

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	Romania	Component	TB
Funding Request Start Date	01 April 2015	Funding Request End Date	31 March 2018
Principal Recipient(s)	Romanian Angel Appeal Foundation		

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.

a. Current and evolving epidemiology

Romania reported 12,860 new tuberculosis (TB) cases, 3,851 retreatment cases, and 1,136 TB-related deaths in 2013 and has the highest TB incidence in the European Union/European Economic Area region. Global incidence peaked in 2002 with 142.2 cases per 100,000 declining to 73.0 cases per 100,000 in 2013. In 2013, out of the total new cases, 17.9% were extra-pulmonary and 82.1% were pulmonary out of which 59.2% smear-positive and 39.7% smear-negative. The majority of cases (77%) were classified as new, while 15.9% were relapse cases and 7.1% were other re-treatments.

Demographics: TB affects more men than women with rates in males accounting of 68% of all cases in 2013. The highest rates were reported for adults aged 45-64 years old and in young adults (15-44 years) with, respectively, 95.0 and 78.1 cases per 100,000 (global incidence). The median age was 44 years (range 0-96 years). Pediatric cases fell from 48.2 cases per 100,000 in 2002 to 22.0 cases per 100,000 in 2013. A total of 697 pediatric cases occurred in 2013 with 247 cases age 0-4 years and 450 were 5-14 years.

Geographic Variation: Regional differences exist in the country with TB notifications ranging from 26 cases per 100,000 population (2013) in the least affected county to 113 cases per 100,000 in the highest impacted area. Variations are related to the socio-economic status with higher case rates reported in the Eastern, Western and Southern parts and lower rates in the Central and North-western parts.

MDR-TB: Romania has estimated 500 – 1,100 new multi-drug resistant (MDR-TB) cases per year, but detects only 66% of cases. According to the Global Tuberculosis Report 2012, the estimated MDR-TB burden in the country in 2011 was 2.8% among new (1.8-4.2) and 11% (8-15) among retreatment cases. The number of cases reported represents the total case burden due to the low drug sensitivity test (DST) coverage of all culture positive cases. Culture confirmation was available in 77.1% of all TB cases with DST results for Isoniazid and Rifampicin available only for 62.1% of culture confirmed cases (7473/12030) in 2012. Out of the pulmonary cases tested for MDR-TB, a total of 680 cases were diagnosed.

HIV/AIDS and TB/HIV Co-Infection: In 2013 the HIV/AIDS situation in Romania remains stable, with no major changes in incidence in adults or in children. As in the previous

years, the main route of transmission has been heterosexual (54.58% of all new cases). Most new HIV/AIDS cases (35%) have been registered in the age group 20 to 24 and are represented by late presenters. However, an increase in the number of HIV cases is observed among IDUs. Data indicates that IDUs represented 29.23% of the new cases of HIV/AIDS diagnosed in 2013 (compared to 3% in 2010). The proportion of MSM among the newly diagnosed cases has maintained at 11.4%, almost at the same level as in the previous couple of years.

TB/HIV co-infection remains relatively low in Romania. In 2008/2009 the percentage of HIV positive cases among TB cases was 3.3%, declining to 2.6% in 2013. The total number of cases was 267 (2013), which was a slight increase over the prior year. According to National AIDS Commission, all HIV cases are tested for TB. According to the NTP, the number and percentage of TB patients tested for HIV increased since 2008. In 2013, the NTP reported that 61.0% of TB patients have been tested for HIV, but this percentage is not accurately reflecting the real number of TB patients tested for HIV as not all the data is registered into the national TB database.

Treatment Outcomes: Romania has successfully treated over 82% of new pulmonary confirmed cases since 2002 reaching 86% in 2012 (for 2011 cohort) and 86% for smear-negative and extra-pulmonary cases, but successful treatment outcomes remains low among retreatment cases (61.1%). Treatment for MDR-TB has been divided into two groups. The first group involves patients enrolled in a comprehensive treatment program, funded by the GFATM and supported by the GLC with drugs provided through the Global Drug Facility (GDF). The remaining MDR-TB patients receive drugs that are available through Romania's current drug procurement process. Between 2004 and 2014 (30th June), a total of 1,157 patients were enrolled in the GLC program supported by GFATM funding, with 79 more patients to be enrolled by 31st December 2014. Treatment success for patients in the GLC patient cohorts have ranged from 59% for the first cohort (2006) to 75% in cohort 2 (2007-08) and 66.2% in cohort 3 (2009). In comparison, the treatment outcomes for the non-GLC cohorts are extremely less favorable with the 2011 treatment cohort achieving only 20% treatment success. The primary factor for the poor outcomes for non-GLC cohorts has been the lack of appropriate medications and support.

TB Mortality: Adjusted TB mortality rates from vital registration systems reflect an overall downward trend from 10.2 in 2003 to 5.3 per 100,000 population in 2013.

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

TB adversely affects the most vulnerable segments of Romania. In Romania, most of the population affected by tuberculosis is at risk of poverty or belong to a vulnerable group such as the homeless, injecting drug users (*a population among which HIV infection, hepatitis B and C increased progressively since 2010*), or the country's rural population with has limited access to health services.

The country's rural population, which comprises 45% of the population, suffers from high rates of poverty and low socio-economic development. Only about 50% of rural residents have access to improved sanitation facilities, and 40% have difficulty with access to primary healthcare services compared to only 15% in urban areas. Rural populations are more affected by TB and are at higher risk for treatment default. The minority Roma population are also disproportionately poorer than the majority Romanians, with as many

as 75 percent of Roma living in poverty compared to 32.2 percent overall of Romanians (source: Amnesty International). While the NTP does not collect specific ethnic data on patients, TB rates among Roma have been reported to be double that of the general population and up to four times higher in adults ages 55-64¹.

TB among Homeless Population: There are an estimated 11,000 homeless in Romania with 5,000-6,000 living in Bucharest. A 2011 study² estimated that TB prevalence in the Bucharest homeless population at 6,700 cases per 100,000, or 50 times higher than the general population. According to data from the National Tuberculosis Programme, homelessness was associated with 135 TB cases in 2013 up from 127 in 2012.

IDU Population: An emerging concern involves the rise in injectable drug users (IDU). Within Romania, the number of IDUs increased during the past few years to an estimated 20,000 drug users in Bucharest (2011). There has also been a rise in the percentage of PLHIV co-infected with TB among the IDU population: national data shows a dramatic increase over the last five years in the absolute number of IDUs diagnosed with HIV/AIDS (from 8 in 2009 to 260 in 2013) and a consequent increase of their proportion among the new cases (3% in 2010, about 30% in 2013). Most recent data confirms an expected association between HIV and TB: about 1 in 5 IDUs diagnosed with HIV/AIDS during the first six months of 2014 were co-infected with tuberculosis, the next most important co-infection after hepatitis C (76%) (National AIDS Commission, June 2014).

Moreover, an RDS study conducted in 2012 among IDUs living in Bucharest (N=417) showed that the population is at high risk of contracting and transmitting TB: 26% are homeless or are squatting, 34% live in households with more than five people, while more than half have an imprisonment history and most have no health insurance (76.8%). Moreover, less than 1 in 3 IDUs know that TB treatment is free of charge although they know that TB can be treated (70.5%). In this context, only 36% of IDUs access medical services when experiencing symptoms potentially related to TB³.

TB in Prisons: There are 38 penitentiary centres and six prison hospitals in Romania. Within the penitentiary system, the TB notification rate declined from 2,235 per 100,000 in 2003 to 479 per 100,000 in 2013, but this is still 6 times higher than in general population.

The National Administration of Penitentiaries currently implements a National TB Plan (National Administration of Penitentiaries' Decision N°672 of 21 September 2012) that outlines all TB prevention and control activities to be undertaken in prison. With the support of the Global Fund the National Administration of Penitentiaries has achieved very satisfactory results during the past years. It collaborates closely with NTP, adopting same guidelines and be supplied with all anti-TB drugs from the MoH budget. The national plan for TB infection control in prisons has been very effective in reducing transmission, counting on more than 4,000 prison security staff specifically trained since 2006. Impressive is the health education programme, with 840 among guardians, social workers and nurses trained as health educators since 2004 (source: WHO Regional Office for Romania: Review of the National Tuberculosis Programme in Romania, 10–21 March

¹ European Roma Rights Centre, October 2013

² Furtunescu F., Domnariu C.D., Cioran N., Mincă D.G. (2011) Improving the TB control in homeless people in Romania - model of partnership among public institutions and civil society. European Journal of Public Health, 21, 1 (S): 142

³ NIHD, 2014, https://intra.tai.ee/images/prints/documents/139766011328_TUBIDU_study%20report_final_2014.pdf

2014). As a result, the National Administration of Penitentiaries is currently successfully continuing the infection control and TB education activities which have been funded by the previous GFATM grants, while the other services (such as diagnostic, care and treatment) are already well integrated.

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

Within Romania, the diagnosis and treatment of TB is free of charge. Treatment costs are paid for by National Health Insurance program regardless of the insurance status of a patient. However, there remain challenges with access to diagnosis in rural areas and for both diagnosis and treatment in the case of Romania's TB and M/XDR-TB patient population. Drug-sensitive TB patients lack appropriate treatment supervision in many regions of Romania and all lack financial support except those few who hold salaried positions which offer paid sick leave. M/XDR-TB diagnosis and treatment remains inadequate in regard to achieving rapid quality diagnosis, continuous, quality treatment and appropriate support. This places a great burden on the poorest patients with the weakest social networks who are often unable to complete treatment due to the economic necessity to support their families.

Only 20% of MDR-TB patients successfully complete treatment; one of the lowest rates recorded in the world and less than half of the regional average. Of the total number of M/XDR-TB Romanian patients, only part are on appropriate treatment in accordance with international standards due to gaps in drug availability.

There is also uneven distribution and shortages of family doctors across the country. Family doctors are most scarce in rural, hard-to-reach areas. The presence of a family doctor in one's community does not guarantee TB patients access as these doctors have a ceiling of 2,200 insured patients. Uninsured patients are technically assured for certain services, but because of the rules for compensation as well as a lack of willingness to treat TB, some of the neediest patients may find themselves without access to a family doctor. This leads to delayed diagnosis, as patients wait until their symptoms are severe before going to the hospital, while the TB disease is progressing and patients become sources for TB spread, increasing the TB infection reservoir. Diagnosis is also affected by geographic differences in access to laboratory services. There is no established system to ensure that these services (including the transportation of sputum and referral to labs offering rapid testing) are uniformly available which affects quality of medical care.

d. The health systems and community systems context in the country, including any constraints.

Romania is politically organized into 41 counties along with the Municipality of Bucharest. Each county is administered by a county council, responsible for local affairs. The counties are further subdivided into cities and communes, who have their own mayor and local council. At the county level Public Health Directorates (PHD) are responsible for public health in their counties with the Ministry of Health (MOH) having the central authority in public health including communicable diseases. The MOH sets organizational and functional standards, develops and finances national public health programs, and collect and analyzes data on the population's health status.

The National Program on Tuberculosis (NTP), located in the Marius Nasta Institute in Bucharest, maintains responsibility for setting diagnostic and treatment standards, conducting surveillance, and developing technical capacity. The MoH, allocates resources for TB care, drugs and consumables to Marius Nasta Institute and to all TB units in the country. An NTP coordinator manages the program through a Central Coordination Unit

(CCU). The NTP currently consists of 10 employees (8 are part-time and 2 full-time employees).

Diagnostic and treatment services for TB are provided through a network of facilities referred to as the Romanian TB Network. The Network includes more than 700 doctors and over 2,000 nurses across the country. Diagnosis and ambulatory care are provided by 174 TB dispensaries supported by a series of laboratories, while in-patient treatment services are provided through 93 TB hospitals and TB departments located in general hospitals (municipal, county, and regional tertiary centres). Forty-one county hospitals are organized into eight regions which offer a range of clinical services and beds dedicated to TB patients. The dispensaries, hospitals and workforce in the network operate under local counties (Judets) and municipalities through county public health departments. While these facilities are essentially autonomous through Romania's decentralization of healthcare reforms they are required to follow guidelines developed by the NTP and set by the MoH which funds prevention and disease control activities.

Family doctors, who work independently from the public health system, provide the majority of primary care services. These doctors receive contracts and payments through the National Health Insurance House (NHIH) to care for a specific list of insured population. As of 2013, there were around 10,000 doctors with an average list of 2,000 patients. While family doctors are not part of the formal TB network, the doctors - with their nursing staff - have played until 2009 an important role in TB referrals, contact tracing and continuation of care. The role of family doctors has been adversely affected by changes in how doctors are compensated for TB services. Doctors were paid for diagnosing and supervising TB patients, but the government ceased these payments in 2010 in exchange for a fee per-service structure with very limited reimbursement for TB care. As a result fewer and fewer family doctors are interested to take on TB patients or assist with public health activities.

While there is currently a broad network of facilities and personnel involved with TB control, there are several important challenges that must be considered to sustain effective TB control program:

1. Unavailability of rapid testing for MDR-TB that creates a time lag between the request for drug sensitivity testing and availability of results;
2. Poorly managed second-line treatment outside the limited number of patients in the Global Fund-treatment cohort due to missing second-line drugs (SLDs) on the Romanian market;
3. Costly, and often unnecessary, hospitalization of TB patients;
4. Insufficient infection control in hospitals and laboratories exposing patients, families and health care workers to higher risk of contracting TB;
5. Poor DOT during outpatient treatment for both sensitive and resistant TB cases due to weak community worker network and lack of involvement of family doctors;
6. Limited social support for patients with TB, insufficient psychological support provided to TB patients;
7. Insufficient scale-up of education and prevention activities among poor and vulnerable populations (homeless, rural populations, and Roma);
8. TB screening, diagnosis and treatment in high risk groups insufficiently addressed; and
9. Insufficient trained workforce for TB control and no systematic method to develop personnel skills and capacities.

1.2 National Disease Strategic Plans

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 requests⁴, 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.

a. Key goals, objectives and priority program areas.

Romania recently revised its National Strategic Plan for the Control of Tuberculosis in Romania 2015-2020 (NSP). The current plan covers 2015-2020 with the following major objectives:

Objective 1 - Ensure universal access to rapid diagnosis methods for DS-TB and M/XDR-TB by 2020

Objective 2 - Diagnose at least 85% of all estimated DS-TB and MDR-TB cases

Objective 3 - Successfully treat at least 90% of new culture positive TB cases and 85% of all retreatment cases by 2020.

Objective 4 - Successfully treat 75% of MDR-TB cases by 2020.

Objective 5 - Reduce overall TB mortality rate to 4.3 per 100 000 population by 2020.

Objective 6 - No affected families facing catastrophic costs due to tuberculosis.

Objective 7 - Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and relapse cases will decrease from 73 in 2013 to 46.59 cases per 100 000 population by 2020.

Objective 8 - Improve health system capacity to control TB.

The NSP is based on the WHO's post-2015 strategy for TB and is structured around the following three core components:

- Integrated Patient-Centered Care and Prevention
- Bold Policies and Supportive Systems
- Innovative Research and Evidence-based Strategies

⁴ 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.

The following major interventions will be conducted in pursuance of the newly adopted TB NSP:

Pillar 1: Integrated Patient-Centered Care and Prevention

Interventions:

- 1.1. Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing
- 1.2. Improve the timeliness and accuracy of diagnosis of TB
- 1.3. Effectively treat TB patients by following WHO-treatment recommendations
- 1.4. Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation
- 1.5. Improve patient support and case holding systems
- 1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control
- 1.7. Ensure collaborative tuberculosis/HIV activities

Pillar 2: Bold Policies and Supportive Systems

Interventions:

- 2.1. Ensure adequate resources for tuberculosis care and prevention
- 2.2. Strengthen the capacity of the National TB Program for TB control
- 2.3. Develop human resource capacity for TB care and prevention
- 2.4. Establish centralized procurement and distribution of first, second and third-line anti-TB medications
- 2.5. Establish infection control standards and requirements for healthcare facilities
- 2.6. Engage and facilitate involvement of impacted communities and civil society organizations in TB control
- 2.7. Support the involvement of public sector and family doctors and community workers to provide ambulatory and community-based TB care and services

Pillar 3: Innovative Research and Evidence-Based Strategies

Interventions:

- 3.1. Ensure a dynamic and effective TB surveillance system
- 3.2. Develop epidemiological and research capacity for TB control
- 3.3. Conduct operational and epidemiological research to improve TB control

b. Implementation to date, including the main outcomes and impact achieved.

The current strategy for TB builds upon past efforts which began in 1997 when Romania piloted the WHO DOTS Strategy. Following this, Romania adopted its revised “Tuberculosis National Strategic Plan for the Control of Tuberculosis 2015-2020” in alignment with the WHO’s six-point Stop TB Strategy 2006-2015. That plan was updated several times with the most recent version entitled “Tuberculosis National Strategic Plan, 2013-2017”. As part of the last plan, the NTP established the following primary targets to be achieved by 2017: 1) reduce by 50% TB prevalence and mortality (2002 baseline); 2) maintain a case detection rate of new smear-positive pulmonary TB cases over 70%; and 3) maintain the treatment success rate among new pulmonary TB sputum-positive cases of 85%. The major intervention areas corresponded to the six components of the Stop TB Strategy: 1) Pursue high-quality DOTS countrywide and enhancement; 2) Address TB-HIV, MDR-TB and the needs of poor and vulnerable populations; 3) Contribute to health system strengthening; 4) Increase engagement all care providers in TB infection control; 5) Empower people with TB and communities in order to fight TB, and 6) Enable and promote research. Romania subsequently drafted a separate strategic plan for MDR-TB,

the “National plan to prevent and control M/XDR-TB, 2012-2015”, officially launched in October 2012, however, implementation was delayed due to the lack of financial resources during the recent economic crisis. As part of the current national strategy, 2015-2020, MDR-TB activities have been incorporated into the current overall plan. The National TB Control Program (NTP) in Romania has made remarkable progress to detect and treat TB. For instance, Romania achieved the following targets:

- Case detection of TB regularly exceeds the international target of 75%;
- TB incidence declined from its a peak of 142.2 cases per 100,000 (2002) to 73.0 cases per 100,000 in 2013;
- The total number of cases notified fell to 16,711 total cases (2013);
- Treatment success rates for new smear-positive TB cases reached 86% in 2012 (for 2011 cohort), and 86% for smear-negative and extra-pulmonary TB cases;
- TB-related deaths fell from 10.8 (2002) to 5.3% in 2013;
- Establishment of patient-peer education program.

However, the country did not achieve several of its targets. In particular, culture confirmation was available for only 73.4% of cases, but drug sensitivity test (DST) results for Isoniazid and Rifampicin were available only for 62.1% of culture confirmed cases (7473/12030) in 2012 (Source: NSP 2015-2020).

Treatment outcomes for patients in the GLC cohorts have ranged from 59% treatment success for the first cohort (2004-05) to 75% in cohort 2 (2006-07) and 66.2% in cohort 3 (2009), however the treatment outcomes for the majority of MDR-TB patients who not part of the GLC cohorts treatment cohort remain unacceptable with around 20% treatment success rate (Source: NSP 2015-2020).

c. Limitations to implementation

Romania recently conducted a national program review for TB that identified several significant challenges. Some of the key challenges include the following:

- Unavailability of rapid testing for MDR-TB that creates a time lag between the request for drug sensitivity testing and availability of results;
- Poorly managed second-line treatment outside the limited number of patients in the Global Fund-treatment cohort due to missing second-line drugs (SLDs) on the Romanian market;
- Unreliable drug supplies caused by decentralized procurement;
- Costly, and often unnecessary, hospitalization of TB patients;
- Insufficient infection control in hospitals and laboratories exposing patients, families and health care workers to higher risk of contracting TB;
- Poor DOT during outpatient treatment for both sensitive and resistant TB cases
- Limited social support for patients with TB, insufficient psychological support provided to TB patients;
- TB screening, diagnosis and treatment in high risk groups insufficiently addressed, and;
- Insufficient scale-up of education and prevention activities among poor and vulnerable populations.
- Insufficient trained workforce for TB control and no systematic method to develop personnel skills and capacities.

While laboratory services in Romania overall performed adequately for the identification of new TB cases, a number of challenges and gaps need attention to ensure that patients are placed on the most effective treatment regimens. Laboratories in Romania lack new

diagnostic technology, reliable supply of consumables, and adequate infection control measures. Staff are also not appropriately trained and supervised. In addition, a number of laboratories do not meet minimum processing thresholds and the overall system EQA is weak. This will require modernizing diagnostic facilities with more rapid technologies, reducing facilities that do not meet performance standards, and ensuring sufficient, trained laboratory staff to carry out important laboratory functions. Romania recently received external support for Norway that will be used to assist in meeting many of these challenges and other related needs that are proposed in the new NSP 2015 - 2020.

The primary factors for the poor treatment outcomes with the non-GLC, MDR-TB patients have been the lack of appropriate medications and support. To improve the drug procurement situation, Romania must develop a more effective system for securing and managing anti-tuberculosis medications, in particular to obtain WHO-recommend second-line drugs (SLD). Romania requires policies and regulations that will urgently resolve procurement barriers for SLDs including allowing for emergency public health exceptions for tenders in order to purchase critical medications through mechanisms such as the GDF. The system also needs to be capable to monitor at national level the orders, consumption and stocks. Once established, trainings on drug management: quantification, ordering, stores management are needed to build sustainable capacity. A plan to address these issues is part of the new NSP 2015 – 2020.

In terms of health system capacity objectives, while several trainings were conducted, ensuring a sufficiently trained workforce for TB control remains a challenge. There is not a systematic method to develop personnel skills and capacities and there is no focal staff responsible to develop and rationally plan for human resource needs. Most training occurs on-the-job. If there is a training, it is often episodic and not followed up by mentoring or supportive supervision. Many of the current personnel working on TB are aging and are not being replaced due to unattractive low salaries and the inability to compete with private sector opportunities both inside Romania and within the EU region. Under the new plan, a comprehensive HRD assessment and education/training plan will be developed and technical assistance has been proposed to secure technical assistance responsible for these activities.

In the past, “private sector” family doctors were paid for diagnosing and supervising TB patients, but the government ceased these payments in 2010 in exchange for a fee per-service structure with very limited reimbursement for TB care. As a result fewer and fewer family doctors are interested to take on TB patients or assist with public health activities. Under the new strategy, the Ministry of Health (MoH) will address the compensation barriers to involve more family doctors.

The NTP also does not routinely conduct research or critically analyze TB data. With support from the Government of Norway, Romania’s TB surveillance system will be updated and staff trained for using TB data. Under the new NSP 2015 - 2020, Romania will develop the overall epidemiological capacity for TB and conduct critical operational research.

Finally, Romania included in the NSP 2015-2020, the development and implementation of a major reform aimed on changing the current system of care for TB cases from in-patient to out-patient care, which will result in reduction of hospitalization cost while redirecting more resources to ambulatory and patient-centered care, including additional support for DOT, ensuring incentives for patients including housing for homeless TB patients,

palliative care measures and re-organisation of 2 medical centers to assist TB/X/MDR-TB socially deprived cases during the treatment. The steps of this reform are described as follows:

- Conduct a national assessment regarding the situation of ambulatory and hospitalized treatment in Romania including current situation of engagement of all TB care providers in service delivery in Romania and the implementation of PAL strategy.
- Development of the reform plan with objectives, targets and responsible parties
- Assessment and revision of the financial mechanism of TB and family doctors reimbursement including unit cost per service provided and framework of payments for each medical staff category.
- Elaboration of the financial mechanism for the community workers and NGOs.
- Re-organisation of 2 medical centers to assist TB/X/MDR-TB socially deprived cases during the treatment.
- Development of the comprehensive national guideline for the diagnosis, treatment and case management of TB that reflect updated policies and recommendations, including the criteria selection of TB patients for hospitalization or for ambulatory care.
- Provision of TB training sessions for family doctors, community workers and NGOs.
- Starting the implementation of the reform in 6 TB counties with high TB burden through provision of adapted services for the ambulatory patients:
 - Establish multidisciplinary teams to provide medical, social and psychological services to all cases diagnosed with TB. These teams will evaluate patients for non-adherence and establish an individualized plan to address social and psychological support needs.
 - Provision of patient education on treatment and treatment adherence through:
 - Provision of directly observed treatment to new and retreatment DS-TB patients through TB units, but also through a range of DOT supporters for TB including community health workers, family doctors, social assistants, NGO/CSO representatives.
 - Provision of social support in the form of incentives and enablers (food and transport) for all patients in treatment ambulatory phase.
 - Provision of psychological and peer support for the patients at high-risk of default based on assessment provided by the multidisciplinary teams through specialized psychologist and peers
- Approval of the legislative framework by all the stakeholders involved.
- Scale up the reform including each year additional counties.
- Secure the funds saved from hospitalization for TB related activities through yearly budget requests from NTP and MoH to the Ministry of Finance.
- Monitoring and evaluation of the ambulatory model of care, including a cost-analysis study.

Through the implementation of this reform, it is expected that the cost for hospitalization for TB will decrease from 23 million EURO per year in 2015 to less than 6 million per year

in 2020, through:

- Progressive decrease in the number of hospitalization days from 561,000 days in 2015 to 132,720 days in 2020 by:
 - Progressive decrease in the percentage of TB patients hospitalized, from 92% in 2015 to 50% in 2020 and the period of hospitalization from 33 days/patient in 2015 to 20 days/patient in 2020.
 - Progressive decrease in the percentage of MDR-TB patients hospitalized from 95% in 2015 to 60% in 2020 and the period of hospitalization from 93 days/patient in 2015 to 50 days/patient in 2020.

d. The main areas of linkage to the national health strategy, including how implementation of this strategy impacts relevant disease outcomes.

The current structure of the Romanian health system reflects a process that began in December 1989 with the end of the Socialist Republic of Romania and following accession within the European Union. Romania's health system moved away from the Semashko Soviet model to a model of health care delivery relying upon a network of family medicine practices and facility-based outpatient services with specialists and in-patient hospital services. The public health network is devoted to health promotion, prevention and environmental health supported by a small network of civil society organizations involved in outreach activities, mainly concentrated in large cities and depending of external funds.

The most important recent health care reforms include passage of the Health Insurance Law in 1997 and the Health Reform Law passed in 2006. The Health Insurance Law transferred health care institutions ownership and replaced central planning to the National Health Insurance House (purchasing services) and the health facilities providing services. The coverage of the national health insurance was designed to be universal, covering all Romanian residents and with compulsory payment excluding people with conditions of public health relevance such as TB and HIV. In 2006, the Health Reform Law focused on prevention and primary health care, clarified the role of the private sector, and improved linkages between the public health care and social assistance systems. The new TB control strategy seeks to strengthen the relationship with private sector practitioners, develop local capacity for health care planning and decision-making, and provide rational health care services in terms of diagnostics (laboratories following standards of practice) and clinical care (develop patient-centered strategies and alternatives to hospitalization while maintaining critical public health infrastructure and capacity).

e. Describe existing TB/HIV collaborative activities

The testing for HIV among TB patients is regulated by a 1993 MOH order and updated in 1999. In 2011, the MOH, NTP and National Commission to Fight AIDS developed a TB/HIV collaborative protocol to strengthen HIV/TB activities including testing and reporting of TB and HIV. As part of this protocol, all TB cases (bacteriological confirmed or non-confirmed) should be tested for HIV and, conversely, all persons infected with HIV should be screened for TB at infectious disease hospitals. Any case suspected of TB is referred for further investigation. The current target for testing of HIV status in TB patients is 90%. However, this target has not been met. In 2013, out of 16,711 registered TB patients, a little more of one-half of TB patients (61.0%) had a known HIV status reported with 267 patients (2.6%) identified as HIV infected. Improvements are needed to both improve the timeliness and accuracy of TB tests in HIV positive patients and to increase the number of TB patients who know their HIV status. These steps are required to ensure that the problem of TB-HIV

co-infection remains under control.

If a patient with HIV has TB diagnosed, that patient is started on anti-TB treatment, which has priority over anti-retroviral treatment (ART). The treatment of patients with HIV infection and smear positive TB is done in pulmonary departments. Treatment should occur within the TB hospital to prevent the exposure and transmission of infectious TB to other patients, but this does not always occur. Isoniazid preventive therapy (IPT) is recommended only to HIV positive patients have a high risk of TB. In 2012, (according to TB Monitoring and Evaluation, WHO, 2012), the many of the HIV-positive TB patients were on Co-trimoxazole preventive therapy (CPT) meaning 145 or 61.2%. Also, 211 (89.0%) patients were provided antiretroviral therapy (ART). Unfortunately, co-infected patients continue to experience worse treatment outcomes than HIV-negative patients: 69.3% success rate for pulmonary new cases C+, and HIV+, compared to 86.1% success rate for pulmonary new cases C+, HIV-negative for 2011 cohort. Non-adherence is very frequent among injection drug users (IDUs), even in those in substitution therapy, due to many factors including methadone interactions with TB medication.

f. Country processes for reviewing and revising the national disease strategic plan(s)

The National Strategic Plan for Tuberculosis, 2015-2020 was designed through a collaborative process led by a working group comprised of representatives from the Ministry of Health, the National Tuberculosis Program, the World Health Organization (WHO), and with various other governmental and non-governmental organizations. The purpose of the plan was to set national tuberculosis control strategies based on Romania's current epidemiological and program needs and to set national targets for improving program performance. To ensure implementation of the National TB Control Strategy 2015-2020, the proposed strategy was reviewed by key governmental partners and stakeholders and supported through governmental approval.

To monitor and evaluate the implementation and outcomes of the NSP, the NTP will coordinate and supervise implementation of the strategy and annually report on progress and barriers to both the CCM and the TB Network. Progress reports will be made available to the MOH and government representatives as well as to the public. Monitoring and evaluation will measure the success of activities from the perspective of process and impact results.

Periodic evaluation regarding the implementation of the NSP shall be done at every 2-3 years, by the international bodies with expertise in the area of TB (WHO, ECDC, IUATLD), in collaboration with local experts.

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.

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).

Romania developed a new National Strategic Plan for TB Control, 2015-2020 (NSP) through a collaborative process to identify critical challenges based on Romania's current epidemiological and program needs, to elaborate national strategies, and set targets for improving program performance. During the NSP design process, a range of potential funding sources were researched and identified, including World Bank loan, GFATM NFM, and European Social Funds (ESF) along with domestic funding, to address these strategies and implement the key interventions included in the NSP.

The main financial sources⁵ identified to allow implementation of the NSP 2015 – 2020 include: The Government of Romania, The Global Fund, The Norway Financial Mechanism, The European Social Fund (via the Ministry of Health) and World Bank.

The total necessary budget to ensure the implementation of all interventions included in the NSP 2015 - 2020 is of **279,029,902.7 Euro for six years**, out of which the following commitments or expected commitments are detailed in the table below.

The areas that are adequately resourced and, therefore, not included in the request to the Global Fund are the following (highlighted in green in the table below):

- Prevent transmission of TB through vaccinations, targeted screenings, and infection control
- Strengthen the capacity of the National TB Program for TB control
- Ensure a dynamic and effective TB surveillance system
- Conduct operational and epidemiological research to improve TB control.

The areas that are included in the financial request to the Global Fund are highlighted in yellow in the table below. The figures represent the percentage of funding per programme area per identified funding source out of the total budget of NSP 2015-2020:

⁵ Other sources include grants from GDF (Global Drug Facility) and EUCOM (United States European Command).

No	Programme Area (Interventions as per NSP)	GoR	GFATM	NORWAY GRANTS	ESF	WORLD BANK	OTHER
1.1	Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing	49.6%	3.8%	12.5%	27.0%	7.0%	0.3%
1.2	Improve the timeliness and accuracy of diagnosis of TB	46.4%	7.5%	0.1%	45.8%	0.3%	0.0%
1.3	Effectively treat TB patients by following WHO-treatment recommendations	99.3%	0.3%	0.0%	0.0%	0.0%	0.3%
1.4	Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation	70.6%	13.2%	16.0%	0.2%	0.0%	0.0%
1.5	Development and implementation of a comprehensive ambulatory care and support system	51.1%	6.9%	1.9%	33.4%	6.7%	0.0%
1.6	Prevent transmission of TB through vaccinations, targeted screenings, and infection control	61.9%	0.0%	18.2%	0.1%	18.3%	1.5%
1.7	Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities	66.5%	1.9%	0.0%	31.7%	0.0%	0.0%
2.1	Ensure adequate resources for tuberculosis care and prevention	98.0%	0.8%	0.0%	1.1%	0.0%	0.0%
2.2	Strengthen the capacity of the National TB Program for TB control	99.3%	0.0%	0.3%	0.4%	0.0%	0.0%
2.3	Develop human resource capacity for tuberculosis care and prevention	0.0%	1.7%	4.6%	93.7%	0.0%	0.0%
2.4	Establish centralized procurement and distribution of first, second and third-line anti-TB medications	47.6%	26.8%	25.6%	0.0%	0.0%	0.0%
2.5	Establish infection control standards and requirements for healthcare facilities	0.0%	21.3%	78.7%	0.0%	0.0%	0.0%
2.6	Engage and facilitate involvement of impacted communities and civil society organizations in TB control	0.0%	60.0%	0.0%	40.0%	0.0%	0.0%
2.7	Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and services	0.0%	58.4%	0.0%	41.6%	0.0%	0.0%
3.1	Ensure a dynamic and effective TB surveillance system	4.6%	0.0%	95.4%	0.0%	0.0%	0.0%
3.3	Conduct operational and epidemiological research to improve TB control	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%

Since all the funding sources for the successful implementation of the NSP 2015-2020 have been identified, among which the Government of Romania being the largest carrier of the financial burden, the sustainability of the interventions lay on the approval by Government Decision of the National Strategic Plan for the Control of Tuberculosis in Romania 2015-2020. At the very moment of submission of this funding request, the Ministry of Health is preparing the NSP to be uploaded on the MOH website for public debate as prerequisite (according to Romanian legislation), for the issuing of a Government Decision. It is expected that the Government Decision regarding the approval of the NSP 2015-2020 to be formally issued by early 2015.

b. How the proposed Global Fund investment has leveraged other donor resources.

Despite the economic crisis, the proposed Global Fund investment has garnered the commitment from the Ministry of Health. Moreover, during the country dialogue and during the process of development of the NSP 2015-2020, the CCM conducted transparent discussion with all potential donors in order to identify all available resources and catalyse all these financial efforts in order to meet strategic objectives and targets contained in the NSP. Along the Global Fund, the World Bank, the Norway Financial Mechanism, the European Social Fund and the Ministry of Health are the main donors whose financial support would contribute to the implementation of the TB NSP 2015 – 2020 in Romania.

c. For program areas that have significant funding gaps, planned actions to address these gaps.

The NSP 2015-2020 was elaborated based on the full assessment of the needs versus programmatic and financial gaps and as reflected in **TABLE 1 – Financial Gap Analysis and Counterpart Financing Table**, there is no other significant programmatic and financial gap.

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 (partially) ☐ No	YES (partially): The financing provided by the Ministry of Health and National Health Insurance House is stated in the letter issued by the Ministry of Health No. 55144/11.09.2014 (Annexes 8 and 9). Funding for health workforce in TB dispensaries (doctors, nurses and auxiliary staff) and for hospitalization of TB and MDR-TB cases paid by National Health Insurance House, were calculated based on the assumptions from the NSP 2015-2020 budget, which are detailed in the Annex 1: Additional Data for Standard Financial Gap” and supporting documents (Annexes 5, 6, 7, 10, 11 and 12) . Assumptions were used instead of budgets communicated by Government institution because in Romania, TB related costs (hospitalization, human resources, administrative costs) are included under the costs of the larger medical specialty called “pneumo-ftiziology” along with other lung diseases and conditions. As a result, the financial information regarding staff payments and hospitalization for TB only is not available.
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper	☒ Yes ☐ No	The government contribution to disease program is 96% (as per the Table1: Financial Gap Analysis and Counterpart Financing).

lower-middle income-40%, upper middle income-60%)		
iii. Increasing government contribution to disease program	☒ Yes ☐ No	
b. Compared to previous years, what additional government investments are committed to the national programs (TB and HIV) 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.		
b. The overall government budget for TB control will reach the maximum pick in 2016 and will gradually decrease by 2019 due to: i. The decrease in the total number of TB patients and ii. The reduction of hospitalization cost by implementation of the ambulatory care system. However, the domestic budget for the specific activities included in the National TB Program (diagnostic, treatment, DOT, etc.) will gradually increase, so that the NTP budget in 2017 will be 50% higher than the amount corresponding to year 2014. The interventions or activities that are expected to be financed by the additional government resources are detailed in the Programmatic and Financial Gap Analysis of the new National Strategic Plan 2015 – 2020. These commitments will be tracked through the annual reports of the National TB Programme as mentioned in the NSP 2015 – 2020. In addition, the NSP 2015-2020 includes a mid-term evaluation by a common WHO-ECDC mission planned for 2017, which will assess both programmatic and financial performance in the implementation of the NSP. c. The financing provided by the Ministry of Health and National Health Insurance House is stated in the letter issued by the Ministry of Health No. 55144/11.09.2014 (Annexes 8 and 9). Funding for health workforce in TB dispensaries (doctors, nurses and auxiliary staff) and for hospitalization of TB and MDR-TB cases paid by National Health Insurance House, were calculated based on the assumptions from the NSP 2015-2020 budget, which are detailed in the Annex 1 “Additional Data for Standard Financial Gap”. Assumptions were used instead of budgets communicated by Government institution because in Romania, TB related costs (hospitalization, human resources, and administrative costs) are included under the costs of the larger medical specialty called “pneumo-ftiziologie” along with other lung diseases and conditions. As a result, the financial information regarding staff payments and hospitalization for TB only is not available.		

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.

For two out of the four modules of the financial request (Module "TB Care and Prevention" and Module "MDR-TB") predefined standard indicators have been used. For the other 2 modules have been created special indicators to allow measuring the activities that will be implemented.

Regarding the Module "TB Care and Prevention": 8 indicators have been used out of the 11 predefined indicators, due to the following:

- Indicator DOTS-3: Percentage of laboratories showing adequate performance in external quality assurance for smear microscopy among the total number of laboratories that undertake smear microscopy during the reporting period: no data available at national level or the ability to aggregate the data collection in Romania, in addition there are any activities included in the financial request related to this indicator.
- Indicator DOTS-4: Percentage of reporting units reporting no stock-out of first-line anti-TB drugs on the last day of the quarter: At this time, the acquisition of drugs is the responsibility of each hospital, each hospital having its own system of medicines management, so no centralized data nationwide available. Among the activities included in this grant application is included recentralization of procurement by 2017 and consequently, centralized national drug management data aggregation by the Ministry of Health / NHIH will be possible from 2017 onwards.
- Indicator DOTS-5: Number of children <5 in contact with TB patients who began IPT: There is no system for collecting information on the number of contacts and / or suspects on age and data centralization of contacts/suspects on chemo-prophylaxis. The national database is including only patients with TB declared. In addition, in the current grant application there is no activity directly linked with chemo-prophylaxis (IPT).

All figures for this module introduced in the Programmatic Gap Analysis, are consistent with data reported by NTP and projections are based on NSP 2015-2020 targets.

Module "MDR-TB": there were used all 5 predefined indicators exclusively. All figures for this module introduced in the Programmatic Gap Analysis, are consistent with data reported by NTP, and projections are based on NSP 2015-2020 targets.

For the Module "Policy and Governance" it was established the indicator "Number of comprehensive legal framework regulating TB control in Romania developed" that actually will change the legal framework regarding the hospitalization, reimbursement of TB doctors and family doctors, ambulatory care, infection control and procurement of quality second and third-line anti-TB drugs to all MDR-TB and XDR-TB patients. We estimate that at the end of 2016 all documents will be developed, following by official approval by end of 2017. The policies to be developed under this grant application are consistent with those provided in the NSP 2015-2020.

For the Module "Program Management" there were established two indicators, an

indicator for measuring the programmatic performance and one for measuring the financial performance.

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 present funding request of **8,408,179 Euro** (as per the Annex 3 – Detailed Budget”) address the gaps and challenges identified in TB control in Romania by increasing the effectiveness and reach of diagnosis, treatment across the continuum of care for TB patients with a special focus on key populations, through a strategic mix of quality-assured TB testing approaches, provision of appropriate treatment, improving adherence and case holding, and strengthening links between services, governance and policies.

The **goal** of the request is to contribute to the achievement of reductions in TB incidence and mortality in Romania through improved high impact intervention (diagnosis, treatment, care and prevention) with special focus on key affected population through the following objectives:

- Early and quality assured TB diagnosis through the strengthening of TB laboratory capacity;
- Implementation of a patient centered interventions in 6 high TB burden counties in Romania;
- Improvement of treatment outcomes for M/XDR TB patients by provision of complete, non-interrupted drug regimens;
- Strengthening the national legal framework to regulate the TB control in Romania.

As shown in 2015-2020 programmatic and financial gap analysis, through the use of various funding sources (including GFATM), all programmatic and financial gaps will be covered. The main constraints and challenges of the national TB control program and the interventions planned to cover these needs, specifying each programmed funding sources to finance these interventions are detailed in the following table:

Challenges and constrains	Intervention	Activity	Total need resulted from Programm atic Gap Analysis	Identified financial sources to cover the gaps	
				GFATM	Government and other donors
Unavailability of rapid testing for MDR-TB resulting in timely and accurate diagnosis	a. Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing	Implementation of genetic methods (LPA) in 9 regional laboratories: equipment	6	2	4
		Implementation of MGIT liquid method (culture and drug susceptibility tests) in 9 regional laboratories: equipment	9	2	7
		Implementation of GeneXpert for peripheral TB lab level: equipment	40	6	34

		Ensuring the necessary consumables for rapid testing until 2017	100%	9%	91%
	b. Improve proficiencies and efficiencies among Romania's TB laboratories through	Elaboration of the strategic documents for strengthening the laboratory capacity (standards, guidelines, etc)	1	1	0
		Elaboration of the review process to ensure that laboratories follow standards and meet performance criteria	1	1	0
Poorly managed second-line treatment, apart from Global Fund MDR-TB treatment cohort due to unavailable second-line drugs (SLDs)	Expansion of the comprehensive and continuous treatment capacity for MDR-TB patients through a multi-faceted approach:	Increasing the number of MDR-TB centers providing comprehensive TB care tenable easier access to complex MDR-TB treatment and case management surfaces in order to reduce the burden on MDR-TB patients and their families to travel to distant facilities while ensuring quality of care and oversight, including renovation and reorganisation of an MDR-TB facility for patients who are at highest risk of non-adherence, default and death due to poor economic status and precarious living conditions.	2	1	1
		Strengthening of the outpatient treatment for both drug-susceptible and MDR-TB patients by implementation of the ambulatory care for DS-TB and MDR-TB	42	6	36
	Universal access treatment for M/XDR TB patients (including second and third-line anti-TB drugs) in accordance with WHO-treatment recommendations.	Number of patients treated by 2020 (TB and M/XDR TB)	3394	460	2934
	Development of an effective and rationale system for planning and managing anti-tuberculosis medications through elaboration of policies and regulation and monitoring at national level the orders, consumption and stocks	Effective and rationale system for planning and management of anti TB drugs implemented	1	1	0
	Costly, and often unnecessary, hospitalization of TB patients	Revision of laws and reimbursement practices that contribute to hospitalization and research models of care that are principally	1	1	0

consuming limited resources	patients through:	ambulatory			
		Development of protocols and guidelines for outpatient and inpatient treatment	1	1	0
	Scaling up implementation of the ambulatory model of care, from 6 counties in 2015 up till Romania counties by the end of 2020.	Ambulatory model of care implemented at national level (42 counties)	42	6	32
	Monitoring and evaluation of the ambulatory model of care, including a cost-analysis study.	1 evaluation study (including a cost analysis study) performed	1	1	0
Insufficient infection control in hospitals and laboratories exposing patients, families and health care workers to higher risk of contracting TB	Establish infection control standards and requirements for healthcare facilities by revising the legislative framework to address infection control measures for TB transmission	1 legislative framework developed	1	1	0
	Improvement of infection control practices to reduce transmission and exposure of TB through:	Elaboration of an educational program on infection control.	1	0	1
		Provision of financial and material support for the implementation of infection control measures (administrative, environmental, and personal respiratory protection) as well as regularly monitor and evaluate implementation of the infection control guidelines in all facilities. It is expected that 100% of health care facilities will implement infection control practices for TB.	1	0	1
		Regular monitoring and evaluate the implementation of the infection control practices in TB facilities.	1	0	1
Poor Directly Observed Therapy (DOT) during outpatient treatment for both sensitive and resistant TB	Improve patient support and case holding systems through:	Establishment of multidisciplinary teams to provide medical, social and psychological services to all cases diagnosed with TB	42	6	36
		Provision of directly observed treatment to new and retreatment DS-TB patients by 2020	58607	5850	52757

cases and Limited social support for patients with TB, insufficient psychological support provided to TB patients		Provision of social support in the form of incentives and enablers (food and transport) to all patients in treatment ambulatory phase	36837	5850	30987
		Implementation of compassionate and palliative care	225	0	225
Insufficient scale-up of prevention and education activities in poor and vulnerable populations and Insufficiently addressed TB screening, diagnosis and treatment in high risk groups	Engage and facilitate involvement of impacted communities and civil society organizations in TB control through development of the legal framework to involve and subcontract NGOs working with vulnerable and hard to reach groups	1 legal framework to involve and subcontract NGOs working with vulnerable and hard to reach groups	1	1	0
	Ensure funding and compensation for primary care providers	The funding and compensation for primary care providers legislative framework developed	1	1	0
	Elaboration of the strategy to guide active case finding	The national strategy for active case detection and finding elaborated	1	1	0
	Implementation of education, active case detection and harm reduction activities for key affected population (homeless, prisoners, IDUs and poor population with limited access to health services)	Number of TB patients detected among KAP	18413	1745	16668
	Referral of TB suspects identified among key affected population with symptoms TB local diagnostic centers	Number of TB suspects among KAP referred to TB local units	85700	8500	77200
	Provision of DOT through a specialized network of DOT supporters (peer, community workers, family doctors, etc.)	Number of TB patients under DOT	58607	5850	52757
	Provision of housing support for homeless and vulnerable patients during the treatment period	Number of homeless and other vulnerable patients provided with housing support during the treatment period	1500	0	1500
	Provision of social support in the form of incentives and enablers (food and transport) tall TB identified patients in treatment	Number of patients reached with social support	36837	5850	30987
Insufficient trained workforce for TB control and systematic method to develop personnel	Mapping the TB workforce needs	1 study regarding TB workforce needs performed	1	0	1
	Elaboration of a human resource plan for TB that identifies personnel needs, skills, and establishes recruitment and financing process	The plan for TB human resources developed	1	1	0

skills and capacities	Elaboration of a coherent training plan to address the needs identified	The training plan for TB network developed	1	1	0
	Delivery of training sessions to TB network workforce	Training sessions delivered to TB network	60	0	60

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:

- Explain the rationale for the selection and prioritization of modules and interventions.
- 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.

a. The rationale for the selection and prioritization of modules and interventions

The selected modules for Romania's Concept Note application are based on Romania's National Strategic Plan 2015 – 2020 with specific interventions and activities and targets chosen by the CCM to address national priorities and programmatic and financial gaps faced by Romania National Tuberculosis Programme.

A series of key challenges, outlined in the NSP 2015-2020, contribute to ongoing transmission, unfavourable treatment outcomes, and the rise in MDR-TB. To prevent the MDR-TB situation from worsening and sustain other TB control achievements, Romania needs to address several the following concerns: 1) the timeliness and completeness of MDR-TB diagnosis and treatment; 2) system-barriers resulting in excessive hospitalization of TB patients; 3) inadequate infection control; 4) lack of patient-centered approaches such as Directly Observed Therapy (DOT), and; 5) insufficient education and prevention activities among poor and vulnerable populations (homeless, rural, and minority populations).

The proposed CN interventions include a strategic mix of quality-assured TB testing approaches, provision of appropriate treatment, targeted actions to improve adherence and case holding, and strengthening links between services, governance and policies that will improve TB diagnosis and treatment outcomes and benefit the country's most vulnerable populations.

Module: "TB Care and Prevention"

Two specific interventions with a series of sub-activities are planned under the TB Care and Prevention module, as follows:

1. Case detection and diagnosis:

- Improve the timeliness and accuracy of diagnosis of TB by development of strategic guidelines for TB laboratory network.
- Develop diagnostic capacity for TB and M/XDR TB using genetic methods, liquid culture and DST.

2. Key affected populations

- Improve the timeliness and accuracy of TB diagnosis through active case finding among high risk populations.
- Improve patient support and case holding systems through community based TB care

- and prevention and through mobile/outreach services of the ambulatory care model.
- c. Renovation and reorganisation of an MDR-TB facility for patients who are at highest risk of non-adherence, default and death due to poor economic status and precarious living conditions.

While Romania's laboratory service have performed exceptionally well a number of challenges require attention to ensure that patients are placed on the most effective treatment regimens. As of 2013, TB diagnosis was realized in fourteen (14) level I laboratories which perform only microscopy, while the 47 level II laboratories conducted smear microscopy and cultures, and 44 level III laboratories processed smears, cultures, and drug sensitivity testing for isoniazid (INH) and rifampicin (RMP). Two of the level III labs have an additional role as a national reference laboratory (NRL) for the country. The NRLs also conduct second-line drug susceptibility (SLDST) testing and genetic tests. The workloads vary tremendously among the laboratories with microscopy analysis in level I facilities ranging from 39 to 2707 specimens a year. In level III laboratories, the number of smears analysed ranged from 1689-20,442 while the number of cultures processed on solid media ranged from 248 to 20,442. The work load in some laboratories falls short of expected levels needed to maintain capacity and ensure quality of diagnosis. The work levels in some facilities indicate a need to rationalize and consolidate laboratory services.

Laboratory results are also adversely affected by laboratories not following guidelines or having standard operating procedures (SOPs) for processing and managing specimens. For instance, some laboratories do not collect the recommended number of specimens, properly stain slides and deviate for number of tubes for cultures inoculated for a specimen, or incorrect operating speeds with the centrifuge equipment. Laboratory operations have also been adversely affected by the lack of equipment and resources to process specimens in an accurate and safe manner.

Finally, the transportation of specimens functions well in the south-west of Romania, but does not function adequately in other regions.

In terms of timely and accurate TB diagnosis, culture confirmation was available in 73.4% of cases, but DST results for Isoniazid and Rifampicin were available only for 49.8% of culture confirmed cases (5,966/11,974) in 2012. The prevalence of MDR-TB reported was 4.18% out of all registered TB cases indicating a reservoir of MDR-TB, but the overall number may be under-diagnosed as not every case with resistance to Rifampicin is tested for second-line DST.

To improve the laboratory diagnostics requires modernizing Romania's labs with more rapid technologies, reducing facilities that do not meet performance standards, and ensuring sufficient, trained laboratory staff to carry out important laboratory functions. Romania also plans to expand use of rapid diagnosis methods for TB and M/XDR TB and developing capacity within Romania's TB laboratory network for genetic methods and liquid culture and DST.

While overall treatment outcomes for TB reflects the ability to successfully manage and treat most TB cases, there is a significant percentage of patients who do not complete therapy. Several factors contribute to this situation including improper diagnosis related to the lack of timely DST testing. As a result, MDR-TB goes undiagnosed and patients are given months of ineffective treatment. Regardless of whether a patient is drug susceptible or has drug resistance, the treatment is often lengthy and difficult to adhere to. There is

little ongoing or institutional social support provided to TB patients with a few exceptions. The loss of income and lack of social support have been reported as a contributing factor for non-adherence. The problem with non-adherence, in particular with retreatment cases, constitutes the need for more patient centered strategies.

The concerns about vulnerable populations are addressed in NSP 2015-2020. Within Romania, TB adversely affects the most vulnerable populations often at greater risk of exposure due to their living situation and at greater risk to progressing to active TB disease due to poorer health status and weaker use and access to health care services. The country's rural population, which comprises 45% of the population, suffers from high rates of poverty and low socio-economic development. Only about 50% of rural residents have access to improved sanitation facilities and 40% have difficulty with access to primary healthcare services compared to only 15% in urban areas. Rural populations, in general, are disproportionately affected by TB as well as likely to experience higher treatment failure and default. Within urban areas, there is a growing homeless population at high risk of TB with TB diagnosed in 135 homeless patients in 2013.

There is also growing concern about an emerging population at risk of both HIV and TB, namely injecting drug users (IDU). Only in Bucharest, there are about 20,000 high risk drug users (mostly IDUs) (National Anti-drug Agency, 2013). The portion of IDUs among new HIV annual cases rose from 3% in 2010 to 29% in 2013, given that the overall number HIV/AIDS cases diagnosed increased steadily (from 505 in 2009 to 895 in 2013) (CNLAS, June, 2014). According to the most recent data released by the National AIDS Commission for the period January –June 2014, out of the total number of 319 HIV positive newly diagnosed cases, 81 (25%) are IDUs and of them 15 (18.5%) are TB co-infected. Although Romania employs the model of providing combination services to IDUs (in clinic and outreach), currently there are no TB-control services targeting IDUs or tailored to their needs – services that are low-threshold, equipped to deal with co-morbidities related to the drug abuse. However, international recommendations point at the importance of providing routine TB testing and referral to treatment for IDUs, as part of the essential harm reduction service package (ECDC, 2012).

In response to the difficulty in reaching some vulnerable populations, interventions will be implemented to improve the timeliness and accuracy of TB diagnosis among vulnerable populations (IDUs, homeless, poor population with limited access to health services) using active case strategies to educate, refer and accompany of TB suspects to TB diagnosis and treatment services as well as to provide harm reduction services for IDUs).

Romania will implement patient support and case holding systems by adapting the existing treatment and care structures to meet the needs of key populations through community based TB care and prevention and through mobile/outreach services of the ambulatory care model. As part of these activities, technical assistance will be secured to develop the legal framework and national guidelines related to active case finding and treatment.

Romania proposed to develop outpatient models of care as part of its process to rationalize treatment of TB and reduce unnecessary hospitalization. Patients are often unnecessarily hospitalized for excessive periods, rather than being provided effective community-based treatment, further contributing to isolation and frustration. Hospitalization may be warranted in cases of serious illness, but it should not be the sole option for care.

To improve the outpatient system of care, Romania will develop ambulatory care models

in six (6) TB high burden counties. This intervention will include: establishment of multidisciplinary teams for integrated care of TB and to assess and respond to non-adherence, provide counseling regarding the patient's legal rights, DOT, and incentives to TB for adherence; Provision of a package of DOT, psychological counseling, peer-support counseling and incentives to TB patients evaluated as at highest risk for non-adherence; Provision of DOT and incentives to TB patients with limited access to primary care services and DOT; Provision of incentives to TB patients, who have access to primary care services and DOT; Provision of DOT, peer support, social counseling and services, incentives to IDUs and homeless TB patients from capital city of Bucharest, through fixed and mobile teams.

Romania will also renovate and reorganise an MDR-TB facility for patients who are at highest risk of non-adherence, default and death due to poor economic status and precarious living conditions (i.e. lack of house or inappropriate living conditions, etc.). A treatment facility is necessary because most of the TB hospitals are subject to health reform and at risk to dismantling or massive reduction in number of beds. Moreover, such an MDR-TB facility for so called "social cases" would need besides an experienced and qualified multidisciplinary team, a well based infection control system.

Module: "MDR TB"

Under this module, Romania will carry out the intervention named **Treatment: MDR-TB**. While first-line medications are readily available in Romania to treat drug-susceptible TB in adults, there is an urgent need to address the procurement of second-line medications to treat multi-drug resistant TB. Under this intervention, Romania will develop the legal and regulatory framework to ensure uninterrupted, centrally procured supply of quality second and third-line anti-TB drugs to all MDR-TB and XDR-TB patients. Specific actions will be taken to ensure the procurement of high-quality, non-interrupted regimens of second line and group 5 anti TB drugs for 460 M/XDR TB patients. According to the NSP, the full implementation of the centralized procurement mechanism will be in place only in 2018, therefore, it is compulsory to continue under this grant, provision of treatment for 460 M/XDR TB patients which cannot be funded from other sources by 2018.

Module: "Policy and Governance"

Under this module, Romania will develop and enact a series of health legislation, strategy and policies. There are several key legislative issues that require a dedicated plan of action including drug procurement, infection control, and human resources. While Romania has an extensive network of personnel working on TB issues, many of these healthcare workers are aging and not being replaced. The staff that does exist does not receive routine or target skills development reflecting an overall lack of a human resource plan for TB control. Family doctors can serve as an important gateway provider for TB control. However, changes in how they are funded and reimbursed have adversely affected their interest in TB control. GFATM resources will be used to strengthen NTP and Human Resource Development. Funds will enable Romania to review and develop policy, assess human resource needs and development a sustainable and qualified pool of staff for TB control. In addition, resources will be used to establish infection control policies, standards and requirements for healthcare facilities and to conduct a review of TB hospitalization policy with the aim of reducing the number of hospital beds for TB and increase ambulatory care.

Module: “Programme Management”

One intervention – **Grant Management** is included under this module in order to ensure effective implementation of the GFATM grant.

b. 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.

The proposed interventions included in the Modules “Care and Prevention” and “MDR TB” will contribute to the achievement of the following targets set in the National Strategic Plan:

- 100 % of TB patients will be tested through culture, DST1 and DST2 and will have access to rapid genetic diagnostic.
- 85,700 TB suspects from key populations will be referred to TB diagnostic and treatment services.
- 18,413 TB patients from key populations will be assisted through the implementation of the ambulatory care model.
- 100% of M/XDR TB patients will receive complete, quality, non-interrupted and monitored treatment regimens.

These targets which will be achieved through interventions implemented with national funds and donor support by 2020 (including GFATM-NFM grant), will lead to fulfillment of major country impact and outcome indicators as follows:

- TB mortality rate will decrease from 5.52 to 4.3/100,000 population.
- Case notification rate of all forms of TB/100,000 population will decrease from 72.83 to 46.59/100,000 population.
- Case notification rate/100.000 population bacteriologically confirmed will decrease from 49.7 to 31.95/100,000 population.
- Treatment success rate bacteriologically confirmed new TB cases will increase from 86 to 90%.
- Treatment success rate of MDR TB: percentage of bacteriologically confirmed drug resistant TB cases successfully treated will increase from 50 to 75%.

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:

- 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.
- 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.

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.

The funding request focuses 100% of the budget on the underserved and key populations as well as on highest impact interventions such as active case detection of suspects and referral, treatment and care are addressing the needs of homeless, IDUs and poor populations with limited access to health services (including roma population), early diagnosis, treatment and support for an increased adherence provided to X/MDR-TB

cases, out of which, a large proportion is represented by poor populations. The highest impact interventions addressing the needs of key affected populations, included in the funding request are described below:

Active case detection:

- **Implementation of education, active case detection and harm reduction activities for key affected population (homeless, IDUs and poor population with limited access to health services), followed by referral of TB suspects to local diagnostic and treatment centers:**
 - Homeless population will be targeted by interventions performed by NGO social workers and peer-educators who will provide TB IEC sessions and will be able to recognise the symptoms of TB. Social workers and peer supporters will refer the homeless suspects to TB medical services for diagnostic and treatment.
 - IDUs will be targeted by interventions provided in outreach and low threshold clinics run by NGO. Condoms, needles and syringes, Hep. B, C & HIV testing, Hep. A, B vaccination will be provided to all IDUs who access the 2 outreach mobile services and 2 low threshold clinics in Bucharest. Trained NGO social workers / nurses will provide TB IEC sessions to IDUs and will also be able to recognise the symptoms of TB and to refer the IDU suspects to the TB medical services for diagnostic and treatment.
- **Referral of TB suspects identified among key affected population with symptoms to local diagnostic centers**
 - Following the diagnostic, the TB patients diagnosed among homeless and IDUs will be supported through counselling and incentives (social vouchers for food) for adherence during the entire duration of the treatment, and will be helped by the project teams to obtain access to legal rights (ID card, health and other social benefits, etc.).

Strengthening of the outpatient treatment for both drug-susceptible and MDR-TB patients by implementation of the ambulatory care for DS-TB and MDR-TB through a multi-faceted approach:

- **Develop policies and practices that will strengthen outpatient treatment for TB and reduce unnecessary hospitalization of TB patients through:**
 - Revision of laws and reimbursement practices that contribute to hospitalization and research models of ambulatory care.
 - Development of protocols and guidelines for outpatient and inpatient treatment, including criteria for hospitalization and outpatient care.
- **Establishment of multidisciplinary teams to provide medical, social and psychological services to all cases diagnosed with TB:**
 - Multidisciplinary teams (doctor, social worker, psychologist, nurse) will be established at the level of main TB centers in 6 counties with high TB incidence. These teams will follow the criteria for outpatient and inpatient treatment and will decide upon hospitalization or ambulatory care of each individual TB case. Moreover, the multidisciplinary teams will develop individualized intervention plans for each TB patient to be followed in ambulatory phase, after assessing the risk of non-adherence.
- **Provision of directly observed treatment to new and retreatment DS-TB and M/XDR TB patients**

- DOT will be available for DS-TB and M/XDR TB patients in 6 counties through involvement of a large palette of workers who will be identified at community level and stimulated through incentives (i.e. community nurses, roma mediators, nurses working in family doctors' clinics, NGO volunteers).
- **Provision of patient education on treatment and treatment adherence.**
 - All DS-TB and M/XDR TB patients from the 6 counties will be provided by the community workers with information and education on treatment and treatment adherence. Community workers who ensure DOT and education on treatment adherence will be incentivized during the project lifetime.
- **Over 5,000 DS-TB and M/XDR TB patients from the 6 counties will be provided with incentives (social vouchers for food) during treatment ambulatory phase**
 - Social vouchers for food will be purchased and distributed by the community workers to over 5,000 TB/X/MDR-TB patients in ambulatory treatment in the 6 counties
- **Psychological support will be also available to DS-TB and M/XDR TB at highest risk of default patients from the 6 counties included in the project.**
 - Psychological support will be provided to the TB/X/MDR-TB patients at highest risk of non-adherence, by trained psychologists as well as by peer supporters (former TB patients, patients living with HIV).
- **Monitoring and evaluation of the ambulatory model of care, including a cost-analysis study**
 - The implementation of the ambulatory care will be assessed through a cost-analysis study in order to identify the feasibility of scaling up this model of care at national level.

Provision of treatment for TB and M/XDR TB patients (including second and third-line anti-TB drugs) in accordance with WHO-treatment recommendations:

- Second line and group 5 anti-TB drugs will be procured under the project for the treatment of 460 X/MDR-TB patients.
- Rifabutin will be procured and distributed to by the project teams to the TB patients detected among IDUs who are on opioid substitution therapy.

Provision of laboratory equipment and the necessary consumables for rapid diagnostic, as follows:

- Six GeneXpert equipment will be procured under the grant, alongside with over 5,000 tests for rapid diagnostic in order to cover the programmatic gap in the NSP 2015-2020.
- Two LPA equipment and the necessary consumables (over 5,000 first line tests and 1,000 second line tests)
- Two MGIT equipment and the necessary consumables (5,000 liquid culture, 2,000 DST first line, 1,000 DST second line tests).

The development and implementation of a major reform aimed on changing the current system of care for TB cases from in-patient to out-patient care. The GFATM grant will contribute, alongside with other funds, to the development of this system whose steps have been detailed in Section 1.2. National Disease Strategic Plans, point c. Limitation to implementation.

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 non-government 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. If applicable, the reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement (i.e. both government and non-government sector Principal Recipient(s).

On 24th June 2014, the CCM re-nominated the Romanian Angel Appeal Foundation (NGO) as Principal Recipient (PR) of the NFM funding request following the CCM's bylaw procedures for nominating a PR. The dual-tracking financing arrangement was not a feasible option, due to the frequent changes featuring the Romanian political environment. For instance, six Ministers of Health with six different subordinated teams have succeeded over the last two years. This high turn-over of decision-making top positions and subordinating staff at different levels of the Ministry of Health, doubled by the high level of bureaucracy featuring government sector might turn onto a high risk of unwanted delays in implementation of the grant. Such a delay is already experimented by the Ministry of the Health for the programme Public Health Initiatives funded by the Norway grants, for which the Ministry of Health is Programme Operator (equivalent of Principal Recipient). For example, although the TB project RO 19.01 placed under this programme was approved for funding in June 2013, the implementation was significantly delayed, project duration diminished from 24 to 20 months and the funds are still not transferred into the implementers' accounts after 17 months from the project approval due to various bureaucratic barriers in Romania governmental sector. On the other hand, the demonstrated performance of RAA Foundation - publicly acknowledged by the CCM Chair (representing Ministry of Health) - was a strong reason for the re-nomination of the existing PR.

b. If more than one Principal Recipient is nominated, how coordination will occur between Principal Recipients.

Not applicable.

c. The type of sub-recipient management arrangements likely to be put into place and whether sub-recipients have been identified.

The grant activities financed under the NFM will be implemented by entities belonging to both governmental and non-governmental sectors, under the coordination of the Principal Recipient (PR). The PR will have an active role not only in the grant management but will also implement some strategic components of the grant. The sub-recipients will be selected by the PR following the second meeting of the Grand Approval Committee

(GAC). The selection of sub-recipients will be based on meeting at least four of the following criteria:

- i. Legal and administrative capacity to enter into a sub-grant agreement under the GF-NFM grant,
- ii. Programmatic, M&E, financial and procurement capacity to implement the proposed interventions;
- iii. Prior experience of interventions implemented in the concerned areas;
- iv. Submission of a cost-effective proposal concerning the proposed interventions.

d. How coordination will occur between each nominated Principal Recipient and its respective sub-recipients.

RAA Foundation developed a sub-recipient management system during the previous GFATM grants that examines performance, cost-efficiency and reducing risks. The system addresses the following processes:

1. Evaluation of sub-recipients and sub-sub recipients in terms of legal and administrative capacity, programmatic and financial capacity, and risk assessment related to each sub-recipient and formulation of measures to avoid, counteract, and mitigate risks.
2. Elaboration of clear sub-grant agreements specifying the services, activities and conditions of the financing; transposition measures to avoid - or counter risks - in conditions that sub-recipients must comply with in accordance with the terms of the sub-grant agreement.
3. Training and technical assistance provided to sub-recipients, including provision of operational support throughout the implementation, in order to maximize the impact and interventions and the overall performance of the grant.
4. Monitoring and evaluation: tracking the programmatic and financial progress of each activity provided by the sub-recipient, performance assessment, re-assessment of risks, follow-up, preventive and corrective measures.

RAA Foundation established and documented these processes since the beginning of the takeover of PR function in 2007 and it has improved implementation over time, developing a range of tools, materials and methods in support of sub-recipients and the team RAA in order to:

- Strengthen programmatic and financial monitoring and verification
- Ensure fluency of interventions and services provided and reduce unnecessary bureaucracy
- Ensure a smooth financing of projects
- Reduce costs
- Improve the quality of services.

RAA communication with SR's teams is based on mutual respect and deep understanding of the work performed by sub-recipients under the grant. SR institutions and organizations can call the RAA team for operational support at any time. RAA Foundation is constantly working to improve the management system of sub-recipients and in this respect, annually collects their feedback on team performance in relation RAA sub-recipient organizations and institutions.

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.

The representatives of the key populations, including representatives from a TB patient organization, have been involved in the elaboration of the Concept Note.

It is expected, considering the expertise already gained in the implementation of various projects addressing TB issues under the previous grants that representatives of key affected populations will also participate to the selection of SR for the implementation of the NFM grant. Moreover, a series of activities included in the funding request will be implemented by peers of IDUs, homeless and MDR-TB patients, who will be directly involved in service delivery. The CCM will also include people from key affected populations in the oversight process.

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.

Not Applicable for Romania

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 Name	1	Romanian Angel Appeal Foundation	Sector	NGO
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?			X Yes ☐ No	
Minimum Standards	CCM assessment			
1. The Principal Recipient demonstrates effective management structures and planning	The re-nominated PR - Romanian Angel Appeal Foundation (RAA) - implemented since 2005 the Quality Management System (QMS), obtaining in March 2007 the certification for ISO 9001:2001 QMS standards. In 2010, RAA obtained certification under the revised standard ISO 9001: 2008, maintaining this period and to date a quality management system oriented towards the satisfaction of beneficiaries, partners and donors, continuously improving all processes that contribute to achieving good quality of services provided. Since 2007, the Foundation Romanian Angel Appeal there is a separate department that provides programmatic management, finance and procurement for GFATM programs with the following structure: - Program Manager - Financial Manager - Procurement Manager - Financial Controller - Program Assistants - Financial Officers - M& E Officers - Legal Counsellor			

	- Accountants - HR Coordinator, etc. All staff involved in programmatic, financial and procurement management of the GFATM grants has training and expertise in the specific field, coupled with over 7 year experience in managing programmatic, financial and procurement programs implemented at national level in the field of prevention and control of TB and HIV / AIDS grants financed from international sources. Thanks to a robust human resource management, the turn-over of staff in the department of program management was and is almost zero, a situation that contributed to ensuring a stable professional environment in relation to national actors involved in GFATM programs: sub-recipients, CCM, partner institutions and agencies, etc. From the start of its PR mission until now, the team responsible for managing the GFATM grants developed a significant amount of documents, procedures and tools, among which: - Online reporting system implemented - An operational manual for sub-recipients developed and regularly revised - Procedures and documentation regarding the selection of sub-recipients - Procedures and tools for the management of sub-recipients - Plans for the management of procurement and supply chain - Plans for quality control of drugs and diagnostic products, etc. Since taking up the PR responsibility, RAA Foundation complied with regulations stipulated in the CCM by-laws regarding: - transparency of grant implementation, with periodic information on progress provided to CCM members, programmatic financial procurement and grants (periodical reports presented during CCM meetings: http://www.raa.ro/gfatm-reports-ccm-meetings/ ; all progress reports and grant applications, letters to FG, etc. transparently available on the public site, dedicated section RAA Foundation funded programs FG: http://www.raa.ro/gfatm-progress-reports-disbursement-request/) - early identification of programmatic and financial risks and measures to avoid / counterbalance the risks, etc. RAA also complied with all the conditions stipulated in the grant agreement and sub-grant agreements. No transfer of funds to sub-recipients program has been delayed whatsoever, allowing smooth running, and seamless financing of all of over 100 projects implemented in the GFATM grants managed by RAA so far. The expenditure rate exceeded 99%. In addition, thanks to quality management of grants in the spirit of cost-effectiveness, they RAA achieved higher targets than those established in the grant agreement for projects with major impact (eg. number of MDR-TB patients enrolled in full course
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	quality treatment regimens was 952 vs. 780 planned).
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	RAA Foundation has developed a management system to monitor sub-recipient performance, project cost-efficiency and risks reducing-oriented, which includes the following basic processes: 1. Evaluation of sub-recipients and sub-sub recipients in terms of legal and administrative capacity, programmatic and financial capacity. Risk assessment is performed related to each sub-recipient and measures to avoid, counteract, and mitigate risks are formulated. 2. Elaboration of clear sub-grant agreements specifying the services, activities and conditions of the financing; transposition measures to avoid or counter risks in precedent conditions that sub-recipients must comply with in accordance with the terms of the sub-grant agreement. 3. Training and technical assistance provided to sub-recipients, including provision of operational support throughout the implementation, in order to maximize the impact and interventions and the overall performance of the grant. 4. Monitoring and evaluation: tracking the programmatic and financial progress of each activity provided by the sub-recipient, performance assessment, re-assessment of risks, follow-up, preventive and corrective measures, etc. RAA Foundation has established and documented these processes since the beginning of the takeover of PR function. RAA improved this system over time, developing a range of tools, materials and methods that come both in support of sub-recipients and the team RAA in order to: - Strengthen programmatic and financial monitoring and verification - Ensure fluency of interventions and services provided and reduce unnecessary bureaucracy - Ensure a smooth financing of projects - Reduce costs - Improve the quality of services. RAA communication with SR's teams is based on mutual respect and deep understanding of the work performed by sub-recipients under the grant. Anytime, any SR institution or organization can call the RAA team for operational support. RAA Foundation is constantly working to improve the management system of sub-recipients. In this respect, RAA annually collects their feedback on RAA team performance in relation sub-recipient organizations and institutions. During the 7 years of management of GFATM grants, RAA managed over 100 projects implemented by more than 35 SR institutions and organizations. Simultaneously, by providing operational support and technical assistance, RAA contributed to the

	capacity development of non-governmental sector organizations involved in the fight against HIV / AIDS and Tuberculosis.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	Prior to signing any sub-grant agreement, RAA evaluates the SRs' capacity centred on a risk-based approach. Key areas of assessment are: M&E, PSM, Finance and Governance. The sub-grant agreement clearly stipulates terms and conditions related to SR's commitments, including precedent conditions that the SR need to fulfil as well as a risk management plan. The RAA team of experts (financial, legal, M & E) develop the terms and conditions and annexes of sub-grant agreements. RAA developed an Operational Manual (OM) on implementation of projects funded by GFATM, which becomes integral part of the sub-grant agreement. The financial chapter of the OM highlights procedures related to segregation of duties between financial and accounting team members, financial and accounting document circuits and payments authorization. OM also sets rules on income and their control, grant expenditures and their control, contracting of expenditures and reimbursement of expenses incurred by employees, fees and travel, fixed asset and property management inventory. Additionally, RAA has developed an online reporting system that allows real-time monitoring of income and expenditure of each SR and tracking differences arising between the approved budget and expenditures, highlighting overspendings (if applicable) or unauthorized reallocations between budget lines.
4. The financial management system of the Principal Recipient is effective and accurate	RAA financial management system is developed based on the principles of quality management system. RAA uses the funds in the spirit of cost-efficiency, financial probity and transparency and in full compliance with applicable Romanian and international legislation. RAA has an effective financial and accounting team, including members with experience in managing and implementing GFATM Grants. The financial & accounting team includes the following positions: Financial Manager with over 7 year experience in management of GFATM funds; Financial Officer with over 5 year experience in Financial Management of SRs; Chartered Accountant; Financial Controller; Cashier. The tools developed and used by RAA in financial management are: the Operational Manual developed for GFATM grant, RAA's general operational manuals (RAA financial operational manual, RAA Quality Manual) and the web based financial reporting system developed for GFATM grants. The web based tool provides simultaneous access of all parties involved (SR, PR staff, independent auditor, and donor) to the project's financial records in real time. RAA's accounting system is implemented in accordance with

	laws and regulations in the field. RAA has accounting and salary customised software / programmes which are updated and maintained on a monthly basis, as well as legislative update subscription. RAA implements analytical accounting on each project / programme. Analytical accounting system allows highlighting of income and expenditures per project and donor. Supporting documents are retained according to the law and the regulations set by each donor. RAA has a contract with a specialised company for safety archiving of the financial & accounting documents. RAA holds bank accounts for each project and programme implemented, so that the received funds are easily traceable. According to the Procedures Manual of the RAA any banking transaction needs double signature and all RAA projects are audited by an independent audit company.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	The central warehousing is needed especially for the MDR/XDR-TB drugs and is provided by UNIFARM. UNIFARM SA is the national company founded under the authority of the Ministry of Health (MoH). It possesses certificates from the National Drug Regulatory Agency (NDA) in Romania for drug storage and distribution of drugs to the TB dispensaries nation-wide. UNIFARM is also accredited ISO 9001:2008 and is periodically monitored by NDA and MoH if they are compliant to the provisions and regulations of the national legislation. UNIFARM has installed a computerized temperature and humidity monitoring system. The MDR/XDR-TB drugs and the warehouse where these are stored are assured through an insurance company for all possible risks such as theft, flooding, fire, etc. Furthermore, in accordance with national provisions and Global Fund guidelines at least once a year the MDR/XDR-TB drugs are sampled and tested for quality control. So far, all the QC tests performed within the past years of Global Fund programme implementation had excellent results proving that UNIFARM warehouse conditions are aligned to good storage and distribution practices.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	UNIFARM SA has more than 7 years of experience in distributing the MDR-TB drugs purchased with GF funds, always performing at highest standards in terms of compliance with set delivery schedule and drug quantities, despite any possible local challenges encountered (weak roads infrastructure especially in rural areas, traffic issues, bad weather conditions, etc.). The distribution of MDR/XDR-TB drugs is performed quarterly, with one month buffer in order to prevent stock out situations. For the patients discharged from hospitals and treated in ambulatory, the treatment is distributed by UNIFARM in advance to their home arrival. RAA monitors the performance of UNIFARM in terms of product storage and distribution.

7. Data-collection capacity and tools are in place to monitor program performance	The PR has dedicated M&E staff (Program Manager, M&E Officer, MDR-TB expert). All SRs staff with M&E responsibilities was trained by the PR team during the capacity building workshops conducted during the implementation of the grant. The PR structure includes a M&E unit, with experienced staff in the field of TB programs implementations, as follows: M&E Officers (one public health specialist with more than 5 years in M&E of the TB programs, one PHD sociologist with more than 7 year experience in M&E, one social assistance specialist with more than 3 year experience in M&E), Program Manager (physician qualified in M&E of HIV programs, with more than 7 year experience in management of GFATM HIV and TB programs). The team is assisted by the IT Manager who ensures maintenance and proper functioning of the M&E database. The increase of the SRs' capacity to monitor and evaluate their interventions represented one of the key principles governing the implementation of the Round 6 programs. In this respect, the PR provided on-going support to the SRs: • During the planned supervisory field visits • During the periodic meetings organized by PR, where M&E issues are addressed • By providing M&E resources for the SRs (via e-mail) • Leading the development of project methodologies and data collection tools. M&E coordination: There are two collaborating management structures involved in the M&E of the grant: The NTP Central Coordination Unit and the Principal Recipient. For the diagnosis and treatment related interventions, the M&E coordination is provided by the central coordination unit of the NTP, which represents the national management structure in charge with TB monitoring and evaluation. The NTP is directly coordinating the country units (MDR-TB centers, TB Hospitals, TB Laboratories and TB Dispensaries) while the Principal Recipient is directly coordinating all the SRs involved in the implementation of the GFATM TB grant. The NTP, as well as the SRs are regularly providing data to the PR for the purpose of progress reporting to GFATM. The two entities – NTP Central Coordination Unit and the PR are closely collaborating in order to ensure alignment and harmonization of country indicators and to report to GFATM and WHO (i.e. national TB data and yearly cohort results are sent by NTP to WHO for regular monitoring at regional and global level).
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Data storage: The data collected from the project's current activity is stored by each sub-recipient in the form of electronic and printed databases, so that data analysis and consecutive reports are made in a short time and with as less errors as possible. The PR also stores the program data in the local M&E electronic system hosted at RAA office and plans to preserve the data from SRs on a newly developed on-line system in the

very near future. The upgrade of the on-line M&E system will facilitate the timely and accurate elaboration of the half-yearly and yearly report on the global progress of the TB program. All TB cases data is stored in the National TB programme electronic data base. The data collected by the PR from the sub-recipients is stored in electronic database that are integrated in a computer M&E data management system. The system facilitates the timely correct elaboration of the half-yearly and yearly report on the global progress of the TB program.

Data analysis and reporting: The quarterly and annual reports provided by the sub-recipients to the PR are based on the analysis of the data collected from the projects' work documents such as training reports, list of participants, lists of beneficiaries receiving services, patients' database, and other available data sources. The PR team analyses and aggregates the collected data from the reports and based on these, draw up the half-yearly and annual reports regarding the programs' performance. The deadlines for data reports (sub-recipients' to PR and PR to GFATM, LFA) are stipulated in the sub grant agreements (signed between PR and sub-recipients), respectively in the grant agreements (concluded between the PR and the GFATM).

The data quality mechanisms for ensuring the quality of data during data collection, transfer, compilation analysis and storage can be summarized as follows. The NTP central coordination unit is responsible for collection of data from MDR centers, TB hospitals, TB dispensaries and laboratories in the national TB database. At the level of NTP coordination unit there is specialized staff, in charge with data verification (through desk review and supervisory visits) as well as with regular transfer of data to the Principal Recipient for reporting purpose to the GFATM. The NTP database is stored at the level of NTP central coordination unit and maintained by dedicated staff. The Principal Recipient performs routine data quality checks on a quarterly basis, by desk review of data submitted by the SRs in quarterly reports and by visits at the SRs' offices and service delivery sites. The PR verifies that at the level of all the projects' outcomes and activities are being documented (e.g.: using the relevant work documents, survey reports) and that the collected data is properly stored and archived.

Following the monitoring results, the SRs and the PR ensure that the collected data observe the quality criteria recommended by the GFATM: are correctly (avoiding the errors, double counting), timely and objectively registered (reflecting in a proper manner the measured phenomena). The finding of the PR's data quality checks are summarized in the visit report submitted to the SR. If the quality of data is affected

	in any way, the PR and the SRs makes all the necessary efforts to solve the data quality problem in a reasonable amount and time. In case the PR identifies major M&E issues at the level of SRs, these issues together with recommendations to be implemented by SR are included in an implementation letter, becoming part of the sub-grant agreement. The implementation of the recommendations is checked by the M&E staff of the PR. The PR makes sure that collected data is stored by each SR in the electronic database, so that the data analysis and the report are elaborated in a short time, with as less errors as possible. The data collected by the PR from the SRs is properly stored in an electronic database which is periodically archived by the IT Manager of the PR. The quarterly reports provided by the SRs to the PR are based on the analysis of the collected data from the projects' work documents and other available national data sources. All SRs that are involved in the implementation of TFM grant have been previously assessed by the PR regarding the M&E capacity, so that, all capacity building needs have been properly addressed as described in the next chapter.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	RAA developed an Operation Manual (OM) for the grants financed by the Global Fund. One relevant section of the OM concerns procurement where the procedures, steps and type of documents necessary are detailed (i.e. procurement procedures applicable to the grant, organization's responsibilities and also the responsibilities of the Evaluation Committee members regarding preparing technical specifications with minimum quality requirements accepted, and evaluation criteria). The OM is applicable both to PR and SRs. In the particular case of RAA the capacity to comply with quality requirement and to monitor product quality is reinforced by the fact that RAA is certified for quality management system ISO 9001:2008. Being ISO certified RAA is annually evaluated and its management system assessed and recertified, thus proving that the quality requirements are fulfilled (one of the requirements of ISO is that a product which is non-compliant to the quality requirements requested or proves to have hidden flaws has to be replaced by the supplier on its own expense). Although the SRs under Round 6 proved to have capacity to comply with the quality requirements, the PR provided technical assistance and supervised all the procurement procedures realized by the SRs. Moreover, RAA performed an evaluation of each supplier selected to supply goods or services under the GFATM grant, both from administrative and qualitative point of view (i.e. the Tender applicants were requested to prove their capacity in fulfilling a contract with similar goods or services as the ones budgeted in the grant). RAA as re-nominated PR will perform an assessment of each potential Sub-Recipient regarding the programmatic,

	financial and procurement capacity. The organizations applying to become SRs have to prove compliance with the quality standards requested by the Global Fund. After going through an evaluation process the organizations that have proven to have adequate programmatic, financial and procurement system will become Sub-Recipients and will have to sign a sub-grant agreement with the PR. The sub-agreement will include all the provisions applicable to the PR and detailed standard terms and conditions from the grant agreement signed between GFATM and RAA. Applying the quality requirement standards detailed in the OM and the ISO system, RAA has been able to prevent and avoid gaps or stock outs under Round 6 grant, and thus proving that it has the capacity to monitor the products/ services quality throughout the supply chain. Special attention has nee, and will continue to be, paid to the procurement of drugs – all procurement involving medicine or health products will be conducted in a centralized manner by RAA. The medicines are procured based on the specifications and treatment regimens established with the MDR TB experts in accordance with WHO recommendations. RAA implemented under Round 6 grant a system that allows customs clearance of medicines within 24 hours from their arrival in customs office and moved to the main warehouse. The warehouse (UNIFARM) where the medicines are stored is accredited at national level by Romanian National Drug Regulatory Agency (NDA), which is recognized globally as a rigorous NDA. The medicines are tested once a year from quality point of view to ensure the storage and distribution chains comply with quality requirements. The laboratory that has performed under Round 6 grant quality control tests is an independent one, accredited by Romanian NDA, and is in process of re-obtaining ISO 17025 certification. Moreover, during the goods/services contract implementation representatives of RAA Foundation periodically conduct monitoring visits to suppliers’ warehouses and/or offices (i.e. UNIFARM, ICCF, etc.) and to TB dispensaries where the goods/services had to be delivered. This way RAA performed a crossed quality product monitoring from the supplier’s warehouse to end user.
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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.	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.

The Concept Note (CN) includes all recommendations included in the Portfolio Analysis, as follows:

- The CCM based the CN on a robust, ambitious and a multi-year budgeted National Strategic Plan (NSP) elaborated by a multi-sectorial group including NTP, WHO, NGOs and representatives of key affected populations, under the leadership of the Ministry of Health. The budget of the NSP includes resources provided by other donors, including the Norway grants, European Social Fund and the Global Fund NFM grant.
- The CCM integrated in the CN the recommendations included in the report “Review of the National Tuberculosis Programme in Romania”; issued by the WHO in 2014, with a special focus on addressing the very low treatment success rate for MDR-TB. Thus, the CN includes: 1) creation of an effective centralized procurement and the uninterrupted supply of all internationally recommended anti-TB drugs required to constitute a regimen compliant with WHO treatment regimens; 2) expansion of out-patient treatment of TB patients; 3) rationalization of hospitalization practices in order to prevent further spread of drug resistance and more efficient use the available resources from the governmental budget, and 4); optimisation of the laboratory network and expansion of rapid diagnosis of TB and MDR-TB.
- The CCM addressed in the NSP and CN sustainability issue by identification of additional funds. The budget of the National Strategic Plan is based on sustainability principle utilizing domestic funds and leveraging funds from the Norway Mechanism Fund, World Bank loan and European Social Funds identified during the Concept Note elaboration and submission.

b. Describe the proposed risk-mitigation measures (including technical assistance) included in the funding request.

Risks Related to Performance:

There are no major risks related to implementation capacity, taking into account the high qualitative and quantitative rating indicators obtained so far by the re-nominated Principal Recipient (Romanian Angel Appeal Foundation).

However, two operational risks have been identified as follows:

1. Since the contribution of the Global Fund will strengthen services targeting IDUs, there is a risk that during the life of the grant that the non-TB services funded from other sources will be affected by the discontinuation of funding (caused by a grant ending or the funder being unable to secure the funds).
 - Mitigation measure: Sub-recipients will develop, with support from PR, risk mitigation plans for individual services that might be at risk of being discontinued during the life of the grant.
2. The risk of a difficult cooperation between the NGOs providing harm reduction services (including TB prevention) to IDUs and the public health institutions from the HIV and NTP system. They all have to agree that detection of TB and treatment among IDUs needs a different approach than in the general population, as a typical IDU has many co-morbidities and have a great deal of difficulty in adhering to (any) treatment.
 - Mitigation measure: Increase cooperation between the actors providing services to IDUs, through trainings and operational meetings led by Principal Recipient.

Risks related to implementation environment:

The only major risk in Romania, which might negatively affect the performance of the

proposed interventions is related to the frequent political changes translated in frequent replacements of decision-makers' representatives and/or entire teams, which might lead to domestic budget revisions in accordance to their priorities.

- Mitigation measure: This risk was already mitigated by the Ministry of Health by the forthcoming approval of the multi-year budgeted National Strategic Plan for the Control of Tuberculosis in Romania, 2015-2020 through Government Decision. Moreover, technical assistance from WHO was included in the funding request for the elaboration of policies, strategies and guidelines related to the implementation of the above mentioned recommendations.

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
- ☒ Table 2: Programmatic Gap Table(s)
- ☒ Table 3: Modular Template
- ☒ Table 4: List of Abbreviations and Annexes
- ☒ CCM Eligibility Requirements
- ☒ CCM Endorsement of Concept Note