A Practical Handbook for National TB Laboratory Strategic Plan Development

FACILITATORS MANUAL

TB CARE I

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A Practical Handbook for National TB Laboratory Strategic Plan Development
Facilitators Manual

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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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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.

Chapter 1:

Introduction

This manual should be used as a guide to facilitating two workshops for the development of a TB laboratory plan, utilizing the exercises in Chapters 2-8 and the Excel-based work plan and budget tool designed specifically for the development of TB laboratory plans.

An instruction manual for the Excel-based work plan and budget tool may be found in Annex I of this Facilitators manual. The Excel work plan and budget tool may be used for exercises for **Chapter 5** to **Chapter 7**.

It is recommended that you set up the Excel tool and familiarize yourself with its use prior to exercises in **Chapter 5**.

A master copy of the draft TB laboratory plan and excel tool should be maintained with others (individuals or groups) contributing to these master documents during, in between and after the workshops. Should the Excel tool not work in your country for some reason e.g. macros, you may develop your own work plan with the templates and formats that we provide in the handbook and the exercises.

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

Use this checklist in the preparation for both workshops and for appointing responsible persons. If available, use the 'reference materials required list' to gather appropriate documentation ahead of the workshops. If you do not have an NTP plan at least in draft form and diagnostic algorithms, the workshop cannot proceed.

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 the coordination of activities related to the TB laboratory plan development
2. Secure funds for 2 one-week workshops with 10–20 participants each and a consultant. Smaller countries should have fewer representatives whereas larger ones will have more. A prerequisite 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 finance 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 number of working groups)
   - Extension cords and adapters
   - CDs or memory sticks
   - Files for papers
   - Printer
   - Printing paper
   - Stickers
   - Markers
   - Handouts (both printed and electronic, e.g. 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

REFERENCE MATERIALS RECOMMENDED BY CHAPTER
CHAPTER 3 **Developing a Vision and a Mission**
National TB Program (NTP) vision and mission Current National TB reference laboratory (NTRL) vision and mission, if it exists National Medical Laboratory vision and mission, if it exists
CHAPTER 4 **TB-specific contextual analysis**
NTP guidelines NTP plan (MANDATORY) National Medical Laboratories Strategic Plan, if it exists Current NTRL strategic plan, if it exists WHO Global Report on TB (most recent) NTP surveillance, policy and technical reports Review/assessment reports Latest drug-resistance survey (DRS) report HIV/AIDS surveillance, policy and technical reports
TB-specific TESTS CURRENTLY AVAILABLE and Coverage
Medical Laboratories Policy NTRL quality manual Microscopy, culture, drug susceptibility testing (DST), molecular assays statistics Statistics on the number of TB diagnostic laboratories and work-load
STRUCTURE OF THE LABORATORY NETWORK of TB diagnostics
Medical Laboratories Policy TB laboratory Network Organogram
INFRASTRUCTURE OF THE LABORATORY NETWORK for TB diagnostics
NTP review/assessment reports Laboratory network review/assessment reports from partners Biosafety manual Infection control (IC) guidelines National waste management regulations
HUMAN RESOURCES for the TB lab network
MoH strategic human resource development (HRD) plan NTP HRD strategic plan National Medical Laboratories Strategic Plan, if it exists NTP review reports AFB microscopy EQA reports Reports on external assessments of the NTRL and laboratory network Laboratory School curricula
EQUIPMENT MAINTENANCE AND VALIDATION of TB lab equipment
Medical laboratories policy NTRL quality manual NTP review reports Reports on external assessments of the NTRL and laboratory network

LABORATORY QUALITY MANAGEMENT SYSTEMS within the TB lab network
Medical laboratories policy NTRL quality manual AFB microscopy EQA plan DST EQA plan EQA reports on smear microscopy and DST Reports on external assessments of the NTRL and laboratory network
MANAGEMENT OF LABORATORY COMMODITIES AND SUPPLIES within the TB lab network
Medical laboratories policy NTP/assessment review reports Central Medical Stores (CMS)/Supply and commodities management system (SCMS) List of supplies NTRL external assessments reports
LABORATORY INFORMATION AND DATA MANAGEMENT for the TB lab network
Mycobacterial request/report form Microscopy and culture/DST register MDR-TB report tool TB/HIV request and report tool Manuals/SOPs for laboratory informational systems in use
SAMPLE REFERRAL SYSTEMS for the TB lab network
Medical laboratories policy Specimen collection and transportation manual NTP manual
OPERATIONAL RESEARCH regarding the TB laboratory network
NTP strategic plan National Medical Laboratories Strategic Plan, if it exists Current NTRL strategic plan, if it exists Partners' plans
LEGAL AND POLICY REVIEW for TB
Medical laboratories policy NTRL quality manual
FINANCES for TB laboratory services
National Medical Laboratories Strategic Plan, if it exists NTP plan Partners' agreement documents, reports and plans
CHAPTER 5
NTP plans Diagnostic algorithms
CHAPTER 6
NTP plan indicators and targets
CHAPTER 7
Minimum budget available/pledged by source for 5-year TB laboratory plan (as many years as possible)

Workshop Agenda for 1st One-week Workshop

{COUNTRY} National TB laboratory plan workshop:
Agenda
{DATE]
{LOCATION}

Day 1 Monday {DATE}

8:30-8:45
Opening
NHL/NTP

8:45-9:00
Introductions
All stakeholders

9:00-9:15
Proposed objectives and agenda for workshop
Consultant or national coordinator of workshop

9:15-10:30
Developing a vision for a TB laboratory plan
Stakeholders divided into 4 groups

10:30-10:50
Tea/Coffee break

10:50-12:30
Developing a vision and mission for a TB laboratory plan
Stakeholders divided into 4 groups
Exercise 3a: Vision (continued)
Exercise 3b: Mission
Presentations of visions and mission by group and agreement on which draft to utilize

12:30-13:30
Lunch

13:30-15:00
Situational analysis of TB laboratory network
Stakeholders divided into 4 groups
Exercise 4a: Situational analysis

15:00-15:20
Tea/Coffee break

15:20-16:20
Situational analysis of TB laboratory network
Exercise 4a (continued): Drafts to be turned in by end of session

16:20-16:30
Closure for the Day

DAY 2 Tuesday {DATE}

8:30-10:30
Situational analysis of TB laboratory network
Presentations and discussion of situational analysis

10:30-10:50
Tea/Coffee break

10:50-12:30
Situational analysis of TB laboratory network: SWOT
Stakeholders divided into 4 groups
Exercise 4b: Situational analysis SWOT

12:30-13:30
Lunch

13:30-15:00
Situational analysis of TB laboratory network SWOT
Exercise 4b (continued): continued and group presentations

15:00-15:20
Tea/Coffee break

15:20-16:20
Situational analysis of TB laboratory network: framework
Stakeholders divided into 4 groups
Exercise 4c: Situational analysis framework

16:20-16:30
Closure for the Day

DAY 3 Wednesday {DATE}

8:30-10:30
Situational analysis of TB laboratory network
Presentations and discussion of situational analysis framework

10:30-10:50
Tea/Coffee break

10:50-12:30
Defining targets by goal and objectives
Stakeholders divided into 4 groups
Exercise 5a: Targets:
1. Detection of smear-positive TB
2. Detection of smear-negative TB
3. Detection of MDRTB
4. Quality management systems

12:30-13:30
Lunch

13:30-15:00
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b: 4 groups

15:00-15:20
Tea/Coffee break

15:20-16:20
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b (continued): 4 groups

16:20-16:30
Closure for the Day

DAY 4 Thursday {DATE}

8:30-9:30
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b (continued): Finalization, presentations and discussion

9:30-10:30
Setting strategies within objectives for a TB laboratory plan
Exercise 5c Setting strategies: break into 4 groups

10:30-10:50
Tea/Coffee break

10:50-12:30
Setting strategies within objectives for a TB laboratory plan
Exercise 5c Setting strategies (Continued): break into groups
Finalization and discussion

12:30-13:30
Lunch

13:30-15:00
Setting strategic activities within identified objectives and strategies
Exercise 5d Setting strategic activities: break into 4 groups

15:00-15:20
Tea/Coffee break

15:20-16:20
Setting strategic activities within identified objectives and strategies
Exercise 5d (Continued) Setting strategic activities: break into groups

16:20-16:30
Closure for the Day

DAY 5 Friday {DATE}

8:30-10:30
Setting strategic activities within identified objectives and strategies
Exercise 5b (continued): Finalization, presentations and discussion

10:30-10:50
Tea/Coffee break

10:50-12:30
Developing indicators and targets for TB laboratory plan
Exercises 6a-6b: Indicators and targets
Break into groups

12:30-13:30
Lunch

13:30-15:00
Developing indicators and targets for TB laboratory plan
Exercise 6a-6b (Continued): Indicators and targets
Break into groups
Finalization and presentation

15:00-15:20
Tea/Coffee break

15:20-16:20
Wrapping up and closure

Workshop Agenda for 2nd One-week Workshop **(Customized per country, dependent on gaps identified in the draft TB laboratory plan prior to this workshop)**

{COUNTRY} National TB Laboratory Plan Workshop:
Agenda
{DATE]
{LOCATION}

Day 1 Monday {DATE}

8:30-8:45
Opening
NHL/NTP

8:45-9:00
Introductions
All stakeholders

9:00-9:15
Proposed justification, objectives and agenda for workshop
Consultant or national coordinator of workshop

9:15-10:30
Overview of the draft TB-specific lab strategic plan handbook and "Where we are now" with the 1st draft of the {COUNTRY} National TB Reference Laboratory (NTRL) Strategic Plan from the 1st workshop in {DATE}
Consultant or national coordinator of workshop

10:30-10:50
Tea/Coffee break

10:50-11:30
Introduction to the Monitoring and Evaluation (M&E) framework for the lab strategic plan
Consultant or national coordinator of workshop

11:30-12:30
Retrospectively (moving backward) :
Update the existing draft NTRL strategic plan sections not fully completed from the previous workshop including the situational analysis and priorities
Prospectively (moving forward):
Develop M&E section from scratch for the draft NTRL strategic plan

Stakeholders divided into 3 groups:
1. Retrospective: Situational analysis update [Chapter (Ch.) 4 of Laboratory Plan Handbook]
2. Retrospective: Priorities update [Ch. 5]
3. Prospective: M&E development [Ch. 6]

12:30-13:30
Lunch

13:30-15:00
Retrospectively:
Updating the existing draft NTRL strategic plan including situational analysis and priorities
Prospectively:
M&E section for the draft NTRL strategic plan continued
Stakeholders divided into 3 groups:
1. Retrospective: Situational analysis update [Ch. 4]
2. Retrospective: Priorities (particularly focused on Objective 2 (Improve the diagnosis of TB among AFB-negative cases) as this was not developed fully in the last workshop) update [Ch. 5]
3. Prospective: M&E development [Ch. 6]

15:00-15:20
Tea/Coffee break

15:20-16:20
Retrospectively:
Update existing draft NTRL strategic plan-key strategic activities
Prospectively:
M&E section for the draft NTRL strategic plan continued

Stakeholders divided into 4 groups:
1. Retrospective: Activities
Objective 1 (Increase access to quality-assured AFB microscopy) [Ch. 5]
2. Retrospective: Activities
Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
3. Retrospective: Activities
Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
4. Prospective: M&E development [Ch. 6]
Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 2 Tuesday {DATE}

8:30-9:30
Introduction to the work plan framework
Consultant or national coordinator of workshop

9:30-10:30
Retrospectively:
Update existing draft NTRL strategic plan-key strategic activities
Prospectively:
Prepare work plan from scratch for the draft NTRL strategic plan

Stakeholders divided into 4 groups:
1. Retrospective: Activities- Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
2. Retrospective: Activities-Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
3. Retrospective: Activities-Objective 4 (Establish laboratory quality management systems for TB) [Ch. 5]
4. Prospective: Develop work plan with already defined activities (by objective and strategy) and simultaneously plug in information from Groups 1-3. [Ch. 7]

10:30-10:50
Tea/Coffee break

10:50-12:30
Retrospectively (moving backward) :
Update existing draft NTRL strategic plan: key strategic activities
Prospectively (moving forward):
Work plan for the draft NTRL strategic plan continued

Stakeholders divided into 4 groups:
1. Retrospective: Activities-Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
2. Retrospective: Activities-Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
3. Retrospective: Activities-Objective 4 (Establish laboratory quality management systems for TB [Ch. 5]
4. Prospective: Develop work plan with already activities (by objective and strategy) and simultaneously plug in information from Groups 1-3. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Introduction to budget tool and costing
Consultant or national coordinator of workshop
[Chapter 7 of the TB Laboratory Plan Handbook]

15:00-15:20
Tea/Coffee break

15:20-16:20
Retrospectively:
Updating existing draft NTRL strategic plan: monitoring and evaluation framework and work plan
Prospectively:
Work plan for the draft NTRL strategic plan continued
Prospectively:
Begin budget development from scratch for the draft TB laboratory plan

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Goal and Objectives 1-4 [Ch. 6]
2. Prospective: Develop work plan with already identified activities (by objective and activity) and simultaneously plug in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 3 Wednesday {DATE}

8:30-9:30

Retrospectively:
Updating existing draft NTRL strategic plan: monitoring and evaluation framework and work plan
Prospectively:
Work plan for the draft NTRL strategic plan continued
Prospectively:
Budget for the draft NTRL strategic plan continued

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Objectives 1-4 [Ch. 6]
2. Prospective: Develop work plan with already known activities (by objective and strategy) and plug in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known objectives, strategies and activities and simultaneously plugging in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

DAY 3

10:30-10:50
Tea/Coffee break

10:50-12:30
Retrospectively :
Updating existing draft NTRL strategic plan: monitoring and evaluation framework
Prospectively :
Work plan for the draft NTRL strategic plan continued
Prospectively :
Budget for the draft NTRL strategic plan continued

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Objectives 1-5 [Ch. 6]
2. Prospective: Develop work plan with already known objectives, strategies and activities and simultaneously plugging in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Where are we now? Putting it all together
Plenary with MOH (NTRL/NTP) and consultant

15:00-15:20
Tea/Coffee break

15:20-16:20
Prospectively:
Budget for the draft NTRL strategic plan continued
Prospectively:
Budget for the draft NTRL strategic plan continued

Putting it all together introduced

Stakeholders divided into 3 groups:
1. Prospective: Develop work plan with already activities and indicators. [Ch. 7]
2: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group [Ch. 7]
3. Putting it all together: Identify gaps and assign individuals and groups to complete including content, formatting, etc.... [Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 4 Thursday {DATE}

8:30-9:30

Putting it all together: Identify areas to be completed and fill in gaps

Putting it all together
Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP strategic plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

DAY 4

10:30-10:50
Tea/Coffee break

10:50-12:30
Putting it all together:
Identify areas to be completed and fill in gaps continued

Putting it all together: Group and individual assignments
[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Putting it all together: Identify areas to be completed and fill in gaps continued

Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization
9. Master document editing for consistency

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

DAY 4

15:00-15:20
Tea/Coffee break

15:20-16:20

Putting it all together: Identify areas to be completed and fill in gaps continued

Putting it all together: Group and individual assignments [Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 5 Friday {DATE}

8:30-9:30

Putting it all together: Identify areas to be completed and fill in gaps continued

Putting it all together
Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP strategic plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization
9. Master document editing for consistency

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

10:30-10:50
Tea/Coffee break

10:50-12:30
Putting it all together: Identify areas to be completed-Finalization of TB laboratory strategic plan

Putting it all together-Final Round
Group and individual assignments continued

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-14:30
Review of compiled NTRL draft laboratory plan

All stakeholders go through compiled document and discuss in plenary

14:30-14:45
Discuss next steps for endorsement

MOH/NTP

14:45-15:00
Feedback on the workshop and tools used

All Stakeholders

15:00-15:20
Tea/Coffee break

15:20-16:00

Wrapping up and closure

Define a Vision and a Mission

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

Process

Step 1. Imagine the Future

- Say: "We are going to create a shared vision. This is the picture of what we want to create in the future together as a national TB reference laboratory. We are not going to discuss the obstacles now, but what we most want to see happen."
- Ask the participants to think about a time in the future.
- Say: "Imagine it is 5 or more years from now and we are looking back. We have accomplished all that is important to us. What picture do you see in your mind that represents that accomplishment?"
- Ask each participant to write a newspaper headline reporting on the group's accomplishments in the year 20XX (five or more years from now). Each individual writes a statement to describe what s/he is most proud of.

Step 2. Integrate Your Vision with Others

- Group the participants in pairs and ask them share to their visions of their future accomplishments with each other
- Ask each pair of participants to create one shared vision combining the best aspects of both visions
- Have groups of four (two pairs), discuss the combined visions
- Have each group of four further combine the visions to arrive at one shared vision.

Step 3. Record key elements of vision statements

- Ask each group of four to record the key elements or phrases of their vision statement on four-by-six-inch cards or removable self-stick notes. (Give each group six to eight cards; groups should write only one element or key phrase on each card)

Resources recommended for this chapter:

- NTP mission and vision
- NHL mission and vision (if available)
- Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infection with and affected by HIV/AIDS, TB and Malaria 2010.
- Managers Who Lead. A Handbook for Improving Health Services. Management Sciences for Health, 2005

Step 4. Organize elements and key phrases into categories

- Ask each group, one group at a time, to tape its cards showing key elements on the wall (or on a set of flipcharts taped to the wall)
- Ask each successive group to place its cards with other cards that have similar elements. If a card doesn't fit with any other card, it stands alone
- Once all the cards are posted, ask the participants to come up to the wall and move the cards around, grouping similar messages and phrases together until they are all arranged into categories
- Alternatively, this categorization can be done in a plenary session, in which you ask the participants to suggest which cards should be grouped together (or remain apart)
- Decide on a name for each category, write the

name on a new card (of a different color), and place the card above the appropriate groupings of cards
- Read all the categories aloud.

Step 5. Draft a Shared Vision Statement
- Have a small team synthesize the messages that pertain to each category and write a statement that reflects the shared vision. Remind the team to retain the pride and feeling that the vision expresses. This synthesis is best done overnight or during lunch break.

Step 6. Present the Draft Shared Vision Statement
- Write the shared vision on a clean flipchart.
- Put the shared vision statement in the front of the room for all to see. This initial shared vision statement will probably need to be fine-tuned. It should help guide further discussions and refinement

Step 7. Wrap up and plan next steps
- Decide on a deadline for finalizing this draft vision statement and who needs to be involved in finalizing it, and finalize the vision statement
- Discuss with the group how to use the vision as an alignment tool
- Discuss the final vision statement with people (other stakeholders) outside your immediate group who need to know your vision or could help you move closer to realizing the vision
- Make the vision statement accessible (and easily visible) to everyone throughout the duration of each workshop.

Alternative:
An alternative approach, particularly with a small group as was the case in Botswana which worked well, is to have stake-holders individually develop their visions and then have the individual stakeholders discuss their vision in pairs then they individually fine-tune their visions and then turn the revised vision on a 'sticky note' or 'note card' to a moderator who types them into the computer and projects them. The moderator can harmonize all the key words into one vision with group participation and the vision can be fine-tuned and finalized this way. Colored fonts can be used to highlight key points, adjectives etc. The moderator, however, should keep in mind the guidelines from the handbook on how to define a vision as well as key words suggested in the handbook (Chapter 3).

Note for the facilitator:
Generally, a vision statement expresses what the organization aspires to, and gives an overarching definition of where the future lies for the entity. It is a longer narrative than the mission statement and provides a cogent explanation of the future for the laboratory system.

As an example, we modified a non-TB specific example from the Management Sciences for Health's Managers Who Lead as follows: *"Our TB laboratory network is known for consistently producing excellent service results and patients can count on our services for TB diagnostics. Further, surrounding country laboratories can count on our capacity to further validate their own results. As a result of our TB laboratory network, we have improved TB diagnostics and therefore saved lives and improved quality of life for patients not only in our own country but in surrounding countries in the region".*

Another example of a vision statement courtesy of the stakeholders in a TB-specific national lab strategic workshop in November 2011 in Botswana: *"To become a recognized Center of Excellence in the sustained provision of quality tuberculosis laboratory services in Botswana and internationally. Our concept of quality includes timeliness, high level of accuracy, and reliability of laboratory services to the satisfaction of our customers. As a recognized Center of Excellence, we pride ourselves in utilizing the most up-to-date internationally-recommended diagnostic technologies".*

In most cases the NTP will have a mission and vision statement. These should be provided to stakeholders during this exercise for reflection. However, the NTRL vision and mission should try to support the NTP vision and mission from the lab perspective contribution only. In some cases the NTRL and NHL may already have vision and mission statements. These should be provided to stakeholders during this exercise. If the NTRL has a vision and mission statement already, the stakeholders will have to agree in an plenary whether these meet the technical requirements specified or need to be updated. If the NHL

already has a vision and mission statement, the stakeholders can consider adapting key words from this vision and mission from the TB-laboratory perspective.

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

This exercise is an adaptation of an exercise to guide a large group through the process of creating a shared vision that has been modified from a Management Sciences for Health exercise (*Managers Who Lead. A handbook for Improving Health Services. Management Sciences for Health, 2005*)

Process

Step 1. Imagine the Future

- Say: "We are going to create a shared mission. This is the picture of what we want to create in the future together as a national TB reference laboratory. We are not going to discuss the obstacles now, but what we most want to see happen."
- Ask the participants to think about a time in the future.
- Say: "Imagine it is 5 or more years from now and we are looking back. We have accomplished all that is important to us. What picture do you see in your mind that represents that accomplishment?"
- Ask each participant to describe in one concise statement and reflecting the mission statement on the vision statement that was developed in Exercise 1:
  1. What does the NTRL do?
  2. Why does it exist?
  3. Who does it serve
  4. How does it work?

Step 2. Integrate your mission with others

- Group the participants in pairs and ask them share to their mission with each other
- Ask each pair of participants to create one shared mission combining the best aspects of both visions
- Have groups of four (two pairs), discuss the combined mission
- Have each group of four further combine the visions to arrive at one shared mission.

Resources Needed:

- Flipchart or overhead projector with computer
- Colored sticky notes or colored note cards

Key concepts to consider for vision and mission statements:

- Quality-assured
- Timely
- Advancement
- Reliable
- High-quality
- Customer satisfaction
- Accurate
- Internationally-recognized
- Saving lives

Step 3. Record key elements of mission statements

- Ask each group of four to record the key elements or phrases of their mission statement on four-by-six-inch cards or removable self-stick notes. (Give each group six to eight cards; groups should write only one element or key phrase on each card.)

Step 4. Organize elements and key phrases into categories

- Ask each group, one group at a time, to tape its cards showing key elements on the wall (or on a set of flip charts taped to the wall).
- Ask each successive group to place its cards with other cards that have similar elements. If a card doesn't fit with any other card, it stands alone.
- Once all the cards are posted, ask the participants to come up to the wall and move the cards around, grouping similar messages and phrases together until they are all arranged into categories.
- Alternatively, this categorization can be done in a plenary session, in which you ask the participants to suggest which cards should be grouped together (or remain apart).
- Decide on a name for each category, write the name on a new card (of a different color), and place the card above the appropriate groupings of cards.
- Read all the categories aloud.

Step 5. Draft a shared mission statement

- Have a small team synthesize the messages that pertain to each category and write a statement that reflects the shared reflecting on the reflecting on the vision developed thus far developed thus far lunch break.

Step 6. Present the draft shared mission statement

- Write the shared vision on a clean flip chart.
- Put the shared mission statement in the front of the room for all to see. This initial shared mission statement will probably need to be fine-tuned. It should help guide further discussions and refinement.

Step 7. Wrap up and plan next steps

- Decide on a deadline for finalizing this draft mission statement and who needs to be involved in finalizing it, and finalize the mission statement.
- Discuss with the group how to use the mission as an alignment tool:
- Discuss the final mission statement with people (other stakeholders) outside your immediate group who need to know your vision or could help you move closer to realizing the mission.

Note for the Facilitator:

An alternative approach, particularly with a small group as was the case in Botswana which worked well, is to have stake-holders individually develop their mission and then have the individual stakeholders discuss their mission in pairs then they individually fine-tune their mission statement and then turn the revised mission on a sticky note or note card to a moderator who types them into the computer and projects them. The moderator can harmonize all the key words into one mission with group participation and the mission can be fine-tuned and finalized this way. Colored fonts can be used to highlight key points, adjectives etc... The moderator, however, should keep in mind the guidelines from the handbook on how to define a mission as well as key words suggested in the handbook (Chapter 3).

A mission statement is concise and succinctly describes what the organization does, why it exists, who it serves and how it does its work. A mission statement must be understood at all levels of the system and provide a compelling explanation of the greater purpose of the organization. As an example, we modified a non-TB specific WHO AFRO laboratory strategic guidelines example as follows: "To improve the health status of our country and region by advancing the capacity of all laboratories performing TB diagnostics"

Another example of a mission statement courtesy of the stakeholders in a TB-specific national lab strategic workshop in November 2011 in Botswana:

"*The Botswana national tuberculosis reference laboratory exists to provide its customers with high-quality services by utilizing the latest recommended TB diagnostic technologies, research, training and quality-assurance to aid wider efforts of TB control*".

Make the vision and mission statements accessible (and easily visible) to everyone throughout the duration of each workshop (such as on a flip chart).

In most cases the NTP will have a mission and vision statement. These should be provided to stakeholders during this exercise for reflection. However, the NTRL vision and mission should try to support the NTP vision and mission from the lab perspective contribution only. In some cases the NTRL and NHL may already have vision and mission statements. These should be provided to stakeholders during this exercise. If the NTRL has a vision and mission statement already, the stakeholders will have to agree in an plenary whether these meet the technical requirements specified or need to be updated. If the NHL has a vision and mission statement already, the stakeholders can consider adapting key words from this vision and mission from the TB-laboratory perspective.

TB Laboratory Situational Analysis

Exercise 4a: TB-specific situational analysis

With this exercise from Chapter 4, you should refer to the examples for each section in that chapter. The templates are provided here. The templates are divided for this exercise into 3 groups who should work separately on the sections and then they can be subsequently combined. Ideally, each group should consist of 2-5 persons. You may also adjust the exercise to have smaller or larger groups, dependent on the number of participants in your workshop and division of expertise e.g. NRL vs. NTP vs. others.

Resources recommended for this chapter:

- NTP mission and vision
- NHL mission and vision (if available)
- Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infection with and affected by HIV/AIDS, TB and Malaria 2010.
- Managers Who Lead. A Handbook for Improving Health Services. Management Sciences for Health, 2005

The template includes the following sections:

1. The TB specific contextual analysis
   a. Epidemiological situation for TB
   b. Laboratory objectives and targets according to the NTP strategic plan and current linkages with NTP
   c. National TB diagnostic and treatment guidelines
   d. Linkages with supra-national reference laboratories
   e. Linkages with the general health system
   f. Linkages with private sector
   g. Regulatory, legal, political and economic issues
2. TB specific tests currently available and coverage
3. Structure of the laboratory network of TB diagnostics
4. Infrastructure of the laboratory network for TB diagnostics
5. Human resources for the TB laboratory network
6. Equipment maintenance and validation of TB laboratory equipment
7. Laboratory quality management systems within the TB laboratory network
8. Management of laboratory commodities and supplies within the TB laboratory network
9. Laboratory information and data management for the TB laboratory network
10. Sample referral systems for the TB laboratory network
11. Operational research regarding the TB laboratory network
12. Legal and policy review for TB
13. Finances for TB laboratory services

Group 1:

1. The TB specific contextual analysis:
   a. Epidemiological situation for TB
   b. Laboratory objectives and targets according to the NTP strategic plan and current linkages with NTP
   c. National TB diagnostic and treatment guidelines
   d. Linkages with supra-national reference laboratories
   e. Linkages with the general health system
   f. Linkages with private sector
   g. Regulatory, legal, political and economic issues [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 diagnostic [Relevant reference materials: Medical 3. 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]

Group 2:

5. Human resources for the TB laboratory 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]

Group 3:

9. Laboratory information and data management for the TB lab network [Relevant reference materials: NTRL quality manual, any paper-based and/or electronic data management system manual in place or anticipated e.g. 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 finances for TB laboratory services [Relevant reference materials: NHL strategic plan, NTP strategic plan, partners' reports and plans]
13. Finances for TB laboratory services

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

For this exercise, break up into the same groups as in Exercise 3a and complete the tables for the same assigned sections. These sections should be saved in an electronic format, turned in to the workshop coordinator and merged.

DEVELOPING STRATEGIC SWOT ANALYSIS

An effective way of gaining insights regarding the organization's assets and liabilities and also to identify what's happening in its environment is to undertake a SWOT analysis.

This is a common approach in business planning and analysis.

A SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) can assist you to identify areas for development and can be the basis of an overall strategy for future advancement.

Probably the strongest message from a SWOT analysis is that, whatever course of action is decided, decision making should contain each of the following elements: ***building on Strengths, minimizing Weaknesses, seizing Opportunities, and counteracting Threats.***

In order to be most effectively used, a SWOT analysis needs to be flexible. Situations change with the passage of time and an updated analysis should be made frequently.

SWOT is neither cumbersome nor time-consuming and is effective because of its simplicity. Used creatively, SWOT can form a foundation upon which to construct numerous strategic plans.

SWOT: Strategic Planning Process Worksheet[3]

Strengths - Organization characteristics that allow the organization to take advantage of opportunities or reduce the impact of barriers.

Weaknesses - Organization characteristics that could stand in the way of the organization taking advantage of opportunities or reducing the impact of barriers.

Opportunities - Factors outside the organization that allow it to develop its activities and/or position.

Threats - Factors outside the organization that stand in the way of its efforts or that may jeopardize its position or existence.

Factors	Internal	External
Positive	Strength	Opportunities
Negative	Weaknesses	Threats

After completing the SWOT analysis, ask yourself these questions:

1. How can we use the organization's strengths to enable it to take advantage of the opportunities we have identified?
2. How can we use these strengths to overcome the threats identified?
3. What do we need to do to overcome the identified weaknesses in order to take advantage of the opportunities?
4. How will we minimize the organization's weaknesses to overcome the identified threats?

3 Sources: Adapted from Pearce, J.A. and Robinson, R.B., Strategic Management: **Strategy Formulation and Implementation**, 1988.

	Strength	Weaknesses
Opportunities	Strategy: S-O.	Strategy: W-O.
Threats	Strategy: S-T	Strategy: W-T.

DRAWBACKS OF SWOT

SWOTs usually reflect a person's existing position and viewpoint, which can be misused to justify a previously decided course of action rather than used as a means to open up new possibilities. It is important to note that sometimes threats can also be viewed as opportunities, depending on the people or groups involved.

SWOTs can allow institutions to take a lazy course and look for 'fit' rather than to 'stretch' - they look for strengths that match opportunities yet ignore the opportunities they do not feel they can use to their advantage. A more active approach would be to involve identifying the most attractive opportunities and then plan to stretch to meet these opportunities. This would make strategy a challenge to the institution rather than a fit between its existing strengths and the opportunities it chooses to develop (Glass, 1991).

REFERENCES

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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	Laboratory objectives and targets for AFB-microscopy have been included in a 5-year Laboratory Strategic Plan	The NTP Strategic Plan has still to be adapted to incorporate the TB-microscopy objectives and targets	Increasing strengthening of collaboration between the NRL and the NTP	Inadequate attention of NTP to maintaining close collaboration with the NRL
TB specific tests currently available and coverage	NTP has adapted gradual replacement of ZN microscopy by LED fluorescence microscopy	A policy on priority labs for LED microscopy has still to be developed	Increasing interest by international agencies to provide LED fluorescence microscopes	Decreasing quality of smear microscopy due to insufficient training capacity of laboratory staff in the use of LED fluorescence microscopes
Structure of the laboratory network of TB diagnostics	Increasing NTP focus on collaboration with the private sectors in strengthening the TB laboratory network	A strategy and plan for collaboration with the private sectors does not yet exist	Increasing interest and commitment from private sectors to collaborate with the NTP	Inadequate NTP attention for participation of private sectors in planning of their involvement may result in loss of interest and commitment
Infrastructure of the laboratory network of TB diagnostics	Sound laboratory infrastructure to strengthen the TB microscopy network	Insufficient human resources at all levels of the TB microscopy network	Increasing international emphasis on strengthening the TB microscopy network	Decreasing international financial support due to financial constraints
Human resources for the TB laboratory network	MoH is substantially increasing the training facilities for laboratory staff	Only a small proportion of trained laboratory staff are motivated for a career in TB	Many international opportunities for laboratory staff for attendance of laboratory training courses on technical and management skills	Lack of an appropriate Government human resource capacity building plan with incentive structure to recruit and retain competent staff

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Maintenance and validation of TB laboratory equipment	NTP has developed SOPs for maintenance and validation of TB microscopy equipment	SOPs are hardly implemented, as Government maintenance services are very limited	The number of private national agencies that provide maintenance services for laboratory equipment is increasing	Government policy does not permit private agencies to maintain equipment at Government facilities
Quality management systems within the laboratory network	NRL has developed guidelines for EQA of smear microscopy	EQA for smear microscopy is implemented in only 40% of TB diagnostic facilities	Local partners are committed to provide human resources for extension of EQA of smear microscopy	Insufficient guarantee for gradual expansion of EQA because of high turn-over of staff employed by local partners
Management of laboratory commodities and supplies within the TB laboratory network	NRL has developed specifications and quality standards for smear microscopy commodities and supplies	Quality standards for smear microscopy supplies and equipment are often not respected by the procurement dept. of MoH	Increasing international support in provision of high quality supplies and equipment	Decreasing capacity and increasing delays by agencies in delivery supplies and equipment
Laboratory information and data management for the TB laboratory network	NRL has developed an electronic laboratory data management system, distributed it to regions and districts and trained the staff	Only 45% of districts use the electronic data management system	International support has been offered in strengthening implementation of the data management system	Frequent international recommendations for revision of the data management system
Sample referral system for the TB laboratory network	NRL has developed and distributed guidelines for referral of samples for smear microscopy	Only 40% of samples reach the laboratories in time	Decreasing reluctance by public transport organizations to transport sputum specimens	Decreasing national support for sample referral
Operational research regarding the TB laboratory	Increasing MoH interest and commitment for research	Lack of national capacity for research	Increasing international focus on research	Decreasing collaboration with NTP in defining research priorities

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Legal policy and review for TB	35% of TB microscopy is done by locally trained microscopists	Recent MoH policy is that only certified laboratory technicians should carry out TB microscopy	Government has given priority for microscopists to be trained as laboratory technician	A legal policy for retaining of microscopists trained as technician for the TB services does not exist
Finances for the TB laboratory services	Gradual increase of MoH budget for the TB microscopy services	The NRL has no control over the MoH budget for the TB laboratory services	Access to multiple international sources of funding	Complicated government regulations lead to under-utilized expenditures which in turn jeopardizes future

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	Algorithms for the diagnosis of TB among AFB-negative cases, including HIV-positive individuals, have been defined	Only 25% of HIV-positive individuals are referred for TB testing	Collaboration between the NTP and the NAP has been strengthened substantially	Inadequate attention to maintaining strong collaboration between NTP and NAP
TB specific tests currently available and coverage	The NTP has identified GeneXpert as the test for diagnosis of TB in HIV-positive individuals	Access to GeneXpert is limited to the national, and some regional and district laboratories	Increasing international support for expansion of GeneXpert	Insufficient government resources for procurement of supplies for GeneXpert
Structure of the laboratory network of TB diagnostics	X-ray facilities are available at all district hospitals	There are frequent stocks-out of X-ray films and chemicals	Increasing budget allocations by the government for procurement of X-ray films and chemicals	Complicated government budget allocation and procurement procedures, jeopardizing timely availability of supplies

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**
Infrastructure of the laboratory network of TB diagnostics	GeneXpert has been installed in five facilities	13 GeneXpert machines have not yet been installed, awaiting release of funding for air conditioning and generator	Increasing international support in providing funding for infrastructure improvement for installation of GeneXpert machines	Insufficient government allocation of funds for fuel for generators
Human resources for the TB laboratory network	Four laboratory staff has attended international training on GeneXpert	A local training course for laboratory staff on GeneXpert has not been developed	WHO has established a regional training course on GeneXpert	Trained staff may leave the government service for better job opportunities at the private sector
Maintenance and validation of TB laboratory equipment	A maintenance plan for X-ray machines has been included in the NRL Strategic Plan	Maintenance of X-Ray machines is not yet functional due to shortage of technical staff	Private companies have shown interest in maintenance of the X-Ray machines	Government procedures for contracting-out maintenance may take a long time
Quality management systems within the laboratory network	NTP and NRL are committed to implement quality management of GeneXpert	There are no international guidelines for quality management of GeneXpert	The Global Laboratory Initiative has initiated preparation of guidelines for quality management of GeneXpert	Quality of GeneXpert may decline because of unavailability of quality management guidelines
Management of laboratory commodities and supplies within the TB laboratory network	NTP has prepared quality standards for X-Ray films and chemicals	Quality standards are often not respected by the procurement department of the MoH	MoH has agreed to follow international guidelines for quality standards	Delays in implementation because of government bureaucratic procedures
Laboratory information and data management for the TB laboratory network	NTP has revised the recording and reporting formats incorporating diagnosis of TB among HIV-positive patients by GeneXpert	The revised recording and reporting formats have not yet been incorporated in the national electronic data base	International donors require information on GeneXpert testing of HIV-positive patients for TB	No funding for TA to revise the national electronic data base

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**
Sample referral system for the TB laboratory network	Procedures for sample referral from HIV-positive patients for GeneXpert have been included in the SOP for sample referral	Supplies for sample referral are not available	International donor has provided funding for supplies for one year	Shortage of supplies after the one year of international support
Operational research regarding the TB laboratory	Operational research on the use of GeneXpert at district level is planned	NRL has insufficient capacity to carry out/guide operational research	An international agency has expressed a willingness to provide TA for conducting operational research on GeneXpert	Government policy does not allow international consultants to carry out operational research
Legal policy and review for TB	The government has legalized the use of GeneXpert for the diagnosis of TB in HIV-positive patients and for MDR-TB	Only certified laboratory technicians, who are in shortage at district level are allowed to use GeneXpert	Government has given priority for microscopists to be trained as laboratory technicians	Laboratory technicians may leave government services for better job opportunities in the private sector
Finances for the TB laboratory services	Inputs for GeneXpert, equipment, supplies, training funds and operational costs, have been provided by international donors	There is no budget for GeneXpert in the 5-year strategic NTP plan	The government has expressed commitment to include a budget for GeneXpert in its budget plans	Government funding may not be available after the one year of external funding for supplies and operational costs

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	The results of the recent DST survey have been analyzed and are being used for planning	Only 25% of retreatment patients can presently be tested for MDR-TB	Provision of 10 GeneXpert machines by international donors and an additional 15 machines committed	Continuing spread of M/XDR-TB in the community

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 tests currently available and coverage	Hain test and GeneXpert at NTR, GeneXpert at the 3 TB regional reference labs and 7 GeneXpert machines at district TB laboratories	Remote areas with a high percentage of retreatment patients are poorly covered	International donors have expressed a willingness to supply 10 additional GeneXpert machines	Sustainability of funding for supplies, maintenance and validation of the equipment
Structure of the laboratory network of TB diagnostics	Tests for the rapid diagnosis of MDR-TB are available at national, regional and selected district levels	Due to environmental conditions, temperature control, water/electricity, GeneXpert cannot be used beyond district level, making access for people in remote areas difficult	International donors have expressed a willingness to support the improvement of environmental conditions in selected remote areas with a high % of retreatment patients	Sustainability in funding, maintenance of equipment etc.
Infrastructure of the laboratory network of TB diagnostics	Biosafety measures for all levels of the TB laboratory network are included in the TB laboratory SOPs	Minimal safety measures have not yet been secured for 2 of the 3 regional TB laboratories	Government has committed to provide support in securing minimal security measures in 2 of the 3 regional TB laboratories	Safety risk to laboratory staff handling specimens while minimal safety measures are not in place
Human resources for the TB laboratory network	MoH has recently assigned 3 additional laboratory technicians to the NRL and one to each of the 3 regional TB reference laboratories	The estimated workload to cover MDR-TB testing of all retreatment patients requires 10 more laboratory technicians at district level	NRL has identified 12 experienced laboratory staff that could be trained in MDR-TB testing at district level	Government policy as regards the use of non-certified laboratory staff for MDR-TB testing
Maintenance and validation of TB laboratory equipment	The policy for the maintenance of equipment at the NRL has been implemented	The maintenance of equipment at the regional TB reference labs has not yet been implemented	The MoH is aware of the need to extend maintenance of equipment beyond the NRL	Continuous safety risks of staff of the regional TB reference labs
Quality management systems within the laboratory network	The NRL is aware of the need for the development of quality management systems for rapid tests	There are no international guidelines for the quality management for the rapid tests for diagnosis of MDR-TB	The GLI is preparing guidelines on the quality management of rapid tests	Substandard quality of rapid tests

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**
Management of laboratory commodities and supplies within the TB laboratory network	NRL has sufficient supplies for one year of rapid tests provided through donors	NRL has still to prepare specifications of supplies for rapid tests and their required quality standards	International support for development of a distribution system for supplies for rapid tests	Stock-outs and expired GeneXpert cartridges
Laboratory information and data management for the TB laboratory network	Information on the numbers of M/XDR-TB patients diagnosed and treated has been included in the NTP recording and reporting systems	The revised recording and reporting formats have not yet been incorporated in the national electronic data base	International donors providing support for GeneXpert require information on the number of MDR-TB patients diagnosed	No funding for TA to revise the national electronic database
Sample referral system for the TB laboratory network	Procedures for sample referral from suspect M/XDR-TB patients for culture/DST have been included in the SOPs for sample referral	Sufficient supplies for sample referral are not available	International donor has provided funding for supplies for one year	Shortage of supplies after the one year of international support
Operational research regarding the TB laboratory	Operational research on referral systems for samples of suspect M/XDR-TB patients is planned	Insufficient capacity at the NRL and regional reference labs to carry out operational research	The National Institute for Health has shown interest in carrying out research for the NTP/NRL	NTP may not obtain ownership of the research outcomes
Legal policy and review for TB	The MoH Regulatory Dept. has approved the use of GeneXpert for the diagnosis of MDR-TB	Only certified laboratory technicians, who are in shortage at district level,are allowed to use GeneXpert	Government has given priority for microscopists to be trained as laboratory technicians	Laboratory technicians may leave the government services for better job opportunities at the private sector
Finances for the TB laboratory services	International donors have provided supplies for rapid tests for one year	In the government budget for 2012-2016 no resources are allocated for rapid tests	Increasing international support for the expansion of rapid tests	Insufficient supplies after donor support stops/ decreases

Objective 4: Establish Laboratory Quality Management Systems				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis	SOPs for EQA of smear microscopy have been prepared	The SOPs for EQA of smear microscopy do not include procedures for rechecking of smears stained with auramine	A laboratory mission is planned to assist the NRL in updating its SOPs	Rechecking of ZN and auramine stained smears may overload the EQA laboratories, jeopardizing the quality of rechecking
TB specific tests currently available and coverage	Liquid culture has been established at the NRL	A linkage with the SNRL for quality control has not yet been established	The SNRL of a neighboring country has expressed an interest in establishing QC linkage	Insufficient financial resources for the regular sending of specimens to the SNRL
Structure of the laboratory network of TB diagnostics	Private laboratories are included in the quality management system of smear microscopy	Only 40% of collaborating laboratories are returning results of panel testing	Collaboration between the NRL and the private laboratories has recently been intensified	A shortage of financial resources to intensify supervision of private laboratories
Infrastructure of the laboratory network of TB diagnostics	The NRL has been renovated	Biosafety measures are not yet adequate according to international standards	International support is available for improving biosafety measures	Risk for staff if culture and DST is done without the improvement of biosafety measures
Human resources for the TB laboratory network	EQA rechecking laboratories have been established	The quality of 30% of the first controllers is inadequate according to several errors observed by the second controllers	Funds are available for retraining of first controllers	The quality of first controllers may not improve substantially, as it appears that several of them are not motivated for the work
Maintenance and validation of TB laboratory equipment	Frequency and procedures for the maintenance and validation of culture/DST equipment are included in the NRL SOPs	The government department for the maintenance of laboratory equipment is understaffed	An increasing number of private companies provide maintenance services for laboratory equipment	Government procedures for sourcing-out maintenance take a long time, risking delays in maintenance of the equipment

Objective 4: Establish Laboratory Quality Management Systems				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Quality management systems within the laboratory network	Collaboration for QC of culture/DST has been established with a SNRL	There is no budget provision for the referral of specimens to the SNRL	Negotiations are taking place with internal donors on the provision of a one-year budget for the referral of specimens	Insufficient funding if donor contribution stops
Management of laboratory commodities and supplies within the TB laboratory network	Quality standards for laboratory supplies have been included in the NRL SOPs	The procurement department of the MoH does not always respect quality standards	The MoH has agreed to establish a committee that will oversee that quality standards for supplies will be respected	Procurement of quality supplies may be delayed due to the required approval of the standards by the regularity authority
Laboratory information and data management for the TB laboratory network	Computerized monitoring and analysis of EQA rechecking results at the regional and national levels has been developed	The quality of the paper reports of 35% of EQA centers is substandard-incomplete and/or inconsistent data	Funding has been provided to intensify the supervision of EQA rechecking centers	Results of supervision alone may be insufficient as the supervisors have been given very superficial training on the EQA method and process
Sample referral system for the TB laboratory network	Procedures for the appropriate packing of sputum for GeneXpert have been developed and implemented	40% of the specimens received are inappropriately packed, sometimes with leakage of the contents	District trainings have been planned, including proper collection, packing and dispatch of sputum	Risk of contact with infectious materials for people handling the packages
Operational research regarding the TB laboratory	OR on low cost waste management at peripheral laboratories has been planned	Over one third of the peripheral laboratories do not have appropriate waste management in place	A local firm has shown interest in assisting the NTP/NRL in improving waste management	Risk of contact with infectious materials for staff and the community

Objective 4: Establish Laboratory Quality Management Systems				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Legal policy and review for TB	Safety procedures for culture/DST laboratories have been developed	The safety procedures have been implemented in the NRL, but as yet not in regional TB laboratories with TB culture facilities	The government regulatory authority has approved the safety procedures for the handling of sputum for culture/DST	Delays in the implementation of the safety procedures in all TB culture/DST laboratories due to inadequate budget
Finances for the TB laboratory services	Validation of GeneXpert has been included in the budget part of the Laboratory Strategic Plan	There are no funds for the validation of GeneXpert in the NTP budget	External donors are in the process of contracting and paying for GeneXpert validation expertise which will serve several countries	Decreasing reliability of GeneXpert results

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 by Stop TB objective

For this exercise, again break up into the same groups as in Exercise 4a and 4b complete the tables for the same assigned sections for each of the four Stop TB Objectives. Examples of these tables filled out may be found below followed by blank tables for you to fill in. These sections should be saved in an electronic format, turned in to the workshop coordinator and merged.

The following are examples of the TB-specific analysis for the four objectives:

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	The NTP Strategic Plan does not include a policy for the use of LED microscopes	LED microscopes should replace light microscopes at laboratories with a high microscopy workload	Distribution of LED microscopes is not according to microscopy workload	The NTP, in cooperation with NRL, should develop guidelines for laboratories eligible for a LED microscope, to be included in the NTP and NRL Strategic Plan
Tests Currently Available	LED microscopes are available at the regional laboratories	LED microscopes should be available at regional and district laboratories and at peripheral laboratories with high microscopy workload by the end of 2013	Many district laboratories have a high microscopy workload which jeopardizes the quality of smear microscopy	A plan for the gradual replacement of light microscopes with LED microscopes should be prepared and implemented
Structure	Only 10% of private laboratories are collaborating with the NTP in smear microscopy	Gradual expansion of the involvement of private laboratories, reaching 40% coverage in 2015	Substantial delays in partnership with private laboratories; the existing national coordinating committee is not functional	Revive the national coordinating committee; prepare and implement a plan for expansion of TB microscopy in private laboratories and follow-up progress in implementation quarterly
Infrastructure	40% of peripheral laboratories need basic renovation	Smear microscopy laboratories should have adequate hand-washing facilities and sufficient bench space to perform duties	A lack of renovation affects the quality of work in the peripheral laboratories	Develop a phased implementation plan for the physical renovation of peripheral laboratories and present this plan to the government for funding

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**
Human Resources	In 40% of laboratories smear microscopy is done by microscopists (8th grade leavers who have been trained for 3 weeks in smear microscopy)	The government policy is that TB microscopy should be done by graduated laboratory technicians	Shortage of laboratory technicians, especially in rural areas	Prepare a 5 year plan to gradually phase out microscopists, based on expected output of graduated lab. technicians, with incentives for work in remote areas and have this approved by the relevant authorities
Equipment validation and maintenance	Regular maintenance of microscopes is not done	Microscopes should be checked routinely (every 2 years)	There is no information on the condition of microscopes; needed replacement of microscopes, or parts	Prepare an annual plan for the maintenance of microscopes and present this to the MoH for implementation by the government maintenance unit
Laboratory quality management systems	Rechecking of a sample of smears is implemented in only 45% of the AFB-microscopy laboratories	All AFB microscopy laboratories should implement rechecking by the end of 2013	Substantial delay in expansion of rechecking, mainly because of the long absence of the national EQA laboratory technician	Revise the rechecking expansion plan, to cover the remaining 55% of laboratories within 2 years
Management of laboratory commodities and supplies	There are frequent shortages of AFB-microscopy consumables at the laboratories	Laboratories should have sufficient quantities of AFB microscopy supplies	Frequent shortages of AFB microscopy supplies due to the long process of ordering supplies and delays in distribution from the national level to the peripheral levels	Gradually build-up a buffer stock of laboratory supplies; negotiate with the procurement authority to shorten the procurement process and ensure 3-monthly supplies to the peripheral level based on requirements and stock positions

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**
Laboratory information and data management	About 15% of laboratories either do not report to the national level, or report incomplete data	All laboratories should report complete data in a timely manner	National data are incomplete and there is no feedback system for non-reporting or incomplete data	Develop a mechanism for feedback to reporting levels on non-reporting or incomplete data, follow-up quarterly, and emphasize the importance of complete and timely data during training and supervision
Sample referral systems	Over 50% of smears prepared at community smearing centers reach the laboratory after 3 days	Smears prepared at community smearing centers should reach a laboratory within 3 days	Shortage of funds to transport the smears to the laboratories	NTP should obtain funds for the transportation of smears to laboratories
Operational research	There is no research planned or implemented	OR should focus on finding solutions for problems experienced in access to diagnosis and the quality of smear microscopy under local conditions	Several operational problems in improving access to diagnosis, and the quality of smear microscopy are not addressed	NTP/NRL should seek assistance from national and international institutions in carrying out OR on finding solutions for the operational problems
Legal and policy review	The procurement authority does not allow the inclusion of quality standards of supplies in the procurement request	TB diagnostic facilities should be supplied with high quality supplies, based on international recommendations	Substandard quality of some supplies, in particular oil immersion and stains	Develop national standards for supplies, according to international recommendations; lobby with authorities responsible for procurement policies and regulation to include these standards in the procurement requests
Finances	35% of the recurrent budget for laboratory supplies is covered by the government, compared to 45% two years ago	The government will gradually increase the recurrent budget for laboratory supplies	The quantities of laboratories ordered by the government do not cover the needs, resulting in frequent shortages	High level lobbying at ministerial level to maintain the government commitment for increasing the budget for laboratory supplies

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	Due to a shortage of functioning government X-Ray facilities, about 50% of patients requiring an X-Ray have to attend private facilities for which they have to pay	According to government policy chest X-Ray examination for diagnosis of TB in HIV+ individuals is free of charge	Although the number of government X-Ray facilities is sufficient, many face frequent shortage of films and/or chemicals	Lobby the MoH to provide sufficient X-Ray films and chemicals to hospitals and chest clinics
Tests Currently Available	At the regional hospitals GeneXpert machines are available for testing HIV+ individuals suspected of having of TB	All HIV+ individuals with symptoms suggestive of TB and with negative sputum smears should be tested with GeneXpert	Only 30% of HIV+ individuals have access to GeneXpert	Distribute additional GeneXpert machines committed by international donors to areas with a high prevalence of HIV
Structure	GeneXpert machines are available at the NRL and two regional TB reference laboratories	All HIV+ individuals with symptoms suggestive of TB and with negative sputum smears should be tested with GeneXpert	GeneXpert is in practice exclusively used for MDR/ Rif testing of retreatment TB patients	Inform hospital doctors, regional TB coordinators, the NRL and regional TB reference laboratories that the GeneXpert machines should also be used for diagnosis of TB among HIV+ individuals
Infrastructure	Only 50% of the population have access to X-Ray facilities at government hospitals	Smear-negative patients with persistent symptoms, managed according to NTP policy, should have a chest X-Ray	The diagnosis TB, based on X-Ray reading at private facilities, in patients referred to the government centers can often not be confirmed by government doctors	Establish a diagnostic committee of government and private doctors on the consensus of chest X-Ray readings

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**
Human Resources	A training program has been developed for operation of GeneXpert machines	Staff assigned to operate GeneXpert machines should be trained	7 out of the 10 facilities where GeneXpert machines will be stationed have not yet selected staff to operate the machines causing delays in making the machines operational and in using the cartridges before they expire	Request the regional TB coordinators and in-charges of facilities where the GeneXpert machines will be installed to urgently select the required staff; and inform them about the dates for training of the staff
Equipment validation and maintenance	Annual validation of GeneXpert has been included in the NRL SOPs	GeneXpert machines should be validated annually	Government does not have technical expertise for the validation of GeneXpert machines	Seek advice and funding from the international donors of the GeneXpert machines on the development of a mechanism for annual validation of the machines
Laboratory quality management systems	In 35% of HIV+ individuals referred for TB examination, smear examination (according to NTP policy) is not done. They are diagnosed with smear-negative TB based on X-Ray examination or on clinical grounds, particularly at private hospitals and clinics	Smear examination should be done in all HIV+ individuals suspected of having of TB	A higher than expected % of HIV+ individuals are diagnosed with smear-negative TB. Staff of the government facilities receiving the patients usually do not examine the smears	Discuss this issue at the national and regional PPM committees insist on smear examinations of all TB suspects, including HIV+ individuals and follow-up during subsequent meetings presenting results. Instruct regional and district TB coordinators to examine smears in all patients referred with the diagnosis PTB without smear results

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**
Management of laboratory commodities and supplies	Supplies for GeneXpert are provided by international donors	NTP, in collaboration with NRL, should provide specification of laboratory supplies and prepare annual quantities for procurement	Quantities of supplies provided by donors are not based on needs; time needed to operationalize the donated GeneXpert machines was longer than anticipated; so far in only a few HIV+ individuals GeneXpert has been used	Request donors who have indicated support to provide supplies for GeneXpert supplies to collaborate with NTP/NRL in calculation and timing of the support
Laboratory information and data management	Diagnosis of TB in HIV+ individuals has been included in the national electronic database	Diagnosis of TB among HIV+ individuals should be reported to the NTP	20% of districts do not report TB cases detected among HIV+ individuals	Alert regional and district TB coordinators on routine reporting of TB detection among HIV+ individuals and include this in the refresher trainings and meetings of the TB coordinators
Sample referral systems	SOPs have been prepared for specimen referral and transport	Specimens of HIV+ patients for detection of TB should be collected at the district laboratories	Patients face problems with transport costs to attend the district laboratories	Explore the practicality and feasibility of collection of specimens at the peripheral health facilities
Operational research	No OR is planned or implemented	OR should identify operational requirements for use of GeneXpert at district and lower levels	Insufficient government staff to carry out OR	International organizations have offered assistance in carrying out OR on the requirements and use of GeneXpert at peripheral facilities

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**
Legal and policy review	The government regulatory authority has approved the use of GeneXpert at district health facilities	The use of GeneXpert should be approved by the government regulatory authority	Algorithms for the use of GeneXpert have not yet been prepared; the 10 donated machines are awaiting distribution and part of the cartridges will soon expire	NTP should develop and distribute algorithms for the use of GeneXpert, and distribute the machines as soon as possible, while instructing regional TB coordinators to inform the facilities receiving the machines to strictly adhere to algorithms
Finances	The NTP budget for 2012-2016 does not include a budget for GeneXpert cartridges and annual validation of the machines	A budget for operation of GeneXpert machines should be available	The cartridges donated with GeneXpert machines last for about 6 months	Negotiate with MoH and external donors to provide a budget for cartridges and validation of GeneXpert machines

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	Guidelines have been prepared for DR-TB surveillance among new and retreatment patients	All retreatment patients and 25% of new patients should be tested for (M) DR-TB	Only 50% of retreatment patients and 5% of new patients are tested for (M)DR-TB, because the peripheral laboratories fail to send specimens to the NRL	Alert the regional and district TB coordinators on sending the specimens, according to NTP policy, to the NRL; follow this up quarterly, and provide feedback
Tests currently available	>90% of DR tests are done with the conventional method of solid LJ medium, <10% are done with GeneXpert, or LPA	Conventional culture/ DST should gradually be replaced by GeneXpert and LPA	Long lead time before the results are available leading to several patients being lost for treatment	Revise the initial plan of establishing conventional culture facilities at all regional TB labs and DST at selected regional labs into a plan of gradual introduction of GeneXpert at all regional TB laboratories
Structure	GeneXpert is available at the NRL and some regional hospitals	GeneXpert should be available at the national and regional hospitals and at district hospitals in areas with a high HIV+ prevalence and/or high prevalence of MDR-TB	Due to transport problems and transport costs for patients, many retreatment patients are not tested for TB	Prepare a plan for distribution of available and committed GeneXpert machines based on current policy and operational/environmental conditions
Infrastructure	Only the NRL and some regional laboratories fulfill the environmental requirements for use of GeneXpert	GeneXpert should be available at the national and regional hospitals and at district hospitals in areas with a high HIV+ prevalence and/or high prevalence of MDR-TB	Many retreatment patients are not tested for (M)DR-TB	Prepare an inventory of national, regional and district hospitals eligible for GeneXpert equipment or required environment improvements and present this to the government for funding

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**
Human Resources	Shortage of qualified laboratory staff at the NRL for culture/DST of all eligible patients according to NTP policy	All retreatment patients and 25% of new patients should be tested for (M)DR -TB, as well as contacts of MDR-TB patients	High % of qualified laboratory staff leave the government for better working conditions at the private sector	Negotiate with the government for incentives for NRL laboratory staff responsible for culture/DST
Equipment validation and maintenance	SOPs are available for maintenance of culture/ DST equipment	Culture/DST equipment should be maintained annually	The government has insufficient technical staff to carry out the regular maintenance of laboratory equipment	Negotiate with the government to contract a private firm for regular maintenance
Laboratory quality management systems	A contract has been signed with an SNRL on the quality control of culture/ DST on samples examined at the NRL	Each NRL should establish a working relationship with a SNRL for QC of culture/ DST	Materials for referral of the samples are not available; contact with an airline for transportation of the specimens has not been established and transport cost are not included in the NTP budget	Prepare a budget for materials and transport costs and negotiate with the government and potential donor(s) for covering the costs; contact airline(s) for transport of the specimens
Management of laboratory commodities and supplies	The NRL provides specifications for the supplies required for culture/DST	High quality supplies, according to international standards and recommendations, should be procured	NRL is frequently forced to accept supplies ordered by the government procurement department that are not according to internationally recommended standards	Negotiate with the government and the procurement department on the development of a policy to respect internationally recommended standards for supplies

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**
Laboratory information and data management	Diagnosis of M/XDR-TB by GeneXpert, and/or LPA has been included in the national electronic data base	Data on diagnosis of MDR-TB by the different methods should be included in the national electronic data base	Paper copies of the reporting forms do not accommodate diagnosis of MDR-TB by the different methods	M&E unit of the NTP to accommodate diagnosis of MDR-TB by the different methods in the paper reporting forms
Sample referral systems	Sputum of retreatment patients for GeneXpert examination is collected at regional and district TB laboratories	Of all retreatment patients sputum should be collected and be examined by GeneXpert within 15 days after collection	Of 35 % of retreatment patients whose sputum was sent, it arrived 15 or more days after collection	Investigate the reasons for delays and find and implement solutions for the observed bottlenecks
Operational research	No OR is implemented or planned	GeneXpert should be piloted, in particular as regards operational issues at peripheral sites	Insufficient laboratory staff for doing operational research	Seek assistance from national institutes for carrying out OR
Legal and policy review	The government regulatory authority has approved the use of GeneXpert at district health facilities	The use of GeneXpert should be approved by the government regulatory authority	NTP has still to develop the algorithm for diagnosis of M/XDR-TB, in particular whether or not conventional culture/DST or LPA should be done after GeneXpert MTB/RIF is positive and in which types of patients	Seek assistance from international experts in establishing the algorithms
Finances	Funds for sending sputum from collection points to GeneXpert facilities are not included in the NTP budget	All retreatment patients and 25% of new patients should have their sputum examined for MDR/TB	Funds from international donors for sending the sputum are available for only about 50% of the eligible patients	Calculate the cost of sending the sputum to the GeneXpert facilities, Identify underutilized budget line(s), and request the government and/or external donors to approve re-allocation of funds

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	SOPs for EQA rechecking of a random sample of smears, including auramine-stained smears, have been developed	SOPs for EQA should be according to international recommendations	Rechecking of auramine-stained smears is not yet done, because EQA controllers have not yet been trained and the recording/reporting has not yet been adopted	Plan and implement training of EQA controllers and adopt the recording/ reporting system accommodating auramine-stained smears
Tests currently available	SOPs for QC of conventional culture/DST have been developed	SOPs should be available for QC all methods of culture/DST	SOPs for QC of liquid culture and LPA are not available jeopardizing the quality of these tests, in particular since maintenance of the equipment is not yet done	NTP to seek advice from GLI on QC of liquid culture and LPA
Structure	Linkage between the NTP/NRL and private laboratories on EQA rechecking has not yet been established	All laboratories collaborating with the NTP should implement EQA rechecking	Smear results of several private laboratories indicate problems in the quality of smear microscopy, such as no scanty results and almost all positive results are ≥2+. The PPM committee agenda excludes discussion on the microscopy services	Prepare a report of the findings of smear microscopy at the private laboratories; share this with the PPM committee, including the need for including the private laboratories in EQA rechecking and a plan to gradually expand rechecking in the private laboratories

Objective 4: Establish Laboratory Quality Management Systems				
Situational Analysis Topic	**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Infrastructure	TB supervisors and laboratory staff are not supervising private laboratories	All laboratories collaborating with NTP should be supervised, according to NTP policy and schedule	There is evidence from smear results reports that the quality of smear microscopy at private laboratories needs improvement. The management of many private laboratories do not allow government staff to supervise its laboratories	Strengthen collaboration with the private sector on smear microscopy through the PPM committee, explain the purpose of supportive supervision and request its collaboration in supervision visits by NTP staff
Human Resources	At 20% of laboratories the laboratory staff has to examine >20 smears per person per day on average, jeopardizing the quality of smear microscopy	All retreatment patients and 25% of new patients should be tested for (M)DR -TB, as well as contacts of MDR-TB patients	The EQA rechecking reports show that the quality of AFB-microscopy decreases with increases of the daily smear examination workload	Laboratories with >20 daily smears per laboratory member, should either identify a motivated person who should be trained by the NRL in smear microscopy or select an additional person for smear microscopy
Equipment validation and maintenance	SOPs for the regular maintenance of equipment of culture/DST equipment have been developed	Maintenance of culture and DST equipment should be done annually	The government has insufficient technical staff to carry out regular maintenance; 20% of cultures are contaminated	Lobby with the government to out-source the maintenance of the culture/DST equipment by a local private firm

Objective 4: Establish Laboratory Quality Management Systems				
Situational Analysis Topic	**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Laboratory quality management systems	Investigation of reasons for unsatisfactory rechecking results by the laboratories or first controllers is not routinely done	Regional/district EQA rechecking coordinators should investigate possible reasons for unsatisfactory results and take actions for their improvement	District and regional EQA rechecking reports are prepared and forwarded to the next level without analysis of the results; the NRL files the reports without analysis	NRL should take the lead in analysis of the reports, providing feedback to the regional EQA coordinators, requesting actions taken in case of unsatisfactory results and stress the importance of monitoring results and action taking during trainings and supervision
Management of laboratory commodities and supplies	NRL provides specification of quality of AFB-microscopy laboratory supplies to the government procurement department	AFB-microscopy supplies should be of high quality, according to international recommendations	Against the recommendation of the NRL the procurement department tends to consider price above quality; this has e.g. resulted in procurement of poor quality fuchsin which created rapid fading problems in EQA rechecking	Explain the observed problems with the poor quality supply and the possible consequences for the patients to the government and the procurement department and request that supplies according to international standards are ordered
Laboratory information and data management	SOPs for the national information systems do not routinely collect indicators to monitor the quality of laboratory performance	SOPs for laboratory information systems should allow monitoring of the quality of the laboratory performance	NTP/NRL have insufficient information on the performance of the laboratory network, making it not possible to identify laboratories that need intensified supervision	With technical support from a government computer specialist , performance indicators should be built into the national laboratory information system

Objective 4: Establish Laboratory Quality Management Systems				
Situational Analysis Topic	**Current Situation**	**Current policies/ Expectations/ Standards (national/ international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Sample referral systems	SOPs have been prepared on the required quality of specimens referred, including instructions on the production of quality sputum	Over 90% of sputum specimens referred should be of appropriate quality	30% of the specimens consists of saliva only and are not processed for culture and GeneXpert	NRL should remind regional and district coordinators about the importance of appropriate sputum and instructions to patients on production of sputum
Operational research	As on average 20% of TB cultures at the regional TB reference laboratories are contaminated, OR is planned on decreasing the percentage of contaminated cultures	< 5% of TB cultures should be contaminated	Insufficient staff to conduct the research	Collaborate with the National Institute of Medical Research in carrying out the research
Legal and policy review	QC of culture/DST by a SNRL has been approved by the government Policy Regulatory Committee	Based on international recommendations a sample of cultures/DSTs should be checked at a SNRL	Latest results show that 15% of DST results of the NRL could not be confirmed by the SNRL	Invite a laboratory DST expert to assist NRL in identification of possible reasons for the unsatisfactory performance and in improvements of the quality of DST
Finances	The budget for monitoring of EQA rechecking, including supervision of laboratories is entirely covered by external donors	The government should contribute an increasing percentage of the cost of the TB laboratory services, including quality management	Several disruptions in monitoring of EQA and laboratory supervision, because of delays in signing (extension of) contracts with existing or new donors	Lobby the government as regards its commitment to provide increasing funding for the TB laboratory services

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

In this exercise, you need to establish relevant baseline and yearly targets for the laboratory relevant input into the NTP's goal for case-detection with laboratory methods as well as for each objective with standardized indicators (listed in Annex 4a in the handbook). If these are not already available, consider a separate consultative process with the NTP and possibly international consultants to establish these baseline assessments and targets. You may also consider Global Fund proposal harmonization with these targets, but keep in mind that this TB laboratory plan should represent the entire TB laboratory network from all sources and not just the Global Fund. Therefore, your targets might even be higher than those for the Global Fund.

Part I: GOAL- EXAMPLE

	Baseline	Year 1: 2013	Year 2: 2014	Year 3: 2015	Year 4: 2016	Year 5: 2017
% of TB cases (all forms) notified	Year: 2012 10,000	11,000	12,000	13,000	14,000	15,000
% of new laboratory-confirmed TB cases notified	Year: 2012 5,000	7,000	8,500	9,500	11,000	12,500
Prevalence of laboratory-confirmed TB	Year: 2009 250 cases per 100,000 (based on latest prevalence survey)		Planned survey: expected prevalence 200 cases per 100,000			
Prevalence of laboratory-confirmed MDR-TB	Year: 2010 2.5% MDR-TB new cases 8.9% MDR-TB re-treatment cases (based on latest national drug-resistance survey)			Planned survey: Expected MDR-TB drug resistance 2.0% MDR-TB new cases 8.0% MDR-TB re-treatment cases		

Part II: Stop TB Global Plan objective targets

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

	Baseline	Year 1: 2013	Year 2: 2014	Year 3: 2015	Year 4: 2016	Year 5: 2017
# of laboratories performing acid-fast bacilli (AFB microscopy)	Year: 2012 90-	110	120	125	150	150
% of AFB microscopy laboratories that are quality-assured	Year: 2012 25%	50%	75%	100%	100%	100%
% of AFB microscopy laboratories that are using LED microscopy	Year: 2012 0%	25%	50%	75%	100%	100%

Objective 2: Improving the diagnosis of TB among AFB smear-negative TB cases, especially among people living with HIV-EXAMPLE

	Baseline	Year 1: 2013	Year 2: 2014	Year 3: 2015	Year 4: 2016	Year 5: 2017
# of laboratories performing culture	Year: 2012 1	1	2	3	4	5
# of laboratories performing rapid molecular diagnosis	Year: 2012 0	5	10	20	25	30
% of AFB smear-negative, newly notified TB cases screened using culture and/or molecular-based tests	Year: 2012 5%	20%	40%	70%	80%	100%
% of AFB smear-negative, previously treated TB cases screened using culture and/or molecular-based tests	Year: 2012 5%	20%	40%	70%	80%	100%

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

	Baseline	Year 1: 2013	Year 2: 2014	Year 3: 2015	Year 4: 2016	Year 5: 2017
# of laboratories performing DST	Year: 2012 1	1	1	2	3	4
# of laboratories Performing DST using new diagnostic tools	Year: 2012 0	5	10	20	25	30
% of previously treated TB patients tested for drug-resistance	Year: 2012 5%	20%	35%	75%	80%	100%
% of new TB patients tested for drug-resistance	Year: 2012 1%	10%	15%	15%	20%	20%
% of tests for drug resistance performed on previously treated cases done using rapid tests	Year: 2012 0%	15%	35%	65%	65%	65%
% of tests for drug resistance performed on new cases done using rapid tests	Year: 2012 0%	15%	35%	65%	65%	65%
% of confirmed cases of MDR-TB with a DST result for fluoroquinolones and a second-line injectable drug	Year: 2012 0%	0%	5%	20%	50%	100%

Objective 4: Establish laboratory quality management systems-EXAMPLE

	Baseline	Year 1: 2013	Year 2: 2014	Year 3: 2015	Year 4: 2016	Year 5: 2017
% of national and regional reference laboratories implementing a quality management system according to international standards per national strategies	Year: 2012 0%	25%	50%	75%	100%	100%
% of TB laboratories with appropriate biosafety measures in place	Year: 2012 0%	50%	100%	100%	100%	100%
AFB microscopy network accreditation (with GLI tool)	Year: 2012 Not yet accredited			Accreditation achieved	Accreditation maintained	Accreditation maintained

Blank Templates for the participants

Part I: GOAL

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
# of TB cases (all forms) notified						
# 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
# of laboratories performing AFB microscopy						
% of AFB microscopy laboratories that are quality-assured						
% of AFB microscopy laboratories that are using LED microscopy						

Objective 2: Improving the diagnosis of TB among AFB smear-negative TB cases, especially among people living with HIV

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
#of laboratories performing culture						
# of laboratories performing rapid molecular diagnosis						
% of AFB smear-negative, newly notified TB cases screened using culture and/or molecular-based tests						
% of 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
# of laboratories performing DST						
# of laboratories Performing DST using new diagnostic tools						
% of previously treated TB patients tested for drug-resistance						
% of new TB patients tested for drug-resistance						
% of tests for drug resistance performed on previously treated cases done using rapid tests						
% of tests for drug resistance performed on new cases done using rapid tests						
% 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 per 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

In this exercise, guide the participants to follow the instructions below. Three of the four priority areas have examples provided below (smear-positive, smear-negative and MDR-TB) from country examples. However, of course, you should facilitate the participants to come up with their own priorities in each area using the 4 priority blank templates after the country examples. You should also revisit the problems identified in Chapter 4 e.g. SWOT and Situational analysis to come up with issues to be addressed. Additional problems can also be prioritized should they be identified.

Part 1:

Divide into 4 groups: 1 group for detection of smear-positive cases, 1 group for smear-negative cases, 1 group for MDR-TB cases, and 1 group for quality management systems.

Use 4 different colors of paper or sticky notes for each group

Ask each individual in each group to write down up to 5 broad priorities they see as important to achieve their assigned Stop TB objective

Ask each group to discuss their activities to see if there are overlaps to harmonize (if the groups are large you can start by making a smaller group to convene with the larger group and repeat)

Ask each group to prioritize the activities in order of importance (ranking highest priority to lowest priority)

NOTE: You can add small stickers/stars to the various sticky notes or colored paper to prioritize e.g. gold or green for high priority, silver or white for medium priority and bronze or red for low priority.

Part 2:

Each group should fill in the corresponding table

Part 3:

Present results in plenary for discussion

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

Broad Priority identified (in order of priority with highest priority listed first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework	Where are you now and where to you want to be?	Achievable in 5 years?
Implementation of Fluorescent Microscopy	Procure LED microscopes for all public health laboratories (27)	Laboratory infrastructure and maintenance	LED microscopes have been procured for 10 labs to date. All (37) government laboratories in the country using LED by 2016	Yes
	Develop training curricular for LED microscopy	Laboratory human resource development	Internationally developed training package is available It needs to be customized for Botswana Customized training package is available	Yes
	Train lab workers in LED microscopy	Laboratory human resource development	NTRL is experienced in fluorescent microscopy and training	Yes If funds available
	Develop EQA program for LED microscopy	Laboratory human resource development	Currently the NTRL has coverage for 25% EQA but we want 100% coverage for LED Microscopy	Yes
	Implement EQA for LED microscopy	Laboratory quality management systems	NTRL has implemented country-wide EQA program for ZN microscopy	Yes If funds available
Increase Microscopy Capacity	Establish an additional 6 microscopy centers in the districts with less than 1 lab per 60,000 population	Laboratory human resource development	Currently average microscopy coverage is 1 lab per 35,000 population, however in some areas there is less than the 1 lab per 100,000 recommended	Yes

Improve Quality of Sputum	Training of Health Care Workers in Sputum collection	Laboratory human resource development	288 Lab technicians and 500 nurses, 50 doctors, 25 TB Coordinators trained in sputum collection. We need these health care workers trained and re-trained every 2 years.	Yes
	Provision of storage facilities for specimens to prevent denaturation for the purposes of GeneXpert and culturing	Laboratory infrastructure and maintenance	Fridges are available in some facilities but are used for drugs, NTP supported the procurement of 10 fridges for laboratories. Procure fridges for specimen storage in 630 facilities	Yes but dependent on financial resource allocation and electricity First need to do infrastructure assessment to ascertain needs
Strengthen Quality systems in Peripheral labs	Develop an AFB microscopy manual	Laboratory human resource development	NTRL has a full package of SOPs to be used in the development of the manual	Yes
	Monitor quality laboratory indicators in peripheral labs (positivity rate, proportion of smear grades)	Laboratory quality management systems	Availability of statistics (SPR and grades proportion) should be included in supervisory visits checklist	Yes
Improve Equipment Maintenance in microscopy Labs	Develop a program for key equipment maintenance and validation	Equipment validation and maintenance	Equipment is serviced through Biomedical Engineering Services and by partners. Develop a maintenance program for equipment maintenance to include all key equipment by 2017	Yes
Ensure Sustainability of EQA Program for AFB Microscopy	Conduct EQA program	Laboratory quality management systems	On site supervisory visits currently supported by Global Fund (GF). GF is ending and there is a risk of financial shortages that might disrupt EQA for microscopy. We aim to have adequate funding from the government for sustainable uninterrupted EQA.	Yes

Improve Reporting of Results	Implement SMS printers for point of care facilities	Laboratory information and data management systems	Concept paper in place in NTP. We want to pilot SMS printer technology in Gaborone then scale –up to all point of care facilities (state number of point of care facilities) NOTE: Same technology currently piloted for PMTCT in Gaborone-Collaboration. Collaborate and harmonize activities between the two programs. It this is not possible the TB program should do this on its own.	Yes
Improve Infection Control in Peripheral Laboratories	Assess airflow at labs Provision of extraction fans at labs with inadequate ventilation	Laboratory infrastructure and maintenance	Review records from EQA on site visits Records of biosafety conditions available.	
Strengthen Supply Management	Procurement of reagents and supplies	Management of laboratory commodities and supplies	At present, there are occasional shortages of funds for reagents. These are procured by CMS and NHL through government funding. CDC Botswana also procures reagents through SCMS. We aim not to have stock-outs.	Yes
Improve Sensitivity of Microscopy in Peripheral Labs	Implement concentrated smear microscopy using cytocentrifugation	Laboratory infrastructure and maintenance HRD	Currently smear microscopy in all but NTRL labs is direct. SPR at NTRL varies from 25 to 34%, in peripheral labs from 8 to 15%. Thus the introduction of cytocentrifugation will increase sensitivity of microscopy.	Yes if funds available

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 (listed in order of priority with highest first)	Main activities (in order of priority)	Category per GLI framework	Where are you now?	Where do you want to be?	Achievable in 5 years? Yes/No/Partially (If No or Partially explain)
Introduce testing of TB using clinical sample (sputum) in smear negative HIV+ patients	Implement TB Molecular methods (Line Probe Assay - LPA)	Laboratory infrastructure, and maintenance	Currently 3 (NIMR Lagos, NTBLTC Zaria and LHMH Calabar) TB reference laboratories are implementing LPA with Biosafety Level 2 infrastructures majorly with support from partner funds	The plan is to implement LPA in all six zonal laboratories and one private reference laboratory in addition to the existing three laboratories providing ongoing support	This can be achieved as the laboratories are currently BSL-2. With support from the government and local partners, the relevant infrastructure will be installed
Introduce testing of TB using clinical sample (sputum) in smear negative HIV+ patients	Implement TB Molecular methods (GeneXpert)	Laboratory infrastructure, and maintenance	Currently 17 GeneXpert machine have been installed 15 more are proposed to be procured. These machines are available in 11 states out of 37 states proposed by the NTBLCP.	The plan is to install at least one GeneXpert machine in each state, as well as in the two national, six zonal and one private reference laboratories	This is achievable in five years, 37% (17/46) of the set target has been achieved
Introduce testing of TB using clinical sample (sputum) in smear negative HIV+ patients	Implement TB culture methods (liquid and solid culture methods/ DST)	Laboratory infrastructure and maintenance	Currently there are three BSL-3 laboratories (NIMR Lagos, NTBLTC Zaria and LHMH Calabar) with six BSL-2 zonal laboratories. The private reference laboratory has been upgraded to a BSL-2. Most of the BSL-2 laboratories implement BSL-3 practices and procedures. However, the NIMR and the laboratory at Zaria also have additional enhanced BSL-2 facilities.	The NTBLCP/National plan is to empower each state with a culture/ reference laboratory. In addition, there is an ongoing plan to upgrade the zonal laboratory capacity to BSL2.	This is achievable with increased government contribution and local partners' support.

Strengthen Laboratory Human Resource Development for smear negative TB diagnostics	• Analyze and identify training and personnel gaps existing within the laboratory network • Adopt international TB curriculum for TB molecular methods (LPA, GeneXpert) and culture/DST • In-service training of laboratory staff at different levels of the TB laboratory network • Capacity retention strategy	Laboratory Human resource development	• Currently there are trained laboratory personnel at various levels within the TB Laboratory network. However there are existing shortages of specific cadres of personnel at the different levels. Staff have been trained on TB molecular methods, culture/DST though there still exist gross inadequacy. The training of site staff on quality management system is still inadequate • Currently, there are no existing curricula for in-country training of laboratory personnel on TB molecular methods, culture and DST • Most staff were trained on various diagnostic techniques four years ago. • There is excessive staff attrition at all levels, resulting in challenges to retain trained staff on their specific assignment.	There is a need to standardize the number, and cadre of laboratory staff per site. A TB peripheral laboratory requires a minimum of two trained TB microscopists; State reference laboratories require a minimum of 5 laboratory personnel trained on diagnosis; the zonal reference laboratory will require at least 15 trained laboratory personnel (MMLA- 3, MLT – 3, MLS – 5, Data Manager – 2, support staff – 2); the national reference laboratories will require a minimum of 24 trained laboratory personnel (MLA- 4, MLT – 6, MLS – 9, Data Manager – 2, support staff – 3); Laboratory Scientist, and 2 Medical	This is an achievable target. Most sites have at least 50% of the recommended workforce

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 (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Use of Rapid Techniques	Procurement of GeneXpert machines	Management of laboratory commodities and supplies	1 GeneXpert machine is in the country (UPENN) but it is used for Operational Research only. 15 machines are planned to be brought in for XPRESS study (CDC Botswana, The African Comprehensive HIV/AIDS Partnerships) 20 machines estimated to be purchased through World Bank these will used for programmatic purposes (Not OR).	Yes, achievable. It is certain that 16 machines will be in the country through partners' support Additional 20 machines will be purchased through World Bank
	Procurement of GeneXpert, LPA reagents and commodities	Management of laboratory commodities and supplies	Currently there are no cartridges for routine GeneXpert and LPA testing. 22,220 MTB/RIF cartridges are estimated to be needed annually. Annual number of LPA tests estimated to be approximately 7500	GeneXpert Machines cartridges will procured through CDC, ACHAP and World Bank. For LPA Will be through NHL/MOH
	Recruitment and training/ re-training of personnel	Laboratory human resource development	Currently there are no personnel dedicated to GeneXpert and LPA testing at NTRL and peripheral labs and point of care .	Yes achievable Estimated 500 lab personnel will be on GeneXpert/MTB/ RIF through CDC, ACHAP, BNTP and NHL funding 20 trained on LPA at NTRL
	Maintenance	Equipment validation and maintenance	Currently GeneXpert MTB/RIF machines and PCR equipment has been purchased with maintenance contracts	Achievable through CDC,ACHAP, BNTP and NHL
	Validation	Equipment validation and maintenance	The NTRL has developed a protocol for validation of GeneXpert modules using control strains. 1 machine (UPENN) was validated. Validation of PCR equipment is a part of setting up of PCR lab. All GeneXpert machines are to be validated at performing sites before start of use.	Achievable

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with (in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Increase Capacity for Culture/DST	Procurement of containerized laboratories and equipment	Laboratory infrastructure and maintenance	Currently there is only one culture/DST laboratory.	Achievable if funds available provided GF11 proposal is approved 4 containerized laboratories and equipment will be procurement
	Procurement of culture /DST reagents and commodities (consumables)	Management of laboratory commodities and supplies	Erratic supplies from CMS and NHL	Achievable if funds available provided GF11 proposal is approved
	Recruitment of personnel	Laboratory human resource development	Currently staff capacity is not sufficient for the current workload at the NTRL and peripheral labs 20 staff for 4 containerized labs, 12 technical staff and 2 auxiliaries for culture/DST in Francistown.	Achievable if funds available provided GF11 proposal is approved and with partners' support
	Training/re-training	Laboratory human resource development	Recruitment of additional staff for additional labs will require training. Training will be done at the NTRL. Funds will be required for travel/accommodation/per diem Current staff receives timely re-training on present techniques and upgrades skills (new technologies; data management etc.)	Achievable if funds available provided GF11 proposal is approved and with partners' support
	Ensure service contracts for all major equipment in culture/DST labs	Equipment validation and maintenance	Currently capacity for the maintenance of culture/DST lab equipment is not adequate in terms of finances and skills All the major equipment in culture/DST labs has a maintenance contract All equipment validated	Achievable if funds available provided GF11 proposal is approved and/or with partners' support

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Strengthen Routine Surveillance	Recruitment of M&E officer for NTRL	Laboratory human resource development	Currently reporting of DR data to BNTP is sporadic and stimulated by requests Currently NTRL is setting up an M&E system for quality laboratory indicators Culture/DST reports are submitted to BNTP on a quarterly basis	Achievable with MoH/ partners' support
	Set up routine monitoring of laboratory quality and program-related indicators	Data management		Achievable if the heads of sections at NTRL have sufficient time allocated for the activity
	Use statistical program for analysis	Data management	Currently the NTRL does not use any statistical programs, Epi-Info can be downloaded Staff skilled in using Statistical programs	Achievable, Training available online http://www.tbrieder.org/epidata/epidata.html
Use of electronic means for rapid reporting results	Connect NTRL to peripheral labs via mobile network	Laboratory information and data management systems	NTRL has implemented and uses LIS which allows dispatch of results by email and SMS Currently NTRL reports results by post, cars, MDR cases by email and to 2 labs through LIS The NTRL connected to all labs via the internet	Achievable if funds available

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Improve Quality of Specimens	Training/ re-training of collectors	Laboratory human resource development	Currently the proportion of good quality sputum submitted for culture is about 50%. Proportion of good sputum specimen should be not less than 75%	Achievable if funds available for training and supervision
	Providing sputum collection sites/labs with refrigerators	Laboratory infrastructure and maintenance	Recently NTRL provided refrigerators for cool storage of specimens for 10 of the highest volume laboratories All sputum collection sites and laboratories need to be equipped with refrigerators An assessment need to be done to determine which of these sites are equipped with refrigerators or not.	Achievable with financial support from MoH and partners
	Contract courier services	Specimen transport and referral mechanisms	Currently the NTRL rejects specimens collected more than two weeks earlier. Specimens for culture delivered within 5 days for culture and for GeneXpert within 2 days if refrigerated	Achievable if funds available for courier services (other solutions?) to deliver specimens at least 2 times a week
		Management of laboratory commodities and supplies	All specimens collection sites/labs have a sufficient number of cooler boxes	Achievable if funds available
	Strengthen monitoring of sputum quality	Laboratory information and data management systems	The NTRL has got access to data on sputum quality through request form, data are being computerized in LIS The NTRL should monitor the quality of sputum and report to NTP on regular basis	Achievable if the NTRL monitors and reports to the BNTP quality of sputum by districts/facilities

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Strengthen Culture and DST EQA	Recruitment of additional (2) staff for EQA unit at NTRL	Laboratory human resource development	Currently there are 3 staff in the EQA unit at the NTRL performing Proficiency Testing, Blind Rechecking and support visits Introduction of GeneXpert, increasing number of culture laboratories will require additional staff at the EQA unit for providing EQA services	Achievable if funds available (GF approved, partners' support)
	Re-checking of 10% of DST results at SNRL	Laboratory quality management systems	Currently the NTRL participates in MRC, CAP and NICD DST panel testing programs The NTRL needs to implement program for quarterly re-checking of 10% of DST results at SNRL	Achievable if funds available for testing fees at SNRL
	Fund courier services for transportation of EQA samples	Specimen transport and referral mechanisms	Currently the NTRL is using NTP Clinic cars for the distribution of microscopy panels and courier for sending of referral samples to MRC. The NTRL needs to implement a program for quarterly re-checking of 10% of DST results at SNRL and culture/DST EQA program for additional in-country culture/DST labs. Funds are needed for the safe transportation of bio-hazard samples and courier fees	Achievable if there is budget line in MoH budget/if there is partners' support
	Fund annual supervisory support visits from SNRL	Laboratory quality management systems	The NTRL regularly receives external assessment, however never from the SNRL NTRL visited by supervising SNRL at least annually	Achievable if there is budget line in MoH budget/if there is partners' support

Broad priority identified (listed in order of priority with highest first)	Main activities (in order of priority, intensity, expense)	Category per GLI framework with (in order of priority, intensity, expense)	Where are you now and where to you want to be?	Achievable in 5 years? Yes/NO/partially
Improve Transportation of Specimens	Fund courier services	Specimen transport and referral mechanisms	Currently specimens are transported to NTRL either by facilities cars or by courier. Currently the NTRL rejects specimens collected more than two weeks earlier. Specimens for culture delivered within 5 days for GeneXpert within 2 days if refrigerated	Achievable if there is budget line in MoH budget/if there is partners' support
	Procurement of biosafety specimen transportation system (zip lock bags, absorbent, ice packs)	Management of laboratory commodities and supplies	Currently specimens for mycobacteriology are transported in plain cooler boxes. The emergence of MDR/XDR requires strengthened biosafety within the existing transport system ALL specimens delivered in biosafe conditions	Achievable if funds available for courier services (other solutions?) to deliver specimens at least 2 times a week from any facility
Strengthen TB Laboratory Quality Management System	• Develop Laboratory procedures manual • Implement QMS in culture/DST/ LPA • TB Laboratory accreditation • Enroll TB culture laboratories into proficiency scheme.	Laboratory Quality Management System	• Currently the TB laboratory network has no uniform QMS at the higher laboratories implementing TB culture and DST • Only three TB laboratories have been enrolled for the national and international accreditation scheme • 4 TB culture laboratories are enrolled in the TB culture/DST proficiency scheme, however the distribution of the proficiency panel is irregular • Develop a uniform QMS for the higher laboratories • Ensure the enrolment of all 47 TB culture laboratories in the QMS activities • Enroll an additional six reference laboratories for national and international accreditation	This is achievable if more of the laboratories enrolled into the national QMS scheme are provided with panels that are purchased by the government from international vendors, in a sustainable manner.

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)**
Establish fundamentals of quality managements systems (Phase –I)	Purchase ISO 15189 : 2007 standards	QMS		Accreditation of NRL	Yes in five years
	Formation of a quality project team.	QMS	NOT yet Notified	Project team notified and trained	Yes in the next year
	Conduct QMS courses (both staff and management).	HRD	NOT yet Implemented	Trained project team available at NRL	Yes in the next year
	Development of SOPs for the laboratory tests	International TA	SOPs are available but not complete in document form	All SOPs available signed and verified	Yes in the next year
	Develop SOPs and maintenance schedule for the laboratory equipment to assure proper and safe use of equipment.	Equipment validation	Annual contract not established for equipment servicing, Equipment servicing done on ad hoc basis	SOPs and schedule developed and equipment maintenance done as per schedule.	Yes in the next year

Upgrade Laboratory Biosafety	Appointment of a biosafety officer	HRD	There is no biosafety officer	Trained biosafety officer available	Yes in next year
	Develop biosafety manual		Some biosafety SOPs are available but complete biosafety manual not available	Biosafety manual available and followed at NRL	Yes in the next 2 years
	Organizing safety / biosafety training	HRD	Adhoc staff received training on biosafety at international level but is no longer working in NRL	Biosafety officer receives sufficient and up to date training on Biosafety	Yes in the next 2 years
	Conduct risk assessments	QMS	No risk assessment is carried out at NRL	Risk assessment report available	Yes in the next 2 years
	Procurement of safety equipment	Supply management	Personal Protective Equipment is available		
Expand quality management systems (Phase –II)	Develop SOPs for all laboratory processes	TA	SOPs are available for most laboratory tests but not for processes	Complete SOPs on all laboratory tests and procedures are available	Yes in the next 2 years
	Designing and using of forms (e.g. temperature log sheets, request forms, etc.) to enable the tracking of activities	TA	Temperature is recorded in an irregular manner and not documented properly.	Reporting and recording forms are appropriately used for temperature logs/ requests/tracking etc.	Yes in the next 2 years
	Establish document control systems	TA	No documented procedure for document control	Document control system is established and relevant staff are trained	Yes in the next 3 years

Development and execution of a quality management plans. (Phase-III)	Development of QMS plans	QMS	No QMS plans are established	QMS plans are established and reviewed regularly for progress	
	Development of a quality manual	QMS	QC procedures are not described in any quality manual for NRL		
	Development of an internal auditing system	QMS	No established mechanism of regular internal audit	Regular internal audit report are available	
	Developing documentation control	QMS		Proper Recording and handling of complaints, notifications and improvement	
To ensure continuous improvement and building up of history. (Phase –IV)	Validation of methods and equipment	QMS	PT of DST is done on a regular basis but all methods are not validated	All methods and equipment are validated	
	NRL is accredited to ISO 15189	QMS			

The following four tables are the blank templates for the participants to fill in.

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 (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 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 (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 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

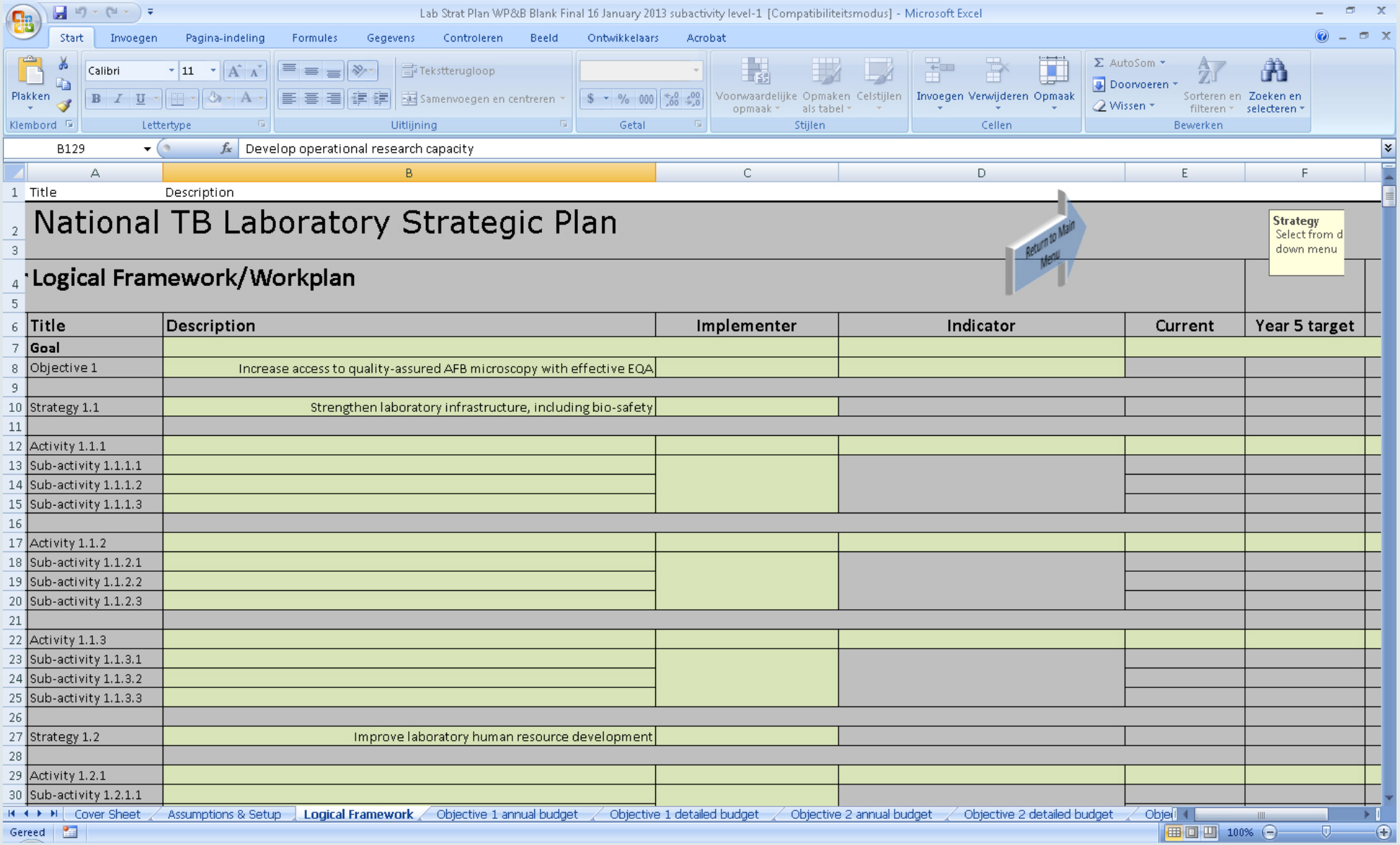
In this exercise, break into groups to identify key strategies for each Stop TB Objective
Define Strategies as per guidelines from Chapter 5 and develop electronic tables for each. As mentioned in Chapter 5, you do not need to address all the strategies available but the merit of each should be considered for each Objective based on previous exercises.

Note: Number your strategies using a logical hierarchical structure, as shown in the figure below. At this point you can use either the Excel tool (recommended) or MS Word versions of the tables. It is preferable that you break into 4 groups (one per objective) to agree upon the strategies to achieve the each of the four Stop TB objectives for your specific country TB laboratory plan.

It is recommended that you begin using the Excel budget and work plan tool with this exercise. For further instructions, see Annex I of this facilitators manual. It is advisable that you set-up the excel tool at least the day before beginning this exercise. To begin using the Excel tool:

Step 1 : Fill in information in assumption sheet

Step 2 : Insert Goal, Objectives and Strategies in logical frame work



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 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	
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	

Turn in strategies to moderator

Present and discuss in a plenary. Update, if necessary, based on discussion

NOTE: This can best be done by projecting the activities on a projector and discussing and updating, if necessary, line-by-line

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

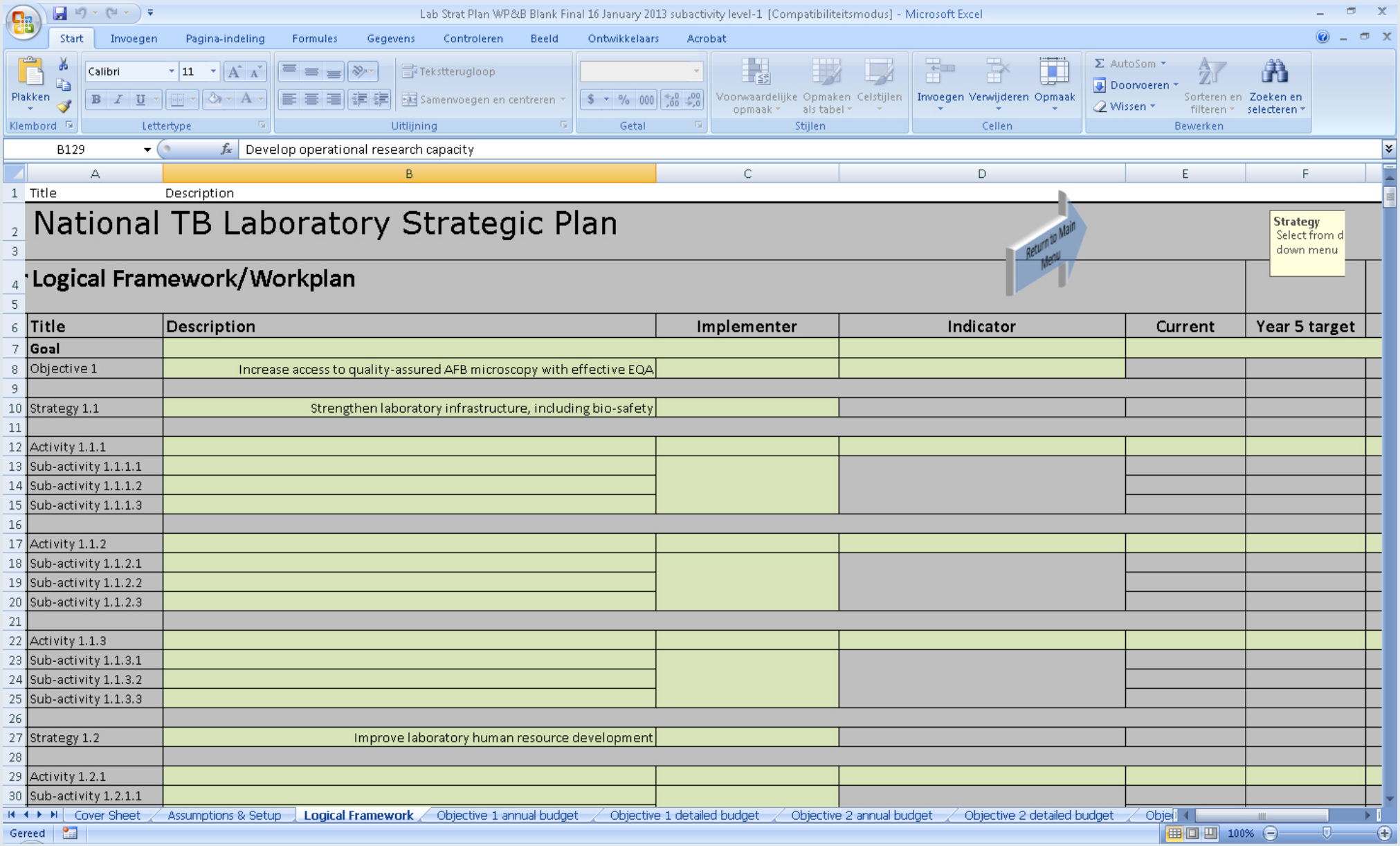
After you decide as a plenary which strategies will be utilized as recommended/described in the guidelines from Chapter 5:

Break into groups to identify key activities for the Stop TB Objectives identified.
Define activities and sub-activities as per guidelines from **Chapter 5**.

Utilize the existing templates developed for the objectives and strategies to develop the activities and sub-activities preferably from the Excel tool

Note: Number your activities as multilevel lists with logical correspondence as per the example below. It is recommended that you use MS Excel to complete this exercise as described in **Annex I** of the facilitators manual. Alternatively, you can copy this table for each strategy and adapt for your country-specific TB laboratory plan objectives, strategies and activities (from the previous exercise) in MS Word.

With the MS Excel tool, insert activities and sub-activities into the logical framework:



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

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	Improve infection control measures in microscopy laboratories
Sub-activity 1.1.1.1	Develop laboratory specific infection control plans based upon on site assessments
Sub-activity 1.1.1.2	Provide selected microscopy laboratories with extraction fans
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	Improve human resource capacity for microscopy laboratories
Sub-activity 1.2.1.1	Conduct assessment of training needs
Sub-activity 1.2.1.2	Develop training materials
Sub-activity 1.2.1.3	Train laboratory technicians
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	Conduct EQA for microscopy
Sub-activity 1.3.1.1	Support visits to peripheral laboratories
Sub-activity 1.3.1.2	Procure panel slides
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment
Sub-activity 1.4.1.1	Procure reagents for fluorescent microscopy
Sub-activity 1.4.1.2	Contract equipment maintenance services
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	Improve turn-around time for specimen delivery and reporting of results
Sub-activity 1.5.1.1	Contract courier services for specimens delivery
Sub-activity 1.5.1.2	Purchase airtime for reporting of results
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	Improve data management in the TB laboratory network
Sub-activity 1.6.1.1	Develop national data collection tools
Sub-activity 1.6.1.2	Print national data collection tools
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	Strengthen the legal and regulatory framework to support implementation of national laboratory policy
Sub-activity 1.7.1.1	Develop, establish and disseminate national standards for TB laboratory equipment & reagents
Sub-activity 1.7.1.2	Develop a quality assurance program for TB laboratory services
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	Conduct an operational research study to measure potential reduction in initial default with front loading AFB microscopy services
Sub-activity 1.8.1.1	Develop a study protocol in a workshop with external technical assistance
Sub-activity 1.8.1.2	Implement study in selected sites including ethics approval, data abstraction, and data entry
Sub-activity 1.8.1.3	Analyze and report results in a workshop with policy change considerations dependent on findings

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among PLHIV

Strategy 2.1	**Strengthen laboratory infrastructure including biosafety**
Activity 2.1.1	Ensure a stable uninterrupted electricity supply for GeneXpert labs
Sub-activity 2.1.1.1	Procure generators
Sub-activity 2.1.1.2	Procure solar power panels
Strategy 2.2	**Improve laboratory human resource development**
Activity 2.2.1	Train and re-train lab and medical staff on GeneXpert
Sub-activity 2.2.1.1	Conduct training of trainers
Sub-activity 2.2.1.2	Conduct district-level trainings for laboratorians and clinicians
Strategy 2.3	**Develop and maintain laboratory quality management systems**
Activity 2.3.1	Participate in internationally recognized EQA program for GeneXpert
Sub-activity 2.3.1.1	Procure GeneXpert EQA panels
Sub-activity 2.3.1.2	Establish remedial measure for low performers e.g., re-training, increased supervision, re-assignment of staff
Strategy 2.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 2.4.1	Procure and maintain a stable supply chain of GeneXpert cartridges
Sub-activity 2.4.1.1	Establish a supply chain protocol
Sub-activity 2.4.1.2	Procure cartridges with a buffer stock
Strategy 2.5	**Fortify specimen transport and referral mechanisms**
Activity 2.5.1	Establish (maintain) a courier system for sample transport to GeneXpert sites
Sub-activity 2.5.1.1	Procure motorcycles
Sub-activity 2.5.1.2	Procure petrol
Strategy 2.6	**Improve laboratory information and data management systems**
Activity 2.6.1	Establish and maintain a recording and reporting system with GeneXpert integrated
Sub-activity 2.6.1.1	Revise recording and reporting system with GeneXpert integrated
Sub-activity 2.6.1.2	Print revised forms and registers
Strategy 2.7	**Establish a laboratory Regulatory framework**
Activity 2.7.1	Ensure national authorities have recognized use of GeneXpert
Sub-activity 2.7.1.1	Meeting(s) with national authorities
Sub-activity 2.7.1.2	Pay regulatory licensing fee and legal fees (if relevant)
Strategy 2.8	**Develop Operational Research capacity**
Activity 2.8.1	Evaluate the added value of GeneXpert in SS- detection among PLWHAs
Sub-activity 2.8.1.1	Develop a study protocol with a stakeholder workshop facilitated by an external epidemiologist
Sub-activity 2.8.1.2	Implement study protocol including training, printing of data collection forms, ethics approval, data entry
Sub-activity 2.8.1.2	Analyze and report data in the form of a stakeholder workshop. Develop policy recommendations based on findings

Blank template to work from below should you choose to not work in the Excel tool (although using the Excel tool is recommended.

Objective 1.

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	

Turn into the moderator in electronic format

Present and discuss in a plenary and, if necessary, update the activities.

NOTE: This can best be done by projecting the activities on a projector and discussing and updating, if necessary, line-by-line

Identifying indicators and targets in a monitoring and evaluation (M&E) framework

If you used the Excel TB laboratory plan budget and workplan tool to complete Exercises 5c-5d, you can continue to use this for the next two exercises. If you didn't use the Excel TB laboratory plan budget and workplan tool up to this point, you may either retrospectively add them to the tool and continue within this exercise with the tool or take your completed electronic table from **Chapter 5 (Exercises 5c-5d)** with objectives, strategies and activities and place two columns on the right hand side with the labels "indicators" and "targets", respectively, to complete the exercises. You can also choose to do the indicators and their corresponding targets simultaneously.

Resources needed:

- Use NTP strategic plan and indicators
- Use NHL strategic plan and indicators
- List of indicators in Annex 4b from the handbook

REMEMBER: The indicators should be developed only for main activities and not for the sub-activity level.

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

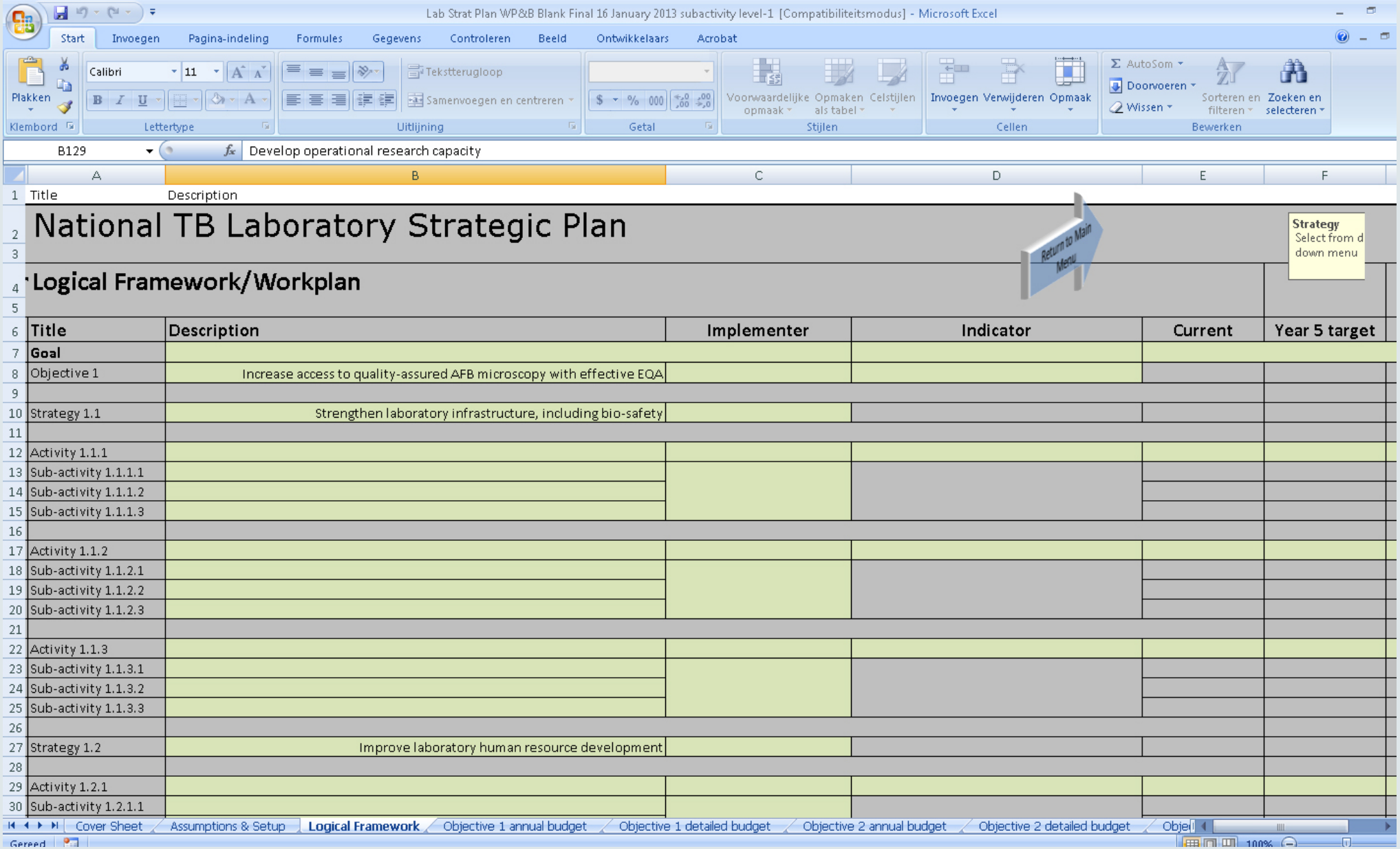
Familiarize yourself with the SMART system for indicators.
Use the SMART system to develop indicators for each strategy and activity along with the provided indicators, if relevant, from **Chapter 6**. You should not do indicators and targets for sub-activities.

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

Develop targets within a 5-year period using your developed indicators.
Turn in the electronic tables to the moderator.
Present and discuss in a plenary.

Note: As mentioned earlier, this is best done by presenting on a projector and editing the version at the same time or highlighting changes for a focal point to edit specific changes subsequently.

With the excel tool (further instructions can be found in Annex I of this facilitators manual): Input implementers, indicators, write current status and add targets.



Lab Strat Plan WP&B Blank Final 16 January 2013 subactivity level-1 [Compatibiliteitsmodus] - Microsoft Excel

B129: Develop operational research capacity

Title	Description	Implementer	Indicator	Current	Year 5 target
Goal					
Objective 1	Increase access to quality-assured AFB microscopy with effective EQA				
Strategy 1.1	Strengthen laboratory infrastructure, including bio-safety				
Activity 1.1.1					
Sub-activity 1.1.1.1					
Sub-activity 1.1.1.2					
Sub-activity 1.1.1.3					
Activity 1.1.2					
Sub-activity 1.1.2.1					
Sub-activity 1.1.2.2					
Sub-activity 1.1.2.3					
Activity 1.1.3					
Sub-activity 1.1.3.1					
Sub-activity 1.1.3.2					
Sub-activity 1.1.3.3					
Strategy 1.2	Improve laboratory human resource development				
Activity 1.2.1					
Sub-activity 1.2.1.1					

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**	**Indicators**	**Targets**
Activity 1.1.1	Improve infection control measures in microscopy laboratories	# (%) of laboratories with improved infection during a specified period of time	35 (80%) laboratories with improved infection control by September 2015
Sub-activity 1.1.1.1	Develop laboratory specific infection control plans based upon on site assessments		
Sub-activity 1.1.1.2	Provide selected microscopy laboratories with extraction fans		
Strategy 1.2	**Improve laboratory human resource development**		
Activity 1.2.1	Improve human resource capacity for microscopy laboratories	# (%) of laboratories with trained staff during a specified period of time	378 (90%) technicians trained by February 2016
Sub-activity 1.2.1.1	Conduct assessment of training needs		
Sub-activity 1.2.1.2	Develop training materials		
Sub-activity 1.2.1.3	Train laboratory technicians		
Strategy 1.3	**Develop and maintain laboratory quality management systems**		
Activity 1.3.1	Conduct EQA for microscopy	# (%) of laboratories involved in EQA during a specified period of time	97 (100%) laboratories involved in EQA program by December 2014
Sub-activity 1.3.1.1	Support visits to peripheral laboratories		
Sub-activity 1.3.1.2	Procure panel slides		
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**		
Activity 1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment	# (%) of laboratories with no stock-outs during a specified period of time	65 (95%) laboratories without stock-outs by July 2014

Sub-activity 1.4.1.1	Procure reagents for fluorescent microscopy		
Sub-activity 1.4.1.2	Contract equipment maintenance services		
Strategy 1.5	**Fortify specimen transport and referral mechanisms**		
Activity 1.5.1	Improve turn-around time for specimen delivery and reporting of results	No (%) of laboratories reporting results within acceptable turnaround time during a specified period of time	80 (90%) laboratories reporting results within acceptable turnaround time by August 2013
Sub-activity 1.5.1.1	Contract courier services for specimens delivery		
Sub-activity 1.5.1.2	Purchase airtime for reporting of results		
Strategy 1.6	**Improve laboratory information and data management systems**		
Activity 1.6.1	Improve data management in the TB laboratory network	No (%) of laboratories submitting regular reports during a specified period of time	56 (85%) laboratories submitting regular reports by November 2015
Sub-activity 1.6.1.1	Develop national data collection tools		
Sub-activity 1.6.1.2	Print national data collection tools		
Strategy 1.7	**Establish a laboratory Regulatory framework**		
Activity 1.7.1	Strengthen the legal and regulatory framework to support implementation of national laboratory policy	No (%) of support documents available during a specified period of time	2 (100%) planned support document available by May 2014
Sub-activity 1.7.1.1	Develop, establish and disseminate national standards for TB laboratory equipment & reagents		
Sub-activity 1.7.1.2	Develop a quality assurance program for TB laboratory services		
Strategy 1.8	**Develop Operational Research capacity**		

Activity 1.8.1	Conduct an operational research study to measure potential reduction in initial default with front loading AFB microscopy services	# (%) of operational research studies conducted related to smear-microscopy out of planned in a specified time period	1 (100%) operational research study is conducted related to smear-microscopy by January 2014
Sub-activity 1.8.1.1	Develop a study protocol in a workshop with external technical assistance		
Sub-activity 1.8.1.2	Implement study in selected sites including ethics approval, data abstraction, and data entry		
Sub-activity 1.8.1.3	Analyze and report results in a workshop with policy change considerations dependent on findings		

Blank template to work from below should you choose to not work in the Excel tool (although using the Excel tool is recommended.

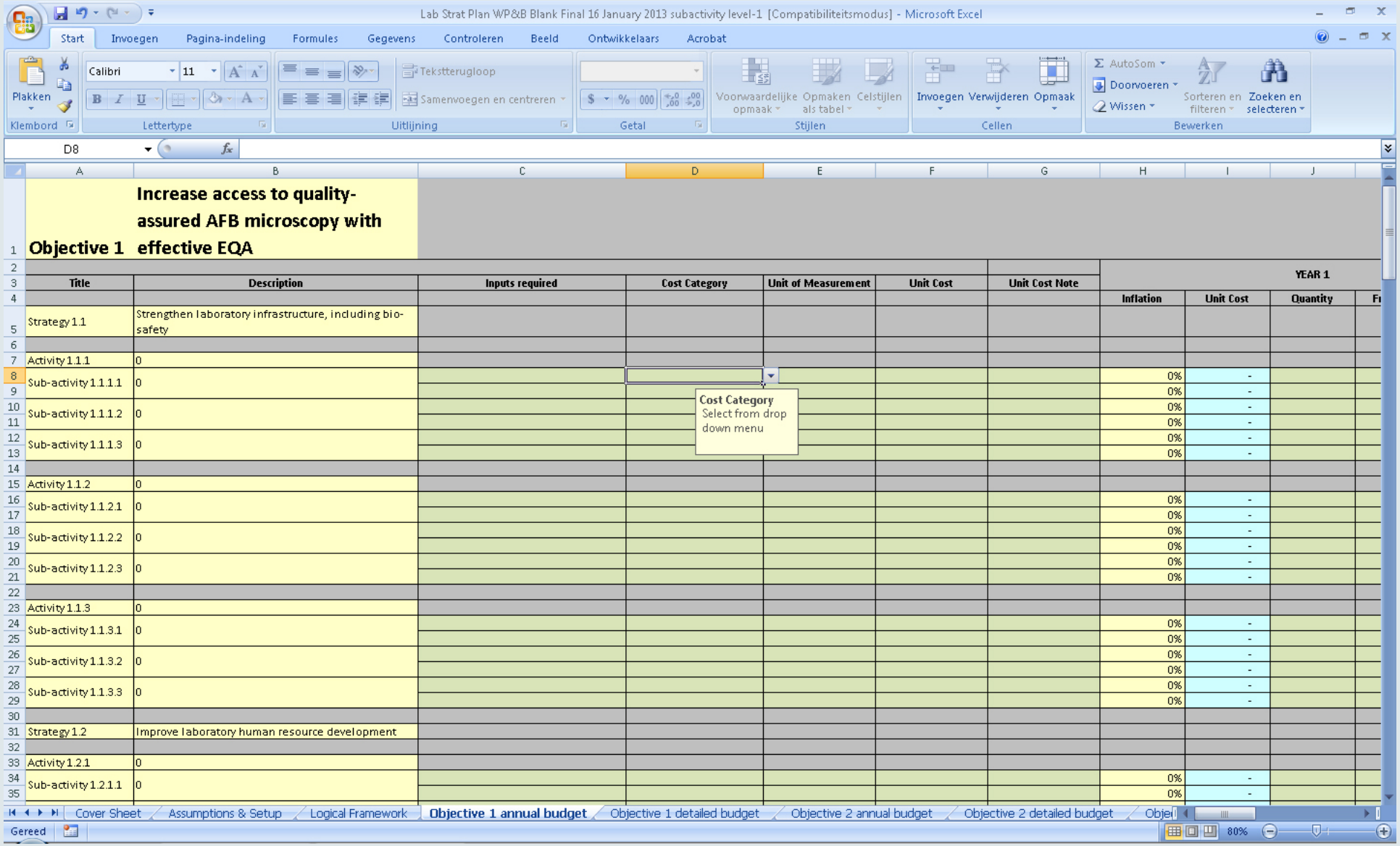
Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**	**Indicators**	**Targets**
Activity 1.1.1			
Sub-activity 1.1.1.1			
Sub-activity 1.1.1.2			
Strategy 1.2			
Activity 1.2.1			
Sub-activity 1.2.1.1			
Sub-activity 1.2.1.2			
Sub-activity 1.2.1.3			
Strategy 1.3			
Activity 1.3.1			
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			
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			
Sub-activity 1.8.1.3			

Develop a TB Laboratory Work Plan and Budget

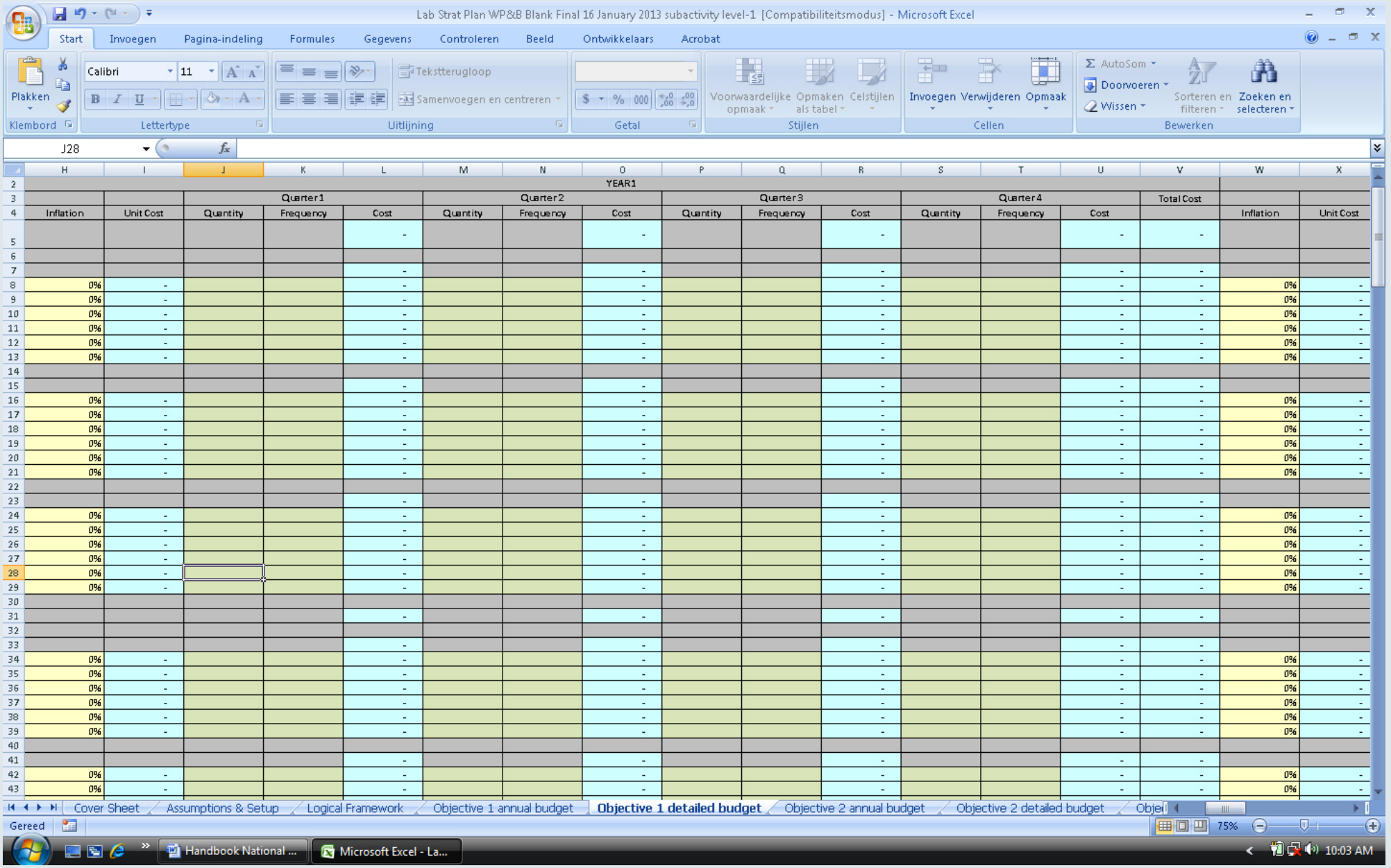
In this exercise, if you have already begun using the Excel-based work plan and budget tool, you start to cost the exercises. If you have not used the tool yet, you will need to input all of the fields per the instruction manual in Annex I of the Facilitators manual e.g. assumptions, strategies, activities and sub-activities, targets and indicators before you can proceed with inputing the budget items. This is best done as a sub-group of 1-2 persons familiar with costing. You might ask the rest of the participants to proceed to Exercise 8b while the appointed people enter this into the Excel-based work plan and budget tool.

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:



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



Putting it All Together

Exercise 8a: Putting it all together

At this point, if you followed the chapter-by-chapter exercises starting with Chapter 2 in this handbook, you should have a working draft of a TB laboratory plan. However, this plan is likely to have some gaps. You are likely to have some sections that still need polishing and perhaps other sections that have not been worked on at all.

You should appoint a sub-group, or an individual (this is less preferable), to go through the draft TB laboratory plan and identify what still needs to be done using the check-list in the Facilitators and Participants manual [See Exercise 8a] which is also summarized below. Besides the technical elements described chapter-by-chapter, once you have a near final draft, you should also consider editing for spelling and consistency as well as for endorsement by the appropriate ministries, printing and distribution.

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. Operations 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 forward (executive summary)				
	Printing				
	Distribution				

User Manual National TB Laboratory Strategic Plan Budget & Work Plan Tool

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1. Introduction

The National Laboratory Strategic Plan Budgeting and Work plan Tool has been developed to assist TB laboratory strengthening consultants, National TB Reference Laboratory and National TB Program management in planning for and costing laboratory specific programs.

The design of the tool is based on a review of various tools used for costing TB Control and other health initiatives. Attempts have been made to incorporate, as far as possible, favorable features of such tools (based on user-feedback), whilst maintaining a user-friendly interface.

It is a simple Excel tool similar to the WHO budgeting tool which provides a simple and methodical approach to strategic planning and budgeting, beginning by allowing the user to outline fundamental assumptions. These include variables such as the currency in which the budget will be reported, inflation and exchange rates incorporated in the budget, and any other general assumptions.

In the next stage the Logical Framework for the Plan is developed in which goals, objectives, strategies, and activities to be accomplished are specified, indicators are selected. In order to enhance uniformity, the tool restricts the user to pre-determined objectives, strategies and indicators through the use of pull-down menus.

The development of the Logical framework is followed by translating this into the work plan by adding targets and timeframes over the period of the strategic plan. The planning periods are split annually, but for those requiring more detailed, planning, the tool allows the user to plan quarterly for the first two years of the plan.

Finally, the activities and/or sub-activities are budgeted and the whole Plan translated into a budget by applying unit costs to the targets.

Two versions of the tool are available.

The first version allows planners in budgeting of **strategic plan** and provides details and cost up to the main activity level for each objective.

A second version is also available for developing detailed **annual implementation** plans and allows accurate costing up to the sub-activity level.

The tool is based on an activity-based approach, enabling the user to examine costs and activities by objectives and primary strategies in summary sheets for the work plan and detailed budget . It also allows a cost category delineation of the strategic plan which are generated in form of summary reports.

2. Instructions for the User

2.1 Macros

In order to open the model, simply copy the file into the location where you want it to be stored, open the file in Excel and follow the instructions regarding the security settings below as these will impact on the functioning of the macros.

This tool contains macros. It will not function correctly unless macros are **enabled**. To ensure macros are enabled, you must adjust your security settings to the appropriate level before opening the workbook.

If using Excel 2003, before opening the workbook, go to the **'Tools > Macro > Security'** menus and set the security setting to "low" or "medium". If "Low" is chosen, macros will be enabled automatically. If "Medium" is chosen, you will be prompted to enable or disable Macros when you open the workbook. Ensure that you enable macros when prompted to do so.

If using Excel 2007 or later, a security warning will appear above the spreadsheet. To the right of the warning you will see an **'Options'** button. Click on the **'Options'** button and then click on **'Enable this content'** followed by **'OK'**. This procedure needs to be repeated each time a workbook is opened as macro settings sometimes change when the workbook is closed.

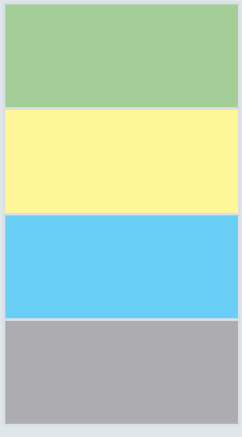
It is possible to enable all macros permanently in the Trust Centre but this is **not** recommended as it may result in the execution of unauthorized code. Should you however wish to do so then repeat the following instructions:

Click on the **'Office'** button, (the round button at the far top most left corner of the spread sheet, or go straight to the **'File'** button in later versions of Excel), and go to **'Excel options > trust center > trust centre settings > macro settings'**. Check **'enable all macros'** and finish by clicking OK.

2.2 Structure of the Workbook

2.2.1 Color Coding

To assist the user, different colors have been used to indicate where data must be entered, where data has been input elsewhere, where data has been calculated, and where no input in necessary. The following color codes apply throughout the workbook:



Cells requiring user input. Where a pull-down menu is available, a button will appear on the right of the cell when you click on it.

Cells showing information input elsewhere.

Cells showing the results of calculations.

Cells which do not require input.

2.2.2 Protection

The workbook contains numerous formulae and will return incorrect results if these are changed or deleted. The workbook is protected to prevent inadvertent deletion or corruption of formulae during data entry. This protection may restrict the flexibility of the tool in certain instances and may impose some limitations on some users. Nevertheless, the integrity of the workbook is considerably improved as a result of the protection.

Some of the macros refer to formats to determine what actions to take and they will not work correctly if formats are changed. Therefore, some formatting is also protected and users cannot change those formats.

2.2.3 Copying and Pasting

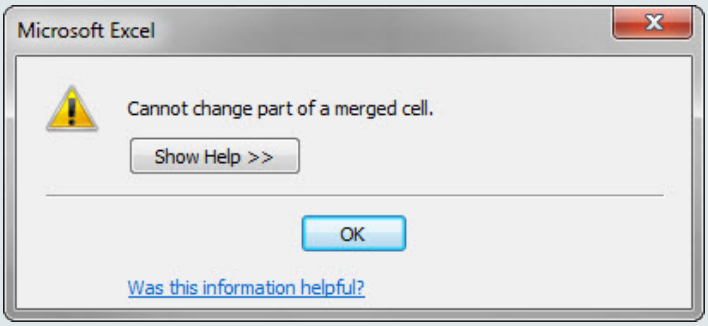
Users may wish to cut or copy text from other spreadsheets or files and paste it into the tool. On certain sheets, the tool allows copying and pasting, but some difficulties may be encountered when using this technique.

First, formats as well as text are imported when pasting data into an excel spreadsheet. Therefore, cutting and pasting may result in a spreadsheet with various font types, sizes and/or colors. Since the tool is protected, users will not be able to change the fonts again once they are pasted into the tool.

The tool contains a macro to reformat cells when the budget and work plan are generated, so this is not a major problem. Nevertheless, users may wish to take steps to ensure that data is pasted into the tool only in the normal format, which is **Arial 10 point Black**. This can be accomplished in two ways:

i. Format the source data (the excel worksheet from which data is being copied) before copying and pasting data into the tool; or
ii. Use the **'Paste special'** function to paste data. To do this, first copy the data from the source sheet and then right click (**or** click on the "edit" function or type ALT+ESC) and select "paste special" which is located just under the "paste" button. In the dialog box under the "paste" heading, select the "values" option button. Do NOT select the "all" or "format" option buttons. Under "operations" heading, select the "none" option button. Click on "OK" and the data will be pasted without the formatting.

Secondly, users may experience difficulty when trying to copy and paste merged cells. Excel cannot copy and paste data from one place to another if the size of the source and destination cells is not identical. If the source data is located in a single cell it can be copied and pasted into a destination that contains two or more merged cells. However, if data is copied from a block that contains two or more merged cells, it cannot be copied into a block that contains a different number of merged cells. If this is attempted, the following error message will appear:



In other cases (i.e. when data is copied from one or more single cells and several cells are selected for the paste) Excel may copy the same data in every cell in the merged block.

In some cases entering value data (as opposed to narrative) also initiates a macro. Where more than one cell is copied from a source to several destination cells, the macro will only run on the first destination cell. For the macro to run accurately the data must then be entered into the other destination cells as well.

To avoid these issues, it is strongly recommended that users copy and paste data one cell at a time or enter values manually.

If multiple, narrative cells are copied and pasted, users must ensure that the size of the source and destination cells are identical - i.e. they must contain the same number of merged cells. This is unlikely to be the case unless this tool is used to collect the data in the first place.

To copy and paste text from non-identical cells, double-click on the source cell, highlight the text in the cell and copy. The text can then be pasted in the destination cell by double-clicking to “enter” the destination cell and pasting the text within the cell.

2.3 Backup Procedure

It is critical that the workbook is saved frequently during use and a back-up copy made at least once a day during a costing assignment on an external storage device. If working on a network, this backup may take place automatically. In many situations this is not the case and the user is required to manually back up onto an external hard drive or similar device.

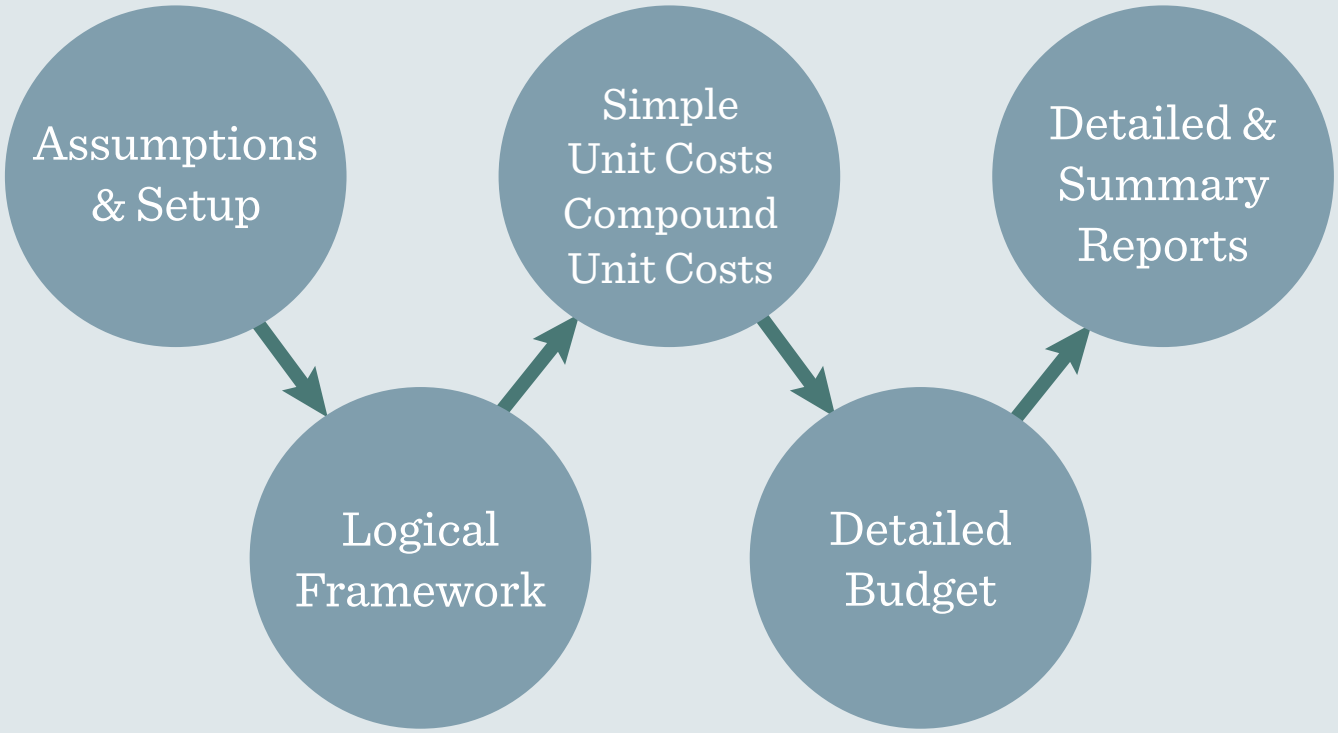
When backing up, it is also critical that a unique identification and date filed is included in the backup file name to ensure that the user is able to keep track of the latest version of the file.

3. Entering data in the Workbook

3.1 Logical Approach to Data Input

As far as possible, the user must follow the sequence presented in the workbook. This will ensure that the work plan and budget are accurately formulated. Although it is possible to make amendments to the assumptions and unit costs at any time during the input process, the logical framework **must** be input first before changes are transferred to the work plan and budget. For example, if the user would like to add or delete an activity after all inputting has been completed, this can only be done from the logical framework sheet.

The cover sheet provides links to the various worksheets in the workbook. The user is recommended to begin with the "Assumptions and Setup" worksheet and then proceed to the "Logical Framework" worksheet before moving to the unit costs worksheets. The figure below illustrates this data entry progression. A return button is provided on each sheet which transfers the user back to the cover sheet and main menu.



3.2 Detailed description of Worksheets

3.2.1 Cover Sheet

No data is required to be input on the cover sheet. Details that appear on this sheet are input through the Assumptions and Setup sheet. The Cover Sheet contains the following details:

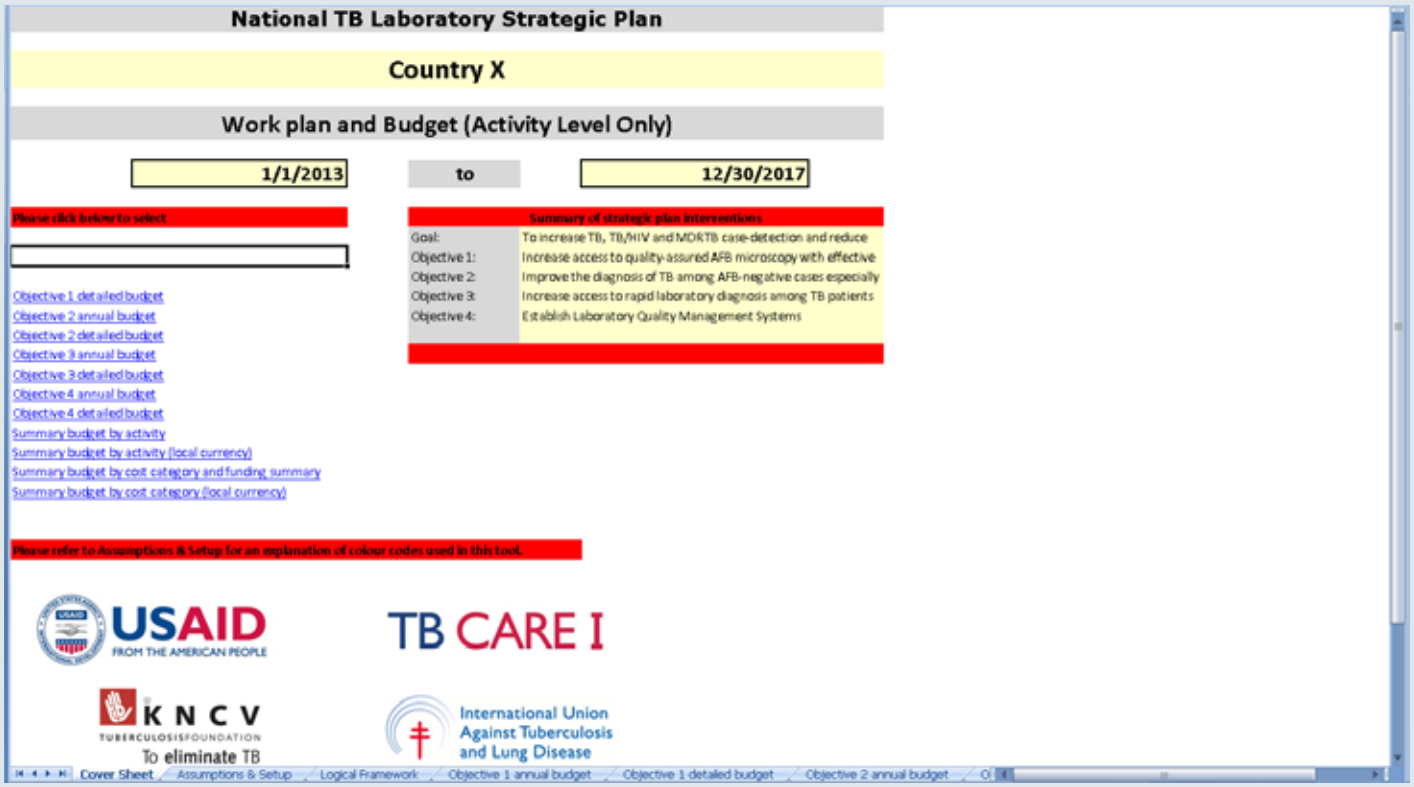
- Plan title
- Country name
- Period of the plan
- Main navigation menu
- Summary of strategic plan interventions
- Logos and credits of sponsors.

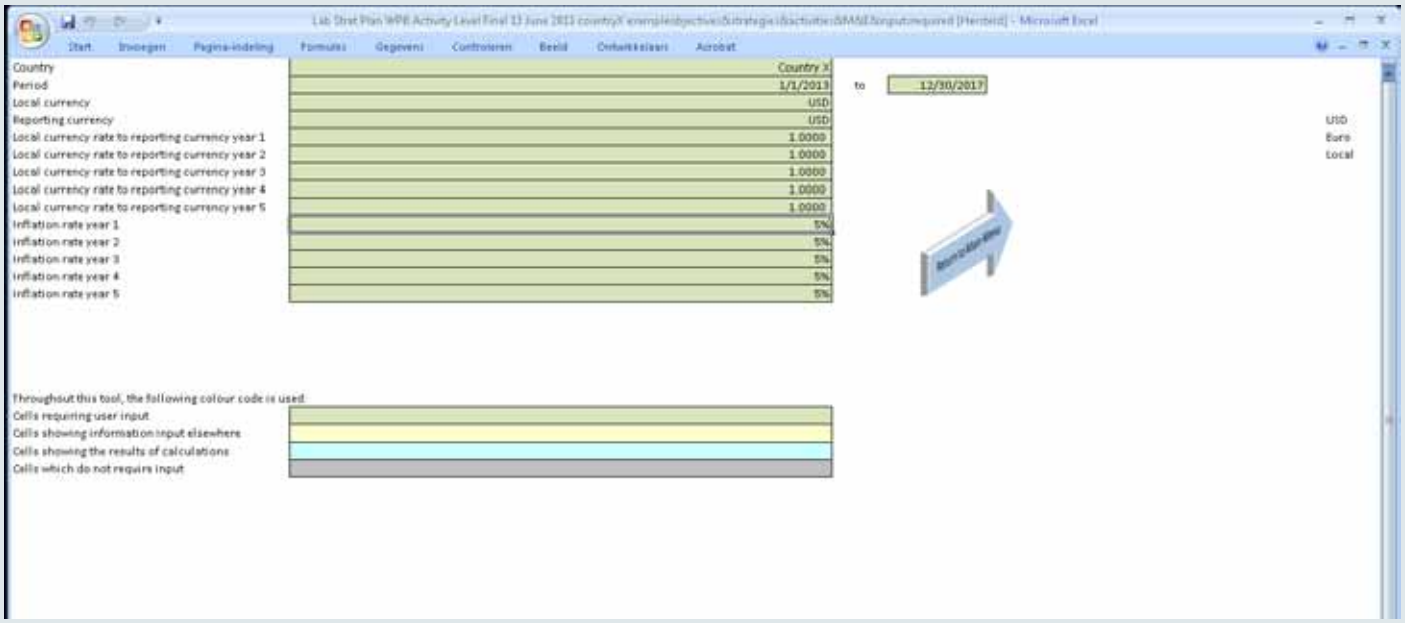
3.2.2 Assumptions and Setup Sheet

This sheet contains the general details and assumptions used in the Plan. These include:

- Country name (input required)
- Local and reporting currencies (input required)
- Currency exchange rates (input required)
- Inflation rates over the proposal period (input required)
- Color scheme of the workbook.

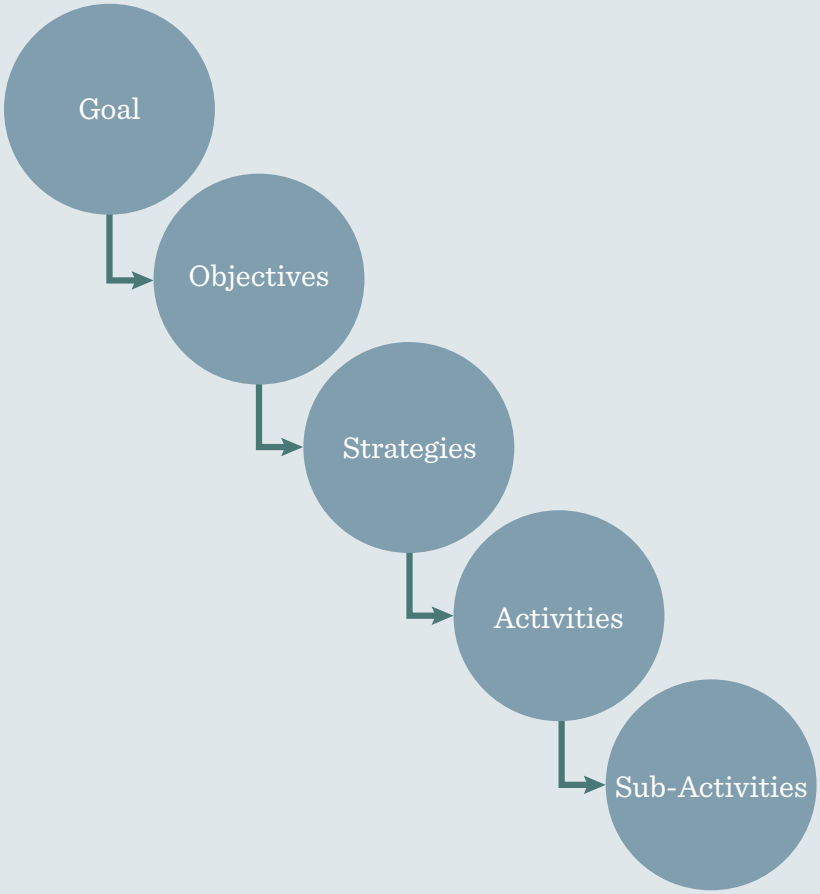
See a screenshot of Assumptions and Set-up at the bottom of the page.





3.2.3 Logical Framework Sheet

The logical framework is the backbone of the structure of the budget and work plan tool. On this sheet, the user enters the main initiatives of the plan ordered in the same hierarchy as outlined in the strategic plan. The diagram below illustrates the organization of this hierarchy in the detailed sub-activity model (the model which ends at main activity level does not include the lowest rung in the hierarchy below):



The user is required to add the required information such as the goal name, objective name, strategy name, activity name and description and the sub-activity name.

There is no limit to the number of activities and sub-activities that can be added. However, in order to enhance uniformity, the tool restricts the user to pre-determined objectives and strategies through the use of pull-down menus. These are outlined below:

Objectives:

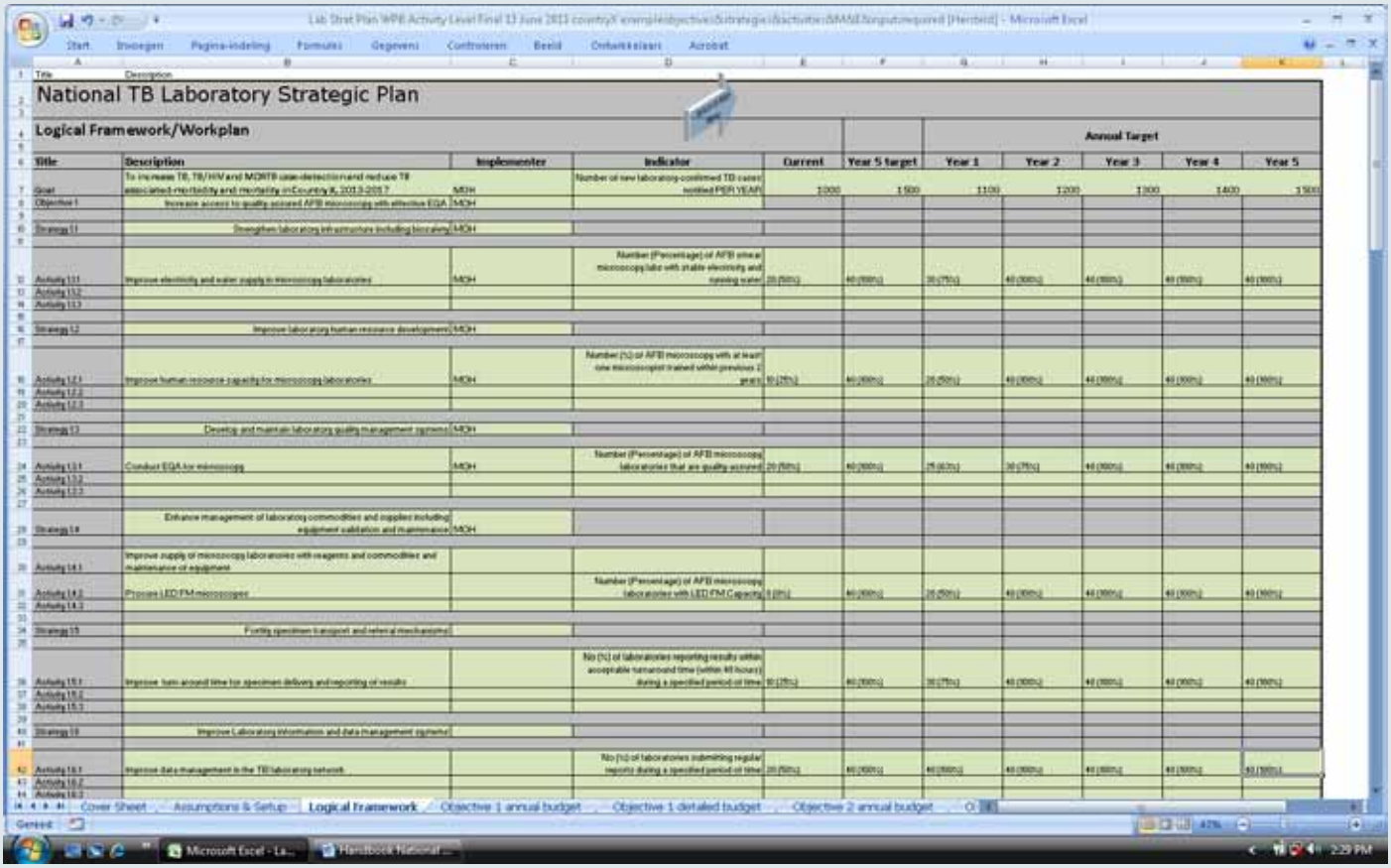
1. Increase access to quality-assured AFB microscopy with effective EQA
2. Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV
3. Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB
4. Establish Laboratory Quality Management Systems.

Strategies:

1. Strengthen laboratory infrastructure, including biosafety
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 laboratory regulatory framework
8. Develop operational research capacity.

Indicators

A drop-down list for indicators described in **Annex 3a and 3b** is available for the goal, objectives and activities. You may also write-in customized indicators within this tool if your indicator of choice is not available in the drop-down menu.



3.2.4 Numbering Convention

The numbering in the workbook should be aligned directly to that in the strategic plan. The following convention is recommended:

Goal	Objective	Strategy	Activity	Sub-activity
-	1	1.1	1.1.1	1.1.1.1
-	1	1.1	1.1.2	1.1.2.1
-	1	1.1	1.1.2	1.1.2.2
-	1	1.2	1.2.1	1.2.1.1
-	1	1.2	1.2.1	1.2.1.2
-	1	1.2	1.2.2	1.2.2.1
-	1	1.2	1.2.2	1.2.2.2
-	2	2.1	2.1.1	2.1.1.1
-	4	4.6	4.6.1	4.6.1.1
-	4	4.6	4.6.1	4.6.1.2
-	4	4.6	4.6.2	4.6.2.1
-	4	4.7	4.7.1	4.7.1.1
-	4	4.7	4.7.1	4.7.1.2

In order to develop the structure in terms of its planning elements, it is necessary to add (and/or delete) all the elements of the structure.

3.2.5 Defining Unit Costs

The tool allows the input of cost data at any level of detail, but it is recommended to provide for input costs at the lowest level of each input cost unit (simple unit cost). Examples of unit costs include the cost of a computer or motor vehicle, one salary day for consultants, one salary month for regular staff, one day for venue rental, one day of per diem and allowances for workshop participants, one airfare, one packet of reagent, and so on.

However, where several input costs can be combined to arrive at an aggregate input cost and all input costs can be included in a single cost category, then use of aggregated input costs is encouraged. For example, the cost of a supervisory visit could consist of fuel, subsistence and travel allowances. These could be aggregated into a single compound cost for a standard 5 day trip.

For uniformity, the tool requires input cost data to be standardized across different activities. The same input cost must be used for all sub-activities which make use of that input cost. For example, if an international consultant hired for 5 days for a particular activity and another for 14 days should be budgeted at the same unit cost.

A worksheet showing all unit cost calculations can be inserted in the workbook. Once the sheet has been completed it can be printed or copied electronically and used to source input costs for defined items. This may require giving certain sections of the input cost sheet to various government officials or employees in a procurement agency, who can then assist by completing the actual cost for each item identified. As an example, the Human Resource section of the sheet can be given to the salaries department in the Ministry of Health for completion. Where this process is well managed and coordinated, significant efficiencies can be achieved.
Defining Cost Category :

The unit cost categories in the model are outlined below, with (as far as possible) guidelines as to their definitions according to the Enhanced Reporting Standards for the Global Fund (GFATM).

1. Human Resources. This includes salaries, wages and related costs (pensions, incentives and other employee benefits, etc.) relating to all employees (including field personnel), and employee recruitment costs, as well as stipends, expense reimbursement and related costs for non-employees such as volunteers.
2. Infrastructure Costs. This includes health infrastructure rehabilitation and renovation and enhancement costs, non-health equipment such as generators and beds, information technology (IT) systems and software, website creation and development. Office equipment, furniture, audio-visual equipment, vehicles, motorcycles, bicycles, related maintenance, spare parts and repair costs.
3. Laboratory Equipment.
4. Laboratory Supplies & Consumables.
5. Monitoring & Evaluation. This includes data collection, surveys, research, analysis, travel, field supervision and oversight visits, and any other costs associated with monitoring and evaluation. Do not include personnel, management or technical assistance or IT systems costs, as these costs should be included in other categories.
6. Other General Costs. These are significant costs which do not fall under other defined categories.
7. Overheads. Overhead costs such as office rent, utilities, internal communication costs (mail, telephone, internet), insurance, fuel, security and cleaning are captured under this category. Management or overhead fees should be included.
8. Planning & Administration. This relates to costs for office supplies, travel, field visits and other costs relating to program planning and administration (including in respect of managing sub-recipient relationships). Legal, translation, accounting and auditing costs, bank charges etc. should be included. Green Light Committee contributions are included here.
9. Procurement & Supply Management. This includes transportation costs for all purchases (equipment, commodities, products,

medicines) including packaging, shipping and handling. Warehouse, PSM office facilities and other logistics requirements including procurement agent fees. Costs for quality assurance (including laboratory testing of samples), and any other costs associated with the purchase, storage and delivery of items should be included. Also include costs associated with pharmaceutical management systems, especially costs associated with Pharmaco-vigilance, Drug resistance surveillance, Quality assurance (including laboratory testing of samples) and National Regulatory Authorities strengthening.

10. Technical & Management Assistance. This relates to costs of all consultants (short or long term) providing technical or management assistance, including consulting fees, travel and per diems, field visits and other costs relating to program planning, supervision and administration.
11. Training. This includes the costs of workshops, meetings, training publications, training-related travel, including training per diems.

3.2.6 Inputting data for the detailed work plan and budget

This is the most complicated step in the process of costing the Plan. The **Detailed Budget** sheet contains all the information required to cost the proposal in one spreadsheet. It contains all the planning elements previously defined and described in the logical framework, and must be carried out by the combined planning team.

Please note that in entering information in and completing the Logical Framework, all the necessary data (objectives, strategies, activities and sub-activities) are automatically transferred and inserted in the detailed work plan and budget.

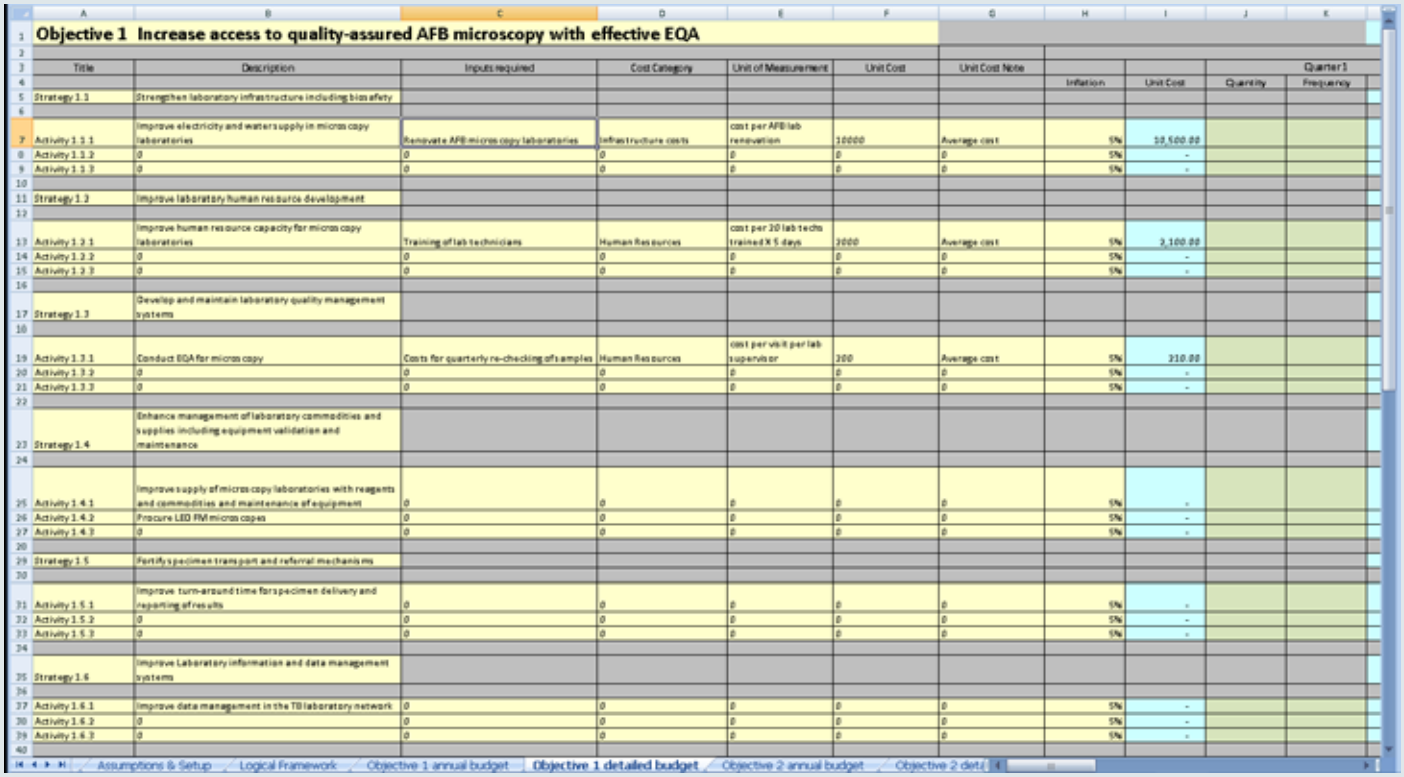
The cost of each activity or sub-activity is calculated on this sheet by multiplying the quantities required by the frequency of occurrence and the unit cost for that activity. The inflation rate automatically adjusts the unit price each year.

The first task in the process is therefore the identification of all the input costs under each activity or sub-activity, representing the type of resources consumed during the implementation of the sub-activity. The cost category is available from a drop down menu. Unit costs and measurement units must be inserted on this worksheet by the user. Care must be taken when defining the unit of measurement as this may be affected by the frequency (which is inserted later).

The next step is to insert quantities for each period for each activity.

Annual totals and a five year total are automatically calculated.

The screenshot overleaf illustrates the detailed budget sheet for the model which limits detail to the main activity level.



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	Inflation	Unit Cost	Quarter1 Quantity	Quarter1 Frequency
Strategy 1.1	Strengthen laboratory infrastructure including biosafety									
Activity 1.1.1	Improve electricity and waters supply in microscopy laboratories	Renovate AFB microscopy laboratories	Infrastructure costs	cost per AFB lab renovation	10000	Average cost	5%	10,500.00		
Activity 1.1.2	0	0	0	0	0	0	5%	-		
Activity 1.1.3	0	0	0	0	0	0	5%	-		
Strategy 1.2	Improve laboratory human resource development									
Activity 1.2.1	Improve human resource capacity for microscopy laboratories	Training of lab technicians	Human Resources	cost per 20 lab techs trained X 5 days	3000	Average cost	5%	3,150.00		
Activity 1.2.2	0	0	0	0	0	0	5%	-		
Activity 1.2.3	0	0	0	0	0	0	5%	-		
Strategy 1.3	Develop and maintain laboratory quality management systems									
Activity 1.3.1	Conduct EQA for microscopy	Costs for quarterly re-checking of samples	Human Resources	cost per visit per lab supervisor	200	Average cost	5%	210.00		
Activity 1.3.2	0	0	0	0	0	0	5%	-		
Activity 1.3.3	0	0	0	0	0	0	5%	-		
Strategy 1.4	Enhance management of laboratory commodities and supplies including equipment validation and maintenance									
Activity 1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment	0	0	0	0	0	5%	-		
Activity 1.4.2	Procure LED FM microscopes	0	0	0	0	0	5%	-		
Activity 1.4.3	0	0	0	0	0	0	5%	-		
Strategy 1.5	Fortify specimen transport and referral mechanisms									
Activity 1.5.1	Improve turn-around time for specimen delivery and reporting of results	0	0	0	0	0	5%	-		
Activity 1.5.2	0	0	0	0	0	0	5%	-		
Activity 1.5.3	0	0	0	0	0	0	5%	-		
Strategy 1.6	Improve Laboratory information and data management systems									
Activity 1.6.1	Improve data management in the TB laboratory network	0	0	0	0	0	5%	-		
Activity 1.6.2	0	0	0	0	0	0	5%	-		
Activity 1.6.3	0	0	0	0	0	0	5%	-		

Assumptions & Setup | Logical Framework | Objective 1 annual budget | Objective 1 detailed budget | Objective 2 annual budget | Objective 2 det

3.2.7 Financial Reports

The final step allows the user to extract various financial reports and the detailed work plan. Where the detailed budget is reported in a currency other than the country local currency, reports can be generated in the local currency.

The reports which can be generated are:

- **Detailed budget and work plan**

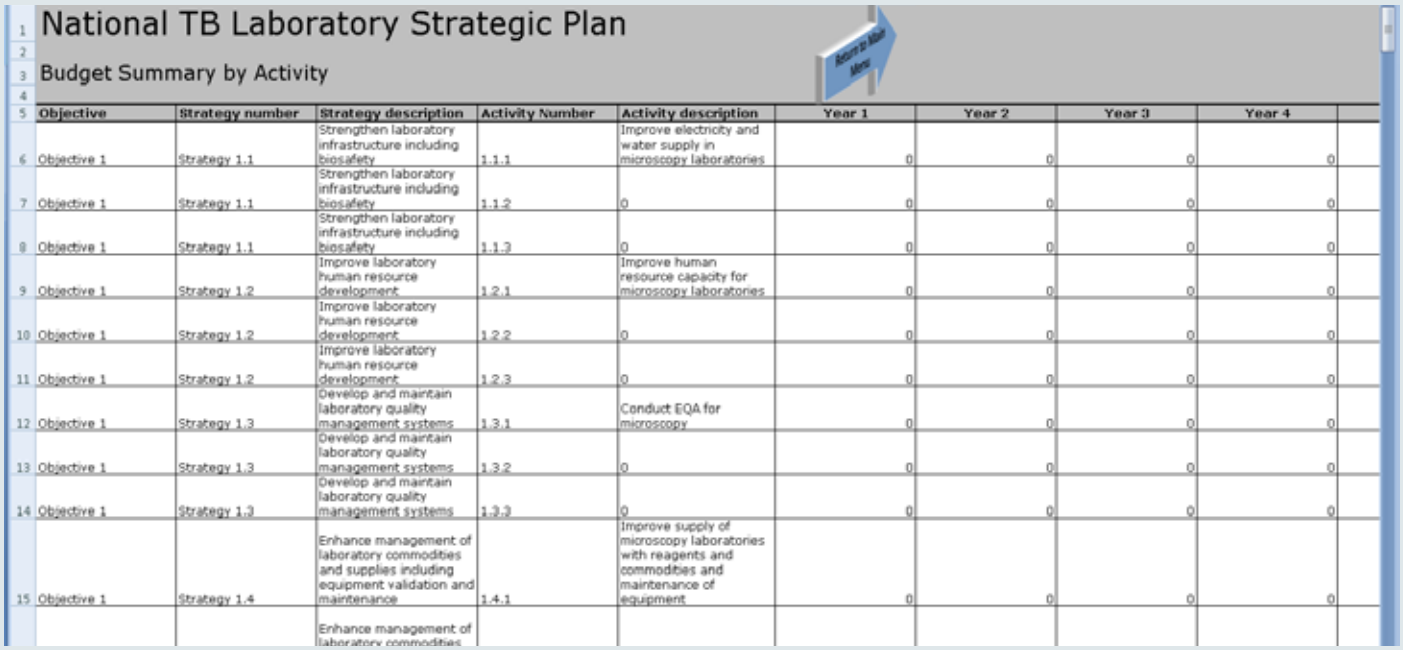
  The detailed budget and work plan shows the master worksheet and all the input cost items for each year, with the first two years by quarter. This report shows all the values and quantities.

- **Unit cost calculations**

  This report shows the calculation of all compound unit costs, but must be generated by the user, as compound costs will differ from entity to entity.

- **Summary Budgets by activity (in reporting and local currencies)**

These reports show a summary of the detailed budget aggregated at activity



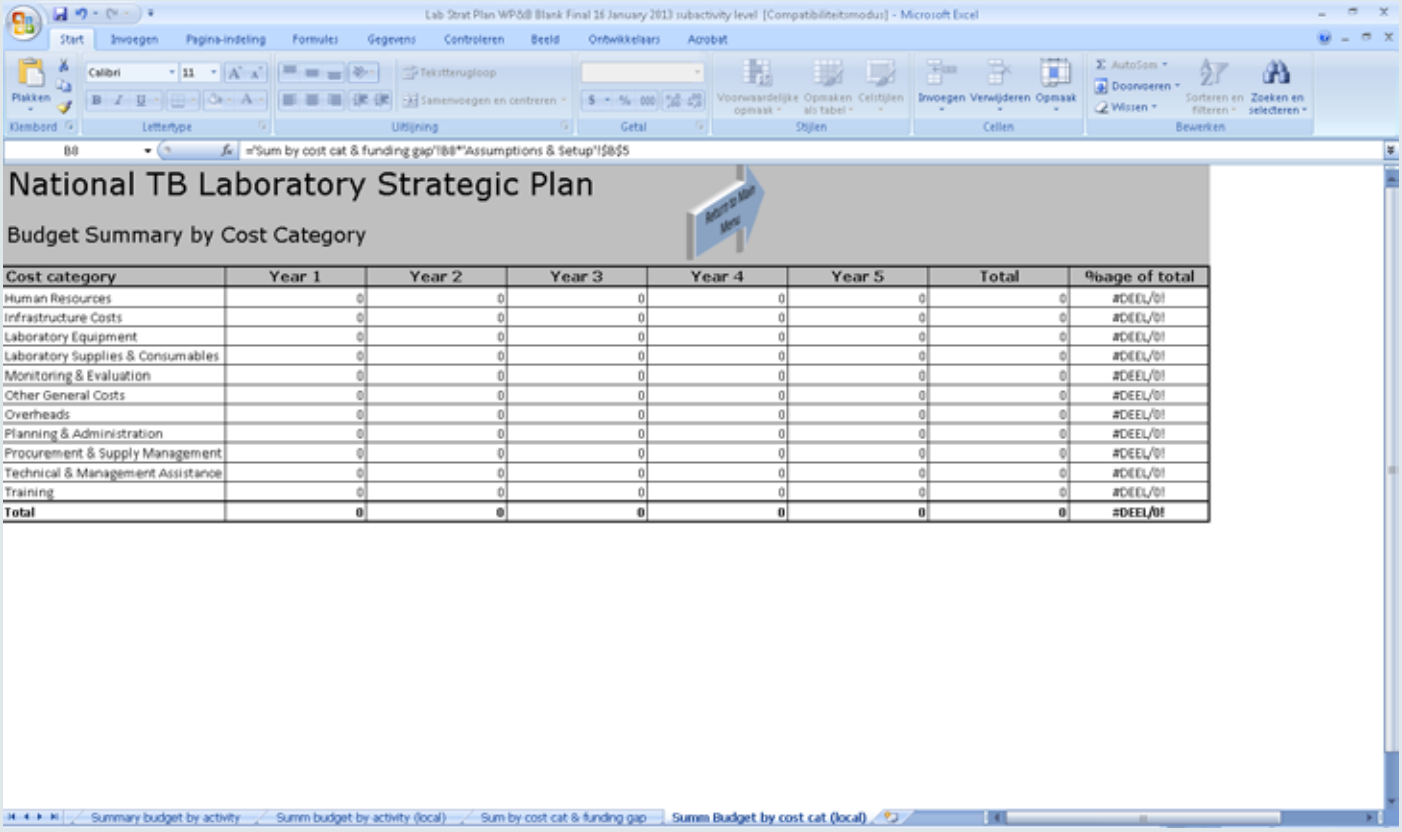
National TB Laboratory Strategic Plan

Budget Summary by Activity

Objective	Strategy number	Strategy description	Activity Number	Activity description	Year 1	Year 2	Year 3	Year 4
Objective 1	Strategy 1.1	Strengthen laboratory infrastructure including biosafety	1.1.1	Improve electricity and water supply in microscopy laboratories	0	0	0	0
Objective 1	Strategy 1.1	Strengthen laboratory infrastructure including biosafety	1.1.2	0	0	0	0	0
Objective 1	Strategy 1.1	Strengthen laboratory infrastructure including biosafety	1.1.3	0	0	0	0	0
Objective 1	Strategy 1.2	Improve laboratory human resource development	1.2.1	Improve human resource capacity for microscopy laboratories	0	0	0	0
Objective 1	Strategy 1.2	Improve laboratory human resource development	1.2.2	0	0	0	0	0
Objective 1	Strategy 1.2	Improve laboratory human resource development	1.2.3	0	0	0	0	0
Objective 1	Strategy 1.3	Develop and maintain laboratory quality management systems	1.3.1	Conduct EQA for microscopy	0	0	0	0
Objective 1	Strategy 1.3	Develop and maintain laboratory quality management systems	1.3.2	0	0	0	0	0
Objective 1	Strategy 1.3	Develop and maintain laboratory quality management systems	1.3.3	0	0	0	0	0
Objective 1	Strategy 1.4	Enhance management of laboratory commodities and supplies including equipment validation and maintenance	1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment	0	0	0	0
		Enhance management of laboratory commodities						

- **Summary Budget by cost category**

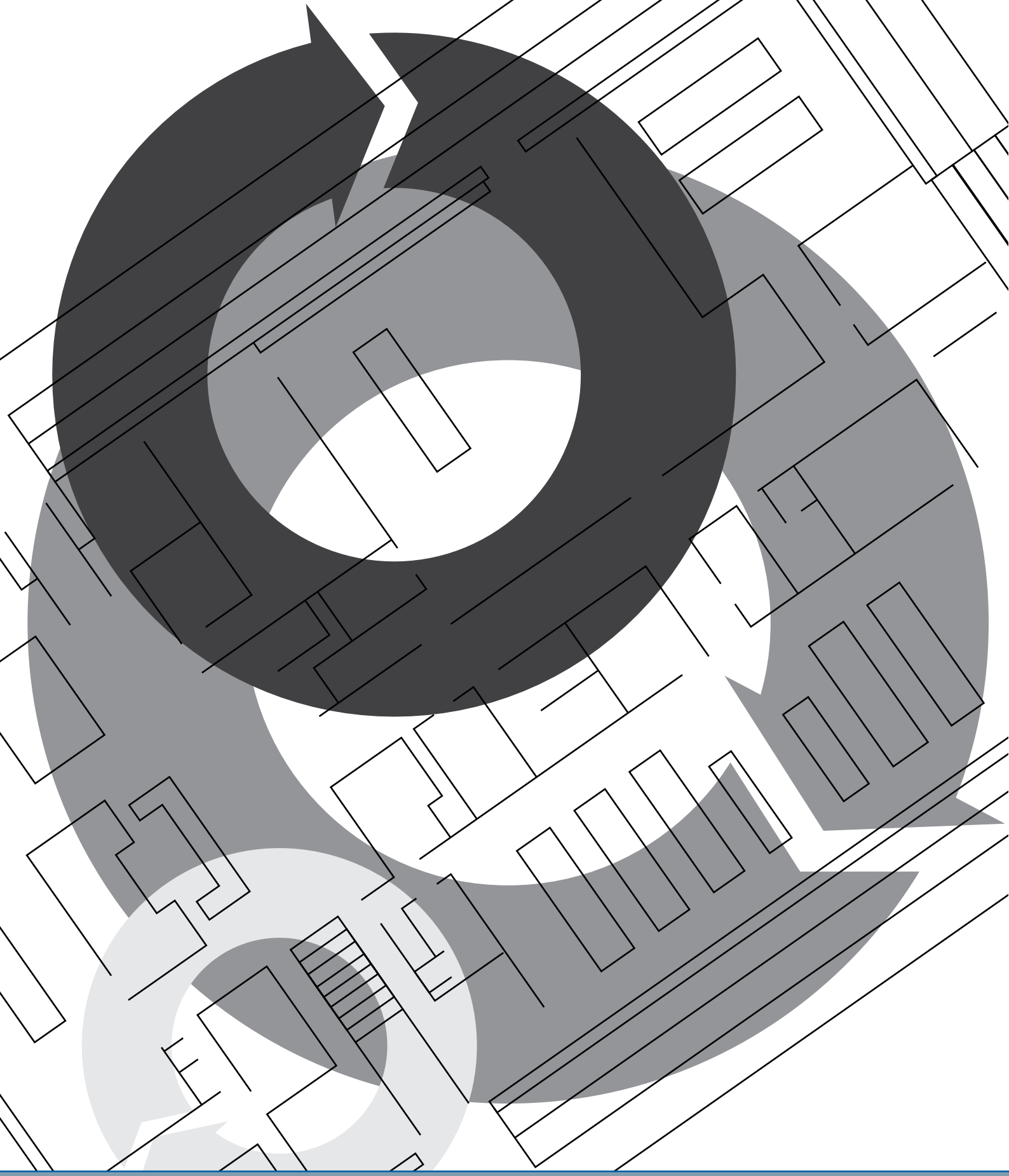
  This report shows a summary of the detailed budget aggregated at cost category level.



National TB Laboratory Strategic Plan

Budget Summary by Cost Category

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5	Total	%age of total
Human Resources	0	0	0	0	0	0	#DEEL/0!
Infrastructure Costs	0	0	0	0	0	0	#DEEL/0!
Laboratory Equipment	0	0	0	0	0	0	#DEEL/0!
Laboratory Supplies & Consumables	0	0	0	0	0	0	#DEEL/0!
Monitoring & Evaluation	0	0	0	0	0	0	#DEEL/0!
Other General Costs	0	0	0	0	0	0	#DEEL/0!
Overheads	0	0	0	0	0	0	#DEEL/0!
Planning & Administration	0	0	0	0	0	0	#DEEL/0!
Procurement & Supply Management	0	0	0	0	0	0	#DEEL/0!
Technical & Management Assistance	0	0	0	0	0	0	#DEEL/0!
Training	0	0	0	0	0	0	#DEEL/0!
Total	**0**	**0**	**0**	**0**	**0**	**0**	**#DEEL/0!**



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