

## SECTIONS IV – VIII: Detailed information on each component of the proposal

**PLEASE COMPLETE THE FOLLOWING SECTIONS FOR EACH COMPONENT**

*Please copy sections IV – VIII as many times as there are components*

*Please note: a component refers to a disease, i.e. your proposal will have more than one component only if it covers more than one disease. There should only be 1 component per disease.*

*If there are any objectives or broad activities within a particular component that are of a system-wide/cross-cutting nature such as capacity building or infrastructure development that may go beyond the scope of that particular component, please indicate those aspects clearly and specify how they would relate to other components of the proposal when detailing them in Question 27. (Guidelines para. IV.47 – 49)*

*If this is a fully integrated proposal, where two or more components are linked in such a way which would not make it realistic or feasible to separate, mark the boxes in Table IV.23 to identify all diseases which would be directly affected by this integrated component. (Guidelines para. 50)*

### **SECTION IV – Scope of proposal**

**23. Identify the component that is detailed in this section (mark with X):**

Table IV.23

Component (mark with X):		HIV/AIDS
	<b>X</b>	Tuberculosis
		Malaria
		HIV/TB

**24. Provide a brief summary of the component** (Specify the rationale, goal, objectives, activities, expected results, how these activities will be implemented and partners involved) (2–3 paragraphs):

The main objectives of this component are those of meeting WHO Recommended TB Control targets, adopted by the World Health Assembly (Resolutions WHA 44.8, 1991 and 46.36, 1993). These targets include curing 85% of newly detected cases of sputum smear positive TB, and detecting 70% of the estimated incidence of sputum smear-positive TB by expanding DOTS coverage to 100% of the country by the end of the project. In addition, DOTS plus protocols for Multi Drug-Resistant Tuberculosis (MDR) will be incorporated into the DOTS strategy. The TB component of this proposal conforms to the National Strategy for TB Control, developed on the basis of the WHO Strategy for TB Control and DOTS implementation. The objectives and activities included in this proposal are the same as those contained in the Romanian National TB Control Programme for 2001- 2005.

This TB component includes three major objectives:

1. Ensuring the expansion of DOTS and prevention programs to bring a stop to the increasing incidence of TB. At the present time, access to DOTS is provided for a mere 80% of hospitalized patients and 25% of patients in the continuation phase. The major activities to be implemented for meet this proposed objective include: well-trained human resources (knowledge, attitudes and practices updated to meet current WHO standards, guidelines and recommendations), the establishment of a system of incentives for TB patients, and the improvement in TB control in children and high-risk groups, such as prisoners, members of the Roma community and HIV infected persons. The Roma

community represents a serious challenge for TB control due to widespread poverty, social exclusion, poor accessibility to the healthcare system and a low level of education. Such activities are destined to ensure 100% DOTS access for all TB patients and to bring about a reduction in the increasing incidence of TB.

2. Strengthening the national healthcare system for TB patients. A patient-centered approach must be promoted to improve both access to and use of health services. Such services need to be enhanced to sustain and expand DOTS without compromising the quality of case detection and treatment. The objective contains three broad categories of activities relating to the strengthening of the bacteriological laboratory network, the establishment of three special centers for diagnosis and treatment of drug-resistant (DR) TB, the rehabilitation or refurbishment of three inpatient clinics, and a proper and adequate drug management system.

3. Strengthening the TB supervision/monitoring and surveillance system for TB within the National Communicable Diseases Surveillance Network. Such a system ensures the assessment of all patients and that of overall programme performance, the latter a basis for correcting identified programme implementation problems. The activities involve the development of a functional supervision and monitoring system with systematic county-level and countrywide visits from the Central Unit. Other activities will strengthen and integrate TB data collection/processing within the National Communicable Diseases Surveillance Network. The objective will be implemented in a coordinated manner, under the authority of the CCM and that of the National TB Programme Central Unit, and will involve a network of partners consisting of government institutions, professional organizations, NGOs, private practitioner organizations and the Romanian Orthodox Church.

Some activities will be implemented by NGOs that have not yet been identified. A tender will be organized to choose the best NGO in terms of costs, and previously registered experience and outcome.

**25. Indicate the estimated duration of the component:**

Table IV.25

<b>From (month/year):</b>	January 2003	<b>To (month/year):</b>	December 2007
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**26. Detailed description of the component for its FULL LIFE-CYCLE:**

*Please note: Each component should have ONE overall goal, which should translate into a series of specific objectives. In turn each specific objective should be broken-down into a set of broad activities necessary to achieve the specific objectives. While the activities should not be too detailed they should be sufficiently descriptive to understand how you aim to achieve your stated objectives.*

**Indicators:** *In addition to a brief narrative, for each level of expected result tied to the goal, objectives and activities, you will need to identify a set of indicators to measure expected result. Please refer to Guidelines paragraph VII.77 – 79 and Annex II for illustrative country level indicators.*

**Baseline data:** *Baseline data should be given in absolute numbers (if possible) and/or percentage. If baseline data is not available, please refer to Guidelines paragraph VII.80. Baseline data should be from the latest year available, and the source must be specified.*

**Targets:** *Clear targets should be provided in absolute numbers (if possible) and percentage.*

**For each level of result, please specify data source, data collection methodologies and frequency of collection.**

An example on how to fill out the tables in questions 26 and 27 is provided as Annex III in the Guidelines for Proposals

**26.1. Goal and expected impact** (Describe overall goal of component and what impact, if applicable, is expected on the targeted populations, the burden of disease, etc.), (1–2 paragraphs):

*Please note: the impact may be linked to broader national-level programs within which this component falls. If that is the case, please ensure the impact indicators reflect the overall national programme and not just this component.*

*Please specify in Table IV.26.1 the baseline data. Targets to measure impact are only required for the end of the full award period.*

The main goal of the TB component is to meet WHO Recommended TB Control targets. This includes the successful treatment of 85% of confirmed cases of pulmonary and bacteriological TB and the detection of at least 70% of estimated infected TB pulmonary patients by expanding DOTS coverage to 100% of the country. The component addresses the main problems and constraints of TB control in Romania, as identified in the National TB Control Programme 2001–2005, and it is expected that the five-year implementation of this will bring about the desired goal and objectives.

Table IV.26.1

Goal:		
Impact indicators (Refer to Annex II)	Baseline	Target (last year of proposal)
	Year:	Year:
% of cure rate for new smear-positive pulmonary TB cases	2001 55	2007 85
% of success rate for new smear-positive pulmonary TB cases	2001 76	2007 93
% of TB mortality rate	2000 9.5	2007 7
TB incidence in children	2000 47.1/100,000	2007 40/100,000
% of population living in areas covered by the DOTS strategy	2001 25	2007 100

**27. Objectives and expected outcomes** (Describe the specific objectives and expected outcomes that will contribute to realizing the stated goal), (1 paragraph per specific objective):

*Question 27 must be answered for each objective separately. Please copy Question 27 and 27.1 as many times as there are objectives.*

*Please note: the outcomes may be linked to broader programs within which this component falls. If that is the case, please ensure the outcome/coverage indicators reflect the overall national programme and not just this component.*

*Specify in Table IV.27 the baseline data to measure outcome/coverage indicators. Targets are only required for Year 2 onwards.*

**Objective 1: Ensure DOTS expansion to reduce increasing rate of TB incidence**

To reach this objective it will be necessary to ensure close collaboration between the networks of specialists in pulmonology and epidemiology, general practitioners (GP) and family doctors (FD), community health and social workers, and other community members (such as religious representatives). Health staff and social workers must be informed of their responsibilities according to the TB Control Program, and the WHO Strategy. The control of TB among children and high-risk groups, such as prisoners, Roma and HIV infected persons must be improved. The activities to be implemented are intended to lead to the development and distribution of the National Strategy and guidelines for the diagnosis and treatment of TB in children. They will also help develop the TB Control Programme in prisons in accordance with the National TB Programme and recommendations made by a group of EU experts for developing a strategy for TB control and health education relating the high-risk groups in Roma communities. It is expected that incentives/enablers for TB patients from areas with high TB incidence could increase compliance with treatment.

<b>Objective 1:</b>	<b>Ensure DOTS expansion to reduce increasing rate of TB incidence</b>				
<b>Outcome/coverage indicators (Refer to Annex II)</b>	<b>Baseline</b>	<b>Targets</b>			
	<b>Year:</b>	<b>Year 2:</b>	<b>Year 3:</b>	<b>Year 4:</b>	<b>Year 5:</b>
% of increase in TB incidence rate	2001 9.4	7	4	2	0
% of TB patients receiving DOT during initial phase	2000 80	85	90	95	100
% of TB patients receiving DOT during continuation phase	2000 30	40	50	60	80
% of sputum conversion rate after 2 <sup>nd</sup> – 3 <sup>rd</sup> months of anti-TB treatment	2001 75	78	80	85	85
HIV sero-prevalence in TB patients	2001 NA				Data available

### **Objective 2: Strengthening the National Healthcare System for TB patients**

Activities to be implemented under this objective are meant to improve the national healthcare system and to facilitate access of TB patients to high quality healthcare. The activities will center on improving the bacteriological laboratory network and the functionality of the quality control system. These will also ensure continuous, uninterrupted and centralized high quality drug procurement and distribution and improve access to second-line drugs and reliable follow-up for patients with drug-resistant TB.

<b>Objective 2:</b>	<b>Strengthening the National Healthcare System for TB patients</b>				
<b>Outcome/coverage indicators (Refer to Annex II)</b>	<b>Baseline</b>	<b>Targets</b>			
	<b>Year:</b>	<b>Year 2:</b>	<b>Year 3:</b>	<b>Year 4:</b>	<b>Year 5:</b>
% of bacteriologically confirmed pulmonary TB cases (number of pulmonary smear-positive cases/total pulmonary TB cases)	2001 54	60	63	66	70
% of bacteriological laboratories for which quality control results are available	2002 0	20	40	80	100
% by which cost of first-line TB drugs can be reduced through centralized procurement	2002 0	10	20	30	40
% MDR TB cases among patients that have never been treated	2000 3.6				2.5

**27.1 Broad activities related to each specific objective and expected output**  
(Describe the main activities to be undertaken, such as specific interventions, to achieve the stated objectives) (1 short paragraph per broad activity):

*Please note: Process/output indicators for the broad activities should directly reflect the specified broad activities of THIS component.*

*Specify in Table IV.27.1 below the baseline data to measure process/output indicators. Targets need to be specified for the first two years of the component.*

*For each broad activity, specify in Table IV.27.1 who the implementing agency or agencies will be.*

**Objective 1: Ensure DOTS expansion to reduce increasing rate of TB incidence**

The major result of these activities is to ensure 100% DOTS access to all TB patients and to reduce the increasing rate of TB incidence.

***Activity 1: Develop an appropriate human resources network for TB control***

Knowledge, attitudes and practices will be updated according to current WHO standards, guidelines and recommendations. This will include the development of a new curricula for medical schools offering post-graduate courses, training and refresher training sessions, seminars and workshops for the following categories of health staff: specialists in lung diseases and epidemiology, general practitioners, laboratory staff, nurses, community health and social workers.

**Activity 1.1**

Because there has been no training in the TB control strategy, DOTS, for the 800 lung disease specialists and 200 specialists in epidemiology in Romania since 1997-1998, this activity will provide refresher training and updated information, including the latest recommendations within the DOTS strategy. This is especially important as epidemiologists develop their future role in TB control and their collaboration with lung disease specialists. Regional centers for training will be set up in 6 regions, where all specialists in lung diseases will meet at least once a year. Similar county-level training will be provided to the 17,000 general practitioners and family doctors, to familiarize them with their role in implementation, and the National Association for general practitioners (GP) and family doctors (FD) will be one of the implementing partners. Regional refresher training will also be available for laboratory staff, including that of the three National Reference Laboratories and the 180 laboratories throughout the country.

**Activity 1.2**

This activity will provide training for nurses, community health and social workers on how to be involved in the implementation/expansion of the country-wide DOTS strategy, to be carried out by the area GP, with the assistance of an NGO as implementing partner. The activity will begin in five pilot areas over the first year and expand if the results are promising. Three joint annual meetings will also be organized involving all those dealing with TB control in a particular area, to discuss major problems, cases and the management of TB cases.

**Activity 1.3**

The current graduate and post-graduate curricula for TB control and case care will be updated, to stress the importance of TB control in Romania, and to bring to the attention of doctors and future doctors the opportunities and constraints in TB diagnosis and treatment.

**Activity 1.4**

Through this activity, county TB managers will receive training in programme management and quality improvement.

***Activity 2: Improve TB control in children and high-risk groups, such as persons infected with HIV, prisoners and Roma***

Develop and distribute National Strategy and guidelines for diagnosis and treatment of TB in children. Develop a TB Control Programme for prisons based on the National TB Programme and recommendations already made by a group of EU experts. Develop a similar strategy for TB control in Roma communities. All registered TB patients will be tested for HIV, to evaluate the magnitude of this problem in TB patients.

**Activities 2.1–2.3 Improve TB control in children**

Through this activity National Strategy and guidelines for TB diagnosis and treatment in children will be developed and distributed. Once these guidelines are developed, two workshops will be organized for pediatricians working with children with TB, and this activity will be implemented with the help of the Association of Pediatricians. Special TB health education activities will also be implemented with similar activities relating to HIV/AIDS, and the curricula will include information on both diseases.

**Activities 2.4–2.6: Improve TB control in prisons**

These activities will be geared to implementing the new strategy for TB control in prisons. This will be done by publishing and distributing the new strategy and guidelines, procuring equipment needed for the collection of sputum samples in each of the 6 prison hospitals and 37 prisons, and equipment and furniture required to isolate TB patients in these prisons. At present, TB patients in the continuation phase are sharing the same room with healthy patients, while in prison hospitals, drug-resistant TB patients share a room with many other non-resistant TB patients. Activities will also include health education for prisoners, something that is now greatly lacking. Materials and hygiene kits will be distributed and discussions will be initiated with prisoners. This activity will be implemented in parallel with the HIV/AIDS component, and the curricula will contain information on both diseases.

**Activities 2.7–2.10: Improve TB control in Roma communities**

This activity will begin in five areas: in three Bucharest sectors, Giurgiu and Calarasi counties. It will consist of data collection, the development of a strategy for TB control, and Information, Education and Communication (IEC) activities for members of this minority community. Medical mediators have already been selected from within the Roma communities through an existing project of the Ministry of Health, and these are expected to facilitate access of health workers to Roma communities, especially in the follow-up of TB patients and contact tracing. These medical mediators will be trained to carry out this important function.

***Activity 3: Establish a system of incentives and enablers for TB patients***

This activity will help establish a system of incentives/enablers, based on international experience and practice. Such a system is greatly needed because of the socioeconomic situation of TB patients in Romania, and the fact that County and dispensary managers are not compensated in any way for the additional responsibilities they take on according to the TB Control Program. In the case of patients, it is expected that a monthly incentive would increase the compliance with DOT.

**Activity 3.1: Social assistance for TB patients**

Such an activity will provide hygiene kits/food bags and cover the costs of transportation for TB patients in selected areas. The patient will receive such incentives only during the continuation phase and if he complies with DOT. This activity will initially be implemented in several pilot areas, and at the end of the first two years a study will be carried out to determine cost effectiveness. If the results are promising, the system will be implemented in further Counties.

Note: Wherever a non-governmental organization is to be involved as responsible/implementing agency, such an NGO will be selected by tender.

Table IV.27.1

<b>Objective 1: Ensure DOTS expansion to reduce increasing rate of TB incidence</b>					
<b>Broad activities</b>	<b>Process/Output indicators (indicate one per activity) (Refer to Annex II)</b>	<b>Baseline (Specify year)</b>	<b>Targets</b>		<b>Responsible/Implementing agency or agencies</b>
			<b>Year 1</b>	<b>Year 2</b>	
<b>1. Develop an appropriate human resources network for TB control</b>					
1.1. Training of specialists in lung diseases, epidemiologists, GPs/FDs and laboratory staff, and promoting joint meetings between these, with the exception of laboratory staff	# of specialists, GP/FD trained in the new TB Control Programme and the new framework for TB control	2002 0	7,000	3,000	Ministry of Health and Family, Central Unit National TB Programme (CU NTP), state and private GP/FD Associations, with WHO technical support
1.2 Instruction of nurses, community health and social workers	% of nurses/community health and social workers trained and involved in DOTS program	2002 0	4,000	8,000	Ministry of Health and Family, CU NTP, Association of Nurses, NGO, with WHO technical support
1.3. Improving curricula Schools of Medicine, as well as those involved in continuous medical training by adding TB guidelines	% of universities/schools adopting the new curricula	2002 Not available	Available	Available and adopted by 40%	Ministry of Health and Family, Ministry of Education
1.4. Programme management training for County TB managers	# of County managers trained in programme management				Ministry of Health and Family, USAID
<b>2. Improve TB control in children and high-risk groups, such as persons infected with HIV, prisoners and Roma</b>					
2.1. Development of the Romanian guidelines for TB diagnosis and treatment in children	Existence of TB guidelines for TB in children	2002 Not available	Available	Available	Ministry of Health and Family, CU NTP, USAID/Baylor, Romanian Association of Pediatricians

2.2 Workshops with pediatricians specialized in TB care	% of pediatricians participating in the workshops	-	50	50	Ministry of Health and Family, CU NTP, USAID, Baylor, Association of Pediatricians	
2.3 Health education program/IEC for children with TB	% of units where the IEC Programme is implemented	-	50	50	Ministry of Health and Family, NGO, Red Cross	
2.4 Printing and distribution of new Strategy/Guidelines for TB Control in prisons	# of units using the guidelines, forms and registers	2002	0	100	Ministry of Health and Family, Ministry of Justice, WHO technical support, Red Cross	
2.5. Procurement of equipment for sputum collection rooms, and equipment and furniture for isolation rooms	% of fully-equipped and refurbished rooms for sputum collection and isolation rooms located in prisons and prison hospitals		0	30	40	Ministry of Health and Family, Ministry of Justice
2.6. Health education session for prisoners	% of units where the IEC Programme is implemented	-	20	20	Ministry of Health and Family, Ministry of Justice, CU NTP, NGO	
2.7 Data collection/needs assessment in 5 pilot areas	% of data and needs assessed	-	100	100	Ministry of Health and Family, CU NTP, NGO	
2.8 Development of a strategy for health education in Roma communities	Existence of a strategy for TB control among the Roma communities	Not available	Available	Available	Ministry of Health and Family, CU NTP, NGO	
2.9 Training for Roma medical mediators for TB	% of medical mediators trained and involved in DOTS programme	0	50	50	Ministry of Health and Family, CU NTP, NGO	
2.10 Health education/IEC for Roma community	# of communities where the IEC Programme is implemented	2001	0	15	26	Ministry of Health and Family, CU NTP, NGO
2.11 HIV testing for all registered TB cases	% HIV/TB patients detected	Not available			Ministry of Health and Family, CU NTP	
<b>3. Establishment of a system of incentives for TB patients</b>						
3.1 Hygiene kits/food bags/transportation tickets for TB patients in selected areas	% of increase in DOT compliance of patients receiving treatment under continuation phase.	30	40	50	Ministry of Health and Family, CU NTP, NGO	

\* activities will use the same implementation capacity as for HIV interventions in the respective area



## **Objective 2 : Strengthen the National Healthcare System for TB patients**

### ***Activity 4: Improve the Bacteriological Laboratory Network and the functionality of the quality control network***

This activity will ensure improved laboratory infrastructure, including necessary equipment for diagnosis and safety measures for staff working in such laboratories. Staff will also be made aware of and apply guidelines for diagnosis of TB in laboratories and of quality control principles.

#### **Activity 4.1 Procurement of laboratory equipment**

Bacteriological laboratories throughout the country are poorly equipped, with outdated and badly worn equipment, and safety measures are non-existent in most of them. The procurement of equipment and consumables/reagents for testing will lead to improved TB diagnosis and follow-up/monitoring of treatment efficiency through microscopy, culture, and drugs susceptibility testing.

#### **Activity 4.2 Implementation of a quality control strategy for bacteriological laboratories**

In 2001, Romania had 59 Level 1 laboratories, which performed 53,165 sputum smear microscopy exams (3,308 positive); 54 Level 2 laboratories, which performed 111,555 sputum smear microscopy exam (10,043 positive) and 126,151 cultures (13,371 positive); and 75 Level 3, which performed 573,410 sputum smear microscopy exams (68,168 positive), 600,448 cultures (85,458 positive) and 18,817 sensitivity tests. The country laboratory network is covered by 3 National Reference Laboratories, in Bucharest, Iasi and Cluj. At the beginning of 2002, guidelines for the quality control of bacteriological laboratories were developed according to WHO recommendations and Romania was included among the countries to participate in the worldwide Drug Resistance Survey. Through this activity, every bacteriological laboratory will be visited twice a year to evaluate the workload and quality of work performed. The results will determine the appropriate measures to be taken.

#### **Activity 4.3 Accreditation of bacteriological laboratories by the national accreditation agency**

This activity will provide for the official accreditation of all bacteriological laboratories, and has already been started by the Ministry of Health and Family through the national accreditation agency.

### ***Activity 5: Improve access to good healthcare for TB patients and chronic TB cases (including drug-resistant TB cases)***

At the present time, Romania's data on chronic TB patients is not evidence-based, nor is there any centralized data on this category of patients. In full accordance with WHO recommendations for Romania, one of the first steps to be taken to improve the care of chronic TB patients is the development of a national register of chronic cases. Such a register will include individual data on the bacteriological status, treatment regimens followed and reasons for such individuals developing chronic TB. Furthermore, bacteriological diagnosis is carried out countrywide in laboratories that do not perform quality control, and there are frequent interruptions second-line drugs. These elements lead to an extremely high risk of spreading drug resistant TB among the families of patients, as well as among the general population. This activity, in keeping with WHO recommendations, will provide for the creation of 3 centers of excellence carrying out high quality diagnosis, with fully-trained staff to ensure the proper treatment for the right period of time, and with a continuous supply of second-line drugs, only available in such centers.

#### **Activity 5.1 Establishment of a national register for chronic cases**

A special team will be involved in the designing and implementation of a national register and will ensure the reliability of collected data.

**Activities 5.2–5.3 Establishment of regional centers and improvement of the infrastructure, to contain high performance laboratory equipment and consumables**

Three centers of excellence will be established in Romania for diagnosing, hospitalizing and treating MDR and DR TB patients. These centers will be new, well equipped and friendly for both patients and health staff.

**Activity 5.4 Provide for highly-trained chronic and drug-resistant TB staff**

This activity will provide for an exchange of experience with staff from countries where the control of chronic and drug-resistant TB patients is already well developed.

**Activity 5.5 Provide for an uninterrupted supply of high-quality second-line drugs**

This activity will ensure a 12-15-month supply of high-quality second-line anti-TB drugs needed to start treatment of MDR TB patients. In the budget for this activity the funding is requested for the full cost of the drugs. Romania is negotiating a price reduction (up to 80%) with the Green Light Committee, following which costs will be adjusted accordingly.

**Activity 5.6 Rehabilitation and refurbishment of three selected TB inpatient facilities**

Some TB inpatient facilities are located in buildings that are over 70 years old and extremely outdated. This activity will ensure the proper selection of three areas for rehabilitation/refurbishment, based on the number of TB patients in the area covered by the unit, the sustainability of such a TB facility, the infrastructure, location and condition of the building, and costs for rehabilitation/refurbishment. All such work will be done on buildings belonging to the Ministry of Health and Family, which are already included in the TB network.

***Activity 6: Improve the Romanian drug management system***

While the procurement of TB drugs has been decentralized for some years, TB unit is entitled to buy its own TB first and second-line drugs, according to available funds and available drugs in local pharmacies. As of 2002, it was decided that TB drug procurement should be centralized, to bring down prices, ensure improved and standard quality, and regular distribution, to prevent shortages. As the procurement of drugs includes also selection, quality assurance, distribution and use, it will be necessary to increase the knowledge regarding a system of drug management (DMS). This process has begun in 2002, with the assistance of USAID and Management Sciences for Health (MSH), but more intensive training will be necessary as will the setting up of a drug management system.

**Activity 6.1: Create a sustainable Drug Management System**

**Activity 6.2: Drug Management System Training**

These two activities will be implemented to improve the drug management system and training, the latter to include all aspects of drug management. Trainees will be representatives of all structures involved in central and peripheral-level drug management.

Note: Wherever a non-governmental organization is to be involved as responsible/implementing agency, such an NGO will be selected by tender.

Table IV.27.1

<b>Objective 2: Strengthen the National System of Healthcare for TB patients</b>					
<b>Broad activities</b>	<b>Process/Output indicators (indicate one per activity) (Refer to Annex II)</b>	<b>Baseline (Specify year)</b>	<b>Targets</b>		<b>Responsible/Implementing agency or agencies</b>
			<b>Year 1</b>	<b>Year 2</b>	
<b>4. Improve the Bacteriological Laboratory Network and the functionality of the quality control network</b>					
4.1 Procurement of laboratory equipment	% of laboratories with standard equipment according to the categorization	Not available	50	100	Ministry of Health and Family, Central Unit National Tuberculosis Programme (CU NTP)
4.2. Implementation of a quality control strategy for bacteriological laboratories	# of laboratories visited for quality control	2002 0	50	100	NTP
4.3 Accreditation of bacteriological laboratories	% of bacteriological laboratories passing through accreditation	2002 0	50	50	Ministry of Health and Family, National Accreditation Agency
<b>5. Improve access to good healthcare for TB patients and chronic TB cases (including drug-resistant TB cases)</b>					
5.1. Establishment of a national register for chronic cases	Existence of a national register	-	1	1	NTP
5.2. Establishment of regional centers and improvement of their infrastructure	# of chronic and DR TB patients treated in regional centers	-			Ministry of Health and Family, NTP, NGO
5.3. Endow regional centers with high performance laboratory equipment and consumables for diagnosis and treatment of Drug-	3 laboratories standard equipped for microscopy, culture and sensitivity tests				Ministry of Health and Family, NTP, NGO

resistant TB cases					
5.4. Provide for highly-trained chronic and drug-resistant TB staff	# of staff trained in MDR TB diagnosis and treatment	0	10	20	Ministry of Health and Family, NTP, NTP Latvia and Estonia
5.5. Provide for an uninterrupted supply of high-quality second-line drugs	% of MDR TB patients completely treated for MDR TB	Not available	70	100	Ministry of Health and Family, CU NTP
5.6. Rehabilitation and refurbishment of three selected TB inpatient facilities	Existence of 3 rehabilitated TB inpatient facilities				Ministry of Health and Family, NTP
<b>6. Improve the Romanian drug management system</b>					
6.1 Create a sustainable drug management system	Existence of a sustainable drug management system	Not available			Ministry of Health and Family, NTP
6.2 Training in drug management system	# of staff trained in DMS	2002 20	50	50	Ministry of Health and Family, NTP

***Objective 3: Strengthen the supervision/monitoring and surveillance system within the National Communicable Disease Surveillance Network***

The TB surveillance system must be improved, including changes and updates in the collection/data processing system, and this must be done by periodic supervision and monitoring visits from the central to the peripheral levels of each County. It is expected that epidemiologists will be involved in this objective. A joint workshop will be organized for NTP managers and County epidemiologists, to define strategy and roles. Specially designed software for data collection will be created, to be installed and used by all County TB managers and the Ministry of Health and Family. Special training sessions will also be organized for all staff involved in data processing.

***Activity 7: Develop a functional supervision and monitoring system***

**Activity 7.1 Supervision and monitoring visits**

In order to evaluate the implementation of DOTS in the field as well and to identify constraints and gaps, two yearly visits are needed in each County from the Central Unit to the peripheral level. These visits will be carried out by a specially-designated Central Unit team that will be required to complete a specially-developed checklist. As of mid-2002, a National Committee for Supervision of the Implementation of the National TB Control Programme has come into existence, consisting of 25 supervisors selected from among the 50 NTP County Managers. Over the past two years, a variety of donors, including the Open Society Institute and the Relief Fund for Romania, have partially covered the cost of such visits with government funding.

**Activity 7.2 County-level supervision visits**

Each County Programme Manager will have to carry out visits to the TB facilities and selected GP units in his/her County. The methodology will be the same as that for national-level supervision, the main purpose being to check on the situation with DOTS implementation, determine problems faced by staff and offer solutions to such problems, and to inform the Central Unit of the outcome of such visits. Each visited unit will also receive feedback from these visits. While such visits are mandatory according to the National TB Program, these are not being carried out for lack of transportation facilities for the County Programme Managers. Therefore, "multipurpose vehicles" will be procured, that will also serve to transport drugs to the peripheral level, sputum samples, and TB patients for their check-ups. The running costs of such vehicles will be covered from the regular national budget.

***Activity 8: Strengthen and integrate the TB surveillance system in the National Communicable Disease Surveillance System***

**Activity 8.1: Workshop for data reporting/processing with County epidemiologists and TB managers**

According to this activity a seminar will be organized for County epidemiologists and TB Managers. The outcome of this seminar will be the development of a common strategy for the improvement of TB surveillance/data collection and data processing in Romania.

**Activity 8.2: Development of specially designed software for TB data collection**

Following this seminar, special software will be developed for TB data collection, to be used by all Counties for reporting to the Ministry of Health and the Program's Central Unit. According to this activity, staff using this software will receive special training in its use.

**Activity 8.3: Training of staff to use specially-designed software for TB data collection**

This activity will provide training for all staff to use the specially-designed software for TB data collection.

Note: Wherever a company is to be involved as responsible/implementing agency, such a company will be selected by tender.

Table IV.27.1

<b>Objective 3: Strengthen the supervision/monitoring and surveillance system within the National Communicable Disease Surveillance Network</b>					
<b>Broad activities</b>	<b>Process/Output indicators (indicate one per activity) (Refer to Annex II)</b>	<b>Baseline (Specify year)</b>	<b>Targets</b>		<b>Responsible/Implementing agency or agencies</b>
			<b>Year 1</b>	<b>Year 2</b>	
<b>7. Develop a functional supervision and monitoring system</b>					
7.1 Supervision and monitoring visits	# of visits performed from the Central Unit to the county-level	2002 25	100	100	National Tuberculosis Programme (NTP)
7.2 County-level supervision visits	% of Counties that received multi-purpose vehicles and use these according to stipulated criteria	0	50	50	Ministry of Health and Family, NTP
<b>8. Strengthen and integrate the TB surveillance system in the National Communicable Disease Surveillance System</b>					
8.1 Workshop or data reporting/processing for county epidemiologists and TB managers	# of units using the recommended forms and registers and reporting according to the strategy		100	220	Ministry of Health and Family, Central Unit NTP, Epidemiology Department of the County Public Health Directorate
8.2 Development of specially designed	% of units using the software in data	0	60	40	Ministry of Health and Family, CU NTP, Epidemiology

software for TB collection and installation on county-level PCs as well as the MOHF level	reporting and processing				Department of the County Public Health Directorate, Software company
8.3 Training of staff involved in data collection and data processing in using the soft	% of staff trained to use special software	0	60	40	Ministry of Health and Family, CU NTP, Epidemiology Department of the County Public Health Directorate, Software company

**28. Describe how the component adds to or complements activities already undertaken by the government, external donors, the private sector or other relevant partner:** (e.g., does the component build on or scale-up existing programs; does the component aim to fill existing gaps in national programs; does the proposal fit within the National Plan; is there a clear link between the component and broader development policies and programs such as Poverty Reduction Strategies or Sector-Wide Approaches, etc.), (Guidelines para. III.41 – 42), (2–3 paragraphs):

The TB component has been developed to complement currently existing and implemented components of the DOTS strategy. This component is in complete accordance with recommendations of the National TB Control programme. It covers activities that are necessary to be implemented either to effectively expand interventions that are not fully funded at the national level or to initiate interventions proposed by the Programme, which have not begun due to budgetary restrictions. Though political commitment for TB control is currently high, it is recognized that the level of national-level resources that can be allocated for implementation and expansion of the National TB Programme and the DOTS strategy is low due to the country's difficult socioeconomic circumstances. Funds being requested from GFFATM are intended to cover the financing gaps over a short period.

Based on positive economic trends over the past few years, it is expected that Romania's health and social spending will generally increase, to ensure the sustainability of the programs and activities proposed to be initiated with GFATM funding.

**29. Briefly describe how the component addresses the following issues** (1 paragraph per item):

**29.1. The involvement of beneficiaries such as people living with HIV/AIDS:**

Various beneficiaries of this proposal were involved in the development of this GFATM Proposal and will continue to be involved in all phases throughout the component lifecycle. Should be also mentioned the involvement of beneficiaries (including TB patients) in the designing and implementation of health education strategy devoted to different target groups as well as monitoring and evaluation activities.

**29.2. Community participation:**

Community participation is ensured through the participation of the major community-based organizations in the CCM and as implementation partners. This component aims to build the capacity of certain communities, such as Roma, MSM and PLWA to respond to the problems related to TB and ensure the sustainability over time of the necessary interventions.

**29.3. Gender equality issues** (Guidelines paragraph IV.53):

Gender distribution among TB cases must be taken into consideration within the TB component. The largest number of cases registered is that of most active age males (25–35 years), while female distribution is generally younger (20–30 years). All of these gender issues have been taken into account in the major areas of intervention proposed in this component, and intervention will be determined according to gender, as well as to responsibilities and opportunities from a social, cultural, and political perspective. Various instruments for monitorization, evaluation and surveillance will be designed accordingly to provide gender desegregated data and determine gender focused interventions.

**29.4. Social equality issues** (Guidelines paragraph IV.53):

The TB component of this Proposal follows the indications of the National TB Control Programme, which stipulates that TB diagnosis and treatment must be free of charge for all TB patients and persons suspected of having TB, a principle that has always been applied in Romania. Several of the major activities aim to ensure equal and equitable access of TB suspects and patients to all DOTS components. Special and adequate interventions (such as the medical mediators for Roma communities) will be developed to suit the particular needs of various disadvantaged groups or groups at high risk.



**29.5. Human Resources development:**

The development of human resources is a major objective throughout the entire proposal. Most of the activities include interventions for capacity-building, and capacity and training expansion, primarily concentrated in the first two years of implementation, and is considered the key element for ensuring long-term sustainability of the programs.

**29.6. For components dealing with essential drugs and medicine, describe which products and treatment protocols will be used and how rational use will be ensured (i.e. to maximize adherence and monitor resistance), (*Guidelines para. IV.55*), (1–2 paragraphs):**

Procurement of second-line TB drugs for patients with drug-resistant TB is included in the TB component. Treatment categories, protocols and regimens are the same as those recommended by WHO for Drug-Resistant TB in its Guidelines for Treatment of Drug-Resistant TB. These WHO Guidelines have been translated into Romanian and were published in issue 2 (2000) of the Journal of Pneumology.

Owing to the existence of the WHO Green Light Committee (GLC), responsible for second-line TB treatment, the component in this proposal which refers to the procurement of second-line drugs and the creation of special centres for treatment, diagnosis and follow-up of patients with drug-resistant TB, should also be reviewed GLC. This will ensure that the TB component is appropriate and fully in line with the recommendations of the DOTS+ Working Group of the Stop TB partnership, thus following the best standard available today.

**SECTION V – Budget information**

<b>Objective 1:</b>							
<b>Broad activity</b>	<b>Total</b>	<b>Year</b>					<b>Responsible/Implementing agency or agencies</b>
		<b>Year 1</b>	<b>Year 2</b>	<b>Year 3 estimate</b>	<b>Year 4 Estimate</b>	<b>Year 5 estimate</b>	
<b>1. Develop an appropriate human resources network for TB control</b>	1,451,640						
1.1. Training of specialists in lung diseases, epidemiologists, GPs/FDs and laboratory staff, and promoting joint meetings between these, with the exception of laboratory staff	943,640	443,00	250,000	100,000	100,000	50,640	Ministry of Health and Family, Central Unit National TB Programme (CU NTP), state and private GP/FD Associations, with WHO technical support
1.2 Instruction of nurses, community health and social workers	400,000	150,000	150,000	100,000			Ministry of Health and Family, CU NTP, Association of Nurses, NGO, with WHO technical support
1.3. Improving curricula Schools of Medicine, as well as those involved in continuous medical training by adding TB guidelines	30,000	30,000					Ministry of Health and Family, Ministry of Education
1.4. Programme management training for County TB managers	78,000	50,000	28,000				Ministry of Health and Family, USAID
<b>2. Improve TB control in children and high-risk groups, such as persons infected with HIV, prisoners and Rroma</b>	2,105,000						
2.1. Development of the Romanian guidelines for TB diagnosis and treatment in children	75,000	45,000	30,000				Ministry of Health and Family, CU NTP, Baylor, Romanian Association of Pediatricians
2.2 Workshops with pediatricians specialized in TB care	100,000	-	50,000	50,000			Ministry of Health and Family, CU NTP, Baylor, Association of Pediatricians

2.3 Health education program/IEC for children with TB	150,000	75,000	75,000				Ministry of Health and Family, NGO, Romanian Red Cross
2.4 Printing and distribution of new Strategy/Guidelines for TB Control in prisons	10,000	10,000					Ministry of Health and Family, Ministry of Justice, WHO technical support, Romanian Red Cross
2.5. Procurement of equipment for sputum collection rooms, and equipment and furniture for isolation rooms	1,195,000	450,000	500,000	230,000	15,000		Ministry of Health and Family, Ministry of Justice
2.6. Health education session for prisoners	150,000	30,000	30,000	30,000	30,000	30,000	Ministry of Health and Family, Ministry of Justice, CU NTP, NGO,
2.7 Data collection/needs assessment in 5 pilot areas	40,000	20,000	20,000				Ministry of Health and Family, CU NTP, NGO, Red Cross
2.8 Development of a strategy for health education in Roma communities	50,000	20,000	20,000	10,000			Ministry of Health and Family, CU NTP, NGO, Red Cross
2.9 Training for Roma medical mediators for TB	45,000	45,000					Ministry of Health and Family, CU NTP, NGO, Red Cross
2.10 Health education/IEC for Roma community	125,000	50,000	25,000	25,000	25,000		Ministry of Health and Family, CU NTP, NGO, Romanian Red Cross
2.11 HIV testing for all registered TB cases	165,000	60,000	60,000	30,000	15,000		Ministry of Health and Family, CU NTP
<b>3. Establishment of a system of incentives for TB patients</b>	600,000						
3.1 Hygiene kits/food bags/transportation tickets for TB patients in selected areas	600,000	300,000					Ministry of Health and Family, CU NTP, NGO
<b>Total</b>	<b>4,156,640</b>						

**Objective 2:**

Broad activities	Total	Year					Responsible/Implementing agency or agencies
		Year 1	Year 2	Year 3 estimate	Year 4 estimate	Year 5 estimate	
<b>4. Improve the Bacteriological Laboratory Network and the functionality of the quality control network</b>	1,134,250						
4.1 Procurement of laboratory equipment	571,750	300,000	271,750				Ministry of Health and Family, CU NTP
4.2. Implementation of a quality control strategy for bacteriological laboratories	112,500	22,500	22,500	22,500	22,500	22,500	NTP
4.3 Accreditation of bacteriological laboratories	450,000	225,000	225,000				Ministry of Health and Family, National Accreditation Agency
<b>5. Improve access to good healthcare for TB patients and chronic TB cases (including drug-resistant TB cases)</b>	10,042,344						
5.1. Establishment of a national register for chronic cases	34,000	34,000					NTP
5.2. Establishment of regional centers and improvement of their infrastructure	600,000	400,000	200,000				Ministry of Health and Family, NTP, NGO/Company
5.3. Endow regional centers with high performance laboratory equipment and consumables for diagnosis and treatment of Drug-resistant TB cases	300,000	200,000	100,000				Ministry of Health and Family, NTP, NGO/Company
5.4. Provide for highly-trained chronic and drug-resistant TB staff	36,000		12,000	12,000		12,000	Ministry of Health and Family, NTP, NTP Latvia and Estonia

5.5. Provide for an uninterrupted supply of high-quality second-line drugs	6,572,344	3,286,172	3,286,172				Ministry of Health and Family, with WHO/Green Light Committee (GLC) technical assistance,
5.6. Rehabilitation and refurbishment of three selected TB inpatient facilities	2,500,000	1,250,000	1,250,000				Ministry of Health and Family, NTP, NGO/Company
<b>6. Improve the Romanian drug management system</b>	500,000						
6.1 Create a sustainable drug management system	350,000	100,000	100,000	100,000	50,000		Ministry of Health and Family, NTP
6.2 Training in drug management system	150,000	50,000	50,000			50,000	Ministry of Health and Family, NTP
<b>Total</b>	<b>5,104,250 + 6,572,334 = 11,676,594</b>						

**Objective 3:**

Broad activities	Total	Years					Responsible/Implementing agency or agencies
		Year 1	Year 2	Year 3 estimate	Year 4 estimate	Year 5 estimate	
<b>7. Develop a functional supervision and monitoring system</b>	1,800,000						
7.1 Supervision and monitoring visits	300,000	60,000	60,000	60,000	60,000	60,000	NTP
7.2 County-level supervision visits	1,500,000	750,000	750,000				Ministry of Health and Family, NTP
<b>8. Strengthen and integrate the TB surveillance system in the National Communicable Disease Surveillance System</b>	650,000						

8.1 Workshop or data reporting/processing for county epidemiologists and TB managers	50,000	50,000					Ministry of Health and Family, CU NTP, Epidemiology Department of the County Public Health Directorate
8.2 Development of specially-designed software for TB collection and installation on county-level PCs as well as the MOHF level	100,000						Ministry of Health and Family, CU NTP, Epidemiology Department of the County Public Health Directorate, Software company
8.3 Training of staff involved in data collection and data processing in using the soft	500,000	150,000	250,000	100,000			Ministry of Health and Family, CU NTP, Epidemiology Department, Software company
<b>Total</b>	<b>2,450,000</b>						

**GRAND TOTAL: 4,156,640 + 11,676,594 + 2,450,000 = 18,283,234**

30. Indicate the summary of the financial resources requested from the Global Fund by year and budget category, (Refer to *Guidelines paragraph V.56 – 58*):

Table V.30

Resources needed (USD)	Year 1	Year 2	Year 3 (Estimate)	Year 4 (Estimate)	Year 5 (Estimate)	Total
Human Resources	375,000	289,000	87,000	45,000	27,000	823,000
Infrastructure/Equipment	3,335,000	3,014,750	230,000	15,000	0	6,594,750
Training/Planning	1,066,500	952,500	423,500	179,500	164,140	2,786,140
Commodities/Products	499,000	439,000	63,000	31,000	16,000	1,048,000
Drugs	3,283,172	3,283,172	0	0	0	6,566,344
Monitoring and Evaluation	102,000	97,000	36,000	25,000	10,000	270,000
Administrative Costs	70,000	65,000	30,000	22,000	8,000	195,000
Other (Please specify)						
<b>Total</b>	<b>8,730,672</b>	<b>8,140,422</b>	<b>869,500</b>	<b>317,500</b>	<b>225,140</b>	<b>18,283,234</b>

***The budget categories may include the following items:***

***Human Resources:*** Consultants, recruitment, salaries of front-line workers, etc.

***Infrastructure/Equipment:*** Building infrastructure, cars, microscopes, etc.

***Training/Planning:*** Training, workshops, meetings, etc.

***Commodities/Products:*** Bednets, condoms, syringes, educational material, etc.

***Drugs:*** ARVs, drugs for opportunistic infections, TB drugs, anti-malaria drugs, etc.

***Monitoring & Evaluation:*** Data collection, analysis, reporting, etc.

***Administrative:*** Overhead, programme management, audit costs, etc

***Other (please specify):***

30.1. For drugs and commodities/products, specify in the table below the unit costs, volumes and total costs, for the FIRST YEAR ONLY:

Table V.30.1

Item/unit	Unit cost (USD)	Volume (specify measure)	Total cost (USD)
Amikacina 1g	5	45,000	225,000
Kanamidina 1g	0.5	45,000	22,500
Prothionamide 250mg	0.5	1,080,000	540,000
Cycloserine 250 mg	2	1,080,000	2,160,000
Ofloxacin 200 mg	0.6	576,000	345,600
Ciprofloxacin 500 mg	1	540,000	540,000
Clarithromycin 500 mg	3	7,300	21,900
Centrifuges	20	3,500	70,000
Autoclaves	15	3,500	52,500
Etuves	16	1000	16,000
UV Lamps	50	215	10,750
Vacuum aspirators	200	20	4,000
Sputum inducing device (aerosols)	700	30	21,000
Thermostat rooms	2,500	12	30,000
Safety cabinets	5,500	40	220,000
Binocular microscopes with immersion	1,500	80	120,000
Multipurpose vehicles	30,000	50	1,500,000

Equipment for sputum collection room for penitentiary system	5,000	43	215,000
Equipment for isolation rooms for penitentiary system including furniture	22,790	43	980,000

**30.2. In cases where Human Resources (HR) is an important share of the budget, explain to what extent HR spending will strengthen health systems capacity at the patient/target population level, and how these salaries will be sustained after the proposal period is over (1 paragraph):**

All activities to be implemented in the TB component were designed in such a way that the human resources be trained and involved in TB control, thereby strengthening and building the capacity of the present health care system. There will be no additional staff recruited, but the health staff already working in TB control will receive additional training and will participate in workshops. Medical mediators that will work in the Roma communities are already part of a network developed by the Ministry of Health. Taking into consideration the high level of political commitment for the TB Programme, any future recruitment will be included under the MOHF staff.

**31. If you are receiving funding from other sources than the Global Fund for activities related to this component, indicate in the Table below overall funding received over the past three years as well as expected funding until 2005 in US dollars (Guidelines para. V.62):**

Table V.31.1

	1999	2000	2001	2002	2003	2004	2005
<b>Domestic</b> (public and private)	7,250,000	10,500,000	9,700,000	6,900,000	NA	NA	NA
<b>External</b>	0	0	11,300	401,600	NA	NA	NA
<b>Total</b>	<b>7,250,000</b>	<b>10,500,000</b>	<b>9,711,300</b>	<b>7,301,600</b>			

*Please note: The sum of yearly totals of Table V.31.1 from each component should correspond to the yearly total in Table 1.b of the Executive Summary. For example, if Year 1 in the proposal is 2003, the column in Table 1.b labeled Year 1 should have in the last row the total of funding from other sources for 2003 for all components of the proposal.*

**32. Provide a full and detailed budget as attachment, which should reflect the broad budget categories mentioned above as well as the component's activities. It should include unit costs and volumes, where appropriate.**

**33. Indicate in the Table below how the requested resources will be allocated to the implementing partners, in percentage (Refer to Guidelines para. V.63):**

Table V.33

Resource allocation to implementing partners* (%)	Year 1	Year 2	Year 3 Estimate	Year 4 Estimate	Year 5 Estimate	Total
<b>Government</b>	6,486,889 74.3%	5,869,224 72.1%	604,302 69.5%	237,490 74.8%	171,781 76.3%	13,369,707 73.12%
<b>NGOs / Community-Based Org.</b>	2,243,782 25.7%	2,271,177 27.9%	265,197 30.5%	80,010 25.2%	53,358 23.7%	4,913,526 26.87%
<b>Private Sector</b>						



<b>People living with HIV/ TB/ malaria</b>						
<b>Academic / Educational Organizations</b>						
<b>Faith-based Organizations</b>						
<b>Others (please specify)</b>						
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>Total in USD</b>	8,730,672	8,140,422	869,500	317,500	225,140	18,283,234

*\* If there is only one partner, please explain why.*

**Please note: The following three sections (VI, VII and VIII) are all related to proposal/component implementation arrangements.**

**If these arrangements are the same for all components, you do not need to answer these questions for each component. If this is the case, please indicate clearly in which component the required information can be found.**

**SECTION VI – Programmatic and Financial management information**

*Please note: Detailed description of programmatic and financial management and arrangements are outlined in Guidelines para. VI. 61 – 73, including the main responsibilities and roles of the Principal Recipient (PR).*

**34. Describe the proposed management arrangements** (outline proposal implementation arrangements, roles and responsibilities of different partners and their relations), (Guidelines para. VI.64), (1–2 paragraphs):

The CCM has the overall role of coordinating the implementation of the Proposal within the general framework of the National AIDS Strategy implementation. The CCM will designate a Executive Committee (EC) to coordinate the elements related to the implementation, to determine what actions are required and resolve obstacles hindering the progress of implementation. The CCM Executive Committee will include the key stakeholders of the CCM (President and Vice Presidents, Principal Recipient (PR), NGO representative, and one international organization). The EC will receive and analyze the reports from the PR, deal with implementation issues that might occur and make adjustments, as needed.

The designated Principal Recipient is the Ministry of Health and Family through its Project Management Unit (PMU), which is already in place for the present World Bank Health Reform Project. The PMU will be responsible for the financial implementation of the proposal and will be accountable to the CCM. The PMU will also be responsible for managing the funds and ensuring efficient disbursement to the implementers. In the period preceding grant approval, the PMU (as part of the CCM) will act as a Project Preparation Unit. As such, it will facilitate the proper preparation of project implementation (Grant Agreement Draft, Government Decision Draft, guidelines for financing and monitoring the implementers, and a general working plan based on the working plans of implementers). UNICEF and the World Bank have expressed their intention of assisting the PMU with supplementary personnel, training and equipment during this preparation period. Once the grant agreement is approved, additional staff will be contracted to fulfill the requirements of PR responsibilities, including procurement, disbursement, accounting, and internal control. The project will be overseen by the PMU, using adapted World Bank procedures for procurement of goods, works and services. This assistance will reinforce the legal framework and transparency of all proposed procedures in respect to international and national legislation. These rules respond to the Global Fund principles, promoting cost-effectiveness, transparency and rapid implementation.

To facilitate timely project implementation, the PMU will establish, maintain, operate and manage a special US Dollar account in a commercial bank, according to agreed terms and conditions. The PMU will manage the use of all funds according to the provision of the Grant Agreement and will report to LFA, CCM and the Global Fund the progress and results of the project.

The PMU will fully handle the management of the project, and will make recommendations on adjustments to be made to the plans of implementers, based on achievements or lack of progress. Sub-recipients will be responsible for driving implementation for each component, and for developing and updating a detailed implementation plan and timetable for their component. Based on their proposal, the PMU together with the Executive Committee and technical partners, as needed, will proceed to finalize the programmes, budgets, and a disbursement plan for the first year. Implementers will liaise with the PMU for procurement, disbursement and project reporting. Sub-recipients (especially Ministries and other government institutions) will designate, by ministerial order, the official entities within the Ministries that will be responsible for implementation. Specific existing procedures of the World Bank will be used to contract with NGOs (Direct Contracting, Quality and Cost Selection). All the sub-recipients will have contractual arrangements with the PMU.

**34.1 Explain the rationale behind the proposed arrangements** (e.g., explain why you have opted for that particular management arrangement), (1 paragraph).

The decision to nominate the PMU on behalf of the Ministry of Health and Family will ensure local ownership and sustainability of the project. Likewise, it will increase the capacity of the Ministry of Health and Family to partner with other government and non-governmental organizations and civil society, to strengthen prevention, care, treatment, and surveillance programmes related to important health issues. The role of the MOHF as PR will be reinforced within the Grant Agreement and a related Government Decision will ratify its role, ensuring the political support of the Romanian Government for the project. The proposed arrangements have proven their efficiency in other programmes and, based on lessons learned, will ensure transparency and flexibility.

**35. Identify your first and second suggestions for the Principal Recipient(s)** (Refer to *Guidelines para. VI.65–67*):

Table VI.35

	First suggestion	Second suggestion
<b>Name of PR</b>	Ministry of Health and Family	
<b>Name of contact</b>	Dr. Carmen Angheluta Project Management Unit	
<b>Address</b>	Strada Cristian Popisteanu nr. 1-3, Bucharest, Sector 1, Romania	
<b>Telephone</b>	+ 40-21 311 29 64	
<b>Fax</b>	+ 40-21 312 35 88	
<b>E-mail</b>	acarmen@ms.ro	

*Please note: If you are suggesting to have several Principal Recipients, please copy Table VI.35 below.*

**35.1 Briefly describe why you think this/these organization(s) is/are best suited to undertake the role of a Principal Recipient for your proposal/component** (e.g. previous experience in similar functions, capacity and systems in place, existing contacts with sub recipients etc), (*Guidelines para. VI.66–67*), (1–2 paragraphs):

The staff of the MOHF PMU is highly qualified in critical aspects of fiscal management and project implementation, stipulated by the Global Fund (project management, financial management and accounting, international procurement, monitoring and evaluation, public health, and management of health services). The core staff for the PR

for this project will be drawn from the present PMU of the World Bank health project, in place since 1997. This team managed and disbursed the first World Bank Loan worth \$150 million, and the same team presently manages a second loan, amounting to \$40 million. During the implementation of WB projects, the team skillfully concluded hundreds of contracts as result of international tenders, international acquisitions, various mechanisms to select consultants, etc. Both projects were nationwide applications and each involved over 25 implementing partners. The objective of the projects supported primary, emergency care, preventive medicine and health promotion (including HIV/AIDS and TB issues), financing and administrative reform, developing a school for public health, etc. The first project had the support of international organizations like USAID, UNICEF, UNFPA, WHO, etc, while the second one is supported by DFID (British Embassy), SDC (Swiss Embassy), CHPS (Open Society Foundation). The World Bank rated the general performance of the first project (1992-1999) as satisfactory. Some components, such as the improvement in reproductive health, and the establishment of the school of health management, were rated highly satisfactory (international donors also financed the component of reproductive health and the PMU implemented a well-coordinated programme of assistance). The World Bank is underlining the performance of the last two years implementation lead by the PMU. The performance of the actual project was rated highly satisfactory. Both projects have been successfully audited by PriceWaterhouseCoopers, KPMG, the Ministry of Public Finance, and the Court of Accounts.

The PMU also successfully managed the implementation and financial arrangements of emergency projects financed through grants from the Swiss and Greek Governments, thereby gaining experience with non-reimbursable funds. The PMU is also responsible for developing new regulations, arrangements and procedures for implementing public-private partnerships in the health sector, based on competitive principles (support from IFC as external consultant). As a result of these efforts, tender procedures will be launched shortly.

**35.2 Briefly describe how your suggested Principal Recipient(s) will relate to the CCM and to other implementing partners** (e.g., reporting back to the CCM, disbursing funds to sub-recipients, etc.), (1 paragraph):

The PR will report quarterly to the CCM on the status of project implementation, according to agreed-upon procedures. It will also describe the physical progress of project implementation, and set forth actual sources and applications of funds for the Global Fund project. Likewise, it will show expenditures financed from the proceeds of the Grant, determine the status of procurement within the project and expenditures under contracts financed from grant proceeds. During the preparation period, the PR will prepare guidelines for financing and monitoring sub-recipients, based on procedures used by international financiers. It will also draw up guidelines to support a working plan (objectives, breakdown of activities, human resources, timing, estimated cost, monitoring indicators) contract arrangements, advance payments, statements of expenditures, etc. Sub-recipients will be responsible for developing, monitoring and updating the plans and timetables for their component and will report these to the PR. Each beneficiary will provide copies of all relevant project financial accounting documents (invoices, contracts, payments, bank statements, etc.) to the PR.

**36. Briefly indicate links between the overall implementation arrangements described above and other existing arrangements** (including, for example, details on annual auditing and other related deadlines). **If required, indicate areas where you require additional resources from the Global Fund to strengthen managerial and implementation capacity**, (1–2 paragraphs):

Once the Grant Agreement is signed, the PR and LFA will identify and appoint qualified auditors to audit the project accounts (including special accounts and statements of expenditure) in accordance with International Standards of Audit. The evaluation of the auditor will include specific references on whether grant funds provided were used in accordance with relevant financial agreements. It will also indicate whether all necessary

supporting documents, records and accounts have been kept in according to all expenditures, including Special Account payments and expenditures made on the basis of Statements of Expenditures (SOE), and give a true and fair view of the financial situation of the project, etc.

In order to strengthen the managerial capacity, some administrative costs will be required. Considering the excellent qualifications of the PMU staff, and the wide range of skills that will be required (managerial capacity, international financing, accounting and procurement, medical and health management, internal controls, monitoring and evaluation capacity, training and assistance to be provided to sub-recipients, additional staffing) project funds must be allocated for salaries. Office equipment, specialized software packages and other costs related to PMU activities would be provided from the administrative cost. The total estimated amount for PR activities is 5% of the total cost of the project.

**SECTION VII – Monitoring and evaluation information**

**37. Outline the plan for conducting monitoring and evaluation including the following information, (1 paragraph per sub-question).**

The plan for conducting monitoring and evaluation is the same as that for HIV/AIDS.

**37.1. Outline of existing health information management systems and current or existing surveys providing relevant information (e.g., Demographic Health Surveys, Living Standard Measurement Surveys, etc.), (Guidelines para. VII.76):**

MOHF has a special department for health statistics that issues annual reports on the major health indicators, while the National Institute for Statistics provides quarterly and annual reports on demographic, social and economic indicators. None of these reports include all the information needed for monitoring and evaluating the implementation of the HIV and TB National Strategies and Programmes.

**37.2. Suggested process, including data collection methodologies and frequency of data collection (e.g., routine health management information, population surveys, etc.):**

For the implementation of this proposal, in the wider context of implementing the HIV, TB and STI strategies, the CCM proposes to establish a special Monitoring and Evaluation (M&E) Unit. This Unit will be part of the Institute for Health Services Management (IHSM), the latter subordinate to MOHF, with a long-standing record in M&E for the major components of Health Reform in Romania. The special M&E Unit would annually review routine health statistics (morbidity and mortality data) collected by MOHF, the Center for Health Statistics, the Institute of Statistics and other institutions.

It is necessary to fill the gap between existing data and data required for a better appreciation of the current situation. The methodology to be used will be population surveys on specific issues, target populations and/or in those regions where there is no reliable data. There will also be monthly monitoring of case management (diagnosis and treatment), training, logistics, communication and advocacy, by record and report (by the implementing institutions), review, direct observation, interviews with health workers and patients.

A change is needed in health indicators (health statistics) and in knowledge, attitudes and practices (by 3 KAP studies carried out at the beginning of a project, at the end of two years, and at the end of the project, as well as an annual anthropological/behavioral study).

**37.3. Timeline:**

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Review of routine health statistics					
Population surveys					

Monitoring the activities of the implementing institutions									
Review health indicators									
KAP studies									
Anthropological/behavioral study									

**37.4. Roles and responsibilities for collecting and analyzing data and information:**

Depending on the specific data, the responsibility for its collection lies with a variety of health workers reporting to the County Public Health Authority, which in turn reports to the MOHF, and with implementing institution staff. Data will be gathered at the Institute of Health Services Management (IHSM), where a four-member Global Fund Monitoring Office will be established. Their main activities will be to review routine health statistics, monitor the activities of the implementing institutions, review health indicators, and provide consultancy to implementing agencies on IEC materials. If certain monitoring issues exceed the human resource capacity of IHSM, this will be sub-contracted to special organizations.

**37.5. Plan for involving target population in the process:**

All the interventions proposed include self monitoring instruments, first to design the interventions tailored to the needs of the target populations, second to pilot the interventions, and third to monitor the impact of that intervention. In all three phases the target population will be directly involved, especially in the design and monitoring of the intervention.

**37.6. Strategy for quality control and validation of data:**

A variety of quality control measures can be used for data coming from implementing institutions, such as: training for data collection, random re-collection of data, record verification, subsequent visits to the field where data was collected, and direct observation of the data collection process. The strategy for quality control and validation of data will be built into the studies that will be contracted outside IHSM.

**37.7. Proposed use of M&E data:**

- Identify and resolve operational problems as soon as they emerge
- Identify causes and corrective actions
- Provide feedback for improving/modifying/reshaping activities of the implementing institutions
- Report to the funding institution (GFFATM)
- Design national programmes
- International reports/studies
- In-country and international comparisons
- Plan the needs for financial support

**38. Recognizing that there may be cases in which applicants may not currently have sufficient capacity to establish and maintain a system(s) to produce baseline data and M&E indicators, please specify, if required, activities, partners and resource requirements for strengthening M&E capacities.**

*Please note: As M&E activities may go beyond specific proposals funded by the Global Fund, please also include resources coming from other sources at the bottom of Table VII.38.*

Examples of activities include collecting data, improving computer systems, analyzing data, preparing reports, etc.

Table VII.38

Activities (aimed at strengthening Monitoring and Evaluation Systems)	Partner(s) (which may help in strengthening M&E capacities)	Resources Required					
		Year 1	Year 2	Year 3	Year 4	Year 5	Total
<b>Regular M&amp;E activities</b>							
Subcontracting for certain M&E activities		100,000	50,000			20,000	170,000
IHSM Global Fund Monitoring Office (staff and administration costs)		50,000	50,000	50,000	50,000	50,000	250,000
Development of monitoring and evaluation methodology		20,000	10,000				30,000
Population surveys		100,000					100,000
Training for procedures and methodology application		50,000	50,000				
On field activities		150,000	150,000				
KAP & Anthropological/behavioral studies		150,000	100,000	30,000	30,000	30,000	340,000
<b>Capacity Strengthening</b>							
Data base development & maintenance		20,000	15,000	15,000	15,000	15,000	80,000
New indicators development		5,000					5,000
IT endowment of central monitoring office (hardware and software)		50,000	15,000				65,000
Strengthening the communication system infrastructure between the involved institutions		50,000	10,000				60,000
<b>Total requested from Global Fund</b>		<b>745,000</b>	<b>450,000</b>	<b>95,000</b>	<b>95,000</b>	<b>115,000</b>	<b>1,500,000</b>

**SECTION VIII – Procurement and supply-chain management information**

39. Describe the existing arrangements for procurement and supply chain management of **public health equipment products** integral to **this component's** proposed disease interventions, including pharmaceutical products as well as equipment such as injections supplies, rapid diagnostics tests, and commodities such as micronutrient supplements, condoms and bed nets (Refer to *Guidelines paragraph VIII.86*).

Table VIII. 39

Component of procurement and supply chain management system	Existing arrangements and capacity (physical and human resources)
How are suppliers of products selected and pre-qualified?	An open and competitive process is used to select implementers, who must prepare the most adequate technical specifications of products (in cooperation with recognized experts). The assessments of the suppliers will take into consideration the results of need analysis and market research to identify the most cost-effective products.
What procurement procedures are used to ensure open and competitive tenders, expedited product availability, and consistency with national and international intellectual property laws and obligations?	The procurement procedures are the same as those of the World Bank and will be described in the Grant Agreement. The Grant Agreement will be ratified by Governments Decision. This will reinforce the legal framework and transparency of all proposed procedures in regard to international and national legislation. For this purpose the tenders will be conducted through the methods described in the Procurement Guidelines for Goods, Works and Services: International Competitive Bidding, Limited International Bidding, Shopping (International and National), Direct Contracting.
What quality assurance mechanisms are in place to assure that all products procured and used are safe and effective?	The quality of procured products will be assured through specific requirements. The Bidding Documents and Technical Specifications will require for each type of product documented evidence of the conformity of the goods and services with international standards of quality. This will be GMP in the case of pharmaceutical products issued by national or international agencies and ISO 900X or CE brands or equivalent European and international accredited standards. Other mandatory requirements to assure that products are safe and effective will include supplier training, warranty periods, etc. Training, counseling, etc. will be provided by the implementers, as needed.
What distribution systems exist and how do they minimize product diversion and maximize broad and non-interrupted supply?	In order to assure that products reach the beneficiary, the suppliers will use existing distribution channels, including hospitals, family planning centres, pharmacies, NGOs, family doctors, etc. If required, new distribution channels will be developed for risk groups.

**40. Describe the existing arrangements for procurement of services (e.g., hiring personnel, contracts, training programs, etc.), (1–2 paragraphs):**

Selection of the personnel will follow the existing rules described in the Guidelines of the World Bank. The most adequate the existing procedures for selection of personnel, services will be used for each category, for example the selection based on job description, experience and qualification. The arrangements for training programs are following the same rules. The contract agreement is based on the training curricula, qualification and experience of the trainer and estimated cost.

Specific procedures of procurement of services described in the Guidelines of the World Bank (Quality and Cost Selection, Least Cost Selection, Single Source Selection, use of NGOs) will be applied. Standard contracts in simple or complex format such as (Lump Sum, Time Based) will be used.

**41. Provide an overview of the additional resources (e.g., infrastructure, human resources) required to support the procurement and distribution of products and services to be used in this component, (2–3 paragraphs):**

**42. Detail in the table below any additional sources from which the applicant plans to obtain products relevant to this component, whether additional requests have been requested or granted already. (For each source, indicate a contact person at the programme in question, the volume of product in the request of grant, and the duration of support. Examples of such programs are the Global TB Drug Facility or product donations from pharmaceutical manufacturers), (*Guidelines para. VIII.88*):**

The arrangements in this Proposal for the procurement of second-line drugs will be evaluated by the Green Light Committee to ensure that these are in keeping with the best standards available at the present time for second-line drugs.

*Table VIII. 42*

<b>Programme name</b>	<b>Contact person (with telephone &amp; email information)</b>	<b>Resources requested (R) or granted (G)</b>	<b>Timeframe and duration of request or grant</b>

**42.1. Explain how the resources requested from the Global Fund for the products relevant to this component will be complementary and not duplicative to the additional sources, if any, described above (1 paragraph):**