South-East Asia Regional Meeting on South-South collaboration on research and innovation in TB

NIRT, Chennai, India, 11–12 July 2023
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Acronyms

ACF active case-finding
ADR adverse drug reaction
aDSM active drug safety monitoring and management
AE adverse event
AI artificial intelligence
BPaL bedaquiline, pretomanid, linezolid
BPaLM bedaquiline, pretomanid, linezolid and moxifloxacin
BRICS Brazil, Russia, India, China, and South Africa
CAD computer-aided detection
CXR chest X-ray
DAT digital adherence technology
DHIS2 District Health Information Software 2
DR-TB drug-resistant TB
DSMB Data Safety Monitoring Board
DS-TB drug-sensitive TB
DST drug sensitivity testing
EPTB extrapulmonary TB
EQA external quality assurance
ERC Ethical Review Committee
GDF Global Drug Facility
GIS geographical information system
GTB Global TB Programme
HH household
HHC household contact
HIV human immunodeficiency virus
ICMR Indian Council of Medical Research
IGRA interferon gamma release assay
KAP knowledge, attitude, and practice
LAMP loop-mediated isothermal amplification
LTBI latent TB infection
LPA Line-probe assay
MDR-TB multidrug-resistant TB
MIP/Mw Mycobacterium indicus pranii
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>mRNA</td>
<td>messenger RNA</td>
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<tr>
<td>NGS</td>
<td>next-generation sequencing</td>
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<td>NSP</td>
<td>national strategic plan</td>
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<td>NTEP</td>
<td>national TB elimination programme</td>
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<td>NTP</td>
<td>national TB programme</td>
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<tr>
<td>OR/IR</td>
<td>operational research/implementation research</td>
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<tr>
<td>PHEIC</td>
<td>Public Health Emergency of International Concern</td>
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<tr>
<td>PLHIV</td>
<td>people living with HIV</td>
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<tr>
<td>PMDT</td>
<td>programmatic management of drug-resistant TB</td>
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<tr>
<td>PoC</td>
<td>point of care</td>
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<tr>
<td>PTB</td>
<td>pulmonary tuberculosis</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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<tr>
<td>rGLC</td>
<td>Regional Green Light Committee</td>
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<tr>
<td>RMP</td>
<td>rifampicin</td>
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<tr>
<td>RR-TB</td>
<td>rifampicin-resistant TB</td>
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<tr>
<td>RTC</td>
<td>randomized controlled trial</td>
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<tr>
<td>SAE</td>
<td>severe adverse event</td>
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<tr>
<td>SE</td>
<td>South-East</td>
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<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TDR</td>
<td>Special Programme for Research and Training in Tropical Diseases</td>
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<tr>
<td>TPT</td>
<td>tuberculosis preventive treatment</td>
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<tr>
<td>TST</td>
<td>tuberculin skin test</td>
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<tr>
<td>WGS</td>
<td>whole-genome sequencing</td>
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<tr>
<td>WHO CC</td>
<td>WHO Collaborating Centre</td>
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<tr>
<td>VOT</td>
<td>video-observed treatment</td>
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<tr>
<td>XDR-TB</td>
<td>extensively drug-resistant tuberculosis</td>
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Executive summary

The two-day “South-East Asia Regional Meeting on South–South Collaboration on Research and Innovation in TB” was held in Chennai, India on 11–12 July 2023. It aimed to lay the foundation for strengthening collaboration on research and innovation to accelerate efforts towards ending TB among Member States in the Region. The participants got an opportunity to share relevant information, experiences, and ideas to strengthen the research network in the Region for capacity-building and fund-raising.

The Director, Communicable Diseases, WHO South-East (SE) Asia Regional Office in his opening remarks emphasized that research and innovation are essential components of the Regional Strategy to end TB. They are needed to address the challenges to regional progress in the fight against TB.

In a presentation by the Global TB Programme, WHO headquarters, the participants were informed about the Director-General’s Flagship Initiative to end TB, 2023–2027. The Initiative aims to put the spotlight on the urgent need to increase domestic and international investments in TB services, and in TB research and innovation, particularly for new vaccine development.

Member States need to define (1) national TB research priorities and (2) a regional approach that would create a good dynamic and synergize the efforts, (3) to focus limited research and development (R&D) resources on high-priority and high-quality research.

Highlights from the recently conducted SE Asia Regional Research Landscape Analysis were also presented, which informed the group about the TB research ecosystem in the SE Asia Region. It also gave insight into the nature and magnitude of intercountry institutional collaborations in research publications from the Region.

The Indian Council of Medical Research (ICMR) shared updates on two TB vaccines that are in the advanced phase of development (1) VPM1002: rBCG vaccine, (2) Immuvac (MIP/Mw) (Mycobacterium indicus pranii). Study details, including the duration, enrolment and initial findings on adverse events, were shared with meeting participants.

Representatives from Member States shared their achievements and ongoing activities related to TB research and innovation. Furthermore, they presented priority areas for TB research and the challenges they faced.

Key research priorities identified during the discussions were as follows:

- Patient pathway analysis to improve outreach for and access to TB services
- Analysis of a pathway for TB preventive treatment (TPT) to improve coverage
- Cost efficiency of chest X-ray (CXR) followed by Xpert
- Early detection algorithm using CXR in health facilities
- Quality assurance of the use of digital X-rays and computer-aided detection
- Feasibility studies for new diagnostics, e.g. TB antigen skin test
➢ Shorter regimens (drug-sensitive TB [DS-TB – 4 months), TPT 0–18 years for DS-TB and drug-resistant TB (DR-TB), 1 HP, 3 HP
➢ Implementation of performance-based financing
➢ Feasibility study for social support
➢ Bovine TB surveillance under One Health.

The group work helped to draft the outline for the regional strategic roadmap for research and innovation planned to be published on World TB Day, 2024. The meeting concluded with the following key recommendations.

➢ To identify context-specific research priorities among Member States
➢ To build the research capacities of Member States
➢ To efficiently and effectively utilize the available resources, including engaging WHO collaborating centres in research capacity-building
➢ To strengthen the regional research network for multicounty studies and gain equitable access to new tools and technologies
➢ To develop and disseminate the Regional Strategic Roadmap for research and innovation.
1. **Inaugural Session**

Dr Suman Rijal, Director, Communicable Diseases Department, WHO Regional Office for South-East (SE) Asia welcomed all the participants, including representatives of national TB programmes, members of the South-East Asia Region Strategic Technical Advisory Group – Tuberculosis (SEAR STAG-TB), representatives of the WHO collaborating centres, partners and donors.

He delivered the opening address on behalf of the Regional Director, WHO SE Asia Region (Annex 1). He conveyed the expectation that the meeting would provide an opportunity to share experiences mutually and strengthen the research network in the Region for capacity-building and fund-raising. He also emphasized the need for intensified research and innovation to end TB in the Region.

Dr C. Padmapriyadarsini, Director, India Council of Medical Research – National Institute for Research in Tuberculosis (ICMR – NIRT) presented the mandate of the Institute in TB research, its ongoing research activities and landmark achievements. This gave an overall idea of its contribution towards TB elimination in the country and beyond.

Dr Vineet Bhatia, Regional Advisor (TB) requested the audience to share their expectations of the regional research meeting. Then, he presented the general and specific objectives of the consultative workshop. He also described the rationale behind the framework of the meeting agenda to strengthen the South–South collaboration on Research and Innovation in TB.

The inaugural session was followed by technical sessions with presentations by representatives from WHO headquarters and the Regional Office, a consultant on research landscape analysis, ICMR on the updates in TB vaccines, representatives of Member States, WHO collaborating centres, partners and donors. At the end of day 1 and day 2, the Regional Advisor (TB) recapped and highlighted the key points.

2. **Session 1: Background: WHO Global Strategy for TB research, support available, and Regional progress towards ending TB**

*The Global Strategy for TB research and innovation*

Dr Nebiat Gebreselassie (WHO headquarters) presented the Global Strategy for TB research and innovation, which was developed and adopted by all Member States in 2020. She explained how research is critical to break the trajectory of the TB epidemic. The objectives of the global strategy are:

1. to create an enabling environment for TB research and innovation;
2. to increase financial investment in TB research and innovation;
3. to promote and improve approaches to data-sharing;
4. to ensure equitable access to the benefits of research and innovation.
Major progress has been made since the End-TB Strategy was adopted in 2015 and research has transformed TB prevention and care in the following ways:

- twelve new diagnostic tests recommended;
- shorter treatment for both drug-sensitive (DS) and drug-resistant (DR)-TB;
- safer and shorter treatment for TB infection;
- positive signal from the M72/AS01E phase IIb trial (vaccine targeted).

Dr Nebiat shared the TB research tracker (https://tbtrialtrack.who.int/#/) to access up-to-date information on clinical trials, operational research and other studies on TB and multidrug-resistant (MDR)-TB.

The diagnostic pipelines remain robust but a simple, point-of-care (POC), rapid, affordable, and accurate test for the detection of TB that can be used for all presumptive TB patients remains a top priority to close the diagnostic gap. She highlighted some of the new drugs and TB preventive regimens to treat TB infection, as given below.

- trials on TB preventive treatment (TPT) for contacts of different forms of DR-TB;
- use of a short-course TPT regimen among very young children;
- co-administration of antiretroviral therapy and short-course TPT.

Dr Nebiat described why fast-tracking the development of new TB vaccines remains a priority: a large number of people have been infected; complex social and biological risk factors drive the epidemic; determinants are worsening due to armed conflicts, climate change and disasters; and it has been 30 years since the Director-General of WHO declared TB a “global public health emergency”.

There are some emerging opportunities, such as:

- positive signals from the M72 vaccine candidate;
- the second UN High-Level Meeting on TB (September 2023);
- lessons learnt from the COVID-19 pandemic.
- Factors that accelerated vaccine development of SARS-CoV-2 include the following
  - discovery: antigen discovery, plug-and-play platform, early chemistry, manufacturing and controls (CMC);
  - clinical development: parallel clinical development, overlapping trial phases, trial harmonization and networking, innovative trial design;
  - enabling conditions: Public Health Emergency of International Concern (PHEIC), visible economic and health consequences in high-, middle- and low-income countries, massive public funding for research and development (R&D), strategic approach to vaccine R&D, advance market/purchase commitment, open science;
  - uptake and impact: accelerated review and approvals, large-scale public health campaign in high-, middle- and low-income countries.
She informed the audience that a “TB Vaccine Accelerator Council” has been established to facilitate the development and availability of TB vaccines that are effective in halting the TB epidemic. The objectives of the Council are to catalyse high-level alignment between funders, global agencies, the government, and communities on the important challenges in TB vaccine development, and on action to address them. The Council will work to boost TB vaccine pipelines and facilitate the licensing and use of safe TB vaccines that have an impact in halting the TB epidemic.

On World TB Day 2023, WHO released the Director-General’s Flagship Initiative to end TB, 2023–2027. The Initiative aims to put a spotlight on the urgent need to increase domestic and international investments in TB services and TB research and innovation, particularly for new vaccine development.

**Support offered by TDR/WHO for research**

Dr Corinne Simone Collette Merle from the Tropical Diseases Research (TDR) shared information on the three core areas of work: global engagement, research capacity-strengthening, and research for implementation. TDR intends to optimize the use of current and new tools. TDR provides three types of support for facilitating the conduct of TB operational research and implementation research (OR/IR):

- support for strengthening the research capacities of national TB programmes (NTPs);
- technical and financial support for conducting country-led OR/IR projects;
- development of research tools/packages for facilitating the set-up and conduct of OR/IR projects.

In line with the Global Action Framework for TB research, TDR promotes (1) the establishment of a national TB research task force, (2) the definition of TB research priorities (at national/subnational level), (3) the evaluation of countries’ TB research capacities and (4) the development of a national TB research agenda. TDR also strengthens the research capacities of NTPs based on national TB research plans and the definition of training needs; develops and conducts customized regional training programmes using various TDR training tools; conducts IR/OR that addresses national TB research priorities with technical and financial support from TDR and partners. The ShORRT initiative supports the performance of OR on all-oral shorter MDR-TB treatment regimens, and 27 countries use this research package.

The Implementation research for digital technologies in TB prevention and control (IR4DTB) Toolkit assists NTPs to develop IR studies to support the adoption and scale up of digital technologies for TB programmes. It can be used as a self-directed learning tool as well as to deliver a week-long training course with technical support and mentorship to countries throughout the IR process.

An OR package to generate data on treatment decision algorithms for PTB in children (TDA4Child) facilitates evaluation of the performance, feasibility, acceptability and impact of treatment decision algorithms for childhood TB. It is a simplified OR protocol to collect and analyse the requisite data necessary and is a generic electronic database that uses Research Electronic Data Capture (REDcap). There are standard operating procedures to conduct and monitor OR studies.
Overview of research activities and capacity-building supported by the SE Asia Regional Office

Dr Manju Rani, Regional Advisor research and innovation in the Regional Office highlighted the importance of quality of research in her presentation. She explained the overarching R&D priorities for TB as defined in the Global Research and Innovation Strategy for TB 2020. The priorities are as follows:

- R&D of affordable and accessible rapid point-of-care (POC) tests for TB infection and disease;
- shorter, safer and more effective treatments for TB infection and TB disease;
- a TB vaccine that is effective before and after exposure.

Innovative strategies to address the broader determinants of TB such as poverty, undernutrition, HIV infection, smoking and diabetes are also priorities as articulated in the Global Research and Innovation Strategy for TB 2020.

The TB research ecosystem in the Region shows that the research investments and research outputs on TB are increasing. Progress in TB R&D: clinical trials (intervention research) related to TB are given below.

- International clinical trial platform (1744 clinical trials between 1999 and 2022)
- US clinical trial registry (162 clinical trials, from five countries – Bangladesh, India, Indonesia, Nepal, and Thailand)
- In national clinical trial registries: Indian clinical trial register: 182 clinical trials, none on the Sri Lanka or Thailand website.

She stressed that research is a public good – not everything needs to be done by each country. The way forward is

- to have better research and management;
- to develop clinical research networks and partnerships;
- to develop capacity and reward researchers willing to upgrade their skills: build capacity to do high-quality research;
- to streamline the regulatory system for research approvals.

The Regional Advisor concluded her presentation with some highlights.

- R&D for TB will be central to the End TB Strategy 2030.
- Both IR and OR will be needed.
- The quantity of research projects has been increasing steadily but the same cannot be said of the quality.
- It is key to focus highly prioritized research conducted by research networks as multicountry research projects with researchers from smaller and low-prevalence countries with prior benefit-sharing agreements.
- Improved research governance and management are essential.

The general objective of the consultation was to strengthen country systems for monitoring TRM performance in the South-East Asia Region.
3. **Session 2: TB research landscape analysis and innovations: TB Vaccines**

**Regional research landscape analysis**

Dr Srinath Satyanarayana, independent consultant, shared the results of a descriptive analysis: Scientific publications on TB from countries of the WHO South-East Asia Region 2017–2022. The objectives of the study were to assess the following:

- the contribution of countries in the Region to scientific publications;
- how many were published in journals indexed in the US National Library of Medicine’s MEDLINE database during the past five years (2017–2022);
- the number of clinical trials/randomized controlled trials (RCTs) in the Region;
- the nature and magnitude of intercountry institutional collaboration in the studies.

The Consultant explained the methods of the study. The US National Library of Medicine database was searched using the PubMed search engine with the key terms “tuberculosis”, the “country name” and the time period for “1/1/2017 to 31/10/2022’ (~5 years). The rationale for choosing the US National Library of Medicine’s MEDLINE database was that it is one of the largest scientific medical databases in the world and an analysis of the articles published in this database would give indicative information on the research activities in the SE Asia Region. Data on clinical trials from the Region were assessed without time limits from https://clinicaltrials.gov.

- The total number of publications on TB in the Region in the initial search was 9765 and the number screened was 4068 (42%). The number found relevant was 3468 (85%) from 2017 to 2022.
- Types of TB studies published from the WHO South-East Asian countries (January 2017 to October 2022) were categorized as original research (56–62%) during this period. However, clinical trials were about 1–2% only.
- Extrapulmonary TB (EPTB) was the most common research topic (with >30 studies) followed by diagnostics and DR-TB.
- Out of 162 regional-level clinical trials, 92 had been completed and 32 were recruiting.
- Network diagrams were shown to illustrate intercountry collaborations on TB publications in the Region, 2017–2022.
- A limitation of the study was that only PubMed and Clinicaltrials.gov were searched. National journals that were not indexed were missed out and there may be subjectivity in the classification of TB topics.
- Dr Srinath provided the key messages: many publications on TB (~1500 per year) from the Region. In most regional countries, the number of publications (year-on-year) showed an increasing trend, most of the studies were observational ones, followed by case reports and commentaries. RCTs and modelling studies were very few; the contribution of the Region to RCTs is minimal, only five countries had undertaken RCTs. The 162 trials represent about 13% of the 1283 trials on TB registered on https://clinicaltrials.gov.
Large numbers of intercountry collaboration in research were observed in all high TB-burden countries and the institutional mechanisms facilitating such collaborations needs further exploration.

**Update on TB vaccines (Indian Council of Medical Research – ICMR’s TB Vaccine Trial)**

Dr Manjula Singh provided updates on two TB vaccines.

- **Vaccines in the advanced phase:**
  - VPM1002: rBCG vaccine
    - safe and immunogenic in adults, newborns (both BCG-naive and -exposed)
    - effective in preventing recurrence of TB (Phase II).
  - Immuvac (MIP/Mw) (Mycobacterium indicus pranii)
    - heat-killed suspension of Mw
    - marketed for leprosy cases and contacts
    - protective against pulmonary TB
    - effective in Category II TB patients.
  - Other vaccines
    - MTBVAC (Biofabri) (in Phase III)
    - M72 + AS01 (Glaxo) (Phase II completed)
    - DAR1002 (Phase II completed)
    - M. vaccae (Phase III completed)

TB is an airborne disease, and there is evidence that the maximum risk of TB infection and disease is among household contacts (HHCs). A TB prevalence of 3–5% among HHCs was the rationale for the vaccine trial in HHCs. Therefore, a preventive TB vaccine trial in HHCs was proposed with two vaccines. A presentation was made on a Phase III, randomized, double-blind, three-arm placebo-controlled trial to evaluate the efficacy and safety of two vaccines VPM1002 and Immuvac (Mw) in preventing TB in healthy HHCs of newly diagnosed smear-positive TB patients. The trial has eight main sites and 10 subsites.

The primary objective was to evaluate the efficacy of VPM1002 and Immuvac by comparing the reduction in the incidence of TB over 3 years among healthy Indian HHCs of smear-positive pulmonary TB (PTB) patients vaccinated with VPM1002 and Immuvac in comparison to placebo.

The progress of the TB vaccine trial was shared with the audience. After all statutory approvals, the study was initiated on 15 July 2019 at the National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi. Other sites were initiated between August and December 2019. The last site was initiated at the end of December 2019. The study duration is 48 months, and the follow-up period is 3 years.
Follow-up has been done for the safety and efficacy of the trial vaccines. Safety has been established since solicited adverse events (AEs) were mild and acceptable. There was no serious adverse event (SAE) related to the investigational product (IP). The total number of TB cases in the study to date were 485, including 39 co-prevalent cases and 446 incident TB cases. Microbiologically confirmed incident TB cases were 241. There were multiple reviews by the Data and Safety Monitoring Board (DSMB) till 24 months of follow-up of all participants.

Based on the interim trial results, the DSMB found no safety concerns and recommended that all the IPs are safe. Follow up is expected to continue.

Another analysis will be presented after all enrolled participants have completed the 32 months of follow up).

4. **Session 3: Presentations by Member States on TB research priorities, ongoing research, challenges and future plans**

*Bangladesh*

On behalf of the National TB Programme, Bangladesh, Dr Nazis Arefin Saki from the WHO Country Office presented key notes related to research done and ongoing research. The big impact of a successful 9-month Bangladesh regimen was shared. It was an observational study, used a standardized regimen, to be implemented in routine programmatic conditions. The treatment success rate (March 2005–June 2011) was 85.2% (439/515). Major surveys completed in the country are (1) the First Bangladesh National Tuberculosis Drug Resistance Survey 2010–2011, (2) National Tuberculosis Prevalence Survey 2015–2016 and (3) Second Bangladesh National Tuberculosis Drug Resistance Survey 2018–2019.

Multicountry studies include (1) The End TB observational study protocol: treatment of MDR-TB with bedaquiline- or delamanid-containing regimens, (2) a multicountry, epidemiological study to assess the interferon-gamma release assay (IGRA) positivity, and to build capacity to conduct a TB vaccine efficacy study, in populations with a high TB-disease burden.

The NTP-funded ongoing OR in Bangladesh included the following:

1. assessment of lung function and health-related quality of life in children after treatment for pulmonary tuberculosis in Bangladesh;
2. the efficacy of interleukin-32 as a biomarker for the diagnosis of tuberculous pleural effusion in Bangladesh: a cross-sectional study;
3. knowledge, attitude, and practice on tuberculosis among health workers of private hospitals in Kushtia, Bangladesh;
4. nutritional status and other associated factors of patients with tuberculosis in selected urban areas of Bangladesh;
(5) programmatic implementation of the WHO-endorsed rapid diagnostic tool geno type MTBDRplus, for MDR and early diagnosis and treatment initiation of pre-extensively drug-resistant (XDR)-TB in Bangladesh.

**Challenges**

- Funding for research is insufficient.
- Coordination and collaboration are lacking between research organizations and the national programme.
- There are administrative barriers in the government funding mechanism.
- Research findings are often not adopted by the Programme.
- NTP-funded studies rarely published in peer-reviewed journals.

**The way forward**

- Advocacy should be conducted for increased funding, both domestic and donor.
- Capacity-building should be done on research of the NTP and partners.
- Coordination should be increased between the NTP and research organizations.
- Peer support needs to be provided for research and publication.
- National programmes should be sensitized on evidence-based policy formulation.

**Bhutan**

Dr Tandin Zangpo, Senior Medical Officer, Gidakom Hospital, Thimphu, Bhutan shared the research priorities of Bhutan:

- Design a plan to implement case-finding using a TB mobile van/unit with CXR/Xpert.
- Clinically evaluate PTB MDR-TB patients after completing treatment for post-tuberculosis lung disease (PTLD).
- Evaluate the feasibility and sustainability of implementing social support schemes (Including non-financial ones).
- Pilot video-observed treatment (VOT) for MDR-TB cases in high-burden districts.
- Implement whole-genome sequencing (WGS) for TB by 2024.

He informed the audience that recently completed research activities were (1) Primary MDR-TB risk factor study, 2017, (2) EPTB risk factor study, 2018 and (3) Treatment outcome and compliance study – shorter and longer regimens, 2019. Additionally, ethical clearance is waited for another study – Tracing the possible source of multidrug-resistant tuberculosis (MDR-TB) into Bhutan: a 2016–2020 retrospective cohort study.
Dr Tandin highlighted the key gaps in screening and testing, treatment, care and support, community outreach and engagement, and health system issues. These gaps were summarized from the Regional Green Light Committee (rGLC) mission report, National Strategic Plan (NSP) and enhanced portfolio review. There were several recommendations from those sources/ reviews. He explained that the future plan of Bhutan will be to implement prioritized interventions as per the recommendations to fill the gaps. These interventions are as follows:

- Implement CXR and Xpert MTB/RIF as the initial tests for the diagnosis of TB.
- Integrate TB in the NSP for improved diagnosis of childhood TB and EPTB and use of Xpert Ultra for childhood TB case-finding.
- Initiate the implementation of WGS to trace the likely source of MDR-TB in the country.
- Introduce and procure new antigen-based skin test for latent TB infection (LTBI) testing.

**India**

Dr Ravinder Kumar, TB specialist, Central TB Division, National TB Elimination Programme, India presented the research activities and challenges in the country. India is committed to ending TB by 2025, five years ahead of the global target of 2030. Achievements included accelerated implementation of a robust National Strategic Plan, increase in private notification to over 30% of the total notification and reduction in missing cases. Dr Ravinder provided the summary of TB research in different areas.

**Areas for research in TB treatment**

- Modelling for the TB disease burden and impact of interventions
- Studies on transmission of TB and impact of personal protective measures to prevent airborne infections
- New short-duration regimens for treatment of TB/DR-TB
- S-tudies on TPT – new regimens, acceptability, completion of treatment and contributing factors
- Studies on information, communication and technology (ICT) tools in treatment adherence.

**Areas for research in TB diagnostics**

- Affordable newer diagnostic technologies
- Loop-mediated isothermal amplification (LAMP)-based diagnostic assays
- Blood-based point-of-care (PoC) test for diagnosis of TB
- Novel techniques for identification of drug resistance, e.g. WGS, nanopore.
Areas for research in TB partnerships and others

- Studies on patient provider support agency (PPSA) services
- Evaluation of implementation status of new policy decisions like community support for TB (Pradhan Mantri TB Mukt Bharat Abhiyaan [PMTB MBA])
- Feasibility and cost–effectiveness of ICT-based systems

Dr Kumar also informed participants of some challenges such as reaching the unreached: hard-to-reach areas, urban slums, migrants; huge reservoir of TB infection; the social determinants of disease causation; quality of care in the private sector; stigma and discrimination; poor outcomes in DR-TB patients; slow uptake of ICT-based self-adherence reporting systems; and issues related to sample logistics because of variations in geography.

Indonesia

On behalf of the NTP, Indonesia, Dr Maria Regina Christian, National Professional Officer from the WHO Country Office presented the TB research landscape in Indonesia, TB research priorities and the need and plans for accelerating TB research in Indonesia. She described the Roadmap on Ending TB in Indonesia; the national target is to reduce 50% of TB incidence by 2025. As per the national commitments towards research and innovation, Presidential Regulation No. 67 Tahun 2021 on the TB control programme includes "Utilizing research findings and technological advancements in TB screening, diagnosis, and management". Presidential Decree No. 67 2021, Chapter 4 talks about acceleration of research and innovation in TB. The strategy to prioritize research in TB was described as a two-stage Delphi survey. The articles were grouped based on themes described in the National Strategy for TB Prevention and Control to identify the gaps.

The top 10 Indonesian national TB research priorities were identified. These include (1) early case detection, (2) diagnosis and treatment of DR-TB, (3) contact investigation, among others. The TB research and innovation situation of Indonesia was also presented.


Dr Regina also explained that JetSet TB Indonesia is an independent national research forum focusing on TB diseases and programmes. Membership is voluntary, all TB researchers can become members of JetSet TB. It was formed in 2017 (formerly: TORG). The 5th Indonesia – Tuberculosis International Meeting (INA-TIME) will be organized from 1 to 2 September 2023.
**Maldives**

Ms Neena Mohamed, Senior Health Research Officer from the Ministry, presented the research activities in Maldives. She informed the audience that TB incidence had decreased from a high-endemic to a low-endemic phase. The number of reported TB cases decreased from 137 in 2017 to 87 in 2021, while the TB case detection rate is highest among immigrants (22% in 2021). Maldives targets ending TB by 2025.

The NTP under the Health Protection Agency oversees TB programme implementation, registration, reporting, monitoring and evaluation; and maintains a national register of TB patients. The National Centre for Respiratory Medicine (NCRM), Indira Gandhi Memorial Hospital (IGMH) is the main place for diagnosis, declaration of treatment outcome and clinical management. The Health Information Management & Research Division of the Ministry of Health (MoH) is the main government agency mandated to conduct health-related national research and coordinates the conduct of research with related stakeholders and serves as the secretariat of the National Health Research Council.

The top 10 health research priority areas listed are: Disease epidemiology and risk factors; Food and nutrition; Health-care quality and safety; Health promotion; Health resource allocation; Advancement of health technology “e-Health, Telemedicine”; Clinical studies; Access to health; Health governance and healthy lifestyle.

Ms Mohamed described the challenges such as inadequate funding for research, inadequate technical capacity to conduct research, inadequate diagnostic capacity in the country and the lack of dedicated staff.

**Myanmar**

Dr Thet Naing Oo, National Professional Officer, WHO Country Office, presented the research activities, challenges and way forward. He informed that the National TB Research Symposium could not be conducted since 2019. Support was available for researchers to conduct TB research and publish till 2020 through various sources of funding (including SORT-IT, terminated since 2020). The last prioritized TB research agenda was conducted in 2017: 38 operational topics were identified, 25 out of 38 priority research topics had been completed till 2022.

Lack of support to trained staff and the issue of motivation have been identified as barriers to performing a continuum of quality research. The NTP has faced problems in retaining trained staff. It is necessary to consider the career path of trained staff. Dr Oo listed the key challenges.

- Limited number of studies after training: great efforts have been made to build the research capacity of the NTP staff in the past five years. However, the NTP has initiated a very limited number of studies, despite the presence of funding opportunities and supportive institutions.
- Shortage of human resources: due to shortage in every category of health professionals in the current context, they are overburdened with a busy schedule and limited time for conducting research.
- Lack of sustainable funding: it is essential to secure funding by the time the current support ends.
Dr Thet Naing Oo shared the proposed thematic areas for TB research priorities under the current NSP:

- Prevention (IGRA and new TB antigen-based skin test)
- Diagnosis (TrueNat, GeneXpert Ultra, CXR CAD, sputum transportation through digital technology, outsourcing to the private sector)
- Case-finding – digital technology (chatbot, social media [Facebook])
- Case-holding – DAT (digital adherence technology), VOT (video-observed treatment)
- New treatment regimen (DR-TB and DS-TB – 4 months), DR-TB support packages
- Childhood TB-related OR/IR (TB meningitis surveillance system)
- Screening (screening for all) in the private sector.

The latest tools/diagnostics, technologies recommended/developed/disseminated by WHO, which will be adopted by the country in the near future included computer-aided detection (CAD) for TB; TB diagnosis with TrueNat, especially in remote areas; stool samples for GX Ultra testing in children; pilot implementation of TPT provision in above-5 HHCs using IGRA (in 10 townships of Yangon Region), the planned pilot implementation of TPT provision in above-5 HHCs using the new TB antigen-based skin test in 2024 (in Yangon Region and Mon State).

The future plan for TB research in Myanmar would be revitalizing research, the M&E Technical Working Group under the TB-Technical Support Group (TSG), TB patient cost survey, strengthening new diagnostic algorithms with expanding GeneXpert testing sites, nationwide scale up of the BPaL and moxifloxacin (BPaLM)/BPaL regimen in 2024, a TB-prioritized research agenda workshop and review in 2024 and the childhood TB mission followed by modification of the guidelines.

Nepal

Dr Roshan Nuepane, Director, Southeast Asia Association for Regional Cooperation (SAARC), TB and AIDS Center, Nepal informed that the vision of the National Strategic Plan (2021/2022–2025/2026) is a TB-free Nepal. The National Tuberculosis Prevalence Survey (April 2018–June 2019) reported a higher incidence estimate at 69 000 (245 per 100 000) for all forms of TB. The protocol for the national anti-TB DR survey has been developed. A pilot study will be done on 3 months of weekly treatment with isoniazid and rifapentine (3HP) (12-dose) regimen for LTBI. This will provide data on costs, acceptance rates and completion in Nepal to inform the scale up of TPT in Nepal.

A randomized phase II trial to evaluate the toxicity of a high dose of rifampicin to treat was done with the objectives of assessing whether increasing the dose of rifampicin (RMP) from 10 mg/kg to 15 or 20 mg/kg results in an increase in grade 3 or 4 hepatic AEs and/or SAEs. The study concluded that “No significant increase in adverse events occurred when the RMP dose was increased from 10 mg/kg to 15 mg/kg or 20 mg/kg”.
A randomized trial to evaluate toxicity and efficacy of 1200 mg and 1800 mg rifampicin for pulmonary tuberculosis was done and it has been in the pipeline for publication.

Dr Nuepane shared information about ongoing studies, given below.

**Target TB study**

- Newly diagnosed patients were recruited in the study.
- 1600 sputum samples were collected from three regions of Nepal: Kathmandu, Banke/Bardia, Pyuthan.
- Whole-genome sequencing will be done to provide knowledge of the origin and DR status of the study population.
- The culture and DNA extraction processes are complete whereas genomic analysis is still in process.

**TB-seq disk assay**

- To evaluate the accuracy, sensitivity and specificity of the newly developed microfluidic TB-Seq DisK assay
- At least 150 study patients were enrolled; 100 of them were assigned to the TB-positive and 50 to the TB-negative cohorts, respectively. Two sputum samples per patient were collected.
- The project was introduced by IML red, Gauting and samples were shipped to Germany for further processing.

Dr Nuepane presented a planned research project: “An evaluation of the patient costs and socioeconomic impact of tuberculosis illness, diagnosis, and care in Nepal”.

Challenges included inadequate human resources in the NTP for research (no separate research wing), need for technical capacity enhancement and no government funding allocated for TB research (research has not been a priority).

**Sri Lanka**

Dr Onali Rajapakse, consultant community physician, Samagi Mawatha, Jaliyagoda, Piliyandala, Sri Lanka explained the status of research on TB in Sri Lanka. She presented the programmatic structure, composition and functions of the national research committee. Research priority areas in TB include: the burden of TB/presumptive TB, diagnosis, management of TB – drug therapy, treatment adherence, directly-observed therapy, short-course (DOTS), pharmacovigilance while on TB treatment, TB and comorbidities/nutrition, TB infection/TPT, equity in care, social determinants of TB, service delivery and utilization, EPTB, TB health information management/health informatics for TB, paediatric TB, TB treatment outcomes, DR-TB, infection control, private/public partnership in TB care, stakeholder analysis.
Research has been conducted on the following: (i) the prevalence of TB among prisoners – 1688/100 000 population; (ii) drug resistance survey (2017): the rates of rifampicin resistance (RR)/MDR-TB – new: 0.56%, retreatment: 5.1%; (iii) TB among patients with diabetes mellitus (2021): proportion of bacteriologically confirmed PTB: 0.1% (95%CI = 0.0–0.3%); (iv) care pathway (2021) – initial care provider private sector, delay in diagnosis (mean: District Chest Clinic – 4 days, government hospitals – 13 days, private sector – 26 days).

Dr Onali shared the planned future research list below.

- Inventory survey
- Drug resistance survey
- Pilot project with Xpert MTB as first-line investigation
- Xpert MTB/XDR machine, IGRA facility to be used within the year (Validation studies)
- Cascade of care in TPT (CRITIC study).

She mentioned challenges such as limited resources (funding, logistics and human resources) and regulatory processes to get necessary approvals, which are time-consuming.

**Thailand**

Dr Phalin Kamolwat presented TB research activities in Thailand. As per the data analysed in the country, the outcomes of MDR-TB improved when treatment changed from kanamycin to amikacin and then to a bedaquiline-containing shorter all-oral regimen. The Thailand NTP set up IGRA centres in 2021, and through a new strategic TB Case-Finding, Treatment and Prevention Public Health Pack in Thailand (CaPThai) Research Project, TPT expanded in 2023 with more IGRA centres. The Thailand Operational Plan to End Tuberculosis 2023–2027 has five strategies and the fifth strategy is to promote research and innovation in TB prevention and control. Thailand TB research networks include both national and international networks (WHO, JICA, Institute of Research for Development).

TB research priorities for Thailand are listed below:

- Shorter oral treatment for DR-TB patients, including the BPaL/M regimen
- Shorter oral treatment for DS-TB patients (4-month regimen)
- Friendly regimen drug (3HP, 1HP) for TPT
- Drug regimen (TPT) for close contacts
- Prevalence survey in each group (TBI).

Dr Phalin provided a list of finished and ongoing research topics in TB.

- Tuberculosis patients’ cost survey in Thailand 2019–2021
- Operational research to examine the effectiveness and safety of the BPaL regimen
South-East Asia Regional Meeting on South-South collaboration on research and innovation in TB

- for the treatment of multidrug-resistant tuberculosis in Thailand, 2021
- Prevalence and associated risk factors of drug-resistant tuberculosis in Thailand: results from the fifth national antituberculosis drug resistance survey, 2021
- Diagnostic performance of whole-genome sequencing for identifying drug-resistant
- TB in Thailand, 2021
- Situation of MDR-TB in Bangkok Province 2017–2020, 2021
- Factors associated with tuberculosis treatment outcomes among patients aged ≥60 years

The WGS study on “Genetic decoding of XDR-TB for surveillance and control of drug-resistant tuberculosis epidemic in Thailand” was completed and published.

- A collaborative project between the Tuberculosis Division and the Royal College of Radiologists of Thailand and Faculty of Engineering Chulalongkorn University has been developing an artificial intelligence program to interpret CXR for primary TB diagnosis. A tuberculosis stigma and discrimination in health-care facility survey was done in 2021 and the REDCap online program was applied.
- The 5th National Tuberculosis Prevalence survey in Thailand (pilot) is one of the ongoing activities.
- Implementation of a new strategic TB Case-Finding, Treatment and Prevention Public Health Pack in Thailand (CaPThai) will be done with the following expected outcomes:
  - establish the new intervention combining active detection and prevention of TB cases among HHCs of TB patients;
  - potential case-finding and screening of TB patients and HHCs with TB infection.

Dr Phalin also described the challenges in Thailand related to the required increase in treatment coverage, decrease in TB incidence and increase in the TB budget.

**Timor-Leste**

Mr Constantino Lopes, Manager of the NTP, Timor-Leste presented the TB research activities of Timor-Leste.

1. The TB catastrophic cost survey, 2016–2017 showed that 83% of patients experienced catastrophic costs (direct + indirect costs).
2. The National Anti-TB Drug Resistance Survey (DRS): the first national DRS in Timor-Leste was done in 2019, and the key findings showed that the overall prevalence of rifampicin resistance (RR) was 0.6% (95% CI: 0.2–1.3%) in new TB patients and 2.7% (95% CI: 0.5–8.2%) in previously treated TB patients.
(3) A vulnerability assessment using mobile TB application in DHIS2 informed that 56% of household (HH) members were found to be malnourished and 17% were smokers. The challenges included continuously working with the developers to get the electronic dashboard and real-time data entry application right. Around 41% of referrals for TB testing are either not tested or the results are not uploaded in the mobile application. The lesson learnt was that real-time data entry from the field using mobile application is a reality. Around 25% of HH and 31% of individuals had a vulnerability score >5. A vulnerability database would inform future targeted End TB interventions. He added that a post-pilot intervention is planned to scale up the vulnerability assessment to 24% of the population in 2022–2023, and also to set up linkages with social protection support for the treatment of malnourishment and tobacco cessation centres.

Mr Lopes spoke about the ongoing TB prevalence survey. He described a case study: Improving low case finding during COVID-19 in Timor-Leste, which was published in the Global Fund quarterly report, 2023.

- There is also ongoing activity such as a pilot financial incentive intervention for TB patients.
- Key research priorities of Timor-Leste are as follows:
  - Operational research SORT-IT course with WHO technical assistance;
  - Feasibility studies of various innovations (mobile TB van initiative; experience in integrated TB, HIV and malaria case-based electronic surveillance in DHIS2; smart medicated container kits [SMCK]; case study on performance-based financing [health and financial information integration]);
  - Follow up of the catastrophic spending survey.

He summarized by saying that a small amount of funding is available from the Global Fund to conduct an operational course with WHO technical assistance. A dedicated research officer is available with the NTP to support research, many forthcoming planned innovations using digital technology requiring pilot studies are in the pipeline. The funding for conducting the OR is not available.

5. **WHO collaborating centres**

Presentations were made by five WHO collaborating centres (WHO CCs) on TB research in the workplan of the CC and current engagement with national programmes.

- All India Institute of Medical Sciences (AIIMS), New Delhi
- National Tuberculosis Institute (NTI), Bangalore
- National Institute of Tuberculosis and Respiratory Diseases (NITRD), New Delhi
- National Institute for Research in Tuberculosis (NIRT), Chennai
- Southeast Asia Association for Regional Cooperation (SAARC) TB, Nepal
**All India Institute of Medical Science (AIIMS, Delhi)**

Dr Neeraj Nischal, Additional Professor, Department of Medicine (AIIMS) described why the Institute focuses on EPTB. According to the Global TB Report 2020, EPTB constituted 16% of the 7.5 million reported TB cases globally and accounted for 19% in South-East Asia.

Dr Nischal enlisted the challenges in managing EPTB:

- can mimic any other disease
- difficult to procure a sample
- low positivity rates from the majority of samples
- varying responses to treatment and its duration
- uncertainty regarding the duration of treatment
- empirical treatment of EPTB prevalent, leading to rampant drug resistance.

The WHO CC (WCC) published the first national guidelines for EPTB in 2016 and provided recommendations on three priority areas for EPTB:

- use of Xpert MTB/RIF in diagnosis
- use of adjunct corticosteroids in treatment
- duration of treatment.

Training modules on EPTB were released in 2023 with the objectives of

- providing training on the management of EPTB in concurrence with the INDEX-TB guidelines developed for the Central TB Division (CTB) Ministry of Health and Family Welfare (MoHFW)
- organizing training workshops as part of capacity-building for the management of EPTB for national and Member States’ health-care providers
- developing an e-learning platform on the management of EPTB.

Other engagements are listed below.

- TB–comorbidity collaborative activities (for the national TB elimination programme [NTEP])
- resource faculty for programmatic management of drug-resistant TB (PMDT)
- resource faculty for various TB-related training in Member countries
- National Institute of Tuberculosis and Respiratory Diseases–CTD–National Task Force (NITRD–CTD–NTF) difficult-to-treat TB clinic
- the Department has been carrying out numerous research activities related to TB and has been publishing numerous papers.

Challenges faced are the differences in perspectives and ideas of research among leaders/officials of the Institute, which hinders a move forward at a desirable pace; the lack of funding opportunities and the need for a real-time research directory.
**National Tuberculosis Institute, Bengaluru (IND 55)**

Dr Somashekar N, Director, NTI, Bangalore presented the Institute’s role in capacity-building and TB research. He enlisted some of the planned activities as a WHO CC. These include the following:

- Capacity-building to improve the quality of TB care services and health system resilience for TB control and elimination
- TB epidemiological modelling – transmission models. Meetings were held to identify priority questions; participants included the NTI faculty, researchers from the Union, ESI Medical College Bengaluru, Indian Council of Medical Research (ICMR), Indian Institute of Technology (IIT) Patna, Sri Sathya Sai Institute of Higher Learning (SSSIHL).
- The following modelling projects are in progress in collaboration with SSSIHL.
  - Prediction of TB treatment adherence and recurrence using AI tools
  - Computer vision techniques for TB diagnosis from digitized microscope sputum slides
  - Bayesian approach for line probe assay for reporting DR-TB
  - to estimate the impact of nutritional supplementation to household contacts of microbiologically confirmed PTB patients in addition to TB preventive treatment.
- A concept note was submitted in November 2022 to conduct a 10-day capacity-building workshop in May 2023 to develop structured protocols.
- Capacity-building activities were conducted in collaboration with FIND towards establishing an external quality assurance (EQA) programme for CBNAAT in countries of the WHO SE Asia Region.

**National Institute of TB and Respiratory Diseases (NITRD), New Delhi**

Dr Ravindra Dewan, Director, NITRD presented the following activities:

- Training of trainers for TB programmes; including DR-TB management through modular training courses
- Training in TB surgery: a new programme has been launched by the NITRD in November 2022 for capacity-building of thoracic surgeons in India.
- Two surgeons were admitted to a certificate programme to receive hands-on experience in performing thoracic surgeries.
- NITRD conducts national and international training in the field of: TB, DR-TB, HIV–TB (programmatic management; clinical management); thoracic surgery in TB; laboratory methods; public health; infection control; research methodology.
- Training of nurses was conducted in PMDT, TB diagnostics, infection control, *Kaya kalp* (a quality improvement programme for health-care facilities in India) and digital health,
Training of other staff: infection control and waste management training was regularly organized for the paramedical staff. Training in TB and DR-TB was also organized for medical and paramedical staff. Training was conducted of paramedical staff on counselling techniques and on digital health.

Expansion of web-based training programme: Extension for Community Healthcare Outcomes (ECHO) training activities:
- difficult-to-treat TB ECHO (DTTC)
- thoracic surgery ECHO.

Development and testing of rapid diagnostic tools for TB – novel sample processing for simple and rapid diagnosis of TB, MDR-TB and XDR-TB

Status report on laboratory capacity in Member States to assist in planning for providing effective technical support to the laboratory network in the Region

Operational research on analysis of GeneXpert data to study yields from various risk groups of presumptive DR-TB patients (status: ongoing).

**ICMR–National Institute for Research in Tuberculosis, Chennai (IND-56)**

Dr C. Padmapriyadarsini, Director, ICMR–NIRT delivered the presentation. Some landmark achievements in TB research are as follows:

- domiciliary treatment for TB: as effective as sanatorium treatment
- short-course chemotherapy for pulmonary, DS- and DR-TB and EPTB
- model DOTS project in Tiruvallur district in south India: for DOTS implementation, training and research
- conducted the largest BCG vaccine trial ever (Chingleput BCG trial)
- TB survey.

The Director shared the following activities:

1. shorter/effective TB treatments (DS-TB, DR-TB, paediatric TB, TPT)
2. TB vaccine trials: efficacy of VPM 1002 and Immuvac (Mw) vaccine in reducing incident TB cases.

She emphasized the community and patient-centric work being carried out: developed new tools, a patient-centric intervention module, a needs assessment form for Nikshay Mitra, and a training manual for community volunteers. She also shared information on the TB awareness-raising programme targeting students, TB–information, education and communication (IEC) materials developed. The Institute is working on newer diagnostics in the pipeline such as Mylab; TATA MD; MTC-Q/MDR for MTB; TRUPCR® Rif/INH (3B BlackBio Biotech).

She also briefed participants about the DARE2ERAD TB and surveillance of DR-TB in India as follows:
- trends and patterns of drug resistance, including newer drugs in India to design proper treatment
- distribution of strain lineage in the country and its association with drug resistance
- transmission dynamics, including outbreaks of TB in the country, to design interventions to prevent transmission.

➢ New technologies being developed by the NIRT scientists include:

  - translated technologies: newer devices for primary Mtb detection and drug-sensitivity testing (DST) using the Luciferase Reporter Phage (LRP) Assay in collaboration with India Institute of Technology, Design and Manufacturing (IITDM-Chennai) and Indian Institute of Technology (IIT-Kharagpur)
  - New anti-TB agents: development of novel anti-TB agents to target the cytochrome of Mtb
  - non-sputum-based diagnostics: stool and urine samples.

Dr Siva Kumar focused on laboratory parts that included the development of novel diagnostic technology for TB and DR-TB. He informed participants that this was an easy and inexpensive diagnostic method to detect rifampicin and isoniazid resistance in Mtb from primary cultures within 6 hours (a concept was filed for patent in collaboration with IIT, Kharagpur). NIRT fabricated a semi-automated device (Photon Max 532) for rapid detection of Mtb drug resistance using LRP assay in collaboration with IIITDM, Chennai. This device is fabricated indigenously with inbuilt AI. Validation is to be done.

Protecting and improving public health globally: building laboratory, surveillance and workforce capacity to detect, respond to, and prevent DR-TB in India. The scope of work is given below.

➢ The mutation catalogue can be utilized to direct the development of new and improved molecular assays for determination of resistance as well as act as a reference point for future genomic comparisons of DR-TB strain profiles.

➢ Identification of recent areas of transmission/hotspots for intervention to prevent spread of transmission and combat acquired resistance in vulnerable populations through cluster interventions

➢ Capacity for next-generation sequencing (NGS) and novel minimum inhibitory concentration (MIC)-based assays to optimally detect and survey DR-TB

➢ Capacity for data analysis for NGS with a novel analytics pipeline and national database.

➢ Survey for state-wise and district-wise prevalence of microbiologically confirmed PTB in India

➢ Sentinel surveillance to measure the TB burden and trends in high-risk groups for TB (completed)

➢ Research to identify biomarkers for the rapid diagnosis of TB, predicting the risk of progression from latent infection to active disease and monitoring the treatment response

➢ Capacity-building through skill development for TB diagnostic activities, including newer diagnostics.
**SAARC Tuberculosis and HIV/AIDS Centre**

Dr Roshan Neupane, the Director (SAARC) spoke on the SAARC Tuberculosis and HIV/AIDS Centre, Nepal.

- Three SAARC Member States, namely, India, Pakistan and Bangladesh, are among the 30 high TB-burden countries. Nepal is among the high MDR-TB countries along with the three high TB-burden countries.

The planned activities under the WHO Collaborating Centre (2022–2026) included the following.

- SAARC regional training of trainers on management of DR-TB
- SAARC regional training of trainers on TPT
- SAARC regional training of trainers on management of antiretroviral therapy, TB/HIV and other opportunistic infections
- SAARC regional training on health research methodology
- SAARC regional workshop on scale up of activities for improving case-finding for TB and HIV/AIDS
- SAARC regional workshop on development/monitoring of mechanisms for cross-border activities for TB and HIV/AIDS.

### 6. Session 5: Partner’s and stakeholders’ presentations

**TB Alliance**

Dr Sandeep Juneja presented “Operations research to support implementation of new regimens”. He explained the regimen development approach: BPaL regimen and the feasibility, acceptability, costing studies that provided evidence such as:

- global saving: $740 million/year
- feasibility: 88%
- acceptability: up to 93%
- cost/patient saved: up to 78%.

- The high-level progress of the LIFT-TB was explained, operational research (OR) enrolment has been completed, data analysis is in progress and the interim success rate is consistent with clinical trials.

- LIFT-TB OR: the interim success rate (May 2023) was 92.4% (365/395).

Dr Sandeep Juneja described the upcoming activities of TB Alliance.

- Peer-to-peer learning could prevent reinventing the wheel and speed up implementation.
- The approach recommended is in WHO’s BPaL call to action.
- LIFT-TB is pioneering roll-out; four project countries are in Asia-Pacific!
The region may leverage LIFT-TB learnings/experiences and a variety of tools
- need assessment for laboratory and diagnostics,
- pilot implementation protocols,
- training materials and capacity-building,
- clinical expertise for initial case management,

TB Alliance can facilitate and coordinate with support from key partners and donors for the adoption and scale up of the BPaL regimen.

**UNITAID**

Dr Cherise Scott presented UNITAID’s investment in TB research in support of access and innovation. She provided an overview of UNITAID’s Strategic Approach to TB, which is to scale up better TB treatment for children, and a better, shorter treatment regimen for MDR-TB.

- Prevention: programmatic priority #1 is to introduce and optimize prevention tools, and some of the activities for this are as follows:
  - benefit – TB champ MDR-TB prevention trial of levofloxacin for children: provide treatment support
  - IMPAACT4TB – increased access to more affordable TPT with a focus on 3HP in people living with HIV (PLHIV) and child contacts and this project provides treatment support and demand creation

- Diagnostics: programmatic priority #2 is to accelerate access to new detection tools: DR- and DS-TB diagnostics. The following are some of the activities.
  - Seq&Trt (next generation sequencing for drug-resistant TB testing) catalyse the use of targeted NGS (tNGS) for rapid and comprehensive TB drug resistance testing
  - DriveDx4TB – introduction of three new technology classes (third-generation lipoarabinomannan (LAM); point-of-care molecular diagnostics (POC MDx and near-POC MDx)
  - Start 4-All – optimized TB diagnostic combinations at primary care level by combining diagnostic screening and testing approaches, evaluating their effectiveness, determining the most accurate, feasible, acceptable, and cost-effective solutions to improve access to TB diagnosis.

- Treatment: programmatic priority #3 is to accelerate access to new drugs and regimens. The projects are
  - ASCENT (Adherence Support Coalition to End TB) – scalable, affordable, patient-centred treatment support package informed by digital adherence technology (DAT)
  - EndTB (Expansion of new TB drugs) – shorter, safer, simpler to administer, more effective and affordable MDR-TB regimens
- BENEFIT (Better evidence and formulation for improved MDR-TB Treatment in children) – improved child-friendly prevention and treatment solutions for MDR-TB.

Dr Cherise Scott then provided an overview of the opportunities, including market shaping (through coordination, reaching sustainable price and supply targets for key drugs with shorter DR-TB regimens), informing implementation (defining and building consensus related to a supportive care package to inform implementation efforts considering diverse geographies and contexts) and demand creation (catalysing uptake of a supportive care package [adherence, safety, monitoring, diagnostics/DST, etc.] for responsible product introduction of new DR-TB regimens).

**UNITE4TB**

Professor Daniela Maria Cirillo presented the UNITE4TB project: part of the Innovative Medicines Initiative 2 (IMI-2). Its start/end dates are June 2021 to May 2028.

UNITE4TB project has 30 partners with the following objectives:

- Accelerate and improve the clinical evaluation of new drugs/drug combinations for DS- and DR-TB.
- Establish an efficient global network to implement phase 2A and phase 2B/C clinical trials that conform to the highest regulatory standards.
- Integrate an adaptive trial design with biomarkers of treatment success.
- Employ advanced pharmacokinetic/pharmacodynamic models and artificial intelligence/machine learning techniques to select, test, and deliver new drugs/drug combinations with a high probability of success in phase 3.
- Set new standards for the development of new drugs/combinations, upgrading clinical trial methodology, and enhancing efficiency with which new drugs/regimens are delivered.
- Build a state-of-the-art data management and sharing platform that enables efficient analysis and learning from partners’ trial data, and from existing (pre-)clinical consortia.
- Build a global forum and exchange interface for sharing knowledge and best practices with key stakeholders, and for exploring and implementing collaboration with other consortia.

UNITE4TB upcoming clinical trials include

- **UNITE4TB-01: PARADIGM4TB**
  (Platform Assessing Regimens And Durations InGlobal Multisite Consortium f or TB). This is for the evaluation of treatment with multiple regimens and durations containing either or GSK656* or BTZ043** in adult people with rifampicin-susceptible PTB.

- **UNITE4TB-02: BTZ043 DECISION**
  (BTZ043 Dose Evaluation in Combination and SelectION) for the evaluation of treatment with BTZ043** in combination with bedaquiline and delamanid in adult people with rifampicin-susceptible PTB. It will start in September/October 2023, total – 1 year.
Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association

Dr Seiya Kato shared the research activities of RIT/JATA. Countries in South-East Asia that RIT provided technical support to for prevalence surveys and/or drug-resistance surveys included Bangladesh, Myanmar, Nepal and Thailand.

The iceberg phenomenon of prevalent TB disease was explained. He elaborated on studies on the performance of computer-aided detection (CAD) like the performance of CAD is the same as that of an experienced human, while it has higher accuracy than junior human readers. Most studies were conducted for symptomatic presumptive TB in clinical settings. As community-based systematic screening for TB is carried out in high-burden countries, mass CXR reading is one of the bottlenecks, and CAD will be the most promising solution.

Research questions are listed below:

- Can CAD replace human readers in community-based active case-finding (ACF)?
- How can we use CAD in clinical settings?
  - CAD→ human reader (for confirmation)
  - human reader →CAD (ancillary to human reading?)
  - human reader and CAD (independently), followed by the third human reader?
- Which should be the initial test for a cost-effective algorithm for a people-centred framework (PCF) of presumptive TB at a facility)?
  - molecular diagnostic test
  - CXR screening by CAD

Dr Kato presented the operational research on TB mass screening and explained the new guideline: screening with CXR images + AI Assist, TB-LAMP, the algorithm for community-based active case-finding in Nepal, the planning in Gujarat, India by Fuji Film and JATA with funding from MITI of the Japanese government. He explained the treatment of LTBI using genome analysis (with Riken). The previous research collaboration was with Thailand, of JATA with NIID, Riken and Tokyo University: NAT2 is associated with liver dysfunction in Thais. JATA will conduct a study with Thailand (Department of Medical Science and Department of Diseases Control) and Riken in northern Thailand.

Stop TB Partnership

Dr Sreenivas A. Nair presented Stop TB Partnership’s work on innovations. He pointed out that innovation is needed to end TB, and the global TB response was not on course to end TB by 2030 (SDG target 3.3). He shared some reasons (not exhaustive):

Diagnosis: 3 million (30%) incident TB cases are missing from care each year.
Diagnosis is late, after TB is already transmitted to contacts.

- Treatment is long and difficult.
- Preventive treatment is not achieving scale.
- There is a lack of an effective TB vaccine.
- People face barriers in accessing care and prevention.
- Possible innovations (examples)
  - products/tools: new molecular diagnostics for peripheral laboratories, screening tools, alternative specimens for testing

TB REACH projects were launched in 2010. Ten funding waves have been launched, which provided more than 350 grants in more than 50 countries for local implementers.

TB REACH-funded innovations include bringing TB diagnostic services to communities, the ultra-portable X-ray, AI to read CXR, identify hotspots, new non-sputum-based diagnostics, pooling sputum to save tests/time/costs and working with key populations.

The objectives and approach of introducing the New Tools Project (iNTP) are

- $26.8 million of commodities: products have been supplied via Stop TB’s GDF and through monetary grants to local organizations.
- Stop TB and the United States Agency for International Development (USAID) are collaborating in programmatic planning, organization of training, implementation research and monitoring product implementation.
- USAID supports in-country implementation through missions and implementing partners.
- Practical guides and training packages for TrueNat and X-ray/CAD have been developed by Stop TB and USAID. Funding is available for civil society and communities.

The Global Fund

Dr Mohammed Yassin, Senior Disease Advisor (TB) of the Global Fund presented remotely and explained that Global Fund allocates US$ 10 million annually for research, specifically for surveys. However, the money remains mostly underutilized. He stated that if any of the countries have missed including research in the original proposal, it is recommended to discuss this during the negotiation process. The Global Fund generally supports operational and implementation research only. For clinical trials, it is generally advised to look for other partners and resources. The Global Fund may consider supporting later stages of clinical trials depending on the nature of the study and if it aligns with the mandate.
Dr Amar Shah, Senior TB Advisor, Strategy and Innovation, USAID India, presented USAID’s structure and key functions. The Agency has been supporting 24 high TB-burden countries through several missions and managing the bilateral programmes. Countries supported in the SE Asia Region include Bangladesh, India, Indonesia and Myanmar.

The USAID TB elimination strategy is similar to that of WHO. USAID operates jointly with NTPs, and all other institutes such as WHO, CDC. USAID avoids any duplication.

- He informed the audience that funding support available for research and innovation is for:
  - supporting NTP TB mortality estimates;
  - diagnostics: introduce Xpert MTB/RIF feasibility tests;
  - TA for laboratory network assessment;
  - treatment: STREAM Trial, and BPaL/M regimen;
  - together with NTP: LPA, CAD; and
  - programmatic research.

- There are innovation grants for which any organization can apply.

- At the regional level: e.g. Bangladesh team will come to India for cross-learning purpose.

7. **Session 6: Group work: discussion and presentations**

The participants were divided into four groups and explained the discussions to be undertaken in the group work, with the overall objective of facilitating better collaboration among Member States.

- Group 1: Product development partnership (PDP) for new drugs and vaccines
- Group 2: Operational research on new regimens and quick adoption; identifying research priorities for the Region and opportunities for collaboration on research and innovation and capacity-building
- Group 3: How to improve investments in research and innovation
- Group 4: Development of an SE Asia regional roadmap for research.

After two hours of discussion, a representative from each group presented the salient points discussed during the group discussion. Some of the key highlights of the discussions are given below.
Operational/implementation research on new regimens/diagnostics and quick adoption

- It is recommended to create a platform among Member countries to share their experiences and progress in adopting a new regimen (example: BPaL regimen).
- WHO guidance is requested for adoption of the updated guidelines.
- Identifying roadblocks to adopting new regimens/diagnostics is required (ethical clearance from the country, level of recommendation, strengthened laboratory capacity to detect drug resistance, Member States to do gap analysis and training for HR).
- Training is needed on new regimens/diagnostics for all Member States together, including planning and preparation, and strategies to overcome potential challenges.
- Engagement with major (key) stakeholders should be done, including government officials and implementing partners.
- Compliance with national registration of newer drugs must be done.
- A forum (platform) of Member States should be created to share protocols (online) and standardize these in the Regional Office for the introduction of new regimens/diagnostics – validation protocols.
- Diagnostics – use of biobanks – Regional facilitation/expert support is required.
- Aligning the priority of Member States is necessary.
- Finding missing cases needs to be enhanced using CXR and reverse transcriptase polymerase chain reaction (RT-PCR); these investigations need to be made accessible.
- We learnt (Find cases Actively, Separate safely, Treat effectively) FAST TRACK from our response to the COVID–19 pandemic (clinical protocols for COVID-19 management and massive national vaccination).
- We need to work with professional national societies for effective implementation.
- Getting the highest level of political commitment is key for success.

Capacity-building

- Utilize the resources we have within Member States and strengthen our capacity for research with a structured plan and calendar.
- Use of AI needs to be promoted.
- Retention of skilled human resources (HR) for research is an issue.
- Laboratory capacity-building needs to be done – (turnaround time [TAT], second-line DST), research methodology workshops, capacity-building for data management, analysis and graphic designs.
Standardized/model protocols are required for validation of innovations.

Research priorities are to be synthesized and insourcing and outsourcing talent is requested.

Collaboration should be established with academic institutions such as AIIMS, BPKIHS, NTI, NITRD, NIRT, SAARC TB/HIV Centre.

**Research priorities for the Region and opportunities for collaboration**

Below are the research priorities for the SE Asia Region.

- Innovation to estimate the subnational TB burden
- Missing cases in the defined population
- Stopping transmission
- Subclinical TB management
- Paediatric TB
- EPTB (huge research question)
- Cost-effective diagnostic tools, introducing PoC tests (GeneXpert testing is expensive)
- Cost–benefit analysis of TB interventions
- DR-TB diagnosis and treatment, specifically the use of patient-friendly shorter regimens
- Interventions to reduce TB mortality
- Nutrition and TB
- Social support and TB.

**Development of an SE Asia regional roadmap for research**

The outline drafted is given below.

- Period of the roadmap
- Contents
- Core members, roles and responsibilities
- Workplan and timeline
- Recommendations.

The period for the planned roadmap is 2 years (2024–2025) because the scenario is rapidly changing. This will help in aligning the roadmap to the Regional Strategic Plan (2021–2025). The contents of the regional roadmap 2024–2025 would include background and rationale, vision statement, strategic objectives and activities for each objective, partners and their roles and responsibilities, the timeline, funding requirement, monitoring indicators and the annexures.
An enabling environment is needed, such as cooperative or collaborative agreements/ memoranda of understanding (MoUs) between research institutions, capacity-building, and enhanced networking.

Budgetary estimates are required to support all types of research in the Region and therefore it should be estimated and specified. To promote and improve approaches to data-sharing, the mechanisms for sharing of all types of data (research, programmatic data) need to be identified.

It was also emphasized that fast-track approval of products and political commitment are essential to promote equitable access to the benefits of research and innovation.

- The drafting committee would include the following.
  - Focal: Regional Office
  - Drafting committee: 5–6 members from different Member countries
  - Inputs and review: 5–6 members from different Member countries

- Some of the action points would be
  - to map the research capacities of NTPs in the Region
  - to define their needs in terms of research capacity-strengthening
  - to map their TB research opportunities and national collaborations that they could build on to enhance TB research in their countries.

8. Session 7: Closing session

- The Regional Advisor (TB) made the closing remarks and thanked NIRT and the organizing team for making this meeting a grand success.
- Dr C. Padmapriyadarsini thanked all the meeting participants for their active participation in the meeting.
- The valedictory function was concluded with the distribution of certificates.
Annex 1

Message from the Regional Director, Dr Poonam Khetrapal Singh

The WHO South-East Asia Region has 26% of the world’s population but the highest burden of TB, accounting for more than 45% of global new TB cases in 2021 and half the number of deaths. The Region also accounts for more than 38% of the estimated global incidence of rifampicin-resistant (RR-TB) and multi-drug resistant TB (MDR-TB) cases. Six of the 30 global high TB-burden countries are in the SE Asia Region.

Patient cost surveys in the SE Asia Region found that between 30% and 80% of households bear catastrophic costs due to the disease. COVID-19 has impacted our achievements and reversed years of progress made towards ending TB.

In 2021, only 62% (3 million/4.8 million) of the estimated TB incidence was notified. Due to many missing cases in our Region, the burden will be much higher than before COVID-19. More than 780,000 people are estimated to have died from TB and TB-HIV coinfection in the Region in 2021, which is about 20% higher than the 2019 figure.

It is estimated that an additional 7 million people are likely to develop TB and 1.5 million more will die due to TB between 2021 and 2025 in the Region because of COVID-19-related disruptions. The preliminary data shared with WHO shows a strong recovery in TB notification in most countries of the Region. However, we need more effort and must use innovative tools and approaches to reach our desired targets.

Tuberculosis (TB) research and innovation are essential to achieving global TB targets for reductions in TB incidence and TB deaths. The “Intensified research and innovation” is the third pillar of the End TB Strategy.

The Political Declaration at the first UN High-Level Meeting on TB, held in 2018, included the first global funding target for TB research to be agreed by all UN Member States: US$ 2 billion per year in the period 2018–2022. Although funding has been slowly increasing the available budget was less than half of the global target.

The Global Strategy for TB Research and Innovation has four objectives:

- Create an enabling environment for high-quality TB research and innovation.
- Increase financial investment in TB research and innovation.
- Promote and improve approaches to data sharing.
- Promote quality access to the benefits of research and innovation.

The WHO South-East Asia regional strategic plan to End TB (2021–2025) recognizes that research and innovation in various domains – from basic sciences to clinical trials, operational research, systems review, and policy research – are needed to address the challenges that have led to suboptimal regional progress in the fight against TB. The Region has differential capacity to conduct research in the various Member States.
The ongoing/recently completed key research activities in the Region include operational research such as ongoing research on shorter all-oral regimens for drug-resistant TB in India, Indonesia, Myanmar, and Bangladesh; evaluation of active case-finding methods; and direct-benefit transfer ongoing in India, along with several other operational research studies. Epidemiological research such as prevalence surveys was completed in India and planned in Thailand and Indonesia. Drug resistance surveys were completed in Indonesia, Myanmar, and Timor-Leste. Vulnerability assessments are being undertaken in India and Timor-Leste. Basic/c clinical research included a Phase 3 clinical trial of TB preventive vaccine for household contacts of TB patients and post TB vaccine to prevent TB recurrence, which is ongoing in India by the Indian Council of Medical Research. Catastrophic cost survey data are available from Myanmar, Indonesia, Thailand, and Timor-Leste.

We have key challenges: very few countries have dedicated human and financial resources for research; most of the capacity for research lies outside the national programmes; even where funding is available, the process of accessing the funds is not always easy because of administrative requirements for proposal clearance; capacity for research translation and use of local evidence for policy-making is weak; the institutional mechanisms to promote and coordinate research activities among countries in the Region are suboptimal.

WHO stands committed to supporting Member States and our way forward would be to promote research and innovation; have greater access to new diagnostics and medicines; gear up to catch up on the missing cases reach set End-TB targets and establish platforms for greater South–South collaboration where collective research efforts are made and benefits of research in any Member State are accrued by patients across the Region.

We believe that after this workshop, representatives from countries have new insights, and explore better opportunities for research and innovation, which is in alignment with the agenda of ending TB in the Region. All stakeholders must make concerted efforts and collaborate; committing to the investments or partnerships (or both) needed to accelerate research and innovation. I wish you all the best in this two-day meeting.
Annex 2

Agenda

(1) **Inaugural session**: including opening remarks, candlelight ceremony, history, functions and achievement of host institute, objectives and agenda, introductions, and logistics

(2) **Session 1**: Presentations by WHO (headquarters, WHO/TDR and Regional Office):
   - The Global Strategy for TB research and innovation
   - Support offered by TDR/WHO for research
   - Overview of research activities and capacity-building supported by the SE Asia Regional Office
   - Discussion and remarks

(3) **Session 2**: TB Research Landscape Analysis and Innovations: TB vaccines
   - Regional research landscape analysis
   - Discussion and remarks
   - Update on TB vaccines (ICMR's TB Vaccine Trial)

(4) **Session 3**: Presentations by Member States on TB research priorities, ongoing research, challenges and future plans
   - Bangladesh
   - Bhutan
   - India
   - Indonesia
   - Maldives
   - Myanmar
   - Nepal
   - Sri Lanka
   - Thailand
   - Timor-Leste

(5) **Session 4**: WHO collaborating centres (TB research in the workplan of the collaborating centre and current engagement with national programmes)
   - AIIMS, New Delhi
   - NTI, Bangalore
South-East Asia Regional Meeting on South-South collaboration on research and innovation in TB

- NITRD, New Delhi
- NIRT, Chennai
- SAARC TB and HIV Center, Nepal

(6) **Session 5: Presentations by stakeholders and partners on the support offered for research**

- UNITE4TB (clinical research)
- TB Alliance (operations research for new regimens)
- UNITAID (UNITAID’s investments in TB research in support of access and innovation)
- The Global Fund
- RIT/JATA (epidemiological research)
- Stop TB Partnership (Stop TB’s work on supporting innovations and implementation research)
- USAID

(7) **Session 6: Group work**

- Group work in four groups
  
  I. Product development partnership (PDP) for new drugs and vaccines
  II. Operational research on new regimens and quick adoption
  III. Identifying research priorities for the Region and opportunities for collaboration on research and innovation
  IV. How to improve investments in research and innovation
  V. Building research capacity in the Region
  VI. Inputs for the development of a SE Asia regional roadmap for research

- Presentation of group work

(8) **Session 7: Conclusion and closing remarks**
Annex 3

List of participants

**Bhutan**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Institution</th>
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</thead>
<tbody>
<tr>
<td>Dr Tandin Zangpo</td>
<td>Senior Medical Officer</td>
<td>Gidakom Hospital</td>
</tr>
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<td>Thimphu</td>
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**India**

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Dr Dina Nair</td>
<td>Scientist D</td>
<td>National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chennai, Tamil Nadu</td>
</tr>
<tr>
<td>Dr Ravinder Kumar</td>
<td>TB Specialist</td>
<td>Central TB Division</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ground Floor, Jeevan Vihar Building</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3, Sansad Marg, Connaught Place, New Delhi – 110001</td>
</tr>
<tr>
<td>Professor Ravindra Kumar Dewan</td>
<td>Director</td>
<td>National Institute of TB and Respiratory Diseases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Delhi</td>
</tr>
<tr>
<td>Dr Somashekar N</td>
<td>Consultant-TB and Director</td>
<td>WHO Collaborating Centre</td>
</tr>
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<td></td>
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<td>National Tuberculosis Institute</td>
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**Maldives**

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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Ms Neena Mohamed</td>
<td>Senior Health Research Officer</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Republic of Maldives</td>
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<td>Roashanee Building</td>
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<td>Sosun Magu</td>
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<td>Male, Maldives</td>
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**Nepal**

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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Dr Ashesh Dhungana</td>
<td>Chief Consultant Chest Physician</td>
<td>Department of Medicine</td>
</tr>
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<td></td>
<td></td>
<td>National Academy of Medical Sciences</td>
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<td>Bir Hospital</td>
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<td></td>
<td></td>
<td>Kathmandu, Nepal</td>
</tr>
<tr>
<td>Dr Bikash Gauchan</td>
<td>Executive Director</td>
<td>Infectious and Communicable Disease Hospital</td>
</tr>
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<td>Gandaki Province, Kaski</td>
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**Sri Lanka**

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<tbody>
<tr>
<td>Dr Onali BW Rajapakse</td>
<td>Consultant Community Physician</td>
<td>Samagi Mawatha, Jaliyagoda, Pillyandala</td>
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**Thailand**

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<th>Name</th>
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<tbody>
<tr>
<td>Dr Phalin Kamolwat</td>
<td>Director</td>
<td>Division of Tuberculosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ministry of Public Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tivanond Road</td>
</tr>
<tr>
<td>Mrs Kulyanee Junthima</td>
<td>Public Health Technical Officer</td>
<td>Senior Professional Level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Office of Disease Prevention and Control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Region 9, Nakhon Ratchasima</td>
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<td>Department of Disease Control</td>
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<td>Nonthaburi, Thailand</td>
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**Timor-Leste**

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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Mr Constantino Lopes</td>
<td>National Tuberculosis Programme Manager</td>
<td>National TB Programme</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lahan, Dili, Timor-Leste</td>
</tr>
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**Expert**

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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Dr Srinath Satyanarayana</td>
<td>Independent Consultant</td>
<td>1421, Sector D, Pocket 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vasant Kunj</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Delhi- 110070</td>
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**STAG Members**

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<tr>
<th>Name</th>
<th>Position</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Dr Anurag Bhargava</td>
<td>(virtual)</td>
<td>Head, Center for Nutrition Studies, Yenepoya, Mangalore, Karnataka</td>
</tr>
</tbody>
</table>

| Dr Christine S. Ho    | TB Advisor/Branch Chief         | CDC India                                        |
|                       |                                 | US Embassy                                        |
|                       |                                 | New Delhi – 110021                                |
Dr Ikushi Onozaki
Executive Adviser
International Department
Japan Anti-TB Association
Tokyo, Japan

WHO CCs

Dr Neeraj Nischal
Additional Professor
Department of Medicine
All India Institute of Medical Sciences
New Delhi

Dr Padmapriyadarsini Chandrasekaran
Director
ICMR – National Institute for Research in Tuberculosis
No. 1 Mayor Satyamoorthy Road
Chetpet, Chennai

Dr Nivedita Gupta
Head-ECD Division of ICMR
NlCED, Kolkata

Dr Roshan Nuepane
Director
SAARC, TB and AIDS Center
Nepal

Partners

Gates Foundation

Dr Sameer Kumta
Senior Programme Officer
Global Health Division
Bill and Melinda Gates Foundation
Mumbai
Maharashtra

Global Fund

Dr Mohammed Yassin (virtual)
Senior Disease Advisor, TB
Technical Advice and Partnerships Department
The Global Fund
Geneva, Switzerland

JATA

Dr Seiya Kato
Director
Research Institute of Tuberculosis
Japan Anti-Tuberculosis Association (RIT/JATA)
Kiyose, Tokyo
Japan

Stop TB Partnership

Dr Sreenivas Nair
Regional Advisor for Asia
Stop TB Partnership
Stop TB Partnership Secretariat
Chemin du Pommier 40,
1218 Le Grand-Saconnex, Geneva
Switzerland

TB Alliance

Dr Sandeep Juneja (virtual)
Senior Vice President – Market Access, TB Alliance
80, Pine Street, New York

Dr Sunil Khaparde
Consultant for India
TB Alliance
80, Pine Street, New York

UNITAID

Dr Cherise Scott (virtual)
Senior Technical Manager
Strategy Team
Email: cscott@unitaid.who.int

UNITE4TB

Professor Daniela Maria Cirillo (virtual)
Head of Emerging Bacterial Pathogens Unit
WHO Collaborating Centre and TB Supranational Reference Laboratory
San Raffaele Scientific Institute
Milano, Italy

USAID

Dr Amar Shah
Senior TB Advisor
Strategy and Innovation
USAID India | Health Office
American Embassy, Chanakyapuri
New Delhi - 110021

ICMR

Dr Manjula Singh
Scientist E, ECD division
ICMR HQ, New Delhi

WHO Country offices

Bangladesh

Dr Nazis Arefin Saki
National Professional Officer (Tuberculosis)
WHO Country Office for Bangladesh
India
Dr Ranjani Ramachandran (regret)
National Professional Officer (Labs)
WHO Country Office for India

Indonesia
Dr Maria Regina Christian (virtual)
National Professional Officer
WHO Country Office for Indonesia

Myanmar
Dr Thet Naing Oo
National Professional Officer - TB
WHO Country Office for Myanmar
Maldives (regret)

Nepal
Dr Prakash Shakya
NPO (One Health and NTDs)
WHO Country Office for Nepal

Thailand
Dr Deyer Gopinath (virtually)
Medical Officer
WHO Country Office, Thailand

Timor-Leste
Dr Debashish Kundu (virtual)
Technical Officer, Communicable Diseases
WHO Country Office
Dili, Timor-Leste

WHO headquarters
Dr Nebiat Gebreselassie (virtual)
Technical Officer – UCN
Global TB Programme
WHO headquarters
Geneva

Dr Corinne Simone Collette Merle
Scientist
TDR/IMP
WHO headquarters
Geneva

WHO SE Asia Regional Office
Dr Suman Rijal (virtual)
Director, CDS
World Health Organization
Regional Office for South-East Asia

Observers
Mr Raghav Rao
Director – Portfolio, India Health Fund
India

Dr Kirankumar
National Professional Officer
WHO Country Office for India
New Delhi, India

Setiawan Jati Laksono
National Professional Officer
WHO Country Office
Indonesia

Bandana Pandey
TA for CDS
WHO Country Office for Nepal
Nepal

Dr Tin Mi Mi Khaing
Senior National Technical Officer
WHO Country Office
Myanmar

Dr Myint Myint Sein
National Technical Officer
WHO Country Office for Myanmar

Dr Ye Win Thein
National Technical Officer
WHO Country Office for Myanmar

Participants from ICMR – NIRT
Dr Makesh Kumar
Scientist D
ICMR – National Institute for Research in Tuberculosis
Chennai, India
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Institute</th>
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<tr>
<td>Dr Kannan</td>
<td>Scientist E</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr Newtonraj</td>
<td>Scientist E</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr R. Priya</td>
<td>Scientist C</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr VV Banu Rekha</td>
<td>Scientist E</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr PK Bhavani</td>
<td>Scientist D</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr I Leeberk Raja</td>
<td>Scientist E</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr N Pavan Kumar</td>
<td>Scientist C</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
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<td>Dr A Stephen</td>
<td>Scientist B</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
</tr>
<tr>
<td>Dr S Vignes Anand</td>
<td>Scientist B</td>
<td>ICMR – National Institute for Research in Tuberculosis</td>
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South-East Asia Regional Meeting on South-South collaboration on research and innovation in TB

NIRT, Chennai, India, 11–12 July 2023