EXECUTIVE SUMMARY

Prepared by:
Juliana Victor-Ahuchogu
Katie Delisio
Violet Ketani

With input from:
Vance Whitfield
Gavin Macgregor-Skinner

Submitted by:
Cardno Emerging Markets USA, Ltd.

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I. ACKNOWLEDGMENTS

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## II. ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACILT</td>
<td>African Centre for Integrated Laboratory Training</td>
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<tr>
<td>ASM</td>
<td>American Society of Microbiology</td>
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<td>ART</td>
<td>Anti-Retroviral Therapy</td>
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<td>BD</td>
<td>Becton, Dickinson &amp; Company</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CDC P4</td>
<td>Centers for Disease Control and Prevention Public-Private Partnerships in PEPFAR Countries Project</td>
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<td>CD4</td>
<td>Cluster of Differentiation 4</td>
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<tr>
<td>COP</td>
<td>Country Operational Plan</td>
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<td>CPHL</td>
<td>Central Public Health Laboratories</td>
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<td>DBS</td>
<td>Dried Blood Spot Analysis</td>
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<td>DRI</td>
<td>Direct Relief International</td>
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<td>DST</td>
<td>Drug Susceptibility Testing</td>
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<td>EQA</td>
<td>External Quality Assessment</td>
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<tr>
<td>EHNRI</td>
<td>Ethiopian Health and Nutrition Research Institute</td>
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<td>GAP ILB</td>
<td>CDC’s Global AIDS Program International Laboratory Branch</td>
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<td>GIS</td>
<td>Geographical Information Systems</td>
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<td>GLP</td>
<td>Good Laboratory Practices</td>
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<td>GPS</td>
<td>Global Positioning System</td>
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<td>HMIS</td>
<td>Health Management Information Systems</td>
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<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome</td>
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<td>HSSP III</td>
<td>Uganda Health Sector Strategic Plan</td>
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<td>IDI</td>
<td>Uganda Infectious Diseases Institute</td>
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<td>INS</td>
<td>Mozambique National Institute of Health</td>
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<tr>
<td>LIS</td>
<td>Laboratory Information System</td>
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<td>LQM</td>
<td>Laboratory Quality Management</td>
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<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
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<tr>
<td>MDR</td>
<td>Multi Drug Resistant</td>
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<tr>
<td>MISAU</td>
<td>Ministério de Saúde (Mozambique Ministry of Health)</td>
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<td>MOA</td>
<td>Memorandum of Agreement</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>NGO</td>
<td>Non-governmental Organization</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>NHLS</td>
<td>National Health Laboratory Service</td>
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<td>NTRL</td>
<td>National TB Reference Laboratory</td>
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<td>OGAC</td>
<td>Office of the Global AIDS Coordinator</td>
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<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<td>PLP</td>
<td>Planning and Leading Projects</td>
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<td>PPP</td>
<td>Public-Private Partnership</td>
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<td>SLMTA</td>
<td>Strengthening Laboratory Management Towards Accreditation</td>
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<td>SRS</td>
<td>Specimen Referral Systems</td>
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<td>TAT</td>
<td>Turnaround Time</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<td>ToT</td>
<td>Training of Trainers</td>
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<td>TB SRS</td>
<td>TB Specimen Referral System</td>
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<td>UK-NEQAS</td>
<td>United Kingdom National External Quality Assessment Service</td>
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<td>USG</td>
<td>United States Government</td>
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<td>WHO</td>
<td>World Health Organization</td>
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III. EXECUTIVE SUMMARY

Laboratory systems are a critical underpinning of HIV/AIDS and Tuberculosis (TB) prevention, care, and treatment efforts, since they are essential to providing accurate, reliable, and timely diagnosis of disease. Despite their importance, however, laboratory systems have historically been under-recognized and under-funded in global health. Within a few years after the onset of the President’s Emergency Plan for AIDS Relief (PEPFAR), the gaps in laboratory systems and their inability to support the attempted scale of prevention, care, and treatment efforts had become abundantly clear and were seen as an issue which could not be solved by either the public sector or the private sector alone.

Despite their importance, laboratory systems have historically been under-recognized and under-funded in global health. Laboratory systems in many of the countries highly affected by the HIV/AIDS and TB epidemics continue to remain underdeveloped, and this has been an obstacle to achieving prevention, care, and treatment goals in these countries. To address this problem, the U.S. Government (USG) joined forces with Becton, Dickinson and Company (BD), a U.S.-based medical technology company, to pursue the BD-PEPFAR Laboratory Strengthening Public-Private Partnership (PPP).

The objective of the five-year PPP (2007–2012) was to improve laboratory systems in select resource-constrained countries highly burdened by HIV/AIDS and TB. Over time, in-country activities were focused on three countries: Ethiopia, Uganda, and Mozambique. In addition, a total of 16 countries have been reached through joint training programs on TB culture and drug susceptibility testing (DST) provided by BD and Centers for Disease Control and Prevention (CDC) through the African Centre for Integrated Laboratory Training (ACILT) in South Africa.

A. Goals of the BD-PEPFAR Laboratory Strengthening PPP

The original goals of the PPP, as documented in the global MOU between BD and PEPFAR, are presented below. These goals were built from two major pieces of foundational work that BD had previously done. These were

- **Good laboratory practices training.** BD had conducted this training previously in Africa to build laboratory capacity for CD4 testing. Although this partnership could not conduct training in CD4 testing specifically—this would have been a conflict of interest—BD transformed the good laboratory practices (GLP) training into a more general laboratory quality management (LQM) training, which strengthened quality assurance in laboratories for external quality assessment (EQA).

- **BD volunteer program.** After Mr. Cohen returned from a trip to Africa in 2003, BD began a volunteer program to give BD associates the same opportunity to give back by lending their talents to developing countries.

**Goal 1: Improve quality of laboratory diagnostics critical to the management of HIV/AIDS patients**

**Key Objectives:**

- Establish country-specific work plans for five target countries with measurable objectives and achievable milestones along a six-month, one-year, and three-year timeline. First work plan to be delivered in six months, followed by a successive work plan each quarter.

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1 Memorandum of understanding on cooperation in support of laboratory strengthening between the Office of the Global AIDS Coordinator, U.S. Department of State and Becton, Dickinson and Company (2007)
- Develop training plans, activities, and evaluations on LQM in the area of HIV/CD4 testing and TB within nine months, with a plan for assessment and retraining as needed.
- Deploy technical trainers, short-term (two–three weeks) and long-term (three–six months) within 12 months and rotation cycles for the next three years.
- Use core competencies of volunteers to implement under-utilized CD4 testing capacity in Malawi and Mozambique within six months with expansion plans.
- Roll-out training package for HIV rapid tests to two countries in eight months and five countries in 18 months.
- Implement EQA for CD4 testing for five countries in 12 months.
- Improve country laboratory policies in conjunction with laboratory working group partners in line with COPs in four countries over one year.
- Increase number of laboratory training workshops in target countries (number to be determined by working plans).

**GOAL 2: IMPLEMENT SHORT-TERM IMPROVEMENTS IN QUALITY OF EXISTING TB DIAGNOSTIC CAPACITY**

**Key Objectives:**
- Roll-out of training materials and EQA for TB smear microscopy to seven countries in 12 months.
- Increase availability of TB laboratory trainers through collaboration with American Society of Microbiology (ASM).

**GOAL 3: INCREASE ACCESS TO TB CULTURE IN ACCORDANCE WITH NEW WORLD HEALTH ORGANIZATION (WHO) GUIDELINES FOR LIQUID CULTURE USE IN HIV PATIENTS**

**Key Objectives:**
- Develop at least two national TB reference laboratories in high-burden countries to be training facilities for culture and DST in 12 months.
  - First priority is to support the CDC proposal to develop a TB/HIV Regional Laboratory Training Center in South Africa in conjunction with CDC Office of Global Health Field Epidemiology and Laboratory Training Program and the South African National Health Laboratory, the CDC Global AIDS Program International Laboratory Branch (GAP ILB), and TB/HIV Program Team.
  - A second TB reference site (country) will be identified with an implementation plan underway in six months.
- Strengthen capacity for performing liquid TB culture in three sites (countries) highly burdened with HIV/TB co-infection in 18 months.
- Ongoing training, consultation, and mentorship to support national reference laboratories.

When the PPP entered its final year of implementation, the USG (through the Office of the Global AIDS Coordinator (OGAC)) commissioned Cardno to conduct an independent third-party assessment of the PPP. PPPs represent a valuable alternative to traditional funding mechanisms. This executive summary report presents the highlights of the findings and recommendations of the assessment. Cardno mobilized a core team of five staff, whose combined expertise enabled the team to implement a comprehensive assessment of the PPP. The assessment team was led by Juliana Victor-Ahuchogu, a senior M&E expert with 17 years of experience in over 40 countries. Supporting Ms. Victor-Ahuchogu were Dr. Gavin Macgregor-Skinner, consultant in laboratory systems strengthening; Katie Delisio, HIV/AIDS and
Cardno’s assessment utilized both qualitative and quantitative techniques through a combined methodology involving desk reviews, key informant interviews, beneficiary surveys, and site visits to Ethiopia, Uganda, Mozambique, and South Africa. The assessment began in late January 2012 and lasted approximately five months. Cardno hosted a Debrief meeting to present the initial findings to key representatives from OGAC, BD, and CDC. The assessment culminated with a final report to OGAC, CDC and BD.

B. Assessment Goals

1. Document the value added of the partnership in terms of BD and PEPFAR shared goals and objectives, resources leveraged, and the results achieved through the partnership, while recognizing the non-binding nature of the MOU and flexible nature of such program goals and objectives.

2. Characterize and quantify on the basis of existing data the impact of the PPP on the overall delivery of services and the impact on patient testing, diagnosis, and health outcomes.

3. Distill the lessons learned from the PPP and provide recommendations on how these lessons can be transferred for development of new PPPs and strengthening of existing PPPs, including lessons that can be adopted by other private companies interested in supporting similar efforts.

4. Assess potential opportunities for PPP replicability and sustainability and identify new, additive and scaling opportunities, e.g., for diagnosing diseases that are known risk factors for HIV and TB.

The assessment team derived four key questions based on these goals, as summarized in Figure 1.

**Figure 1. Key questions and sub-questions**

<table>
<thead>
<tr>
<th>Key Question 1:</th>
<th>Sub-Questions:</th>
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<tbody>
<tr>
<td>What were the resource inputs, activities, and outputs of supported activities?</td>
<td>■ What was the total value of monetary and in-kind resources that each partner contributed to the partnership?</td>
</tr>
<tr>
<td></td>
<td>■ Have the terms of the partnership been adhered to by the partners?</td>
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<tr>
<td></td>
<td>■ To what extent have the partnership’s original goals and objectives been met?</td>
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<td></td>
<td>■ Did each party deliver what they said they would?</td>
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<tr>
<td></td>
<td>■ Was this partnership essential to meet the objectives and activities?</td>
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<tr>
<td></td>
<td>■ What is the value added of the PPP?</td>
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<thead>
<tr>
<th>Key Question 2:</th>
<th>Sub-Questions:</th>
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<tbody>
<tr>
<td>To what extent has the partnership contributed to improvement in the quality of laboratory diagnostics critical to the management of HIV/AIDS and TB?</td>
<td>■ What are the short- and medium-term health outcomes at the country level?</td>
</tr>
<tr>
<td></td>
<td>■ What is the value added of the partnership in terms of BD and PEPFAR’s shared goals and objectives and resources leveraged?</td>
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<tr>
<td></td>
<td>■ How does the output from the partnership translate into health outcomes?</td>
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| | ■ What were the monitoring and evaluation arrangements, how did they support tracking of program outputs and
Key Question 3: Is the PPP replicable?

Sub-Questions:
- What are the comparative advantages and disadvantages of the BD model of system strengthening vs. other models of private sector system strengthening support? What are some areas of refinement?
- What are the opportunities emanating from the partnership for BD’s future partnerships with PEPFAR?
- What are the lessons from the PPP that can be adopted by other companies?
- What are the critical lessons USG learned from the PPP? How can these be transferred for the development of future PPPs related to lab strengthening?
- Are there any opportunities for replicability of critical inputs and activities to date?

Key Question 4: Is the PPP sustainable in terms of its activities, model, and impact on laboratory systems?

Sub-Questions:
- How sustainable is this particular PPP model?
- How has the PPP contributed to sustainable improvements in laboratory systems?
- How will activities initiated be sustained at the close of the PPP?

C. Assessment Approach and Methodology

Key informant interviews. The assessment team conducted key informant interviews with representatives from BD, CDC/Atlanta, CDC in-country teams, OGAC, MoH representatives, other implementing partners, and managers at participating laboratories. Both BD and CDC were very helpful in introducing the assessment team to key informants and helping coordinate travel dates. The following levels of key informants were interviewed:

- Global level
  - BD executive management
  - BD mid-level managers (presidents and vice presidents/general managers)
  - Representatives from BD’s Global Health Group
  - BD volunteers
  - OGAC representatives,
  - CDC/Atlanta representatives
  - Non-governmental organizations (NGOs) supporting BD work on the PPP at the global and country level (e.g., Accordia Foundation and Direct Relief International (DRI)).

- Country level
  - MoH representatives
  - CDC in-country laboratory directors/advisors and team members
• Other PEPFAR partners
• Managers of participating laboratories
• BD trainees

Country case studies. The assessment team created two country case studies—for Ethiopia and Uganda—to provide a holistic and in-depth look at the PPP value added for those countries. As part of the country case studies, the team assessed work planning processes; the status of MOUs and MOAs between BD and the host government; contributions made to the PPP from stakeholders, including host governments, resources leveraged, implementation successes and challenges, results achieved, including health service delivery outcomes; and lessons learned. Ethiopia and Uganda were selected as the two countries for the case studies based on the assumption that they were where the most critical inputs of the PPP have been made to date.

Assessment of training. The Kirkpatrick Model of Training Evaluation was adapted to the fullest extent possible given available data and utilized for the assessment of the training component of the PPP.

D. Assessment Results

**KEY QUESTION 1: WHAT WERE THE RESOURCE INPUTS, ACTIVITIES, AND OUTPUTS OF SUPPORTED ACTIVITIES?**

BD and PEPFAR (through the CDC) contributed both monetary and in-kind resources to the PPP. BD’s contributions included the labor of staff and volunteers, training supplies, specimen transportation containers, Geographical Information Systems (GIS) software, network/computer equipment, and technical assistance in quality assurance mentorship, Laboratory Quality Management (LQM), specimen referral, data management, GIS, curriculum development, program planning, and leadership and project management. BD’s total monetary and in-kind contributions from the inception of the PPP through the end are estimated to be $6,921,738.

Although there was no mechanism for tracking CDC contributions to the PPP, they are estimated to be as much if not more than the total BD contributions, as annual PEPFAR funding for laboratory system strengthening in the PPP target countries is over $10,000,000 per year. CDC’s contributions were in the form of training-related costs covering host government lab staff training cost (travel, per diem, lodging, and venues) and CDC staff time on PPP activities. CDC country-specific contributions to the PPP have included CDC/Ethiopia support for the Specimen Referral System (SRS), which was over $2,000,000 for 2011; CDC/Mozambique annual laboratory strengthening funding of approximately $4,000,000; and CDC/Uganda major contribution by way of a seconded CDC staff who worked 100% on the PPP. ACILT is fully funded by CDC with an estimated cost of $800,000/year.

The partnership proved to be an effective means of strengthening laboratory diagnostics for TB and HIV in the PEPFAR countries where it was implemented. Since its inception in 2007, the partnership has trained more than 500 healthcare workers in SRS, LQM, TB culture and identification, TB DST, GIS, planning and leading projects, and laboratory strategic planning. The partnership has also filled gaps in infrastructure and equipment such as servers, GIS software, and specimen collection containers.

In Uganda, the partnership’s activities focused on strengthening the national TB Specimen Referral System (TBSRS) and improving quality assurance for Cluster of Differentiation 4 (CD4) testing. The initial goal of the BD-PEPFAR lab PPP in Uganda was to implement an LQM training program. This included training Ugandan trainers so that they could more effectively teach LQM in the regions. The purpose of the training was to build quality assurance skills for laboratory workers sufficiently so the country could effectively roll-out a CD4 EQA program nationally.

To support the Ugandan TB Specimen Referral System, BD helped to establish a Global Information
System/Global Positioning System (GIS/GPS). Prior to the establishment of the GIS program, the identity and locations of many TB microscopy sites were unknown, quality of microscopy site results was unknown, and there was no process for identifying testing, quality, and patient needs. MDR rates, nationally, were unknown. This system has enabled laboratory data to be retrieved, catalogued, and stored on a GIS database, improving quality and access to TB diagnosis and care.

In Ethiopia, the partnership focused on strengthening the Specimen Referral System (SRS). Implementation of BD-PEPFAR Laboratory Strengthening Program activities in Ethiopia began in January 2011. Over a period of one year from January to December 2011, the partnership worked to address issues of incorrect specimen handling and ad hoc, unreliable specimen transportation. In collaboration with the Ministry of Health (MoH)/Ethiopia Health, Nutrition and Research Institute (EHNRI), the partnership worked to pilot a more sustainable model for specimen referral, which utilized the national postal service to transport specimens to and from diagnostic sites. The Ethiopia model was based on the successful TBSRS model which was successfully implemented in Uganda through the support of the PPP.

In Mozambique, the partnership conducted quality management mentorships, World Health Organization (WHO) checklist laboratory assessments, strategic planning facilitation, and project management training and coaching with Ministry of Health (MISAU) personnel, Strengthening Laboratory Management Towards Accreditation (SLMTA) supervisors, and other laboratory system managers.

In South Africa, the partnership contributed to trainings held at ACILT. ACILT was created 3.5 years ago with funding from CDC to provide training to laboratory technicians on new laboratory technology and techniques. To help fulfill a previously unmet need for training in TB diagnostics at ACILT, the PPP delivered nine trainings in TB culture and identification and two trainings in TB DST. PPP-supported courses resulted in marked improvement in participants’ knowledge over time, as demonstrated by pre- and post-test scores

**Key Question 2: To What Extent Has the Partnership Contributed to Improvement in the Quality of Laboratory Diagnostics Critical to the Management of HIV/AIDS and TB?**

The assessment found that the partnership made valuable contributions to strengthening laboratory diagnostics for HIV/AIDS and TB in target countries. Although results from Mozambique, Uganda, and Ethiopia and the support to ACILT were positive, the PPP made its deepest impact in Ethiopia and Uganda. Highlights of key results are summarized below.

**Improved quality of diagnostic testing for better patient monitoring and treatment.** In Uganda, the partnership’s activities focused on strengthening the national TB SRS and improving quality assurance for CD4 testing. The partnership trained 120 Ugandan trainers and laboratory workers (selected from laboratories across Uganda) in Laboratory Quality Management (LQM) for CD4 testing and increased the number of laboratories participating in external quality assessments (EQAs) through the United Kingdom National External Quality Assessment Service (UK-NEQAS) from 43 (2008 baseline) to 96 of 104 laboratories by 2010. The percentage of enrolled laboratories reporting satisfactory results (based on UK-NEQAS standards) increased from 54% (2008) to 72% in 2010. The PPP ensured the quality of CD4 results and ultimately provided access to timely and accurate treatment to people on anti-retroviral therapy (ART). The PPP ensured the quality of CD4 results, ultimately providing access to timely and accurate treatment to people on antiretroviral therapy (ART).

**Decreased TB specimen turnaround time and improved quality of diagnostic testing for TB.** To support the Ugandan TB SRS, the PPP supported the establishment of a GIS/GPS system in collaboration with local stakeholders to identify and characterize TB site and specimen data. Smear positive sputum samples are referred from health facilities via Posta Uganda (local postal service system) to the National TB Reference Laboratory (NTRL) for culture and drug susceptibility testing (DST) for TB. This led to more specimens being referred to NTRL, ultimately enabling the national TB program to map out cases
of multi drug-resistant (MDR) TB across the country, which in turn led to the finding that 14% of Uganda’s retreatment TB cases have multi-drug resistant (MDR) TB, a much higher rate than the previously reported rate of 4.4%² among previously treated TB cases (2007).

Uganda’s TBSRS is now seen as an international model and has received World Bank and WHO recognition. Before the start of the PPP, from September to December 2008, 153 specimens were referred to NTRL; during 2009, 882 samples were referred, and the number surged to 1344 in 2011. The support for GIS/GPS also contributed to a reduction in specimen turnaround time (TAT) for TB testing from three weeks at baseline (2008) to three days by 2010. Uganda, armed with improved epidemiological data on the geographical distribution and scale of MDR-TB, is now better prepared to address the issue of MDR TB.

Increased capacity for specimen referral system in Ethiopia. The primary goal of the BD-PEPFAR lab PPP in Ethiopia was to facilitate the country’s implementation of a national integrated specimen referral system (SRS) for laboratory and postal workers. Implementation of BD-PEPFAR Laboratory Strengthening Program activities in Ethiopia began in January 2011. Over a period of one year from January to December 2011, BD—in collaboration with other PPP partners—implemented a central pilot training in Addis Ababa, regional trainings in Bahir Dar, Adama, and Awassa, and conducted a national training for regional trainers (selected from nine out of 11 regions in Adama). The partnership trained 293 Ethiopian laboratory and postal workers in specimen referral, handling, and transportation. Additionally, 554 health facilities (including health centers and hospitals) have been linked to next reference laboratories capable of performing advanced diagnostic tests. DBS for early infant diagnosis of HIV is being referred from many facilities all over the country to eight diagnostic centers (regional and national reference laboratories). Improvements to SRS enhanced access to laboratory diagnostics, decreased TAT, and decreased the number of specimen rejected for testing.

Improved specimen TAT and quality in Ethiopia. The improved SRS has enhanced access to laboratory diagnostics, decreased TAT for collecting specimens and reporting results, and decreased number of specimens rejected for testing. Laboratory technicians believe that the stronger specimen transportation and reporting system and some operational funding have enabled them to undertake their functions more effectively and that this has increased their credibility with the communities they serve. This has also strengthened working relationships between health care workers and laboratory staff.

Patients coming back to public health clinics. In Ethiopia, as a result of the improvements in the SRS, patients are now more confident that their laboratory results will be turned around more reliably and more quickly. Public health officials have reported that patients who had stopped coming to public health facilities are now coming back. This is a great success for Ethiopia’s public health system, and its improved reputation will pave the way for it to serve more of the local population.

Improved evidence-based health programming. GIS database enables lab system managers to monitor laboratory quality improvements and referral processes to mapped sites on an individual basis. Based on the success of the GIS/GPS program for TB in Uganda, the partnership trained 21 EHNRI staff in GIS/GPS mapping, with the objective of enhancing specimen referral and diagnostics in Ethiopia. Although it is still too early to document the effect of the GIS support on the SRS program in Ethiopia, the training provided EHNRI with software and the ability to create maps and visualize epidemiology data.

This has illuminated new discoveries about the geographical distribution of malaria in Ethiopia. A powerful example of this occurred when BD-PEPFAR volunteers mapped the burden of malaria cases across the country and superimposed it on a map of the country’s railroad tracks. Although the purpose of

the exercise was simply to show how one data set could be overlaid on another, Ethiopian stakeholders immediately recognized what the data was showing them: Most of the country’s malaria cases were clustered around railroad tracks. The Ethiopian government is using discoveries such as this to serve as a basis for evidence-based health programming and revised funding allocations to different regions.

**Increased human resource capacity for TB diagnostics.** The partnership contributed to the ACILT TB training program. ACILT was created 3.5 years ago with funding from CDC to provide training to laboratory technicians on new laboratory technology and techniques. Since 2008, the PPP has co-delivered nine trainings in TB culture and identification to a total of 130 participants, two trainings in TB Drug Susceptibility to a total of 12 participants, and one training in National Laboratory Strategic Planning to eight participants, representing a total of 16 countries, predominantly in the African and Latin American/Caribbean regions. Participants achieved improvement from pre-test to post-test (by varying degrees); however, linkages to improved laboratory practices are difficult to concretize due to lack of evaluation data at the ACILT level.

**KEY QUESTION 3: IS THE PPP REPLICABLE?**

The assessment found that there is potential for replicating components of the PPP. The SRS work support in Ethiopia is viewed as one of the most successful components of the PPP, and the model piloted (i.e., utilizing the national postal service to transport specimens to and from diagnostic facilities) could be replicated in countries that have the foundational elements of this system, including a national postal service and a government entity to champion the effort. Additionally, the PPP could help replicate the success of Uganda’s TB SRS through support for regional or sub-regional training on GIS/GPS mapping for TB SRS, in collaboration with the Ugandan National TB Reference Laboratory.

BD and PEPFAR could also explore cross-fertilization opportunities in other countries to leverage BD’s experience with other PEPFAR-BD PPPs. For instance, BD’s work with the Phlebotomy PPP in Kenya could be leveraged to support the expansion of the Laboratory Strengthening PPP into Kenya; however, due diligence should be done to ensure that an enabling environment is in place, that there is a demonstrated need for the PPP’s services, and buy-in from the Ministry of Health (MoH) and CDC in-country team. Similarly, the Laboratory Strengthening PPP could leverage the successes of the Phlebotomy PPP to support blood safety activities in Mozambique and Uganda.

**KEY QUESTION 4: IS THE PPP SUSTAINABLE IN TERMS OF ITS ACTIVITIES, MODEL, AND IMPACT ON LABORATORY SYSTEMS?**

The PPP achieved varying degrees of sustainability in its target countries.

In Ethiopia, the PPP laid a solid foundation for achieving scale and sustainability in its SRS and GIS work. Achieving full-scale sustainability is highly possible but wholly dependent on an assured source of funding for training and operational activities in addition to the existing commitments by PEPFAR, BD, and the Ethiopian Government. The GIS program is building sustainable human capacity at EHNRI by training and mentoring staff on integrating and mapping epidemiological data so that they no longer need to rely on external organizations to perform this function. There is a high degree of country ownership for these activities in Ethiopia—more so than for PPP activities in any other country—and this is essential to sustainability. Involving and maintaining local stakeholders in BD training and technical assistance teams (from start to finish) will further enhance country ownership and country leadership and buy-in, while providing local troubling-shooting experts who can be drawn upon by the government and local partners as the SRS system evolves.

In Uganda, the TB SRS is widely regarded as successful, and the GIS activity has been instrumental to this success. There are further steps needed to ensure the sustainability of these activities, including additional GPS machines at NTRL and refresher trainings in TB quantitative data analysis. The LQM
support component of the PPP program lost momentum due to the departure of the CDC technical advisor seconded to the Central Public Health Laboratories (CPHL). To regain momentum, there is need for BD to rebuild trust with the government and all local stakeholders. The PPP must also improve coordination and communication structures within its own country team and with local partners to ensure that working relationships remain intact.

In Mozambique, the audit program that began in March 2012 is viewed as very valuable and provides opportunity for larger scale support to Mozambique. At the time of the assessment, discussions were ongoing on processes and mechanisms for supporting trained auditors in continuing audit activities in order to support the process of accreditation. Supervision and follow-up of training is a critical next step, essential for sustainability. The PPP is not encouraged to further pursue Planning and Leading Projects (PLP) trainings, as this area is not considered to be its comparative advantage.

For ACILT, the assessment found that while the PPP contributed to filling the unmet need for trainings in TB diagnosis, the demand for these trainings continues to far outweigh the supply. One solution for expanding the number of people reached through ACILT TB trainings would be to adopt a training of trainers (ToT) approach. In this model, upon certification by ACILT, representatives of each participating country could be trained as “master trainers” to deliver training to laboratory staff in their home country. This would be an important step to achieving scale and sustainability.

**Critical Success Factors**

The partnership was built on the core competencies of each partner. BD brought its expertise in laboratory diagnostics and technologies, committed staff with a wide range of cutting-edge skills who possessed a true motivation to serve, state-of-the-art training tools for LQM, SRS, and TB culture and DST. CDC brought its expertise in laboratory diagnostics and public health as well as its in-depth knowledge of the country context in PPP focus countries. Additionally, CDC, as a trusted partner of MoH in each country, gave BD access to these ministries and other key local partners. BD on its own would not have had such access.

The PPP was built around existing gaps in laboratory systems strengthening programs based on National Laboratory Strategic Plans and Country Operational Plans (COP). In addition, the partnership, for the most part, followed an excellent country-focused work plan/scope development process, with country-level priorities driving the PPP’s scope of work.

**E. Recommendations and Lessons Learned**

The assessment generated valuable findings on which to build recommendations for the next phase of the PPP, as well as specific recommendations for Office OGAC, CDC, and BD.

**PPP Model, Scope, and Sustainability Considerations**

The assessment illuminated several options for the PPP’s scope in its next phase. One option would be for the PPP to continue its most successful and essential activities in each of the countries where it is currently operating so as to maximize impact and sustainability of this subset of activities. If this option is chosen, the subset of activities to be continued should be jointly determined at the country level with BD, CDC in country, MoH, and other key stakeholders and facilitated by CDC in country.

Another option would be for the PPP to take a component that worked very well, specimen referral system strengthening, and replicate it in other countries. All options should be considered with an eye toward impact, sustainability, and feasibility. The assessment found that the PPP model is not appropriate for every situation or public health problem; the challenge is to first discern where PPPs are appropriate and then have the PPP focus on those areas.
Another scope-related consideration was whether the PPP in its next phase should aim for depth (limiting its work to a small set of countries so as to maximize results) or breadth (reaching as many countries as possible with limited interventions in each). The assessment posits that the PPP should aim for depth rather than breadth by focusing mainly on the countries where it is currently implemented. However, depending on the level of work to be done in each of those countries and the level of available resources, BD and PEPFAR could explore cross-fertilization opportunities in other countries that leverage BD’s experience with other PPPs. For instance, BD’s great work with the Phlebotomy PPP in Kenya could be leveraged to support the expansion of the Laboratory Strengthening PPP into Kenya. Similarly, the Laboratory Strengthening PPP could leverage the successes of the Phlebotomy PPP to begin blood safety activities in Mozambique and Uganda.

In transitioning to the second phase of the PPP, the assessors recommend closing out the PPP in a clear manner after its first five years are over, then forming a new PPP with a new Memorandum of Understanding (MOU). This PPP should build on the experience to date, but it should set new goals and make a fresh start. It should follow the same timeframe as the previous MOU, with a three-year base period and a two-year option period.

**Operationalizing the MOU and PPP terms of engagement.** One of the assessment’s major findings is that terms of engagement for BD and CDC were never completely developed or operationalized, leading to confusion at the country level in several instances. The assessment team recommends a multi-step procedure for operationalizing these terms of engagement and the rest of the MOU (as presented in the report). Lack of monitoring and evaluation arrangements and a mechanism for tracking matching funds are serious challenges that need to be rectified in the next phase of the PPP.

**Conclusions and overall recommendations.** The assessment found that the PPP met and exceeded its goals and objectives. The PPP’s activities evolved from what was originally laid out in MOU to respond to the needs of each country. This did not detract from meeting the goals in the MOU; rather, it strengthened the PPP’s ability to achieve the goals because it was more responsive to country needs. BD and CDC fulfilled their roles and responsibilities, as broadly defined by the MOU.

Below is a summary of the assessment team’s overall high-level programmatic recommendations for the PPP.

- The next phase of the PPP should aim for depth rather than breadth. The PPP should take a deep dive in existing countries to maximize impact rather than going into several countries with limited activities.
- The MOU and the terms of the engagement should be operationalized through the creation of an “Operational Plan” governing stakeholder interactions, coordination and communication structures, and decision-making processes, among other important factors. A mechanism for USG matching funds should be established, and USG contributions to the PPP should be tracked.
- OGAC, CDC, and BD should form consensus around the PPP’s scope, determining, for instance, whether the PPP’s most successful activities in each country should be continued or whether the PPP should take its most successful components and replicate it in other countries.
- If resources are available, the PPP should explore cross-fertilization opportunities in other countries that leverage BD’s experience with other PPPs.
- The PPP should not pursue MOAs in country; joint work planning is sufficient.
- The PPP should put in place the necessary systems to implement the Kirkpatrick model of training evaluations. An important piece of this is conducting post-training assessments to evaluate how participants have applied what they learned to their jobs.
- The partnership should find ways to reduce the number of volunteers sent to host countries and increase the length of assignments. If this is impossible due to business constraints, an alternative
volunteer model should be considered. One potential option would be for BD to create a fellowship program that draws upon recent graduates from doctoral programs.

■ Volunteers traveling to help implement the PPP should be more thoroughly briefed on the country context, including local partners doing similar or complementary work.

■ BD should connect its volunteer experience to improving research and development (R&D) efforts at the company.

■ It is critical for BD to fully engage with CDC in-country teams as a partner throughout the implementation of the PPP.

■ CDC/Atlanta must strengthen the role of CDC teams in country in the PPP. Ideally, CDC in-country teams should facilitate joint work planning with MoH, BD, and other key stakeholders on a yearly basis; should have stronger engagement in the implementation and monitoring and evaluation (M&E) of the PPP; should be in the driver’s seat in terms of relating to local stakeholders; and should be briefed by CDC/Atlanta on their roles and responsibilities.
**ANNEX 1: KEY CONTACTS**

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<th>Name</th>
<th>Title</th>
<th>Organization</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renee Saunders</td>
<td>Project Officer/Senior Public Health Advisor</td>
<td>CDC/Atlanta Center for Global Health/Division of Global HIV/AIDS</td>
<td><a href="mailto:rjs4@cdc.gov">rjs4@cdc.gov</a></td>
</tr>
<tr>
<td>Dr. Ritu Shrivastava</td>
<td>Senior Service Fellow</td>
<td>CDC/Atlanta International Laboratory Branch</td>
<td><a href="mailto:zni4@cdc.gov">zni4@cdc.gov</a></td>
</tr>
<tr>
<td>Renuka Gadde</td>
<td>Vice President, Global Health</td>
<td>Becton, Dickinson and Company</td>
<td><a href="mailto:Renuka_Gadde@bd.com">Renuka_Gadde@bd.com</a></td>
</tr>
<tr>
<td>Ophelia McMurray</td>
<td>Project Director, CDC’s PPPs in PEPFAR Countries Project</td>
<td>Cardno USA, Ltd.</td>
<td><a href="mailto:Ophelia.Mcmurray@cardnoem.com">Ophelia.Mcmurray@cardnoem.com</a></td>
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