Project Update

22th April 2025

Critical Pathway Analysis for New TB Diagnostics Adoption in Bangladesh

Presented by

Mohammad Shahidul Islam, PhD

Child Health Research Foundation
CHRF *Prevent Infections, Save Lives*

BILL & MELINDA GATES foundation

McGill

CPA Bangladesh Team

Senjuti Saha, PhD
Deputy Executive Director
(CHRF)

Mohammad Shahidul Islam, PhD
Associate Scientist
(CHRF)

Dr. Suvarthy Dey
Research Physician
(CHRF)

Dr. Sultana Aflatun
Program Research Manager
(CHRF)

Dr. Abu Jamil Faisel
Advisor

Strategic Objectives

- Defining the TB diagnostic approval pathways and opportunities for regional regulatory harmonization
- Identification of key challenges in the adoption and early implementation of TB diagnostics
- To create a country-specific guide roadmaps for early uptake of new TB diagnostics

Methodological Approach

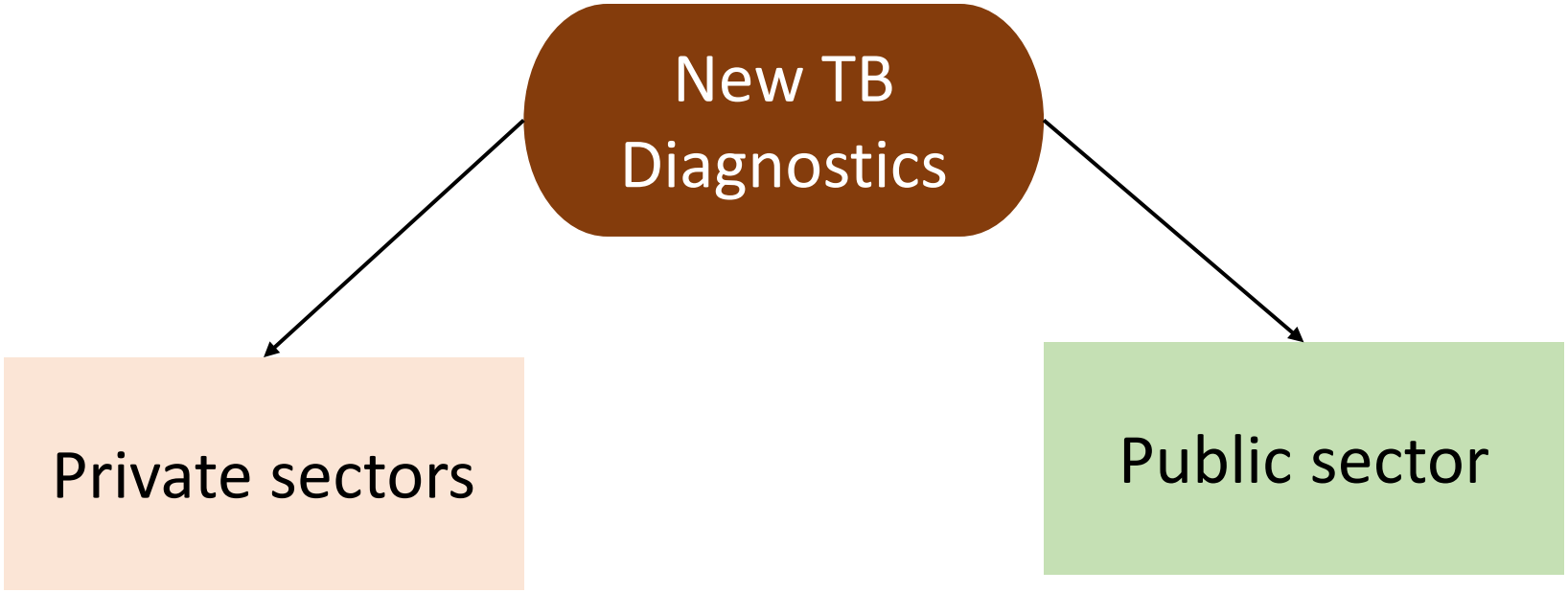
Review of Existing Literature and Program Reports to understand the TB diagnostic landscape

Identifying Key Stakeholders involved in the TB control program

Interviewed experts to understand challenges and barriers in quick adoption of TB diagnostics

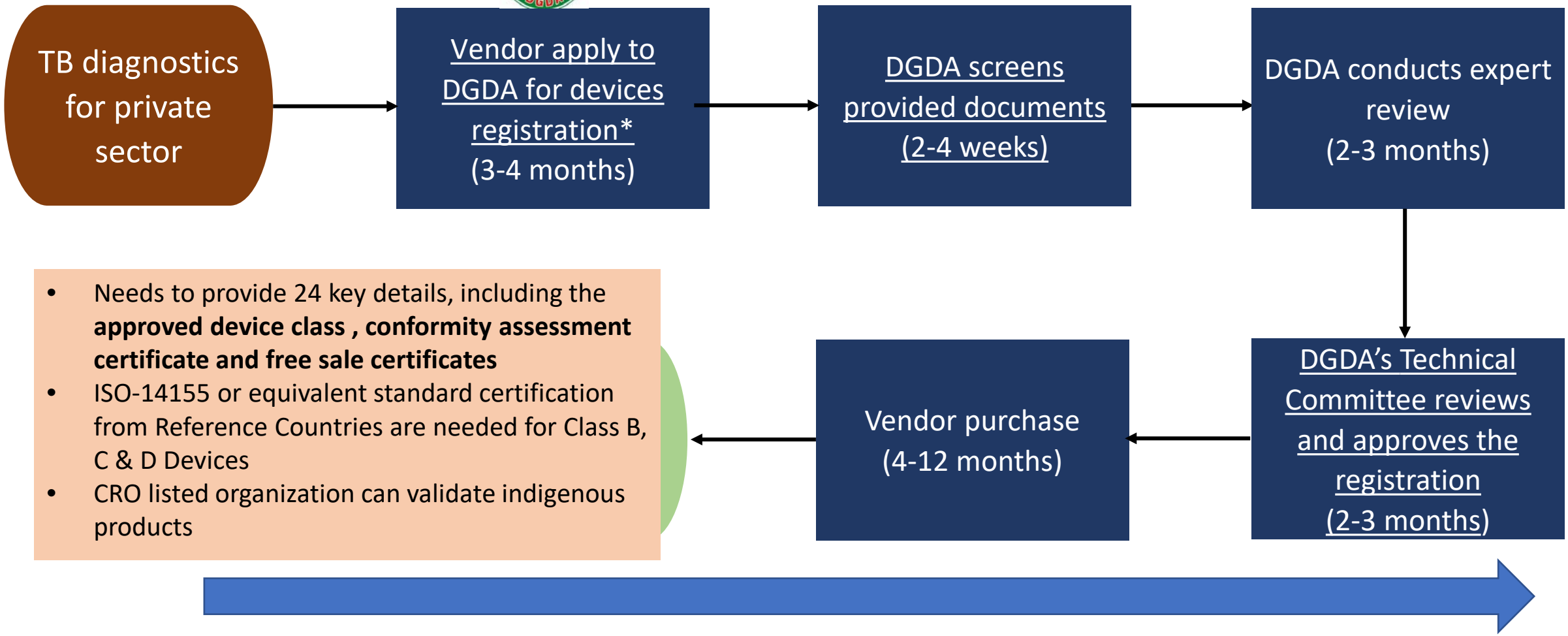
Policy dialogue for creating a tailored pathway for early adoption of TB diagnostics

Usages of TB Diagnostic in Bangladesh



Note: As of now, Bangladesh has not manufactured any diagnostic devices, TB diagnosis solely supported by imported technologies

TB Diagnostics Adoption in Private Sectors of Bangladesh



1-2 years

DGDA: Director General of Drug Administration

Drivers for TB Diagnostics Adoption in Private Sector

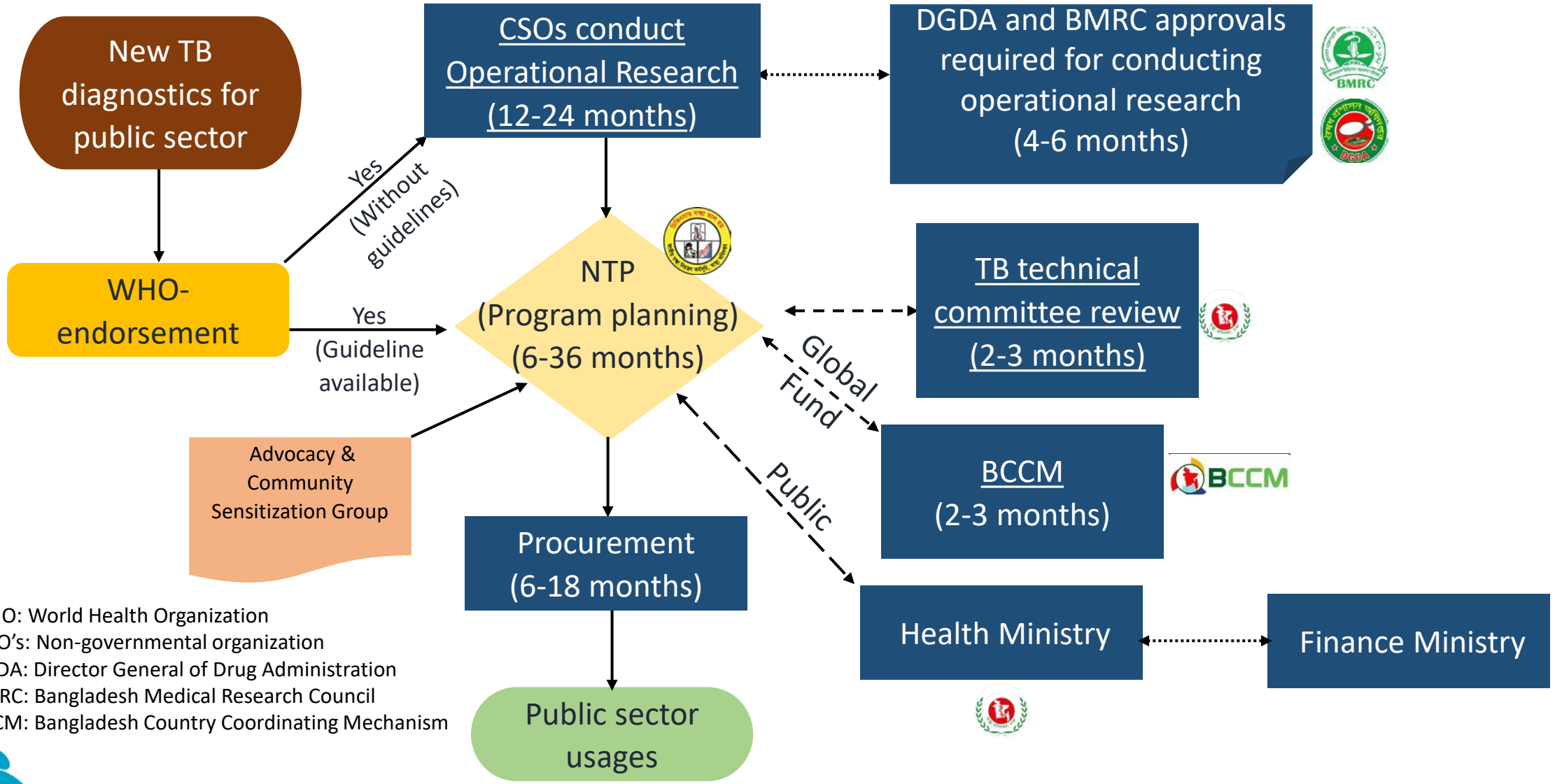
Enablers:

a. Strong presence, 70% of the medical cares are provided by private sectors

Barriers:

a. Free public health services are limiting private sector engagement in TB diagnostics
b. Devices that emit radiation or use chemicals listed as hazardous product need clearance certificate from responsible departments for custom clearance

TB Diagnostics Adoption in Public Sector of Bangladesh



WHO: World Health Organization
NGO's: Non-governmental organization
DGDA: Director General of Drug Administration
BMRC: Bangladesh Medical Research Council
BCCM: Bangladesh Country Coordinating Mechanism

3-6 years

Drivers for TB Diagnostics Adoption in Public Sector

Enablers:

- WHO endorsement
- FDA, CE or ISO certifications
- Supporting data from other high burden countries
- Financial support from donors

Barriers:

- Inadequate need assessment
- Inadequate supporting logistics
- Suboptimal community sensitization
- Lack of post-warranty support

Summary

- Rapid adoption of TB diagnostics in public sectors is a challenge and takes 3-6 years to incorporate in National TB Program
- Drug Administration which follows bureaucratic process to approve the import permit which delay the adoption process
- WHO endorsement is a key but other certification (e.g. FDA, CE and ISO) also helps in rapid approval process
- Donor support expedite adoption process as Bangladesh not ready to heavily investments on TB diagnostics
- Despite being a high burden country, limited private sectors role in TB diagnosis provides an opportunity to work on

Resources

- Registration Guidelines for Medical Devices Bangladesh 2015 (http://dgdagov.info/index.php/information-center/guidance-documents/1135-medical-device-registration-guideline-2015)
- Guidance for Industry (http://dgdagov.info/index.php/information-center/guidance-documents/1130-guidance-for-industry/file)
- New Product Registration Procedure (http://dgdagov.info/index.php/publications/5-new-product-registration-procedure)
- Medical Device Technical Sub-committee for DCC (http://dgdagov.info/index.php/about-dgda/committees/drug-technical-sub-committee/632-medical-device-technical-sub-committee-for-dcc)
- National Guidelines on TB/HIV Management Program Collaboration & Implementation Manual. (https://ntp.gov.bd/wp-content/uploads/2021/07/21-TB-HIVGuidelines-2nd-edition.pdf)
- MDCG 2019-13. Guidance on sampling of MDR Class IIa/Class IIb and IVDR Class B/Class C devices for the assessment of the technical documentation. December 2019. (https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_13_sampling_mdr_ivdr_en_0.pdf)

Thank You

Things to provide to DGDA with device registration application

1. Name, address, and communication details of the Manufacturer /Agent in Bangladesh
2. Authorization letter of the Authorized Agent
3. Name, address, and communication details of the manufacturer
4. Are the products already imported in Bangladesh? if so, since when
5. Name of the product, including its generic name, if any
6. Device class and classification system followed—attached conformity assessment certificate.
7. Details of the Confirmation Assessment body
8. Since how long has the device been used commercially? Has clinical evaluation and safety issues been addressed for the device?
9. The principal use of the device
10. Is it a drug-device combination?
11. If the above is “yes”, is the drug a new drug

Things to provide to DGDA with device registration application-continued

12. Is it a kit comprising more than one device?
13. Sizes of the device
14. Is the Device Master File submitted?
15. Short description of the Manufacturing process
16. Procedure for sterilization
17. Procedure for the release of the Device in the market
18. name and qualifications of technical personnel for manufacturing and quality assurance
19. A layout plan of the premises accompanied by the floor plan.
20. Details of QMS and manual
21. Is the product tested before release? if yes, submit details; if no, specify criteria for release
22. Has the product been withdrawn due to any reasons? If yes please specify.
23. Recall procedure to be followed in case the product has to be withdrawn
24. Names of the countries where the device is exported.

DGDA Requirements for operational research

1. A comprehensive research proposal to DGDA
   - Study objectives and rationale
   - Study design, methodology, and duration
   - Target population and study settings
   - Risk management and safety monitoring plans
   - Data collection, management, and analysis plans
2. Detailed device description and classification
3. Conformity Documentation
4. Provide relevant certifications and documentation (e.g. ISO certification, CE marking, FDA clearance, or approval from other recognized regulatory authorities)
5. Evidence of ethical approval from a recognized committee
6. Collaboration with Registered Facilities

Studies validating TB diagnostics often follow **WHO evaluation frameworks** or **use protocols from other high-burden settings**

Medical Device Technical Sub-Committee

Key Responsibilities of

- Evaluate technical specifications and compliance with national/international standards
- Review classification, conformity, and certifications (e.g., ISO, FDA, CE)
- Advise on medical device regulations and policy updates
- Collaborate with stakeholders to support safe innovation and public health

National TB technical working group

Structure of national TB technical Committee

1. Director MBDC- Chairperson
2. Program Manager (NTP)- Co-Chairperson
3. Program Manager (NASP)- Co-Chairperson
4. Focal person, TB/HIV- Member Secretary
5. Representative from NGO partners (One member each from a key partner)- Member
6. Representative from WHO- Member
7. Focal person from NASP- Member
8. Representative from tertiary hospitals (BSMMU, NIDCH, IDH, and another GoB)- Member
9. Representative from research Institute (IEDCR, icddrb and others) -Member
10. Representative from UNAIDS- Member
11. Representative from USAIDS- Member
12. Representative from professional association- Member
13. Representatives from faith-based organization- Member

National TB technical working group:

Terms of reference

- Undertake periodic review and analysis of performance of collaborative TB/HIV activities using district wise program data
- To facilitate development and updating of national TB/HIV guidelines and other normative tools
- To discuss operational issues, identify bottlenecks and suggest solutions for scale-up of TB/HIV interventions across the country
- Identify data gaps and research gaps and promote operational research to strengthen collaborative TB/HIV activities
- To plan and undertake review missions for evaluation of implementation of TB/HIV activities as per need
- To co-ordinate efforts of all partners and stakeholders in scale-up and strengthening collaborative TB/HIV activities

Bangladesh Country Coordinating Mechanism (BCCM)

The Bangladesh Country Coordinating Mechanism (BCCM) is a multi-sectoral national platform mandated by the Global Fund to oversee and coordinate the implementation of grants for HIV/AIDS, tuberculosis (TB), malaria, and COVID-19 in Bangladesh.

- **Key Functions of BCCM:**
- Ensures Global Fund-supported programs align with national health priorities and are implemented effectively
- Selects one or more public or private organizations to serve as Principal Recipients for each grant
- Provides recommendations to strengthen the impact of disease control programs.
- Tracks program performance and facilitates improvements to enhance outcomes and transparency

Methodological Approach

Review of Existing Literature and Program Reports

Review of TB control policies, program reports, and scientific literature to assess the current TB diagnostic landscape in Bangladesh and critical steps in diagnostics adoption

Identifying Key Stakeholders in the TB Control Program

Mapping key stakeholders involved in adopting new TB diagnostic technologies in Bangladesh

In-Depth Interviews of Selected Experts

Conducting discussions with a selected group of experts to gain deeper insights into the barriers and facilitators of new TB diagnostics adoption in the country

Plotting the flexibility for Future TB Diagnostics

A high-level policy dialogue will be held with policymakers to share findings and strategize on accelerating TB diagnostic adoption