Critical Pathway Analysis for New TB Diagnostics Adoption in Bangladesh

Child Health Research Foundation
CHRF
Prevent Infections, Save Lives

BILL & MELINDA GATES *foundation*

McGill

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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

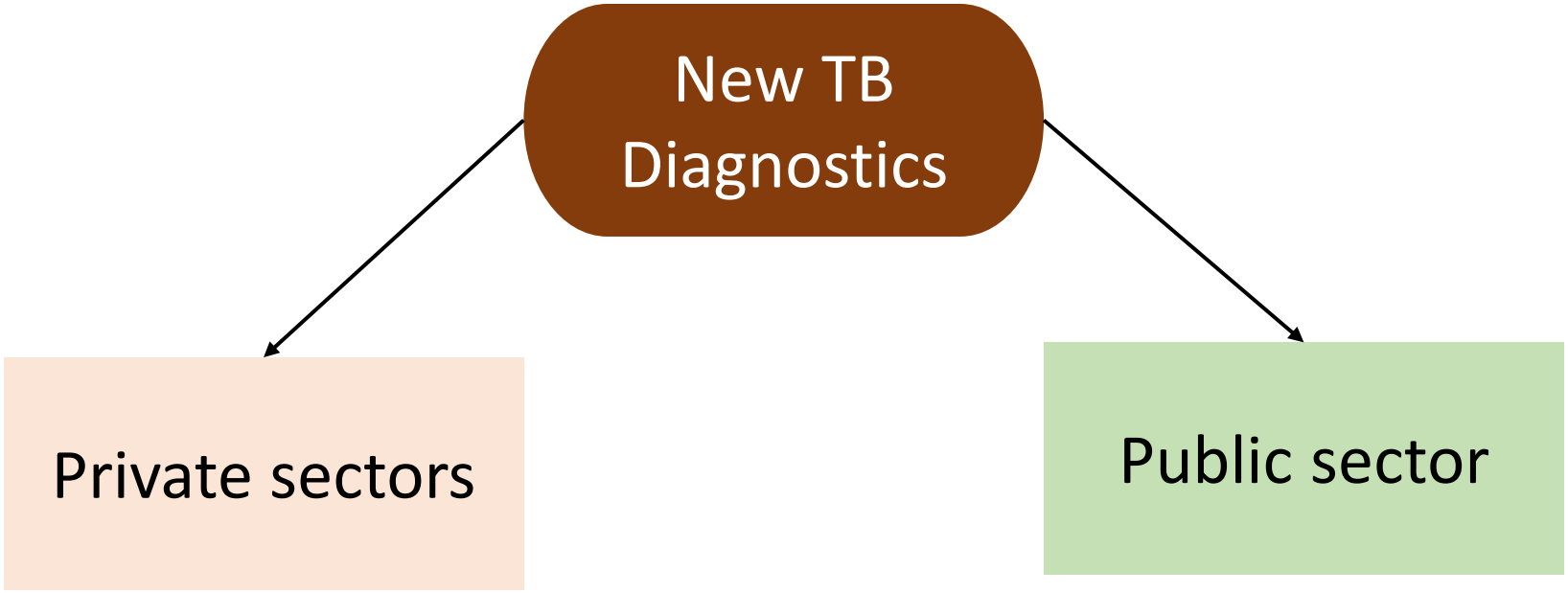
Review of Existing Literature and Program Reports to understand the TB diagnostic landscape

Identifying Key Stakeholders involved in the TB control program

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

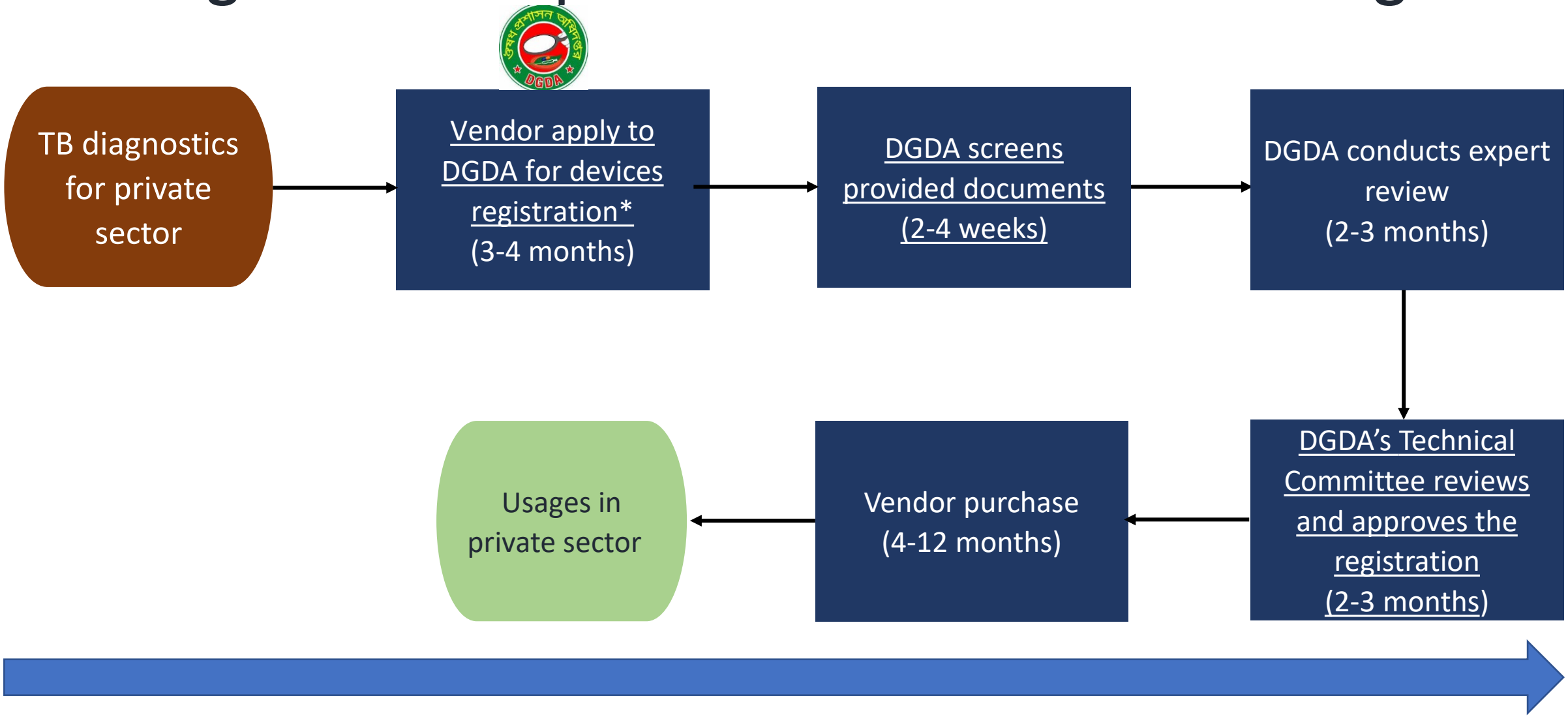
Policy dialogue for creating a tailored pathway for early adoption of TB diagnostics

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



DGDA: Director General of Drug Administration

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Drivers for TB Diagnostics Adoption in Private Sector

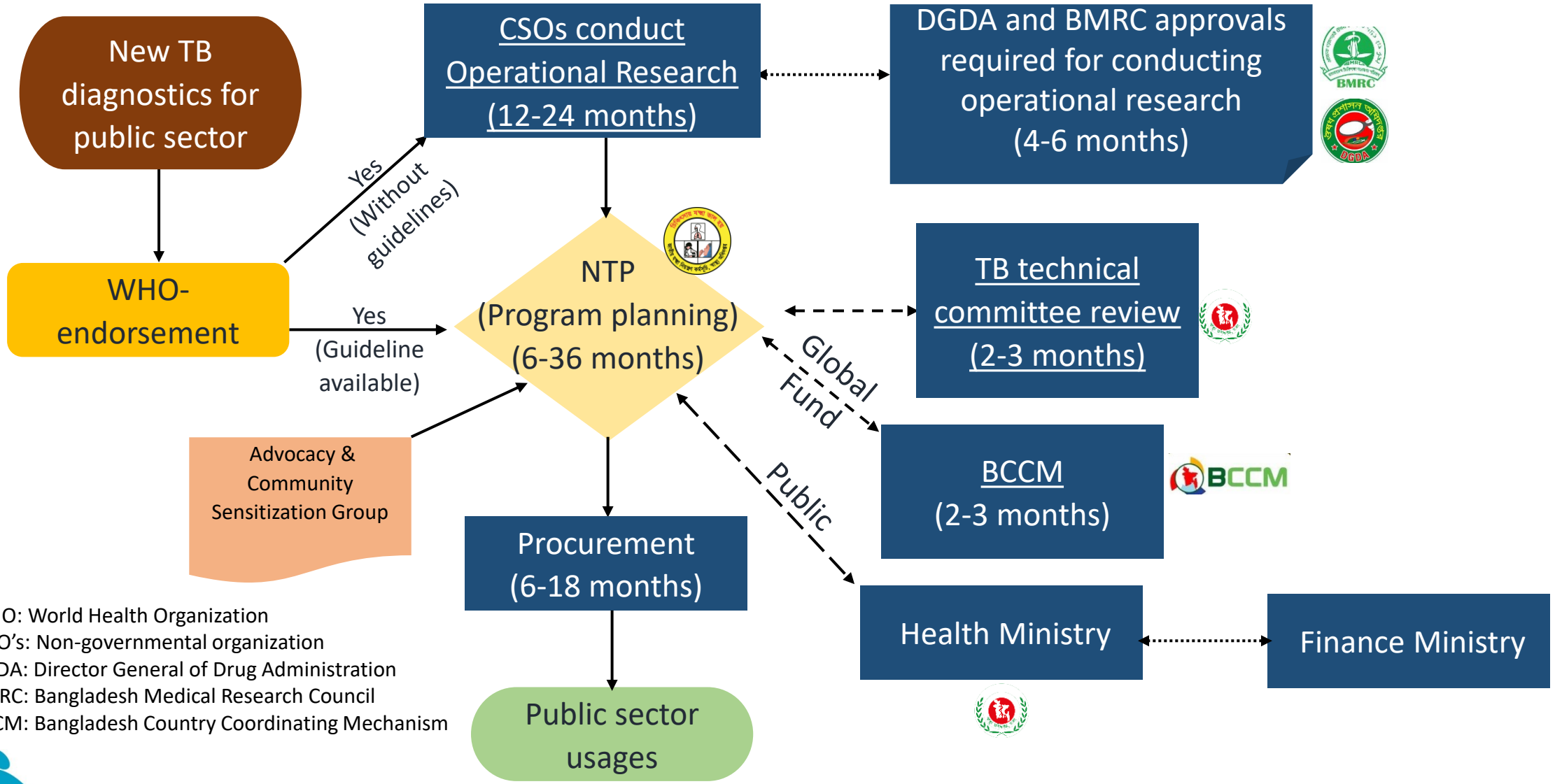
Enablers:

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

Fast-Tracking TB Diagnostics: Policy Strategies for Timely Uptake

Accelerating TB Test Adoption: Developer Perspective

Technical aspects

- Priority should be given to devices that deliver rapid, affordable, and highly reproducible results
- Devices should be capable of running in the open platform or should be capable of multipurpose use
- Devices should require less technical expertise to operate, and low maintenance support

Contextual aspects

- A market landscape analysis should be conducted to understand the desirable local needs
- Obtain regulatory approval from recognized reference regulatory authorities such as FDA, CE, or ISO for quick in-country approval
- Ensure regulatory dossiers align with in-country requirements
- Identify and assign an in-country distributor who is reliable trusted and capable of providing post-sale services

Accelerating TB Test Adoption: NTP/MOH Perspective

Systemic Strengthening

- ✓ Strengthen infrastructure and develop educational resources
- ✓ Optimize device allocation based on needs assessments

Policy & Guideline Update

- ✓ Update policies to enable the rapid integration of new diagnostics into the national TB control program
- ✓ Develop a checklist to fast-track the adoption of new diagnostic devices
- ✓ Prioritize devices that can be sustainably scaled up without donor support

Financial sustainability

- ✓ Establish a core fund to support the adoption of new devices for the TB control program
- ✓ Strengthen public–private partnerships to reduce reliance on donor funding for TB diagnostics

Accelerating TB Test Adoption: Donor's Perspective

Fund scalable diagnostics for long-term sustainability and accessibility

Support context-driven market analyses to understand country-specific TB diagnostic requirements

Fund in-country tech validation studies

Finance local capacity building on technical expertise and equipment maintenance

Promote training and education initiatives to enhance local skills in implementing, maintaining, and troubleshooting

Accelerating TB Test Adoption: WHO Perspective

- Update prequalification guidelines to create a simpler and faster approval pathway
- Advocate for political commitment and resource mobilization to expand TB diagnostics
- Strengthen data sharing and surveillance to monitor TB diagnostic coverage and effectiveness
- Promote regulatory harmonization across countries to accelerate approval and adoption of new diagnostics
- Provide resources for countries to compare and optimize global TB device usage

Summary

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

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:

- 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