PROJECT INFORMATION DOCUMENT (PID) 
APPRAISAL STAGE 

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<th>Project Name</th>
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1. Country and Sector Background

Key Development Issues

Public health threats

1. The Africa region is ill prepared to deal with regional and global public health threats. Rampant poverty and the search for new economic opportunities combined with political instability in some countries has resulted in high levels of migration, refugee movements across porous borders, and an elevated threat of communicable disease outbreaks (e.g. cholera, meningitis). The emergence of drug
resistant strains of TB also raises serious public health concerns given the risk of cross border and global transmission. Finally, the region faces new threats from emerging global epidemics (e.g. H1N1 influenza).

Weak and poorly networked public health laboratories

2. **Laboratories are the weakest link in health systems in the region, seriously hindering governments’ ability to confirm and respond in a coordinated manner to disease outbreaks.** An efficient public health laboratory system is critical for: (i) supporting integrated disease surveillance; (ii) complying with international health regulations; and (iii) conducting clinical diagnosis, guiding treatment, and managing the spread of drug resistance (e.g. TB, malaria). Lack of access to accurate lab services hinders a timely response to outbreaks, and results in inaccurate testing and misdiagnosis, which in turn leads to higher costs and compromised patient care.\(^1\) In many cases diagnosis based on clinical symptoms alone leads to inappropriate treatment, increased morbidity, and unnecessary loss of life.

3. **Well functioning laboratories with modern diagnostic technology are also critical for the timely diagnosis of drug-resistant TB, particularly for people living with HIV/AIDS.** Liquid culture, drug susceptibility testing, and molecular diagnostics are at the cutting edge of the battle to safeguard the regional and global public good of controlling the spread of drug resistance. Regional capacity to conduct drug susceptibility testing and drug resistance surveys is very limited. Putting in place such capacity for TB is expected to have benefits for other communicable diseases which require the same skills and technology. Currently there is only one regional reference laboratory in sub-Saharan Africa which cannot respond to the demand from countries for conducting external quality assurance, drug resistance surveillance, and training. Furthermore, most countries have limited or no capacity to diagnose HIV related tuberculosis which requires more efficacious diagnostic techniques (e.g. liquid culture).

4. **Effective laboratory networks are essential in the provision of public health goods.** Networking is critical for: (i) sharing timely information across countries, and (ii) contributing to joint investigations of disease outbreaks. Networks can ensure that capacity to diagnose diseases, identify public health threats, and conduct surveillance is done more effectively. Networks also serve as effective platforms for learning and knowledge sharing. TB control programs have been pioneers in promoting tiered networks of laboratories providing a continuum of quality assured services and hence provide a good entry point for broader lab strengthening. While all participating countries have relatively good national networks of microscopy centers supported by governments and partners, regional networking remains poorly developed.

Regional mechanisms

5. **A coordinated regional approach is critical for activities which have high positive externalities with benefits accruing across borders, where individual countries may not have the incentives and resources to invest.** Given inherent market failures a regional approach to communicable diseases is critical to delivering public goods. Any country that strives to control or eliminate a communicable

\(^1\) For example, in Botswana one study found evidence of TB infection in only 52 percent of patients suspected with TB (Petti, C., et. al., Laboratory Medicine in Africa: A Barrier to Effective Health Care, Laboratory Medicine in Africa, Clinical Infectious Diseases, 2006).
disease without engaging its neighbors is unlikely to attain or sustain its efforts. As demonstrated by successes in eradicating small pox and progress in elimination of Onchocerciasis and polio, collective regional action is needed to complement national disease control efforts.

6. **Collective action at the regional level hinges on country capacities.** Hence, regional action needs to be viewed in the context of nationally led efforts whereby governments: (i) adhere to a negotiated set of norms and standards; (ii) strengthen their capacity for disease control, including surveillance, prevention, and treatment; and (iii) engage in regional or international dialogue, planning and information sharing. As illustrated by the example of disease surveillance, national efforts are critical but insufficient.²

7. **There is strong ownership at the national and regional levels to adopt a coordinated approach and governments have made important international commitments.** Historically, there has been long standing regional collaboration on public health issues in East Africa. Since independence a number of important regional institutions have been established and are engaged in regional disease control activities. Virtually all African countries have signed the 2005 International Health Regulations (IHR), committing them to early identification of public health emergencies of international concern but progress remains slow ³ In order for the IHR to be fully effective, countries are required to put in place core surveillance and response capacities by June 2012.

8. **There is an urgent need to demonstrate the operational feasibility of regional approaches to improving access to critical services for vulnerable populations, such as migrants, and rural dwellers in cross border areas.** Building effective networks of practitioners, establishing a sub-regional lab network, and developing cross border activities for the delivery of public goods are essential to containing the spread of diseases and promoting regional and global public health security. There are also important economies of scale in the adoption of a regional approach, and diseconomies in carrying out the same activities country by country.

2. **Objectives**

9. The development objective of the project is to establish a network of efficient, high quality, accessible public health laboratories for the diagnosis and surveillance of TB and other communicable diseases. To this end, the project will: (i) strengthen capacity to rapidly diagnose communicable diseases of public health importance and share information to mount an effective regional response (Component I); (ii) conduct joint training and capacity building to expand the pool of qualified laboratory technicians (Component II); and (iii) carry out joint operational research and promote knowledge sharing to enhance the evidence base for these investments (Component III). These activities are consistent with the broader health policy documents of participating countries. They are also complementary to activities funded by

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² If, for example, one country is unable to collect data and identify a disease outbreak, this places other countries at risk of importing disease resistant parasites or disease vectors and of mounting a timely and effective response. By contrast, countries with enhanced surveillance and drug resistance monitoring capacities will be better positioned to provide timely disease outbreak information at regional and global levels.

³ The International Health Regulations 2005 (IHR 2005) which came into force on June 15, 2007 is the new legal framework that was adopted by WHO member states to ensure maximum protection against the international spread of infectious diseases while minimizing restrictions on travel and trade.
other partners who will be collaborating on establishing the lab network, including accreditation and technical training.

10. Following broad based consultations, the four countries have agreed to function as a community of practitioners by promoting cross country learning. The countries will provide regional leadership in thematic areas where each has a comparative advantage and would serve as a center of excellence, as follows:

- **KENYA: Integrated Disease Surveillance and Response**: Building on its relatively strong IDSR system Kenya will serve as a center of excellence for disease surveillance. It will lead the development of harmonized tools; promote cross border surveillance and joint outbreak investigations; share lessons from the successful field epidemiology fellowship program and offer training programs to build regional surveillance capacities.

- **UGANDA: Lab networking and accreditation**: Uganda will provide leadership in establishing the East Africa public health regional lab network which will involve: (i) development of common standards; (ii) standardization of quality assurance systems; (iii) introduction of peer review mechanisms; (iv) establishment of a Regional Accreditation Body; and (v) application of the WHO Step-wise Accreditation process to accredit all laboratories in the proposed network to progressively meet the international gold standard certification with clearly defined parameters for turnaround time, quality, and proficiency.

- **TANZANIA: Training and capacity building**: Tanzania will provide high quality training in laboratory techniques at its new state of the art Quality Assurance Training facility and at the Muhimbili University of Health and Allied Sciences. Tanzania will use a phased approach: (i) initially offering short term courses; (ii) sharing training curricula and programs with other countries; (iii) providing technical assistance to other countries to develop continuing education programs; and (iv) developing e-learning approaches for distance learning.

- **RWANDA: Information and communication Technologies (ICT), Performance Based Financing (PBF), Multidrug Resistant Tuberculosis (MDR-TB)**: Rwanda has proposed to take a regional lead in expanding use of ICT and promoting PBF approaches for lab services, building on its well recognized successes in these areas. It will: (i) share its tools (e.g. standards and guidelines, reporting forms, request for proposals); (ii) provide related training, capacity building, and technical support as well as organize site visits; (iii) take a lead in determining the applicability of the PBF approach to public health laboratories and document and share lessons. Rwanda has been selected by KNCV (Dutch TB Foundation) as a center of excellence for MDR-TB for the Africa region and will also share lessons in this area.

3. **Rationale for Bank Involvement**

11. *In light of the institutional focus on global public goods, the Bank is well placed to tackle the regional dimensions of communicable disease prevention and control.* All criteria set out in the global public goods framework for Bank engagement are met⁴:

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• **There is an international consensus that global action is required.** There is strong demand from countries, as reflected in the 2008 Maputo Declaration on Strengthening of Laboratory Systems and in the 59th meeting of African Ministers of Health which called for strengthening public health laboratories, and tackling the spread of drug resistance to AIDS, TB, and malaria. There is a call for public health action, as TB was declared a global public health emergency in 2005. There are international commitments to establish integrated disease surveillance systems (IDSR) and to alert neighboring countries of disease outbreaks (IHR). The project represents an important contribution towards meeting these commitments and building public health capacity.

• **There are critical regional gaps that are not always adequately addressed.** While the Global Fund to Fight AIDS, TB and Malaria (GFATM) and bilateral donors finance primarily disease specific and country-focused investments, the Bank is better placed to tackle regional public health challenges. Despite an increase in health funding, gaps persist in many countries.  

• **The Bank has the capabilities and resources to be effective,** as it has a growing body of experience with regional investments and with innovative reforms. The Bank’s ability to broker partnerships with regional institutions has facilitated the design of this project. The Bank’s expertise in supporting innovations, such as performance contracting can be brought to bear to attract and retain high quality laboratory personnel.

• **The Bank can provide flexible financing to tackle both health systems and communicable disease challenges,** in line with the 2007 Health, Nutrition and Population Strategy. Recognizing ongoing risks of communicable disease pandemics the Bank has a unique opportunity to assist African countries to prepare for such emergencies rather than react when outbreaks arise. The proposal to establish a robust, responsive, and quality-assured network of laboratories is part of the Africa region TB control strategy which was endorsed by senior management.

12. **The project is fully in line with the Regional Integration Strategy (2008-2012) and the Africa Action Plan.** The project fits under Pillar III (Coordinated Interventions to provide Regional Public Goods), to the extent that it will: (i) bolster capacities to track communicable diseases using harmonized policies, strategies, and protocols; (ii) share high quality and reliable information; and (iii) promote coordinated cross-country responses.

13. **The proposed project will contribute to improving health outcomes in participating countries and the sub-region.** It will contribute to the achievement of Millennium Development Goal 6 (Combat HIV/AIDS, malaria and other diseases), and more specifically to the global targets to “reduce the prevalence and death rates associated with TB” and to increase the “proportion of TB cases detected and cured”. It will also contribute to poverty reduction (MDG1) as the poor are disproportionately affected by communicable diseases.

14. **At the regional level, the project provides a vehicle for implementing key disease control strategic priorities of regional institutions.** The East African Community (EAC) partner states (Burundi, Kenya, Rwanda, Tanzania, and Uganda) are fully committed to utilizing a regional approach, as highlighted in their 2007-2012 Regional Plan for Prevention and Control of Human and Animal trans-boundary Diseases. The East, Central, and Southern Health Community (ECSA) has a strategic focus

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which is closely linked to the proposed project, a sound track record, and a long history of receiving funds from member states since its establishment in the mid 1970s. Both institutions have activities to combat cross-border diseases, and to standardize and harmonize quality assurance of laboratories, which will be supported under the project.

15. **The objectives and rationale fit in well with the human development strategies in the Country Assistance Strategies of participating countries.** The Bank’s strategy in Tanzania is to focus on improving technical efficiency in health care, expanding capacity to respond to regional and global epidemics, and promoting partnerships. The Human Development objectives of the Kenya CAS are related to governance and system-building in the health sector and control of HIV/AIDS. The regional operation fits in well with these overall themes, as enhanced diagnostic capacity would aid in the care of TB/HIV+ patients and support the broader goal of comprehensive HIV/AIDS care. The Joint Assistance Strategy for Uganda promotes regional integration. Reducing the burden of TB and improving service delivery through a sector wide approach are some of the key goals of the JAS. The Rwanda CAS seeks to sustain benefits gained under the PRSPs and provide support for strengthening health systems to reduce social vulnerability among the poor.

16. **The proposed project is also in line with the Africa Regional Communicable Disease Control and Preparedness Strategy which lays out the rationale for regional action and proposes a three-pronged approach:** (i) strengthening regional institutions for cross-border and inter-country collaboration; (ii) developing regional capacity for integrated multi-disease surveillance and response; and (iii) bolstering regional capacity to provide high quality lab services to support diagnosis of infectious diseases. The strategy envisions the development of several sub-regional projects with each targeting a distinct geographical area to respond to different epidemiological patterns. The proposed project targeting East Africa is the first under the strategy. The countries to participate are Kenya, Rwanda, Tanzania and Uganda. Burundi, the other EAC member state, may join this regional program in the future, once core health systems issues are addressed. Countries were selected based on: (a) commitment to a coordinated regional approach; (b) geographical proximity which will facilitate cross border activities; (c) clear policy framework which outlines the country’s commitment to strengthening laboratory systems and communicable disease control; and (d) disease burden.

4. **Description**

The project includes three mutually reinforcing components:

**Component I: Regional Diagnostic and Surveillance Capacity (US$40.4 million)**

17. The first component will provide targeted support to create and render functional the sub-regional laboratory network. Uganda, working in close collaboration with ECSA and under the guidance of the proposed Regional Advisory Panel\(^6\) will lead the establishment of the network. The network aims to: (a) *enhance access to diagnostic services for vulnerable groups* to contain the spread of diseases in cross border areas; (b) *improve capacity to provide specialized diagnostic services* and conduct drug resistance monitoring at regional level; (c) *contribute to disease surveillance and emergency preparedness efforts*

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\(^6\) The Regional Advisory Panel will provide oversight to inter-country learning and facilitate lessons drawing, as discussed in Annex 6.
through the availability of timely lab data to provide early warning of public health events; and (d) serve as a platform for conducting training and research. Priority attention will be given to networking labs that serve cross border and migrant populations, and those that provide specialized diagnostic services. The network will thus include: (i) satellite laboratories in cross border areas across the four countries; and (ii) central public health laboratories.

18. **Diagnostic Services for Vulnerable Populations in Cross Border Areas** (US$20 million) The project will support about five satellite laboratories in each of the participating countries. These labs are typically based at regional hospitals in strategic cross border areas and/or in densely populated peri-urban areas where poverty is rampant and slum conditions serve as a breeding ground for the spread of diseases. Each country has carefully selected these sites based on the following criteria: (i) hospitals which are located in high transmission areas with large numbers of migrants or refugees; (ii) regional hospitals which can serve as centers of excellence for conducting training and research; and (iii) commitment to collaborate and coordinate efforts within and across countries.

19. Bank financing will promote a systems approach to laboratory development based on quality management principles. The sites will benefit from overall strengthening for core functions (e.g. bacteriology, parasitology, chemistry, and hematology) and will be supported to take advantage of the WHO/CDC Stepwise Accreditation process, reaching a two star status by project completion. Satellite labs will serve as sentinel surveillance sites to monitor hot spots for disease transmission. Project financing will facilitate sharing of information by establishing lines of communications (video conferencing, telemedicine) and by putting in place effective lab information systems which will allow personnel across sites to consult each other and to have access to timely information about disease outbreaks.

20. **Reference and Specialized Services and Drug Resistance Monitoring** (US$10 million) The project will bolster the capacities of the Central Public Health Laboratories in the participating countries and network them to share information, conduct joint training and research, and collaborate in harmonizing policies and strategies. This process will focus on the TB laboratory functions (which have been relatively neglected), supporting one of the labs to be upgraded to a Supranational Regional Laboratory (SRL). The project will finance inter-laboratory external quality assessments among the four East African countries, and standardization of procedures and protocols to ensure that diagnostic procedures are performed by appropriately trained technicians against clear regional and international proficiency and quality standards. As national capacities are enhanced and the network becomes fully functional, one of the four labs would play the role of a regional laboratory for East Africa, providing services (e.g. quality control; support with drug resistance surveys; higher-level testing, including second line drug susceptibility testing and molecular diagnostics) to other laboratories in neighboring countries, thus reducing the need to ship specimens to labs on other continents. The process of accreditation is being led by the WHO and other technical partners. Once a decision is taken on which laboratory will play the SRL role, the project will be used to develop the financial arrangements and operational modalities for the regional lab to provide services and for other countries to acquire those services.

21. **Disease Surveillance and Preparedness** (US$10.4 million) The project will complement ongoing regional and global initiatives to improve Integrated Disease Surveillance and Response (IDSR) country systems. It will support the IDSR strategic goals to improve availability of quality information by: (i) strengthening competence of lab and facility personnel to collect, analyze, and use surveillance data; (ii) reinforcing lab networking and district capacity (particularly those in border areas) to report, investigate, and adequately respond to disease outbreaks; and (ii) strengthening communications and data sharing to
22. Bank funding will assist the countries to comply with their commitments under the International Health Regulations. To this end, the project will support laboratory-based disease surveillance efforts, by: (i) strengthening etiological confirmation of pathogens and promoting active participation of lab personnel in disease surveillance; (ii) collaborating in investigations of disease outbreaks, (iii) establishing and maintaining an integrated data management system; and (iv) facilitating sharing of relevant data across the sub-region, including publication of periodic newsletters and quarterly and annual disease surveillance reports. The strategy is to start gradually and prioritize a few diseases for Bank support, including those which are: (a) outbreak prone (cholera, meningitis, hemorrhagic fever), (b) endemic (malaria, multi-drug resistant TB), or have (c) pandemic potential (influenza). The project will also provide complementary support to the EAC for the East Africa Integrated Disease Surveillance Network to enhance its effectiveness, and facilitate the production of quarterly regional surveillance bulletins. In addition to technical support, provision of equipment for national public health labs and selected laboratories in the border districts, and communication resources for data sharing across countries, the project will focus on targeted training in areas such as field epidemiology, microbiology, virology, and communications.

23. To summarize, in respect to all activities under Component I the project will finance the following: (i) rehabilitation, expansion, and/or construction lab facilities; (ii) computer equipment, software, and technical support for integrated laboratory information systems and connecting facilities; (iii) lab equipment and supplies; (iv) materials and protective gear (e.g. masks, gloves) and related waste management equipment to ensure the safety of lab personnel; (v) telemedicine capacity to allow laboratory technicians and clinicians across participating sites to share expertise and consult in case of complex cases; and (vi) provision of operating funds to render the laboratories functional, including strengthening human resources which are the backbone of quality diagnostics; each participating laboratory would receive an annual budget and would be held accountable for attaining specific results as agreed upon in annual work plans.

Component II: Joint Training and Capacity Building (US$7.5 million)

24. The project will support training in a range of institutions in the four countries and across the region. Tanzania will provide leadership in this area and establish a regional training hub. It will provide practical training at its state of the art National Health Laboratory Quality Assurance and Training Centre and in-service training and post-graduate mentorships at the Muhimbili University of Health and Allied Sciences. Other regional training programs (such as the Arusha training on TB control) and other training centers like the African Center for Integrated Laboratory Training in Johannesburg will be supported, particularly for training trainers. Main priority areas identified by countries include: (i) laboratory quality management systems; (ii) internal and external quality assessments; (iii) technical training in new technologies; (iv) lab services for emergency and outbreak preparedness and response; (v) epidemiology and statistics for laboratory management; and (vi) training in preventive maintenance of equipment. Each country has prepared a training plan with these priority short-term and long-term training activities.
25. The Bank project will finance: (i) attendance at training courses at national and regional institutes; (ii) laboratory attachments, fellowships, and regional exchanges at recognized centers of laboratory excellence; (iii) selective graduate training, as may be required to support specialized services; (iv) technical assistance to review and develop standards and training curricula and generic specifications for equipment; and (v) regional workshops to facilitate knowledge sharing.

Component III: Joint Operational Research and Knowledge Sharing/Regional Coordination and Program Management (US$8.1 million)

26. The project will finance relevant operational research which is related to activities supported under the project. The main research priorities identified by countries to date relate to the need to evaluate the effectiveness of the new technologies at the programmatic level, to assess alternative models of care for management of drug resistant patients, to map malaria drug resistance patterns, and to assess the effectiveness of the regional approach to communicable disease prevention and control. The evidence generated through this joint operational research will help inform public policy and the scale up of these interventions in the participating countries and in the region. As agreed during project preparation, ECSA would establish an independent peer review mechanism for selecting proposals, convening stakeholders to firm up the operational research agenda, overseeing the award process, and establishing a forum for sharing results and lessons. The project will fund: (i) technical assistance to support operational research; and (ii) operating costs to organize regional workshops to share results and explore policy implications.

5. Financing

Source: ($m.)
BORROWER/RECIPIENT 0
International Development Association (IDA) 56
Total 56

6. Implementation

Partnership arrangements

27. The Bank has established partnerships with several development partners, including WHO, the International Union Against Tuberculosis and lung Disease, CDC, USAID (United States Agency for International Development), and UNITAID. The Stop TB Department of the WHO was instrumental in providing guidance throughout the preparation process. The Global Lab Initiative Secretariat, which is hosted by the Stop TB Department, assisted to lay out the rationale for many of the proposed activities and prepared simulations to document the TB diagnostic gaps across Africa. The Union provided a forum for discussing the Bank-funded regional initiative in its October 2008 annual conference which brought together leading experts from around the world. The Union country offices in Uganda participated actively in project preparation. The US Centers for Disease Control and Prevention mobilized a team of experts from headquarters who assisted in carrying out the initial scoping missions in Kenya, Tanzania and Uganda. The Rwanda and Tanzania CDC country offices supported the preparation process. USAID played an important role supporting the preparation in Uganda and Kenya by providing technical support through its TB-CAP (TB Control Assistance Program) with KNCV (Dutch Tuberculosis Foundation) as the lead partner. Partners have been extensively involved in a series of video conferences and at a critical meeting in Nairobi which brought together all stakeholders in December 2009.
28. Partnerships are also expected to guide the implementation phase. This will be important for continuing to harmonize activities, minimize duplication, and tap technical expertise. Partners will provide technical support for: lab accreditation; technical training; lab assessments; and facility design. Key partners will participate in the Regional Advisory Panel as discussed below. The bulk of this technical support will be provided as part of on-going bilateral arrangements between countries and these technical agencies. However, funding for more complex and lengthy consultations will be provided through the regional project. Grant financing will be provided for specialized diagnostic equipment through UNITAID/FIND. Co-financing arrangements will be finalized during the appraisal mission.

Institutional and implementation arrangements

29. National arrangements Though institutional arrangements vary from country to country, the basic principles are the same, namely to rely and strengthen existing institutional and implementation structures. Technical aspects of project implementation will be fully covered and integrated into the appropriate operating divisions of Ministries of Health (MOH). Within each ministry there will be one lead office which will coordinate and monitor implementation of project activities at the national level. Other sections responsible for implementing specific activities (e.g., health infrastructure, human resources, etc.) will be strengthened to deal with the additional workload. Each participating laboratory will prepare an annual work plan. For the satellite labs this will be done in collaboration with the district teams. The annual work plans will be approved by the units which are responsible for coordinating the project, after ascertaining conformity with the agreed scope of the project and after reviewing progress made in previous year. Details of these arrangements are summarized below:

30. In Kenya, the Ministry of Public Health and Sanitation (MoPHS) will have overall responsibility for implementation of the project. The Head of Disease Prevention and Control will be the focal point for the project and a small project support team consisting of a project officer, an epidemiologist, an information technology expert, an accountant and an operations officer, will handle day to day operations and reporting requirements. To ensure effective coordination with the Ministry of Medical Services (MoMS) and surveillance program, a coordination committee will be established which will include a hospital administrator from MoMS, and heads of disease surveillance, tuberculosis, leprosy and lung diseases, national public health laboratories, and malaria control programs. The coordination committee will review annual work plans and recommend them for final approval by the MoPHS.

31. In Rwanda the overall implementation responsibility for the project will rest with the Ministry of Health. The Permanent Secretary (PS) will have overall oversight. The project activities will be coordinated by the ministry’s Project Management Unit which successfully managed the recently closed Bank-funded HIV/AIDS project and numerous Global Fund grants. A small project support team will be established to ensure effective coordination and handle day to day operations. The team will consist of a project officer, an epidemiologist, a microbiologist, an information technology expert, an accountant, and an operations officer. The team will work under the overall guidance of the Permanent Secretary, as well as the head of the TRAC + (Center for Treatment and Research on AIDS, Malaria, TB, and Other Epidemics, Ministry of Health) and the National Reference Laboratory (NRL) in their technical position as the main sub recipients of the grant. The NRL will take leadership in laboratory networking and systems development while the TRAC+ will focus on improving laboratory linkages with integrated disease surveillance. In line with the decentralization efforts, district health steering committees will have a key role in project implementation at district level and will have oversight responsibilities for the satellite labs.
32. In Tanzania, no new structures will be established for the proposed project. As is the case for other Bank funding outside the pooled funds, the project will be managed by the Health Sector Reform Secretariat under the Directorate of Policy and Planning (DPP). A full time project coordinator/public health specialist will be recruited to coordinate the activities under the regional project, an accountant to manage the financial operations, and other staff. The Chief Medical Officer would have overall responsibility for the project and will designate officers in the infrastructure and human resources sections to assist with implementation.

33. In Uganda, as agreed during the preparation of the Bank-funded national Health Systems Strengthening Project, the Government team would use mainly its own country systems and procedures, in line with the Paris declaration on harmonization. The regional project would respect the Long-Term Institutional Arrangements (LTIA) which aim to strengthen ministry structures and ensure broad based ownership. The Permanent Secretary (PS) would have overall responsibility for the project. The PS would designate a project coordinator with appropriate qualifications in public health and project management. The Permanent Secretary Ministry of Health will be the focal point for the project and a small project support team consisting of a project officer, an epidemiologist; an information technology expert, an accountant and an operations officer, will handle day to day operations and reporting requirements. The PS would also designate officers in the infrastructure and human resources sections to assist with the design, and implementation of the project activities.

34. Regional arrangements While implementation is the key responsibility of the individual countries, ECSA will coordinate activities at the regional level, and work in close collaboration with the EAC health desk. Assessments of ECSA conducted during project preparation found that the organization has good coordination and convening capacities. ECSA has developed regionally relevant training programs and institutionalized them in member countries; built capacity of research institutions; developed advocacy tools; and supported development and dissemination of regionally relevant operational guidelines, including those for infection prevention and control.

35. ECSA will set up a Regional Advisory Panel (RAP) which will meet annually (or more often as needed in the initial years) to facilitate learning among participating countries. This will enable countries to take stock of progress, discuss challenges, share experiences, and draw lessons. The RAP will be chaired by a high-level representative of the EAC to ensure consistency with broader health and economic policies and initiatives in East Africa. The RAP is expected to serve as a vehicle for multi-country and multi-stakeholder expert engagement and dialogue. Participating countries have agreed to contribute a portion of their IDA credits/grants for coordination of these activities. Each country will sign an Implementation Agreement with ECSA stipulating the activities to be carried out and the financial arrangements. These institutional arrangements will be reviewed and amended during the mid-term review.

Monitoring and evaluation of outcomes/results

36. The countries are committed to using a common framework for monitoring performance of the regional project. Support to improving the availability, reliability, and timeliness of routine lab information is an important part of the project. The development and introduction of standardized lab and surveillance information is expected to facilitate the task of data collection and monitoring.
**Performance Indicators**

37. To monitor results a core set of performance indicators has been agreed upon:

- Reduced average turn-around time for TB liquid culture tests (days)
- Satellite laboratories awarded two star status under regional accreditation program based on WHO step wise approach (number, percent)
- Number of beneficiaries (direct and/or indirect; out of which x percent female)
- People receiving TB drug susceptibility tests among Directly Observed Treatment Short Course (DOTS) treated TB cases not responding to treatment (number, percent)
- Share of reported communicable disease outbreaks having laboratory confirmation of etiological agent (percent)
- Outbreaks for which cross border investigations undertaken (number)

**Sustainability**

38. In the medium to long term, sustainability will be enhanced by three key factors:

- **Institutional**: At the national level, the strategy of relying and strengthening existing structures and elevating laboratory issues in policy dialogues will improve chances of sustainability. At the regional level, the EAC annual meeting of Ministers of Health will be used as a forum for sustaining high-level political support. ECSA will convene other high-level policymakers and technicians to sustain commitment. ECSA capacities will be further strengthened, so that the knowhow for supporting regional harmonization will be available on a sustained basis following project completion. There is strong and broad based ownership in the four countries to the proposed laboratory network. The establishment of an SRL in East Africa will further strengthen ownership and enhance the chances of sustainability in the long-term.

- **Financial**: Sustainability will also hinge on making adequate and timely provision for recurrent cost financing associated with the proposed activities at both the national and regional levels. Dated covenants will be included in each financing agreement to reflect commitment to provide financing for the labs as well as for regional coordination. Recurrent costs are expected to represent a relatively modest share of total projected health recurrent spending. Compliance will be monitored during supervision missions and annual budget reviews.

- **Human Resources**: Development of human resource capacity will be critical to providing the required manpower for laboratory facilities supported under the project. One of the key intermediate outcomes of the project is to strengthen the availability of critical manpower and to bolster motivation. The proposed regional training, enhancements in the safety of the work environment, and improvements in lab capacity more broadly will enable laboratory technicians to deliver high quality services. A dated covenant will be included in each financing agreement for preparing a policy that ensures adequate financing to address critical human resources constraints and to ensure that a career path for advancement of lab personnel is developed and introduced, including performance linked incentives.

**Lessons Learned from Past Operations in the Country/Sector**
39. It is well recognized that regional projects are inherently more challenging to design and implement but have the potential to generate results which are not easily attained through national investments. The World Bank has a growing portfolio of regional operations and enhanced knowledge of how to tackle challenges and potential risks. Drawing on the Regional Integration IDA 15 Mid-Term Review as well as findings from evaluations of regional programs from the Bank’s Internal Evaluation Group (IEG), the following key lessons have been incorporated into the design:

- **Ensure ownership:** Project preparation has benefited from high-level support from ministers, and permanent secretaries who have welcomed this initiative and provided strong leadership and tremendous support from program managers and partners who have contributed actively to the preparation process. The project builds on long standing collaboration on health issues within the East Africa community, and ongoing collaboration between ECSA and participating countries.

- **Promote partnerships:** The preparation and design of the proposed operation was conducted in close collaboration with key partners involved in lab strengthening and TB control to take advantage of global expertise and country knowledge and to identify opportunities for complementary support.

- **Adopt coordinated approaches:** As seen during the eradication of smallpox, in progress towards elimination of Onchocerciasis, and in control of meningitis, a high level of regional collaboration and collective action is critical to successful public health initiatives. For example, it is widely recognized that stepped up regional surveillance efforts, cross border collaboration, information sharing among laboratories, and regional stockpiling of vaccines have been critical in equipping countries to better cope with frequent meningitis outbreaks.

- **Ensure design simplicity:** The project has three components. It will rely and strengthen existing implementation structures and not create new ones. To avoid legal complexities each country will have a separate financing agreement.

- **Leverage national institutions:** Drawing on lessons from successful regional operations, the project promotes the concept of “design regionally--implement nationally” by relying on national institutions for execution and implementation of program interventions at the country level, and on regional institutions for supportive services that cannot be performed efficiently by national agencies, such as coordination.

- **Develop a strong Monitoring and Evaluation framework:** The project design has a strong focus on M&E which is critical to enhancing the evidence base for rolling out new technologies and approaches. Drawing on lessons from regional projects, the main research topics were agreed up front and a Regional Advisory Panel will be established to facilitate multi-country learning.

- **Plan for sustainability:** The team adopted a health systems approach which focuses attention on how this regional program will add value to service delivery at the country level, what will be required to sustain activities and country commitment, and how the Bank’s annual sector and budget reviews can be used to foster support. The Bank will monitor the availability of resources
for labs supported under the project and ensure that personnel recruited under the project are absorbed into the civil service or by other partners.

- **Leverage field-based staff**: Project preparation has relied primarily on field-based staff to enhance coordination with other Bank-funded health operations and our broader policy dialogue in the four countries, to tap country knowledge on fiduciary issues, and to increase the Bank’s responsiveness. The same strategy will be applied to supervision.

9. **Safeguard Policies** (including public consultation)

40. The project's poverty reduction and social development outcomes are anticipated at two levels. **First**, the poverty and social impacts are significant for the anticipated poorest beneficiaries who will avail of timely response to outbreaks, especially among the densely populated peri-urban poorest settlements and remote rural villages in border areas of Kenya, Tanzania, Uganda, and Rwanda. Early diagnosis and treatment will reduce stigma and improve quality of life. Since most of the disease-affected populations are vulnerable groups such as slum dwellers, migrants, refugees, who live in households subsisting on less than two dollars a day, the preventive and curative approaches to TB and other communicable diseases supported by the project will improve health conditions. **Second**, the widespread benefits from improved diagnostic services for highly vulnerable HIV positive individuals, as well as those afflicted with drug resistant strains of TB would cover the poorest populations, especially women and children.

41. Key stakeholder groups have been consulted throughout project preparation. The design of the project incorporates a participatory approach, including civil society groups that promote patient rights and conduct advocacy among vulnerable groups. During implementation, the project will support its partner institutions in-country to take advantage of the broader participation of civil society to strengthen accountability by citizens, community groups, and afflicted communities.

42. For Kenya only, the Indigenous Peoples safeguard has been triggered. An Indigenous Peoples Plan Framework (IPPF) has been prepared to ensure that the development process fully respects the dignity, rights, economies, and cultures of these communities and that the project is able to gain the broad community support of affected indigenous peoples and other vulnerable marginalized groups.

43. The regional project has triggered OP 4.01 due to the planned construction/rehabilitation of laboratories as well as the generation of medical waste at laboratories and has been assigned the environmental category B. To ensure proper assessment and mitigation of potential adverse environmental and social impacts, an environmental and Social Management Framework (ESMF) has been prepared for the project and Kenya has elaborated an IPP. The ESMF outlines the steps in the environmental and social screening process, and includes Environmental Guidelines for Contractors, a summary of the Bank’s safeguard policies, an Environmental and Social Checklist, generic Environmental Assessment (EA) terms of reference to be applied in the event that the screening results indicate the need for a separate EA report, and an Environmental and Social Management Plan (ESMP). Countries have also revised their waste management plans which focus on laboratory waste generation as well as segregation, storage, collection, transport, and final disposal practices; technologies for waste disposal; public awareness programs; and relevant national legislation. **The ESMF along with the IPP (Kenya only), will be disclosed in Kenya, Rwanda, Tanzania, and Uganda, and at the Bank’s Info-shop prior to appraisal.**
Safeguard Policies Triggered by the Project

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[a] The IP has been triggered for Kenya.

10. List of Factual Technical Documents

KENYA:
- Kenya Project Technical Annex
- National Health Sector Strategic Plan II
- National Public Health Laboratory (NPHL) Plan
- Division of Leprosy, TB and Lung Disease (DLTLD) Strategic Plan
- Draft CTRL Strategic Plan
- Country Assistance Strategy (2007)
- Laboratory Waste Management Plan (2009)
- Indigenous/Marginalized Peoples Planning Framework (2009)

TANZANIA:
- Tanzania Project Technical Annex
- National Health Laboratory Strategic Plan (2009-2015)
- Country Assistance Strategy (2007)
- Laboratory Waste Management Plan (2009)

UGANDA:
- Uganda Project Technical Annex
- Country Assistance Strategy (2005-2009)

RWANDA:
- National Environmental Health Policy (2008)

* By supporting the proposed project, the Bank does not intend to prejudice the final determination of the parties' claims on the disputed areas
• National Healthcare Waste Management (2009)
• Rwanda Country Assistance Strategy (2002-2006)

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