A Practical Handbook for National TB Laboratory Strategic Plan Development

PARTICIPANTS MANUAL

TB CARE I

USAID
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A Practical Handbook for National TB Laboratory Strategic Plan Development
Participants Manual

Second English Edition February 2014

KNCV
To eliminate TB

TUBERCULOSISFOUNDATION

International Union Against
Tuberculosis and Lung Disease
Health solutions for the poor

msh
Management Sciences for Health

gli
global laboratory initiative
advancing TB diagnosis

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Contents

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Terms and Abbreviations

AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ATT	Anti-TB Treatment
CDC	Centers for Disease Control and Prevention
CMS	Central Medical Stores
Cx	Culture
CXR	Chest X-ray
DRS	Drug Resistance Survey
DST	Drugs Susceptibility Testing
EQA	External Quality Assessment
FM	Fluorescent Microscopy
GLI	Global Laboratory Initiative
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HRD	Human Resource Development
IC	Infection Control
KNCV	KNCV Tuberculosis Foundation
LED	Light Emitting Diode
LPA	Line Probe Assay
M&E	Monitoring and Evaluation
MDR	Multi Drug Resistant
MoH	Ministry of Health
NHL	National Health Laboratories
NRL	National Reference Laboratory
NTP	National Tuberculosis Program
NTRL	National Tuberculosis Reference Laboratory
PLWHA	People Living with HIV/AIDS
QM	Quality Management
RIF	Rifampicin
SCMS	Supply and commodities management system
SM	Smear
SOP	Standard Operating Procedure
SNRL	Supra National Reference Laboratory
SS+	Sputum Smear Positive
SS-	Sputum Smear Negative
SWOT	Strength Weakness Opportunity Threat (analysis)
TAT	Turn-around time
TB	Tuberculosis
ToR	Terms of Reference
WHO	World Health Organization
WHO AFRO	World Health Organization Africa
XDR	Extensively Drug Resistant

Glossary

National TB program (NTP) Strategic Plans:	These plans are now common to most TB programs and delineate how countries will achieve their overall TB control strategy over a 5-year period, usually based on addressing the Global Stop TB strategy objectives. These plans include both laboratory and non-laboratory interventions. In this handbook such a strategic plan is abbreviated as **NTP plans.**
National Medical Laboratory Plans:	These plans are sector-wide, health-system strengthening laboratory strategic plans. These strategic plans are becoming more common. As all diseases are included, the portion dedicated specifically to TB is typically minimal. If a national medical laboratory plan exists, such strategy should be incorporated into the TB-specific laboratory strategic plan development. On the other hand, once written, the TB-specific laboratory strategic plan should be utilized for the development of any national medical laboratory plan.
TB-specific Laboratory Strategic Plans:	These plans are new to most countries and are the basis for this handbook. They are, similar to the NTP plans, in that are also 5-year plans but focus only on laboratory interventions to achieve the goals of the NTP plans. In this handbook such strategic plans are abbreviated as **TB laboratory plans.**
Objectives:	For the purposes of the TB- laboratory plan described by this handbook, an **objective** is a pre-defined (per Global Plan Stop TB 2011-2015 laboratory strengthening Objectives 1-4) as a broad goal by technical area where you want the national TB laboratory network to be in 5 years: **Objective 1:** Increase access to quality-assured AFB microscopy with effective External Quality Assessment (EQA) **Objective 2:** Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV **Objective 3:** Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB **Objective 4:** Establish Laboratory Quality Management Systems.
Strategies:	For the purposes of the TB laboratory plan described by this handbook, a **strategy** is a sub-objective to achieve the objective. These pre-defined strategies in this handbook include the seven WHO AFRO-GLI strategic priorities (defined in Chapter 5) plus operational research (OR): 1. Strengthen laboratory infrastructure and maintenance contracts 2. Improve laboratory human resource development 3. Develop and maintain laboratory quality management systems 4. Enhance management of laboratory commodities and supplies including equipment validation and maintenance 5. Fortify specimen transport and referral mechanisms 6. Improve Laboratory information and data management systems 7. Establish a TB laboratory regulatory framework 8. Develop OR capacity.

PARTICIPANTS MANUAL:

A Practical Handbook for National TB Laboratory Strategic Plan Development

Introduction

This manual includes step-by-step exercises for the development of the TB laboratory plan. Such exercises are indicative and can be adapted per national requirements and preferences. These exercises should be facilitated, ideally, by a skilled international consultant or by an appointed national focal point familiar with strategic planning and TB-specific technical areas, particularly regarding laboratory strengthening linked with NTP strategies.

Preparation, Political Commitment, Financing and Planning for TB Laboratory Plan Development

Exercise 2a: Preparation for the TB Laboratory Plan Workshop

Steps and checklist for preparation to develop the TB laboratory plan:

1. Designate a local focal point for coordination of activities related to the TB laboratory plan development
2. Secure funds for 2 one-week workshops for 10 – 20 participants each and a consultant. Smaller countries should have fewer representatives whereas larger ones more. **A pre-requisite for invitation must be full-time participation throughout the workshop**
3. Inform all stakeholders about your plans to develop TB laboratory plan well in advance
4. Develop and send out an agenda and invitations at least 2 weeks before the planning workshop (see the end of this chapter for example agenda templates)
5. Invite: MoH, National Health Laboratory, NTP, pediatricians, MDR-TB, TB/HIV, supply and finances specialists and partners
6. Book an adequate venue with break-away rooms to work in sub-groups
7. Prepare:

- Computers (also ask participants to bring their own computers)
- Projector
- Flipcharts (2 or 3 – depending on the number of working groups)
- Extension cords and adapters
- CDs or memory sticks
- Files for papers
- Printer
- Printing paper
- Stickers
- Markers
- Handouts (both printed and on CDs or memory sticks)
  - Agenda
  - Handbook
  - Templates for exercises
  - Reference materials
    - International
      - WHO and GLI policies, guidelines, targets and indicators
      - Global TB reports
    - Country specific
      - National guidelines (TB manual, MDR-TB, TB/HIV, Infection control, etc.) and algorithms for diagnosis of TB and DR-TB
      - NTP strategic plan and epidemiological data
      - Country TB reports
      - Review/assessment reports
      - National Health Laboratory Policy, Strategic Plan

        - TB laboratory SOPs
        - TB laboratory statistics
        - Country data (demographics, geography etc.)
    - Data needed for exercises abstracted from the reference materials
- Attendance list

Define a Vision and a Mission

Exercise 3a: Development of a TB laboratory plan vision statement

Vision:

Exercise 3b: Development of a TB laboratory plan mission statement

Mission:

Chapter 4: **Participants Manual**

TB laboratory Situational Analysis

Exercise 4a: TB-specific situational analysis

Exercise 4a: TB Specific Situational Analysis

GROUP 1 (☐ Square Group)

1. The TB specific contextual analysis (GROUP 1):

    a. Epidemiological situation for TB
    b. Description of NTP program and linkages between BNTP and NTRL
    c. Laboratory objectives and targets according to the NTP strategic plan and the National health laboratories TB-specific objectives
    d. National TB diagnostic and treatment guidelines

    [Relevant reference materials: NTP guidelines, NTP strategic plan, national health laboratories strategic plan, WHO Global Report on TB (2011), National statistics reports, latest DRS surveys report, HIV/AIDS reports]

2. TB specific TESTS CURRENTLY AVAILABLE and Coverage
    [Relevant reference materials: Medical Laboratories Policy, NTRL quality manual]

3. STRUCTURE OF THE LABORATORY NETWORK of TB diagnostics
    [Relevant reference materials: Medical Laboratories Policy, AFB microscopy EQA implementation plan]

4. INFRASTRUCTURE OF THE LABORATORY NETWORK for TB diagnostics
    [Relevant reference materials: NTP review reports, IC guidelines, EQA support visits reports]

Exercise 4a: TB Specific Situational Analysis

GROUP 2 (△ Triangle Group)

5. HUMAN RESOURCES for the TB lab network
   [Relevant reference materials: MoH strategic HRD plan, NTP HRD strategic plan, NHL strategic plan, NTP review reports, AFB EQA reports, external assessment of NTRL reports]

6. EQUIPMENT MAINTENANCE AND VALIDATION of TB lab equipment
   [Relevant reference materials: Medical laboratories policy, NTRL quality manual, NTP review reports, external assessment of NTRL reports]

7. LABORATORY QUALITY MANAGEMENT SYSTEMS within the TB lab network
   [Relevant reference materials: Medical laboratories policy, NTRL quality manual, AFB microscopy EQA plan, accreditation reports]

8. MANAGEMENT OF LABORATORY COMMODITIES AND SUPPLIES within the TB lab network [Relevant reference materials: Medical laboratories policy, NTRL quality manual, NTP review reports, AFB EQA reports, CMS /SCMS list of supplies, external assessment of NTRL reports]

Exercise 4a: TB Specific Situational Analysis

GROUP 3 (◯ Circle Group)

9. LABORATORY INFORMATION AND DATA MANAGEMENT for the TB lab network
   [Relevant reference materials: NTRL quality manual, DISA manual, Meditech, PIMS, ETR, Open MRS, mycobacterial request/report form, microscopy and culture/DST register, MDR report tool]

10. SAMPLE REFERRAL SYSTEMS for the TB lab network
    [Relevant reference materials: Medical laboratories policy, NTRL quality manual, Specimen collection and transportation manual]

11. OPERATIONAL RESEARCH regarding the TB laboratory network
    [Relevant reference materials: NTRL quality manual, NTP strategic plan, NHL strategic plan, partners' plans?]

12. LEGAL AND POLICY REVIEW for TB

13. FINANCES for TB laboratory services
    [Relevant reference materials: NHL strategic plan, NTP strategic plan, partners' reports and plans?]

	Actual		Planned	
	Last year:	**This year:**	**Next year:**	**Year after next:**
DOMESTIC FUNDING RESOURCES for TB Laboratory Services				
Domestic source A1 Loans and debt relief ⟶ provide name of source here				
Domestic source A2 National funding resources				
Domestic source A3 Private sector contributions (national)				
LINE A: Total current & planned DOMESTIC resources ⟶ Total of Section B entries				
EXTERNAL FUNDING RESOURCES for TB Laboratory Services				
External source B1 ⟶ provide source name here				
External source B2 ⟶ provide source name here				
External source B3 Private sector contributions (International)				
LINE B: Total current & planned EXTERNAL resources ⟶ Total of Section C entries				
LINE C : Total current and planned resources for TB Laboratory Services ⟶ Line C = Line A+ Line B				

Exercise 4b: TB Laboratory plan-SWOT analysis by Stop TB objectives

The following four tables should be used for the participants to develop their SWOT for each of the four Stop TB objectives.

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis				
TB specific tests currently available and coverage				
Structure of the laboratory network of TB diagnostics				
Infrastructure of the laboratory network of TB diagnostics				
Human resources for the TB laboratory network				
Maintenance and validation of TB laboratory equipment				
Quality management systems within the laboratory network				
Management of laboratory commodities and supplies within the TB laboratory network				
Laboratory information and data management for the TB laboratory network				
Sample referral system for the TB laboratory network				
Operational research regarding the TB laboratory				
Legal policy and review for TB				
Finances for the TB laboratory services				

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis				
TB specific tests currently available and coverage				
Structure of the laboratory network of TB diagnostics				
Infrastructure of the laboratory network of TB diagnostics				
Human resources for the TB laboratory network				
Maintenance and validation of TB laboratory equipment				
Quality management systems within the laboratory network				
Management of laboratory commodities and supplies within the TB laboratory network				
Laboratory information and data management for the TB laboratory network				
Sample referral system for the TB laboratory network				
Operational research regarding the TB laboratory				
Legal policy and review for TB				
Finances for the TB laboratory services				

Objective 3: Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis				
TB specific tests currently available and coverage				
Structure of the laboratory network of TB diagnostics				
Infrastructure of the laboratory network of TB diagnostics				
Human resources for the TB laboratory network				
Maintenance and validation of TB laboratory equipment				
Quality management systems within the laboratory network				
Management of laboratory commodities and supplies within the TB laboratory network				
Laboratory information and data management for the TB laboratory network				
Sample referral system for the TB laboratory network				
Operational research regarding the TB laboratory				
Legal policy and review for TB				
Finances for the TB laboratory services				

Objective 4: Establish Laboratory Quality Management Systems				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis				
TB specific tests currently available and coverage				
Structure of the laboratory network of TB diagnostics				
Infrastructure of the laboratory network of TB diagnostics				
Human resources for the TB laboratory network				
Maintenance and validation of TB laboratory equipment				
Quality management systems within the laboratory network				
Management of laboratory commodities and supplies within the TB laboratory network				
Laboratory information and data management for the TB laboratory network				
Sample referral system for the TB laboratory network				
Operational research regarding the TB laboratory				
Legal policy and review for TB				
Finances for the TB laboratory services				

Exercise 4c: TB laboratory plan situational analysis framework with major challenges and potential solutions for each Stop TB objective

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA					
Situational Analysis Topic		**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/ Gaps**	**Potential Solutions**
TB specific contextual analysis	□				
Tests currently available	□				
Structure	□				
Infrastructure	□				
Human Resources	△				
Equipment validation and maintenance	△				
Laboratory quality management systems	△				
Management of laboratory commodities and supplies	△				
Laboratory information and data management	○				
Sample referral systems	○				
Operational research	○				
Legal and policy review	○				
Finances	○				

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV					
Situational Analysis Topic		**Current situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/ Gaps**	**Potential Solutions**
TB specific contextual analysis	□				
Tests currently available	□				
Structure	□				
Infrastructure	□				
Human Resources	△				
Equipment validation and maintenance	△				
Laboratory quality management systems	△				
Management of laboratory commodities and supplies	△				
Laboratory information and data management	○				
Sample referral systems	○				
Operational research	○				
Legal and policy review	○				
Finances	○				

Objective 3: Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB					
Situational Analysis Topic		**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/ Gaps**	**Potential Solutions**
TB specific contextual analysis	□				
Tests currently available	□				
Structure	□				
Infrastructure	□				
Human Resources	△				
Equipment validation and maintenance	△				
Laboratory quality management systems	△				
Management of laboratory commodities and supplies	△				
Laboratory information and data management	○				
Sample referral systems	○				
Operational research	○				
Legal and policy review	○				
Finances	○				

Objective 4: Establish Laboratory Quality Management Systems					
Situational Analysis Topic		**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/ Gaps**	**Potential Solutions**
TB specific contextual analysis	□				
Tests currently available	□				
Structure	□				
Infrastructure	□				
Human Resources	△				
Equipment validation and maintenance	△				
Laboratory quality management systems	△				
Management of laboratory commodities and supplies	△				
Laboratory information and data management	○				
Sample referral systems	○				
Operational research	○				
Legal and policy review	○				
Finances	○				

Prioritization of Strategies and Activities within Stop TB Objectives

Exercise 5a: Establishing targets for detection of smear-positive TB, smear-negative TB, MDR-TB and for quality management systems

Part I: GOAL

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Number of TB cases (all forms) notified						
Number of new laboratory- confirmed TB cases notified						
Prevalence of laboratory- confirmed TB						
Prevalence of laboratory-confirmed MDR-TB						

Part II: Stop TB Global Plan objective targets

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Number of laboratories performing AFB microscopy						
Percentage of AFB microscopy laboratories that are quality-assured						
Percentage of AFB microscopy laboratories that are using LED microscopy						

Objective 2: Improving the diagnosis of TB among AFB smear-negative TB cases, especially among PLHIV

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Number of laboratories performing culture						
Number of laboratories performing rapid molecular diagnosis						
Percentage of acid-fast bacilli (AFB) smear-negative, newly notified TB cases screened using culture and/or molecular-based tests						
Percentage of acid-fast bacilli (AFB) smear-negative, previously treated TB cases screened using culture and/or molecular-based tests						

Objective 3: Increase access to rapid laboratory diagnosis of drug-resistant TB among TB patients considered at risk of M/XDR-TB

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Number of laboratories performing DST						
Number of laboratories Performing DST using new diagnostic tools						
Percentage of previously treated TB patients tested for drug-resistance						
Percentage of new TB patients tested for drug-resistance						
Percentage of tests for drug resistance performed on previously treated cases done using rapid tests						
Percentage of tests for drug resistance performed on new cases done using rapid tests						
Percentage of confirmed cases of MDR-TB with a DST result for fluoroquinolones and a second-line injectable drug						

Objective 4: Establish Laboratory Quality Management Systems

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Percentage of national and regional reference laboratories implementing a quality management system according to international standards according to national strategies						
Percentage of TB laboratories with appropriate biosafety measures in place						
AFB microscopy network accreditation (with GLI tool)						

Exercise 5b: Priority areas for detection of TB (smear-positive and smear-negative cases), priorities for detection of MDR-TB cases and priorities for quality management systems

Which lab issues need to be addressed to increase access to quality-assured AFB microscopy with effective EQA?

1. Priorities for increasing access to quality-assured AFB microscopy with effective EQA

Broad priority identified (listed in order of priority with highest first)	**Main activities (in order of priority)**	**Category per GLI framework: Infrastructure, HRD, QMS, Supply management and equipment validation, Specimen transport and referral, Information and data management, Regulatory framework, or Operational research**	**Where are you now?**	**Where do you want to be?**	**Achievable in 5 years? Yes/No/Partially (If No or Partially explain)**

Which lab issues need to be addressed to improve the diagnosis of TB among AFB smear-negative TB cases, especially among people living with HIV?

2. Priorities for improving the diagnosis of TB among AFB smear-negative TB cases, especially among people living with HIV

Broad priority identified (in order of priority with highest priority listed first)	**Main activities (in order of priority)**	**Category per GLI framework: Infrastructure, HRD, QMS, Supply management and equipment validation, Specimen transport and referral, Information and data management, Regulatory framework, or Operational research**	**Where are you now?**	**Where do you want to be?**	**Achievable in 5 years? Yes/No/Partially (If No or Partially explain)**

Which lab issues need to be addressed to appropriately detect MDR-TB cases?

3. Priorities for increased access to rapid laboratory diagnosis of drug-resistant TB among TB patients considered at risk of M/XDR-TB

Broad priority identified (in order of priority with highest priority listed first)	Main activities (in order of priority)	Category per GLI framework: Infrastructure, HRD, QMS, Supply management and equipment validation, Specimen transport and referral, Information and data management, Regulatory framework, or Operational research	Where are you now?	Where do you want to be?	Achievable in 5 years? Yes/No/Partially (If No or Partially explain)

Which lab issues need to be addressed to establish quality management systems?

4. Priorities for establishing laboratory quality management systems

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority)	Category per GLI framework: Infrastructure, HRD, QMS, Supply management and equipment validation, Specimen transport and referral, Information and data management, Regulatory framework, or Operational research	Where are you now?	Where do you want to be?	Achievable in 5 years? Yes/No/Partially (If No or Partially explain)

Exercise 5c: Prioritizing Strategies within STOP TB Objectives

Example:
Objective 1: Increase access to quality-assured AFB microscopy with effective EQA

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	
Sub-activity 1.3.1.1	
Sub-activity 1.3.1.2	
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	
Sub-activity 1.5.1.1	
Sub-activity 1.5.1.2	
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Objective 2: Improve the Diagnosis of TB among AFB-negative Cases especially among PLHIV

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	
Sub-activity 1.3.1.1	
Sub-activity 1.3.1.2	
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	
Sub-activity 1.5.1.1	
Sub-activity 1.5.1.2	
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Objective 3: Increase Access to Rapid Laboratory Diagnosis among TB patients considered at risk for M/XDR-TB

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	
Sub-activity 1.3.1.1	
Sub-activity 1.3.1.2	
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	
Sub-activity 1.5.1.1	
Sub-activity 1.5.1.2	
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Objective 4: Establish Laboratory Quality Management Systems

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	
Sub-activity 1.3.1.1	
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Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
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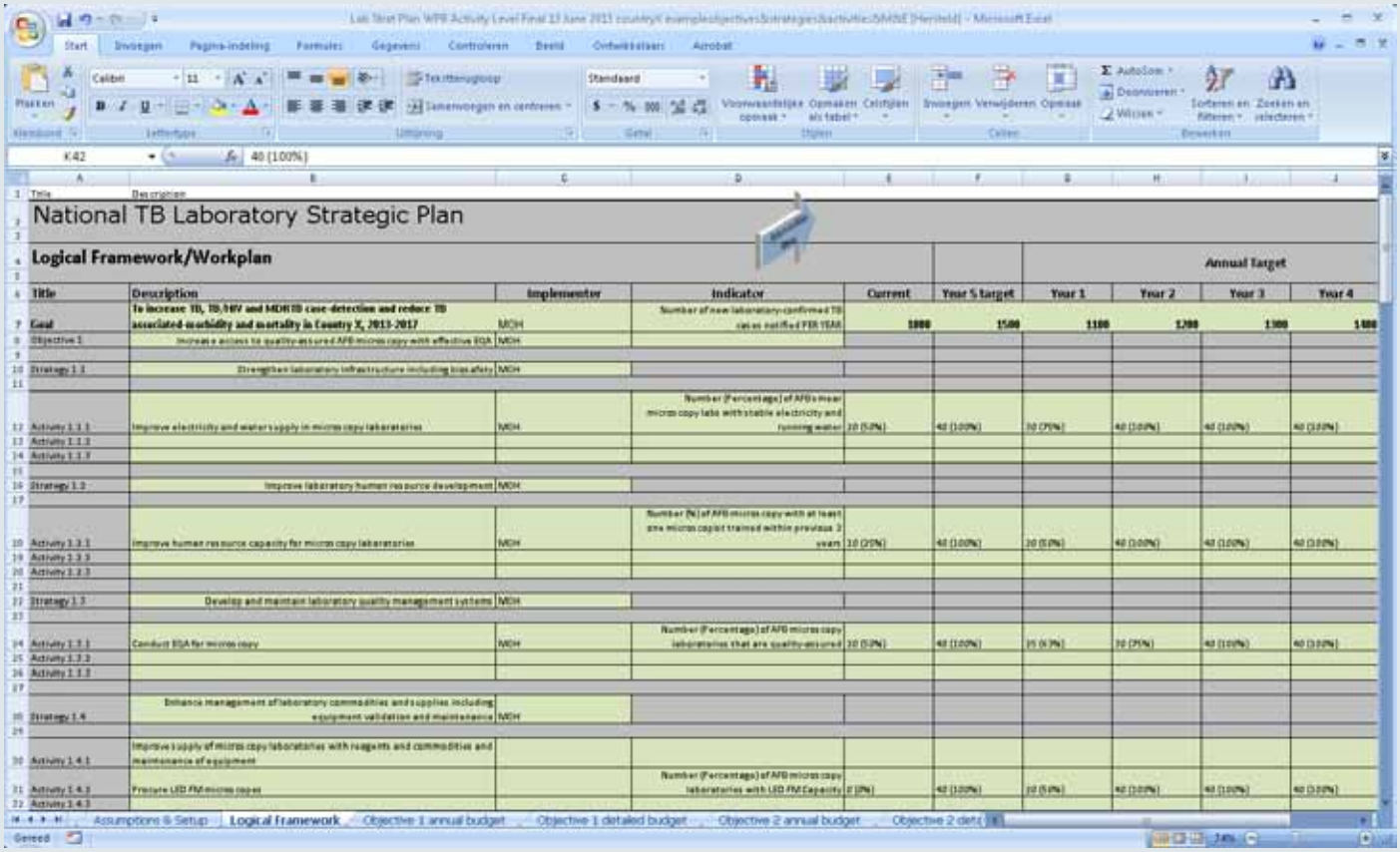
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Exercise 5d: Prioritizing main and sub- activities by strategies within STOP TB objectives

With the Excel tool, Insert activities and sub-activities into the logical frame work



National TB Laboratory Strategic Plan

Logical Framework/Workplan

Title	Description	Implementor	Indicator	Current	Year 5 target	Annual Target Year 1	Year 2	Year 3	Year 4
Goal	To increase TB, TB/HIV and MDRTB case-detection and reduce TB associated morbidity and mortality in Country X, 2013-2017	MOH	Number of new laboratory-confirmed TB cases notified PER YEAR	1000	1500	1100	1200	1300	1400
Objective 1	Increase access to quality-assured AFB microscopy with effective EQA	MOH							
Strategy 1.1	Strengthen laboratory infrastructure including bio-safety	MOH							
Activity 1.1.1	Improve electricity and water supply in microscopy laboratories	MOH	Number (Percentage) of AFB smear microscopy labs with stable electricity and running water	30 (50%)	60 (100%)	30 (75%)	40 (100%)	40 (100%)	40 (100%)
Activity 1.1.2									
Activity 1.1.3									
Strategy 1.2	Improve laboratory human resource development	MOH							
Activity 1.2.1	Improve human resource capacity for microscopy laboratories	MOH	Number (%) of AFB microscopy with at least one microscopist trained within previous 3 years	10 (25%)	40 (100%)	20 (50%)	40 (100%)	40 (100%)	40 (100%)
Activity 1.2.2									
Activity 1.2.3									
Strategy 1.3	Develop and maintain laboratory quality management systems	MOH							
Activity 1.3.1	Conduct EQA for microscopy	MOH	Number (Percentage) of AFB microscopy laboratories that are quality-assured	10 (50%)	40 (100%)	35 (87%)	30 (75%)	40 (100%)	40 (100%)
Activity 1.3.2									
Activity 1.3.3									
Strategy 1.4	Enhance management of laboratory commodities and supplies including equipment validation and maintenance	MOH							
Activity 1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment								
Activity 1.4.2	Procure LED FM microscopes		Number (Percentage) of AFB microscopy laboratories with LED FM Capacity	2 (8%)	40 (100%)	20 (50%)	40 (100%)	40 (100%)	40 (100%)
Activity 1.4.3									

Strategy 1.1	
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	
Activity 1.3.1	
Sub-activity 1.3.1.1	
Sub-activity 1.3.1.2	
Strategy 1.4	
Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
Strategy 1.5	

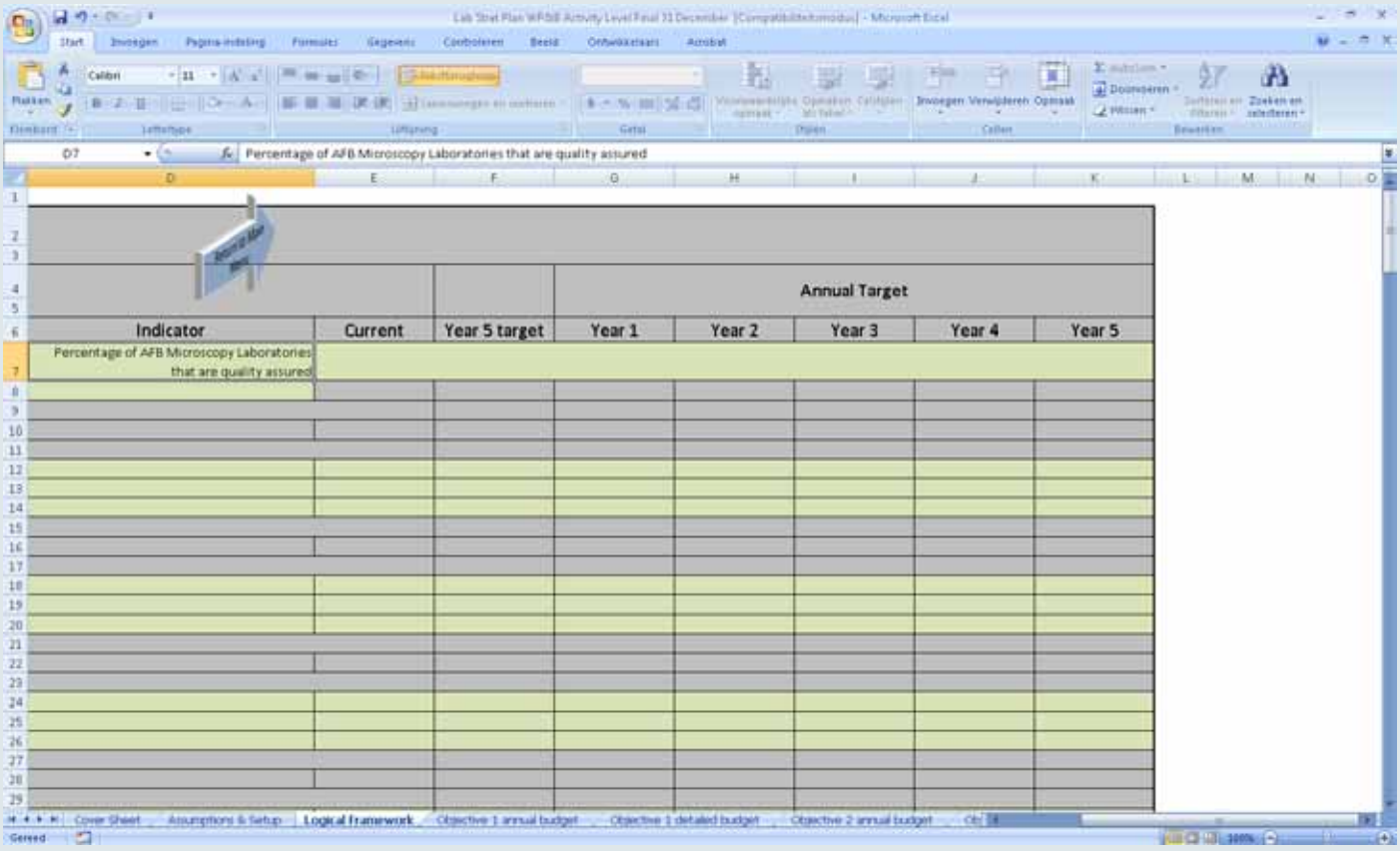
Activity 1.5.1	
Sub-activity 1.5.1.1	
Sub-activity 1.5.1.2	
Strategy 1.6	
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Identifying Indicators and Targets in a Monitoring and Evaluation (M&E) Framework

Exercise 6a: Developing M&E indicators for activities within STOP TB objectives

Exercise 6b: Developing M&E targets for activities within STOP TB objectives

With the Excel tool: Input the implementers, indicators, write the current status and add targets.



Should you choose to not work in the Excel tool (which is recommended), use template below to work from below:

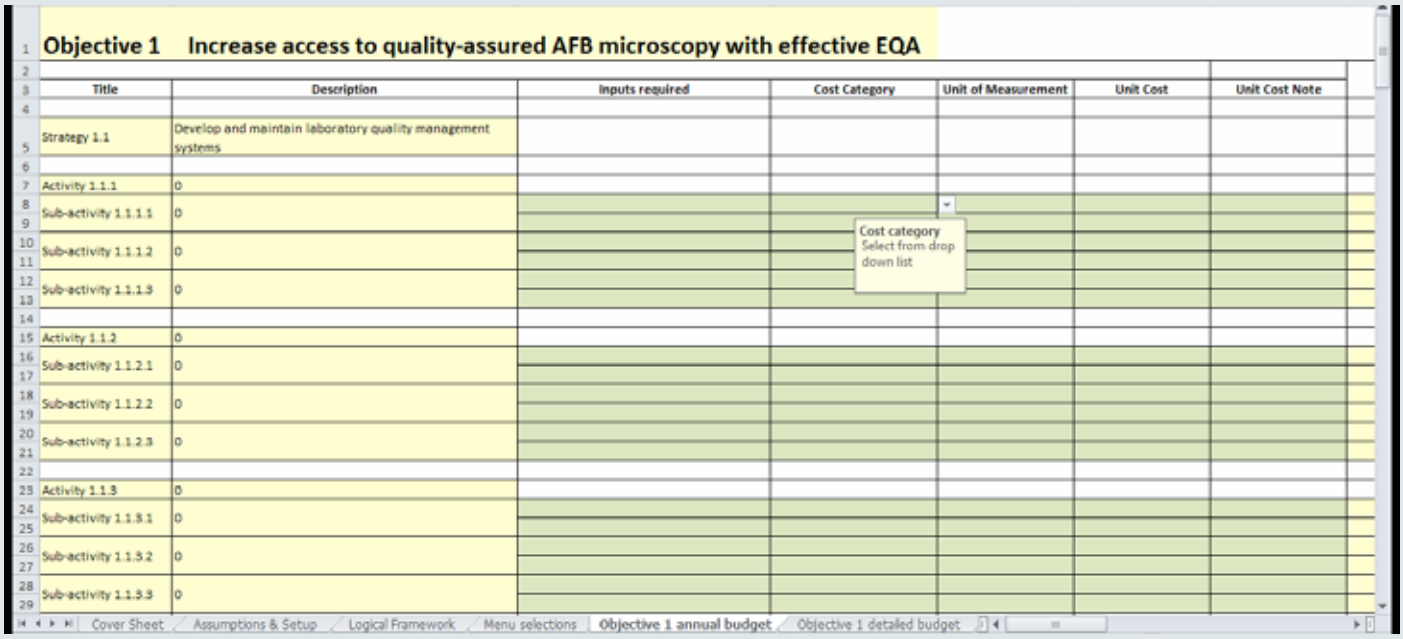
Objective 1:

Strategy 1.1	**Description**	**Indicators**	**Targets**
Activity 1.1.1			
Sub-activity 1.1.1.1			
Sub-activity 1.1.1.2			
Strategy 1.2			
Activity 1.2.1			
Sub-activity 1.2.1.1			
Sub-activity 1.2.1.2			
Sub-activity 1.2.1.3			
Strategy 1.3			
Activity 1.3.1			
Sub-activity 1.3.1.1			
Sub-activity 1.3.1.2			
Strategy 1.4			
Activity 1.4.1			
Sub-activity 1.4.1.1			
Sub-activity 1.4.1.2			
Strategy 1.5			
Activity 1.5.1			
Sub-activity 1.5.1.1			
Sub-activity 1.5.1.2			
Strategy 1.6			
Activity 1.6.1			
Sub-activity 1.6.1.1			
Sub-activity 1.6.1.2			

Develop a TB Laboratory Plan Work Plan and Budget

Exercise 7a: Work plan and budget-costing (sub-) activities

Input into the annual budget sheet. Define the unit of measurement, and the unit costs and quantities:



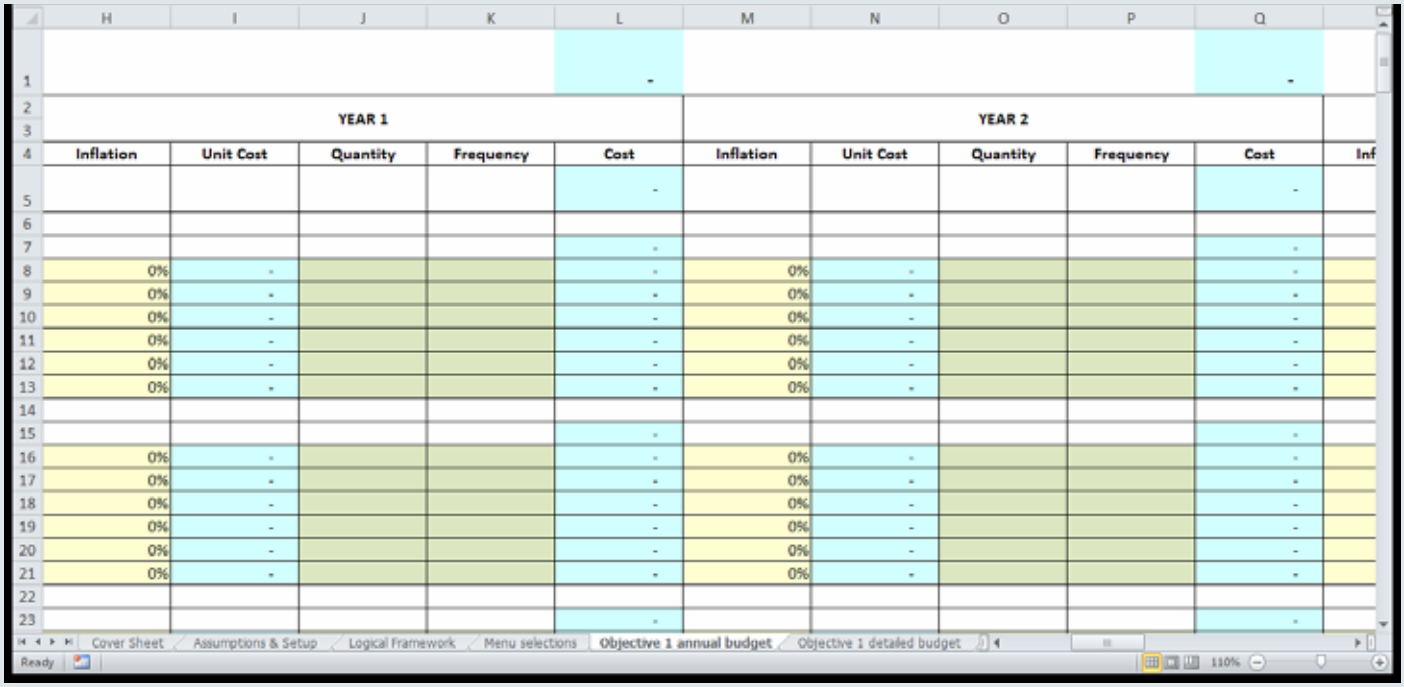
Objective 1 Increase access to quality-assured AFB microscopy with effective EQA

Title	Description	Inputs required	Cost Category	Unit of Measurement	Unit Cost	Unit Cost Note
Strategy 1.1	Develop and maintain laboratory quality management systems					
Activity 1.1.1	0					
Sub-activity 1.1.1.1	0					
Sub-activity 1.1.1.2	0					
Sub-activity 1.1.1.3	0					
Activity 1.1.2	0					
Sub-activity 1.1.2.1	0					
Sub-activity 1.1.2.2	0					
Sub-activity 1.1.2.3	0					
Activity 1.1.3	0					
Sub-activity 1.1.3.1	0					
Sub-activity 1.1.3.2	0					
Sub-activity 1.1.3.3	0					

Cost category
Select from drop down list

Cover Sheet | Assumptions & Setup | Logical Framework | Menu selections | Objective 1 annual budget | Objective 1 detailed budget

Add quantities and the frequency of these quantities in the respective columns:



	YEAR 1					YEAR 2				
Inflation	Unit Cost	Quantity	Frequency	Cost	Inflation	Unit Cost	Quantity	Frequency	Cost	Inf
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	
0%	-			-	0%	-			-	

Cover Sheet | Assumptions & Setup | Logical Framework | Menu selections | Objective 1 annual budget | Objective 1 detailed budget

Ready

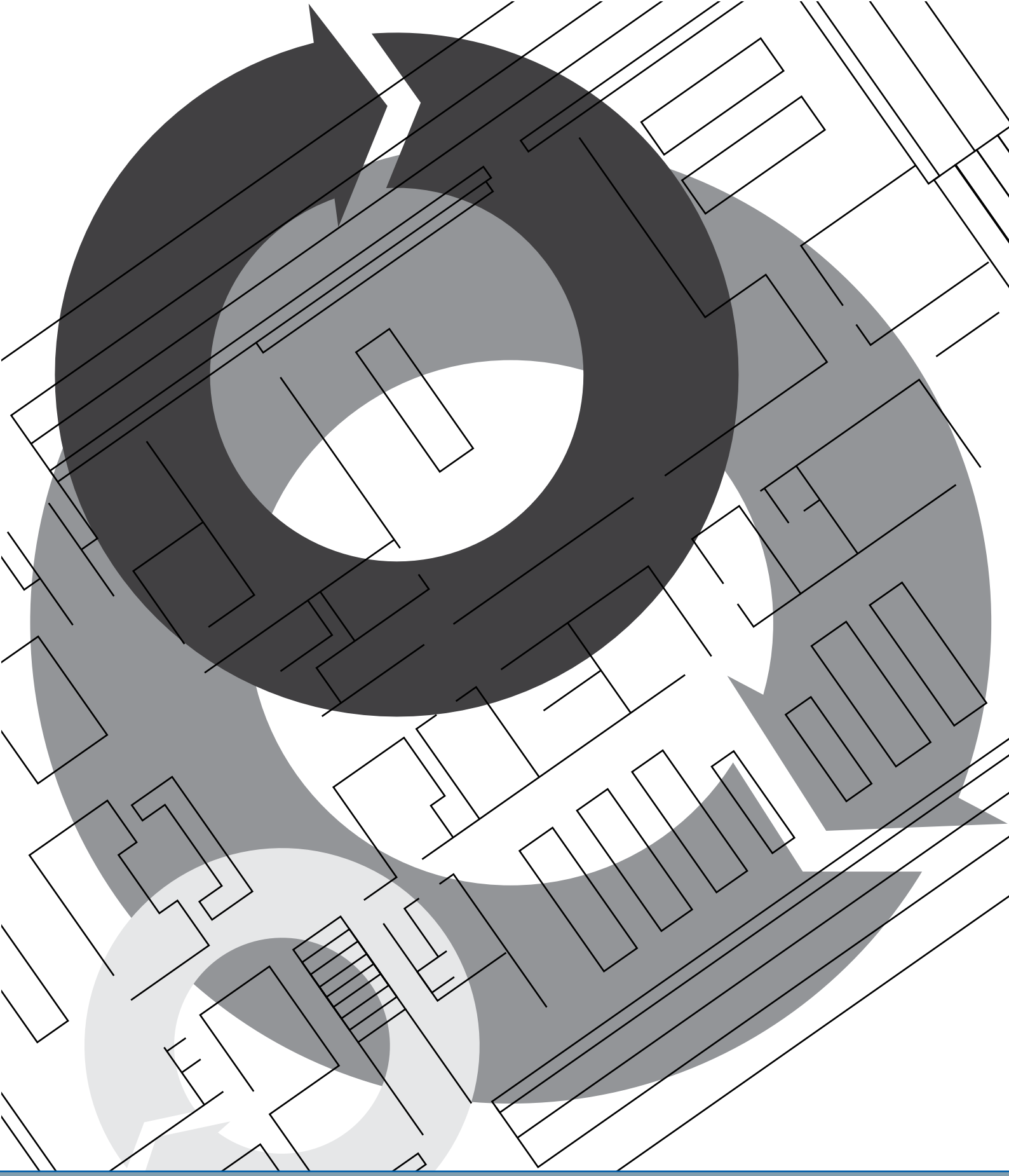
Putting it all Together

Exercise 8a: Putting it all together

Check if completed ✓	Component	What needs to be done to complete this section?	Who Does This? Organization/person	Due date
☐	Title page with appropriate logos and date.			
☐	**I.** Table of contents			
☐	**II.** Foreword			
☐	**III.** Acknowledgments of contributors			
☐	**IV.** Executive summary highlighting the key elements for an overview of the TB-specific Plan			
☐	**V.** Abbreviations			
☐	**VI.** Mission and vision statement [derived from Exercises 3a-3b]			
☐	**VII.** Situational analysis including:			
☐	Narrative of sections 4.1-4.13 [derived from Exercise 4a]			
☐	**A-B.** TB specific contextual analysis			
☐	**C.** TB specific tests currently available and coverage			
☐	**D.** Structure of the laboratory network of TB diagnostics			
☐	**E.** Infrastructure of the laboratory network of TB diagnostics			
☐	**F.** Human resources for the TB laboratory network			

☐		**G.** Equipment maintenance and validation for TB laboratory equipment			
☐		**H.** Quality management systems of TB laboratory network			
☐		**I.** Management of laboratory commodities and supplies for the TB laboratory network			
☐		**J.** Laboratory information and data management for the TB laboratory network			
☐		**K.** Sample transport and referral system for the TB laboratory network			
☐		**L.** Operational research within the TB laboratory network			
☐		**M.** Legal policy and review for TB laboratory network			
☐		**N.** Financing for the TB laboratory services			
☐		Strengths, weaknesses, opportunities and threats (SWOT) of TB laboratory network [derived from Exercise 4b]			
☐		Situational analysis framework by key challenges and specific areas with potential solutions [derived from Exercise 4c]			
☐	**VIII.**	Defined Priority targets, Areas, strategies, main activities and sub-activities of the TB laboratory Plan [derived from Exercises 5a-5d]			
☐	**IX.**	Monitoring and evaluation framework of TB-specific Plan [derived from Exercises 6a-6b]			
☐	**X.**	Work plan and budget of TB-specific Plan [Exercise 7a]			
☐	**XII.**	References			
☐	**XIII.**	Annexes			
☐	Editing for consistency of terms within document				
☐	Editing for grammar and language				
☐	Spell-check				

☐	Cross-check for consistency of terms (language and technical), harmonization, between this TB-specific Plan and the TB-specific Plan mission			
☐	Cross-check for consistency of terms (language and technical), harmonization, between this TB-specific Plan and the NTP strategic plan including activities, indicators and targets			
☐	Cross-check for consistency of terms (language and technical), harmonization, between this TB-specific Plan and the NHL strategic plan including activities, indicators and targets			
☐	Endorsement by an appropriate official with foreword (executive summary)			
☐	Printing			
☐	Distribution			



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