

# STANDARD **CONCEPT NOTE**

## Investing for impact against HIV, tuberculosis or malaria

A concept note outlines the reasons for Global Fund investment. Each concept note should describe a strategy, supported by technical data that shows why this approach will be effective. Guided by a national health strategy and a national disease strategic plan, it prioritizes a country's needs within a broader context. Further, it describes how implementation of the resulting grants can maximize the impact of the investment, by reaching the greatest number of people and by achieving the greatest possible effect on their health.

A concept note is divided into the following sections:

- Section 1: A description of the country's epidemiological situation, including health systems and barriers to access, as well as the national response.
- **Section 2:** Information on the national funding landscape and sustainability.
- Section 3: A funding request to the Global Fund, including a programmatic gap analysis, rationale and description, and modular template.
- **Section 4:** Implementation arrangements and risk assessment.

IMPORTANT NOTE: Applicants should refer to the Standard Concept Note Instructions to complete this template.

SUMMARY INFORMATION					
Applicant Information					
Country	Sao Tome Principe	Component	ТВ		
Funding Request Start Date	2015	Funding Request End Date	2017		
Principal Recipient(s)	United Nations Development Programme				

## **Funding Request Summary Table**

A funding request summary table will be automatically generated in the online grant management platform based on the information presented in the programmatic gap table and modular templates.

#### **SECTION 1: COUNTRY CONTEXT**

This section requests information on the country context, including the disease epidemiology, the health systems and community systems setting, and the human rights situation. This description is critical for justifying the choice of appropriate interventions.

#### 1.1 Country Disease, Health and Community Systems Context

With reference to the latest available epidemiological information, in addition to the portfolio analysis provided by the Global Fund, highlight:

- a. The current and evolving epidemiology of the disease(s) and any significant geographic variations in disease risk or prevalence.
- b. Key populations that may have disproportionately low access to prevention and treatment services (and for HIV and TB, the availability of care and support services), and the contributing factors to this inequality.
- c. Key human rights barriers and gender inequalities that may impede access to health services.
- d. The health systems and community systems context in the country, including any constraints.

## Summary

Sao Tome and Principe is a lower middle income country, characterised by low human development, with a population of 183,118 in 2013. It is a recipient of the Round 8 Tuberculosis grant of the Global Fund which has improved programme results but is due to end in June 2015 (extended from November 2014). According to WHO, the country has the second highest incidence (93 cases / 100 000) of tuberculosis compared to islands with similar characteristics in Africa.

Treatment success rate among new smear positive cases (72%) in Sao Tome and Principe is low. The country is facing a problem of under detection (only 66% of estimated cases were detected) in both the general population and key populations (children, contacts of smear-positive and of MDR-TB cases, prisoners, PLHIV and other groups). In addition, patient monitoring is not adequately carried out, which results in a very high failure rate for first line treatment (19%, i.e. 10 out of 53 cases). Treatment outcomes among retreatment cases are not very positive either, with a treatment success rate of 31% (5 out of 16), a treatment failure rate of 37% (6 out of 16); and a re-treatment rate after default of 25% (4 out of 16). Subsequently, the number of MDR-TB cases has increased from 1 in 2006 to 8 cases in 2012, of which 7 were retreatment cases. Furthermore, culture and sensitivity tests are not available in the country and are done through Institut Pasteur, based in Cameroon. Xpert MTB/RIF is not available either. Collaborative TB/HIV activities are not organised in a coordinated manner, resulting in late detection of TB/HIV co-infection and high case fatality rates among TB/HIV co-infected patients (100% of SS+/HIV). The case reporting system presents significant weaknesses with a large number of clinically diagnosed cases and low quality control of the microscopy network.

The current funding for the National TB Programme (NTP) is provided mainly by the Global Fund. Lack of continuity in funding prevents the strengthening of tuberculosis control activities in the country and hampers performance.

In May 2012, an evaluation of the NTP (See Report in Annex 1) outlined weaknesses that could negatively affect the Programme's performance and recommended the strengthening of TB control activities; the provision of additional resources by the Government (human resources, support to operating costs, etc.); and the mobilisation of additional resources from the Global Fund and other partners. Under the New Funding Model, Sao Tome and Principe submits its Request for funding to the Global Fund, in a national context of financial gap and dwindling state resources. In order to address identified gaps and eventually achieve impact, the Country requests from the Global Fund the amount of 1,534,681 USD (see Detailed Budget in Annex 3), representing 100% of the amount allocated to Sao Tome and Principe to fund the following modules and priority interventions. These are described in the 2013-2017 NTP Strategic Plan (Annex 2):

- TB Care and Prevention (diagnosis, screening and treatment of cases, including key populations; prevention of TB in children)
- MDR-TB (screening, diagnosis and treatment of cases, surveillance of MDR-TB)
- TB-HIV (collaborative activities with the National HIV/aids Programme)
- Monitoring and Evaluation (routine reporting, analysis, review and transparency)
- Programme Management (policy, planning, coordination and management, grant management), and
- Community Systems Strengthening (social mobilisation, building community linkages, collaboration and coordination)

The specific objectives pursued by the country under these modules are:

- To improve tuberculosis detection rate in the general population and key populations with new, more sensitive, diagnostic technologies (LED microscopy, Xpert MTB / RIF and digital radiography); by strengthening the sputum collection and transport system from health posts to district laboratories; through the organisation of mini campaigns for TB screening, early TB detection in the population, etc.
- To improve the treatment success rate through the following:
  - Xpert tests for all diagnosed TB cases in order to initiate appropriate treatment for MDR-TB patients
  - Strengthening the management and oversight of directly observed treatment by community workers at district health centers
  - Provision of nutritional support to patients
- To provide adequate treatment and monitoring for TB-HIV co-infection and MDR-TB
- To ensure proper management of the grant under the responsibility of the Principal Recipient, UNDP, which offers significant experience in Global Fund grant management.

The implementation of these priority interventions will enable Sao Tome and Principe to increase the number of reported cases by 20-24%, compared with 2012 data, during the 2015 -2017 period, in the general population and among at-risk groups. It will also increase treatment success rates beyond 85%. It will help treat more than 90% of MDR-TB and TB cases diagnosed with HIV infection. It will improve treatment outcomes and eventually reduce the number of MDR-TB cases.

## ✓ Overview of Sao Tome and Principe

Sao Tome and Principe is an archipelago of two islands (Sao Tome and Principe) in the Gulf of Guinea to the northwest of Gabon. Its population was estimated at 183 118 in 2013. 43.5% are under 15 years old and 63.4% live in urban areas according to the 2012 census data. Sao Tome and Principe is classified by the United Nations Development Programme (UNDP) as 144th out of 187 countries on its Human Development Index (HDI), with a Gross National Product (GNP) per capita of 1,805 USD. This places Sao Tome and Principe among lower middle-income and low human development countries.

#### Organisation of Tuberculosis control in Sao Tome and Principe

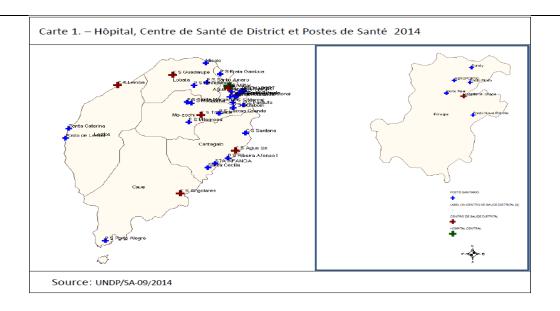
<u>Table</u> 1 : Health facilities and tuberculosis services

Administrative division	Health facilities	Tuberculosis services
Central/São Tome	Hospital Dr. Ayres of Menezes (HAM)	Central Unit (housed in Endemic Diseases National Office) BMU/NRL
Periphery : 1 Hospital and 6	1 Hospital / Autonomous Region of Principe	BMU
District Health Centers (6 in Sao Tome)	6 Health Centers 27 Health Posts	BMU
	22 Community Health Posts	

NB: BMU = Basic Management Unit NRL = National Reference Laboratory

The organisation of the National Tuberculosis Programme (NTP) is aligned with the health system of Sao Tome and Principe (Table 1) with a central coordination unit, Dr. Ayres de Menezes Hospital (HAM), with its reference service and the National Tuberculosis Reference Laboratory (NRL). The peripheral level is integrated in the district health centers where TB Focal Points responsible for district level implementation of the NTP activities are based. All districts are involved in the management of TB for both intensive and continuation phases of treatment. Overall, 6 district health centers and two hospitals (HAM, Principe Regional Hospital) are currently providing tuberculosis diagnosis and treatment services. Their distribution is presented in Map 1 below. Population coverage for TB diagnosis is set at one centre for 26,688 inhabitants. Culture and sensitivity tests are performed at Institut Pasteur in Cameroon. Sao Tome and Principe's NRL ensures quality control and oversight of the training of laboratory technicians of the microscopy network. Xpert MTB/RIF is not available in Sao Tome and Principe.

The 27 health posts ensure the collection and transport of sputum samples to district laboratories for smear tests. In addition, agents running 22 community posts are involved in community outreach, identification and referral of suspected cases of TB. They are also involved in DOT and patient monitoring.



#### a) Epidemiology of tuberculosis in Sao Tome and Principe

Table 2: TB burden estimates in Sao Tome and Principe, 2012

Estimation TB	Number	Rate per 100 000 population
Incidence (includes HIV+ TB)	170 (140–210)	93 (76–111)
Detection rate, all forms		66% (55–80)
TB-HIV	17 (14 - 21)	9,2% (7,5–11)
MDR-TB among new SS+	2 (0–3)	1,8% (0,1–3,4)
MDR-TB among retreatment cases	13 (7-15)	88% (47–100)

Source: WHO Report 2013, Global Tuberculosis Control

The tuberculosis endemic in Sao Tome and Principe is significant with an estimated incidence of 93 [76-111] new pulmonary tuberculosis all forms per 100 000 inhabitants (2012). In 2012, the detection rate for all forms of tuberculosis was 66% [55-80%] and the estimated HIV prevalence among TB was 9.2% [7.5 to 11%].

The rate of MDR-TB is estimated at 1.8% [0.1 to 3.4%] among new cases and 88% [47-100%] among previously treated cases (WHO Global Report 2013).

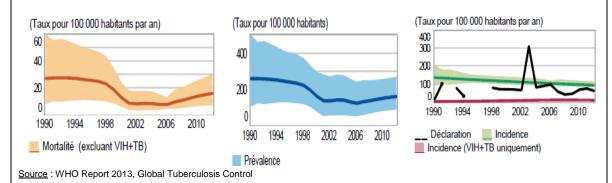


Figure 1: Trends in mortality, prevalence and incidence in Sao Tome and Principe, 1990-2012

In Figure 1 above, the estimated TB mortality of 27 cases per 100,000 inhabitants in 1990 decreases to 13 cases / 100,000 in 2000 and even to 7 cases / 100,000 in 2005. From 2006 onwards, it increases and reaches 16 cases / 100,000 inhabitants in 2012. Prevalence follows almost the same trend as mortality over the same period. On the other hand, incidence has declined since 1990, when it was 135 cases / 100,000, and reaches 93 cases / 100,000 in 2012.

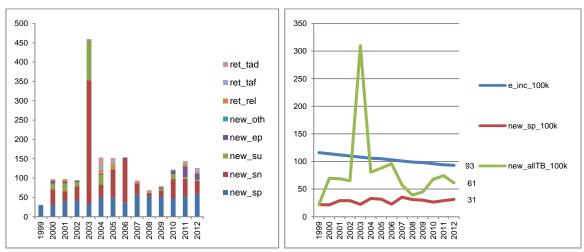
Tuberculosis control in Sao Tome and Principe has shown mixed progress towards achieving the Millennium Development Goal (MDG) 6C but not towards the Stop TB Partnership and Global Plan targets, as follows:

- The MDG target 6C i.e. "to reduce the incidence of TB by 2015 compared to 1990", was met in Sao Tome and Principe in 2012.
- The Stop TB Partnership target of halving TB mortality and TB prevalence in 2015 compared to their 1990 values was not achieved in 2012. The country is however on track to achieve the target.
- The Global Partnership for TB Plan objectives on raising the detection rate to 70% or more and the treatment success rate to 90% or more by 2015, have not been met. The country is also on track to achieve the target.

#### National response to the epidemiology of tuberculosis

The right part of Figure 2 below shows near stagnation in the rate of notification of new SS+ cases averaged at around 30 cases per 100,000 inhabitants. The trend of notification of new TB cases (SS+, SS-, extra pulmonary and relapses) is irregular, probably due to unreliable reporting of clinically diagnosed cases.

The trend in the number of reported cases of tuberculosis by form and type (SS+, SS-, Extra pulmonary, relapse, after default, failed) is irregular with a higher proportion of SS- as well as indeterminate forms. This is due to problems related to the understanding of case definition, a situation which has improved over the years. Notifications of microbiologically confirmed forms (new SS+ cases and relapses) and clinically diagnosed forms fluctuate from lows to peaks, making it difficult to conclude to an upward or a downward trend. Notification rates between 75 to 149 cases per 100,000 inhabitants are observed for the Autonomous Region of Principe (despite low population size) and in the districts of Água Grande and Mezóchi, the population of which is relatively larger. Furthermore, 96% of cases are detected in Sao Tome, which includes 6 districts out of 7 and 96% of the total population.



Source: WHO Report 2013, Global Tuberculosis Control

Figure 2: Number of TB cases per form and type (left) and TB notification rate / 100,000 inhabitants (right), 1999-2012

The sex ratio is 1.6 (men/women). The age distribution is typical with the majority of cases reported in the 25-34 age group. This indicates significant transmission in a younger age group. More critically, it implies insufficient diagnosis of cases in the 0-4 age group (including SS- and extra pulmonary), low case notification in the 5-14 age group, and overall, lack of diagnosis and / or reporting of pediatric tuberculosis, especially in the 0-4 age group.

TB among key populations (contacts of smear-positive and of MDR-TB patients, prisoners, PLHIV) is also under notified, with cases being undocumented. According to the 2013 WHO Report, HIV testing among TB patients is comprehensive with nearly 100% of TB cases tested for several years. 14% (18 cases out of 126) of TB/HIV+ cases in 2012, 100% of TB/HIV cases on ART and cotrimoxazole. Data on the screening of TB in PLHIV or on past access to INH preventive treatment (IPT) is not available. HIV prevalence in the general population aged 15-49 is estimated at 1.5% (DHS, 2008-2009). UNAIDS 2013 Report estimates HIV prevalence in the same age group at 0.8% (from 1.0 to 1.4%) in 2012, placing the country in a context of concentrated low incidence HIV epidemic.

Since 2011, 15 cases of multi-resistant tuberculosis have been diagnosed and treated. The fact that 47% (7 out of 15 cases) of retreatment cases are MDR-TB cases is of significance.

According to the 2013 WHO Global Report, treatment success rate is low, at 72%, for SS+ and at 65% in clinically diagnosed forms (SS- and Extra pulmonary) in the 2011 cohort, without great disparity among districts. In addition, treatment failure rate (19% i.e. 10 of 53 cases) is very high in new SS+ cases of the same cohort. In the 2011 cohort of retreatment cases, treatment success rate is at 31% (5 of 16 cases), failure rate is at 37% (6 out of 16 cases) and retreatment rate after default is at 25% (4 of 16 cases). This correlates with the high rate of MDR-TB reported among these patients. Besides, the default rate is relatively low (6% of smear positive and 10% of TPM- and EPT). Also, 100% of deaths in the SS+ new and retreatment cases are TB/HIV co-infection cases. This could be due to late diagnosis of TB or HIV or to long delays in the initiation of ART.

### b) Key populations that may have disproportionately low access to prevention and treatment services and the contributing factors to this inequality

Key populations who may face difficulties in accessing TB treatment and care in Sao Tome and Principe are children under 5, the contacts of smear-positive and of MDR-TB patients, prisoners, people living with HIV (PLHIV) and other groups. Over the past 10 years (2003-2012), the following trends have been observed:

- The number of children aged under 15 years old screened for TB is on average one (1) case per year, indicating under detection of cases among children
- There is insufficient provision of specific screening for SS+ contacts and MDR-TB contacts. Their size is estimated at 296 in 2013, calculated on the basis of a household of 4 people on average and 74 infectious cases (new, retreatment, including MDR-TB)
- TB screening among PLHIV is an ongoing activity of the National AIDS Programme. However the data is not yet available. According to UNAIDS 2013 estimates, there are around 1,200 people living with HIV aged 15 years and over in Sao Tome and Principe
- There is a lack of screening services designed for the 199 prisoners registered in Sao Tome in 2013. HIV prevalence among prisoners is at 4% according to the 2013 National AIDS Programme sero-surveillance survey.

The situation described above results from a lack of activities designed for / with at- risk groups and the lack of access to newly designed TB screening tools such as Xpert MTB/RIF and digital radiography.

#### c) Key human rights barriers and gender inequalities that may impede access to health services

Tuberculosis control activities cover all districts of Sao Tome and Principe. Treatment and care is standardised for all patients regardless of place of residence, nationality, gender and religion. However, disparity in access to care exists because of poor road conditions especially in rural areas. Key populations suspected to be at risk are insufficiently researched and supported.

According to current legislation in Sao Tome and Principe, prisoners have the same rights to health services as the general population. In reality, prisoners' access to treatment and care is limited, often due to lack of resources. Synergies between the TB and AIDS National Programmes (the latter is already involved in prisons) will help, not only monitor epidemiological data among the prison population, but also improve their access to health services.

There is little knowledge available on gender disparities in access to care in Sao Tome and Principe. It may be the case that the socio-cultural characteristics of the population (rural, traditional) results in less access for women (and their children) to health services. As part of its routine activities, the NTP will perform gender-based data analysis among TB suspects in order to assess gender disparity, since 2 male TB cases for 1 female case are notified in Sao Tome and Principe. Whilst the ratio is common in West Africa, the results of the analysis might eventually be used to verify and address the issue of gender inequality in access to care. The idea here is to check whether the gender disparity reflects the actual outcomes of the medical consultation (i.e. there are more TB infected men than women) or lack of access to diagnostic services by TB symptomatic women.

#### d) Health systems and community systems including any constraints

An analysis of the situation in Sao Tome and Principe based on the six pillars of health systems strengthening shows the following constraints:

#### - Human Resources

In Sao Tome and Principe, the doctor per capita ratio is 32 /100,000 and the nurse per capita ratio is 226/100,000 compared to a global average of, respectively, 146/100,000 and 334/100,000. This shows an obvious lack of these health professionals.

Furthermore, the situation is compounded by great instability of health personnel due to internal and external mobility, resulting from low pay and lack of incentives. Critically, 83% of staff working at the central level of the NTP are not professionals of the Programme.

#### - Supply of medicines and other pharmaceutical products

The National Drugs Fund (NDF) is the Ministry of Health agency responsible for forecasting needs in terms of drugs and health products, the supply of these products, their storage and distribution to health centers for all public health services. Forecasting of needs for anti-tuberculosis drugs and other related supplies is carried out by the NTP based on epidemiological data and history of consumption. The actual procurement and storage of drugs and related supplies at the national level, is led by partners which use competitive procurement mechanisms. In relation to distribution, requests for drugs are submitted to the NTP, which authorises their delivery. Stock management and monitoring is carried out through monthly stock reports disseminated by the NDF. Currently, the NDF is not equipped with sufficient tools for the forecasting of needs. Staff assigned to procurement activities and inventory management presents capacity gaps. Storage conditions at district level are inadequate.

#### - Health Information System (SIS)

Despite improvements (construction of a central platform, capacity building of technicians), deficiencies remain such as the absence of an appropriate legislative and institutional framework; of norms and rules which could foster a rational and coordinated functioning; the lack of a direct connection between the central platform and the district-level platforms. This situation creates a plurality of parallel information systems.

#### - Service delivery

The country presents good coverage of health services, with 95.5% of the population located within an hour by foot of a health center (Survey Report on Access to Essential Medicines, STP, 2008). However, there are relatively frequent stock-outs of medical and pharmaceutical products, which have a negative impact on the continuity and quality of health care provision.

With regards to the community system, 162 Community Health Workers (CHWs) have been trained, of which 105 are active in the response to tuberculosis. This figure corresponds to a coverage of 13 CHW per health district. The 22 community health posts operate with CHW, most of whom work on a voluntary basis. They contribute to community awareness raising, identification and referral of TB suspected cases, monitoring and supervision of drug intake during patient treatment. With the support of the Round 8 TB Global Fund grant and the Government, these CHWs have received motorcycles and remuneration for supervisory visits and other activities at community level.

In addition, Zatona Adil, Cruz Vermelha and Sao Tome's Association for Family Planning (ASPF) are currently involved in raising awareness and promoting preventive measures in Sao Tome and Principe. ASPF is also active in the provision of care, including HIV testing. Main issues related to community systems relate to weak management and oversight of CHWs which can be associated with high levels of treatment failure cases among new patients and resistance cases in retreatments. Poor visibility of NGO activities in TB and poor coordination among NGOs also hamper the community response to TB.

#### 1.2 National Disease Strategic Plans

Standard Concept Note Template

With clear references to the current national disease strategic plan(s) and supporting documentation (include the name of the document and specific page reference), briefly summarize:

- a. The key goals, objectives and priority program areas.
- b. Implementation to date, including the main outcomes and impact achieved.
- c. Limitations to implementation and any lessons learned that will inform future implementation. In particular, highlight how the inequalities and key constraints described in question 1.1 are being addressed.
- d. The main areas of linkage to the national health strategy, including how implementation of this strategy impacts relevant disease outcomes.
- e. For standard HIV or TB funding requests<sup>1</sup>, describe existing TB/HIV collaborative activities, including linkages between the respective national TB and HIV programs in areas such as: diagnostics, service delivery, information systems and monitoring and evaluation, capacity building, policy development and coordination processes.
- f. Country processes for reviewing and revising the national disease strategic plan(s) and results of these assessments. Explain the process and timeline for the development of a new plan (if current one is valid for 18 months or less from funding request start date), including how key populations will be meaningfully engaged.

The Programme is aligned with the National Health Development Plan as well as the 2013-2017 National Tuberculosis Strategic Plan entitled "Strengthening the Decentralisation and Integration of the Response to Tuberculosis in Sao Tome and Principe". Its long-term goal is to make Sao Tome and Principe a country free of tuberculosis. To this end, the Plan includes health promotion,

<sup>1</sup> Countries with high co-infection rates of HIV and TB must submit a TB and HIV concept note. Countries with high burden of TB/HIV are considered to have a high estimated TB/HIV incidence (in numbers) as well as high HIV positivity rate among people infected with TB.

prevention, diagnosis and quality care services which are to be offered to the entire population. This will be achieved through the effective and efficient expansion of the Tuberculosis Programme, based on the "Stop TB strategy", in a functional health system and with community support.

#### a) Goals, objectives and priority areas of the Programme

The following are the specific objectives of the Programme. They were defined within the framework of the 2013-2017 Strategic Plan. They are informed by the country dialogue, the portfolio analysis and post-2015 goals in terms of reduction of TB-related mortality and morbidity:

- Increase TB case notification rate from 71 cases / 100,000 inhabitants in 2012 to 80 cases / 100,000 in 2017 through increased screening among key populations
- Increase TB treatment success rate to more than 85%, by putting the emphasis on rigorous directly observed treatment
- Provide routine screening of resistance through Xpert test in all TB cases and the treatment of MDR-TB
- Provide care and support to more than 95% of TB/HIV co-infected patients through HIV testing of more than 95% of TB patients; TB screening for all PLHIV; and treatment provision (Cotrimoxazole, ART) to TB/HIV;
- To improve the managerial capacity of the NTP.

Priority areas resulting from these objectives are:

- > Case detection within the general population and among key populations: the coverage in diagnostic services is relatively good. Early case detection coupled with proper case management as well as adequate and rigorous DOT will be established through a) strengthening the sputum collection and transport system; b) implementing active screening in key and vulnerable populations (children, contacts of SS+ and MDR-TB contacts, prisoners, PLHIV and other at-risk groups, if possible); c) use of new diagnostic technologies (LED microscopy, Xpert MTB / RIF, digital radiography). Pursuing and overseeing community involvement will promote early TB detection and adequate patient monitoring. A particular emphasis will be put on the diagnosis and management of pediatric tuberculosis, which has been under notified to date (dissemination and training on the diagnostic algorithm, provision of new diagnosis tools).
- **Treatment**: The priority will be to increase treatment success rate from 72%, in the 2011 cohort, to more than 85% by 2017. This will be done by ensuring the availability of quality medication and adequate nutritional support. There will also be a special emphasis on proper oversight of patient follow-up during their treatment and even among key populations (therapeutic education at treatment initiation, nutritional support at least during the intensive phase of treatment, regular DOT supervision, questioning of patients on DOT effectiveness during routine supervision visits, CHWs awareness raising on the importance of DOT, etc.). A specific approach will be developed in order to improve the relatively low treatment success rate among retreatment cases. A nurse will conduct daily patient monitoring during the intensive phase of treatment. During the continuation phase, CHW will ensure DOT follow-up, with weekly support/supervision from the nurse. Additionally, on a monthly basis, the NTP will assess the status of all cases including retreatment ones. The treatment will be taken closer to patients by maintaining the decentralisation of supervised drug intake at health centers and health posts, in collaboration with community-based agents.
- > MDR-TB: The MDR-TB challenge will be addressed through a two-thronged approach: on one hand, early MDR-TB screening among at risk individuals (retreatment cases, MDR-TB contacts and diagnosed cases of TB) and on the other hand, the treatment of MDR-TB cases. Plans include the coverage of 100% of retreatment cases with Xpert, culture and sensitivity tests and the provision of treatment and care to more than 90% of patients

diagnosed with MDR-TB. Early screening will be extended to all new cases of TB given the very high failure rate for first treatments in the country. Xpert MTB / RIF will be used for rapid and early detection of MDR-TB. Culture and sensitivity tests will be pursued with Institut Pasteur in Cameroon (IPC) in order to identify resistance profile in TB Rif positive cases. Meanwhile, MDR-TB treatment will be provided as soon as the GeneXpert result is available. The antibiogram will allow the adjustment of antibiotics as needed. The MDR-TB treatment regimen currently applied is that of 20 months. However, during the grant period, short-term treatment (9 months) could be considered for operational research purposes (at no additional cost, thereby learning from the experiences of Central and West Africa countries). All arrangements have been made to send samples to IPC. Culture and sensitivity tests will be provided by the Sao Tome and Principe LRN which is being built thanks to the Brazilian Cooperation.

- TB/HIV co-infection: The Programme plans include maintaining the current coverage of HIV testing among TB patients at 95% at least and the coverage of early antiretroviral therapy among HIV-positive TB patients at 90% at least. Implementation of TB screening among PLHIV was initiated within the National AIDS Programme. The data will soon be reported by the latter. Use of the Xpert MTB/RIF and radiography will facilitate the diagnosis of TB among PLHIV. The National TB and HIV/aids Programmes will continue to offer TB screening and prevention services to PLHIV, considering the emergence of HIV infection among TB patients which rose from 3% in 2005 to 20 % in 2013. Activities will be conducted in a collaborative manner by the two Programmes, but under the responsibility of the National AIDS Programme. In addition, HIV testing will be systematically offered to TB suspects at HAM for operational research purposes. Collaboration between the HIV/aids and TB programmes should improve through these approaches.
- Management of the program, including monitoring and evaluation and operational research: Strengthening the management of the Programme will involve: strengthening of the central Unit (renewal of equipment, staff assignment and motivation, training, operating costs) and strengthening the Centers of diagnosis and treatment (rehabilitation of laboratory, equipment, staff assignment and training). Strengthening the monitoring and evaluation system will be achieved through a) the updating of monitoring and evaluation tools in compliance with the new 2013 WHO definitions and framework; b) the design and installation of a database to ensure computerisation of data at the Central unit; c) enhanced efforts through structured supervisions and quarterly data review meetings, with a view to improving the system's quality and reliability. In order to obtain solid data and better target Programme interventions, three instances of operational research are proposed i.e. mapping of notified TB cases; a KAP survey and a national tuberculin survey.

#### b) Implementation, key results and impact achieved

The execution of Sao Tome and Principe's National TB Strategic Plan (2007-2011), in alignment with the "Stop TB Strategy", thanks to Global Fund Round 8 resources, has helped speed up the process of implementing the following actions:

- Strengthening Programme Management (recruitment of six additional officers, appointment and training of TB Focal Points, technical assistance in planning, management and monitoring and evaluation, case management and treatment, laboratory and communication)
- Decentralisation of tuberculosis case management and treatment in the seven health districts
- Provision of nutritional support to MDR-TB patients (15 patients)
- Improved monitoring and evaluation (revision of data collection tools, creation of TB database, District Focal Points training in epidemiology, supervision and coordination)
- Development of cooperation protocols with Institut Pasteur in Cameroon for the screening and monitoring of resistance cases and for the quality control of laboratory tests

- Training of 79% of doctors (45/57), 83% of nurses (252/302) and 87.8% (72/82) of laboratory technicians in the management of TB cases and TB-HIV co-infection
- Production and dissemination of prevention messages and TB treatment through radio, TV and in communities)
- More than 200 awareness raising sessions in schools, churches, prisons and within communities
- Training of Trainers in MDR-TB and PAL
- Training of 105 Community workers and some NGO members in interpersonal communication (sensitisation for behaviour change)

Developed within the framework of the Strategic Plan, these actions have allowed the following:

- A gradual reduction of the incidence rate (from 135 to 93 per 100 000 inhabitants, between 1990 and 2012), which reflects a relative improvement of TB control in the country
- A downward trend towards reduction of TB prevalence, which has decreased from 258 to 159 per 100,000 inhabitants between 1990 and 2012
- An increase in the detection rate of all forms of TB cases from 11% to 66% between 1990 and 2012
- Achieving a treatment success rate of 72% in 2011
- An improved diagnosis and notification of MDR-TB cases (1 in 2006, 4 in 2011 and 8 in
- A reduction of 44% (27 to15) in the number of retreatment cases between 2005 and 2012
- From 2011 onwards, 100% treatment and coverage for TB / HIV co-infection cases (screening, antiretroviral and cotrimoxazole)

The data listed above originate from WHO 1990-2012 database.

#### c) Limitations of implementation

Throughout the setting up of the 2007-2011 Strategic Plan, specific screening actions targeting atrisk groups (children, SS+ contacts and MDR-TB contacts, PLHIV and others) had been insufficient. This could explain the under notification of TB. The scale, effectiveness and value added of the sputum collection and transport system in relation to tuberculosis screening have not been evaluated. The sputum transport flow will be monitored on an ongoing basis during the NTP quarterly supervision visits. It will be assessed every six months during national meetings with TB laboratories stakeholders and through annual visits of the Cameroon-based Institut Pasteur.

Nevertheless, it will be necessary to strengthen the system in order to increase the number of suspects who require TB case management. Besides, new diagnostic techniques such as LED microscopy, Xpert MTB / RIF and mobile digital radiography are nonexistent within the Programme. This could reduce the sensitivity of diagnosis and explain the low rate of positivity among suspects.

In its early stages, the enhanced decentralisation initiated in 2011 resulted in high default rates (12 to 13%). This may help explain the high rate of treatment failure and the current TB resistance in the country. Furthermore, inexistent local capacity to diagnose MDR-TB, and difficulties in sending sputum samples to an external laboratory often delay diagnosis (frequent refusals of the travel agency).

Weak TB and HIV integration is observed which is characterised by the absence of guidelines for TB screening among PLHIV. 100% of deaths occurred in the 2011 cohort are SS+ HIV co-infected cases. Isoniazid preventive treatment for PLHIV is not available in Sao Tome and Principe.

The issue of Government-supported human resources assigned to TB control activities is problematic. The number of health personnel specifically tasked with TB control activities is insufficient. Overall, and for the entire country, 11 doctors, 40 nurses and 9 laboratory technicians are involved in the management of tuberculosis - in addition to leprosy - 02 of whom are paid with external financing. In order to achieve a functional decentralisation, coordination should be strengthened and staff expected to perform TB (and HIV) screening and treatment activities should be trained on an ongoing basis.

At Programme Coordination level, the Coordinator is the only staff member assigned by the Government to manage the programme. At the time of writing this Concept Note, the Coordinator's salary was provided by the HAM through the Coordinator's consultations and curative activities. The Coordinator is supported by three (3) Supervisors and one (1) Administration Officer who are all remunerated through the Global Fund Project. The only vehicle available for the Coordination team to conduct field level monitoring of TB control activities is old, depreciated and also serves for Leprosy-related activities. In case community level TB screening activities were strengthened, lack of access to means of transport would slow down the normal execution of the Programme.

#### **Constraint management**

Deficiencies noted in 1.1 relate to lack of human resources assigned to TB control activities; frequent mobility of those currently working in the health system; weak nature of available diagnostic equipment; weak procurement and supply management system; weak information system, etc. These weaknesses and constraints will be managed by the Programme with the support of partners and also of the Government. Hence, the Malaria Programme has earmarked 643,066 USD and the AIDS Programme 112,539 USD for human resources capacity building (training, staff recruitment, technical assistance); for the strengthening of the health information system (sentinel surveys, supervisions); for supply chain management (strengthening infrastructure capacity, development of policies and standards for the procurement of medicines and other pharmaceutical products); and for service delivery (fuel for CHWs' motorcycles). Details of HSS activities per Programme are included in the detailed budget in Annex 3.

#### d) Main areas of linkage with the national health strategy

The National Health Development Plan (NHDP) outlines the following guidelines for the response to TB:

- Systematic and priority detection of potential cases and treatment of actual cases as soon as possible
- Creation of human and material conditions for the reception, diagnosis and treatment in district health centers and development of a reference system for the central level, according to criteria which promote confidence and encourage patients to undergo regular treatment monitoring as a guarantee of success

Interventions and actions proposed in the Plan relate to the strengthening of human resources; adequate case management; implementation of health communication campaigns; epidemiological surveillance; training and capacity building of health personnel; strengthening case diagnosis and management capacity as well as capacity in operations research.

Therefore, Sao Tome and Principe's national health policy aims for universal access to health care for the entire population without any discrimination. Within the National TB Strategic Plan actions aimed at strengthening the health system are related to the national strategy (extension and equipment of the TB care centers network, training and refresher retraining of staff, training through supervision, etc.).

#### e) Existing TB/HIV collaborative activities

From 2011 onwards, a collaboration framework has been established between the National TB and AIDS Programmes through a central coordinating committee for joint TB/HIV activities. As mentioned above, 100% of TB cases are tested for HIV. However, the screening of TB among PLHIV is not yet effective despite the existence of an algorithm introduced this year. In addition, INH preventive treatment for PLHIV is not in its operational phase yet.

## f) Country processes for reviewing and revising the national disease strategic plan

At the end of the period covered by the 2007-2011 Strategic Plan, national authorities requested technical and financial support from WHO to conduct an external NTP review in May 2012. The technical evaluation group was made of 21 participants from NTP, health districts, NGOs and partners supported by three international consultants. The recommendations from this review were used to develop the 2013-2017 National TB Strategic Plan. This Plan was then revised in order to re-programme for 2014 activities which were not implemented in 2013 due to lack of funding. The Plan was also revised in order to update the MDR-TB Expansion Plan (Annex 5) as well as epidemiological data. Health professionals, former TB patients, PLHIV, members of NGOs, development partners (WHO and Brazil), etc. were involved in this process.

The new version of the Plan was approved in June 2014 with the participation of health districts, partners (WHO, Health for All, UNDP) and members of NGOs. Besides, the current Strategic Plan lifespan is 3 years from 2015 onwards. This corresponds to the planned implementation period of the requested grant.

#### SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

To achieve lasting impact against the three diseases, financial commitments from domestic sources must play a key role in a national strategy. Global Fund allocates resources which are far from sufficient to address the full cost of a technically sound program. It is therefore critical to assess how the funding requested fits within the overall funding landscape and how the national government plans to commit increased resources to the national disease program and health sector each year.

## 2.1 Overall Funding Landscape for Upcoming Implementation Period

In order to understand the overall funding landscape of the national program and how this funding request fits within this, briefly describe:

- a. The availability of funds for each program area and the source of such funding (government and/or donor). Highlight any program areas that are adequately resourced (and are therefore not included in the request to the Global Fund).
- b. How the proposed Global Fund investment has leveraged other donor resources.
- c. For program areas that have significant funding gaps, planned actions to address these gaps.

"Table 1 - Funding gaps" annexed to this funding request indicate that the needs for the 2015- 2017 period are 1,657,419 USD. The deficit will be covered by Government as well as partner resources.

## a) No area is adequately covered by the contribution of a single partner:

- Government contribution during the 2015-2017 period amounted to 296,000 USD. This contribution will be used to guarantee funding for drugs required for the management of TB treatment side effects. It will also be earmarked for a fixed contribution to the Programme management costs. The Regional Government of Principe will continue to provide nutritional support in order to reduce treatment default.
- Cooperation of Portugal (IPAD) contribution of 10,750 USD will be used for the procurement of first line anti-TB drugs procurement during 2015.

- The Brazilian Agency for Cooperation (ABC) will ensure the construction of the National TB Reference Laboratory during the 2014-2015 period, with a contribution of 1,151,066 USD, of which 575,533 USD is scheduled for 2015. The Laboratory installation process, quality control and staff training will occur in 2016 with support from the same partner. This laboratory will ensure culture and sensitivity tests for 1st and 2nd line drugs, from 2017 onwards.
- During 2015-2017, WHO will contribute funding for Strategic Plan activities with a lump sum of 15,000 USD within the framework of its biannual plans. WHO is also ready to contribute with technical assistance in various areas. It will continue to collaborate in training activities, the revision of technical guidelines, in the conduct of mid-term and final Program evaluation and in operations research.

It should be noted that, despite promises of funding from various partners, including the Government, over the 2015-2017 period, no area is completely covered. The contribution of the Global Fund is therefore essential in each of these areas.

#### b) Resources from other donors:

The expression of needs within the framework of the Strategic Plan constitutes an opportunity for the Government to own the TB control priorities. It puts the Government in a position to mobilise not only its contribution to the financing of the Plan but also to continue advocating for partners' contribution to the implementation of the Strategic Plan (traditional partners and others). Besides, traditional partners (bilateral and multilateral partners) were associated with the drafting and revision of the Strategic Plan. Through the process, they have pledged to continue providing technical and financial support to strengthen TB control activities.

#### c) Funding Gap:

Government will gradually mobilise resources in order to ensure sustainability of the Programme and cover current funding gaps through greater contribution. It may also undertake advocacy vis-àvis public and private sector partners, bilateral and multilateral cooperation for the mobilisation of additional funds.

The Government, through the CCM, will continue to coordinate and oversee the implementation of the Plan, for a better optimisation of resources and for their effective and efficient use.

#### 2.2 Counterpart Financing Requirements

Complete the Financial Gap Analysis and Counterpart Financing Table (Table 1). The counterpart financing requirements are set forth in the Global Fund Eligibility and Counterpart Financing Policy.

a. Indicate below whether the counterpart financing requirements have been met. If not, provide a justification that includes actions planned during implementation to reach compliance.

Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	⊠Yes □ No	

ii. Minimum threshold government contribution to disease program (low income-5%, lower lower- middle income-20%, upper lower-middle income-40%, upper middle income-60%)	□Yes	⊠ No	The Government contribution is currently 18%, which is slightly below the required 20%. National health accounts which are being put in place will help better record other government actions in support of TB control. This information will be updated during grant implementation. Please refer to point a) ii below for further explanation.
iii. Increasing government contribution to disease program	⊠Yes	□ No	The Government has made commitments to increase its contribution to TB control activities during the 2015-2017 period. A status update on this commitment will be produced before grant implementation.

- b. Compared to previous years, what additional government investments are committed to the national programs in the next implementation period that counts towards accessing the willingness-to-pay allocation from the Global Fund. Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.
- c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.

a) ii. It has to be noted that the Government of STP struggles with an ongoing scarcity of financial resources exacerbated by frequent political changes. Nevertheless, over the years, the Government has managed to sustain its earmarked allocations in the national response to Tuberculosis. Also, in spite of these relatively adverse circumstances, the Government has demonstrated its ability to increase its investment in crisis situations. This was the case in 2012 when the Government procured MDR-TB drugs in order to avoid treatment interruption for patients and subsequent grave consequences in terms of mortality and spreading of multi resistant bacilli within the general population.

Given this context, the Government contribution is currently at 18% which is 2% below the required 20%. It has to be emphasised that these 18% only represent the MDR-TB procurement and earmarked allocations i.e. health personnel salaries. There are essential expenditures within the national health system which are financed by the Government but are not reflected in this percentage. These include service delivery and out-patient care.

In that regard, the absence of National Health Accounts does not allow for realistic accounting and reporting of Government expenditure per disease. Plans are currently under way to correct this situation, with technical assistance from WHO. National health accounts will imply more accurate recording of Government contributions to the TB response as well as greater transparency. Considering that the WHO technical assistance will have been provided by the first semester of 2015, stakeholders, including the Global Fund, will be able to use national health accounts to monitor Government commitments and contributions during the NFM period. Information related to Government contributions will therefore be updated during grant implementation.

b) Sao Tomé and Principe's Government is involved in tuberculosis control activities through an annual average funding of 98,667 USD. This contribution will be revised upwards for the purposes of the Government's "willingness to pay", within the framework of this TB funding request to the Global Fund (see Annex 6). This additional Government commitment will be used to procure anti tuberculosis drugs, and pay for salaries and operating costs. Monitoring of this commitment will be carried out by the Ministry of Health Finance Directorate through State Budget quarterly reports. Information will be available at the end of the year in the Table of State Financial Operations. In the future, follow-up will be done through national health accounts which will facilitate reporting on and tracking of Government contributions. The Global Fund will be able to use the accounts to monitor the effectiveness of the Government's willingness to pay.

It is important to highlight that this Concept Note has been finalised at a time of political transition in Sao Tome and Principe. Parliamentary elections were held on 12 October 2014 from which a new Government has emerged and will soon be established.

c) Sources of financial data announced through this document are comprehensive, reliable, available and verifiable.

#### SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

This section details the request for funding and how the investment is strategically targeted to achieve greater impact on the disease and health systems. It requests an analysis of the key programmatic gaps, which forms the basis upon which the request is prioritized. The modular template (Table 3) organizes the request to clearly link the selected modules of interventions to the goals and objectives of the program, and associates these with indicators, targets, and costs.

#### 3.1 Programmatic Gap Analysis

## A programmatic gap analysis needs to be conducted for the three to six priority modules within the applicant's funding request.

Complete a programmatic gap table (Table 2) detailing the quantifiable priority modules within the applicant's funding request. Ensure that the coverage levels for the priority modules selected are consistent with the coverage targets in section D of the modular template (Table 3).

For any selected priority modules that are difficult to quantify (i.e. not service delivery modules), explain the gaps, the types of activities in place, the populations or groups involved, and the current funding sources and gaps.

The funding request addresses to the Global Fund focuses on six priority modules: TB care and prevention, MDR-TB, Co-infection TB/HIV, Program Management, Monitoring and Evaluation and Community Systems Strengthening. For the three quantifiable priority modules, coverage targets

Table 4 : Coverage of priority quantifiable interventions

Modules	Baseline (2012)	2015	2016 2017
TB care and prevention			
Number of TB suspects examined in microscopy network	1329	2550	2550 2550

Number of notified cases of all form of TB –bacteriological confirmed plus clinically diagnosed (new and release)	127	153	156	160
Tuberculosis / HIV				
Percentage of HIV- positive TB patients who were screening for TB in HIV care or treatment settings *	-	-		-
Percentage of TB patients- who has an HIV test result recorded in TB register	99%	>95%	>95%	>95%
Percentage of HIV positive registered TB patients given anti-retroviral therapy during TB treatment.	100%	>90%	>90%	>90%
MDR-TB				
Number of bacteriologically confirmed drug resistant TB (RR TB and/or MDR-TB) notified to the national TB program.	8	11	11	11
Number of cases with drug resistant TB (RR TB and/or MDR-TB) that began second-line treatment	8	11	11	11

<sup>\*</sup> The screening of TB in PLWHIV is the responsibility of AIDS Programme, who will notify and report this information.

Modules which are difficult to quantify are Programme Management, including Monitoring and Evaluation, and Community Systems Strengthening.

#### Programme Management, including Monitoring and Evaluation

Impact of activities related to programme management is not easily quantifiable in relation to improving Programme performance in TB diagnosis, treatment and prevention.

#### <u>Gaps</u>

NTP Coordination and district TB Focal Points do not have sufficient human resources involved in TB activities, or sufficient material and financial resources and infrastructure to ensure adequate management of tuberculosis control activities. 80% of Programme staff at central level is remunerated with external financing.

There is only one vehicle, already depreciated, which is accessible for field level implementation and monitoring of TB control activities. In case the Global Fund grant is put to an end, there will not be a budget available over the next three years for operating costs, annual audits, training, participation in scientific meetings, regular staff training, subsidies, supervisions, etc. at the level of the Programme.

## Types of activities in place

Activities which are in place mainly include remuneration of central level staff, coordination meetings, supervision visits, fuel, communication costs, tools development, etc. These are scheduled within the framework of the Round 8 Phase 2 TB grant, which has been extended from November 2014 to June 2015.

#### Populations or groups involved:

Coordination teams at central and district levels and the grant management team.

#### Current funding sources and gaps:

The current deficit amounts to around 90% at this level (the balance is supported by the State).

#### > Strengthening the Community system

It is difficult to measure the impact of awareness raising activities on the increased demand of TB services. However, lack of information could hamper demand for services. Nevertheless, a collaboration framework between NTP, community and civil society actors will be set up to raise further the population's awareness of the management of tuberculosis and stimulate the demand for TB services.

#### Gaps:

Community Health Workers (CHW) and NGO members have been under used in the past due to lack of support and supervision by the NTP. During the second phase of the TB grant the situation has improved slightly (supervision of CHW in supporting DOT, participation of NGOs in sensitisation activities). That being said, terms of reference for their activities need to be reviewed in order to broaden their scope of work, with regular oversight and within the framework of NTP activities.

#### Types of activities in place

DOT, collection and transportation of sputum samples, patient monitoring conducted by community-based agents who are recruited and paid through Phase 2 of Global Fund Round 8 grant (extended from November 2014 to June 2015). NGO-led sensitisation activities are also carried out under the same grant.

## Populations or groups involved:

There are four target groups for these activities: family members of notified patients; patients presenting a risk of becoming "irregular" (to be identified by TB staff services); the general population especially where mapping indicates "concentrations of cases" inducing TB transmission and incidence; at risk populations such as prisoners.

#### Current funding sources and gaps:

The deficit for this component is at 100%.

#### 3.2 Applicant Funding Request

Provide a strategic overview of the applicant's funding request to the Global Fund, including both the proposed investment of the allocation amount and the request above this amount. Describe how it addresses the gaps and constraints described in questions 1, 2 and 3.1. If the Global Fund is supporting existing programs, explain how they will be adapted to maximize impact.

The amount allocated for TB by the Global Fund in the country programme split is 1,386,423 USD, out of which 614 010 USD are existing funds for the 2014-2016 period. The CCM-defined programme split includes an allocation of 1,903,063.20 USD for TB, out of which 1, 289,053.20 USD correspond to additional funding. The budget available from 1 July 2015 onwards is 1,534,681.20 USD. The amount requested under this concept note is 1,534,681.20 USD for the 2015-2017 period. This is in line with the determination of the allocated amount.

Initial versions of the concept note included above-allocations amounts. It was subsequently found out that these additional activities could be funded out of the savings identified during the negotiation of the extension budget/existing pipeline of funding. The option and need for the above allocation amount therefore foreclosed. No funds beyond the allocated amount are being hereby requested.

Sao Tome and Principe request to the Global Fund under the New Funding Model is based on the recommendations of the May 2012 Programme review, the portfolio analysis as well as recommendations from the country dialogue. Initiated in April 2014, the country dialogue included all relevant stakeholders i.e. representatives of affected people, target groups, technical and financial partners, etc. The country dialogue also catalysed the revision of the 2013-2017 National Strategic Plan, which was validated on June 11, 2014 by all stakeholders. The development of this concept note was led by a committee/task force made of representatives of stakeholders. The concept note was ultimately approved by all members of Sao Tome and Principe's CCM.

The following was observed through the country dialogue and the TB control context revealed by the Programme review:

#### Screening:

- Decline in the quality of diagnosis with an increase in extra pulmonary TB, functional deficiencies in the sputum collection and transportation system
- Lack of screening actions targeting at-risk groups (children, SS+ contacts and contacts of MDR-TB, prisoners and others)
- Inadequate infrastructure in some laboratories, weak quality assurance system in the microscopy network, absence of new technologies such as sensitive diagnostic LED microscopy, Xpert MTB/RIF and digital radiography

#### Treatment:

- Inadequate monitoring of patients under treatment
- Lack of procurement and supply management tools
- Poor storage conditions at district level
- Absence of staff training in stock management

#### TB / HIV:

- The National NTP and AIDS Programme's collaborative framework is not functional due to the inexistence of a TB / HIV collaboration work plan
- The screening of TB among PLHIV has just started; reporting is not yet effective
- Preventive treatment with Isoniazid is not offered to eligible PLHIV

#### MDR-TB:

- The number of MDR-TB cases is increasing, especially among retreatment cases (47% of the total since 2011)
- Lack of adequate diagnostic tool on site
- Inexistence of hospital facilities which are compliant with MDR-TB patients treatment protocol (infection control)
- Insufficient management of MDR-TB information: lack of compliance with official channel for information transfer; patient information management not respected; insufficient information on identified patients at health care facilities

#### **Program Management**

- Insufficient Government-supported human resources
- Pay insecurity of national level staff resulting in high levels of rotation
- Lack of consultation meetings with or guidelines for district level personnel
- Health districts conduct case detection and treatment monitoring activities in an insufficient manner

Other care providers apart from TB Focal Points are insufficiently integrated into TB control activities at district level

#### **Monitoring and Evaluation**

- Human Resources in charge of M&E are not trained in TB control monitoring and evaluation
- Treatment cards are inadequately completed
- Insufficient annual activity reports which would document the outcomes of the monitoring and evaluation of the Programme activities
- No external evaluation has been organised during the 5 years of implementation of 2007-2011 Strategic Plan

#### Social mobilisation

Low capacity of the NTP in communication and advocacy activities: lack of attention to communication and advocacy. Few community organisations are involved in the response to TB control. The country lacks capacity for the monitoring and evaluation of community action on TB.

The basic strategic approach to be used in order to meet the relative under notification of TB cases is to identify, within the general and at-risk population, as many suspected cases as possible. It also consists of treating identified patients while increasing therapeutic success rate beyond 85%. To mitigate the endemic and break as much as possible the transmission chain, a special effort will be made in terms of active case finding among key populations as well as early and effective diagnosis, using rational algorithms and the range of new diagnostic technologies. The strategic investment proposed and adopted within the framework of this concept note is in line with the National Strategic Plan strategic priorities in the following areas: TB Treatment, Care and Prevention; MDR-TB: TB/HIV co-infection; Monitoring and Evaluation; Program Management; Community Systems Strengthening. These areas are meant to fill identified gaps and achieve a major impact in the near future.

#### 1. TB Care and Prevention

The funding requested from the Global Fund will be used for tuberculosis screening and treatment activities throughout the territory of Sao Tome and Principe.

Diagnosis and TB case detection, including key populations: activities relate to the adequate setting up of TB diagnostic services so as to reach a maximum of suspected tuberculosis cases. The objective is to detect a maximum number of existing cases within communities during the Strategic Plan period. Activities include:

- Rehabilitate the laboratories of 3 district health centers
- Procure 7 standard microscopes and 1 LED fluorescence microscope
- Procure 1 Xpert MTB/RIF and adequate cartridges for HAM for the screening of multi drug resistance (retreatments, contacts of MDR-TB and all diagnosed cases of TB) and the screening of tuberculosis in children and PLHIV presenting symptoms suggestive of TB
- Procure 2 mobile digital radiography (one for each island) to facilitate early detection of TB among prisoners, BK- and HIV + cases
- Ensure the supply of laboratory reagents and consumables for microscopy
- Ensure the organisation of monthly (district level and national level) quality control and supervision of laboratory activities
- Train / retrain all staff within the microscopy network and who are involved in the diagnosis
- Train district level TB service providers in TB management as well as in the diagnosis of pediatric TB, including the interpretation of radiographs
- Organise active TB screening of contacts while ensuring case mapping. It is planned that, for each TB SS+ case, 2 children will be put on INH prophylaxis

- On an annual basis, conduct active, radiography-based TB screening among prisoners and prison staff, PLHIV, children and other at-risk patients (annual radiography for all prisoners using Xpert for those whose scans show signs suggestive of TB; using radiography and Xpert for PLHIV at the request of prescribers; and for children, using radiography and Xpert on sputum collected by intubation)
- On a quarterly basis, conduct community-based mini campaigns for TB screening in each island (based on the case mapping) and on an annual basis in prisons. A team composed by a nurse and a laboratory technician, and supported by the district CHW (for the mobilisation of suspected cases) will travel to health posts in order to perform sputum smear examination, using Xpert and radiography.

Proposed algorithms for the efficient use of new technologies can be found in Annex 4 (to be validated by the clinicians involved).

<u>Treatment and prevention of tuberculosis</u>: the following activities are essential in the sense that they will help strengthen directly observed treatment and ensure proper patient monitoring:

- Rehabilitate and equip the HAM patients ward
- Procure first line TB drugs and ensure regular quality control
- Provision of nutritional support to patients during treatment
- Procure and provide INH chemoprophylaxis to children aged under 5 and living with an infectious case
- Train Central and district level staff, as well as National Drug Fund staff in the management of anti-TB drugs
- Sensitise all district level service providers and community-based agents on the necessity of effectively ensuring DOT among patients at least during the intensive phase of treatment
- Equipping warehouses at the peripheral level, providing them with air conditioners and warehouse management tools
- Provide incentives for community-based agents to ensure directly observed treatment and monitoring of patients during treatment

The treatment regimen of new cases lasts 6 months i.e. 2 {ERHZ} / {4} RH, applied to all forms of TB (SS+, SS-, EPT). The retreatment regimen is for 8 months i.e. 2S {ERHZ} / {1} ERHZ / 5} {ERH. Treatment is directly observed at least during its intensive phase. Children with TB will receive treatment in pediatric form based on the same WHO recommendations. For TB contact children without evidence of diseases, preventive therapy with isoniazid alone (10 mg / kg) for 6 months is planned.

<u>NB</u>: Nutritional support to TB patients during their treatment is highly desirable, for all cases, and strongly recommended for malnourished patients, children, MDR-TB and TB/HIV patients. Patients are mostly from disadvantaged social strata in a country already characterised by a high proportion (66.2%) of the population living with less than 1.25 USD a day. Nutritional support is provided in standard food kits following a basic nutritional assessment.

#### 2. MDR-TB

The requested investment is intended primarily for the surveillance of MDR-TB among at-risk groups (all retreatment cases, MDR-TB contacts and if possible all SS+ cases). Subsequently, the management of all diagnosed cases will be ensured. Within this framework, the following is planned:

- Have all cases at risk of MDR-TB undergo an Xpert MTB / RIF test (retreatments, MDR-TB contacts and all TB cases) and if possible contacts of TB / BK+. Ensure culture and sensitivity tests by the Institut Pasteur of Cameroon to identify the resistance profile.
- Procure complete treatment using the Global Fund budget and pay for GLC costs

- Provide nutritional support to MDR patients throughout the treatment phases
- Procure drugs for the treatment of side effects
- Train staff in the management of MDR-TB
- Ensure the availability of accommodation for MDR-TB patients at HAM
- Train staff in infection control in health care services

#### 3. TB/HIV

As part of this module, investment is planned with a view to ensuring formal collaboration between the two programmes for collaborative TB and HIV activities and for the care and support of co-infected patients. Activities include:

- Ensure the organisation of quarterly TB/HIV steering committee meetings, based on a work plan of joint activities
- Procure and supply HIV tests, cotrimoxazole and ART at the level of NTP for the management of TB/HIV co-infection (the National AIDS Programme will provide ARVs and will be responsible for ARV treatment). ARV treatment will be provided by a medical doctor, following the national protocol
- Organise routine HIV testing among TB patients after counseling
- Test suspected TB cases for HIV infection (in a first instance as a pilot activity at the level of HAM)
- Train National AIDS Programme Medical Doctor Focal Points in early diagnosis of TB in
- Organise the systematic screening of TB among PLHIV in collaboration with the National AIDS Programme
- Ensure the provision of IPT to eligible PLHIV in collaboration with the National AIDS Programme

#### 4. Monitoring and Evaluation

Monitoring and evaluation is a key component of the management of Global Fund grants which relates to results-based management. It is thus important to have tools which comply with the new WHO Framework. These will allow the collection of information which will be useful in assessing programme performance and measuring progress. Planned activities include:

- Revise monitoring and evaluation tools, adapting them to the new WHO Reporting Framework
- Produce tools and make them available to diagnostic and treatment centers
- Adapt the Programme computer-based system to the new tools
- Train all NTP staff at different levels in monitoring and evaluation
- Every three months, organise mid-term reviews of the annual Programme activities involving district Focal Points
- Pursue weekly (district level to health facilities) and quarterly (central to district level) supervision visits
- Produce an annual report of Programme activities every year
- Organise an annual national review meeting to discuss TB control results at central level and adjust programme activities accordingly
- Organise 3 instances of operational research (case mapping, KAP survey and tuberculin survey)

#### 5. Program Management

NTP Coordination and its representatives at district level do not have access to sufficient human, material and financial resources which would ensure adequate management of TB control activities. Activities listed below are planned with a view to strengthening the Programme coordination. These include:

- Ensure the remuneration of personnel assigned to TB control activities at the central level and the payment of performance-based incentives to district health teams
- Equip the Programme Coordination and district teams with computer equipment (computer, printer, copier, consumables, etc.),
- Ensure the NTP operating costs (fuel, office supplies, etc.),
- Develop / review the Programme technical guides (TB Guide; TB / HIV, MDR-TB guides; laboratories network guide, infection control guide, etc.),
- Conduct an annual financial audit of the grant
- Acquire one 4x4 vehicle for field level implementation and monitoring activities
- Provide capacity building opportunities for staff (participation in international scientific meetings; in supply management; programme management; management of TB / HIV; monitoring and evaluation)
- Ensure grant management costs
- Ensure mid-term and final project evaluations

NB: Incentives for district teams involved in TB control activities will be a set amount, the payment of which will be subject to at least a B1 rating for the programme. It is envisaged that the payment of performance-based incentives will temporarily compensate for low wages. It should ensure that teams are not busy finding other work to make ends meet, thereby neglecting the Programme activities.

#### 6.Community Systems Strengthening

Investment in strengthening community structures (community-based organisations - CBOs), NGOs, CHWs), could help stimulate demand for anti-TB treatment. These structures are meant to play a key role as an intermediary between health services and patients. Awareness raising on TB and available services; provision of patient support; expressing patients' expectations vis-à-vis health services feature among areas in which community structures can play their part. In addition, they can help reduce stigmatisation of TB within the population. Planned activities to be funded include:

- Design messages and work methodology of community-based actors on TB; ensure their training, given the fact that they will continue to support DOT, transportation of sputum samples and patient monitoring.
- Ensure the organisation of activities on the World Day for Tuberculosis
- Produce communication tools (image boxes, posters, flyers, etc.)
- Organise awareness raising sessions on TB in communities and in health services which will be led by NGOs, community groups and others
- Broadcast messages, organise games and debates on tuberculosis on television and on radio.
- Supervise community-based agents' activities

NB: Collaboration between TB health services and community-based agents will be based on a contract including terms of reference suited to local circumstances (needs, capacity of communitybased agents).

Furthermore, in relation to the NTP, several actions are planned for health systems strengthening within the framework of this concept note. Among these feature the acquisition of conventional and LED microscopes, the Xpert MTB / RIF and digital radiography; the rehabilitation of three laboratories; training and motivation of personnel involved in the response to TB; motivating community workers for monitoring TB patients; providing equipment and management tools for district pharmaceutical warehouses, etc. Details with costs are included in the budget file attached to the "RSS" sheet. The total cost of these HSS activities amount to 447,126 USD, representing 29% of the budget requested from for the Global Fund the 2015-2017 period.

Table 3 below presents the funding request budget by selected modules and interventions.

Table 3: Summary of the budget module and action

		Budget Fonds Mondial				
Modules	Interventions	Année 1	Année 2	Année 3	Total	%
Prise en charge et prévention de la		200 425	200.025	422.700	700 700	470
tuberculose		306,135	298,925	123,709	728,769	479
	Dépistage et diagnostic des maladies	186, 196	202,884	38,667	427,747	289
	Populations clés touchées	20,200	14,200	14,200	48,600	3%
	Traitement	99,739	81,842	70,842	252,422	169
	Prévention	-	-	•	-	0%
2 Tuberculose Multi résistante		63,557	77,277	77,819	218,652	149
	dépistage et diagnostic des maladies : tuberculose Multi résistante	5,583	5,583	5,583	16,748	1%
	traitement : tuberculose Multi résistante	57,974	71,694	72,236	201,905	139
Tuberculose/VIH		1,541	10,100	11,490	23,132	2%
	Interventions concertées de lutte contre la tuberculose et le VIH	1,541	10,100	11,490	23,132	2%
Suivi et évaluation		28,764	14,000	53,725	96,489	6%
	Communication régulière de l'information	10,763	-	8, 269	19,032	1%
	Analyse, examen et transparence	18,000	14,000	45,456	77,457	5%
Gestion de Programme		178,647	128,866	115,626	423,139	289
	Politique, planification, coordination et gestion	135,899	90,794	87,158	313,851	209
	Gestion de la subvention	42,748	38,072	28,468	109,287	7%
6 Renforcement des systèmes communautaires		29,500	7,500	7,500	44,500	3%
	Mobilisation sociale, renforcement des liens communautaires, de la collaboration et de la	00.5	7.50	7.50-		
	coordination	29,500	7,500	7,500	44,500	3%
	TOTAL	608,143	536,668	389,870	1,534,681	

## 3.3 Modular Template

Complete the modular template (Table 3). To accompany the modular template, for both the allocation amount and the request above this amount, briefly:

- a. Explain the rationale for the selection and prioritization of modules and interventions.
- b. Describe the expected impact and outcomes, referring to evidence of effectiveness of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

Selected modules and priority interventions relate to the current context of TB control in Sao Tome and Principe and were confirmed through the 2012 Programme review. These modules and interventions reflect the priorities identified by stakeholders as part of the National Strategic Plan which include high-impact interventions, focusing on key populations and which have been endorsed by the National Coordinating Committee (CCM). They also take into account current and expected funding including domestic resources.

The requested funding covers six priority modules: TB care and prevention, MDR-TB, TB/HIV, Monitoring and Evaluation, Programme Management, Community Systems Strengthening.

The rationale for the selection of modules and interventions and the impact and expected results are as follows:

#### TB care and prevention

#### Rationale for selection

According to WHO estimates, the rate of TB screening in Sao Tome and Principe was 66% of the total number of expected cases in 2012. This implies that there are still tuberculosis cases which are undetected within the population. It therefore becomes important to focus more on groups that do not have access to services, such as contacts of smear-positive and of MDR-TB patients, prisoners, PLHIV and other groups. Proposed strategies include on one hand strengthening the diagnostic setup and on the other hand facilitation of access to services (active screening in some key groups, strengthening the collection and transport of sputum etc.) in order to further decentralise the management of tuberculosis. Intense screening activities combined with the treatment and care of additional reported cases must be undertaken, while steadily increasing the Programme's current rate of therapeutic success, with a special emphasis on DOT management.

#### Outcome and evidence of effectiveness of interventions proposed

Number of TB suspects examined: 7 650

Number of reported cases which are put on treatment in the general population: 328

Number of identified cases and put on treatment among key populations: 141

Maintain a treatment success rate of more than 85%

Impact: The morbidity and mortality associated with TB disease in the population of Sao Tome and Principe will be reduced.

#### MDR-TB

#### Rationale for selection

Given its threat to a TB control program, MDR-TB monitoring and management is an essential component of a NTP. This module was selected to enable the NTP establish a real MDR routine surveillance system among retreatment cases, contact-subjects of MDR-TB reported cases and new TB cases and to ensure their treatment and care.

#### Outcome and evidence of effectiveness of interventions proposed

Monitoring of MDR-TB in Sao Tome and Principe: 100% of reported cases for retreatment, all MDR-TB cases contact subjects presenting TB symptoms of TB and new TB cases undergo GeneXpert test for the identification of rifampicin resistance and sensitivity test when Xpert Rif+.

Management of MDR-TB: Taking into account the results of susceptibility tests, suspected cases (Rif Xpert +) and confirmed MDR-TB cases will be put on anti-TB treatment. All confirmed cases will access free MDR-TB treatment. Free care will also include an initial patient assessment, monitoring and nutritional support.

Impact: Morbidity and mortality due to MDR-TB in Sao Tome and Principe will be reduced and MDR-TB trend will be curbed before it reaches endemic proportions.

#### TB / HIV

#### Rationale for selection

Given that HIV prevalence in the general population (1.5%) and also among TB patients is high (15%, 18 cases out of 126 cases reported in 2012), this module was chosen to a) make the existing NTP-National AIDS Programme cooperation framework functional; b) ensure a satisfactory level of care for co-infection in all TB patients; and c) intensify the screening of TB among PLHIV.

#### Outcome and evidence of effectiveness of proposed interventions proposed

Collaboration between NTP and NAP: 4 meetings per year of the Steering Committee Rate of TB cases tested for HIV: more than 95%

Rate of TB/HIV co-infected cases treated according to current TB guidelines: more than 95% Rate of PLHIV screened for TB according to the instructions (algorithms) currently in force (to be reported by the National AIDS Programme)

Impact: Morbidity and mortality due to TB / HIV co-infection in the population of Sao Tome and Principe will be reduced.

#### **Program Management**

#### Rationale for selection

The reason for selection of this module is to ensure that the NTP a) provides sufficient information for effective management of programme resources and b) has the capacity to manage Global Fund resources effectively and efficiently (availability of human resources, transportation, equipment, operating costs, facilitating supervision, participation in international conferences)

#### Outcome and evidence of effectiveness of interventions proposed

Financial Management Program: Disbursement requests are submitted on time; related supporting documents are available on time; NTP financial audit reports are unqualified.

Technical Program Management: Key programme data is available and accessible. NTP activities occur as planned.

Administrative management of the Program: Activities of sub-recipients - if any - and establishment and monitoring of contracts correspond to usual standards. The NTP has organised records. The administrative management of the Program meets usual organisational standards.

Impact: The NTP operates in a transparent manner and on the basis of established procedures. It possesses all the information which may be the object of a request for information, either from the Ministry of Health, from partners or from the Global Fund.

#### **Monitoring and Evaluation**

#### Rationale for selection

Monitoring and evaluation is essential for the ongoing measuring of performance and progress in TB control. The definition of the programme key indicators, Programme management tools and the reporting system require revision, updating, and alignment with the 2013 WHO Framework of definitions and reporting.

#### Outcome and evidence of effectiveness of interventions proposed

Definition of key indicators: The NTP has a notification and reporting system which complies with WHO recommendations

Routine reporting: 100% of scheduled reports are available within the deadline specified in instructions

Periodic evaluation: The NTP will periodically review Programme progress and redirect activities and interventions based on the results of these evaluations

Annual program reports: Annual reports are available within the deadline set in the instructions and in a format consistent with international recommendations.

Impact: The NTP notification and reporting system meets internationally defined norms and the reported data is used to guide the Programme strategic directions and interventions.

#### **Community System Strengthening**

#### Rationale for selection

Access to health care in Sao Tome and Principe is supposed to be determined by the general public's level of information on diseases and by the offer of services (this is also valid for TB). The funding request includes this component in order to get the population closer to services and vice versa. The requested funding will enable the NTP to access the resources required to strengthen the capacity of community-based actors for sensitisation, social mobilisation and support to patients throughout their treatment. The NTP also expects to reduce cultural barriers in accessing treatment and care services as well as the stigma associated with TB.

#### Outcome and evidence of effectiveness of interventions proposed

Training of community actors, including the design of messages to convey to communities: representatives of civil society, the national TV and radio stations have engaged with each other during an awareness raising workshop on TB.

Contracting with community structures: a contract has been signed with community structures on an annual basis. The contract terms of reference describe the IEC advocacy and patient support activities which will be carried out.

Organize patient support by members of the community structures

Impact: Barriers to access to health services, in particular, to TB services and stigmatisation of TB patients are reduced.

#### 3.4 Focus on Key Populations and/or Highest-impact Interventions

#### This question is not applicable for low-income countries.

Describe whether the focus of the funding request meets the Global Fund's Eligibility and Counterpart Financing Policy requirements as listed below:

- a. If the applicant is a lower-middle-income country, describe how the funding request focuses at least 50 percent of the budget on underserved and key populations and/or highest-impact interventions.
- b. If the applicant is an upper-middle-income country, describe how the funding request focuses 100 percent of the budget on underserved and key populations and/or highest-impact interventions.

Sao Tome and Principe is a lower middle income country. Priority modules and associated interventions aim at a high impact. In addition, specific interventions towards key populations are being proposed. Hence, 63% of the Request's total budget is dedicated to improving screening among key populations, patient treatment and monitoring, MDR-TB and TB/HIV co-infection.

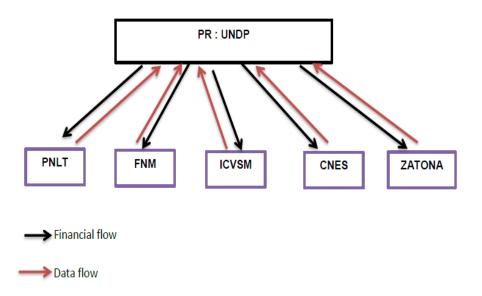
#### SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

#### 4.1 Overview of Implementation Arrangements

Provide an overview of the proposed implementation arrangements for the funding request. In the response, describe:

- a. If applicable, the reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement (i.e. both government and nongovernment sector Principal Recipient(s).
- b. If more than one Principal Recipient is nominated, how coordination will occur between Principal Recipients.
- c. The type of sub-recipient management arrangements likely to be put into place and whether sub-recipients have been identified.
- d. How coordination will occur between each nominated Principal Recipient and its respective sub-recipients.
- e. How representatives of women's organizations, people living with the three diseases, and other key populations will actively participate in the implementation of this funding request.
- a) At the end of the selection process, only one Principal Recipient met the requirements. Therefore a dual-track financing arrangement has not been possible. Besides, the selected Principal Recipient (PR) is managing the Global Fund TB grant for Sao Tome and Principe, alongside the HIV and Malaria grants.
- b) A single PR has been designated, therefore PR coordination is not an issue.
- c) Sub-recipients (SRs) are the same as the SRs under Phase 2 of the TB which is currently implemented. Since there is only one designated PR, the latter will carry out SR management on the basis of contracts which include the work plan, the budget and disbursement procedures. To this end, specific SR bank accounts will be opened so as to help track transactions. SR will submit quarterly reports to the PR fifteen (15) days after the end of a quarter. The PR will conduct quarterly SR monitoring visits. Like the

PR, SR will be subject to annual audits of their accounts. Financial and data information flows between the PR and SRs are as follows:



- d) The designated PR will ensure the coordination of its SRs
- e) Representatives of organisations of former TB patients, people living with HIV and key populations were involved in the country dialogue. Representatives of former TB patients and people living with HIV feature among CCM members. They can also be requested by community-based organisations to support awareness raising and social mobilisation activities.

#### 4.2 Ensuring Implementation Efficiencies

Complete this question only if the Country Coordinating Mechanism (CCM) is overseeing other Global Fund grants.

Describe how the funding requested links to existing Global Fund grants or other funding requests being submitted by the CCM.

In particular, from a program management perspective, explain how this request complements (and does not duplicate) any human resources, training, monitoring and evaluation, and supervision activities.

The CCM of Sao Tome and Principe currently oversees three grants addressing the three diseases. These grants are referenced as STP-809-G04-T, STP-011-G05-H and STP-M-UNDP by the Global Fund. All grants are managed by the same PR, UNDP with the same project management team. There is therefore no duplication of human resources.

As part of the management of the current Tuberculosis grant, a reassessment of UNDP needs as PR will be undertaken. Additional resources will be allocated to the PR if necessary.

## 4.3 Minimum Standards for Principal Recipients and Program Delivery

Complete this table for each nominated Principal Recipient. For more information on minimum standards, please refer to the concept note instructions.

PR 1 Name	United Nations Development Programme (UNDP)	Sector	Partner	
Does this Principal Regrant(s) for this disease system strengthening	⊠Yes	□No		
Minimum Standards	5	CCM assessment		
The Principal management structure	UNDP has accumulated experience in managing Global Fund grants. It has a multidisciplinary team which integrates key functions such as management, finance, procurement etc.			
•	ipient has the capacity and systems for ment and oversight of sub-recipients sub-recipients)	UNDP already Sub Recipier active Global Fo	its under	
3. The internal contreffective to preven	The system in place at the level of UNDP allows for efficient management and the avoidance of abuse and fraud.			
4. The financial management is effection	UNDP financial management system is satisfactory			
5. Central warehou capacity, and are ensure adequate of products	The central and regional warehouses have the required capacity and adhere to good storage practices			
6. The distribution sy are efficient to en health products to disruptions	Distribution systems and transport arrangements are effective and allow for continued and safe supply of healthcare products			
7. Data-collection ca program performa	Data collection capacity and tools exist and will be strengthened			
			system place is	
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain  Implementers are above the in-country supply chain  Implementers are above the in-country supply chain			ments for	

#### 4.4 Current or Anticipated Risks to Program Delivery and Principal Recipient(s) **Performance**

- a. With reference to the portfolio analysis, describe any major risks in the country and implementation environment that might negatively affect the performance of the proposed interventions including external risks, Principal Recipient and key implementers' capacity, and past and current performance issues.
- b. Describe the proposed risk-mitigation measures (including technical assistance) included in the funding request.
  - a) The portfolio analysis did not reveal any major risks related to management. It did not show significant risks inherent to the active HIV and Malaria grants either. To our knowledge, there are no major risks in the country and in the implementation environment which would adversely impact on the results of proposed interventions. However, political instability and weak management at SR level may affect grant results. A weak information system generating low quality data may also lead to a false appreciation of actual grant performance.
  - b) Government support, regular grant oversight by the CCM Oversight Committee and access to relevant technical assistance will allow the mitigation of most of these risks.

#### CORE TABLES, CCM ELIGIBILITY AND ENDORSEMENT OF THE CONCEPT NOTE

Before submitting the concept note, ensure that all the core tables, CCM eligibility and endorsement of the concept note shown below have been filled in using the online grant management platform or, in exceptional cases, attached to the application using the offline templates provided. These documents can only be submitted by email if the applicant receives Secretariat permission to do so.

- Table 1: Financial Gap Analysis and Counterpart Financing Table  $\boxtimes$
- $\boxtimes$ Table 2: Programmatic Gap Table(s)
- $\boxtimes$ Table 3: Modular Template
- $\boxtimes$ Table 4: List of Abbreviations and Annexes
- **CCM Eligibility Requirements**  $\boxtimes$
- $\boxtimes$ **CCM Endorsement of Concept Note**