CCM Request for Renewal

31 March 2013

CCM Request for Renewal Outline

SECTION 1: SUMMARY OF REQUEST

1.1 General Program Information

Applicant	**Country Coordinating Mechanism (CCM) Georgia**
Country	**Georgia**
Component	**Tuberculosis**
Component Implementation Period	**01 January 2014 – 30 June 2016**
Cut-off date	**31 December 2012**
Renewal date	**31 March 2013 (submission), 01 January 2014 (start of Period 2)**
Current Phase/Implementation Period Currency:	**EUR**
Next Phase/Implementation Period Currency:	**EUR**

Principal Recipient (PR) Name	Grant/SSF Number	Grant/SSF start date
PR 1: Global Projects Implementation Center (GPIC)	GEO-T-GPIC	01 July 2011

1.2 CCM Approval of Request for Renewal

See annex 16 – scan copy of the CCM Approval of Request for Renewal with signatures

Role	Name	Title / Organization
CCM Chair	**Sandra Elisabeth Roelofs**	Director/Founder, "SOCO" *Sector represented: NGO*
CCM Vice Chair	**David Sergeenko**	Minister, Ministry of Labor, Health and Social Affairs *Sector represented: GOV*
CCM Secretary (CCM Focal Point)	**Eka Iashvili**	Consultant to the CCM, CCM Secretariat *Sector represented: OTH*
CCM member	**Giorgi Tsereteli**	Vice Chairman, Deputy Chairman of the Healthcare and Social Issues Committee Parliament of Georgia *Sector represented: GOV*
CCM member	**Archimandrite Adam / Vakhtang Akhaladze**	Head of Public Health Department, Patriarchate of Georgia, *Sector represented: FBO*
CCM member	**Archil Talakvadze**	Deputy Minister, Ministry of Corrections and Legal Assistance *Sector represented: GOV*
CCM member	**Ketevan Natriashvili**	Deputy Minister, Ministry of Educations and Science *Sector represented: GOV*
CCM member	**Ketevan Tsikhelashvili**	First Deputy Minister, Ministry of Reintegration *Sector represented: GOV*
CCM member	**Amiran Gamkrelidze**	Executive Director, National Center for Disease Control and Public Health (NCDCPH) *Sector represented: GOV*
CCM member	**Philip Dimitrov**	Ambassador, Head of Delegation, EU Delegation to Georgia *Sector represented: ML/BL*
CCM member	**Koba Khabazi**	Former TB patient *Sector represented: PLWD*
CCM member	**Zurab Vadachkoria**	Rector, Tbilisi State Medical University *Sector represented: EDU*
CCM member	**Tengiz Tsertsvadze**	General Director, Infectious Diseases, AIDS and Clinical Immunology Research Center *Sector represented: EDU*
CCM member	**Khatuna Todadze**	Deputy Director, OST Program Director, Center for Mental Health and Prevention of Addiction *Sector represented: EDU*
CCM member	**Mamuka Japaridze**	Director, National Center for Tuberculosis and Lung Diseases (NCTBLD) *Sector represented: GOV*
CCM member	**Akaki Lochoshvili**	Executive Director, Global Projects Implementation Center (GPIC) *Sector represented: NGO*
CCM member	**Lia Tavadze**	Social Mobilization Adviser, UNAIDS *Sector represented: ML/BL*

CCM member	**Tamar Sirbiladze**	Senior Health Adviser, USAID Caucasus/Tbilisi *Sector represented: ML/BL*
CCM member	**Zurab Danelia**	Executive Director, The Union of Victims of the Conflict in Abkhazia "TANADGOMA" Sector represented: NGO
CCM member	**Nino Tsereteli**	Executive Director, Center for Information and Counseling on Reproductive Health - TANADGOMA *Sector represented: NGO*
CCM member	**Maia Kavtaradze**	Project Coordinator, GOPA /KFW *Sector represented: ML/BL*
CCM member	**Rusudan Klimiashvili**	Head of Country Office, WHO, Georgia *Sector represented: ML/BL*
CCM member	**Tamar Gabunia**	Chief of Party, University Research Corporation (URC) *Sector represented: NGO*
CCM member	**Elguja Meladze**	President, Employers' Association of Georgia *Sector represented: PS*
CCM member	**Izoleta Bodokia**	Director, HIV/AIDS Support Foundation *Sector represented: NGO*
CCM member	**David Ananiashvili**	Director, "Georgian Plus Group" *Sector represented: PLWD*
CCM member	**Fati Dzotsenidze**	Board Member, Georgian National Association for Palliative Care *Sector represented: NGO*

** Please add a row for each remaining member of the CCM, as each CCM Member is required to approve this CCM Request for Renewal.*

1.3 Summary of CCM Request for Renewal

1.3.1 Summary of Request

Please provide a brief overview of the current progress toward goals and objectives of the proposal as well as main observations, the recommendations and the rationale for the Request for Renewal.

This application represents a Request for Renewal of the TB grant from the Global Fund in Georgia covering the period of 2.5 years between 01 January 2014 and 30 June 2016. The program is financed through the Single Stream of Financing (SSF) projects from TGF TB grants obtained in Round 4 (RCC grant) and Round 10 and supports the implementation of the recently (on 21 March 2013) approved *National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015*.

This proposal is built to support the key priorities of the National TB Strategy, i.e. sustaining universal access to diagnosis and treatment of all forms of TB, improving the service performance through multisectoral and multidisciplinary patient-centered approaches, and improving governance, program management and monitoring for effective national response to emerging TB challenges, first and foremost to the challenge of drug-resistant TB.

The Government of Georgia faces continuing fiscal constraints, exacerbated by the consequences of the global financial crisis during the last four years that have resulted in the need to reduce the overall public expenditures and reorient them towards strictly defined priority interventions, e.g. in the health sector. Nevertheless, the Government has demonstrated commitment to TB control, including sustaining and expanding financing of TB interventions. There are a number of recent developments that document this commitment including further optimization of the laboratory network, optimization of inpatient TB care, takeover of surveillance system and other substantial costs of staff and facility expenses.

At the same time, domestic funding resources remain insufficient to cover all costs of costly DR-TB management interventions, and the mechanisms are not yet in place to channel public resources for important community-based patient support activities. Therefore, the need of external funding for TB control remains important in Georgia, and the current application aims at obtaining additional resources from the Global Fund and channeling them effectively towards priorities not covered by domestic funding resources.

The overall goal of the program remains unchanged and is ***To reduce the burden of tuberculosis in Georgia by sustaining universal access to quality diagnosis and treatment of all forms of tuberculosis***. The interventions included in the proposal for Period 2 are aligned with the priorities of the National TB Strategy and continue to have focus on strengthening the programmatic management of TB including drug-resistant TB, supporting patients and consolidating health service's capacities for successful TB case management, with a special focus on groups at high risk such as prisoners. The application is built to uphold the goal, scope and key directions of the ongoing TGF-financed TB program. At the same time, it complies with current TGF requirements (including mandatory budget reduction); for this purpose, the activities implemented through both Principal Recipients during the previous phase of the consolidated grant, have been re-organized under four main ***Objectives***:

1. To strengthen the National TB Control Program management, coordination, monitoring and evaluation;
2. To improve diagnosis of TB including M/XDR-TB;
3. To ensure quality treatment of all forms of TB;
4. To ensure adherence to TB treatment by intensive patient support and follow up.

Objective 1. To strengthen the National TB Control Program management, coordination, monitoring and evaluation

Activities under this Objective aim at sustaining the achievements of the national program through strengthening NTP capacities for programmatic management, coordination, monitoring and evaluation in both civilian and penitentiary sectors, central and regional NTP supervision.

Activities:

1.1 Technical assistance in priority issues of TB control

1.2 Training in NTP management and attendance of international conferences abroad

1.3 Support to central NTP supervision

1.4 Support to regional NTP supervision to TB facilities

1.5 Support to regional NTP supervision to PHC facilities

1.6 Support to supervision and monitoring visits in the penitentiary system

1.7 Post-supervision meetings

1.8 NTP vehicles maintenance

1.9 Program management and administration expenses of the NTP Central Unit and Regional Units

1.10 Technical assistance (local), TB M&E system and management of the national TB database

1.11 Printing of recording and reporting forms

Objective 2. To improve diagnosis of TB including M/XDR-TB

The interventions under this Objective aim at strengthening laboratory capacities for TB diagnosis, including sustaining reliable routine drug resistance surveillance and quality rapid diagnosis of DR-TB cases for timely initiation of treatment. They include support for regular specimen transportation system country-wide, upgrading reference and regional laboratories for rapid DR-TB diagnosis and ensuring external laboratory quality control and quality assurance, as well as targeted support to case finding activities among at-risk population groups (prisoners and IDUs).

Activities:

2.1 Sputum smear microscopy investigations (ZN)

2.2 Culture investigations (automated method on liquid media)

2.3 Culture investigations (manual method on solid media)

2.4 LED microscopy investigations

2.5 DST to first-line line drugs for DR-TB diagnosis (automated MGIT technique)

2.6 DST to first-line drugs (manual technique)

2.7 Tests for rapid identification of R/H resistance (LPA Hain)

2.8 Laboratory equipment for DR-TB diagnosis (automated detection and MDR screening, Xpert MTB/RIF technology)

2.9 Tests for rapid detection and MDR screening (Xpert MTB/RIF technology)

2.10 Entry screening for TB in penitentiary institutions

2.11 Screening of IDUs for TB

2.12 Operational research on effectiveness of entry and massive screening at penitentiary system

2.13 Diagnostic counseling and testing for HIV among TB patients

Objective 3. To ensure quality treatment of all forms of TB

The Period 2 project aims at sustaining universal access to quality treatment of all forms of TB in Georgia including M/XDR-TB cases. The interventions under this Objective include, mainly, procurement of anti-TB drugs for different categories of patients according to their resistance profile. Additionally, limited support is sought for ensuring proper laboratory and clinical monitoring of effectiveness of TB treatment and for ensuring individual infection control and protection measures for the staff.

Activities:

3.1 First-line anti-TB drugs for drug-sensitive TB cases

3.2 First-line and second-line anti-TB drugs for PDR-TB patients

3.3 Second- line anti-TB drugs for MDR-TB patients

3.4 Second-line and third-line anti-TB drugs for XDR-TB patients

3.5 Drugs for management of adverse reactions caused by second-line drugs

3.6 DST to second-line drugs for DR-TB patients on treatment

3.7 Clinical investigations for DR-TB patients on treatment

3.8 Individual measures for infection control: respirators

3.9 Support to the Green Light Committee operations

Objective 4. To ensure adherence to TB treatment by intensive patient support and follow up

The project places a special emphasis on strengthening adherence to TB treatment as the key means to halt the spread and amplification of drug resistance. The task is especially difficult for M/XDR-TB patients, who have to undergo a complex and lengthy (up to 2 years or more in case of XDR) course of therapy; however ensuring patients' adherence to treatment and full direct observation of drug intake during are the fundamental requirements for effective management of M/XDR-TB cases. A specific important challenge remains to ensure continuation of treatment among ex-prisoners with TB who are discharged from the penitentiaries and need to complete treatment in the civilian sector.

Activities:

4.1 Support to treatment adherence: incentives for TB patients (first-line and PDR-TB regimens)

4.2 Support to treatment adherence: incentives for M/XDR-TB patients

4.3 Support to treatment adherence / DOT: transportation of visiting DOT supporters

4.4 Support to treatment adherence / DOT: transportation of patients to DOT canters

4.5 Vehicles for intensive patient support program

4.6 Operational expenses - patient support component: Monitoring Officers

4.7 Operational expenses - patient support component: Monitoring visits to TB and PHC facilities in the regions

4.8 Support to treatment adherence / DOT: incentives for PHC nurses

The total amount of funds required is EUR 15,354,860, and the incremental request for Period 2 is EUR 8,715,333 (taking into account the TGF-mandated reductions vis-à-vis the initial TRP approved budget as well as undisbursed amount and the amount of cash at hand at cut-off date).

* * *

1.3.2 Proposed Changes in Programmatic, Budgetary and Implementation Arrangements

1. Are you proposing any changes in the Implementation Arrangements of the grant/program? Yes/No (delete as applicable)

If yes, please indicate the nature of the change.

Reallocation of funds between PRs	Changes in institutional arrangements	Budgetary changes
No / Not applicable	No	Yes

Please describe and provide rationale and justification for each proposed change.

The budgetary changes represent over 10% reduction from the total TRP clarified amount for years 2014-2016 (Rounds 4 RCC and Round 10 TB grants) as currently mandated by the Global Fund for renewals of grants in lower-middle income countries.

If you are adding new PR(s) to the grant/program, please provide name(s).

Not applicable

If you are discontinuing any PR(s) in the grant/program, please provide name(s).

Not applicable

2. Are you proposing any changes to the scope and/or scale of the performance framework of the grant/program? **No**

If yes, please describe and provide rationale and justification for the proposed change.

No substantial changes are proposed to the scope / scale of the program or to the Performance Framework. The scope of interventions (i.e. the number of diagnostics, number of patients to be enrolled in treatment by category, patient support measures etc.) for Period 2 have been refined using the updated estimates based on the most recent epidemiological data including drug resistance burden and the resulting calculation of DR-TB management needs, however they remain within the slight deviations range from the initially planned project coverage. Accordingly, all indicators in the PF have been adjusted.

Do the proposed changes entail material reprogramming compared to the original proposal(s)? **No**

If yes, please indicate and explain whether the changes affect the entire program or a specific PR.

Not applicable

1.3.3 CCM Request for Renewal

CCM Requested Budget for Renewal				
		PR 1[1]	PR 2	Total Program
a	Adjusted TRP clarified amount for the next Phase/ Implementation Period *(please insert numbers from section 6.2)*	10,696,213		**10,696,213**
b	*Total budget requested (after cut-off date to the end of the next Phase/Implementation Period)*	15,354,860		**15,354,860**
c	Undisbursed amount at cut-off date	5,738,048		**5,738,048**
d	Cash at cut-off date *(please insert numbers from section 5.2)*	901,479		**901,479**
e	*= Incremental amount requested*	8,715,333		**8,715,333**
f	*% of adjusted TRP clarified amount (cannot exceed 100% of adjusted TRP clarified amount)*	81%		**81%**

Has the CCM taken into account any Board-approved funding limitations? **Yes**
(Please refer to the CCM Invitation Letter for further details).

[1] Total amounts for each PR.

SECTION 2: CCM GOVERNANCE

2.1 CCM Governance Overview

Please refer to the CCM Requirements listed in the CCM Request Guidelines.

2.1.1 When was the last Round that the CCM/RCM/sub-CCM applied for funding? **Round 10, August 2010**

Was the CCM/RCM/sub-CCM determined compliant with the CCM requirements at this time? **Yes**

If the CCM/RCM/sub-CCM was not compliant when they last applied, please describe what remedial actions were taken by the CCM/RCM/sub-CCM?

Not applicable

CCMs/RCMs/sub-CCMs should answer questions 2.1.2 and 2.1.3, 2.1.4, and 2.1.5 (not 2.1.6)
Non-CCM applicants should proceed directly to question 2.1.6.

2.1.2 CCM Membership

a) When was the last time that changes were made in the CCM/RCM/sub-CCM membership of people living with HIV and people affected by tuberculosis and malaria? Please provide details for those changes, including the current membership of people living with and/or affected by the diseases.

The Country Coordination Mechanism (CCM) in Georgia was formed in 2002 as a Coordinating Authority in order to coordinate and provide monitoring of implementation of the Global Fund to Fight AIDS, Tuberculosis and Malaria and other Programs. On 01 May 2007 Ministry of Labor, Health and Social Affairs (MoLHSA) of Georgia approved (Order # 144) Country Coordinating Mechanism Membership and Charter for Projects of the Global Fund in Georgia and other Programs in Relation with AIDS and Tuberculosis within the Country (based on resolution N249 of 31/12/2005 of the Government of Georgia). On 18 June 2012 the CCM and its regulation was approved by the Resolution (#220) of the Cabinet of Ministers of Georgia – hereinafter CCM Regulation. The CCM is a standing advisory and consultative body under the Cabinet of Ministers of Georgia, engaged in intersectoral and multisectoral coordination of the national response to epidemics of HIV/AIDS, TB and Malaria. The membership of the National HIV/AIDS, TB and Malaria Council is multisectoral and includes representatives of governmental, non-governmental and private organizations as well as other civil society representatives.

Since Georgia submitted its Round 10 Proposal to the GF, the CCM membership has not been changed. The Parliamentary elections in 2012 and subsequent changes in the Government did not affect the composition of the CCM as well as the civil society constituency in CCM. In addition to two representatives of people living with the diseases (one member representing PLHIV and one former TB patient), the CCM membership includes NGOs working to provide care and support to PLHIV, MARPs (FSWs, IDUs, MSM, Prisoners, TB patients). Based on OIG recommendations, the representation of two NGOs is rotation based and was prolonged for the current year as well.

b) When was the last time that changes were made in the representation of non-government constituencies (e.g. community based organizations, faith based organizations, private sector, private academic institutions, people living with and/or affected by the diseases, key affected populations) on the CCM/RCM/sub-CCM? Please describe how new members were selected by their own constituencies based on a documented, transparent process developed within each constituency.

The election of CCM members on behalf of non-government constituencies is made in accordance with the CCM Regulations. According to the Regulations, the government agencies delegate their representatives in CCM by written notification, while international and national non-governmental organization ensure an open and transparent process of electing their representative from among those organizations that expressed their desire and commitment to coordinate joint activities in TB and HIV/AIDS areas. Documentary evidence of transparent decision to delegate the authority to the representative of the group of stakeholders is submitted to the CCM Secretariat.

On 3 February 2012, the NGO constituencies changed their representation: Mrs. Tamar Gabunia, URC Chief of Party was elected as a CCM member. URC is implementing USAID funded TB Prevention Program. Along with GFATM funded TB grant this project represents a major assistance to the National TB program for the next four years. NGO representation at the CCM regarding of HIV/AIDS is on rotational basis and HIV/AIDS Prevention Task Force (PTF) that includes all NGOs active in this field selects two NGOs that represent the PTF at the CCM through transparent voting. In case of TB programs, URC is the only one NGO that works in this area in Georgia implementing very important project and CCM took in the account importance of having international expertise on TB.

Based on the current membership, the civil society has a 37.5% representation on the CCM.

2.1.3. Program Oversight

Does your CCM have an oversight plan which has been approved by the CCM? **Yes**

If no, explain the reasons.

Not applicable

If yes, describe the oversight activities which are detailed in the plan. How has the CCM been implementing this plan? How does the CCM engage program stakeholders in oversight, including the CCM members and non-members, in particular non-government constituencies and people living with and/or affected by the diseases.

The draft of the CCM oversight plan has been updated by the CCM secretariat during December 2012 – January 2013 based on GFATM recommendations and as agreed during the CCM meeting from 31 January 2013 it has been circulated and approved by the members via e-mail on 12 February 2013.

The Plan is aimed at improving the TGF aid effectiveness through oversight of the performance of the Principal and Sub-Recipients and assesses the outcomes and impact of the TGF Grant Programs on the epidemics. The key areas of oversight for the CCM are defined as follows: Proposal Development, Grant Negotiations, Grant Implementation, Donor Coordination and Alignment with Health Systems, Grant Closure. The CCM could nominate the Oversight Committee (OC) with the task of gathering, reviewing and condensing information into briefs that can be presented to the CCM. The OC should be chaired by a CCM member and comprised of maximum six members, from CCM, secretariat and non-CCM members, respectively three, one and two.

Each of the OC members should have specific management, financial, procurement or other technical skills to assist with the task of information review and analysis. The OC may from time to time delegate or refer specific tasks, questions or areas of inquiry beyond its capacity to address to other groups including Technical Working Groups, individuals with specific expertise, or individuals or groups within the national programs for HIV/AIDS, TB and Malaria. The OC will meet quarterly. The OC debrief of grant progress and findings will be a regular feature on the agenda of all CCM meetings. The OC, with input from the CCM, will decide what information it will track in executing an appropriate oversight role.

The following areas of inquiry will be addressed: Finance; Procurement; Implementation; Result; Reporting; Technical Assistance. The CCM and the OC will have at its disposal a variety of information sources, both formal and informal (Work plans; Budgets; Monitoring & Evaluation Plan; Procurement and Supply Management Plan and other relevant documents; Grant Score Card (GSC) Any survey or operational research

reports- Grant Performance Report (GPR); Informal reports Progress Update/ Disbursement Request (PU/DR), etc.).

The CCM should conduct site visits to places where services are being delivered or other grant activities are taken place. The CCM and/or OC may need technical support to carry out its oversight activities. It may be possible for the CCM to obtain these kinds of technical support from partner organizations such as UNAIDS, WHO and bilateral donors. The plan describes key communication/functions related to oversight: GFATM's management letters; PUDRs; PR's should annual work and visiting plan; PR grant's calendar of milestones. In the process of problems' identification they can be classified into one of several categories. The plan gives the resolution models for the problems according to the category they lie within.

The copy of the plan is attached to the renewal request (Annex 06).

Please include the document with the CCM Request.

2.1.4 Managing Conflicts of Interest and Constituency Engagement

How does your CCM manage conflict of interest among its members and/or grant implementers who sit on the CCM? What measures are in place to ensure the CCM's conflict of interest section from your CCM governance documents is applied? How is the management of conflict of interest documented by the CCM?

The conflict of interest is mitigated based on conflict of interest policy, as approved by the CCM regulation on 18 June 2012 (Annex 07). The policy highlights the importance of the issue and defines the responsibilities of the CCM and its members regarding the disclosure of the conflict of interest and its management.

Before voting for his or her CCM membership each potential member shall declare in writing in the Conflict of Interest Register maintained by the CCM Secretariat the interests that such person or the organization that he or she represents may have in any activity of CCM.

In any situation that may give rise to a conflict of interest or a potential conflict of interest, the member concerned shall declare the same to the CCM Secretariat before vote and the Secretariat shall notify the same to all CCM members, or the Chair CCM during a meeting of the CCM.

If the conflict of interest is likely to undermine or raise questions about the decision or action of CCM, the Chair (with the approval of CCM members) should take appropriate action to avoid or minimize that impact. Depending on the seriousness of the conflict of interest, ideally the member concerned should step down from any involvement in the particular decision or action of CCM. This may be done by not participating in the relevant meeting of CCM or not taking part in discussion concerning the decision or action in question and not participating in the relevant votes.

Where this is not possible because the member concerned is the most suitable for taking part in the discussion, or the only member with the relevant expertise, the Chair with the approval of CCM members should explore ways in which actual or potential bias can be overcome (e.g. seeking referees or outside expert opinion, or documenting the conflict of interest etc.). Wider consultation with non-Member experts may also be considered to minimize the impact of any actual or perceived bias.

CCM asks the members if there is any conflict of interest regarding the issue to be discussed at each meeting. Where any conflict of interest is disclosed in a meeting it is recorded in the minutes together with the decision of the CCM in respect thereof. In case of a failure to do disclose the serious conflict of interest, the CCM may choose to disqualify the individual or the organization concerned from its' membership.

Please include the document(s) with the CCM Request.

2.1.5 In case of any proposed changes in Programmatic, Budgetary and Implementation arrangements (1.3.2), please describe the documented and transparent processes followed to ensure participation of all constituencies represented on the CCM/RCM/sub-CCM (including members and non-members) in the development and approval of these changes. Please describe

the process that was used to ensure effective management of any potential conflict of interest that might have affected this process.

One of the CCM functions is to evaluate and recommend to the Government solutions regarding budget estimations and identification of financial resources needed for the implementation of TB and HIV/AIDS national programs. If specific changes need to be made in programmatic, budgetary and/or implementation arrangements with respect to TB or HIV responses, then the initiative is preliminarily discussed amongst stakeholders active in the field.

Announcement on the TB grant renewal was done at the CCM meeting on 31 January 2013.

After the meeting and before the circulation of draft outlines among CCM members the Secretariat has convened midterm meetings on 15 February, 26 February and 12 March 2013, with the purpose to ensure participation of broad range of stakeholders (other than CCM members) in the grant renewal development process (Annex 10). The draft of the elaborated document was shared with CCM members in advance to the CCM Meeting held on 21 March 2013.

After presentation, thorough review of the document followed with discussion it has received unanimous endorsement by CCM members confirmed by signature of the grant renewal hardcopy by all permanent and rotational members of the Country Coordinating Mechanism.

Non-CCM applicants only

2.1.6 Please refer to the original proposal(s) and provide a brief update on the status of exceptional conditions for which you were last approved as a non-CCM applicant (maximum 1/2 page).

Not applicable

SECTION 3: COUNTRY CONTEXT

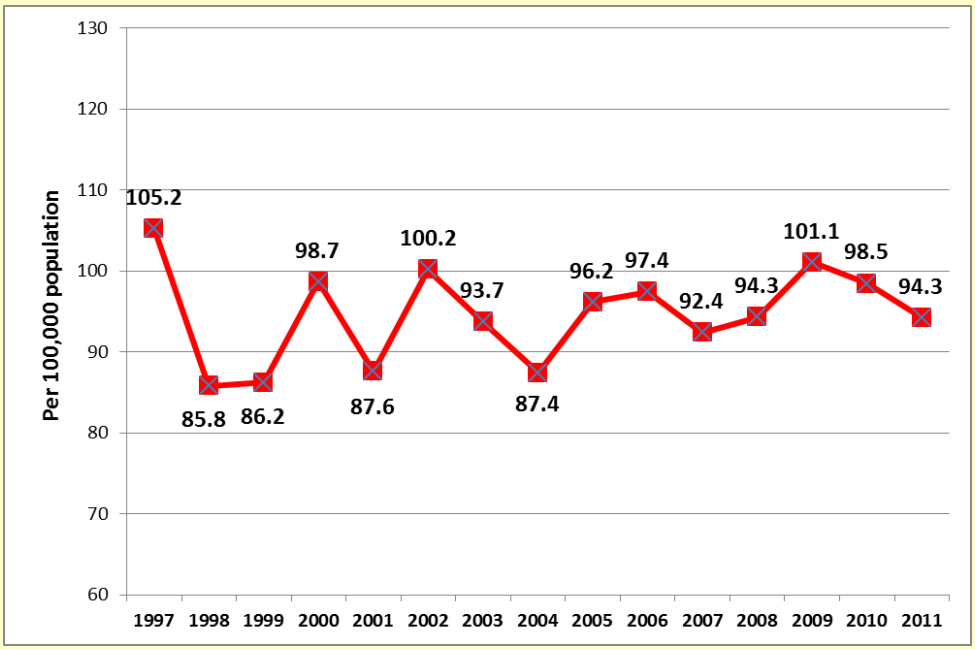
3.1 Epidemiological situation

Please describe any changes to the disease epidemiological situation that is likely to affect program implementation or strategies. (Please indicate sources of information)

Georgia is a country in transition in South Caucasus which re-gained independence after the breakdown of the Soviet Union in 1991. The total population is 4.50 million (as of 01 January 2012, *source*: National Statistics Office of Georgia, www.geostat.ge) including the separated regions of Abkhazia and South Ossetia. Administratively the country is divided in 10 regions and the capital city of Tbilisi. The Gross National Income (GNI) was USD 2,860 per capita in 2011 (*source*: World Bank, Atlas method, http://devdata.worldbank.org/AAG/geo_aag.pdf). Tuberculosis re-emerged as an important public health problem after independence and its burden remains high in Georgia. The WHO-estimated TB incidence (new cases and relapses) for 2011 was 125 per 100,000 population and is the 6th highest among the 53 countries of the WHO European Region (*source*: *Global tuberculosis report 2012*, WHO).

Over the last 15 years, the number of notified new TB cases, while with some annual fluctuations, remained relatively stable and, over the last five years, was in the range 94-101 per 100,000 (figure below).

Figure. Number of new TB cases per 100,000 population in Georgia, 1997-2011 (source: NTP Georgia)

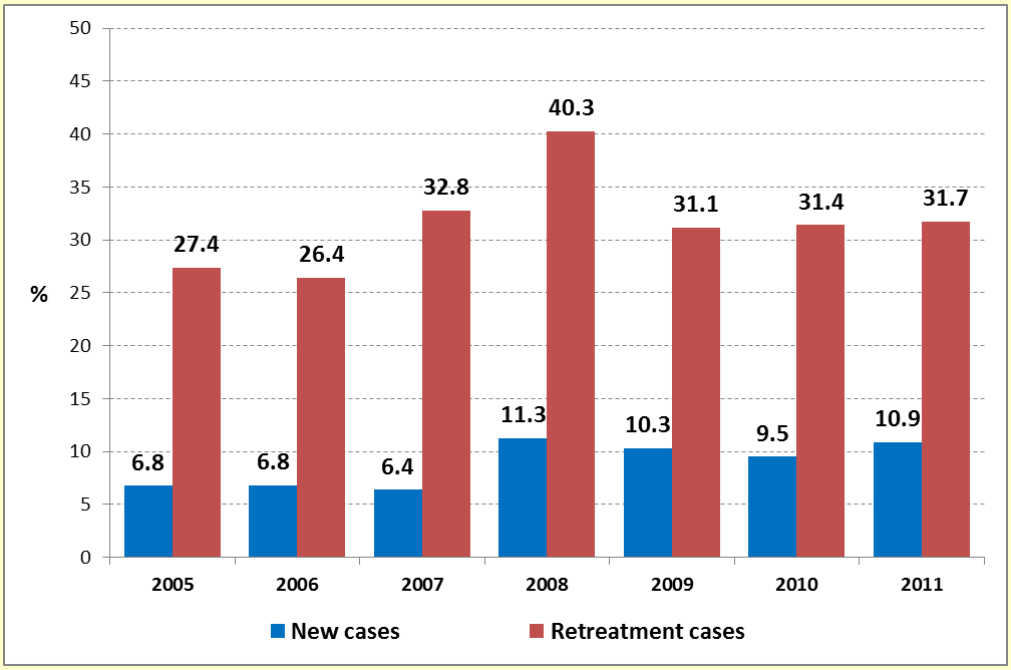


According to the NTP data for 2012 (preliminary at the time of submission of this Request for Renewal), the total number of notified TB cases, all forms, was 5,502 (compared to 5,536 in 2011, 5,798 in 2010 and 5,982 in 2009), which is similar to that in 2011 but represents a 8% decrease compared to 2009 level. The total number of notified new cases in 2012 was 3,822, which represents a further decrease compared to 2011 (4,226). A positive trend in TB epidemiology is the reduction in the proportion of retreatment cases among all notified TB cases in Georgia; this share has been steadily decreasing from about 35% in the beginning of 2000's to 23.7% in 2011.

Resistance to anti-TB drugs represents an acute challenge to the effectiveness of TB control in Georgia. At the same time, it should be noted that, after the first nationwide representative Drug Resistance Survey (DRS) in 2005 and the establishment of a routine drug resistance system since then, the trend in MDR-TB prevalence has been rather stable (see figure below), and the proportion of MDR among new and retreatment cases in Georgia is substantially (2-3 times) lower compared to the levels registered (or estimated) in the other countries of the former Soviet Union. The national program attributes this to the fact that the in-patient TB infrastructure and the level of hospitalizations of patients with TB were substantially reduced since the late 1990s, and emphasis had been placed on outpatient management of TB cases with DOT and adherence

support, e.g. with the assistance of the Global Fund.

Figure. MDR-TB prevalence rate in new and previously treated culture positive cases in Georgia, 2005-2011, % (source: NTP/NRL)



Still the prevalence of MDR remains substantial and accounted for 10.9% of culture-positive new TB cases and 31.7% of retreatment cases in whom DST was performed in 2011 (15.8% of all cases tested; the full resistance pattern is given in the following table.

Figure. Resistance profile to first-line anti-TB drugs among new and previously treated culture positive cases in Georgia, 2011 (source: NTP/NRL)

Resistance profile	***New cases***		***Retreatment cases***		***All cases***	
	Abs.	*%*	*Abs.*	*%*	*Abs.*	*%*
Total tested for DST	**2,197**	**100.0**	**675**	**100.0**	**2,872**	**100.0**
All sensitive	**1,154**	**52.5**	**240**	**35.6**	**1,394**	**48.5**
Any resistance	**1,043**	**47.5**	**435**	**64.4**	**1,478**	**51.5**
Mono-R	**591**	**26.9**	**158**	**23.4**	**749**	**26.1**
H	86	3.9	29	4.3	115	4.0
R	9	0.4	3	0.4	12	0.4
E	13	0.6	5	0.7	18	0.6
S	483	22.0	121	17.9	604	21.0
PDR H+	**196**	**8.9**	**54**	**8.0**	**250**	**8.7**
HE	7	0.3	0	0.0	7	0.2
HS	160	7.3	39	5.8	199	6.9
HES	29	1.3	15	2.2	44	1.5
PDR R+	**14**	**0.6**	**6**	**0.9**	**20**	**0.7**
RE	0	0.0	0	0.0	0	0.0
RS	13	0.6	6	0.9	19	0.7
RES	1	0.0	0	0.0	1	0.0
PDR other	**3**	**0.1**	**3**	**0.4**	**6**	**0.2**
ES	3	0.1	3	0.4	6	0.2
MDR	**239**	**10.9**	**214**	**31.7**	**453**	**15.8**
HR	6	0.3	9	1.3	15	0.5
HRE	1	0.0	2	0.3	3	0.1
HRS	38	1.7	17	2.5	55	1.9
HRES	194	8.8	186	27.6	380	13.2

The burden of drug resistance continues to be key challenge to the NTP and shapes the program

implementation and necessitates relevant adjustments to the program design and budget (i.e. in view of the expanding diagnostic capacities and the resulting increase in the number of DR-TB patients diagnosed and requiring increased quantities and costs of 2nd line TB drugs to be procured). This application for Period 2 has been designed taking into account the epidemiological and resistance profile, which is reflected in relevant calculations (estimates) for the expected number of patients by category, in need of treatment and patient support measures.

3.2 Country Context

Please describe the relevant key changes in the national or program context (political environment, economic situation, social situation and legal context) and the effect of these on program implementation. Elaborate on the changes adversely influencing the program performance and any strategies put in place to mitigate the negative effect on the program. (Please indicate sources of information).

Although there have been changes in political situation in the country during the recent years, they have not influenced program implementation. For the period 2 (2014-2016), no further circumstances are expected in terms of political environment, economic situation, social situation or legal context that would require any substantial changes to the program design or implementation arrangements or undertake other measures to mitigate the negative effects on the program.

3.3 Health Systems Analysis

Please comment on the status of the HSS (Health System Strengthening) actions undertaken with the Global Fund and/or other domestic or partner support and how the identified health system constraints have been addressed.

Although the Global Fund support in Georgia has not had special HSS components, a number of health system strengthening interventions have been implemented; these activities in the first place concerned strengthening involvement and participation of Primary Health Care (PHC) in TB control and strengthening cooperation between PHC and specialized TB services in TB case detection, referral, patient follow up and support under observation by PHC providers, as well as work at community level. For Period 2, although the majority of training / capacity building activities have been excluded as transferred to the national authorities or USAID-funded project (URC, see section 6.1. for details), it is foreseen that all interventions will be implemented in a coordinated manner and aligned with the previous achievements as well as with the ongoing process of health sector development in Georgia.

In terms of health financing, the Georgian health care system is dominated by direct out of pocket payments - 68.35% of total health expenditure in 2010 - for services and pharmaceuticals, with budgetary revenues funding state programs. The government share in total health expenditure varied from 17.0% in 2001 to 23.4% in 2010, remaining at about 2.4% of the Gross Domestic Product and 6.5% of the state budget. In 2009, drugs purchased through retail outlets consumed 42% of the total health expenditure, being much higher than in the other countries in the region and even OECD countries (WHO-EURO Health For All Database, August 2012, http://data.euro.who.int/hfadb). A small percentage of the general population purchases private insurance.

Up to 2007, publicly funded services were purchased through a single state purchaser. Private insurance was operating with about 1% of total health expenditure. During 2006 - 2007 the government initiated bold health care financing reforms by purchasing private insurance coverage for the poor population and for certain public sector employees, and also promoting private self-insurance for the rest. As a result of these efforts, about 1.7 million people (38% of total population) had health insurance by the end of 2010. This contributed to encouraging development of an institutional setup, with the hope that this would decrease out of pocket payments through the development of voluntary health insurance. Although private insurance infrastructure has developed, voluntary health insurance has not sufficiently increased to the level anticipated.

The long-term goal of the health reform is to achieve universal insurance coverage through state subsidization and generally through the development of health insurance market. Currently, benefit packages include free diagnostic and treatment services for TB financed through state budget allocations, besides support from the Global Fund for procurement of drugs, diagnostic supplies and patient support interventions. The Government of Georgia has significantly increased public expenditures over the last five years. However, continued support from TGF remains critical for sustaining progress and further accelerating the national TB response. TGF

significantly contributed to health system strengthening in relation to TB control, as considerable investments in infrastructure, diagnostic capacities, along with covering significant share of treatment costs, made it possible to improve quality of and access to TB services.

Georgia has been undertaking sweeping changes in the health care delivery system. Health care reform priorities aim to improve the health system performance and stronger intersectoral collaboration. Within the strategic objective of increasing geographic and financial access to quality health care, the Ministry of Labor, Health and Social Affairs (MoLHSA) launched far-reaching hospital restructuring initiatives. Up to 2007, inpatient services were delivered mainly by publicly owned institutions. In 2007, the Government introduced a hospital master plan calling for the replacement of the existing hospital infrastructure within a 3-year period by transferring full ownership rights from the State to the private sector. With the help of private investors and public investments, 50 modernly equipped hospitals have started functioning by the end of 2011. The Government of Georgia plans to have a total of 150 newly constructed / renovated medical facilities by the end of 2013. These new facilities are expected to emerge on the principles of a referral network and will offer inpatient, outpatient and pre-hospital (ambulance) services. Although there are few specialized TB inpatient facilities in the country, they are also involved in this reform project, while appropriate measures are secured by the MoLHSA and the NTP to secure full geographical and financial accessibility of necessary diagnostic and treatment services to the entire population notwithstanding the insurance status.

Although the reforms initiated in 2007, to some extent weakened the functionality of the primary care sector in Georgia, public health initiatives have been selectively strengthened during the last few years, such as those targeted at improving immunization, preventive services for cancer screening, cross-sectoral efforts to reduce road-traffic accident related deaths, interventions against illegal drug use, improving living conditions and medical assistance in the penitentiary system (including TB services), etc.

MoLHSA oversees implementation of the national TB program and is responsible for ensuring adequate access to and quality of TB services. The National Center for Tuberculosis and Lung Diseases (NCTBLD) is considered as the center for clinical excellence and the leading agency responsible for setting and implementing TB care quality standards. In addition to clinical functions, its central unit was recognized by a 2009 Ministerial decree as the leading entity of the National TB Program. Recent reforms aimed at improving efficiency of the system resulted in the transfer of the part of TB surveillance role to the National Center for Disease Control and Public Health (NCDCPH).

Until 2012, 11 regional NTP coordinators reported directly to the NCTBLD, and also served as directors of stand-alone TB dispensaries and supervisors of TB staff in their region. They have played key roles in supervision, laboratory oversight, surveillance, and drug management. Now part of their non-clinical time is supported by the NCTBLD and part by the NCDCPH. The current joint work of the NCTBLD and NCDCPH focuses on defining the roles and responsibilities of the regional coordinators vis-à-vis 'dual' administrative and reporting requirements, and avoiding duplication and administrative constraints in terms of the TB program implementation.

Private general hospitals / outpatient clinics, which became part of TB service delivery network in early 2012, are responsible to meet the TB program requirements: maintain a full time TB team composed of a physician and a nurse, ensure unlimited access to all necessary diagnostic services and coordinate the roles with PHC regarding adherence support / DOT, TB reporting / recording and quality assurance.

MoLHSA, jointly with the Medical Division of the Penitentiary Department of the Ministry of Corrections and Legal Advice (MoCLA) bears the responsibility for TB control activities in prisons, per a 2010 joint decree.

Enhancing coordination and governance of the national response has been identified as one of the strategic areas of the recently (end of March 2013) *National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015* (Annex 11). In particular, under Strategic Area 3 ('Effective governance, adequate financing and monitoring of Georgia's TB response'), it is acknowledged that stewardship is a critical building block of the health system, and requires proper management, oversight, policy guidance, collaboration, regulation, and accountability for effective TB control. The key activities / interventions to be implemented include: revising and redefining the roles and responsibilities of national and regional structures in planning, implementing and monitoring the country's TB program in the context of the ongoing reforms; introducing effective mechanisms to improve coordination between MoCLA and MOLHSA in controlling TB within the prisons, and continuity of

TB care upon release; providing technical support to strengthen management capacity of MOLHSA, NCDCPH, NCTBLD and other structures involved in the national TB response; facilitating effective operational planning of NTP interventions; conducting operational research to identify barriers and motivators for private providers to provide TB services

Integration of TB control interventions with the overall reform process is paid significant attention by the MoLHSA and NTP and are being addressed within the external support programs, in particular, by the World Bank and USAID (TB Prevention Project implemented by URC). The Period 2 application is aligned with the strengthening the main functions of the health system (governance, financing, care delivery and resource development) which directly or indirectly influence health system performance in regard to TB control.

Please answer the following question if you are submitting the CCM Request for a HSS grant/program. Otherwise proceed to the next HSS question.

In the context of the national health system strategic plan, goals and objectives, please elaborate on how the HSS grant/program has contributed to the progress towards MDGs 4, 5 and 6. Please also describe if the HSS grant/program has resulted in any demonstrable improvements in access (addressing geographic and gender inequalities), coverage and quality of services.

Not applicable

Please elaborate on any lessons learned and what health system gaps remain in scaling up the disease program.

The key challenge for the Georgian health system remains to adjust / improve the current TB care delivery model by strengthening links across all levels of care and different types of providers, first and foremost through further strengthening PHC role and performance in TB case finding and case management in conditions of high drug resistance burden. This has become especially important in view of increasing private financing, as well as private arrangements for provision of health services in the country. The main lessons learned during implementation of TGF support are about the need to uphold effective emphasis on outpatient treatment, which requires implementation of multidisciplinary patient centered approaches which often extend beyond the traditional health system's boundaries and involve rigorous actions by other public services (such as social services) and non-state and community actors. In this regard, implementation experience during the first period the SSF grant shows that the direction chosen and priorities are correct but require further streamlining and maintaining and expanding the efforts which, in the near future, will not be possible to manage by domestic resources and therefore necessitate additional TGF support.

The content of Period 2 application takes into account these lessons learned and focuses on bridging the health system gaps in regard to TB control. In particular, interventions included in the proposal under Objective 4 aim to continue patient support activities with the involvement of PHC services, social services and other relevant actors at local level to strengthen adherence to TB treatment. While the staff training program has been handed over to USAID / URC, the Period 2 application maintains the focus on capacity strengthening through upgrading of TB information, monitoring and evaluation system and supporting the program supervision, in alignment with the revised international strategies for TB control (first of all concerning MDR-TB).

SECTION 4: Program OVERVIEW

4.1 Financial Gap Analysis, Counterpart Financing and Additionality

This section is not applicable for G20 UMICs that are no longer eligible for Renewals. Please continue to section 4.2 'Progress Towards Proposal Goals and Impact/Outcome'.

Please provide an update of the financial needs, actual and planned sources of funding, and financial gap of the disease/HSS program.

CCMs must use the 'Financial Gap Analysis and Counterpart Financing' table to provide financial information pertaining to the national program that implements the national disease strategy. Detailed instructions on how to complete the Financial Gap Analysis and Counterpart Financing table are provided is in the Financial template provided with the CCM Invitation package: **Renewals_Financial Template_ FinancialRequest_ResourcesAvailable.**

4.1.1 Overview of Government Financing of the National Program

Please specify the levels of government (central, regional, local) that incur spending on the disease programs and the major agencies through which government funds are spent. Elaborate on the availability of earmarked budget line items to capture government disease spending and the extent to which these budget line items capture total government spending on the disease program.

According to the latest WHO estimates (source: *Health For All Database, WHO/EURO, update August 2012*), the total expenditures on health in Georgia in 2010 constituted 10.1% of GDP, out of which the public expenditures contributed to 2.4% of GDP. The share of health spending in the total government expenditure (6.9%) is below the average for FSU countries (8.7%) and is substantially lower than that in the European Union countries (EU average: 14.8%). At the same time, due to the low level of national income, in absolute terms public health expenditure remained as low as 123 PPP$ per capita in 2010 (EU: 1,609 PPP$ per capita).

In terms of the system of financing and coverage, the Georgian health care system is dominated by direct out of pocket payments - 68.35% of total health expenditure in 2010 - for services and pharmaceuticals, with budgetary revenues funding state programs. The government share in total health expenditure varied from 17.0% in 2001 to 23.4% in 2010, remaining at about 2.4% of the Gross Domestic Product and 6.5% of the state budget. In 2009, drugs purchased through retail outlets consumed 42% of the total health expenditure, being much higher than in the other countries in the region and even OECD countries A small percentage of the general population purchases private insurance.

4.1.2 Estimation of Current and Anticipated Domestic and External Funding

Describe how contributions from various sources of funds were estimated, including reference to:

a. Methodology for estimating current and anticipated funding;
b. Composition of reported government spending (part or all of government spending; programmatic costs alone or includes apportioned health system costs; recurrent costs alone or includes capital costs);
c. Whether amounts contributed by each source for the current and previous years pertain to budget, disbursement, expenditure or an estimate of spending;
d. Whether amounts forecast from each source for the future years pertain to estimation or commitment.

The figures on government expenditure on TB include the government spending by MoLHSA (contributions of other governmental bodies are minimal) and were obtained directly through a specially addressed request (see MoLHSA official letter of response in Annex 12). They include all costs (both recurrent and capital costs) including human resources, targeted for specialized TB service and apportioned costs paid by the government to general health service (PHC).

Amounts contributed for the previous years pertain to expenditures, for the current year – to budget, and for the future years – to estimations based on the commitments for overall public financing for health sector and latest trends.

The investment and technical support in the field of TB control by international partners (USAID, the German Government support through GOPA/KfW, MSF) was included based on the figures provided by respective agencies. GOPA/KfW support will not be available beyond 2013, and MSF could not provide estimates for funding for the next years as it is endorsed on the basis of annual decision by the headquarters.

4.1.3 Financial Gap and Counterpart Financing Data Sources

Please answer the following questions below:

a. Cite the sources used to complete the financial gap analysis and counterpart financing table;
b. Provide an assessment of the completeness and reliability of financial data reported, include any assumptions and caveats associated with the figures;
c. Provide details of how the country plans to improve data quality consistent with the guidelines for reporting of program financial data to technical partners; and
d. If applicable, state if the CCM Request includes a budget for an expenditure tracking study and/or measures to strengthen financial data collection and reporting during the next Phase/Implementation Period.

The information used to complete the financial gap analysis and counterpart financing table was obtained from the MoLHSA – for domestic resources; KfW/GOPA, USAID and MSF local offices – for external sources.

The CCM does not have specific plans to conduct a TB expenditure tracking study and/or measures to strengthen financial data collection and reporting during the next implementation period; at the same time, the Government overall and the MoLHSA work continuously in this area, e.g. on managing the national health accounts (NHA) system and conducting different analyses.

4.1.4 Compliance with Counterpart Financing Requirements

Describe whether the counterpart financing requirements have been met as listed below. If not, provide justification which includes actions planned during the next Phase/Implementation Period to move towards reaching compliance.

a. Minimum threshold for counterpart financing
→*Percentage in Line M of the 'Financial Gap Analysis and Counterpart Financing' table must be greater than or equal to the minimum threshold that applies to the applicant's income level.*
b. Increasing government contribution to national disease program over the next Phase/Implementation Period
→*Figures in Line B of the 'Financial Gap Analysis and Counterpart Financing' table must increase over time.*
c. Increasing government contribution to the overall health sector over the next Phase/Implementation Period
→ *Figures in Line I of the 'Financial Gap Analysis and Counterpart Financing' table must increase over time.*

The counterpart financing requirements have been met:

1. As seen from Line M in the 'Financial Gap Analysis and Counterpart Financing' table, the government contribution share is 55% and is higher than a minimum threshold set for Georgia as per the TGF invitation letter to the CCM (40%)
2. There is an increasing government contribution to national disease program over the next implementation period (figures in Line B of the 'Financial Gap Analysis and Counterpart Financing' table increase over time).
3. There is an increasing government contribution to the overall health sector over the next implementation period (figures in Line I of the 'Financial Gap Analysis and Counterpart Financing' table increase over time).

4.2 Progress towards Proposal Goals and Impact/Outcome

Please refer to the results reported by the PR(s) for impact/outcome indicators included in the Performance Framework and provide additional updates if recent information is available (e.g. survey reports, impact assessment studies, etc.)

Impact/Outcome Indicators	Baseline		2011		2012		2013	
	Date	Baseline	Target	Result	Target	Result	Target	Result
TB Mortality rate: Number of deaths due to TB (all forms) per year per 100.000 population as per ICD10 definition (using vital registration system)	2008	4.2	3.7 (for 2010)	4.1	3.2 (for 2011)	3.2 (2011 cohort)	2.7 (for 2012)	N/A
Notification rate of all forms of TB cases: All TB patients (including new smear positive, new smear negative, extra pulmonary and relapse) registered during	2009	109.6	106 (2011)	101.4	105 (2012)	93 (2012, NTP preliminary data)	104 (2013)	N/A

Impact/Outcome Indicators	Baseline		2011		2012		2013	
	Date	Baseline	Target	Result	Target	Result	Target	Result
a specified period and notified to the national health authorities (number per year per 100,000 population)								
Treatment success rate for new smear positive TB cases: New smear-positive TB cases successfully treated (cured + treatment completed) to the total number of new smear-positive TB cases treated in a given year (percentage)	2008 cohort	73%	82% 2,044 / 2,493 (2010 cohort)	76.5% 1,639 / 2,143 (2010 cohort)	83% 1,810 / 2,180 (2011 cohort)	76% 1,535 / 2,028 (2011 cohort, NTP preliminary data)	84% 1,814 /2,160 (2012 cohort)	N/A
Treatment success rate of MDR-TB patients: Patients who were cured or completed Category IV treatment (% of the total number of patients in the same registration cohort)	2007 MDR-TB cohort7	38%	67% (2009 cohort)	53.7% (2009 cohort)	68% (2010 cohort)	51% (2010 cohort, NTP preliminary data)	69% (2011 cohort)	N/A

Please confirm if the method of data collection and data source is consistent with the M&E framework agreed at the time of signing the Grant/SSF Agreement(s).

The methods of data collection and data sources are consistent with the M&E framework agreed at the time of signing the SSF Agreement. The projects rely on the country M&E system which is consistent with the international guidance and is based on individualized TB reporting and national electronic TB database.

Is there a recent report analyzing information regarding heath impact and outcome available? **Yes**

If yes, when was it conducted? **February 2012, June 2012**

Please summarize the main findings and include a full copy of the report with the CCM Request.

In 2011 and 2012, a number of external monitoring missions to the country took place, which looked at different aspects of TB control. The following reports are attached to this application (most recent missions):

1. *Global Drug Facility (GDF) Monitoring Mission Report* (WHO, June 2012)
2. *Green Light Committee Europe Monitoring Mission Report* (WHO, June 2012)
3. *Improving Quality of TB services under the New Service Delivery Mechanism in Georgia* (USAID, February 2012)

The reports provide analysis of different components of the National TB Program (such as programmatic management of DR-TB, drug management, and health system functions in relation to TB control), including, to various extent, health impact / outcome assessment. The above reports are included in Annexes 13, 14 and15 respectively.

Do you consider the program is making progress towards the goals and objectives of the proposal? If not, provide justification and explain how you intend to address the issues.

Overall, it is considered that the program is making progress towards the goals and objectives of the grant. The grant has achieved or succeeded programmatic targets in terms of coverage / output indicators and their performances are ranked high by the Global Fund (see more in section 5 below). At the same time, there are several factors that impede progress in fully reaching and/or substantially improving impact and outcome targets. First, as shown in many countries, settings and programs, the lifetime period of a Global Fund project

is short to document reliable improvements in impact and outcomes in TB.

Second, the burden of drug resistance is the key factor preventing from achieving progress in treatment success, which, according to the current WHO guidance, is conventionally calculated for all cases in cohort (new or retreatment), without taking into account resistance profile. In Georgia, about or over 10% of new smear / culture positive patients tested for DST have MDR-TB and therefore contribute to lowering the treatment success rate in the overall new cases' cohort. At the same time, it should be noted (see also above in section 3.1) that the MDR-TB prevalence rates in Georgia are substantially lower compared to those in other former USSR countries and, consequently, the treatment success rates are higher as well.

Currently WHO and other international partners are revising the estimates and principles for setting the targets for TB control worldwide (e.g. to take into account DR-TB issue), which had already led to some notable changes like as abolishment of such indicator as case detection rate for smear positive cases, etc.; this year, WHO aims come up with the final recommendations for revising the framework for TB recording and reporting system including new definitions for case classifications and treatment outcomes including disaggregation by resistance status, and likely with revised targets for TB impact and outcome indicators (the new dataset is being piloted in several countries since end-2012).

The Performance Framework for Period 2 was reviewed and revised, i.e. to be aligned with the targets set forth in the recently developed *National TB Strategy 2013-2015*, and has been agreed within the CCM technical working group comprised by all relevant national stakeholders and international agencies. Please refer to more details in section 6.1 below and the attached PF.

4.3 Program Effectiveness

4.3.1 Aid Effectiveness

Did you discuss within the CCM how to improve the aid effectiveness of implementation arrangements of Global Fund financing? **Yes**

If no, please explain why no discussion took place, and then proceed to Section 4.3.2.

Not applicable.

If yes, was the process inclusive of key stakeholders, including those involved in donor coordination activities in your country? Please indicate the key stakeholders who participated in the discussion.

Although there were no meetings of CCM dedicated specifically to the issue, different aspects related to external assistance implementation (of the Global Fund and beyond) and aid effectiveness have been paid significant attention by the CCM as well as within other establishments within the Ministry of Labor, Health and Social Affairs (MoLHSA) and the Government of Georgia. The discussion and consultation processes are transparent and inclusive of all relevant national stakeholders and international partner agencies.

Regarding TB, the key governmental partners are the MoLHSA, Ministry of Corrections and Legal Advice (MoCLA), Ministry of Finance, Ministry of Education and Science, Ministry of Reintegration and other ministries and departments (in the health sector, in particular, the National Center for Disease Control and Public Health, NCDCPH). Beyond these, the CCM closely collaborates with the members of the Parliament of Georgia, non-governmental sector, Tbilisi State Medical University and other academic institutions, church (Patriarchate of Georgia) and private establishments (all represented in the CCM). Close contacts, within CCM operations and beyond, are maintained with WHO, World Bank and other country representations of the United Nations family, European Union Delegation, USAID and its sub-contractors (e.g. URC), MSF and other partners.

Please comment on the main findings.

As elsewhere, there has been a growing recognition in Georgia of the need to improve the quality of external aid and development assistance, based on the principles of aid effectiveness enshrined in the Paris Declaration on Aid Effectiveness (2005), namely ownership, alignment, harmonization, orientation for results, and accountability.

The Global Fund support is currently the main and only in most instances source of external funding support in the field of TB control in the country. An important effort has been made by the MoLHSA and NTP, with support of external partners such as USAID and WHO, to develop the *National TB Strategy for 2013-2015* (Annex 11 to this application form). This document represents a platform for a comprehensive approach for effective TB control, which is nationally owned and results oriented, and provides a framework for effective implementation of external aid in a coordinated and complementary way to the national effort to be undertaken, in other words, a nationally-owned program approach which sets the priorities where aid effectiveness measures are expected to improve implementation and to increase the probability of sustainable, high quality results that achieve maximum impact.

In terms of ensuring transparency and accountability of TGF financing for TB, the grants' cycles have been aligned with country cycles, and TGF financing is reflected in country budgets and in national accounting books. An estimate of the mid-term program financial needs and analysis of the funding gap is presented as part of the National TB Strategy document, and the TGF support complements available domestic resources for disease response.

To align with national systems and procedures, TGF projects use existing systems and aim at further strengthening country capacity in implementation, M&E, procurement and supply management (PSM). To streamline reporting, grant reporting have been aligned with country planning and fiscal cycles. The grant data collection and reporting rely on existing national M&E system and the national information flow. Grants' indicators and targets are in line with the national TB strategy. An appropriate part of the grants (in terms of number of activities / tasks as well as the budget) are allocated to M&E. Through the Global Fund project, the in-country systems for the management of pharmaceuticals and other health products are being strengthened and the experience obtained is increasingly used in the national procurement and supply management systems.

The Global Fund-financed activities are coordinated with other donor-funded activities, although, as mentioned above, the inputs from other donors in TB control in Georgia have been decreasing substantially over the last decade. Nevertheless, there is effective coordination of project implementation with technical assistance provided by external partners such as WHO.

In order to ensure sustainability of interventions initiated with TGF support, and avoid potentially negative distort the health sector workforce, the Georgian TB project does not pay salaries for health care staff; in some instances, limited motivation payments are used with the scope of demonstrating the effect of interventions and trigger further takeover by the national authorities.

Based on your discussion did you identify any major risks? If so, please describe them and how you plan to address and monitor each in the next Phase/Implementation Period.

No major risks in relation to aid effectiveness issue above have been identified that may affect program implementation or require additional measures to be applied during Period 2. At the same time, the CCM will continue to monitor the issue and undertake relevant measures as necessary.

4.3.2 Equity

Did you conduct an equity assessment, or was an equity assessment conducted by the national program or other stakeholders, in the current Phase/Implementation Period? **No**

If no, please explain why an assessment was not conducted.

There is no specific assessment focused on equity relevant to TB control in the country. At the same time, relevant issues pertaining to equity are continuously assessed in different ways and are presented, inter alia, in a number of reports or communications by development assistance partners.

Promotion of equitable and rights-based approach to health is a core principle of health protection and care in Georgia and is stipulated in the Constitution and relevant laws and bylaws. The key dimensions of the health system reform in the country, i.e. safeguarding access to essential services of appropriate quality and ensuring fair financing and financial risk protection, are fully compliant with the equity considerations. In particular, the

recent Government subsidiary initiatives for health care of the poor and vulnerable populations, initiated in 2010, aim to uphold equity and solidarity principles regarding financial contributions to health.

The National TB Program in Georgia, supported by the Global Fund grants, is built and implemented within the same framework and aims at ensuring universal access to TB services for all people regardless of age, sex, socio-economic status, geographical location, or other factors commonly considered for in terms of discrimination or limited access. It is well known that TB disease has profound socio-economic grounds and affects first of all persons from poor population groups and other disadvantaged populations such as prisoners and PLWH. In this regard, TGF program, covering the entire country and supporting essential interventions, is seen as fully relevant in terms of upholding equitable access. Besides these, the Period 2 application aims to uphold and streamline relevant interventions targeting high risk population groups such as prisoners and ex-prisoners with TB, as well as community interventions targeting those at highest need, especially poor rural communities.

Patients having drug resistant forms of TB are especially vulnerable in terms of risk of death as well as in terms of likeliness of incurring catastrophic expenditures during complex and lengthy treatment if essential treatment and support services are not provided free of charge at the point of delivery. The Global Fund provides support to cover funding and programmatic gaps which are currently not possible to be bridged with domestic resources, such as supply of 2nd line anti-TB drugs and a set of intensive patient and follow up interventions to ensure adherence to treatment.

At the same time, following the emerging TGF guidance, the CCM will consider conducting a comprehensive equity assessment (in TB as well as HIV grant) in due course during Period 2 of the project implementation.

If yes, please comment on the process for developing the equity assessment.

Not applicable

Please comment on the main findings of the assessment and include additional data, if available, which supports your findings (e.g. disaggregated data by relevant population groups for key indicators, findings from qualitative research, grey literature, etc.).

Not applicable

Based on your discussion did you identify any major risks (e.g. gaps in data availability or data use to assess equity, inequities in service coverage and impact/outcomes, gaps or weaknesses in planning, programming or implementation, or structural barriers)? **No**

If yes, please list and describe the following: (a) how you plan to address those risks in the next Phase/Implementation Period; (b) how progress will be monitored in the next Phase/Implementation Period; and (c) how the M&E system may need to be strengthened to provide data to monitor results.

Not applicable

4.3.3 Value for Money

Please comment on the three dimensions of value for money listed below, demonstrating how the program is maximizing the health impact that can be achieved with available resources.

Economy: is the program minimizing the cost of resources and inputs whilst maintaining quality of services?

Yes. One of the key interventions supported by the program is procurement of quality assured second-line anti-TB drugs at concessionary process through GLC/GDF mechanism. In this instance, it works for both minimizing the cost (compared to much higher prices that would have been obtained through local procurement) and maintaining quality by obtaining quality products from WHO-prequalified manufacturers.

Efficiency: is the program maximizing the output that can be achieved from available resources and achieving its results at the lowest possible cost?

Yes. An example can be the patient support program, which, although receives additional funding from TGF, has the potential key role to mobilize and optimize the use of existing capacities and resources (financial,

human and infrastructural) for effective TB actions through multidisciplinary community-based and patient-oriented approaches, which are known to improve the results at the lowest possible cost. In addition, the Georgian TB care delivery system is predominantly outpatient, which is proved to ensure both effectiveness and efficiency of the program interventions.

Effectiveness: was the program approach and activities well designed to achieve the objectives and correspond to what needs to be done given the disease and local context?

Yes. The implementation experience shows that the program approach is appropriately designed to achieve the objectives and fits well in the disease and local context. At the same time, as mentioned above, there are a number of factors that influence the changes at impact and outcome level; the positive changes in this regard are expected after achieving the full performance of initiated interventions which requires time and may extend until the end or beyond the program cycle.

Have any major risks been identified related to value for money? **No**

If yes, describe how you plan to address those risks and monitor progress in the next Phase/Implementation Period.

Not applicable

4.4 Quality of Services Assessment

This section is not applicable for a cross-cutting HSS grant/programs. Please continue to section 4.5 'Partnerships' if you are submitting the CCM Request for a cross-cutting HSS grant/program.

Please comment on systems to manage quality (quality improvement/quality assurance) that ensure adherence to national guidelines and Standard Operating Procedures (SOPs).

There are a number of measures that are currently applied in country in order to assure quality of TB services. The main document currently regulating all procedures related to TB case detection and diagnosis, TB treatment, referral and functions of different levels of involved services, case and outcome classifications, recording and reporting, supervision and M&E and other special aspects such as TB/HIV, is the National TB Guideline; the previous version was in force since 2006 and in January 2013 was replaced with the new Guideline, developed with the support from USAID / URC and approved by the Association of TB Specialists and Pulmonologists of Georgia. This document incorporated the emerging international guidance and recommendations.

These national TB guidelines contain requirements for quality of services, which are to be observed by all health institutions in the country. The implementation supervision function lies with the NTP Central Unit (National Center of Tuberculosis and Lung Diseases, NCTBLD), which carries this function through regular supervision visits and mentoring to all regional NTP units in the country (and general health services sites as required), issuing and updating specific guidance and methodological materials, refreshing training of staff and other relevant activities.

There is a proper quality control and assurance system in TB laboratories. Standard operating procedures (SOPs) are in place in all laboratories (NRL, Kutaisi reference laboratory and eight regional LSSs). The NRL bears the function of quality control for microscopy and culture of all laboratories in the country through regular supervision (part of NTP M&E system); external laboratory quality assurance (EQA) is carried out by the Supranational Reference Laboratory at the Institute of Tropical Medicine in Antwerp, Belgium.

Please comment on major quality of services risks which have or could have a negative effect on performance, if any. Describe how you plan to address those risks and monitor progress in the next Phase/Implementation Period.

No major quality of services risks are expected during the next implementation period which may have substantial negative effect on performance. The Global Fund support have substantially contributed to strengthening quality control and quality assurance; for Period 2, further support is included for several priority interventions such as NTP supervision, upgrade and maintenance of the recording and reporting

system and the national electronic TB database.

If the RSQA (Rapid Service Quality Assessment) assessment was not conducted in your country, please continue to section 4.5 'Partnerships'

Please refer to the latest available information on quality of services annexed to the CCM Invitation Letter and provide updated information (updated national guidelines/protocols), if available.

The CCM is aware of the new TGF-developed strategy to assess quality of services and integrate this assessment in the performance-based funding model, based on Rapid Services Quality Assessment (RSQA), to be applied during program implementation by the Local Fund Agent in conjunction with the On-Site Data Verification (OSDV). The CCM is also informed that RSQA will be rolled out in a phased manner and the country will participate in the exercise as agreed upon with TGF Secretariat.

4.5 Partnerships

Using the table below, please indicate the technical assistance (TA), if any, already received in the current Phase/Implementation Period or confirmed to be conducted in the next Phase/Implementation period by the PR(s) and /or SR(s).

TA source/TA category	Current Phase/Implementation Period	Next Phase/Implementation Period
Bilateral	√	√
Multilateral	√	√
CSO	□	□
Private Sector	□	□
Academic Inst.	□	□
Mixed/other (specify)	□	□

Describe any current gaps and/or needs in the capacity building that are not being met by the existing TA providers.

The NTP Georgia has gained substantial technical capacities and expertise in different aspects of TB control, e.g. strengthened through a number of technical assistance activities during earlier stages of TGF support implementation. WHO through its Regional Office in Copenhagen continues to provide technical assistance and monitoring and evaluation of program interventions, e.g. through GDF and GLC monitoring missions. At the same time, for Period 2, an additional need in external TA has been identified by the technical working group and is included in the application for priority areas of TB control such as sustaining quality drug resistance surveillance, application of contemporary approaches to diagnosis and treatment of drug-resistant TB, management of TB/HIV co-infection, ensuring access to services for population segments at risk, in particular, prison population (one external technical assistance mission per year, Activity 1.1).

SECTION 5: CURRENT PHASE/IMPLEMENTATION PERIOD PERFORMANCE (PR 1)2

5.1 Programmatic Achievements and Management Performance

5.1.1 Programmatic Achievements

Provide an overall assessment of the progress of the PR during the current Phase/Implementation Period based on the key programmatic indicators in the Performance Framework.

The Principal Recipient for TGF TB Grant (GEO-T-GPIC) is the Global Projects Implementation Center (GPIC), which is a non-entrepreneurial (non-commercial) legal entity, founded on 25 January 2011 (Identification Code 404885291). The GPIC's goal is to contribute to the improvement of health and social wellbeing of the population in Georgia and abroad. GPIC works in close collaboration with the Ministry of Labor, Health and Social Affairs (MoLHSA) and other governmental bodies as well as with relevant international and national partners.

GPIC is the sole Principal Recipient of TGF grants in Georgia and, since its establishment, has managed the grants with the total value of EUR 20.15 million. Currently GPIC acts as the Principal Recipient for two Global Fund grants: GEO-T-GPIC (for TB) and GEO-H-GPIC (for HIV); both grants were consolidated from TB and HIV grants obtained in earlier application rounds under Single Stream Financing (SSF) in 2011.

Regarding the programmatic achievements for GEO-T-GPIC grant, in the first semester the level of overall achievement of targets for 'Top 10' indicators and all indicators was in A2 range (90 and 91%, respectively), but the total rating was downgraded to B1 due to two 'Top 10' indicators, which were in the range of B2 rating (out of 14 indicators reported on, 8 achieved A1 and A2 ratings, 4 – B1 rating and 2 – B2 rating).

In the first semester of SSF grant implementation, the target for indicator "Number of TB patients with DST to first-line drugs at diagnosis" was underachieved (B2) due to the process of reorganization of the laboratory network in Georgia and the need for transportation of cultures to Tbilisi. In the second semester, the performance against this indicator improved dramatically, and the target was fully reached.

The target for indicator "Number of M/XDR-TB patients on treatment receiving patient support" was also under-achieved (B2) in the first semester due to stricter procedures of the incentive scheme as enforced by the NTP, whereby patients would not receive the incentives if they missed just one daily dose of drugs. The performance on this indicator also improved dramatically in the second semester. The incentive scheme is currently being revised and will incorporate different modalities for improving adherence to treatment.

In the second implementation semester, the overall achievement of targets for 'Top 10' indicators and all indicators were also within A2 range (97%), but the rating was again downgraded to B1 due to one 'Top 10' indicator receiving a B2 level. The overall performance improved in the second semester, with 11 of a total of 14 indicators achieving A1 and A2 ratings, two indicators with B1 and one with B2 rating. The B2-rated indicator was the "Number of IDUs screened for TB," which was under-achieved in both periods.

In the third semester, the overall performance for 'Top 10' indicators and all indicators was at A1 level (102% fulfillment), with a total of 13 indicators (out of 15) in A1-A2 range, and two indicators within B1 rating (one additional indicator, "New smear-positive TB cases among prisoners successfully treated", was added to the Performance Framework in the third semester as suggested by TGF Secretariat).

Overall, by the end of the 18 months of the SSF project implementation (July 2011 – December 2012), the program is performing well against its key objectives of expanding access to quality diagnosis and treatment of TB and M/XDR-TB. In terms of case detection and diagnosis, 99.2% of prisoners are screened for TB at entry,

[2] Please fill out the section separately for each PR.

100% of TB patients have sputum and culture performed at diagnosis and 100% of eligible culture-positive TB patients receive DST to first-line drugs. In terms of treatment, the enrolment targets for both sensitive and drug-resistant TB have been over-achieved, with 4,933 TB patients enrolled on first-line treatment and 659 laboratory-confirmed M/XDR-TB patients enrolled on second-line treatment. The adherence support program has also improved, with 69% of sensitive TB patients and 74% of M/XDR-TB patients receiving patient support (incentives and enablers) to strengthen adherence.

At the same time, the overall treatment success rates remain low (76% treatment success among new smear-positive patients and 51% among M/XDR-TB patients). This issue has been continuously discussed within the NTP and with TGF Secretariat, WHO and other partners. The main reasons for under-achieving the desired this outcome-level target are: the continuing social and economic problems faced by the patients and household which de-motivate them to complete treatment but engage in other economic activities to uphold the living of patients and their families (thus leading to defaulting from treatment, especially from lengthy M/XDR treatment), and, in case of sensitive patients, the substantial share of patients with drug-resistant TB, which, according to the current WHO requirements for classification of treatment results, mandates to count them as negative outcomes (i.e. failures) in the overall cohort even if they are diagnosed with MDR at the beginning of treatment and start on Category IV treatment immediately.

Please provide a description of the related actions the CCM/RCM/sub-CCM will take, in its oversight capacity, to address these identified performance issues?

The programmatic, as well as financial, performance of the grant is being systematically discussed within the CCM and its working groups. The corresponding recommendations / suggestions are further addressed by the relevant authorities (i.e. MoLHSA and the NTP Central Unit). The CCM oversight mechanisms are described in section 2.1.3 of this proposal form.

Please summarize the current challenges in M&E systems and capacity based on any recent assessment undertaken during the current Phase/Implementation Period, and provide an update on status of implementation of M&E systems strengthening recommendations supported through Global Fund grant/SSFs and other partners during the current Phase/Implementation Period. Please also comment on the expenditures on M&E (variances, if any) against approved funding under the Global Fund grant/SSF during the current Phase/Implementation Period.

The monitoring and evaluation arrangements are implemented in accordance with, and as an integral part of, the national health M&E system and M&E system of the National TB Control Program; therefore, there is no duplication or 'parallel reporting'. The M&E arrangements are compliant with TGF requirements, in particular: the program is an integral part of the national strategic health development plans; consistency between goals, objectives, strategies and the selected indicators is ensured (i.e. there is full alignment with the nationwide indicators and targets for national TB control as set forward in the recently adopted National TB Strategy); reporting on results builds on and strengthens the existing M&E systems; indicators and targets selected for reporting are supported by the workplan and budget; and the M&E system provides for impact / outcome measurement.

The use of standard indicators provides the National Program with valuable measures of the same indicator in different populations, permitting analysis of trends. Over time, the use of standard indicators also ensures comparability of information across countries. During the process of SSF implementation and preparation of the Renewal Request for Period 2, indicators for monitoring program performance were selected in compliance with the national M&E reporting framework as well as with the Global Fund requirements, namely:

- Use of a limited set of indicators relevant for reporting including impact measurement, which are agreed by a wide range of partners and used in most countries;
- Use of a set of priority indicators and additional indicators at different levels of M&E;

- Selection of consistent indicators that are comparable over time and with clear targets;
- Selection of a number of key indicators that are comparable with other countries.

The key indicators and their definitions were selected from the internationally approved lists and sources developed by WHO and Stop TB Partnership. In particular, Monitoring and Evaluation Toolkit for HIV/AIDS, Tuberculosis and Malaria (the latest edition) was used as reference. Output and process indicators were developed in line with the Service Delivery Areas and Activities included in the proposal's Workplan.

Performance Framework (PF, see Annex 01 to this form) is a key document that presents a detailed description of indicators to be used to monitor the program performance, baseline values and targets to be achieved over specific periods of time as well as methods and frequency of data collection. Besides the PF, which contains a limited set of indicators and serves as the basis for regular reporting to TGF, the Principal Recipient will update the project's Monitoring and Evaluation Plan; this Plan contains an extended set of indicators that will be monitored by the PR to ensure that the activities are implemented according to the Workplan timeframe and preliminary outputs are attained.

Having the overall responsibility for M&E activities for TGF projects, the Principal Recipient's program staff will continue to work in close collaboration with all relevant institutions in the civilian and penitentiary sectors and will have the duty of finalization and clearance of all data and reports which will be deriving from the program implementing entities. They will participate in the design, implementation and oversight of M&E activities implemented within the project including supervisory visits to the field.

The data are collected according to the indicators identified in the M&E Plan using three main sources: i) routine health statistics at the national and sub-national levels; ii) operational surveys and studies; and iii) data collected by the NTP specifically for relevant interventions. Collection of the routine statistical data and special data from service delivery sites will be performed by the PR on a quarterly basis or more frequently as necessitated by the nature of intervention. Standardized forms are used in order to ensure the completeness and uniformity of data across different sources and possibility for further proper compilation and comparability, as well as the electronic data transmission channels from the regions' level to the NTP Central Unit and NCDCPH.

The quality and consistency of data are assured by: internal consistency checking of data collection tools; site visits (e.g. linked to regular NTP supervision) by the NTP and PR; quarterly revision of indicators and activity reports (if applicable), submitted by the Sub-Recipient; quarterly (and more frequent as necessary) meetings of the NTP and PR staff; periodic common meetings with the Sub-Recipient by the PR; and meetings with the Local Fund Agent on M&E issues and site visits by the LFA (e.g. on-site data verification reviews, OSV).

The analysis of information and compilation in relevant reports will be performed by the PR and submitted to the MoLHSA on an agreed-upon frequency bases, including annual reports on the progress of project implementation that will be developed by the PR and submitted to the MoLHSA and CCM as relevant.

The M&E information will be used for providing feedback to the implementing entities, presenting best practices and lessons learned for broad dissemination to the national and international partners, including presentation at the CCM meetings as necessary. The information collected within the program will feed the M&E Reports of the National TB Program, country reports to WHO/EURO, WHO Global TB annual reports and other destinations.

5.1.2 Grant/SSF Risk Management

Please comment on the major grant/SSF management risks and issues, if any, including those attached to the CCM Invitation Letter. Describe how you plan to address those risks and monitor progress in the next Phase/Implementation Period.

The CCM invitation letter for Period 2 (dated 03 December 2012) did not indicate any specific risks for the next phase project implementation. At the same time, the NTP and the PR are addressing technical (programmatic)

recommendations and suggestions contained in the country team pre-assessment report, attached to the CCM invitation letter), in particular, related to strengthening administrative measures for infection control at TB facilities; expanding case detection at PHC level; improving referral mechanisms for TB suspects from PHC and private facilities to specialized TB service; and improving the linkages between penitentiary and civilian TB services, including follow-up of released prisoners to improve access and adherence to treatment.

Currently the Principal Recipient is in the process of responding to the project management issues raised in the report of the Office of the Inspector General (OIG), which was provided by the OIG to the CCM and PR on 15 February 2013.

5.1.3 Grant Performance Rating

Please answer the following questions if you are submitting the CCM Request for a Phase 2 or RCC Phase 2. If you are submitting the CCM Request for Periodic Review, proceed to section 5.2 'Financial Performance'.

Grant Performance Rating for the current Phase (Phase 1/RCC Phase 1)

☐ **A1** ☐ **A2** ☐ **B1** ☐ **B2** ☐ **C**

Please provide a rational and justification for the rating.

Not applicable.

5.2 Financial Performance

5.2.1 Financial situation at cut-off date

Cash at cut-off date

Please note that the financial information required for this section is in the Financial template provided with the CCM Invitation package* Renewals_Financial Template_FinancialRequest_Cash-at-cut-off-date *– the CCM must paste a screenshot of the information to this section in the CCM Request template (Word document) by selecting the relevant cells in Excel and using Paste option in Word to insert as a picture. Financial Request must be filled out in the Excel file only. Do not edit the table after pasting it here!

	PR	SRs	Total
a. Disbursed to PR to cut-off date	€ 6,669,462.45	N/A	6669462.45
b. Less: Disbursed from PR to SRs	€ (650,908.00)	650908	0
c. Less: Expenditure incurred to cut-off date	€ (5,410,999.64)	€ (648,505.39)	-6059505.03
d. Add: Interest received	€ 172,147.59		172147.59
e. Add: Other income - please specify	€ 120,860.40	€ (1,486.22)	119374.18
f. Equals: Cash at cut-off date	900562.8	916.39	901479.19

Please include a **Liabilities summary at cut-off date** with the CCM Request (goods and services received/ordered but not yet paid for) that would need to be part of the budget from the cut-off date forward. It has nothing to do with commitments for activities still to take place. Failure to include them could mean that they will not be included in the funding envelope provided.

As of 31 December 2012, the PR had liabilities of a total amount EUR 1,052,492.67 for the goods and services received / ordered but not paid yet. For more information please see Annex 05.

Have all liabilities at cut-off date been taken into account in the post-cut-off date budget? **Yes**

5.2.2 Analysis of expenditures versus budget

With reference to the latest available EFR at cut-off date, please summarize the main reasons for any under-spending or over-spending against budget.

According to the latest Progress Update as of December 31, 2012, the cumulative budget of the grant GEO-T-GPIC was EUR 8,286,157 and the expenditures incurred amounted to EUR 6,060,355. The total variance equals to EUR 2,225,802, out of which EUR 1,490,744 are considered as savings.

The main categories in which 'under-spending' occurred represent EUR 815,613 for MPP ('Medical and pharmaceutical products' category) and EUR 490,378 for HPE ('Health products and equipment' category), of which EUR 953,094 is considered as savings.

The cumulative figures on budget and expenditure and explanation on variances are presented in the table below (by Objective; more details are to be found in the PU/DR at cut-off date).

Objective	*Cumulative budget*	*Cumulative expenditure*	*Variance*	*Reason for Variance*
1. To strengthen National TB Control Program management, coordination, monitoring and evaluation and capacity building	470,694	359,881	110,813	The major share of variance, EUR 47,580, is unused from the TA for the NTP, followed by EUR 16,814 for attendance of international attendances - this was already utilized in P4. EUR 14,700 are unused funds for organizing the national conference in year 1. Savings also occurred due to the less-than-planned expenses for local training for TB service and PHC staff, although the coverage target was met.
2. To improve diagnosis of TB including M/XDR-TB	614,394	253,085	361,309	'Under-spent' amount includes: EUR 130,707 which was paid in P4 as committed funds for HP procurement. EUR 229,335 is a saving due to the less expenses for HPE and fuel procurement, which was conducted through the competitive bidding process, where smaller unit prices has achieved
3. To ensure quality treatment of all forms of TB	4,965,943	3,766,282	1,199,661	'Under-spent' amount includes: EUR 155,910 which was paid in P4 as the committed funds for MPP procurement. EUR 52,946 were committed for HPE procurement and were also paid in P4. Overall, EUR 990,805 is savings which occurred due to smaller prices for MPP procured through GDF and locally and smaller prices for HPE procured locally through competitive bidding.
4. To ensure adherence to TB treatment by intensive patient support and follow up	1,769,430	1,382,059	387,371	'Under-spent' amount includes: EUR 63,881 which were paid in P4 semester as committed funds for food voucher procurement. EUR 33,351 is the saving out of the budget for vehicles procurement for patient support program. EUR 55,734 from variance are unused from the funds budgeted for patient transportation for DOT. In the current proposal, this is considered and unit cost is decreased from EUR 1.5 to EUR 1.0 per DOT visit. Savings occurred due to cancelled activities e.g. patient education sessions at the Public Health units, which is caused due to the reorganization of the TB network countrywide.
5. To ensure sustainability of collaborative activities for control of TB / HIV co-infection	48,987	24,876	24,110	'Under-spent' amount includes: EUR 1,925 which was paid in P4 as committed funds for procurement of HIV tests. The savings occurred due to the smaller prices and quantities of tests procured as the NCDCPH contributed to HIV test procurement.
6. To inform TB control actions by evidence-based information deriving from operational research	135,961	36,654	99,307	'Under-spent' amount includes: EUR 44,082 committed for OR procurement activities, with that total saving comes to EUR 43,943.51; This is the result of decrease of price of Xpert MTB/RIF cartridges (USD 9.98 from USD 16.86, proper cost) and procurement of other health products and equipment at lower prices through

				competitive bidding. Savings of EUR 11,280 from variance are payments which were carried out in P4 from the funds budgeted for researchers and devices' calibration.
7. Project management	280,749.00	237,518.69	43,230.31	'Under-spent' amount is mainly caused due to savings at HR category and PR staff attendance of international trainings and conferences.
	8,286,157	**6,060,355**	**2,225,802**	

Additional savings were generated in procurement of fuel for the program activities, when the bulk procurement was done for 2 years, but in year 1 the cost per liter was lower than that budgeted and this resulted in EUR 22,220 savings.

Please comment on whether the overall % expenditure versus budget variance at the cut-off date is in line with the average % achievement against all indicators in the performance framework. If not, please explain the reasons.

The overall performance programmatic achievement of targets against performance indicators at cut-off date (31 December 2012) was 102%. The overall financial 'under-spending' is mainly due to lesser expenditures as a result of better prices obtained for procurement of medicines and health products.

SECTION 6: CCM REQUEST FOR RENEWAL (PR 1)[3]

6.1 Programmatic Proposal

6.1.1 Program Objectives, SDAs, Indicators and Targets

Please provide a Performance Framework for the next Phase/Implementation Period and comment on whether indicators and targets are aligned with the national program strategy, plans and systems.

This application represents a Request for Renewal of the TB grant from the Global Fund in Georgia covering the period of 2.5 years between 01 January 2014 and 30 June 2016. The program is financed through the Single Stream of Financing (SSF) projects from TGF TB grants obtained in Round 4 (RCC grant) and Round 10. At the stage of consolidation, the program cycles were aligned across the two SSF grants and to the national fiscal year (starts in January). The two grants are part of one program application supporting the implementation of the recently (on 21 March 2013) approved *National Tuberculosis Strategy and Operational Plan for Georgia 2013-2015* (see Annex 11). This section provides description of the content of the Request for Renewal for Period 2 of the consolidated grant.

This proposal is built to support the key priorities of the National TB Strategy, i.e. sustaining universal access to diagnosis and treatment of all forms of TB, improving the service performance through multisectoral and multidisciplinary patient-centered approaches, and improving governance, program management and monitoring for effective national response to emerging TB challenges, first and foremost to the challenge of drug-resistant TB.

The Government of Georgia faces continuing fiscal constraints, exacerbated by the consequences of the global financial crisis during the last four years that have resulted in the need to reduce the overall public expenditures and reorient them towards strictly defined priority interventions, e.g. in the health sector. Nevertheless, the Government has demonstrated commitment to TB control, including sustaining and expanding financing of TB interventions. There are a number of recent developments that document this commitment including further optimization of the laboratory network, optimization of inpatient TB care, takeover of surveillance system and other substantial costs of staff and facility expenses.

At the same time, domestic funding resources remain insufficient to cover all costs of costly DR-TB management interventions, and the mechanisms are not yet in place to channel public resources for important community-based patient support activities. Therefore, the need of external funding for TB control remains important in Georgia, and the current application aims at obtaining additional resources from the Global Fund and channeling them effectively towards priorities not covered by domestic funding resources.

OBJECTIVES, SERVICE DELIVERY AREAS AND INTERVENTIONS

The overall goal of the program remains unchanged and is ***To reduce the burden of tuberculosis in Georgia by sustaining universal access to quality diagnosis and treatment of all forms of tuberculosis***. The interventions included in the proposal for Period 2 are aligned with the priorities of the National TB Strategy and continue to have focus on strengthening the programmatic management of TB including drug-resistant TB, supporting patients and consolidating health service's capacities for successful TB case management, with a special focus on groups at high risk such as prisoners. The application is built to uphold the goal, scope and key directions of the ongoing TGF-financed TB program. At the same time, it complies with current TGF requirements (including mandatory budget reduction); for this purpose, the activities implemented through both Principal Recipients during the previous phase of the consolidated grant, have been re-organized under four main ***Objectives***:

[3] Please fill out the section separately for each PR.

5. To strengthen the National TB Control Program management, coordination, monitoring and evaluation;
6. To improve diagnosis of TB including M/XDR-TB;
7. To ensure quality treatment of all forms of TB;
8. To ensure adherence to TB treatment by intensive patient support and follow up.

A brief description of activities under each Objective is presented below.

Objective 1. To strengthen the National TB Control Program management, coordination, monitoring and evaluation

Activities under this Objective aim at sustaining the achievements of the national program through strengthening NTP capacities for programmatic management, coordination, monitoring and evaluation in both civilian and penitentiary sectors, central and regional NTP supervision.

Activity No.	*Activity title*	*Service Delivery Area*	*Implementing entity(-ies)*
1.1	Technical assistance in priority issues of TB control	Program management, M&E	SR
1.2	Training in NTP management and attendance of international conferences abroad	Program management, M&E	SR
1.3	Support to central NTP supervision	Program management, M&E	SR, PR
1.4	Support to regional NTP supervision to TB facilities	Program management, M&E	SR, PR
1.5	Support to regional NTP supervision to PHC facilities	Program management, M&E	SR, PR
1.6	Support to supervision and monitoring visits in the penitentiary system	Program management, M&E	SR, PR
1.7	Post-supervision meetings	Program management, M&E	SR
1.8	NTP vehicles	Program management, M&E	SR, PR
1.9	Program management and administration expenses of the NTP Central Unit and Regional Units	Program management, M&E	SR
1.10	Technical assistance (local), TB M&E system and management of the national TB database	Program management, M&E	SR
1.11	Printing of recording and reporting forms	Program management, M&E	SR, PR

Support to continuous NTP capacity building embraces targeted international technical assistance in priority areas related to emerging challenges to TB control in the country, aimed at sustaining quality drug resistance surveillance, application of contemporary approaches to diagnosis and treatment of drug-resistant TB, management of TB/HIV co-infection, ensuring access to services for population segments at risk, in particular, prison population. One external technical assistance mission per year is planned for Period 2. The project will also support attendance of training courses and international conferences abroad by the NTP staff, e.g. training in M/XDR-TB management.

Semi-annual central supervision rounds will be performed by the NTP Central Unit team to 10 regional centers and selected districts within the regions. In turn the Regional Units will conduct monitoring visits to TB service units (on a quarterly basis) and PHC facilities (monthly) in peripheral districts. Supervision will give priority attention to improving cooperation between TB services and PHC services and stimulating

involvement of local public authorities and relevant community establishments in follow-up of TB patients on out-patient treatment, ensuring direct observation, adherence support and defaulter tracking, with special emphasis on M/XDR-TB patients and follow-up of discharged ex-prisoners with TB who continue treatment in the civilian sector. The results of supervision visits will be presented and discussed at quarterly post-supervision meetings at the NTP Central Unit, which are used as an instrument for operational planning for the rounds that will follow.

Given the importance of TB problem in prisons and the need for continuous strengthening of the collaboration between TB services in the civilian and penitentiary sectors, in Period 2 the project will extend its support to regular supervision and monitoring visits in the penitentiary system, which are carried out jointly by the NTP and the Medical Department of the Ministry of Corrections and Legal Advice. Twelve correctional facilities will be visited on a quarterly basis, two sites with high turnover of detainees and poorer detention conditions will be visited monthly, and weekly visits will be carried out to the specialized TB facility in Ksani and to the Central Prison Hospital where TB treatment of prisoners takes place).

The project will continue assistance to the NTP in the management of the national electronic TB information system through supporting the work of four local IT specialists on database maintenance, and printing and distributing the TB recording and reporting forms and registers to TB care delivery sites. Limited support to covering management costs and operational expenses, directly related to implementation of the program interventions, is also included under this Objective.

NOTE. In order to streamline collaboration and coordination with other sources of external assistance, and to comply to TGF requirements regarding value-for-money and reduced level of funding for Period 2, support to a comprehensive training / capacity building program for TB service staff and PHC providers, previously supported by TGF in Period 1 of the SSF grant, is not requested in this application for renewal. This program (previously Activities 1.11-1.16) had been supporting the following training activities: training in direct smear microscopy and refresher training; training for TB doctors and refresher training; training for TB nurses and refresher training; training of PHC doctors in TB control; training of PHC nurses in TB control; and, in addition, organization of national conferences on TB control. Based on a joint agreement between the MOLHSA, NTP, Principal Recipient and USAID, for the duration of Period 2 of TGF project, revised and targeted support to training / capacity building for TB and PHC service providers will be provided by the USAID-funded 'Health Care Improvement Project' in Georgia ('TB Prevention' component), implemented by University Research Co., LLC (URC).

Objective 2. To improve diagnosis of TB including M/XDR-TB

The interventions under this Objective aim at strengthening laboratory capacities for TB diagnosis, including sustaining reliable routine drug resistance surveillance and quality rapid diagnosis of DR-TB cases for timely initiation of treatment. They include support for regular specimen transportation system country-wide, upgrading reference and regional laboratories for rapid DR-TB diagnosis and ensuring external laboratory quality control and quality assurance, as well as targeted support to case finding activities among at-risk population groups (prisoners and IDUs).

Activity No.	*Activity title*	*Service Delivery Area*	*Implementing entity(-ies)*
2.1	Sputum smear microscopy investigations (ZN)	Diagnosis of TB including M/XDR-TB	PR
2.2	Culture investigations (automated method on liquid media)	Diagnosis of TB including M/XDR-TB	PR
2.3	Culture investigations (manual method on solid media)	Diagnosis of TB including M/XDR-TB	PR

2.4	LED microscopy investigations	Diagnosis of TB including M/XDR-TB	PR
2.5	DST to first-line line drugs for DR-TB diagnosis (automated MGIT technique)	Diagnosis of TB including M/XDR-TB	PR
2.6	DST to first-line drugs (manual technique)	Diagnosis of TB including M/XDR-TB	PR
2.7	Tests for rapid identification of R/H resistance (LPA Hain)	Diagnosis of TB including M/XDR-TB	PR
2.8	Laboratory equipment for DR-TB diagnosis (automated detection and MDR screening, Xpert MTB/RIF technology)	Diagnosis of TB including M/XDR-TB	PR
2.9	Tests for rapid detection and MDR screening (Xpert MTB/RIF technology)	Diagnosis of TB including M/XDR-TB	PR
2.10	Entry screening for TB in penitentiary institutions	Diagnosis of TB including M/XDR-TB	SR
2.11	Screening of IDUs for TB	Diagnosis of TB including M/XDR-TB	SR
2.12	Operational research on effectiveness of entry and massive screening at penitentiary system	Diagnosis of TB including M/XDR-TB	SR
2.13	Diagnostic counseling and testing for HIV among TB patients	Diagnosis of TB including M/XDR-TB	PR, SR

In SSF Period 1, the project supported the system of regular transportation of sputum specimens from sputum collection points to microscopy laboratories and further to the National Reference Laboratory and the Regional Laboratory for Western Georgia in Kutaisi for culturing (and DST, which is performed at the NRL), functional in the country since 2005. Starting 2014, the Government through the MOLHSA takes over these activities and related costs, therefore this component has been taken out from the renewal application.

Glassware, reagents and other supplies for direct sputum smear microscopy (DSM) investigations for TB diagnosis and treatment monitoring will be procured. DSM will be performed in accordance with the internationally accepted standard: in all TB suspects for diagnosis (reduced to 2 smears per suspect as per the WHO guidance for quality-assured laboratory networks), at the end of intensive phase, at 5-6 months and after completion of first line treatment (2 smears at each stage), and for treatment monitoring in DR-TB patients (monthly during intensive phase and at least every 3 months during continuation phase (complemented by culturing). The estimated number of DSM tests is about 330,000 for 2.5 years of the duration of the Period 2 renewal request country-wide including penitentiary sector. Proper cold chain conditions are in place as cool boxes for specimens' transportation and refrigerators for peripheral laboratories were supplied during through TGF project in Period 1.

The proposal also includes procurement of reagents and supplies for fluorescent light-emitting diode (LED) microscopy investigations to be performed by the NRL and Kutaisi laboratory, for an estimated total number of tests of 55,500 in Period 2.

Culture investigations (automated MGIT Bactec-960 technique on liquid media will be performed by the NRL and Kutaisi laboratory for diagnosis of TB in all pulmonary patients and for treatment monitoring of PDR patients; the estimated number of tests to be procured is about 28,600 during Years 2-3 (for Year 1, supply of reagents is ensured through FIND / EXPAND-TB). Culturing using manual technique on solid LJ media will be done by these two laboratories for diagnosis of extra-pulmonary TB cases, quality assurance of automated MGIT method and treatment monitoring in M/XDR patients (on average 12 investigations per patient); the estimated number of tests is about 90,000 for Period 2.

To cope with the increasing scope and load of work and in line with the latest international recommendations, the project aims at further supporting the NTP in timely diagnosis of drug-resistant forms of TB. DST to first-line drugs is done by the NRL in all culture-positive patients (both new and previously treated cases) using rapid techniques (automated MGIT method for isolation of strains in liquid culture and molecular line probe assay / polymerase chain reaction (automated LPA Hain method) for MTB identification and detection of resistance to R and H). Given the fact that the supply for 2014 is ensured through EXPAND-TB, the project will support procurement of reagents and supplies for 10,660 first-line DST tests on MGIT and 5,800 LPA Hain tests, covering the needs for the remaining 1.5 years of Period 2 (2015 and the 1st half of 2016). DST to first-line drugs on solid media will be performed for quality assurance of the automated MGIT technique; the number of investigations to be supported by TGF in Period 2 is about 6,600.

This request for renewal seeks support for procurement of equipment and supplies for rapid identification of drug resistance by automated sample processing, DNA amplification and detection of *M. Tuberculosis* and screening for Rifampicin resistance (Xpert MTB/RIF® technology) is planned. This novel technology, allowing identification of MDR-TB patients in just about two hours using sputum as a specimen, was validated by the WHO Strategic Technical Advisory Group on Tuberculosis (STAG) in December 2010 and recommended for use in high DR-TB settings.

Nine 4-module Xpert MTB/RIF instruments will be procured in Year 1 of Period 2 (2014) for 8 regional Laboratory Surveillance Stations (LSSs) in Akhaltsikhe, Ambrolauri, Batumi, Gori, Ozurgeti, Poti, Telavi and Zugdidi and the National Reference Laboratory at NCTBLD in Tbilisi. The LSSs are part of the integrated laboratory network of the National Center of Disease Control and Public Health (NCDCPH) and the hubs for TB laboratory diagnostics for the country. The total calculated need in cartridges (supplies for Xpert tests) for Period 2 is 52,840, which is planned for increasing the coverage of the country-wide needs for Xpert testing from 20% in Year 1 to 80% in Year 3 (the 1st half of 2016). Out of total need above (for instruments and tests), four Xpert MTB/RIF machines and 26,000 of cartridges are procured by EXPAND-TB, while the Period 2 TGF support is sought to cover the remaining needs.

The estimation of quantities of investigations was made on the basis of forecasts of expected patients' numbers and resistance trends. It is planned that with the project support the NTP in attaining and further sustaining the universal coverage of needs with rapid diagnostic tests countrywide including the penitentiary sector. Please refer to the 'Calculations' sheet in the Workplan and Budget file for formulas used and calculation details.

The following table summarizes the extent of coverage of the needs in rapid WHO-recommended TB laboratory diagnostics with TGF support during Period 2.

Table. Total estimated needs in WHO-recommended rapid diagnostic tests, number of investigations included in the Period 2 application and coverage of needs (civilian and penitentiary sectors).

Method	***Total estimated needs***			***No. of investigations included in Period 2 application***			***Coverage of actual needs by TGF in Period 2, %***		
	Year 1	*Year 2*	*Year 3 (6 mon.)*	*Year 1*	*Year 2*	*Year 3 (6 mon.)*	*Year 1*	*Year 2*	*Year 3 (6 mon.)*
Culture (automated MGIT)	20,164	20,117	10,034	18,148	19,111	9,532	90%	95%	95%
DST to 1st line drugs	8,342	8,354	4,184	6,674	7,101	3,556	80%	85%	85%

(automated MGIT)									
MTB identification and H/R resistance (LPA)	5,519	5,524	2,765	3,311	3,867	1,936	60%	70%	70%
Xpert MTB/RIF	44,168	44,048	21,976	8,834	26,429	17,581	20%	60%	80%

As continuation of activities initiated with Round 4 project support, screening for TB among injectable drugs' users (IDUs) by will be supported during SSF Period 2 (administration of questionnaires). The screening by questionnaires takes place at HIV voluntary counseling and testing (VCT) cabinets, and suspected cases are referred to relevant TB institutions for further investigation. Based on the current experience, it is estimated that about 3,500 IDUs will be screened for TB annually.

Support is also sought for screening of prisoners for TB at the time of entry in the detention system. It is estimated that about 1,200 inmates on average need entry screening per month (14,400 per year); this number includes inmates who enter the penitentiary system and those who are transferred from one correctional facility to another. This Activity is complemented by a small operational research study, which will address the effectiveness of entry screening and regular mass screening for TB in prisons, and will aim at collecting additional evidence, inform decisions and facilitate further operational planning of TB control activities, including planning additional investments, in the penitentiary system.

NOTE. Funding for procurement of equipment and supplies for conducting rapid diagnostic tests (automated MGIT and LPA Hain) is available within the EXPAND-TB initiative as per the Memorandum of Understanding (July 2010), until end-2014. Therefore, funding for these activities is included in this application only for the remaining 1.5 years of Period 2 term (2015 and the 1st half of 2016).

Objective 3. To ensure quality treatment of all forms of TB

The Period 2 project aims at sustaining universal access to quality treatment of all forms of TB in Georgia including M/XDR-TB cases. The interventions under this Objective include, mainly, procurement of anti-TB drugs for different categories of patients according to their resistance profile. Additionally, limited support is sought for ensuring proper laboratory and clinical monitoring of effectiveness of TB treatment and for ensuring individual infection control and protection measures for the staff.

Activity No.	*Activity title*	*Service Delivery Area*	*Implementing entity(-ies)*
3.1	First-line anti-TB drugs for drug-sensitive TB cases	Quality treatment of TB cases including M/XDR-TB cases	PR
3.2	First-line and second-line anti-TB drugs for PDR-TB patients	Quality treatment of TB cases including M/XDR-TB cases	PR
3.3	Second- line anti-TB drugs for MDR-TB patients	Quality treatment of TB cases including M/XDR-TB cases	PR
3.4	Second-line and third-line anti-TB drugs for XDR-TB patients	Quality treatment of TB cases including M/XDR-TB cases	PR
3.5	Drugs for management of adverse reactions caused by second-line drugs	Quality treatment of TB cases including M/XDR-	PR

		TB cases	
3.6	DST to second-line drugs for DR-TB patients on treatment	Quality treatment of TB cases including M/XDR-TB cases	PR
3.7	Clinical investigations for DR-TB patients on treatment	Quality treatment of TB cases including M/XDR-TB cases	PR
3.8	Individual measures for infection control: respirators	Quality treatment of TB cases including M/XDR-TB cases	PR
3.9	Support to the Green Light Committee operations	Quality treatment of TB cases including M/XDR-TB cases	PR

The number of patients to be treated during SSF Period 2 was calculated based on recent epidemiological trends and drug resistance profile (see separate sheet in the Workplan Budget file assumptions and calculation details). It is expected that the total number of TB patients to be enrolled in treatment in the country (civilian and penitentiary sectors) during the next 2.5 years will be about 13,800 (all forms). Based on the recent trends, it is also estimated that the prevalence of drug resistance will be stable at 11% among new cases and 32% - among previously treated cases. About 10% of all TB cases will come from the penitentiary sector. The breakdown of cases by treatment category is presented in the table below.

Table. Estimated number of TB patients to be enrolled in treatment during SSF Period 2 project years, by treatment categories

Category	***Year 1 (2014)***	***Year 2 (2015)***	***Year 3 (Jan-Jun 2016)***	***TOTAL 2.5 years***
First-line	4,680	4,665	2,327	11,672
PDR-TB	318	319	160	797
MDR-TB	471	470	234	1,175
XDR-TB	52	52	26	130
TOTAL	**5,521**	**5,506**	**2,747**	**13,774**

First-line anti-TB drugs will be procured through the Global Drug Facility (GDF) using Direct Procurement mechanism. To continue the current practice, the drugs will be procured in the form of 4-FDC blisters. The NTP uses standard treatment regimens recommended by WHO: 2(RHZE) / 4(RH) for drug-sensitive TB cases. The average cost of first-line drugs per patient treatment course for these cases is EUR 24.7 in Year 1, including inspection, insurance, shipment and other costs (about 15% of proper drugs cost) when procuring through GDF based on the current procurement experience. Provisions for the buffer stock are not included in the drugs needs calculations as it is expected to continue from the ongoing purchases. For Period 2 Year 2, a 5% increase in the cost of drugs is added as per GDF projections.

Among PDR-TB cases, the predominant type (over 80%) is resistance to H ± S and/or E, which requires extending the duration of the first-line treatment course to up to 9 months and the addition of a fluoroquinolone to strengthen the regimen for patients with extensive disease. In few instances of other PDR-TB cases (R + other resistance), a treatment regimen, similar to that for MDR-TB patients, of the overall duration of about 20 months, will be administered with first-line and second-line drugs, including an

injectable agent (longer courses in patients with extensive disease). The average cost of drugs for PDR treatment was calculated at EUR 570 per patient (for Year 1) taking into account the ratios of PDR types and the current implementation experience.

The project aims at the extending of the funding support to treatment for M/XDR-TB patients in the civilian sector and in prisons. The Georgian care delivery model (in the civilian sector) is reliant on out-patient treatment under strict supervision and follow-up with direct observation of drug intake and the comprehensive patient support (for the latter, see description of activities under Objective 4 below), through close cooperation between the specialized TB services, PHC providers and the social services with appropriate involvement of the local public authorities and relevant community establishments.

In the civilian sector, in-patient M/XDR-TB is initiated at three sites: the National Center for Tuberculosis and Lung Diseases (NCTBLD) in Tbilisi, Abastumani TB Hospital and Zugdidi TB Dispensary. Based on current practice, it is expected that the average hospital length of stay will not exceed 2-3 months for MDR patients and 6-8 months – for XDR patients, and treatment will continue on out-patient basis. For prisoners, the whole course of treatment is administered at the DR-TB department of the Specialized Medical Institution for Detainees with TB in Ksani and at the Central Prison Hospital (in Tbilisi); continuation of treatment is ensured in the civilian TB services for persons that are discharged from prisons and need to complete the course. The criteria for inclusion / exclusion, treatment regimens, laboratory support, management of side effects, recording and reporting and other details are presented in detail in the recently updated National TB Guidelines and fully correspond to WHO recommendations.

The treatment regimens are applied in accordance with the latest WHO recommendations (e.g. *Guidelines for the programmatic management of drug-resistant tuberculosis' (2011 Update), WHO Geneva*) and other emerging evidence in the field. Standardized Category IV treatment regimen is administered in MDR-TB cases, consisting of: Pyrazinamide (Z), Capreomycin (Cm), Levofloxacin (Lfx) or Moxifloxacin (Mfx), Protionamide (Pto), Cycloserine (Cs) and PASER (PAS). After DST results to second-line drugs become available, the regimen is adjusted; the combinations of drugs depending on the resistance pattern are given in the table below.

Table. Treatment regimens for MDR-TB patients depending on the resistance pattern

Resistance pattern	Treatment regimen
HR, HRE	Z, Cm, Lfx (Mfx), Pto, Cs, PAS
HREZ	Cm, Lfx (Mfx), Pto, Cs, PAS
HRS, HRES, HREZS	Cm, Lfx (Mfx), Pto, Cs, PAS, (±Z)

Taking into account the current resistance profile, which is similar across the regions, the majority of patients receive standardized treatment regimen as presented above. Moxifloxacin (Mfx) is used instead of Lfx in up to 20% of cases with extensive disease and when resistance to older generation fluoroquinolones is documented. The use of other drugs (third-line agents) is considered in the presence of resistance to second-line drugs. Based on the current implementation experience and taking account of the latest trends in drug pricing, the average cost of second-line drugs per full treatment course for MDR-TB patients for Period 2 is expected to be about EUR 3,170 in Year 1 (including delivery and all other associated costs).

This proposal includes support to treatment of 130 XDR-TB patients; in XDR-TB cases, the drugs to be administered are: Z, Cm, Mfx, Eto, Cs, PAS, Amoxicillin / Clavulanate (Amx/Clv), Clofazimine (Cfz), and Clarithromycin (Clr). The average cost of second-line and third-line drugs per full treatment course for XDR-TB patients is EUR 6,160 (including delivery and other associated costs).

Support to laboratory investigations for Category IV patients on treatment is included; culture investigations will be performed in all M/XDR-TB patients on treatment (monthly during intensive phase and every 3 months during continuation phase of treatment). DST to second-line drugs will be done in all cases at the beginning of treatment and repeated in patients with no improvement / culture conversion; the estimated number of investigations to be carried out during Period 2 is 5,185. Continuation of funding is also sought for procurement of pharmaceuticals for management of adverse reactions of second-line drugs and supplies for necessary clinical investigations for M/XDR-TB patients on treatment. Procurement of respirators for TB service staff at high risk of infection (in-patient DR-TB departments, reference laboratories) is also included under this component.

Support to the GLC operations is included in the proposal as per the Global Fund requirements (equivalent to USD 50,000 per year).

Objective 4. To ensure adherence to TB treatment by intensive patient support and follow up

The project places a special emphasis on strengthening adherence to TB treatment as the key means to halt the spread and amplification of drug resistance. The task is especially difficult for M/XDR-TB patients, who have to undergo a complex and lengthy (up to 2 years or more in case of XDR) course of therapy; however ensuring patients' adherence to treatment and full direct observation of drug intake during are the fundamental requirements for effective management of M/XDR-TB cases. A specific important challenge remains to ensure continuation of treatment among ex-prisoners with TB who are discharged from the penitentiaries and need to complete treatment in the civilian sector.

Given the current funding limitations from TGF, the scope of interventions for Period 2 has been reduced to the support to incentives / enablers and operational expenses of the patient support program.

Activity No.	*Activity title*	*Service Delivery Area*	*Implementing entity(-ies)*
4.1	Support to treatment adherence: incentives for TB patients (first-line and PDR-TB regimens)	Patient support	PR
4.2	Support to treatment adherence: incentives for M/XDR-TB patients	Patient support	PR
4.3	Support to treatment adherence / DOT: transportation of visiting DOT supporters	Patient support	PR
4.4	Support to treatment adherence / DOT: transportation of patients to DOT centers	Patient support	SR
4.5	Vehicles for intensive patient support program	Patient support	SR
4.6	Operational expenses - patient support component: Monitoring Officers	Patient support	SR
4.7	Operational expenses - patient support component: Monitoring visits to TB and PHC facilities in the regions	Patient support	SR, PR
4.8	Support to treatment adherence / DOT: incentives for PHC nurses	Patient support	SR

The renewal application includes seeks further support to the implementation of the intensive patient support and follow-up program. This program is implemented by the NTP in collaboration with local public authorities and/or other organizations selected by the Principal Recipient on competitive basis. The program aims at improving treatment outcomes of patients with all forms of TB including those who undergo the full course of treatment in prisons and in those who need to continue it in the civilian sector after discharge. As mentioned above, in Georgia the NTP expands the TB treatment service delivery model based on ambulatory (out-patient) care and therefore needs to be supported by a complex of measures

including psychosocial assistance, patient education, incentives and enablers. Intensive and regular follow-up of patients will be ensured through a close collaboration between TB and PHC services, strengthening links between the penitentiary and civilian sector institutions as well as between the governmental structures and civil society.

While a number of activities had to be reduced for Period 2 due to the funding restrictions from the Global Fund, the following activities will be implemented under this component in Period 2. TB patients (receiving both first-line and second-line regimens) will receive incentives (vouchers for food parcels or monetary incentives) during out-patient treatment (about EUR 9, proper cost). Patients on first-line treatment and PDR-TB patients will receive incentives monthly (during 5-6 months of out-patient treatment) and those with M/XDR-TB – weekly (during 14-16 months). Based on the current implementation experience, it is expected that 70-75% of all TB patients on treatment will need to be provided with incentives to increase adherence. The NTP Central Unit in cooperation with the involved local NGOs and the Medical Division of the MCLA Penitentiary Department will ensure reliable mechanisms for effective and efficient delivery, distribution, recording and reporting, including proper coverage of ex-prisoners with TB after release.

Enablers for DOT supporters will be provided in the form of reimbursement of transportation expenses incurred to deliver drugs to the patients' domiciles. The current practice shows that about 20% of TB patients (including those with M/XDR-TB) will require to be visited at home, and about half of M/XDR TB patients need to cover substantial distances to come to a TB facility or PHC provider during out-patient treatment to take medications; their transportation expenses will be reimbursed to ensure adherence. In addition, the project will provide enablers to 150 PHC nurses to ensure the 6-days-per-week intake of drugs by M/XDR patients under full DOT (including Saturdays).

The application includes support to meeting relevant operational expenses such as transportation costs, involvement of the Monitoring Officers for the patient support program and monitoring visits by the NTP Central Unit to the regions with the purpose of monitoring, evaluation and further operational planning of interventions within the patient support program.

A detailed description of the proposed project activities is presented in the Workplan and Budget file (Annex 02 to this Proposal Form).

* * *

INDICATORS AND TARGETS

The Period 2 Performance Framework includes the following indicators for impact, outcome and output / processes:

Impact Indicator:

- ***TB mortality rate:*** number of deaths attributable to TB (all forms) registered in a specified period per 100,000 population

Outcome Indicators:

- ***Notification rate of all forms of TB cases***: all TB patients (including new smear positive, new smear negative, extrapulmonary and relapses), registered during a specified period and notified to the national health authorities (number per year per 100,000 population);
- ***Treatment success rate for new smear positive TB*** cases: new smear-positive TB cases successfully treated (cured + treatment completed) to the total number of new smear-positive TB cases treated in a given year (percentage);
- ***Treatment success rate of MDR-TB patients***: patients who were cured or completed Category IV

treatment (% of the total number of patients in the same registration cohort).

Output / coverage indicators:

- Number and percentage of TB facilities that provide excellent/good performance during supervision visits;
- Number and percentage of penitentiary facilities with appropriate practices for TB detection and DOT, as documented during supervision visits;
- Number and percentage of TB patients with a sputum culture performed at diagnosis (automated MGIT on liquid media);
- Number and percentage of TB patients with a DST performed for 1st line drugs at diagnosis (automated MGIT on liquid media);
- Percent of prisoners provided with entry screening for TB;
- Number of IDUs screened for TB;
- Number and percentage of TB patients tested for HIV (VCT / DCT and clinical aspects of HIV/AIDS);
- Number of all TB patients (including new smear positive, new smear negative, extra pulmonary and relapse) registered during a specified period and notified to the national health authorities;
- New smear-positive TB cases successfully treated (cured + treatment completed) to the total number of new smear-positive TB cases treated in a given year (number and percentage);
- New smear-positive TB cases among prisoners successfully treated (cured + treatment completed) to the total number of new smear-positive TB cases treated in prisons in a given year (number and percentage);
- Number of TB patients enrolled on standardized 1st line treatment in the specified calendar year;
- Laboratory-confirmed X/MDR-TB patients enrolled on second line anti-TB treatment in the specified calendar year;
- Number of and percentage of TB patients on first-line treatment receiving incentives (food parcels) for better adherence to treatment during out-patient phase;
- Number and percentage of M/XDR-TB patients on treatment receiving patient support (incentives) for better adherence to treatment.

The indicators and targets for Period 2 are presented in detail in the Performance Framework (Annex 01 to this Application Form).

Based on the identified gaps and challenges under section 5.1.1 “Programmatic Achievements” please summarize the key M&E systems strengthening activities, including any planned operations research or evaluations to be undertaken during the next Phase/Implementation Period. Does the CCM propose reallocation of resources to support the above stated M&E strengthening initiatives? If yes, comment on the budgetary and programmatic implications, if any, on the overall request.

The NTP pays priority attention to supervision, monitoring and evaluation activities as the key component of the program management. In this regard, and in the face of continuing difficulties to take over such interventions from the domestic funding sources due to the current limitations in budget classifications and allocation lines, the Period 2 proposal aims to uphold in full the NTP supervision and M&E activities through supporting costs of central supervision to the regions, regional supervision (to service delivery sites in

peripheral TB sites and PHC facilities), regular program supervision and monitoring visits in the penitentiary system, as well as the local experts' support to data management and maintenance of the national electronic TB database (please refer for detail to description of Activities 1.3-1.11 above in section 6.1 and Workplan and Budget file). No additional towards these activities were made during the Period 2 planning, although they have all been maintained despite the need of budget reduction for Period 2 as mandated by the Global Fund.

The budget share of activities assigned to 'Monitoring and Evaluation' budget category for Period 2 is 2.3%, which is considered fully sufficient taking into account the total budget structure, which to the majority extent is shaped by procurement needs (mainly TB drugs but also consumables for laboratory diagnostics and incentives and enablers for patient support).

6.1.2 Pharmaceutical and Health Product Management (if applicable)

Please complete this section only if procurement of Pharmaceutical and Health Products is planned in the next Phase/Implementation Period. Otherwise, continue to section 6.2 "Financial Proposal".

Based on the key risks and challenges in the PHPM area in the current Phase/Implementation Period as identified under section 5.1.2 "Grant/SSF Management", please summarize the measures and/or mechanisms that have been put in place or are proposed in the PSM plan (or the Country Profile if this is already in place) for the next Phase/Implementation Period. Please include an assessment of the risk of treatment interruptions at the health facilities in the next Phase/Implementation Period and a list of the possible underlying causes related to PHPM activities that may have a negative impact on the continuous availability/access to key health products (such as stock outs, diversion and theft of health products).

The management of TB medicines and health products will continue to be performed according to the overall MoLHSA regulations, national TB guidelines and the project PSM Plan. Up to date, the program has accumulated substantial experiences in procurement and supply management of drugs and health products, which is deemed to safeguard from the risk of treatment interruptions, stock outs, diverting health products of any other substantial problems related to supply management. The Procurement Plan for Period 2 is attached in Annex 03.

The Principal Recipient will bear the overall responsibility for customs clearance, storage and inventory management of drugs and other health commodities and products supplied under the Global Fund financing. Port clearance is conducted by the PR on the basis of the authorization from the Government confirming humanitarian (non-commercial) purpose of goods, registration certificates for the drugs in the country of manufacturing and the country of destination and quality certificates for each batch of drugs and health products.

After the necessary port and customs formalities are completed, the drugs are delivered to the storage facility of the National Centre for TB and Lung Diseases (NCTBLD) in Tbilisi, where first-line drugs and second-line drugs are stored before being distributed to the treatment sites. The storage facility is located at the newly constructed NCTBLD building and was furbished and equipped with all necessary features for adequate storage conditions of pharmaceuticals and health products. There is sufficient space to store buffer stock volumes as well. The storage area at NCTBLD is about 200 m^2. The storage capacities at the regional level is also sufficient; the storage areas have been refurbished and equipped with cold chain equipment with the previous TGF support.

The NTP ensures appropriate buffer stock for first-line drugs and second-line drugs used for TB treatment at the central, regional and facility levels; accordingly, buffer stock is included in the annual Direct Procurement Orders to GDF under the project.

First expiry / first out (FEFO) method is applied for inventory management. There is an established system of regular stock taking and reporting that enables the program management to plan distribution, utilize the

products and avoid expiry.

The central store presents quarterly the report on the drugs balance, which includes the following information: name of drugs; strength; packaging; quantity; unit price and total cost; batch number and date of expiry; manufacturer's name and country of origin. The report is accompanied by the list of distribution sites and invoices / receipts for delivered drugs.

The in-patient treatment sites for M/XDR-TB patients have sufficient capacity and storage conditions for second-line TB drugs and other supplies. Regarding out-patient phase of treatment, TB service and PHC facilities are equipped with refrigerators to ensure cold chain conditions as well.

6.2 Financial Proposal

6.2.1 Resources available to finance the grant/SSF after cut-off date

Please note that the financial information required for this section is in the Financial template provided with the CCM Invitation package* Renewals_Financial Template_FinancialRequest_Resources-available *– the CCM must paste a screenshot of the information to this section in the CCM Request template (Word document) by selecting the relevant cells in Excel and using Paste option in Word to insert as a picture. Financial Request must be filled out in the Excel file only. Do not edit the table after pasting it here!

Please note that TRP Clarified Amount must take into account Global Fund Board mandated 90% adjustment

		Year 1 (2014)	Year 2 (2015)	Year 3 (2016)	Total
a. TRP clarified amount allocated to PR		€ 5,003,021.00	€ 5,383,229.00	€ 5,330,719.00	15716969
b. Any Board mandated adjustments		€ (500,302.10)	€ (538,322.90)	€ (533,071.90)	-1571696.9
c. Adjustment +/(-) for (borrowing) and/or staggered commitments not yet committed		€ (3,449,059.46)			
d. Adjusted TRP clarified amount		1053659.44	4844906.1	4797647.1	10696212.64
e. CCM reallocations +/(-) (implementation arrangements)					0
f. Adjusted TRP clarified amount after CCM reallocations		1053659.44	4844906.1	4797647.1	10696212.64
g. + Undisbursed amount at cut-off date					€ 5,738,047.88
h. + Cash at cut-off date					901479.19
i. =Total Resources available (after cut-off date for the next Phase/Implementation Period)					17335739.71

6.2.2 Summary funding request from cut-off date to end of next Phase/Implementation Period

Please note that the financial information required for this section is in the Financial template provided with the CCM Invitation package* Renewals_Financial Template_FinancialRequest_FundingRequest *– the CCM must paste a screenshot of the information to this section in the CCM Request template (Word document) by selecting the relevant cells in Excel and using Paste option in Word to insert as a picture. Financial Request must be filled out in the Excel file only. Do not edit the table after pasting it here!

	Year W after cut-off date	Year X	Year Y	Year Z	Total
a. Total Budget required (after cut-off date for the next Phase/Implementation Period)	€ 4,667,063.39	€ 3,997,742.26	€ 4,419,924.67	€ 2,270,129.70	15354860.02
b. - Undisbursed amount at cut-off date					5738047.884
c. - Cash at cut-off date					901479.19
d. = Incremental amount requested					8715332.943
e. % of adjusted TRP clarified amount (cannot exceed 100% of adjusted TRP clarified amount)					81%

6.2.3 CCM Budget Request for the next Phase/Implementation Period

Please explain how lessons learned from the current Phase/Implementation Period have been factored into this funding request (e.g. budget reallocations, under-spending leading to more realistic budget estimates, reflection of price changes).

The PR carried out a detailed and comprehensive review of the workplan budget and made relevant adjustments in the Period 2 request. These adjustments related to unit prices (i.e. latest updated prices for medicines, health products as well as patient support packages, including PSM costs based on the current implementation experience), as well as to the number of units taking into account the revised calculation of needs in TB diagnosis and treatment (i.e. updated estimates for TB patients to be treated according to resistance profile, on the basis of the latest epidemiological development, see 'Calculations' sheet in the Workplan and Budget file in Annex 02).

The same approach has been applied to budgeting of needs for other than MPP and HPE expenditures, in particular those related to supervision and monitoring visits and other local costs which involve local prices like fuel, etc.

Detailed budget assumptions are given in the Workplan and Budget file.

Does the budget request reflect the average programmatic performance in the current Phase/Implementation Period? If not, please provide an explanation.

Yes, the Period 2 budget amount is requested taking into account the initial Board-mandated adjustment (10% reduction) and, further, in accordance to the programmatic performance and is based on the recent clarification with TGF Secretariat on the amount available for Periodic Review (last communication with the FPM, Tsovinar Sakanyan, on 14 March 2013).

6.3 Compliance with Focus of Proposal Requirement

This question is not applicable for Low Income Countries.

Describe whether the focus of proposal requirement has been met per the threshold based on the income classification for the country.

According to the invitation letter to CCM and based on the Global Fund eligibility criteria, *"Georgia is classified as an Upper Low-Middle Income Country with a severe burden in tuberculosis. This means that Georgia remains eligible to apply for Renewals. Based on the above classification, the CCM Request for Renewal must include the following Focus of Proposal and Counterpart Financing requirements:*

- *50% focus of proposal on specific populations / interventions, and*
- *40% of counterpart financing as a minimum threshold."*

The CCM deems that the requirements above are met for the Period 2 proposal. In terms of financial size of the request (and, in many instances, in terms of the programmatic effort), a substantial share of interventions are 'specific interventions' targeting DR-TB patients which are seen as the especially vulnerable group with limited access to services without TGF support. The funding contribution to these interventions (diagnosis, treatment, patient support), including those for prisoners, PLWH and IDUs, accounts for about 70% of the total funding request, and at least half of the remaining one can be attributed to these populations as well.

Regarding counterpart financing, the share is at least 55% as presented in the Financial Gap Analysis sheet of the Renewals Financial Template (Annex 04)

Supporting Information (to be submitted with the CCM Request)

Mandatory documents

1. **Minutes of the CCM meetings** related to discussion on the CCM Request (including important elements such as reprogramming and/or changes to implementation arrangements, counterpart financing and focus of proposal);
2. **Performance Framework** for the next Phase/Implementation Period consolidated for all grant/SSFs (Template provided);
3. **M&E Plan** for the next Phase/Implementation Period (*if available and not previously submitted*). A grant/SSF specific M&E Plan may be submitted if a National Plan is not available;
4. **Procurement and Supply Management (PSM) Plan** (guidelines provided) (or a Procurement Plan, in case of a Country Profile) for the next Phase/Implementation Period per grant/SSF, if applicable (Template provided);
5. **Financial template** including:
    a) **Financial Gap Analysis and Counterpart Financing** (Template provided);
    b) **CCM Summary Budget Request** for the next Phase/Implementation Period consolidated for all grant/SSFs (Template provided);
    c) **Financial request** for the next Phase/Implementation Period per grant/SSFs (Template provided);
    d) **CCM analysis of the request versus original** budget consolidated for all grant/SSFs (Template provided);
    e) **Reallocation of original budget amount between PRs**, if applicable (Template provided);
6. **Detailed budget and workplan** for the next Phase/Implementation Period per grant/SSF; and
7. **List of liabilities at cut-off date** per grant/SSF.

Supporting documents

1. **National Program Review/Evaluation** report including assessment of programmatic Impact/Outcome[4]; and/or
2. Revised **Program Implementation strategy** (if applicable/necessary) and/or
3. Any other documents considered essential to the Global Fund Secretariat review of the Request, such as a report or study on Equity, Value for Money or Aid Effectiveness, if available.

[4] The Review/Evaluation report will be mandatory from 2012 for Periodic Reviews only.

LIST OF ANNEXES

Annex No.	Annex name
1	Annex 01. Performance Framework
2	Annex 02. Workplan and Budget
3	Annex 03. Renewals Procurement Plan
4	Annex 04. Renewals Financial Template
5	Annex 05. List of liabilities
6	Annex 06. CCM oversight plan
7	Annex 07. CCM Order May 2007 and June 2012
8	Annex 08. Minutes of the 62nd CCM meeting
9	Annex 09. Minutes of the 63nd CCM meeting
10	Annex 10. Minutes of TB working group meetings
11	Annex 11. NSP Georgia 2013-2015
12	Annex 12. MoLHSA letter regarding health sector and TB funding
13	Annex 13. GDF Monitoring Mission Report June 2012
14	Annex 14. GLC Europe Monitoring Mission Report June 2012
15	Annex 15. Improving Quality of TB services under the New Service Delivery mechanism in Georgia February 2012
16	Annex 16. CCM Approval of Request for Renewal with signatures

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