammation. mTOR expression decreased but was maintained, while Akt and Sirt-1 remained stable. Flow cytometry showed 2-DG and Etomoxir decreased Treg levels compared to LTBI. Further studies are exploring additional markers (IL-4, IL-2, TNF-α, IL-17) and memory markers. Preliminary results suggest 2-DG and Etomoxir enhance host protection against TB. Metabolomic studies have also shown that both 2-DG and Oligomycin were able to enhance anti-mycobacterial metabolites in CD4+ T cells. When compared to Oligomycin, many of the metabolites enhanced by 2-DG in CD4+ cells of HC were associated with mycobacterial toxicity.

Translational Potential:

The targeting of specific metabolic pathways and the associated desired immune response deduced from this study will help in designing host-directed therapies for enhancing the host immune response.

49. Gold Standard Datasets on Tuberculosis with radiological Images

Principal Investigator	:	Dr C Ponnuraja
Participating Institutes	:	ICMR- NIRT, IISc Bengaluru
Source of funding	:	ICMR
Study period	:	2024 to 2027
Pillar	:	Detect
Category	:	Development

Background / Objectives:

Tuberculosis (TB) remains a major public health challenge in India, necessitating high-quality, standardized datasets to support advanced research, AI development, and evidence-based decision-making. However, much of the available clinical and radiological TB data remains fragmented and paper-based, limiting its utility for large-scale analysis. To address this gap, the project “Gold Standard Datasets on Tuberculosis with Radiological Images” was initiated to develop a comprehensive, structured, and interoperable dataset integrating both clinical and imaging data.

Methods:

Paper-based records from multiple sources, including clinical main registers, treatment registers, CRFs and treatment analysis cards, are being systematically digitized using standardized data capture formats. To date, approximately 1.11 lakh clinical records and ~9,000 treatment records have been digitized. In parallel, ~50,000 chest X-ray images have been collected from multiple sites, including the ICMR-National Institute for Research in Tuberculosis and its subcentres. A structured dataset framework is being developed through iterative consultation with clinical and research experts, with technical guidance from the Indian Institute of Science. Variable definitions are being standardized, and a TB-specific ontology is under development based on multiple biomedical ontologies to ensure consistency, reduce redundancy, and enhance data interoperability.

Study Progress:

Significant progress has been made in strengthening the foundation for the Gold Standard TB Dataset with Radiological Images initiative. Standard Operating Procedures (SOPs) were developed for uniform data structuring, annotation, and metadata documentation to ensure compliance with FAIR (Findable, Accessible, Interoperable, and Reusable) principles. These SOPs provide a standardized framework for dataset preparation and facilitate consistency across all participating data streams. During implementation, challenges such as heterogeneity in data formats, variable imaging resolutions, and inconsistencies in legacy records were identified. These issues were addressed through the adoption of standardized data templates, pre-processing protocols, and harmonized workflows to improve dataset quality and comparability. In parallel with dataset strengthening activities, work has been initiated on developing National Technical Guidance on Use of AI in TB. Simultaneously, efforts are underway to consolidate and standardize key variables relevant for AI-based tuberculosis analytics.

50. Pan-India antigenic characterization of dengue viruses: Early warning signal for a potential pandemic

Principal Investigator	:	Dr. Provash Sadhukhan, Scientist F, ICMR-NIRBI, Kolkata Co-PI at ICMR-NIRT: Dr. Luke Elizabeth Hanna
Participating Institutes	:	1. ICMR-NIRBI, 2. ICMR-NIRT, 3. ICMR HQ, 4. ICMR-NIV, 5. ICMR-NARFBR, 6. ICMR-RMRCNE, 7. ICMR-RMRC , 8. ICMR-NIIRNCD, 9. ICMR-NIRTH
Source of funding	:	PMABHIM
Study period	:	2023-2026
Pillar	:	Build
Category	:	Discovery

Background:

Vector-borne flaviviruses (especially Dengue, JE and Zika) have an epidemic potential given the endemicity of flaviviruses in India and their peculiar immunopathogenesis. This study aims to establish a network of laboratories across India that can undertake antigenic characterization of dengue viruses on a rolling basis so to provide an early warning signal in real-time.

Objectives:

1. To analyze the antigenic characteristics of dengue viruses circulating in the local populations and to evaluate their immunological relatedness with the vaccine strain.
2. To develop spatio-temporal antigenic maps on real-time basis to indicate the antigenic evolution of dengue viruses across India.

Methods:

Blood samples are collected from presumptive dengue patients and infection is confirmed using Non-Structural Protein 1 (NS1) serology. Environmental data such as temperature, humidity, and rainfall are collected (online) to understand factors affecting vector survival, especially during outbreaks. Dengue-positive samples are identified and serotyped using RT-PCR. Genetic diversity of the envelope and pre-membrane genes are analyzed through nested RT-PCR and Sanger sequencing, with about 30% of samples undergoing next-generation sequencing for deeper analysis. Standardization of PRNT is currently being done to understand the antigenic characterization of the cultured dengue strains.

Study Progress:

A total of 1209 samples have been collected till date, of which 248 were NS1 positive and all were serotyped. DENV1 was the most common serotype (66), followed by DENV2 (50). Out of these, 39 were amplified using NGS. Sixteen samples have been amplified for Pre-membrane and Envelope genes (5 DENV1, 6 DENV2, 3 DENV3, and 2 DENV4) and sequenced. Viral culture of the serotyped samples in C6/36 and Vero cell lines is ongoing for future PRNT assays.

Translational value:

Spatio-temporal antigenic maps developed as part of this study will be used to measure / augment the efficacy of Dengue vaccines currently under development.

51. An integrative approach to biomarker discovery and validation for development of point-of-care tests for TB

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Intramural
Study period	:	2023-26
Pillar	:	Detect
Category	:	Discovery & Development

Background/Objectives:

The dynamic spectrum of tuberculosis (TB) often results in underdiagnosis, warranting the need for better diagnostics to accurately detect *M.tb* in persons with asymptomatic, paucibacillary and EPTB, and to identify individuals at high risk of developing TB disease early so that they are can be managed appropriately. This study aimed to optimize and evaluate the utility of a dual target-based digital droplet PCR (ddPCR) assay to detect circulating cell-free *M.tb* DNA in plasma of individuals at high risk of developing TB disease and in those lacking a clear diagnosis of TB (asymptomatic or clinically diagnosed TB).

Methods:

Forty-six healthy HHCs of patients with PTB who developed TB within two years of follow-up (Progressors), and 92 HHCs who did not progress to TB (Non-progressors) were included in the study. Plasma was obtained and subjected to testing using a ddPCR assay targeting two *M.tb*-specific insertion sequences, IS6110 and IS1081. Sensitivity, specificity, and ROC curves were used to assess the diagnostic performance of the test. Sensitivity of ddPCR assay in detecting *M.tb* ccfDNA in subclinical and clinically diagnosed TB cases is given in the below table (Table 1).

Translational potential:

The dual target-based ddPCR assay demonstrates strong potential for clinical translation as a non-sputum-based, highly sensitive diagnostic tool. Its ability to detect TB in asymptomatic individuals, paucibacillary cases, and extrapulmonary presentations, even several months prior to clinical diagnosis, positions this assay as a valuable adjunct for early disease detection and risk stratification. Patent has been filed and a licensing agreement was signed by ICMR with 2 companies, J. Mitra & Co. Pvt. Ltd., and Meril Diagnostics Pvt. Ltd. on 13th November 2025 for technology transfer and commercialization.

Table 1: Sensitivity of ddPCR assay in detecting *M.tb* ccfDNA in subclinical and clinically diagnosed TB cases

Outcome	No of samples at the time of TB break down	IS6110&IS1081				IS6110				IS1081			
		Positives detected (N)	Sensitivity % (95%CI)	Specificity % (95%CI)	AUC (95%CI)	Positives detected (N)	Sensitivity % (95%CI)	Specificity % (95%CI)	AUC (95%CI)	Positives detected (N)	Sensitivity % (95%CI)	Specificity % (95%CI)	AUC (95%CI)
Confirmed PTB	21	18/21	85·7 (65·4-95·0)	97·8 (92·4-99·6)	0·92 (0·83-1·00)	16/21	76·2 (54·9-89·4)	100·0 (96·0-100·0)	0·88 (0·77-0·99)	10/21	47·6 (28·3-67·6)	97·8 (92·4-99·6)	0·73 (0·58-0·87)
Confirmed EPTB	3	3/3	100·0 (43·9-100·0)	98·9 (94·1-99·9)	1·00 (0·99-1·00)	3/3	100·0 (43·9-100·0)	100·0 (96·0-100·0)	1·00 (1·00-1·00)	3/3	100·0 (43·9-100·0)	98·9 (94·1-99·9)	1·00 (0·99-1·00)
Subclinical PTB	11	10/11	90·9 (62·3-99·5)	97·8 (92·4-99·6)	0·95 (0·84-1·00)	10/11	90·9 (62·3-99·5)	100·0 (96·0-100·0)	0·95 (0·85-1·00)	4/11	36·4 (15·2-64·6)	97·8 (92·4-99·6)	0·67 (0·47-0·87)
Clinically diagnosed PTB	5	3/5	60·0 (23·1-92·9)	98·9 (94·1-99·9)	0·79 (0·52-1·00)	3/5	60·0 (23·1-92·9)	100·0 (96·0-100·0)	0·80 (0·53-1·00)	3/5	60.0 (23·1-92·9)	97·8 (92·4-99·6)	0·79 (0·52-1·00)
Clinically diagnosed EPTB	6	6/6	100·0 (61·0-100·0)	97·8 (92·4-99·6)	0·99 (0·97-1·00)	6/6	100·0 (61·0-100·0)	100·0 (96·0-100·0)	1·00 (1·00-1·00)	3/6	50·0 (18·8-81·2)	97·8 (92·4-99·6)	0·73 (0·48-0·99)

52. Dynamics, phenotype and function of myeloid derived suppressor cells (MDSC) in TB disease and treatment

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT & YRG-CARE, Chennai
Source of funding	:	Intramural
Study period	:	2024-2026
Pillar	:	Treat
Category	:	Discovery

Background:

Myeloid-derived suppressor cells (MDSC) are a heterogenous population of phagocytes comprising of monocytic and polymorphonuclear cells that accumulate under various pathological conditions associated with chronic inflammation. MDSCs suppress both innate and adaptive immune responses in various disease settings and are now being studied as potential targets for HDT. Although important efforts have been taken to understand the role of MDSC in tuberculosis (TB), incomplete knowledge on their differentiation, function and role in TB disease delays the clinical utilization of MDSC-based therapeutics. The present study explores the nature and function of distinct MDSC subsets in the pathophysiology of TB disease and explore their dynamics and influence on outcome during anti-TB treatment.

Objectives:

i. To determine the expansion profile of MDSC subsets (M-MDSC, PMN-MDSC, e-MDSC) in persons with TB disease and to assess changes in frequency during the course of anti-TB treatment.

ii. To evaluate the suppression of anti-mycobacterial activity by different MDSC subsets using the Mycobacterial Growth Inhibition Assay (MGIA).

iii. To investigate the role of MDSC subsets in down-regulating *M.tb*-specific T cell effector functions and to determine the mechanisms underlying this effect.

iv. To determine the contribution of MDSCs to the formation of NETs.

Methods:

Peripheral blood mononuclear cells are obtained from those with microbiologically confirmed TB patients at baseline and longitudinally at 2 months and 6 months post-treatment initiation, and from TB-negative healthy controls at baseline. MDSC subsets, T-cell subsets, and regulatory T cells are quantified using multicolour flow cytometry. T-cell function is evaluated through antigen-specific stimulation with CFP-10/ESAT-6 peptides, followed by assessment of T cell activation and cytokine production. Mechanistic studies will subsequently be performed using inhibitors of TGF-β, arginase, and iNOS pathways, with gene expression quantification by RT-PCR. All findings will be correlated with disease severity, bacterial burden, and treatment outcomes to identify potential biomarkers of TB progression and treatment response.

Study progress:

Project implementation commenced on 22 July 2024, and recruitment is currently ongoing. To date, a total of 66 participants has been screened, including 6 TB cases

and 60 healthy controls, and enrolled in the study. Immunophenotyping to determine the frequency of MDSCs, T-cell subsets, and regulatory T cells has been performed for all samples collected till date. The MDSC sorting procedure has been successfully standardized.

53. Role of Persistent Immune Activation and Systemic Inflammation on accelerated Immune Senescence and Increased Mortality in Successfully Treated and Cured TB patients

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Adhoc Scheme
Study period	:	2022-2025
Pillar	:	Treat
Category	:	Discovery

Background:

Several studies have reported significantly higher mortality rates among patients who have been successfully treated and cured as compared to the general population. Approximately 20% of post-treatment deaths in individuals with a history of TB are attributed to co-morbid conditions such as cardiovascular disease and cancer. Experimental studies have shown that TB patients exhibit increased levels of immune activation, which decrease with anti-TB therapy but do not return to the levels observed in healthy individuals, even after complete microbiological cure. We hypothesize that persistent immune activation and systemic inflammation following TB cure may lead to accelerated immunosenescence, thereby contributing to the elevated mortality observed in individuals with prior TB.

Objectives:

- To investigate the role of systemic inflammation, immune activation and immune senescence in the increased morbidity and mortality seen in successfully treated and cured TB patients.
- To analyze the extent of immune activation by assessing soluble and cellular markers of activation.
- To evaluate immunological senescence by measuring the expression of senescence markers on immune cells.
- To examine alterations in the frequency of CD4 and CD8 memory cell subsets.
- To evaluate the cytotoxic potential of terminally differentiated immune cells.
- To assess the extent of mitochondrial dysfunction and telomerase activity in immune cells.

Methods:

Cured TB cases (n=100) and healthy controls with no present or past history of TB (n=100) were included in the present study. Both groups were matched for age, sex and life style (smoking, alcohol use, etc.) Socio-demographic data, past history of TB, etc. were collected from the participants using a standardized questionnaire. Blood was collected for routine haematological and biochemical investigations. All samples were screened for :, Hepatitis B and Hepatitis C. PBMCs

were isolated and used for immunological analyses (estimation of plasma cytokine levels, frequency of immune cell subsets, beta galactosidase activity) and molecular analyses (telomere length, telomerase activity and mitochondrial dysfunction).

Study progress:

Participant recruitment has been completed. Clinical investigations have been done. Blood samples have been screened for HIV, Hepatitis B and C, and Tuberculosis. Hematological analysis and biochemical estimations have been performed. Flow cytometric analyses for apoptosis, myeloid derived suppressor cell frequencies, T cell exhaustion markers and regulatory T cells have been completed. Molecular analyses are ongoing.

54. Study of Virologic response and HIV Drug resistance (pre-treatment and acquired) in adults newly initiated on an INSTI-based first line ART regimen in a representative population from Chennai, Tamil Nadu

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT, GHTM-Tambaram
Source of funding	:	ICMR intramural
Study period	:	2022-2026
Pillar	:	Detect
Category	:	Description

Background / Objectives:

Subsequent to WHO's recommendations, the National Antiretroviral Therapy (ART) Program of India introduced dolutegravir (DTG), a drug belonging to the integrase strand transfer inhibitor/INSTI class, into the first line regimen in 2020. As use of DTG-based first-line ART is being scaled up in the country, it becomes important to conduct periodic surveys to document the emergence of drug resistance mutations to this new class of drugs that may affect population level treatment outcome. The objectives of the study are:

1) To determine the prevalence of baseline HIV drug resistance (HIVDR) in treatment-naive individuals newly initiated on first line ART.
2) To document viral suppression and emergence of HIVDR at one-year post-treatment initiation (Acquired Drug Resistance).
3) To investigate the association between viral failure and drug resistance with specific ART regimen, adherence patterns, and other demographic and clinical factors.

Methods:

This was a prospective observational study that included 200 newly diagnosed HIV-positive individuals who were newly initiated on antiretroviral therapy. Blood samples were collected from all individuals at baseline (prior to initiation of ART) and at the end of one year post-treatment initiation. CD4 counts were estimated using flow cytometry, viral load was measured using RT-PCR on the fully automated Abbott platform. HIV-1 drug resistance testing was performed using an in-house genotyping method.

Study Progress:

Among the 200 participants enrolled (median-age: 44.5 [IQR:36–52] years),

127 were males, 72 were females and one was a transgender. All individuals were started on a DTG-based regimens as per NACO guidelines. Follow-up has been completed for 109 patients. Of these, 3 (2.75%) showed virological failure at the end of one year of treatment, but the remaining 106 (97.24%) had complete viral suppression. Genotypic Drug resistance testing has been completed for the samples collected at baseline. Drug resistance genotyping is currently being done for the virological failure cases at the one-year time point.

Translational Value:

This study will provide a comprehensive insight into the virological outcome and evolution of drug resistance in HIV-infected persons put on a DTG-based first line regimen under the Indian National AIDS Control Programme.

55. Biomarker discovery through Dual RNAseq analysis of *Mycobacterium tuberculosis*-infected cells

Principal Investigator	:	Dr. V. Umashankar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Intramural
Study period	:	2024-2026
Pillar	:	Detect/Treat
Category	:	Discovery/ Development

Background/ Objectives:

The growing recognition of EPTB, wherein *M.tb* disseminates beyond the lungs to infect multiple organ systems, underscores the need for detailed investigation of host–pathogen interactions in diverse cellular environments. Cell line-based models offer a controlled, reproducible, and non-invasive platform for studying infection dynamics without the confounding effects of biological heterogeneity. Hence we have designed this study to characterize and catalogue the transcriptomic interplay between host and pathogen across different manifestations of TB, with the aim of identifying unique signatures of EPTB that may serve as novel diagnostic biomarkers or therapeutic targets.

Methods:

Four human cell lines, namely A549 (alveolar epithelial), Caco2 (colorectal epithelial-like), HEK-293 (human embryonic kidney), and THP-1 (induced macrophage), were cultured under standard conditions at 37°C with 5% CO_2. Cells were revived, sub-cultured, and infected with *H37Rv (*Laboratory derived strain of *M.tb)* and a clinical isolate at multiplicities of infection of 2:10 and 1:10. Infection was monitored microscopically, and both infected and uninfected controls were used for transcriptomic analysis. RNA extraction was performed using a hybrid approach combining manual methods and commercial kits. The extracted RNA will undergo rigorous quality control, including quantification by Nanodrop, integrity assessment through gel electrophoresis, and validation of host-pathogen RNA through RT-qPCR and

droplet digital PCR prior to downstream sequencing.

Work Progress:

1. Significant progress has been made in both computational and experimental components. Two bioinformatics pipelines, DOMNISEQ v1.0 and DOMINOANN v1.0, have been developed and validated using public datasets. A Bioprotocol on mapping strategy was published (February 5, 2025), and another manuscript on enrichment analysis is accepted and is in press. Copyright registration for DOMNISEQ v1.0 is in progress.
2. Four cell lines have been successfully infected with a laboratory and clinical strain of *M.tb*, and RNA has been extracted.
3. Optimization of dual RNA extraction is ongoing. Extracted DNA will be used for dual RNA sequencing to enable comprehensive host–pathogen transcriptomic profiling.

Translational value:

The study will help identify molecular signatures of the host-pathogen interaction in various forms of EPTB which will may be further explored for their potential to serve as targets of therapy or diagnosis of EPTB.

56. Neutrophil extracellular trap (NET) formation during pulmonary tuberculosis and diabetes co-morbidity

Principal Investigator	:	Dr. Nancy Hilda J
Participating Institutes	:	ICMR- NIRT, RGGGH, GTHTM
Source of funding	:	ICMR-Intramural
Study period	:	2024-2026
Pillar	:	Build
Category	:	Discovery

Background:

Formation of Neutrophil Extracellular Traps is a proven pathological immunological response, yet there are very few studies on NETs in tuberculosis and no studies to our knowledge on PTB-diabetes comorbidity. Conversely, in diabetes, several studies are available proving that NETs are major contributors to pathology. Hence, understanding the role and features of NETs in PTB+diabetes co-morbidity will aid in better understanding of these structures in generating immune response during the disease. Thus, we have designed this study, where we will learn about NETs in four different groups including the PTB-diabetes co-morbid group. As there is no literature available on the changes in NET formation throughout ATT, a longitudinal analysis of NET markers through treatment is being undertaken to better understand NETs. Various immune parameters and their correlation with NETs will also be studied to understand the effect of NETs during tuberculosis treatment.

Methods:

The study population comprised of healthy volunteers (n=45), PTB patients (n=45), PTB patients with Diabetes mellitus

(n=70) and those with Diabetes mellitus alone (n=45). Twelve millilitres of whole blood were collected longitudinally from the study population at four time points (baseline, 2nd month, 4th month and end of treatment). For healthy volunteers and diabetic participants, blood was collected at one time point only. Plasma and neutrophils were isolated from whole blood. A portion of the neutrophils were subjected to culture, oxidative burst and RNA isolation. From cell culture, cells were used to measure degranulation markers, culture supernatants were stored for evaluating NET markers and cytokine levels. RNA will be used to measure upregulation or downregulation of genes related to NET formation.

Study progress:

Participant recruitment began in November 2025. Recruitment of diabetic participants has been complete. Recruitment of PTB and PTB-DM cohort is about to begin in April 2026. From the recruited participants, neutrophils have been isolated and cultured for assessing oxidative burst and NET markers using flow cytometry. The supernatants were collected and stored for measuring cytokines. Data analysis through Flow jo software is ongoing.

Expected Outcome/Translational Value:

The findings of the study will help in understanding the role of neutrophil extracellular traps in the pathogenesis of tuberculosis in individuals with or without diabetes and their potential to serve as diagnostic/ prognostic biomarkers.

57 Harnessing T Cell Repertoires (TCR) and metrics of diversity and clonality for HIV vaccine development

Principal Investigator	:	Dr. Nancy Hilda J
Participating Institutes	:	ICMR- NIRT, GHTM
Source of funding	:	ICMR IAVI IIR call 2023
Study period	:	2024-2027
Pillar	:	Build
Category	:	Discovery

Background:

In CD8 T cell-based vaccine research, the increased use of computational optimization methods has made it conveniently feasible for mosaic and multivalency immunogen design approaches that try to mitigate challenges caused by HIV diversity and optimize the coverage of T cell epitopes. Furthermore, it has been shown that the ability of an epitope to induce clonally diverse T cell responses is dictated by the epitope sequence. We propose to use next generation sequencing (NGS) to assess T Cell Repertoire (TCR) sequences qualitatively and quantitatively before and after antigen challenge to sensitively delineate and characterize immunogenic conserved epitope variants within the HIV-1 gag and pol antigen. This approach will provide clonal level CD8+ T-cell characterization that is crucial for the determination of key immune responses and their immunogenic efficacy for vaccine development.

Methods:

- DNA extraction was done from Dried Blood Spot (DBS) samples using Qiagen DNA Blood Mini Kit (51106, Qiagen) following manufacturer's instructions. RNA extraction from plasma of early-infected adults was performed using Qiagen QIAamp Viral RNA Mini Kit (52904, Qiagen) following manufacturer's instructions.
- cDNA conversion of the extracted RNA was done using SuperScript™ IV First-Strand Synthesis System (18091050, Invitrogen™, ThermoFisher) as per manufacturer's instructions.
- PCR amplification of the gag region was done using nested approach (1st and 2nd round). The second-round product was electrophoresed in an agarose gel to visualise the amplicons. This was followed by gel excision of the desired band (~1500 bp length) using gel cutter tool in a Gel-doc system.
- Extraction of DNA from the cut gel was done using Qiagen QIAquick PCR Purification Kit (28104, Qiagen) as per manufacturer's instructions. Quantification of extracted DNA was performed using Thermo Fisher Nanodrop 2000 spectrophotometer.
- Sequencing of the eluted amplicon was done using Sanger sequencing method in Applied Biosystems 3500 series Genetic Analyzer.

Progress:

Gag region from 120 Early HIV Infected Individuals (EHI) individuals have been sequenced. All these sequences were analysed for HLA binding and 35 9mer peptides which could be identified by HLA molecules with 50% population coverage have been selected using NetMHCpan and IEDB tools. These peptides will be further assessed for their immunogenicity using flow cytometry.

Translational value:

The study will pave way for the design of a universally protective T cell-based vaccine against HIV infection.

58. Structural and Functional Characterisation of Antisense Protein of HIV-1

Principal Investigator	:	Dr Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2021-2027
Pillar	:	Build
Category	:	Discovery

Background:

HIV comprises an ORF in the antisense direction which codes for a protein called Antisense Protein (ASP). The goal of the present study is to characterise the protein by identifying the interacting partners, post-translational modifications and predicting the 3-D structure of the protein.

Methods:

The gene coding for this protein was cloned into pcDNA3.1 vector. Protein expression and purification were optimized using His-tag affinity column purification.

Results:

The purified protein is currently being used in *in vitro* studies for functional characterization and host protein interaction.

Translational value:

By identifying the interacting partners and post-transcriptional modifications could reveal the potential function of this protein in host-viral environment which could contribute to the development of therapeutic targets.

59. Evaluation of Immunogenicity of ChAdOx1 nCoV-19 (Covishield) Vaccine in Adults with Diabetes mellitus

Principal Investigator	:	Dr. P. L. Natarajan
Participating Institutes	:	ICMR-NIRT and RGGGH, Chennai
Source of funding	:	Intramural
Study period	:	2021-2026
Pillar	:	Prevent
Category	:	Description

Background:

Diabetic individuals infected with COVID-19 are associated with significant risk for hospitalisation, impaired anti-SARS-CoV-2 antibody response intensive care unit admission, or death. Hence this study aims to compare the immunogenicity of Covishield vaccine between healthy controls and people with diabetes.

Objectives:

To compare the kinetics of anti-spike IgG antibody, neutralising antibody responses, T follicular helper (Tfh) and B cell responses, to Covishield vaccination between healthy controls and people with diabetes.

Methods:

This was a prospective observational cohort study that recruited participants from the Rajiv Gandhi Govt. General Hospital (RGGGH), Chennai. The study included 4 groups: cohort 1 comprising of Healthy controls, cohort 2 including persons with diabetes, cohort 3 comprising of people with breakthrough infection, and cohort 4 including unvaccinated individuals with COVID-19 infection. Blood samples were collected from all participants. Complete blood count, HbA1c, frequency of follicular T cell (Tfh), B cell memory profiling, cytokine estimation, levels of anti-spike IgG antibody and neutralizing antibody responses were measured at serial time points before and after 3 doses of COVID-19 vaccine in cohorts 1 and 2, and at the time of breakthrough infection in cohorts 3 and 4.

Study progress:

The follow-up of participants has been completed. Estimation of cytokines and neutralizing antibodies is ongoing. Analysis of flow cytometry data is ongoing.

Translational Value:

If the immune cell alterations lead to decreased neutralizing antibody responses in vaccinated diabetic individuals, when compared to controls, it will add evidence for the need of additional booster doses in diabetic individuals.

60. Molecular detection of Mycobacterium tuberculosis-derived circulating cell-free DNA and validation of host transcriptomics signatures and circulating microRNAs for the diagnosis of pulmonary and extrapulmonary tuberculosis: An exploratory study

Principal Investigator	:	Dr. N. Sudhakar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR - Intramural funding
Study period	:	2024-2026
Pillar	:	Detect
Category	:	Discovery

Background:

Delayed or incomplete diagnosis increases the risk of development of multidrug-resistant TB (MDR-TB), which is harder and costlier to treat. Further, undiagnosed individuals will continue to spread TB through aerosols, especially in crowded settings. Hence there is a need for highly sensitive molecular diagnostics that can support early diagnosis of TB.

Primary objectives:

1. To detect *M.tb* derived cell-free DNA in stored plasma samples from PTB and EPTB patients.
2. To compare the sensitivity and specificity of *M.tb* derived cell-free DNA to standard culture and NAAT (GeneXpert).

Secondary objectives:

3. To validate an mRNA-based host transcriptomic signature that was previously identified by us in blood at diagnosis and during treatment in PTB and EPTB patients.
4. To analyze circulating microRNAs (miRNAs) in plasma of PTB and EPTB patients.

Methods:

The study includes smear positive or negative, microbiologically confirmed PTB and EPTB patients and non-TB controls from healthy house-hold contacts of TB patients collected in the earlier C-TRIUMPH study and stored in the NIRT biorepository. The study includes 3 groups: Group A: PTB patients [n=150], Group B: EPTB patients [n=150], Group C: Non-TB controls from healthy house-hold contacts of TB patients [n=150]. ccf DNA) was isolated from 1 ml plasma using QIAmp minelute ccfDNA extraction kit (Qiagen). *M.tb*-specific cfDNA was analyzed using droplet digital PCR using IS6110 and MPT64 gene as dual targets. Expression of FCGR1B, ANKRD22, CARD17, IFITM3, TNFAIP6, FCGBP and KLF12 that was identified by us earlier using bioinformatics analysis as biomarkers for distinguishing between active and latent TB were analyzed using qRT-PCR.

Study Progress:

Out of 110 PTB/EPTB samples, at least one target for *M.tb* specific cfDNA was detected in 47 out of 110 samples, giving a sensitivity of 42.7%. The work is in progress. The less sensitivity in detection of *M.tb* specific cell-free DNA may be due to the long-term stored (more than 10 years old) plasma samples of TB patients.

The *FCGR1B* gene was upregulated 1.177 ± 0.61-fold and *ANKRD22* gene showed upregulation of 1.829 ± 0.64-fold in distinguishing among active and LTBI.

61. Surveillance of Zoonotic Respiratory Viral Infections in animal farms from Tiruvallur District, Tamil Nadu: A model project with a focus on One Health Approach

Principal Investigator	:	Dr. N. Sudhakar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	PM-ABHIM
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Description

Background:

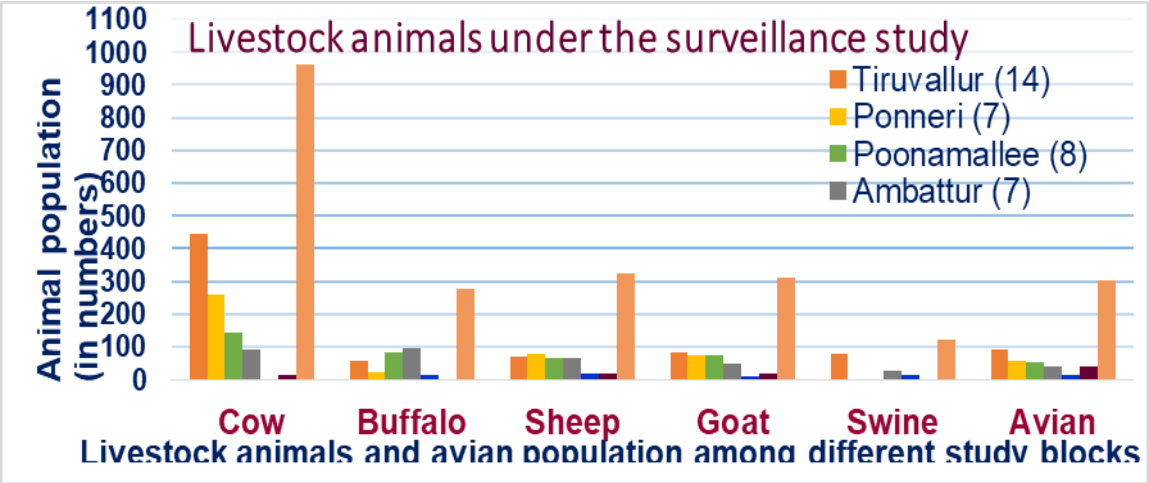
The present study aims to establish a surveillance system for zoonotic respiratory viral infections among farm animals, animal handlers, and the environment. The goal is to enable early detection of emerging and re-emerging zoonotic respiratory viral infections.

Objectives:

1. To establish a surveillance system for zoonotic respiratory viral infections among farm animals, animal handlers, and farm environment for early detection of emerging and re-emerging respiratory viral infections.
2. To identify the zoonotic respiratory viruses circulating among farm animals, animal handlers and environment in the given area and to study the effect on climate on the emergence, transmission and outcome of viral infections.

Methods and study progress:

We conducted surveillance of 42 animal farms from 6 blocks of Tiruvallur district during the last year. A total of 2304 animals were screened from these farms (Figure). Nasal swab samples were collected from 450 animals every month. The total number of animal swab samples collected were 5559. Of these, 385 swab samples were excluded from analysis.



Out of 5279 animal swab samples tested, bovine coronavirus was detected in 247 (4.67%) samples, bovine RSV in 2 samples, Parainfluenzavirus-3 in 22 samples, and SARS CoV-2 in 1 sample. A total of 272 samples (5.1%) tested positive for at least one respiratory virus. Out of 219 samples collected from animal handlers, 2 samples were positive for Influenza A, one sample for Influenza B, 4 samples for SARS CoV-2, and one sample for Influenza C. Five animal handler's samples were positive for Bovine Coronavirus (BCoV). Out of 54 air samples collected from animal farms, BCoV was detected in 04 samples. Out of these 04 samples, 02 samples were detected in both animals as wells as air samples.

Translational potential:

Routine surveillance of zoonotic respiratory viral infections in both animals and animal handlers would enable early detection of zoonotic respiratory viral epidemics and also aid in the development of molecular diagnostics and vaccines for viral pathogens of significance.

62. Early innate immune determinants of protection in tuberculosis vaccination

Principal Investigator	:	Dr. Vidya Vijayan KK
Participating Institutes	:	ICMR-NIRT, IOG Chennai
Source of funding	:	DBT Ramalingaswami fellowship
Study period	:	2025-2027
Pillar	:	Build
Category	:	Description

Background:

The proposed study focuses on understanding the unique aspect of the infant immune system at the molecular level, comprehending the multidimensionality interaction of the immune system at the DNA and RNA level to identify protective determinants of the innate immunity in Bacillus Calmette-Guérin (BCG) vaccination**.**

Objectives:

1. Understanding the molecular changes in monocytes and dendritic cells after BCG vaccination.
2. Understanding trained immunity of monocytes and dendritic cells in infants.
3. Systems biology approach for identifying signature markers and investigating molecular changes induced by BCG vaccination in monocytes and dendritic.
4. Comparing innate immune signatures of infants and BCG revaccinated adult.

Methods:

This will be a prospective longitudinal study comprising of 50 BCG vaccinated infants tested at various time points prior to and post BCG vaccination. After obtaining consent, 5ml of cord and 2 ml of peripheral blood will be collected from study participants. Whole blood and plasma of the study participants will be used for innate immune profiling and cytokine analyses and stored PBMC will be used for transcriptomics and epigenetics studies.

Study progress:

Recruitment of participants and sample collection is ongoing. Whole blood immunophenotyping and TLR expression are being done in real time. Standardization of the sequencing experiments is also being undertaken.

Translational value:

Understanding the early innate immune determinants of BCG vaccination in infants will help build and expand current knowledge on defining the molecular mechanisms of the innate and adaptive immune systems.

63. Characterizing the molecular mechanisms of Protease Inhibitor resistance in HIV-1 infected individuals

Principal Investigator	:	Mrs. Lucia Precilla K
Participating Institutes	:	ICMR-NIRT,GHTM
Source of funding	:	ICMR intramural
Study period	:	2023-2026
Pillar	:	Prevent
Category	:	Discovery

Background / Objectives:

The Protease Inhibitor (PI) class of drugs play a crucial role in the success of ART for HIV patients, by serving as key components of salvage therapy for those who fail on the initial regimen. Some studies indicate that the protease genotype does not always correlate with clinical and virological outcomes. The main goal of this study is to delineate the underlying mechanisms of PI resistance so as to understand the optimal strategies that may be employed to combat resistance to this class of drugs.

Methods:

RNA was extracted from plasma of PI-naive and PI-exposed HIV-1–infected individuals. The protease (PR) and gag genes were amplified by RT-PCR followed by nested PCR and sequenced bi-directionally using the ABI PRISM 3500 genetic analyzer. Sequences were analyzed using the Stanford HIV drug resistance database. For phenotypic assays, viral stocks were generated by infecting PBMCs from healthy donors with patient-derived plasma, followed by $TCID_{50}$ determination for viral quantification.

Study Progress:

HIV-1 protease (PR) sequencing has been completed for 113 PI-unexposed and 73 PI-exposed individuals. As protease inhibitors act as competitive inhibitors by binding to the active site of the HIV-1 protease enzyme, thereby preventing cleavage of the Gag polyprotein into functional structural proteins, these samples are currently being processed for gag gene amplification, with sequencing in progress. Furthermore, phenotypic analysis of viral fitness, infectivity, and PI susceptibility is currently being carried out for 21 samples.

Translational Value:

This study investigates the correlation between HIV drug resistance genotypes, *in vitro* phenotypes, and virologic outcomes to better understand the mechanisms underlying protease inhibitor resistance.

64. Development of a simple and affordable assay for screening of Dolutegravir (DTG) resistance in HIV-1 infected persons

Principal Investigator	:	Mr. S. Manohar Nesakumar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR intramural
Study period	:	2022-2026
Pillar	:	Detect
Category	:	Development

Background / Objectives:

Currently, HIV drug resistance genotyping is not routinely available in the national ART program due to limitations such as the absence of Sanger/NGS sequencing infrastructure and high costs. To address this, a "targeted genotyping" method using modified real-time PCR has been developed to detect drug-specific mutations, particularly for NNRTI-based regimens. In India, where subtype-C HIV prevalence is high and data on integrase inhibitor resistance is lacking, it is crucial to screen for dolutegravir resistance mutations before initiating them on a DTG-based regimen. The objectives of the present study are:

1) To develop a real-time PCR based assay for detection and identification of HIV-1 drug resistance mutations at four important drug resistance associated codons that are markers of various HIV-1 integrase class of inhibitors including Dolutegravir.
2) To design various sets of primers and probes and carry out standardization experiments.
3) To evaluate the performance of the qualified primers and probes set in the initial standardization further using synthetic templates and NGS characterized drug resistant EQAPOL QC panel samples.

Methods:

This is a laboratory assay development and validation project. Bioinformatics tools will be used for primer and probe design. Assay development will employ real time PCR and Sanger sequencing. Assay validation will employ real time PCR.

Study Progress:

Synthetic double-stranded DNA spanning codons 103–192 and 215–288 of the HIV-1 integrase gene were designed to evaluate the sensitivity and specificity of primers and probes designed for the novel qPCR-based test for detection of Integrase drug resistance mutations. Drug-resistant and wild-type codons corresponding to DRP-118, DRP-148, DRP-155, and DRP-263 were incorporated into gBlocks® Gene Fragments (Integrated DNA Technologies, IA, USA), both with and without polymorphic mutations surrounding the probe-binding regions. Various combinations of these mutations were included across 22 different gBlocks, representing both wild-type and mutant genotypes for all four drug resistance-associated codon positions 118, 148, 155, and 263 of the HIV-1 integrase gene.

These gBlock controls were constructed by incorporating multiple mutations in the probe-binding regions, based on sequence data derived from public databases, thereby reflecting clinically relevant

isolates. These DRMs confer resistance to nearly all INSTI class drugs, including Bictegravir, Cabotegravir, Dolutegravir, Elvitegravir, and Raltegravir. The study is ongoing.

Translational Value:

The project aims to deliver a rapid, cost-effective, and field-adaptable tool for HIV drug resistance surveillance and clinical decision-making within routine care settings.

65. Central Biorepository for TB Specimens - Phase II

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	DBT
Study period	:	2023-2026
Pillar	:	Build
Category	:	Development

Background:

The RePORT India Central Biorepository (CBR) was established in 2016 at ICMR-NIRT, Chennai, with support from DBT, and became fully operational in April 2017. The CBR is located in ICMR-NIRT's Tiruvallur campus (Figure 1). The CBR continues to receive, store and distribute high-quality biospecimens linked to well-characterized data to facilitate pertinent research in the field of tuberculosis.

Objectives:

1. To undertake long term storage of biological specimens of study participants enrolled and followed up at all the RePORT India Clinical Research Units.
2. To disburse archived specimens to TB researchers with protocols approved by the Executive Committee (RePORT India Consortium).
3. To implement quarterly Proficiency Testing surveys for PBMC cryopreservation to all RePORT India labs preparing PBMCs for the Consortium.

Methods:

The CBR has been receiving biospecimens from the RePORT India CRUs located in 8 Indian sites. The clinical samples received include *Mycobacterium tuberculosis* isolates, whole blood, plasma, peripheral blood mononuclear cells, serum, QuantiFERON supernatants, sputum, nasopharyngeal aspirate, gastric lavage, saliva, oral swabs, extra pulmonary specimens, urine and stool. The received samples are stored in the CBR at appropriate storage conditions after a stringent quality check. The participating labs are assessed for the quality of PBMCs for long-term storage by ICMR-NIRT's PBMC PT program which administers quarterly surveys and appropriate certification. The CBR also processes requests by researchers with required approvals for sample disbursement.

Study progress:

The CBR has been actively receiving and archiving samples under the RePORT India Phase II common protocols. The CBR has also been regularly rolling out the quarterly surveys of the in-country PBMC External Quality Assessment (EQA) program under the Central Biorepository as part of the RePORT India Phase II initiative. A total of 13 studies were supported during this period (Figure 2)

Figure 1

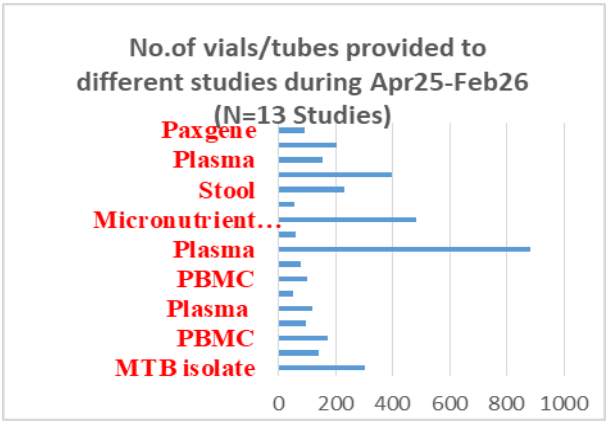


Figure 2

66. Setting up of Nation-wide Network of Laboratories for managing Epidemics and National calamities – Medical College level Virus Research and Diagnostic Laboratory (VRDL)

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	DHR
Study period	:	2021-2026
Pillar	:	Detect
Category	:	Development

Background/Objectives:

The goal of VRDL Network is to establish mechanisms and systems for dealing with outbreak infections and emerging epidemics of public health importance. As part of this initiative, ICMR-NIRT was granted a medical college level VRDL at the NIRT Tiruvallur site and was operationalized in 2024.

The objectives of this project include:

i) Creation of infrastructure for timely identification of viruses and other agents causing epidemics or morbidity significant at the public health level and specifically agents causing epidemics.
ii) Development of capacity for identification of novel and unknown viruses and other organisms, and develop diagnostic kits.
iii) Training to health professionals and Research for identification of emerging and newer genetically active/ modified agents.

Methods:

We test blood/nasopharyngeal swab samples from Tiruvallur GH and Indira Medical college, Tiruvallur for presumptive viral infections. In order to ensure quality and precision, we also participate in national level EQA services conducted by various accredited VRDLs.

Work Done:

At VRDL, ICMR-NIRT, a total of 663 samples from patients with suspected viral infections from GH, Thiruvallur, along with 12 suspected viral samples from Indira Medical College, Thiruvallur were tested during 2025–2026.

Details of EQA programme participation by VRDL, ICMR- NIRT during the reporting period is mentioned in Table 1.

Table 1: External Quality Assurance performed during 2025-2026

Assay Name	No. of Rounds	Test Type /	YEAR
Japanese Encephalitis IgM	2	Serology	2025
Hepatitis A IgM serology	2	Serology	2025
Dengue NS1 & IgM ELISA	2	Serology	2025
HSV 1 & 2 Molecular	2	Molecular	2025
Scrub Typhus IgM ELISA	2	Serology	2025
Influenza A, B, SARS-CoV-2 Panel-2	1	Molecular	2025
Dengue Molecular Serotypes Round 1	1	Molecular	2025
Chikungunya	1	Serology	2025
HSV 1 & 2 Serology	1	Serology	2025
Molecular diagnosis of ZIKA virus	1	Molecular	2026

67. Universal Viral Load Testing of all People Living with HIV across the country under NACP Phase IV extension

Principal Investigator : Dr. Luke Elizabeth Hanna
Participating Institutes : ICMR-NIRT
Source of funding : NACO
Study period : 2009- ongoing
Pillar : Treat & Prevent
Category : Delivery

Background:

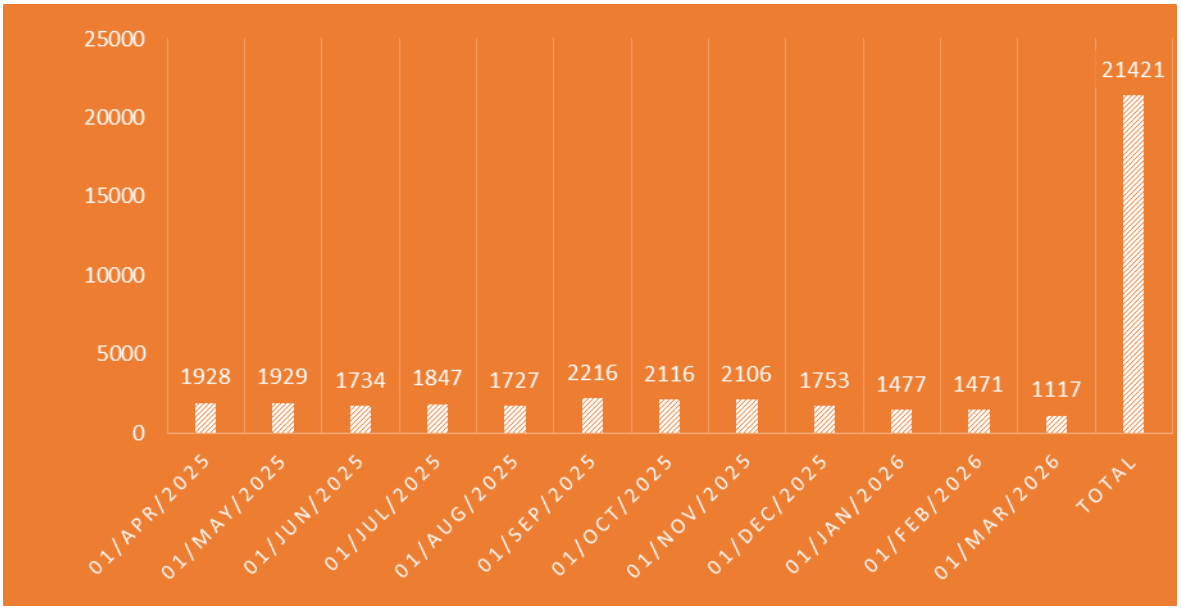
Routine viral load suppression for as long as possible is one of the key goals of antiretroviral therapy (ART). Achieving sustained viral suppression helps reduce HIV transmission and improves the quality of life of patients receiving ART. To meet this goal, it is essential for the programme to utilize the most effective monitoring tests to evaluate viral load suppression among patients on treatment. The introduction of routine viral load monitoring in the national programme aims to provide an early and accurate indication of treatment failure and to

determine the need for switching treatment regimens. This approach helps prevent the accumulation of drug resistance mutations and improves overall patient outcomes. Furthermore, it supports the measurement and achievement of the third “90” target.

Work Done:

ICMR-NIRT has been serving as a Regional Reference Laboratory for HIV-1 viral load testing for NACO since 2009 and was accredited by NABL in 2024. In the last year 21,421 samples were tested for HIV-1 viral load at the ICMR-NIRT laboratory. Month-wise break-up of the testing done is shown in Figure 1.

Figure 1: No. of samples tested for HIV-1 viral load (April 2025 to March 2026)



68. HIV-1 Early Infant Diagnosis (EID) Program

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	NACO
Study period	:	2010- ongoing
Pillar	:	Detect
Category	:	Delivery

Abstract:

HIV-infected babies are the most vulnerable of all patients with ~ mortality > 50% by age 2 in untreated patients. These patients would benefit the most from ART, but diagnosis is difficult due to the presence of maternal HIV antibodies transferred from mother to child during pregnancy, childbirth and breastfeeding. Most infants born to HIV+ mothers would test positive using standard HIV antibody tests such as ELISA or rapid tests until the level of maternal antibody falls below limit

of detection at 18 months. Thus, in infants below 18 months of age, direct detection tests for the virus have to be conducted, and the current test of choice is the HIV-1 PCR which detects HIV pro-viral DNA & RNA. Two types of infants who will need HIV diagnostic testing include infants who are HIV-exposed (mother- known HIV positive from ICTC) and infants who are sick with signs and symptoms of HIV, even if HIV exposure status is unknown.

Work Done:

ICMR-NIRT has been serving as one of the Regional Reference Laboratories in the country for the National EID program since its roll-out in 2010. The laboratory is accredited by NABL for this activity.

Table 1: Testing Details for HIV-1 TNA PCR for 2025-2026

Month/ Year	Total No. of samples tested	Detected	Not detected	Total no. of samples received for confirmatory	Tested	Detected	Not detected
Apr-25	60	1	59	1	2	2	0
May-25	95	1	94	1	1	1	0
Jun-25	70	2	68	2	2	0	2
Jul-25	103	0	103	2	1	1	0
Aug-25	74	1	73	2	2	1	1
Sep-25	102	1	101	0	1	1	0
Oct-25	73	5	68	1	1	1	0
Nov-25	94	5	89	6	4	2	2
Dec-25	146	4	142	7	8	3	5
Jan-26	75	1	74	0	0	0	0
Feb-26	76	0	76	3	3	2	1
March-2026 till 3rd week	62	2	60	2	1	1	0
TOTAL	1030	23	1007	27	26	15	11

COMPLETED STUDIES

S No.	Study Details	Category (Discovery, Development, Delivery, Description)	Pillar Prevent / Detect / Treat / Build	Outcome: Benefits/ policy changes/ implications Mention the translational value / contribution to national programme / patent technology
1.	Title: In-vitro and In-vivo studies on newly identified MDR-TB efflux pump Inhibitors. Name of PI with designation: Dr Azger Dusthackeer V.N, Scientist E Source of funding and duration: ICMR AdHoc 2023-2025	Development	Treat	Provisional Patent Application No - 202611015615.
2.	Title: Evaluation of anti-tubercular, safety and immunomodulatory activities of Unani pharmacopeial formulations (UPF) Qurs-e-TabasheerSartani and &Arq-e-Hara Bhara through in-vitro Name of PI with designation: Dr Azger Dusthackeer V.N, Scientist E Source of funding and duration: Central Council for Research in Unani medicine, 2023-2025	Discovery	Treat	The integrated methodological approach adopted in this study provided strong translational relevance for moderating PTLD wherein the study demonstrated synergistic and immunomodulatory effects of Unani formulation tested in combination with standard anti-tubercular therapy implicating its potential as an ideal host-directed adjunct therapy
3.	Title: Diagnostic evaluation of tongue swab-based tests for detection of M. tuberculosis in presumptive pulmonary TB patients	Development	Detect	The study demonstrated that the tongue swab testing would be useful in presumptive TB patients when sputum is not available

	Name of PI with designation: Dr. R. Priya, Scientist D Source of funding and duration: NIRT intramural, 2024- 2026			
4.	Title: Multicentre validation of phage lysin in comparison with MGIT PANTA to control normal flora in processed sputum specimens for rapid detection of *Mycobacterium tuberculosis* using MGIT 960 system Name of PI with designation: Dr. Balaji Subramanyam, Technical Officer-C. Source of funding and duration: ICMR-Extramural, 2023 to 2025.	Development	Detect	The phage lysin proposal is under the translational research priority of ICMR. The bacteriophages and lysin used in this study are already patented through Intellectual Property Unit of ICMR. The product Phage lysin is currently EOI for Technology Transfer through ICMR Patent Mitra for commercialization.
5.	Title: Generic Protocol for Diagnostic evaluation of index molecular test Kit (s) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis. Name of PI with designation: Dr. S. Sivakumar, Scientist E Source of funding and duration: ICMR Validation Network, 2024-2026	Development	Detect	Five technology for MTB detection was validated and Merinat and Quantiplus® assay has been approved by ICMR and taken up by NTEP as an operational research to introduce into the program
6.	Title: Sentinel drug resistance surveillance of Mycobactium tuberculosis in India. Name of PI with designation: Dr. S. Sivakumar, Scientist E	Description	Detect	The study has been completed and data analysis is ongoing

	Source of funding and duration: ICMR Extramural, 2023-2026			
7.	Title: Artificial intelligence for screening drug resistance in tuberculosis using line probe assay. Name of PI with designation: Dr. S. Sivakumar, Scientist E Source of funding and duration: ICMR Extramural, 2024-2025	Development	Detect	This AI system offers a novel, modular architecture capable of expert-level interpretation of LPA strips. The AI tool performs at par with expert readers and offers a reliable, scalable solution for LPA interpretation.AI tool adoption can reduce interpretation time, enhance result uniformity, and improve treatment delivery across India's TB programme, supporting national goals for TB elimination. This AI system offers a novel, modular architecture capable of expert-level interpretation of LPA strips. The AI tool performs at par with expert readers and offers a reliable, scalable solution for LPA interpretation.AI tool adoption can reduce interpretation time, enhance result uniformity, and improve treatment delivery across India's TB programme, supporting national goals for TB elimination.
8.	Title: Evaluate and validate a software for genomic characterization of Tuberculosis Name of PI with designation: Dr. S. Sivakumar, Scientist E Source of funding and duration: FIND India, 2024-2026	Development	Detect	The performance of ΩTB® (a Make-in-India initiative) as a TB genome analysis software has been commendable, demonstrating over 90% concordance for genotypic drug susceptibility testing (DST) of INH, RIF, STM, EMB, AMK, KM, ETH, PAS, and LZD. For further improvement we have shared recommendations for improvement

9.	Title: Multi-centric prospective cohort study of TB recurrence free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with the 4-month moxifloxacin containing daily regimen Name of PI with designation: Dr V.V. Banu Rekha, Scientist F Source of funding and duration: ICMR Task force, 2022-2025	Development	Treat	The study analysis would help generate evidence for the effectiveness of shorter 4-month moxifloxacin containing regimen in pulmonary TB.
10.	Title: Cost comparison of RT-LAMP diagnostic platforms for tuberculosis in India Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding and duration: DHR, 2025-2026	Description	Detect	The analysis demonstrates that RT-LAMP is a more cost-efficient diagnostic option compared with Truenat for TB detection, with a lower cost per test and slightly higher diagnostic yield. RT-LAMP produced a cost saving of ₹344 per test and ₹3,44,000 per 1,000 tests while detecting marginally more true TB cases. These findings suggest that RT-LAMP could be considered as a cost-saving molecular diagnostic alternative within TB diagnostic algorithms. The evidence may support policy discussions under the National TB Elimination Programme (NTEP) regarding adoption of affordable molecular diagnostics to improve case detection while reducing programme costs.
11.	Title: Cost comparison of molecular real-time PCR (RT-PCR) based diagnostic platforms for tuberculosis in India	Description	Detect	The study provides comparative evidence on the cost, diagnostic performance, and operational characteristics of molecular TB diagnostic platforms

	Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding and duration: DHR, 2025-2026			including GeneXpert, Truenat, Pathodetect, and Quantiplus. All four platforms demonstrated sensitivity and specificity within WHO acceptable limits for detecting Mycobacterium tuberculosis. However, substantial differences were observed in testing costs and operational requirements. Quantiplus showed the lowest cost per test and operational flexibility as an open RT-PCR-based kit compatible with existing laboratory infrastructure. Pathodetect provides the added advantage of detecting rifampicin and isoniazid resistance along with MTB detection. The findings can support procurement and technology adoption decisions under the National TB Elimination Programme (NTEP) to optimise resource allocation and expand cost-efficient molecular diagnostic capacity.
12.	Title: Cost comparison of GeneNAT diagnostic platforms for tuberculosis in India Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding and duration: DHR, 2025-2026	Description	Detect	The analysis shows that GeneNAT is a dominant diagnostic strategy compared with Truenat, as it provides both lower testing costs and improved diagnostic outcomes. GeneNAT reduced the cost per test by ₹106 and generated a total saving of approximately ₹1,06,000 per 1,000 tests while detecting more true positive and true negative TB cases. These findings suggest that GeneNAT could serve as a cost-saving and more efficient molecular diagnostic option for TB detection. The evidence may support

				procurement and diagnostic algorithm decisions under the National TB Elimination Programme (NTEP) to enhance TB case detection while optimizing programme expenditure.
13.	Title: Association of tuberculosis with household expenditure in hard-to-reach areas in Manipur, India Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding and duration: ICMR, 2024-2025	Description	Build	The study provides evidence on the direct and indirect costs incurred by TB patients in a predominantly PVTG population in Manipur. Findings indicate relatively low catastrophic health expenditure, likely due to early diagnosis through Active Case Finding (ACF). However, vulnerable groups such as Scheduled Tribe households, women, and residents of remote blocks experienced higher costs. The results highlight the importance of strengthening ACF strategies, improving access to services in remote tribal areas, and expanding social protection schemes under the National TB Elimination Programme (NTEP) to reduce financial hardship and health inequities.
14.	Title: Clinical efficacy of three months once-weekly Isoniazid and Rifapentine regimen for treatment of Latent TB Infection: A systematic review and meta-analysis Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding and duration: DHR, 2024-2025	Description	Prevent	The study provides consolidated evidence that the shorter 3HP regimen (3-month isoniazid plus rifapentine) has significantly higher treatment completion and comparable or lower severe adverse drug reactions compared with longer 6H and 9H isoniazid regimens. The findings support improved adherence to TB preventive therapy and potential reduction in progression from latent TB infection to active TB. This evidence reinforces global and national

				recommendations promoting shorter TPT regimens such as 3HP, and can inform programmatic decisions under TB control programmes to expand adoption of shorter, patient-friendly LTBI treatment strategies, thereby strengthening TB prevention efforts and contributing toward TB elimination goals.
15.	Title: Clinical Use of Empirical Antibiotics for Septic Arthritis and Osteomyelitis in India, their Bacterial Isolates and Susceptibility Patterns: A Systematic Review and Meta-Analysis Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding: NA Duration: 2025	Development	Treat	This study provides national evidence on empirical antibiotic use, pathogen distribution, and antimicrobial resistance in septic arthritis and osteomyelitis in India. The findings highlight substantial variability in prescribing practices and indicate that nearly 41% of patients receive an initial antibiotic regimen to which the pathogen is resistant. The results support the need for locally informed empirical treatment guidelines, strengthened microbiological diagnostics, and early de-escalation based on culture results. The evidence can contribute to antimicrobial stewardship initiatives and inform national AMR surveillance programmes by incorporating musculoskeletal infections into routine monitoring. No patent technology is involved.
16.	Title: Clinical Symptoms and Signs Necessitating the Use of Antibiotics in Acute Diarrhoea among Children and Adults in India: A Systematic Review and Meta-analysis	Development	Treat	The study highlights substantial overuse of empirical antibiotics in acute diarrhoea despite low prevalence of bacterial infections guidelines and public health and rare occurrence of clinical

	Name of PI with designation: Dr. M Muniyandi, Scientist-E Source of funding: NA Duration: 2025			indications such as bloody diarrhoea. High resistance to commonly used antibiotics such as ampicillin, cotrimoxazole and nalidixic acid was also observed. These findings emphasise the need for diagnostic-guided treatment, rational antibiotic prescribing, and strengthened antimicrobial stewardship. The evidence can inform clinical strategies to reduce inappropriate antibiotic use and support antimicrobial resistance (AMR) control efforts in India.
17.	Title: CRISPR mediated platform for diagnosis and rapid detection of drug resistance pattern in Mycobacterium tuberculosis Name of PI with designation: Dr. K.R. Uma Devi, Scientist F Source of funding and duration: ICMR – Intramural, 2019-2024	Development	Detect	Translational value: The CRISPR-Cas13a-based assay offers a rapid, sensitive, and non-invasive diagnostic approach for TB detection. License Agreement and Technology Transfer Agreement signed with Industrial partner Patent: Based on the assay's performance and findings, a complete patent application was filed on October 20, 2024. The assigned application number is 202311071943
18.	Title: Stigma and Disclosure Study (TB vaccine trial – Capacity Building Project sub study) Name of PI with designation: Dr. P. Murugesan Senior Technical Officer 1 Source of funding and duration: ICMR- Intramural, 2025	Description	Prevent	The study provides evidence to inform the National TB Programme by highlighting stigma as a major barrier to treatment adherence. Findings support integrating family-centred counselling, stigma-reduction community awareness, and improved patient-friendly clinical services into TB care strategies, thereby strengthening treatment continuity, patient support systems, and overall effectiveness of tuberculosis control efforts.

19.	Title: An innovative approach for engaging student and women organizations to improve Tuberculosis case finding and treatment adherence: A step towards Tuberculosis elimination in Senapati District, Manipur Name of PI with designation: Dr. N. Karikalan, Scientist D Source of funding and duration: Intramural, 2023-2025	Description	Detect	The project demonstrates that a community volunteer–driven model can significantly improve TB case detection, awareness, and treatment adherence in remote and hard-to-reach tribal settings. The study provides operational evidence to integrate trained community volunteers into the National Tuberculosis Elimination Programme for sustained active case finding, treatment support, and community-based TB awareness in underserved regions. The model could be scaled up in other tribal and difficult-to-reach areas under the National Health Mission framework. however, the community-driven TB intervention model and implementation framework offer a scalable strategy to strengthen TB control efforts in India and similar low- and middle-income settings.
20.	Title: TB Vaccine India study for accelerating development and introduction of tuberculosis vaccine: A mathematical modelling approach Name of PI with designation: Dr Adhin Bhaskar, Scientist C Source of funding and duration: IAVI, 2025	Description	Prevent	Targeting high-risk groups (e.g., low BMI) with PoD vaccines is projected to achieve greater epidemiological efficiency and should be prioritized for initial deployment. Infection-testing–guided vaccination strategies offer limited additional benefit and are unlikely to be cost-effective due to high costs and low specificity.
21.	Title: Development and validation of artificial intelligence tool for screening/Detection of pulmonary TB and other lung diseases using chest X-RAY	Development	Detect	DeepCXR demonstrated high diagnostic performance in detecting TB-related abnormalities, with rapid (<1 minute) automated interpretation validated against expert radiologist

	Name of PI with designation: Dr C Ponnuraja, Sceintist F Source of funding and duration: ICMR, 2022-2025			readings. The model showed consistent performance across diverse, multi-site datasets, supporting its generalizability. Paper published: Abhishek A, Chalga MS, Yadav RM, Agarwal K, Vohra V, Tayade A et al. Artificial intelligence (AI)-driven ensemble model for comprehensive chest X-ray abnormality detection and deployment. Indian J Med Res 2026; 163: 174–181.
22.	Title: 'Complement proteins as prognostic biomarkers in paediatric tuberculosis' Name of PI with designation: Dr. Nancy Hilda J, Scientist D Source of funding and duration: ICMR-Intramural, 2024-2025	Discovery	Detect	Tuberculosis infection is characterized by robust classical pathway activation and strong upregulation of regulatory proteins, consistent with a controlled yet immunologically active state. In contrast, active TB exhibits persistent complement activation with relatively reduced regulatory capacity and a shift toward terminal pathway components. Together, these observations identify the complement axis as a potential target for biomarker and may represent a rational strategy for host-directed intervention in tuberculosis
23.	Title: Role of interferon stimulated genes (ISGs) in the establishment/ maintenance of latency in HIV and HIV-TB infections Name of PI with designation: Dr. Luke Elizabeth Hanna, Scientist F Source of funding and duration: ICMR, 2022-2025	Discovery	Prevent	The study investigated the role of Type-I interferon signaling and ISGs in the maintenance/reversal of HIV-1 latency using the J-LAT (Jurkat CD4 cell) model of latently infected cells with GFP reporter. We observed that type-1 interferon signalling by itself contributed to strict maintenance of HIV-1 latency, whereas, in combination with a latency-reversal agent such as Vorinostat (a HDAC

				inhibitor), it led to latency reversal. Transcriptomics and pathway analyses identified several ISGs involved in viral latency.
24.	Title: Design and characterization of peptido-mimetics of broadly neutralizing antibodies targeting vulnerable sites on the HIV-1 envelope Name of PI with designation: Dr. Luke Elizabeth Hanna, Scientist 'F' Source of funding and duration: Intramural, 2023-2025	Discovery	Treat	Eleven peptide-mimetics of size six or ten-mers have been identified and demonstrated to be capable of virus inhibition without toxicity. Anti-HIV tested demonstrated inhibitory activity with mean IC_{50} values ranging from 1.5 to 17 μM against laboratory-adapted HIV-1 strains. Notably, two peptide combinations achieved more than 61% inhibition compared to individual peptides. Overall, these findings suggest that short bNAb-derived peptides retain functional neutralization properties and represent promising HIV-1 entry inhibitors, meriting further evaluation in primary isolates. The advantages of shorter peptides are easier synthesis, reduced cost, and better potential for optimization. These findings support the potential of peptide-based HIV entry inhibitors as next-generation antiviral therapeutics.

ELECTRONIC DATA PROCESSING (EDP) UNIT

Overview

At ICMR-NIRT, the Electronic Data Processing (EDP) unit plays a central role in supporting TB research through strong and reliable IT systems. By enabling quick access to data, smooth communication, and efficient data handling, the unit helps researchers work faster and more effectively. Over time, ICMR-NIRT has built a solid in-house capacity in application development, server management, and data systems, which continues to strengthen its contribution to India's TB elimination efforts.

Enabling Research through Digital Technology

Digital tools have become essential to modern research, and the EDP unit ensures that researchers have what they need at every step:

- Easy and instant access to scientific articles, databases, and knowledge resources
- Seamless collaboration with researchers across institutions and countries
- Simple and efficient tools for collecting data from diverse populations
- Secure systems for storing and managing large volumes of data
- Faster communication and analysis, leading to improved research output
- Core IT Support

Core IT support

The EDP unit provides comprehensive support to research activities, including

- Development of customized applications for research projects
- Management of servers and databases
- Maintenance of IT systems and infrastructure
- Support for online data collection platforms
- Ensuring data security through robust cybersecurity practices
- Research and Flagship Projects

Research and Flagship Projects

The unit actively supports a range of ongoing projects by developing and maintaining digital platforms. Some of the key initiatives include

- Institutional website development (Figure 1)
- DLSS and DLAS platforms (Figure 2)
- AccEENDTB project (Figure 3)
- TBNeutox web application
- Validation of AI-based diagnostic tools for chest X-rays
- Development of chest X-ray datasets
- REDCap-based applications
- NIRT CONNECT platform
- Facilities and Infrastructure

Support to National Initiatives

The EDP unit also plays an important role in supporting government initiatives by

1. Ensuring cybersecurity measures are aligned with national guidelines for protecting sensitive TB research data
2. Maintaining repositories of epidemiological survey data
3. Coordinating with ICMR and MeitY through regular cybersecurity reporting
4. Supporting data-related activities with the PMO, including rapid completion of national evaluation exercises
5. Acting as a nodal point for reporting Science & Technology activities to the Department of Science & Technology, Government of India

Figure 1: Website Application Development

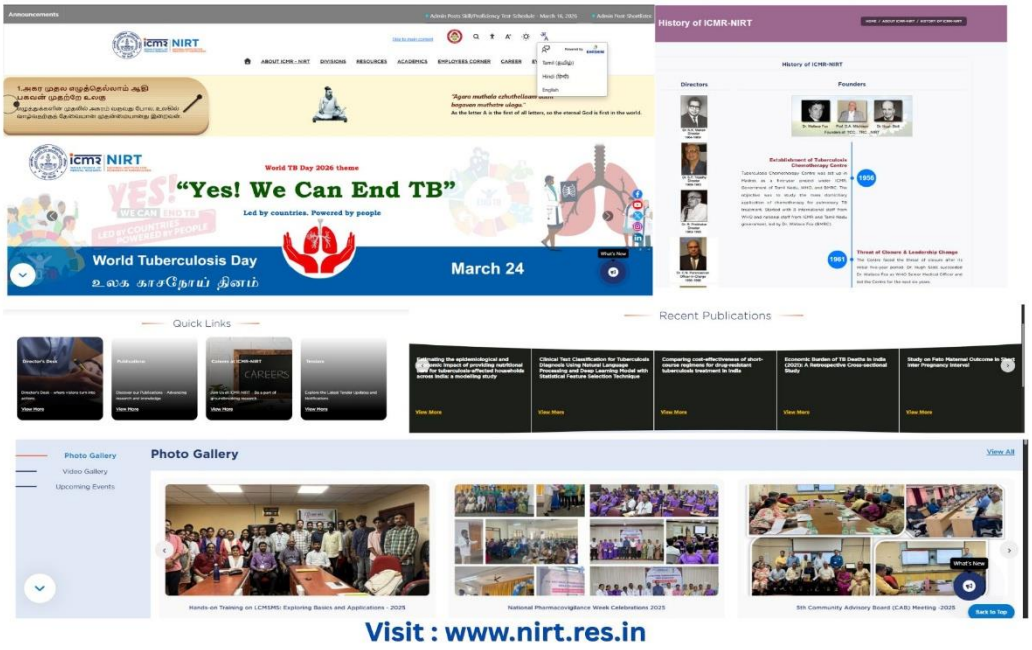


Figure 2: District level annual survey applications (DLAS)

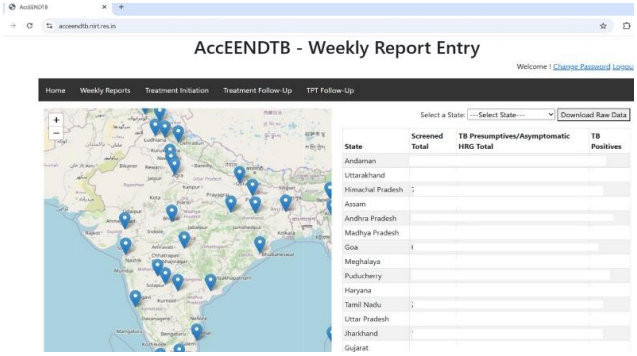
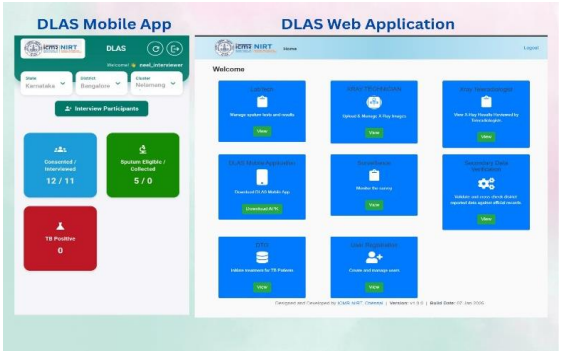


Figure 3: Accelerating Efforts towards Ending TB application (AccEENDTB)



MODEL RURAL HEALTH RESEARCH UNIT (MRHRU) - Madurai

Model Rural Health Research Unit (MRHRU) at Thoppur, Madurai, was sanctioned in March 2024 by Government of India, Department of health research, Ministry of Health and Family Welfare. ICMR-NIRT has been designated as the mentoring institute. Dr. S. Ramesh Kumar, Scientist F & Officer Incharge, ICMR-NIRT, Madurai unit, is the Nodal Officer representing ICMR and Dr. K. Senthil, Professor and Head of the General Medicine department at Madurai Medical College in Madurai, is the nodal officer representing State. In January 2026, the Madurai District Collector and officials from Revenue Department examined a 22,500 square feet plot of property to be used for MRHRU's activities. Following this review, procedures for transferring this land have been initiated.

List of ongoing projects

1. **Population Based Health Survey:** Population based Surveys in MRHRUs is a centrally driven activity, to assess health status and annual trend of change in health status of communities residing in the field practice areas of MRHRUs across India.

2. **Gestational Diabetes Mellitus (GDM) among postpartum mothers:** Newer follow up strategy for delivered GDM mothers to improve case detection of Type II Diabetes Mellitus -An Implementation Research in rural areas of Madurai district.

3. **Chronic Kidney Disease (CKD) among Sakkimangalam village population:** A Comprehensive Health Survey among adults of Sakkimangalam village of Madurai District of Tamil Nadu with special focus on kidney disease.

4. **Nutritional Status of Children with Severe Acute Malnutrition (SAM):** A study to assess the long-term nutritional status of SAM children and to evaluate the sustainability at specified intervals post-discharge to prevent morbidity/complications in children with malnutrition.

Other tasks carried out:

- Second LRAC meeting was conducted on 5th December 2025 and 4 new studies were presented and currently awaiting approval.
- MRHRU Madurai provided funding for faculties of Madurai Medical College and scientists of NIRT for attending "Clinical Trial Workshop" in Salem, organized by DHR on 17th,18th & 19th September 2025.
- As part of "Swasth Nari, Sashakt Parivar Abhiyan" program, MRHRU Madurai, trained Anganwadi health care workers in the field of nutrition health by the investigator of Malnutrition study was conducted on 29th September 2025.
- MRHRU Madurai provided funding for faculties of Madurai Medical College, staff and scientist of NIRT to attend Manuscript Writing & Data Analysis workshop held at Andhra Medical College, Vishakhapatnam on 23rd and 24th January 2026 as per directions by DHR.

PUBLICATIONS

S No.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name, Impact Factor
1	Rajendran P, Nishant K, Himanshu V, Sivakumar S, Thiruvengadam K, Ramamoorthy T, Kishore R, Sidhartha G, Pranav P, Mahmud H, Sridhar A. Multicentric validation of the proof of concept for utility of Trueprep extracted DNA in line probe assay testing. PLOS Global Public Health. 2025 Apr 15;5(4):e0004422.	Rajendran P, Sivakumar S, Thiruvengadam K, Sridhar A	PLOS Global Public Health, 2.5
2	Kang J, Kim HJ, Kim MS; GBD 2023 Substance Use Collaborators; Shin JI, Yon DK. Global burden of amphetamine, cannabis, cocaine and opioid use in 204 countries, 1990-2023: a Global Burden of Disease Study. Nat Med. 2026 Feb;32(2):527-544. doi: 10.1038/s41591-025-04137-0. Epub 2026 Jan 16. PMID: 41545593.	Malaisamy Muniyandi	Nature Medicine, 50.0
3	Saminathan G, Kumar V, Shanmugam S, Rajendran P. Revolutionizing non-tuberculous mycobacteria research: Advances in molecular diagnostics, phylogenetics, and clinical management. Journal of Microbiological Methods. 2025 Aug 12:107226.	Saminathan G, Kumar V, Shanmugam S, Rajendran P	Journal of Microbiological Methods, 1.9
4	Thomas SV, Rajendran P, Shanmugam S. Young lungs cared enough? India's frontiers in diagnosing pediatric TB. Frontiers in Pediatrics. 2025 Aug 11;13:1638167.	Thomas SV, Rajendran P, Shanmugam S	Frontiers in Pediatrics, 2.0
5	Rajendran P, Giridaran P, Thomas SV, Nagaraj N, Thiruvengadam K, Radhika G, Samyuktha R, Selvaraju S, Frederick A, Padmapriyadarsini C, Shanmugam S. Characterisation of M. tuberculosis isolates obtained from Tamil Nadu prevalence survey by whole genome sequencing analysis. Infection, Genetics and Evolution. 2025 Aug 1;132:105763.	Rajendran P, Giridaran P, Thomas SV, Nagaraj N, Thiruvengadam K, Radhika G, Samyuktha R, Selvaraju S, Frederick A, Padmapriyadarsini C, Shanmugam S.	Infection, Genetics and Evolution, 2.6
6	Chauhan A, SivaKumar S, Toley BJ. A minimally instrumented method for the detection of rifampicin resistance-causing mutations in Mycobacterium tuberculosis utilizing lateral flow readout. Analytica Chimica Acta. 2025 Jul 8;1358:344090.	Siva Kumar S	Analytica Chimica Acta, 6.0

S No.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name, Impact Factor
7	Daniel BD, Shanmugam S, Mehta R, Bhalla M, Mariappan M, Ramraj B, Awasthi AK, Patel P, Jain A, Jain P, Kumar C. Long term outcomes in drug resistant tuberculosis with Bedaquiline, Pretomanid and varying doses of Linezolid. Journal of Infection. 2025 Jul 1;91(1):106509.	Bella Devaleenal D, Shanmugam S, Padmapriyadarsini, C	Journal of Infection, 11.9
8	Chauhan K, Gupta RK, Anthwal D, Panwalkar N, Desikan P, Singhal R, Bhalla M, Myneedu VP, Khayyam KU, Shanmugam SK, Chelvi KS. Operational Feasibility of "TB Concentration & Transport" and "TB DNA Extraction" Kits for Biosafe Dry Sputum Transport for Direct Detection of Drug Resistance Using Line Probe Assay: A Field Study in India. InOpen forum infectious diseases 2025 Jul (Vol. 12, No. 7, p. ofaf207). US: Oxford University Press.	Shanmugam SK, Chelvi KS	Open forum infectious diseases, 3.8
9	Vijayakumar Padmavathy B, Shanmugavel AK, Shanmugam S, Narayanan M. Dissecting the effect of single-and co-infection of TB and COVID-19 pathogens on the sputum microbiome. Microbiology Spectrum. 2026 Mar 3:e02220-25.	Shanmugavel AK, Shanmugam S,	Microbiology Spectrum, 3.8
10	Kumar NP, Hissar S, Sivakumar S, Viswanathan V, Bethunaickan R, Kornfeld H, Babu S. Complement profiling for treatment outcomes in pulmonary TB. Frontiers in Immunology. 2026 Feb 11;17:1679947.	Kumar NP, Hissar S, Sivakumar S, Bethunaickan R	Frontiers in Immunology, 5.9
11	Mohanvel SK, Radhakrishnan R, Balraj P, Singh N, Danisetty S, Vats H, Chaudhury A, Choudhary H, Rajendran P, Jayaprakasam M, Vadivel SD. Artificial intelligence for screening drug resistance in tuberculosis. The Indian Journal of Medical Research. 2026 Jan 31;162(6):910.	Mohanvel SK, Radhakrishnan R, Rajendran P, Jayaprakasam M, Vadivel SD, Shanmugam, S. K.	Indian Journal of Medical Research, 2.5
12	Rajadas SE, Nirmal CR, Dusthackeer A, Harshavardhan S, Parthasarathy K. Recent advancements in the research models of infectious diseases. Frontiers in Cellular and Infection Microbiology. 2025 Nov 7;15:1731600.	Dusthackeer A	Frontiers in Cellular and Infection Microbiology, 4.8

S No.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name, Impact Factor
13	Dusthackeer A, Balasubramanian M, Rajadas SE, Nirmal CR, Elango P, Thiruvengadam K, Saadhali SA, Shanmugam SK. Wild-type MIC Distribution and Evaluation of Epidemiological Cut-Offs of Second-line TB-drugs in Susceptible and MDR-TB Clinical Isolates from Chennai, India. Frontiers in Microbiology. 2026;17:1739149.	Dusthackeer A, Balasubramanian M, Rajadas SE, Nirmal CR, Elango P, Thiruvengadam K, Saadhali SA, Shanmugam SK	Frontiers in Microbiology, 4.5
14	Ramraj B, Nagarajan K, Purakayastha DR, Madhukar M, Kumar M, Raj N, Kumar S, Unger BS, Rajamani N, Bangar SD, et al. Qualitative Study of Nutritional Support-Related Perceptions and Preferences Among Persons Affected by TB, Family Caregivers, and Healthcare Providers in India. Tropical Medicine and Infectious Disease. 2025 Apr 21; 10(4):114. https://doi.org/10.3390/tropicalmed10040114	Balaji Ramraj, Karikalan Nagaraj	Tropical Medicine and Infectious Disease, 2.82
15	Muniyandi M, Ramraj B, Vadamalai S, Abdul Salam S, Devaleenal B, Jaju J, Padmapriyadarsini C. Comparing cost-effectiveness of short-course regimens for drug-resistant tuberculosis treatment in India. Int J Technol Assess Health Care. 2025 Jul 21;41(1):e48. https://doi:10.1017/S0266462325100329	Muniyandi Malaisamy, Balaji Ramraj, Bella Devaleenal D	Int J Technol Assess Health Care, 3.2
16	Navaneethapandian P, Sarma PS, Rajendran M, Thankappan KR. Lung Function Impairment and Its Associated Factors in Pulmonary Tuberculosis Patients Upon Treatment Completion in Madurai District, Tamil Nadu: A Cross-Sectional Study. Cureus 2026, 18, https://doi.org/10.7759/cureus.103941.	Poorana Ganga Devi Navaneethapandian, Mahalakshmi Rajendran	Cureus, 1.3
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90	Daniel B D, Padmapriyadarsini C, Giri S, Winarni P S. Diagnosis and management of multidrug resistant tuberculosis BMJ 2025; 390 :2024-080075 doi:10.1136/bmj-2024-080075	Bella Devaleenal D, Padmapriyadarsini C	The BMJ, 42.7
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92	Muniyandi M, Mathiyazhagan K, Karikalan N. Self-reported prevalence of tuberculosis: unveiling spatial representation in the districts of Tamil Nadu. Int Health. 2025;17(3):366-376. doi:10.1093/inthealth/ihae072.	Malaisamy Muniyandi, Karikalan Nagarajan, Kavi Mathiyazhagan	International Health, 2.2
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94	Nagaraj K, Daniel BD, Suresh C, Angamuthu D, Palanisamy S, Malaisamy M. An integrated psycho-social intervention to improve self-efficacy toward TB treatment uptake and infection prevention among patients and family caregivers: a multicentric implementation research study protocol. Front Tuberc. 2026; 4:1713844. doi:10.3389/ftubr.2026.1713844.	Karikalan N, Bella Devaleenal D, A Dhanalakshmi, Shobana, Malaisamy Muniyandi.	Frontiers in Tuberculosis
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114	Sinha P, Karoly M, Padmapriyadarsini C, Paradkar M, Mave V, Gupte N et al. Contribution of key comorbidities to unfavorable treatment outcomes among adults with drug-sensitive pulmonary TB in India: A prospective cohort analysis. Chest 2026; 169: 64–72.	Chinnaiyan Ponnuraja	Chest, 9.2
115	Understanding participation of persons with disabilities in clinical trial research in India—a retrospective analysis of inclusive language of protocols	Karikalan Nagarajan, Malaisamy Muniyandi, Bhaskara Chary Kothoju, Priscilla Rebecca, Angayarkanni Balasubrammnaiyan	BMC Trials, 2.0

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116	Jeyakumar A, Kalaiselvi S, Nair D, Vijayaprabha R, Kabir D, Melfha JM, Bhatnagar T, Srinivasan R, Gayathri K, Boopathi K, Vaman RS, Rajan V, Shanmugasundaram S, Frederick A, Shewade HD. Role of triage audit in an ongoing differentiated TB care initiative to reduce deaths in Tamil Nadu, India. Public Health Action. 2025 Sep 3;15(3):118-123. doi: 10.5588/pha.25.0015. PMID: 40936977; PMCID: PMC12421824.	Dina Nair	Public Health Action, 1.6
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121	Web Annex B.1. Low complexity automated nucleic acid amplification tests (LC-aNAATs) for detection of pulmonary TB and resistance to isoniazid/rifampicin in adults and adolescents: a systematic review of diagnostic accuracy	Leeberk Raja Inbaraj, Adhin Bhaskar, Mukesh Kumar, Sathya Narayanan, Vignes Anand Srinivasalu	World Health Organization
122	Web Annex B.3. Accuracy of LC-aNAATs for extrapulmonary tuberculosis and rifampicin resistance in adults and adolescents: a systematic review	Leeberk Raja Inbaraj, Adhin Bhaskar, Mukesh Kumar Sathya Narayanan, Vignes Anand Srinivasalu	World Health Organization
123	Web Annex B.5. LC-mNAATs for detection of pulmonary and extrapulmonary tuberculosis in adults and adolescents: a systematic review of diagnostic accuracy	Leeberk Raja Inbaraj, Adhin Bhaskar, Mukesh Kumar, Sathya Narayanan, Vignes Anand Srinivasalu	World Health Organization
124	Web Annex B.6. LC-mNAATs for detection of pulmonary and extrapulmonary tuberculosis in children: a systematic review of diagnostic accuracy	Leeberk Raja Inbaraj, Adhin Bhaskar, Mukesh Kumar Sathya Narayanan, Vignes Anand Srinivasalu	World Health Organization

PATENTS

S No.	Title of the patent	Inventors Name	Date of Filing on ICMR's Patent Mitra	Patent status (Filed/ Granted)
1	Efflux Pump Inhibitor-Integrated solid-lipid Nanoparticles for Enhanced Rifampicin and Isoniazid Bioavailability	Dr. Azger Dusthackeer V N, Dr. Shainaba A Saadhali, Mrs. Angayarkanni Balasubramaniam	10th February, 2026	Filed
2	PheGen assay as an alternative to MGIT 960 for rapid and sensitive phenotypic detection of *Mycobacterium tuberculosis* using genotypic methods	Dr. Balaji Subramanyam Dr. S. Sivakumar Mr. Michael Prem Kumar	27th February 2026	Filed
3	2-pyridyl amides as inhibitors of drug resistant tuberculosis	Dr. VN Azger Dusthackeer, Ms. Angayarkanni B	18th September 2025	Filed

ACCREDITATIONS

1. During the reporting year, the Department of Bacteriology was accredited in accordance with the standard ISO 15189:2022 “Medical Laboratories – Requirements for Quality and Competence in the field of Medical Testing for Sputum smear microscopy, NAAT tests (Gene Xpert, LPA), Solid LJ culture and DST, Liquid culture and DST by MGIT.

2. WHO PQ: From 2023 - till date. WHO prequalification of IVDs is a comprehensive quality assessment of individual IVDs through a standardized procedure aimed at determining whether the product meets WHO prequalification requirements. These evaluations must be performed by a designated Performance Evaluation Laboratory (PEL). ICMR-NIRT has been certified as PEL by WHO PQ for TB NAAT assay.

3. During the reporting year, the Viral Load and Early-Infant Diagnosis (EID) divisions were accredited in accordance with the standard ISO 15189:2022 “Medical Laboratories – Requirements for Quality and Competence in the field of Medical Testing for Viral Load and EID testing.

AWARDS

1. ICMR-NIRT won Silver Award for “Institutional Excellence Recognition: ICMR Institute Overall PE” at the 2nd DHR-ICMR Health Research Excellence Summit 2025; received by Dr. Srinath Satyanarayana, Director on behalf of the institute on 13th November 2025 at ICMR-NIMR, Dwarka

2. Dr. K. R. Uma Devi, Scientist F and Mr. P. Venkatesan, Technical Assistant and Part-time Ph.D Scholar has facilitated the transfer of technology entitled “CRISPR-based Molecular Diagnostic Kits for detection of Mycobacterium tuberculosis” to the industrial partner J.Mitra & Co. Pvt. Ltd" under the aegis of ICMR-ITR Unit.

3. Dr. G.Narendran, Scientist F was awarded with SP Agarwal Oration award instituted by TB Association of India, for the year 2025.

4. Dr. Leeberk Raja I, Scientist E was awarded with Kenneth Warren Prize (2025), by Cochrane Collaboration for high methodological quality of Truenat MTB review.

5. Dr. N. Pavan Kumar, Scientist D was awarded the Gold Medal for Best Basic Research Publication at the 2nd DHR–ICMR Health Research Excellence Summit 2025.

6. Dr Adhin Bhaskar, Scientist C was awarded with Smt. Suraj Kali Jain Award of Indian Society for Medical Statistics for 2024, at the 43rd Annual National Conference of the Society (ISMSCON-2025), which took place at AIIMS, Mangalagiri, on November 20–22, 2025.

EVENTS

S. No	Title of the Event	Participant profile	Summary
1	Biosafety in Research: Understanding the Process on Regulatory Approval Date: 21st April 2025	Research scholars, scientific and technical staff of ICMR-NIRT. Total number of participants: 80	An awareness talk on the process of IBSC application and approval was delivered by Prof. Dr. K.G. Tirumurugan, The Member of Review Committee of Genetic Manipulation (RCGM), DBT, Government of India. He enlightened the scientific community of ICMR-NIRT on the process of IBSC application and approval
2	Laboratory training for IRL and NRL on TB diagnostics: NTEP Dates:21st – 22nd April 2025	IRL and C&DST Laboratory personal; 05 participants	Training on FDA and Newer drug DST
3	Labs Save Lives Date: 23rd April 2025	The audience were technical staff, lab professionals from private laboratories and ICMR- NIRT. Total number of participants: 100	“Labs Save Lives” is the theme for ‘World Laboratory Day-2025’ to emphasize the role of the laboratory professional on diagnosis, disease prevention and public health. Scientists from ICMR-NIRT, Anderson Diagnostics and Labs and University of Madras delivered scientific talks regarding laboratory procedures and their importance.
4	Laboratory training for IRL and NRL on TB diagnostics: NTEP Dates:24th- 25th April 2025	IRL and C&DST Laboratory personal; 05 participants	Training on FDA and Newer drug DST
5	Laboratory training for IRL and NRL on TB diagnostics: NTEP Dates:28th- 29th April 2025	IRL and C&DST Laboratory personal; 05 participants	Training on FDA and Newer drug DST
6	Participatory Workshop for GHTM Nursing Staff Date: 8th may 2025	Nursing staff of GHTM	As part of the Wings of Support (WoS) initiative, the Department of Social and Behavioural Research (DSBR) of ICMR-NIRT organized a participatory workshop for nursing staff of the Government Hospital of

S. No	Title of the Event	Participant profile	Summary
			Thoracic Medicine (GHTM), Tambaram Sanatorium, on May 8, 2025. The event commenced with an ice-breaking activity and covered themes such as emotional and mental well-being at the workplace, building resilience, and coping mechanisms.
7	Tuberculosis Awareness Programme for Frontline Workers Date: 16th May 2025	Frontline municipal sanitation workers	ICMR-NIRT, in collaboration with Poonamallee Municipality, Thiruvallur District, Tamil Nadu, and Madras Medical Mission College of Health Sciences, Chennai, organized a Tuberculosis Awareness Programme for frontline municipal sanitation workers on May 16, 2025. The event, aimed to raise awareness about lung health, tuberculosis prevention, and early diagnosis.
8	2nd Sensitization Programme on Health Technology Assessment in Tamil Nadu Date: 21st may 2025	The Programme brought together around 70 senior officials and technical experts from Tamil Nadu. Participants included the Principal Secretary, Mission Director (NHM), Director of Public Health & Preventive Medicine, Additional and Joint Directors, health administrators, program officers, consultants, and experts from ICMR-NIRT, ICMR-NIE, JIPMER, IIT Madras, and the Department of Health Research, Government of India.	The one-day Sensitization Programme on HTA, held on 21st May 2025 in Chennai, was organized by ICMR-National Institute for Research in Tuberculosis and the Department of Health Research (DHR), Government of India, in collaboration with the National Health Mission (NHM) and the Directorate of Public Health & Preventive Medicine (DPH&PM), Government of Tamil Nadu. The programme focused on institutionalizing HTA within Tamil Nadu's public health system to promote evidence-based and cost-effective decision-making. Sessions covered HTA methodology, national progress under HTAIn, economic evaluation tools, and integration of HTA into health planning. Discussions also prioritized potential HTA topics relevant to the state's health system.
9	Empowering ASHA Workers in the Fight Against Tuberculosis: Orientation Session in Mayurbhanj District Date: 27th May 2025	ASHA workers	The Department of Socio-Behavioural Research at ICMR-NIRT, Chennai, organized an orientation session on 27th May, 2025 for ASHA workers at Bangriposi Community Health Centre (CHC) in Mayurbhanj District, Odisha. The session aimed to

S. No	Title of the Event	Participant profile	Summary
			strengthen the role of ASHA workers in the fight against tuberculosis (TB) by emphasizing the importance of psychosocial interventions in TB care.
10	Laboratory training for IRL and NRL on TB diagnostics: NTEP Dates:5th- 6th June 2025	ICMR-NIRT, IRL and C&DST Laboratory personal; 05 participants	Training on FDA and Newer drug DST
11	Capacity Building Workshop on Tobacco Cessation for students and technicians of Madras Medical College Dates: 26th- 27th June 2025	MD students of MMC	A Capacity Building Workshop on "Tobacco Cessation" was jointly organized by the Institute of Community Medicine, MMC; the Institute of Thoracic Medicine, MMC; and ICMR-NIRT from June 26 to 27, 2025, at Madras Medical College, Chennai. This two-day workshop aimed to provide training to 52 PGs and 9 respiratory technicians from the departments of Respiratory Medicine and Community Medicine, MMC, enabling them to implement tobacco cessation treatment and counselling at the Tobacco Cessation Centre at MMC for general population. IEC posters and tobacco counselling flipcharts developed by the Department of Social and Behavioural Research (DSBR), ICMR-NIRT, were officially released.
12	Workshop on Introduction to Systematic reviews and meta-analysis Date: 27th June 2025	Researchers, scholars, nurses and Junior faculty	Conducted by the Technical Resource centre, Centre for evidence based guidelines. Sessions covered lectures and demonstration to sensitize the participants on the steps of systematic review
13	Motivational Training for NTEP staff, Tiruvallur Dates: 1st-2nd July, 2025	NTEP's frontline staff (Health Visitors, Senior Treatment Supervisors, Senior Tuberculosis Laboratory Supervisors, and Laboratory Technicians from various TB units)	The Department of Social and Behavioural Research (DSBR) at ICMR-NIRT, in collaboration with the National Tuberculosis Elimination Programme (NTEP) Tiruvallur, successfully organized a motivational training program for NTEP's frontline staff in Tiruvallur on 1st-2nd July, 2025. The program covered key themes such as work-life balance, time management, and the

S. No	Title of the Event	Participant profile	Summary
			significance of peer support, commencing with an introductory activity. The participatory approach provided valuable motivation and insights for the participants.
14	Hands-on workshop on meta-analysis for intervention reviews Date: 4th July 2025	Scientists, faculty	Conducted by the Technical Resource centre, Centre for evidence based guidelines (DHR). Sessions covered a few lectures and hands-on exercises on meta-analysis using RevMan. Participants acquired skills in performing meta-analysis
15	An Orientation Programme on Health Technology Assessment (HTA) Date: 17th July 2025	The Programme was attended by around 150 participants. Attendees included Ph.D. scholars, postgraduate students, faculty members, researchers, and staff of NIS. The diverse academic participation facilitated discussions on integrating HTA into Siddha research and healthcare delivery.	The Orientation Programme on HTA, held on 17th July 2025 at the National Institute of Siddha (NIS), Chennai, was jointly organized by the National Institute of Siddha (Ministry of AYUSH, Government of India) and ICMR-NIRT, Chennai. The programme introduced key HTA concepts and their relevance to traditional medicine systems. Sessions covered principles of health economics, including cost-effectiveness, cost-utility, cost-benefit, and budget impact analyses. Discussions highlighted potential HTA studies on Siddha interventions in anaemia, maternal health, non-communicable diseases, tuberculosis, and public health integration, and explored opportunities for collaborative research, capacity building, and systematic review training.
16	EMPOWER Initiative: Fostering Well-being and Productivity at the Workplace Date: 28th July 2025	NIRT Permanent employees	EMPOWER'- Employee welfare initiative was introduced in ICMR-National Institute for Research in Tuberculosis (ICMR-NIRT) on 28th July 2025, with the central theme of Empowerment, Motivation, and Productivity through Occupational Well-being and Resilience. The initiative was facilitated by the Department of Social and Behavioral Research (DSBR).

S. No	Title of the Event	Participant profile	Summary
17	Community Engagement activity at District TB Office, Agra -2025 Date: 6th August 2025	Persons with TB, caregivers & stakeholders	As part of behavioural intervention study implemented by Department of Social & Behavioural Research, ICMR-NIRT at Agra, a community engagement event was organized on August 6, 2025, at District TB Office, Agra. The theme of the event was "Commit to End TB" focused on patient centered TB care, including nutritional support. This event was jointly conducted by the National Tuberculosis Elimination Programme (NTEP), Agra; ICMR-National JALMA Institute for Leprosy & Other Mycobacterial Diseases (NJIL&OMD), Agra; and ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai.
18	Good Clinical Laboratory Practice (GCLP) Training Course Dates: 12th August-8th October 2025	19 participants (From Dept. of Immunology, Bacteriology and Biochemistry)	A new project titled TB Vaccine Immunology (TBVIL) has been officially initiated by the Department of Immunology, ICMR –NIRT along with Innovative Clinical Laboratories (PTY) Cape Town, SA (IC Labs) and Gates Foundation. This project marks a significant milestone in ongoing efforts related to TB. As nominated by the HOD of various departments, staffs have been identified for this TB VIL project and their roles and responsibilities are mention for successful execution of this project. To ensure alignment with project goals and efficient execution, a structured training program titled Virtual in-depth Good Clinical Practices (GCLP) developing and training activity have been conducted by the IC Laboratories from South Africa for all selected staff. The training covered 15 different modules and attended by the selected staff as per the Schedule.
19	EMPOWER: Motivational Session for NTEP staff, Greater Chennai Corporation	NTEP staff, GCC (Senior Treatment Supervisors (STS), and Senior Tuberculosis	The Department of Social and Behavioral Research (DSBR) of ICMR-NIRT, in partnership with the NTEP, Greater Chennai Corporation,

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	Date: 20th August 2025	Laboratory Supervisors (STLS) from various TB units)	organized a follow up motivational training session for the frontline staff of NTEP at ICMR-NIRT on 20 th August 2025. The training commenced with an ice breaking activity followed by three sessions, which were focused on Work life balance, and End TB commitment which involved interactive sessions and ended with the feedback from participants.
20	“Beyond the Horizon" Flow Cytometry Workshop Dates: 2nd- 3rd September 2025	50 participants (Internal participants, IIT Madras, CMC-Vellore)	The Department of Immunology, ICMR-NIRT, in collaboration with BD Biosciences, conducted a 2-day flow cytometry workshop titled "Beyond the Horizon" on 2nd and 3rd September, 2025. The workshop was inaugurated by Dr. Srinath Satyanarayana, Director of ICMR-NIRT, in the presence of dignitaries from ICMR-NIRT and BD Biosciences. The workshop focused on theoretical sessions covering topics such as Fluorochrome impact on panel design, spectral plus imaging flow cytometry, and high parameter multi-color flow cytometry panel design. The workshop included hands-on sessions for both beginners and experienced flow users, with acquisition carried out on the recently procured BD FACS Symphony A5 SE Cell analyzer. This collaborative effort provided a platform for researchers to enhance their skills in high parameter flow cytometry panel design, fostering innovation and excellence in research.
21	Tuberculosis Awareness Program for Senior Citizen Date: 3rd September 2025	Senior Citizens	ICMR-NIRT's Department of Social and Behavioral Research organized a Tuberculosis Awareness Program for senior citizens at Akshaya Trust Old Age Home, Chennai, on September 3, 2025. The event aimed to educate residents about TB symptoms, transmission, prevention, and treatment, highlighting nutrition and mental well-being.

S. No	Title of the Event	Participant profile	Summary
22	A Workshop on Systematic Review and Meta-Analysis (SR&MA) Date: 4th September 2025	The Workshop was attended by around 50 participants. Attendees included teaching faculty of Siddha, Deans, Heads of Departments, Medical Officers, researchers, ICMR-NIRT staff, and participants from other institutes. The diverse academic and clinical representation facilitated interdisciplinary discussions and collaborative learning, with active engagement	The Workshop on Systematic Review and Meta-Analysis, held on 04th September 2025 at the National Institute of Siddha (NIS), Chennai, was jointly organized by the National Institute of Siddha, Ministry of AYUSH, Government of India, and ICMR-NIRT, Chennai. The workshop focused on strengthening research capacity through systematic review methodology and meta-analysis techniques. Sessions covered systematic review fundamentals, PROSPERO registration, PRISMA guidelines, the PICO framework, evidence hierarchy, meta-analysis methods, effect size interpretation, PubMed and MeSH search strategies, and the use of Rayyan software for study screening. Hands-on activities and discussions enabled participants to draft research questions relevant to Siddha and integrative health research.
23	Two-days workshop on data science using python software Dates: 22nd- 23rd September 2025	Researchers, students, and professionals interested in applying data science methods in health and biomedical research.	The workshop was organized by the Department of Statistics, ICMR–NIRT to provide participants with practical exposure to data science concepts and Python-based analytical techniques. The workshop covered key topics including data handling, exploratory data analysis, basic statistical modelling, and visualization using Python. The workshop facilitated interactive learning and capacity building, contributing to enhanced analytical competence among participants.
24	Health Technology Assessment (HTA) Session in the Pre-Conference DPHICON25 Dates: 25-27th September 2025	About 100 participants from across Tamil Nadu attended the HTA session at the Pre-Conference of DPHICON 2025. Attendees included District Health Officers, Additional	The HTA session was conducted during the Pre-Conference of DPHICON 2025 at Periyar University, Salem, Tamil Nadu. It was jointly organized by the Directorate of Public Health and Preventive Medicine, Government of Tamil Nadu, and the Regional Resource Hub for HTAIn at ICMR-NIRT, Chennai. The session

S. No	Title of the Event	Participant profile	Summary
		and Joint Directors, Medical Officers, Second Level Officers, Staff Nurses, students, and public health professionals.	focused on promoting evidence-based decision-making through health economics and cost-effectiveness analysis. Sessions covered economic evaluation concepts such as QALY, DALY, sensitivity analysis, and practical HTA case studies on NCD screening, hepatitis, dengue, TB diagnostics, LTBI testing, and DR-TB treatment. Their multidisciplinary participation enabled discussions on cost-effectiveness, quality of life measurement, and economic evaluation, strengthening understanding of HTA in evidence-based public health decision-making.
25	5th Community Advisory Board (CAB) Meeting -2025 Date: 13th October 2025	CAB members	The Community Advisory Board (CAB) meeting of ICMR-NIRT was held on October 13, 2025, at ICMR-NIRT, Chennai. The Principal Investigators of various research projects with community components presented their studies and received critical input from the CAB members. Updates on institutional community engagement activities, focusing on Nikshay Mitra and Wings of Support initiatives were also discussed.
26	Awareness Programme Empowers Sanitation Workers in Agaramthen, Kanchipuram Date: 14th October 2025	Sanitation Workers	ICMR-National Institute for Research in Tuberculosis (ICMR-NIRT), in collaboration with Madras Christian College (MCC) and Agaramthen Panchayat Office, organized a Tuberculosis Awareness Programme for 45 sanitation workers at the Agaramthen Panchayat Office.
27	Motivational Event for National TB Elimination Program Staff, Kanchipuram - 2025 Date: 4th November 2025	NTEP staff, Kancheepuram (Health Visitors, Senior Treatment Supervisors (STS), and Senior Tuberculosis Laboratory Supervisors (STLS) from various TB units)	The Department of Social and Behavioural Research (DSBR) of ICMR-NIRT hosted a motivational event for frontline health staff of the National TB Elimination Program in Kancheepuram District on 4th November 2025. The event aimed to boost morale and provide valuable insights. The interactive session covered essential themes such as work-life balance and peer support,

S. No	Title of the Event	Participant profile	Summary
			facilitated through engaging activities like chart exercises and role-plays.
28	Public Viva – Voce Examination of Mrs. S. Pavithra Date: 7th November 2025	111 Participants attended the event At Robert Koch Auditorium (Lab Building) – ICMR – NIRT	The Ph.D., Public Viva – Voce Examination of Mrs. S. Pavithra for the award of Ph.D., degree held on 7/11/2025. Dr. C. Girish Kumar, Scientist- F, ICMR-NIE, Chennai - 600077 along with Dr. B. Ramalingam, Scientist 'F' & DBT Ramalingaswami Fellow, Department of Immunology, ICMR-NIRT, Chennai 31, Supervisor of the candidate and Convener of the Examination conducted the Public Viva voce of Mrs. S. Pavithra and examined the candidate extensively on the research carried out for her Ph.D. thesis.
29	A Hands-on Workshop on Basics and Application of LCMSMS Dates: 26th- 27th November 2025	Technical Staff (10 nos) from different laboratories of ICMR-NIRT and 18 post graduate and PhD students from different Universities participated. Total number of participants: 28	The training program was well received by the participants. A quiz program was conducted post training to assess the understanding of participants on the subject. Winners received special prizes and participants received certificates.
30	Self-Efficacy Study Review Meeting- 2025 Date: 9th December 2025	Healthcare providers- NTEP, TB survivors & caregivers.	The meeting provided a valuable platform to review progress and share experiences. TB survivors who completed treatment expressed interest in serving as TB Champions. NTEP staff shared practical suggestions to strengthen intervention sessions, and healthcare providers assured continued support for implementation.
31	SARANSH (META program) Dates: 24-28th November 2025	Faculty from medical colleges, National institutes and Scientists from ICMR centres.	Included online sessions and in-person from 24-28, November 2025. Participants successfully developed skills in formulating review questions and protocols, registering protocols in PROSPERO, screening and selecting articles for reviews, assessing methodological quality using

S. No	Title of the Event	Participant profile	Summary
			QUADAS-2 and QUADAS-C, developing review-specific QUADAS-2 tools, and designing and using data extraction forms. The reviews are currently ongoing and mentorship being provided for review completion and publication
32	Advanced TB Diagnostics capacity-building workshop. Dates: 15th - 19th December 2025	The workshop brought together participants from public sector institutions, medical colleges, laboratories, industry partners and TB programmes from India and other countries of the South-East Asian Region	Organizers: ICMR- NIRT & McGill University, Canada. The workshop addressed the full spectrum of TB diagnostics, spanning the pipeline of innovations, target product profiles, and discovery-to-implementation and policy pathways.
33	A Hands-on Workshop on LCMSMS Instrumentation Dates: 17th – 19th February, 2026	The technical sessions were attended by post graduate students, research scholars, technical staff & scientists. In-depth hands-on training was given to 10 technical staff & scientists of ICMR NIRT. Total number of participants: 90	During this workshop, a technical session was organized to all scientific & technical staff of ICMR-NIRT. Following this session, in-depth hands-on training on Therapeutic Drug Monitoring, Metabolomics & Biomarker Discovery Application of LCMSMS was provided to selected scientific & technical staff of various laboratories of ICMR-NIRT
34	SARANSH 2.0 - National workshop on Systematic Reviews and Meta-Analysis Dates: 23-27th February 2026	Participants represented a wide range of institutions across India, including medical colleges, national research institutes, public health organizations, and universities. They were affiliated with institutions such as Christian Medical College, Vellore; ICMR-NIE, Chennai; National Institute of Siddha; IIT Mumbai; Sri Ramachandra Institute of Higher	ICMR-National Institute for Research in Tuberculosis (ICMR-NIRT), Chennai, conducted the SARANSH-2.0 Workshop on Systematic Review and Meta-Analysis from 23-27th February 2026, organized by the Technical Resource Centre (TRC), Centre for Evidence-Based Guidelines. Guided by Dr.M.Muniyandi, the workshop provided training on framing research questions, PRISMA-based study selection, data extraction, review tools, and risk-of-bias assessment. Sessions by expert resource persons and hands-on group activities enhanced practical skills in evidence synthesis. A total of 38 participants

S. No	Title of the Event	Participant profile	Summary
		Education and Research; SRM Institute of Science and Technology; Pondicherry University; PSG College of Pharmacy; Cancer Institute (WIA), Chennai; Piramal Swasthya, and the World Health Organization.	attended the workshop. The valedictory session was presided over by the Director, ICMR-NIRT, who distributed certificates and encouraged participants to apply systematic review methods in evidence-based research and public health decision-making.
35	Symposium on "Update on TB meningitis" Date: 6th March 2026	Doctors, nurses, para-medical professional	Sessions covered multiple lectures on recent update on diagnosis, treatment and management of TB meningitis.
36	National Workshop on tNGS for Drug-Resistant TB. Dates: 9th -13th March 2026.	Study site PI and Co-I, 35 participants	Training on tNGS

Staff List

Please refer the website link or scan the QR code for details:

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