**Terms of References**

**GeneXpert deployment review**

* 1. **Background information**

The End TB Strategy calls for the early diagnosis of TB and universal drug susceptibility testing (DST), highlighting the critical role of laboratories for rapidly and accurately detecting TB and drug resistance. Laboratory confirmation of TB and drug resistance is essential to ensure that individuals with TB are correctly and timely diagnosed and have access to the appropriate treatment as soon as possible. The development of new diagnostic tools such as the Xpert MTB/RIF (Cepheid Inc., Sunnyvale, CA, USA) has changed the diagnostic landscape of tuberculosis (TB) and aided in the diagnosis of TB and MDR TB.

The Xpert MTB/RIF is a cartridge-based rapid tuberculosis (TB) molecular diagnostic tool, which makes use of an GeneXpert machine that can identify the etiologic agent of tuberculosis, Mycobacterium tuberculosis (MTB) DNA and resistance to rifampicin (RIF) by nucleic acid amplification technique with a turn-around time of approximately 2 hours. The use of the rapid molecular test Xpert MTB/RIF continues to expand in line with WHO recommendations for its use since it was endorsed by WHO in  2010 and it has led to the increase  in accurate diagnosis of TB cases (including in pediatrics), as well as an important increase of Rifampicin Resistant -TB cases identified.   Countries have developed guidelines and diagnostic algorithms including Xpert, to support TB and MDR-TB case finding strategies based on disease burden as well as in-country capacities.  Recognizing the potential of this technology, the Global Fund and other partner have invested in GeneXpert machines and/or cartridges to enable and expand its use in countries.

Performing the Xpert assay is relatively simple and involves minimal specimen manipulation. However, there are numerous potential operational and programmatic requirements and challenges associated with the assay. These implementation challenges are both operational and programmatic.  There have been reports that the rollout has been hampered by high costs for underfunded programmes, unavailability of a complete solution package (notably comprehensive training, quality assurance, specimen transport systems, information systems to return results, implementation plans, funding, service and maintenance support, clinical training etc.) and there is a lack of impact assessment. Insufficient focus has been afforded to effective linkages to care of diagnosed patients, and clinical impact has been hampered by weak health systems. This assessment/review aims to provide assurance to the Global Fund that its investment in this technology is having impact and to guide future investment.

* 1. **Implementation information**

1. **Objective:**

The objective of the review is to verify GeneXpert and other rapid molecular tests, culture and DST implementation in [country] with an aim to:

1. Study and review access to GeneXpert instruments’ and other diagnostic tests (LPA, culture and DST) in the country.
2. review the GeneXpert utilization rate and yield for MTB (Mycobacterium tuberculosis and Rifampicin) resistance TB from time of initial deployment to date.
3. Establish the impact of the existing GeneXpert machines on case notification for sensitive, MDR and XDR TB and determine the cost per case identified.
4. Review the sputum transportation mechanism and its implementation in the country.
5. Identify lessons learned on the barriers to expansion/availability of GeneXpert and other rapid molecular tests services.
6. Identify best practices that may improve utilization of existing GeneXpert machines in the country, including health care providers in both public and private sector.
7. Provide recommendations to overcome the challenges identified, to improve the GeneXpert utilization rate within the country and to guide future investment by the Global Fund for impact.
8. Provide recommendations on the need for further expansion of GeneXpert or other rapid molecular diagnosis services within the country.
9. Provide recommendations on the Xpert implementation & scale up plan and any additional aspects that need to be considered/incorporated to accelerate progress towards optimal utilisation of the existing and new Genexpert machines.
10. Review connectivity solution and use of data.
11. **Scope of Work**

This review is expected to be undertaken in the period [specify start and end date] with the final report expected to be submitted to the Global Fund Country Team by [date].

Phase 1 (maximum 2 weeks):

Task 1: Desk Review for the study country

* Desk Review and compilation of existing reports of assessment done and documents on GeneXpert Implementation. Review of WHO country reports, national program reviews, other partner’s reports/assessments and regional specific as well as global published literature etc.)

Task 2: Planning of activity with Global Fund Secretariat staff and country team

* Develop work plan for implementation

Task 3:  Questionnaire development and data collection tools

* Review and adapt questionnaire including country specific questions as required to address the specific objective and the detailed specific objectives of the assessment,  in collaboration with the Global Fund Country Team.
* Develop data collection tool in software that can export data to a spreadsheet
* Adoption/ customization of standard questionnaire and development of data collection electronic tool

The review will be carried out using structured questionnaires (laboratory and clinical) administered to laboratory staff operating the GeneXpert machine for Xpert MTB/RIF and to clinical staff.

* The Clinical site monitoring & evaluation tool Comprehensive site visit assessment can be found at URL <http://www.finddx.org/wp-content/uploads/2016/03/Clinical-Checklist_10-2014.pdf>
* The laboratory questionnaire Laboratory monitoring & evaluation tool Xpert Comprehensive Site Visit Assessment can be found at:
* URL   <http://www.finddx.org/wp-content/uploads/2016/03/Comprehensive-checklist_10-2014.pdf>

Task 4: Sampling

Determine sampling framework based on the most recent and validated national master facility list (MFL) of public and private facilities with exact longitudinal and latitude position. List of facilities that have GeneXpert machines, list of facilities that offer TB diagnosis and treatment, and list of facilities covered by regular transport system should be provided by the planning and health information department and/or the National TB program. Sample methodology and sample size must be chosen to be nationally representative, give a minimum of 95% confidence interval and be focused on Global Fund Investments in GeneXpert machines as far as possible.   The final sampling will be validated by the Country Team.

Phase 2 (maximum 4 weeks)

Task 5: Field visit to finalize the study protocol, review/adapt the questionnaire, recruitment of skilled surveyors, training and piloting of the questionnaire.

Task 6: Field visits for data collection.

The review requires visits to health facilities with data collection based on key informant interviews and observation of key variables.

Task 7: Data entry, analysis, interpretation and report writing

* Enter data using excel or similar software
* Edit, validate and clean data set, checking for consistency, and accuracy
* Export the data set for analysis
* Conduct analyses of data using the standard core variables as well as any country-specific indicators of interest
* Map data
* Draft Report

Task 8: Finalizing the report

* Prepare the final report with detailed recommendations for the Global Fund. The LFA will utilize GIS mapping to collate and synthesize the results of service availability at surveyed sites.
* Agree with the Global Fund Country Team that the latter can share the report with relevant stakeholders in country.
* The LFA is expected to de-brief relevant stakeholders in country on the main findings of the review (as per the [LFA Communication Protocol](https://www.theglobalfund.org/media/3216/lfa_communications_protocol_en.pdf?u=636679305610000000)) as agreed upon with the Global Fund Country Team.
  1. **Expected roles and responsibilities**

Personnel Skills needed

1. Public Health expert with experience in TB programs
2. Medical Laboratory Specialist with experience in TB programs
3. Statistician
4. PSM expert

As part of this review the LFA is expected to consult for information the Directorate of Laboratory Services and the National TB Program (NTP) as well as the local and regional WHO offices, as relevant.

* 1. **Expected Deliverables**

The information and evidence generated from the review would be used by the Global Fund to assess the implementation of GeneXpert MTB/RIF and will be used to inform the current and future planning of Global Fund investments.

Phase 1 deliverables:

* Desk review report
* Draft data collection tool
* Draft study plan including timeline
* Sampling framework

Phase 2 deliverables:

* Final study plan, sampling and questionnaire
* Training of surveyors
* Field work data collection completed
* Data analysis completed
  + Reports including consolidated report with standard indicators included in the final report, as well as a set of clear recommendations, ranked in order of priority, for improving impact of investment in GeneXpert and Xpert cartridges based on the findings.
* Consolidated report with recommendations and dissemination of findings