The Global Fund
To Fight AIDS, Tuberculosis and Malaria

STANDARD CONCEPT NOTE

Investing for impact against HIV, tuberculosis or malaria

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

A concept note is divided into the following sections:

Section 1: A description of the country's epidemiological situation, including health systems and barriers to access, as well as the national response.

Section 2: Information on the national funding landscape and sustainability.

Section 3: A funding request to the Global Fund, including a programmatic gap analysis, rationale and description, and modular template.

Section 4: Implementation arrangements and risk assessment.

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

SUMMARY INFORMATION			
Applicant Information			
Country	**Georgia**	**Component**	**Choose an item.**
Funding Request Start Date	**1 January 2016**	**Funding Request End Date**	**31 December 2018**
Principal Recipient(s)	**The National Centre for Disease Control and Public Health (NCDC)**		

Funding Request Summary Table

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

SECTION 1: COUNTRY CONTEXT

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

1.1 Country Disease, Health and Community Systems Context

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

a. The current and evolving epidemiology of the disease(s) and any significant geographic variations in disease risk or prevalence.

b. Key populations that may have disproportionately low access to prevention and treatment services (and for HIV and TB, the availability of care and support services), and the contributing factors to this inequality.

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

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

2-4 PAGES SUGGESTED

a). The HIV epidemic remains a significant public health concern in Georgia. Since the detection of the first case of HIV in 1989 the rate of new HIV diagnoses in the country has been increasing steadily and reached 10.9 per 100,000 in 2013.[1] The latest estimate (2014) of the number of people living with HIV (PLWH) in Georgia is 6,800,[i] and an estimated 45% of these people are not aware of their status. 4,695 PLWH were officially registered by the end of 2014. Although the infection is mainly located in male population (69% of total reported cases), the proportion of women affected by HIV has been increasing and reached 31% in 2014. The latest available evidence indicates that the HIV epidemic in Georgia remains largely concentrated among the key affected populations (KAP) – men who have sex with men (MSM), people who inject drugs (PWID), and sex workers (SW). Despite a low HIV prevalence (0.07%) in the general population, Georgia faces a significant risk of an expanding epidemic due to widespread high-risk practices, growing HIV prevalence among PWID and MSM, as well as poor detection of HIV cases, which in turn leads to late presentation for care and treatment and adversely affects the treatment outcomes for marginalized populations.

Georgian resort areas adjacent to the Black Sea (Batumi) and those closer to the frozen conflict areas (Zugdidi on the border with the frozen conflict region of Abkhazia) have been found more affected by HIV. This may be explained by greater HIV prevalence in these regions combined with the mobility of the key populations,[ii] higher prevalence of drug use and sex work in these regions. Thus, significantly higher HIV prevalence rates among PWID in Zugdidi (9.1%) and Batumi (5.6%) compared to the national estimated average of 3% were found by 2012 IBBS study among this key population.[5]

2014 study estimated the size of MSM population in Georgia at 17,200.[2] A growing concern is the increasing HIV prevalence in this group from 7% in 2010 to 13% in 2012. MSM have been shown to have the highest rates of recent HIV infection.[3] The share of

i. Spectrum EPP (version 5.03) 2014 data provided by the Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC).
ii. Almost half of PWIDs in Zugdidi (48.3%) and Batumi (47.1%) reported injecting drugs outside the country within the last 12 months, main countries being Turkey, Ukraine and Russia.

transmission attributed to unprotected sex between men increased and reached 9.3% in 2012 and 13% in 2013. According to the 2012 IBBSS findings no more than 67% of MSM used condom at last anal intercourse, 17.4% of MSM were involved in group sexual practices and 69.3% had occasional male partner last year. The same survey reported Syphilis in 32.9% of the target group.[16] The recent increase in HIV prevalence among MSM as well as continuing high-risk practices such as frequent change of partners of both sexes, insufficient use of condoms and involvement in group sexual practices, call for significant strengthening of interventions targeting this key population. In 2012 IBBSS 51.4% of MSM reported having female partner in the last 12 months.[16] High prevalence of sex with female partners among the MSM raises concerns about their bridging role in HIV transmission to general population.

The estimated number of PWID in Georgia is 45,000.[4] Estimated HIV prevalence among PWID ranges from 0.4% to 9.1% across geographic areas covered by integrated bio-behavioral surveillance studies (IBBSS).[5] The share of parenteral transmission associated with injecting drug use (IDU) in the newly registered HIV cases has decreased from 43% in 2012 to 35% in 2013 while heterosexual transmission increased from 45% in 2012 to 49% in 2013. Both these trends indicate the growing spread of HIV among the sexual partners of PWID.

2014 IBBS study conducted in Tbilisi and Batumi has found HIV Prevalence of 0.7% among FSWs. The study has produced an estimate of SW population size of 6,525 people.[6] This figure combines various segments of SW population with varying service needs, which should be addressed with tailored service combinations. IBBSS findings highlight fluctuations in condom use rates (with 90% and 98.8% of FSW reporting use of condom at last sex with client and 67% and 90% of FSW consistently using condoms with clients in Batumi and Tbilisi respectively).[7] This indicates the need for continuous outreach and delivery of prevention information and services. IBBSS has also found relatively low turnover of FSW with almost 70% of the sample having already participated in at least one of the previous IBBS studies. The street-based FSW population is ageing, with the mean number of years working in sex business reaching 10 years in Tbilisi and 8.5 years in Batumi. It is likely that entering sex business is becoming less common among young women and those who do are involved in higher segment of sex business associated with upmarket establishments.

A late case detection results in treatment initiation at late stages of the disease and poses significant challenges to the National HIV response in Georgia. The share of newly diagnosed patients who entered HIV care with CD4 cell count <350 cells/mm^3 remained above 70% during 2011 -2013 peaking at 74% in 2012 and then decreasing to 62% in 2014.[8] This is one of the highest rates in WHO European Region and has detrimental effect on survival, resulting in almost 90% increased risk of short-term mortality. Analysis of engagement in the HIV care continuum in Georgia shows that the major gap occurs at the stage of HIV testing/diagnosis. Out of the estimated 6,800 persons living with HIV almost half is not yet diagnosed. This gap primarily is the result of low HIV testing coverage of KAPs and missed opportunities to test for HIV in the clinical settings.[1]

HIV prevalence among TB patients has been relatively low at about 2% over the last several years (2.1% in 2013), the second lowest in EECA region (after Azerbaijan).[9] However, the high prevalence of MDR Tuberculosis (11% among new and 38% among retreatment cases were confirmed with MDR TB in 2013[9]) poses a significant threat of drug resistant tuberculosis to PLWH. The proportion of HIV positive individuals among MDR TB patients is on the rise and has increased from 3.9% in 2010 to 5.3% in 2013.[10] Active TB is found in more than 16% of people newly diagnosed with HIV, and is the leading cause of death among PLWH (21.3% overall since the start of HIV registration in 1989).[11]

Management of HIV epidemic is further complicated by high prevalence of HCV in this group. Georgia is among the countries with high HCV Prevalence in the World by WHO. The HCV prevalence among HIV infected people is reported as 48,6% and as 73,4% among HIV infected IDUs.[12]

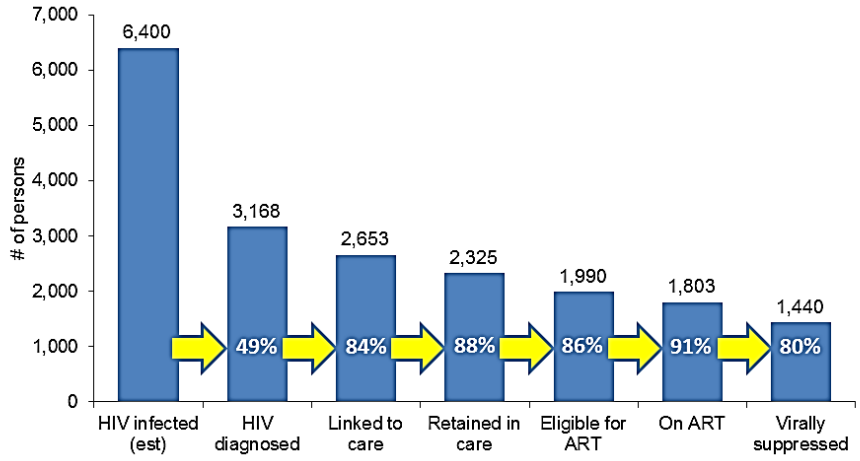
b). Universal access to ART coupled with effective clinical monitoring and adherence support allowed for substantial reduction in AIDS related mortality. There was more than a 3-fold decrease in AIDS-related mortality from 6.49 deaths per 100 PY in 2004 to 2.05 deaths per 100 PY in 2012.[11] However, despite the overall high engagement, loss of patients occurs at each stage of HIV care continuum (see figure 1). Factors associated with disengagement from care include history of IDU. Compared to non-IDUs, persons with history of IDU are less likely to initiate care (88% vs. 80%), to remain in care (79% vs. 67%) and to achieve viral suppression (42% vs. 36%).[13]

PWID require tailored support services in order to facilitate their progression along the continuum of care and improve the treatment outcomes. Access to opioid substitution therapy (OST) and other forms of drug dependency treatment and rehabilitation remains insufficient. By the end of 2014, the capacity of OST system was only sufficient for simultaneous treatment of 2,600 patients (less than 6% of the estimated number of PWID). There are 18 OST sites in the civil sector and two sites in the penitentiary system. The cumulative number of the patients on OST during 2013 was 4613, 4261 of them were treated in civil sector and 352 in penitentiary system. Issues with service organization and quality have affected the retention rates.

As of December 2014, there were six providers (in public and private sector) that offered inpatient abstinence oriented treatment with total bed capacity of up to 80 beds. Five of these clinics are located in Tbilisi and one in Batumi. Some rehabilitation and re-socialization services for former prisoners and persons under probation, with specific focus on people who use drugs (PWUDs) are provided in a form of Social Bureaus, based on case management methodology. One Bureau is functioning in Tbilisi and three Bureaus – in Batumi, Kutaisi and Zugdidi. These services have secured funding by the end of 2015.

Widespread stigma towards KAPs as well as PLWH seriously limits availability and access to community based and clinical care and support for PLWH.[14] High levels of stigma associated with low professional knowledge among health care workers who have HIV associated professional risks,[15] as well as cases of refusal to provide medical services to PLWH have been documented.

Figure 1: Engagement in HIV Care Continuum in Georgia, as of 31 December 2013



Despite the recent successes in reaching certain more hidden sub-populations of KAP (women who inject drugs) certain sub-groups such as younger MSM, remain underserved.[16] Little is known about male sex work in Georgia. In the latest 2012 IBBSS among MSM engagement in commercial sex (having received material remuneration for sex) was reported by 12.4% of respondents. The decreased proportion of SW among MSM compared to 2010 study (28.9%) may be explained by increased migration of male sex workers to neighboring countries. This phenomenon is based on anecdotal evidence and needs to be investigated in the next IBBSS round.[16] Further analysis is required in order to design services addressing the needs of male sex workers.

Special focus on younger segments of MSM and other KAPs, as well as better

segmentation of the target audience and tailoring the outreach strategies and service combinations to the needs of specific sub-populations are required.

c) 2009 law on HIV has improved the overall legal environment for national response, but has not addressed regulatory barriers for drug users and prisoners stemming from criminal code of the country. Strict drug law environment represents a significant obstacle for the effective work of HIV prevention/harm reduction services for PWID. 2012 IBBSS indicated that drug consumption has become even more hidden with the share of PWID who inject in the streets dropping from 15.2% in 2009 to 2.2% in 2012. Continued criminalization of drug consumption drives PWID underground and considerably restricts their access to vital HIV prevention and care services, contributes to low detection of HIV and late presentation for treatment.[5]

As mentioned earlier, an important factor limiting the effectiveness of the national response to HIV is the widespread stigma towards PLWH and KAPs among the general public as well as relevant professionals including health care workers. Continued privatization of the health sector results in limited control of the government over the activities of private clinics, where there is resistance to provide services to HIV-positive patients.

HIV prevention services require further adjustments to ensure their gender sensitivity. The development of women friendly needle and syringe programs needs to continue and OST services should be tailored to accommodate for specific needs of women and attract a larger proportion of female clients.

d). This section describes the health and community systems and explains their influence of HIV response under the WHO main Health Systems building blocks:

Leadership and governance: Improving access to quality health services is a top priority declared by the Government of Georgia (GoG). In 2013, the political commitment to universal health coverage was translated into the universal health program with threefold increased health budget (from 1.7% to 2.7% of GDP in 2013). This development significantly reduced financial access barriers to health services for the entire population. By November 2014 the whole population of the country has been covered by different schemes: 535,505 by private or corporate insurance and the rest by Universal Healthcare program.[iii]

The Georgia Healthcare System State Concept for 2014-2020,[17] which defines key directions of the development of the country's health system recognizes elimination of inequality in access to medical services as one of the core values of the state policy. The concept aims at a stepwise increase in the scope and quality of medical services offered to the Georgian citizens. Improved access to pharmaceuticals to ensure adequate management of common medical conditions leading to mortality and disability is among priorities. The healthcare concept prioritizes improvements in prevention and management of communicable diseases including the reduction in late detection of HIV infection, and the reduction of HIV/TB co-infection burden.

Financing: Over the last several years the share of domestic funding allocated to the HIV response in Georgia has been steadily increasing from 12% in 2008 to 48% in 2014. The Global Fund remained the most significant funding source and provided 34.6% of the overall funding in 2014. The contribution of other international sources has been decreasing and reached 7% in 2014. The future period will be marked by a further decrease of external contributions, which should be balanced by a significant increase in state budget allocation for HIV. A gradual transfer of priority programs funded by external sources (including HIV and TB) to state financing will be achieved through development of financial sustainability plans, detailed allocation of financial obligations, and reflection of these obligations in the financial commitments of the government. The funds required to maintain and expand the delivery of essential services are reflected in the Medium Term Expenditure Framework (MTEF) for 2016-2018. Furthermore, GoG resolution of June 17,

[iii] Ministry of Labor, Health and Social Affairs

2014[18] highlights the need for improved efficiency of State funding and integration of vertical state programs (such as disease oriented programs: Diabetes, TB, HIV etc.) into the Universal Health Program.

Service delivery: The national response to HIV is delivered through joint efforts of the public, private and non-governmental sectors. As a result of recent investments (public, donor and private), the service delivery capacity has increased significantly, however serious challenges remain with access to health services of marginalized populations and PLWH with documented cases of refusal to provide medical care to HIV positive people.

As of December 2014 there were 37 voluntary counseling and testing (VCT) sites in Georgia. Under the Global Fund supported program, 10 VCT sites operate specifically for MSM and sex workers. These sites are located in Tbilisi, Batumi, Kutaisi, Zugdidi and Telavi. 14 harm reduction sites operate with 14 VCT centers in 11 cities of the country offering services to PWIDs. 13 VCT sites operate in the 13 out of 14 detention facilities. More effective utilization of these facilities should be combined with extensive use of mobile VCT units, as well as with introduction of provider initiated testing in other health care facilities in order to improve HIV detection.

The delivery of clinical HIV care is managed by the infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC), which is country's referral institution for HIV diagnosis, treatment and care. Specific clinical services are provided by the dedicated departments of the infectious diseases centers/hospitals in Tbilisi, Kutaisi, Batumi, Zugdidi and Sukhumi. These facilities include AIDS inpatient departments with 39 beds (18 in Tbilisi and the rest in four regional sites) and outpatient departments. ART-specific services include adherence monitoring and support services, including clinic-based services and operation of mobile units that provide home-based services. All HIV treatment sites except for Sukhumi run mobile units.

HIV-related key laboratory capacities are integrated within the overall laboratory facilities of respective centers and provide all necessary services. CD4 cell count monitoring is implemented in all facilities countrywide, while molecular virology assays, including HIV viral load and drug resistance testing, as well as PCR-based HCV analyses are performed at the IDACIRC in Tbilisi. Operation of Sukhumi AIDS Centre is facilitated by the "Zurab Danelia Union Tanadgoma", that oversees program implementation and ensures the delivery of medicines and other health products.

Support and care services operate countrywide in the same locations as clinical centers except of Sukhumi. Non-governmental, community-based network of HIV self-support centers employs 14 counselors and 2 psychologists who provide online, hotline and face-to-face consultations to people living with HIV and their family members. One palliative care mobile unit consisting of physician and a nurse operate in each above-mentioned city.

Several community-based organizations (CBOs) are involved in the delivery of HIV detection, prevention and care services. Stronger focus and greater role of CBOs is expected in the areas of HIV detection among KAPs, facilitated progression of PLWH to care and treatment and delivery of required psychosocial support services, design and implementation of stigma reduction measures, as well as more focused policy development efforts to bring the existing legislation, regulations and policies in line with the effective public health response to HIV and related social challenges.

Health workforce delivering HIV preventive and treatment services include professionals specialized in HIV treatment and diagnostics. The care is specialists driven with limited involvement of primary care providers. This can be explained by a lack of HIV related competencies as well as extremely high level of stigma. The latter prevents PHC providers to offer services that are patient friendly and gain the trust of those infected with or at high risk of HIV. Greater involvement of primary care providers is required to ensure timely referral to HIV diagnoses and provide adequate management of noninfectious comorbid conditions in HIV.

Medical Products and technologies: National HIV Program in Georgia provides equitable access to essential medical products, vaccines and technologies of assured

quality, safety, and efficacy. Use of medical products and technologies are governed by national protocols, which are based on latest WHO and other recognized guidelines. Selection of treatment regimens is based on public health approach outlined in 2013 WHO guidelines, and treatment monitoring approaches include monitoring of viral response every 6 months and immune status every 6-to-12 months.

Information and research: HIV stakeholders in Georgia have access to strategic information that is essential for planning and implementation of effective responses. NCDC coordinates activities for HIV programs monitoring and evaluation. Operational studies and surveillance activities are regularly implemented to identify needs of KAPs and to inform decision making on HIV related issues. These activities are largely externally funded and will require increasing support from domestic sources to sustain after the expected donor phase out.

1.2 National Disease Strategic Plans

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

a. The key goals, objectives and priority program areas.

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

c. Limitations to implementation and any lessons learned that will inform future implementation. In particular, highlight how the inequalities and key constraints described in question 1.1 are being addressed.

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

e. For standard HIV or TB funding requests, describe existing TB/HIV collaborative activities, including linkages between the respective national TB and HIV programs in areas such as: diagnostics, service delivery, information systems and monitoring and evaluation, capacity building, policy development and coordination processes.

f. Country processes for reviewing and revising the national disease strategic plan(s) and results of these assessments. Explain the process and timeline for the development of a new plan (if current one is valid for 18 months or less from funding request start date), including how key populations will be meaningfully engaged.

4-5 PAGES SUGGESTED

a. The key goals, objectives and priority program areas

The current *Georgia National HIV/AIDS Strategic Plan for 2016-2018* (NSP) is a recent revision of the former version that covered 2011-2016. The NSP is the result of inclusive collaborative work of all stakeholders involved in the implementation of HIV related interventions. Intensive consultations took place in December 2014 - March 2015. Expert mission of the WHO has reviewed the plan and provided important recommendations, which have been reflected in the approved version. All key decisions reflected in the plan were discussed and made by the Country Coordinating Mechanism.

The overarching goal of the national strategy for 2016 -2018 is to turn the HIV epidemic in Georgia in the reversal phase through strengthened interventions targeting key affected populations (KAP), and significant improvement in health outcomes for PLWH. Strengthened commitment of the government, greater involvement of civil society, and optimal integration of various branches of the prevention and care continuum will ensure sustainably strong response to the epidemic. The NSP focuses on the following three objectives and priority areas:

Objective 1 (HIV Prevention and Detection): Improve the effectiveness of outreach and prevention and ensure timely detection of HIV and progression to care. The national strategy prioritizes the scale-up of high quality HIV outreach and prevention interventions targeting PWID, MSM and other KAPs, as well as improved detection of HIV in these populations followed by expedient progression to necessary HIV care and treatment services. The achievements in ensuring safety of donor blood, PMTCT, and post-exposure prophylaxis will be sustained. Provider initiated testing on clinical and behavioral indications will be further developed, and PEP will be made available to the victims of sexual violence.

Objective 2 (HIV Care and Treatment): Improve HIV health outcomes through ensuring universal access to quality treatment, care and support. The achievements in ensuring universal access to care and treatment will be further strengthened in 2016-2018. Measures will be taken to reduce the loss of patients at each of the steps of the care cascade including better enrolment and better retention in care. These will be achieved through ensuring access to essential medical care, improved case management, greater involvement of PLWH organizations in the delivery of psychosocial care and support, as well as introduction of specific targets and activities aimed to improve treatment uptake, adherence and effectiveness among people with history of injecting drug use. Links to TB, HCV and OST services will be strengthened. The role of civil society organizations including PLWH support groups in the uptake and provision of HIV care will be strengthened and formalized in the national protocols and other relevant regulations and ToRs.

Measures are currently taken to prepare the HIV care system to handle the influx of PLWH associated with the strengthened detection of HIV in the key populations and scale-up of provider initiated testing. In particular, these measures include rationalization and simplifications of utilized drug regimens and better organization of care, which is expected to allow for significant reduction in associated costs and workload without compromising the quality of care. The optimization of HIV treatment will continue further and result in significant reduction of the numbers of possible treatment regimens in the first, second and third line. These measures are expected to further reduce HIV related mortality in Georgia to not more than 2 deaths per 100,000 population compared to the currently available baseline value of 2.4 per 100,000 (2013).

Objective 3 (Leadership and Policy Development): Ensure sustainably strong response to the epidemic through enhanced government commitment, enabling legislative and operational environment, and greater involvement of civil society. The government is committed to sustaining the essential HIV prevention and care services previously funded from external sources including the Global Fund. The state budget allocations will be gradually increasing to ensure all essential interventions are sufficiently funded.

Specific measures will be taken to introduce legislative changes and develop regulations and operational policies required to ensure uninterrupted delivery of essential HIV prevention and care services with special focus on the key affected populations. Improved collaboration of public and civil society service providers with law enforcement agencies and other relevant stakeholders will ensure the most effective practical application of the developed regulations and policies.

The government will collaborate with community-based organizations representing PLWH and KAPs to design and implement effective stigma reduction strategies, which will have beneficial impact on service uptake and retention.

The stakeholders will sustain the required surveillance and monitoring efforts and continue conducting operational studies to ensure adequate intervention design. Improved knowledge of specific needs and vulnerability factors affecting various segments of KAPs will enable the development of effective and tailored interventions.

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

The current status of the national response in the priority areas identified by the NSP is

described below.

POLICY AND GOVERNANCE. The Government of Georgia is strongly committed to HIV prevention and control since 1996 when the first State HIV Prevention Program was developed. The CCM created as a governance structure related to the Global Fund investment, has become a fully functional body coordinating the national response to HIV and TB. The CCM acts as the sole National Coordinating Authority on HIV and TB, is supported by a secretariat, is regulated by comprehensive by-laws, and has a robust communication system. The CCM includes broad representation from all relevant ministries, government institutions, civil society organizations, bilateral and multilateral agencies, as well as organizations representing PLWH and KAPs. Coordination of the civil society actors is also supported by the HIV prevention task force (PTF), which unites NGOs and professionals working on HIV and engages in HIV related policy development and advocacy.

The role of the CCM remains limited with regards to initiation of legislative and policy changes required creating enabling environment for effective delivery of HIV prevention and care services to KAPs. The recent inclusion of the Ministry of Internal Affairs in the CCM membership is expected to facilitate the policy development dialogue among stakeholders. Another area that requires improvement is the coordination of efforts aimed at elimination of HIV related stigma among the general public, healthcare workers and other relevant professionals.

HIV PREVENTION. Outreach and prevention targeting PWID have been significantly scaled in 2011 - 2014 with support from the current Global Fund grant. Increase in the number of service delivery sites (currently 14), and application of innovative outreach methods have allowed to considerably increase the number of clients. The programs are currently serving 12,000 unique clients per month, which is more than two times higher than in 2013. There has been a delay in the rollout of mobile service delivery, which is supposed to cover up to 45 small cities of the country where VCT services are not available. 4 sites have introduced women-friendly services for PWID. Apart from basic HIV prevention services, harm reduction programs offer community-based VCT performed jointly by community counselors and health workers.

The efforts implemented so far have not been sufficient to contain the growing prevalence of HIV among PWID and MSM. IBBSS data suggest that behaviors that put people at risk of HIV remain prevalent, which is explained by the limited coverage of outreach and prevention services among these populations as well as by intervention quality issues such as weaknesses of communication between outreach workers and clients.

Needle and syringe programs remain fully funded by external sources (Global Fund) and the development of measures and mechanisms to enable the handover of these services to the government is urgently required.

OST services have become more accessible and are provided in 20 sites. 14 out of them are funded by the state. However, the uptake and retention (6 month retention rate within GF supported program is 62%(503/807) by the end of 2014, the data on retention within the State supported program is not available) in OST remain low largely due to ineffective promotion of the service, service fees. The existing services fail to accommodate for the specific needs of female patients.

HIV prevention interventions targeting sex workers (SWs) have achieved considerable progress with regard to condom use with commercial clients (85-98%), as well as increased HIV testing rates during the last 12 months (40.6% in Tbilisi and 66.7% in Batumi). IBBS studies do not indicate growth in HIV prevalence in this group. However, knowledge about HIV transmission remains very low (only 8.8% of SWs in Tbilisi and 21.7% - in Batumi correctly answered questions about HIV transmission),[6] which highlights the need to further strengthen HIV prevention among SWs. Although coverage of SWs with prevention interventions is relatively high (64.3% according to 2014 IBBSS data) further increase and quality improvements are required. In addition to street-based outreach, five specialized clinics (*Healthy Cabinets)* in Tbilisi, Kutaisi, Batumi, Zugdidi and

Telavi provide HIV and STI diagnostic and STI treatment services to SWs and MSM.

Since 2010 HIV testing rates among MSM in Tbilisi has increased significantly but remain low at 33.9% in 2012.[16] Only 36.7% of MSM are aware of HIV transmission routes. Prevention coverage has been increasing since 2010 and reached 48.6% in 2012. Proportion of MSM who reported receiving condoms from preventive programs during the last 12 months increased significantly since 2010 (from 40.3% to 53.7%), and reported condom use during the last anal intercourse has become relatively high (73.2%) but not sufficient for effective prevention. This is demonstrated by the alarming increase in HIV prevalence among MSM from 7% in 2010 to 13% in 2012. Young MSM are less involved in the existing outreach and prevention activities and have been found less likely to undertake HIV or STI testing.

The progress of the interventions aimed at prisoners has been limited partly due to substantive reforms in the penitentiary system. IBBS survey conducted in 2012 has found HIV prevalence of 0.3%.[19] Despite universal availability of HIV VCT in penitentiary facilities, only 18.3% of prisoners received prevention information and were offered confidential HIV testing during last 12 months. Only 21.3% had been tested for HIV and informed about their test results.

HIV prevention efforts targeting blood donors and pregnant women have been effective in Georgia. Universal access to PMTCT has been introduced in Georgia in 2005 and includes screening of pregnant women for HIV and provision of ARV medicines to HIV positive mothers and their newborns. HIV testing coverage among pregnant women is constantly increasing and in 2013 has reached 86%. However, mother to child transmission of HIV still occurs and accounts for 1% of all new HIV infections registered in 2013. HIV prevalence among pregnant remains low, which confirms the concentrated nature of the Georgian HIV epidemic.

Since 2006, all blood donors are being tested for HIV, HCV, HBV and syphilis assuring higher safety of blood products. During 2011-2014 the country has assured that all donated blood is screened in a quality assured manner.

Post exposure prophylaxis treatment is available for all healthcare workers in need. Further elaboration of the PEP regulations, coordination of the relevant HIV prevention and care entities, and in-service training of healthcare workers is required in order to make PEP available to the victims of sexual violence.

CLINICAL AND SOCIAL HIV CARE. Provision of HIV treatment and care services in Georgia has started in the 1990s and the National AIDS Treatment program became operational in 1995. ART is provided by the IDACIRC in Tbilisi and regional facilities in Kutaisi, Batumi and Zugdidi. Since 2008, ART is also available in Abkhazia. Substantial progress in treatment and care component of the national HIV response has been achieved since 2004 with support from the Global Fund. All patients are examined for main clinical and laboratory parameters (CD4 count, HIV viral load and HIV drug resistance) and regularly screened and managed for infectious and non-infectious comorbidities, which also includes provision of in-patient care. The service delivery is supported by the state funded and the Global Fund supported programs, which together ensure universal access to essential HIV-related medical care free of charge. 95% of those diagnosed and known to be in need of treatment were on ART by the end of 2014. According to UNAIDS data Georgia has highest ART coverage in the region of Eastern Europe and Central Asia (EECA).[20] Maintaining universal access to ART for all diagnosed HIV patients as well as increasing coverage on a population level remains a strategic priority towards achieving significant impact on the epidemic.

Treatment improvements have led to more that 3-fold reduction in mortality among HIV patients from 6.49 deaths per 100 Person-years (PY) in 2004 to 2.05 deaths per 100 PY in 2012.[21] 12-month survival increased from 79% in 2011 to 86% in 2012 and remained stable through 2014. AIDS related mortality is strongly associated with late HIV diagnosis. With regard to individual diseases, TB and end stage liver disease (primarily due to HCV infection) were the two leading causes of death accounting for 21.3% and 15.2% of total

deaths respectively.[21] History of injecting drug use is also associated with increased mortality, as PWID are more likely to be diagnosed late, and to have co-infections with HCV and TB. More recent ART program data further confirm that persons with history of IDU are at higher risk of attrition both at 12 and 24 months after starting ART. Also PWID have been shown to be at higher risk of disengagement for the entire HIV care.

HCV is common among HIV patients in Georgia, with up to half of the registered cases carrying antibodies against HCV.[22] The burden even higher among people with history of IDU (73%).[22] Free HCV program for HIV patients was initiated in December 2011 and so far enrolled 422 patients. A large proportion of these are patients with history of IDU. The Government of Georgia declared intention to eliminate hepatitis C in Georgia and this initiative already received strong international support. The national hepatitis C elimination program will become operational in 2015 and all HCV patients, including HIV/HCV co-infected patients, will receive modern DAA-based treatment regimens.

The major gap in HIV care continuum occurs at the stage of HIV testing/diagnosis. Less than a half of the estimated number of PLWH are not diagnosed primarily due to low HIV testing coverage of KAPs.[1] Patient engagement after HIV diagnosis is high with more than 90% of those eligible receiving ART and 80% of them achieving viral suppression. Viral suppression rates reach 84% among those remaining on treatment for at least 12 months.

Apart from free essential HIV treatment services additional ones are also available to enhance treatment adherence and retention, including patient education, counseling, adherence monitoring and support, as well as active case follow up through phone contact and/or outreach. Clinic-based (monthly monitoring and counseling in all centers including Sukhumi) and home-based adherence support services are provided the latter being delivered by mobile units operating countrywide, except of Abkhazia. The effective adherence support contributes to viral load suppression. The proportion of virally suppressed patients among those on treatment increased from 68% in 2008 to 80% in 2013.[13]

Optimization of HIV infection treatment regimens is under way and will lead to increased cost effectiveness of clinical care. Starting from 2014 clinical care service provision has been switching from individualized approach towards public health approach recommended by WHO. The process consists of optimization of ART regimens to provide standard WHO regimens, to limit laboratory evaluations to twice a year and to reduce the number of visits by specialist. Procurement of ARV medicines for 2015 is implemented based on the optimized regimens, which resulted in significant cost savings. These principles have been applied in the revised NSP and the proposed program, which resulted in greater cost-efficiency both for the national program and for the Global Fund one.

c. Limitations to implementation and lessons learned

The future implementation of the national response to HIV will address the following limitations of the previous implementation periods:

- Increased coverage of outreach and basic prevention efforts targeting KAPs, most importantly PWID and MSM, will contain the growth of HIV prevalence rate in these populations, as well as improve detection of HIV infection among these groups leading to timelier presentation for care and treatment and reduction in AIDS related mortality;
- Increase in coverage will be achieved through strengthened capacity of the existing and new service delivery units, including the mobile ones, tailoring outreach strategies and service combinations to meet the needs of specific population segments such as women who inject drugs and younger MSM and SWs, continued utilization of peer-driven approaches based on exploring the natural social networks of key populations, as well as promotion of HIV related services among KAPs;
- Better utilization of HIV prevention and care potential of OST requires promotion of this service among potential and current patients, improved qualifications of staff and quality of services, as well as the development of peer-support and treatment monitoring systems for OST patients;

- Specific targets will be set in order to address specific challenges facing by people with history of IDU with regards to treatment uptake, retention and outcomes;

d. The main areas of linkage to the national health strategy

Please refer to the section 1.1d above for the description of linkages between the Georgia Healthcare System State Concept for 2014-2020 and HIV NSP.

e. Existing TB/HIV collaborative activities

High TB/HIV mortality is of particular concern given that all co-infected patients have access to free medical care for both diseases. In 2013 44 TB/HIV co-infected patients or 88% of the estimated number (50) received treatment for both diseases, and this level of coverage compares favorably to the EECA regional average of 71%. However, high MDR TB rates in Georgia coupled with late diagnosis of both TB and HIV results in increased risk of death from TB.[4] Tuberculosis is the leading cause of death among the ART patients in Georgia and accounts for 21.3% of all deaths. Additional efforts are needed to scale-up timely case finding and to maintain universal access to treatment for both TB and HIV.

The country dialogue involved consultations between the relevant HIV and TB specialists regarding the linkages and collaboration between the components. The HIV NSP includes reduction of morbidity and mortality due to TB and HCV co-infections and IDU as one of the strategic priorities. In line with the latest WHO recommendations, NSP envisages intensification of collaborative activities between HIV and TB programs in order to ensure effective TB detection among HIV patients, provision of VCT for HIV for all TB patients, provision of both TB and HIV treatment for patients with co-infection, as well as administration of Isoniazid preventive therapy (IPT). Based on the National Guideline on management of TB&HIV co-infection HIV testing should be offered to all TB patients at the time of TB treatment initiation. However, the proportion of TB patients with known HIV status is low and present 62% or 2698 patients out of 4319.[9]
Timely detection of TB remains one of the major priorities for the success of HIV care. One strategy the proposed program will utilize to improve TB detection in the populations most vulnerable to HIV infection is the promotion of universal verbal (questionnaire-based) screening of KAP clients for TB in community-based outreach and basic prevention programs for PWID, MSM, and SW. ART patients with history of IDU have higher rates of Tuberculosis, which negatively affects HIV treatment outcomes in this sub-population. TB detection in the community of PWID will be particularly prioritized. Necessary guidance will be included in communication protocols regulating BCC between front-line outreach and HIV prevention service providers and program clients, as well as facilitation of further diagnosis and access to the required treatment in close collaboration with clinical facilities.

f. Country processes for reviewing and revising the NSP

The current NSP is the result of inclusive collaborative effort of all stakeholders involved in the implementation of HIV related interventions. The NSP working group was established under the auspices of CCM composed of representatives of local CSOs, representatives of PLWH and KAP groups, local and international HIV and TB experts. All the required consultations (including a broad civil society forum) and reviews have been conducted in December 2014 – April 2015 followed by endorsement of the NSP by the CCM on 15th of April 2015 and its further presentation for consideration by the Cabinet of Ministers of Georgia.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

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

2.1 Overall Funding Landscape for Upcoming Implementation Period

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

a. The availability of funds for each program area and the source of such funding (government and/or donor). Highlight any program areas that are adequately resourced (and are therefore not included in the request to the Global Fund).

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

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

1-2 PAGES SUGGESTED

Over the last several years, the share of state funding allocated to HIV response in Georgia has been steadily increasing from 15.4% in 2008 to 32% in 2013. The Global Fund remained the most significant funding source and provided 34.6% of the overall funding in 2014. The contribution of other international sources has been decreasing and reached the level of 6.8% in 2014. At the same time, the state budget allocation for HIV increased significantly in 2014 by more than $3Million compared to 2013. The additional funding supported the development of the following components of the national response to HIV:

Prevention and Detection of HIV

- Voluntary counseling and testing (increase of $154.8k);
- Harm reduction programs for PWID (increase of $746.4k);
- Prevention of mother to child transmission of HIV (increase of $82.8k);
- Blood safety (increase of $116.7k);
- Provider-initiated testing and counseling (new allocation of $152k);

HIV Care and Treatment

- Hepatitis C laboratory diagnostics (new allocation of $581.3k);
- Specific HIV related laboratory monitoring (increase of $74.7k);
- Hepatitis C medicines (new allocation of $529.6k);
- In-patient Hepatitis C service (new allocation of $352.4k)

Program management and administration has been strengthened with the associated increase in funding of $870.9k. This includes costs associated with upgrading and construction of infrastructure in the amount of $245.2k.

The future period will be marked by further decrease of external contributions, which will be balanced by a significant increase in state budget allocation for HIV. The Global Fund funding that has peaked at 54% of the total HIV spend in 2012 is expected to decrease to 37.6% in 2016, 28.2% in 2017 and 22.6% in 2018.

The overall funding need has been and will continue to grow steadily due to scale-up of various prevention and care interventions. The annual cost of the national response to HIV has increased from $5.2 million in 2006 to $8 million in 2008 and further to $17.4 million in 2014. HIV program allocations from the state budget will increase from $15.08 million in 2016 to $18.16 million in 2017 and $19.99 million in 2018. Above that one time, capital investment of $5 million in IDACIRC infrastructure is envisioned in 2016 by the State. Furthermore, growth is expected to support the planned increase in coverage and improvements in service quality. The increase is restrained by the on-going optimization of antiretroviral treatment as well as by strengthened standardization of service delivery. The required increase in funding is progressively absorbed by the government rather than external sources, although the Global Fund contribution remains substantial. The next several years will be marked with significant decrease in the share of external investment and increased allocation of state funding to offset the decrease in external contribution and

to meet the challenges of coverage scale-up.

Currently the following areas of the national HIV response are fully funded by the government and are not included in the funding request to the Global Fund:

- Measures to ensure safety of donor blood;
- Inpatient and outpatient clinical services;

The following areas of work are predominantly funded by the government and it will not be challenging for the government to assume full responsibility for their funding when external support will cease:

- PMTCT including HIV testing of pregnant women;
- Post-exposure prophylaxis among health-care workers
- OST services.

The following areas will also be mostly or partly handed over to the government over the course of the proposed grant implementation:

- Treatment for HIV infection;
- Clinical monitoring;
- HIV treatment adherence measures performed by health care workers;
- Remaining OST activities including OST in penitentiary system;
- Community-based VCT (procurement of rapid tests is expected to be covered by the state starting from 2018);
- IBBSS among KAPs in 2018.

The following areas of work will continue to be funded from external sources. Their handover to the government will be planned in the transition plan that will be developed by 2017:

- Focused outreach and basic HIV prevention activities targeting PWID, MSM, SW, and prisoners;
- Community-based care and support services delivered by PLWH organizations;
- Operational and epidemiological studies;
- Community-led policy development and advocacy initiatives.

The HIV spending dynamics for the next three years is defined by the decreasing share of external contributions and by the increasing share of state funding required to ensure sustainable response to HIV epidemic. In particular during 2016 - 2018 the government will eventually assume full responsibility for the procurement of ARV medicines, laboratory monitoring of treatment quality, and opioid substitution treatment, as well as a solid part of expenses associated with the detection of HIV in KAP communities. The following tables present the funding dynamics including the actual expenditure in 2010 – 2014, as well as the planned allocations for 2016 - 2018.

Funding of HIV response by source (in millions of US dollars and %)

Source		2010	2011	2012	2013	2014	2015	2016	2017	2018
1.1.State HIV Program	Mln $	4.36	4.56	4.55	4.95	8.17	7.99	6.11	10.50	12.45
	%	34%	32%	28%	32%	48%	39%	30%	57%	62%
1.2.State investment in Infrastructure	Mln $	-	-	-	-	-	-	5	-	-
	%							23%		
2.TOTAL International	Mln $	6.83	8.52	11.06	9.14	7.02	10.54	7.73	5.59	4.98
	%	53%	59%	68%	58%	41%	52%	38%	31%	25%
2.1. Global Fund[iv]	Mln $	5.3	5.1	8.8	7.5	5.87	10.50	7.45	5.08	4.47

[iv] The table includes the amount requested from the Global Fund for 2016-2018 through this concept note. Other international funding sources have yet to be identified.

	%	41%	36%	54%	48%	34%	49%	37%	28%	22%
3. Household funds (Private Sources)	Mln $	1.61	1.26	0.78	1.60	1.77	1.77	1.38	2.20	2.55
	%	13%	9%	5%	10%	10%	9%	7%	12%	13%
TOTAL		12.80	14.34	16.39	15.69	16.96	20.30	20.08	18.16	19.99

Funding of HIV response by Intervention area (in millions of US dollars)

Intervention area	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevention and Detection	7.22	7.87	7.19	6.49	9.46	9.23	8.21	9.64	10.90
Care and Treatment	3.11	3.76	6.20	6.12	5.20	9.22	5.69	6.53	7.45
Leadership and Policy Development, program management	2.47	2.71	3.00	3.08	2.30	1.86	1.18	1.99	1.64
Infrastructure	-	-	-	-	-	-	5.00	-	-
TOTAL	12.80	14.34	16.39	15.69	16.96	20.30	20.08	18.16	19.99

2.2 Counterpart Financing Requirements

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

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

Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	☐☑ Yes ☐ No	
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%)	☐☑Yes ☐ No	
iii. Increasing government contribution to disease program	☐☑Yes ☐ No	

b. Compared to previous years, what additional government investments are committed to the national programs in the next implementation period that counts towards accessing the willingness-to-pay allocation from the Global Fund. Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.

c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.

2-3 PAGES SUGGESTED

Considering the expected decline in donor financing, the GoG has gradually been increasing the state budget allocations to HIV response. The share of domestic funding in total HIV allocations reached 58% in 2014 and further increase up to 75% is planned by 2018.

The government is strengthening its support in the existing areas and is engaging in funding new areas of work. Specifically the areas where the investment of the government is increasing are:

- HIV treatment and associated activities including clinical monitoring and quality assurance. The government will assume responsibility for the procurement of first line ARV medicines starting from 2015, and for the procurement of second and third line medicines from 2017. Laboratory monitoring (HIV plasma Viral Load and HIV drug resistance testing) expenses will be also handed to the government starting in 2017;
- Opioid substitution services in both civil sector and penitentiary institutions will be handed to the government starting from 2017;
- Starting from 2017 procurement of ARV medicines and the delivery of social services associated with PMTCT will be fully funded by the government.
- Starting from 2016 treatment of HCV among PLWH.

New areas of work where the government is planning to allocate funding are:

- Community-based HIV and HCV testing. The procurement of rapid tests for both infections by the government for distribution among NGOs implementing outreach and basic prevention activities among KAPs is planned for 2017 to cover the needs in 2018;
- In 2018 the government is also expected to take over the IBBS studies among KAPs.

The Revised HIV NSP contains financial information indicating the sources of funding for specific areas of work (either public funds or external resources) throughout the strategy implementation period, which coincide with the proposed program implementation period (2016 – 2018).

The following table provides information on the committed state funding for the responses to HIV and Tuberculosis in Georgia (in USD equivalent):

Government Spending and Commitments by Program	Y-2	Y-1	Y0	Y1	Y2	Y3
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
HIV	4,948,619	8,166,782	7,993,412	11,034,256	10,424,784	12,453,949
Tuberculosis[v]	8,736,597	8,980,010	6,358,757	6,681,237	6,862,916	6,999,175

Below are the willingness-to-pay calculations based on the confirmed government commitment (presented in USD millions):

Component	**Global Fund Allocation**	**Minimum Threshold (MT)**	**Current Govt Spending $M (CP)**				**Govt Commitment $M (NP)**				**Additional Commitment (NP-CP)**
			2013	2014	2015	Total	2016	2017	2018	Total	
HIV	33.9	**13.6**	4.9	8.2	8.0	**21.1**	11.0	10.4	12.5	**33.9**	**12.8**
TB	22.6	**9.0**	8.7	9.0	6.4	**24.1**	6.7	6.9	7.0	**20.5**	**-3.5**
Malaria											
Total	**56.5**		**Current phase spending**			**45.2**	**Commitments for next phase**			**54.5**	**9.3**

[v] Please note: a) that insignificant variations in the TB related projected figures are possible, as the CCM continues working on finalization of the National TB Strategy and preparation of the TB Concept Note; b) Higher allocations for TB program during 2013 and 2014 are the results of the capital investment costs related to the construction of the new prison facility for TB patients at the Ksani Prison.

		HIV	TB	Total
A	Country allocation	33.9	22.6	56.5
B	Allocation tied to CFP = 15% of A	5.1	3.4	8.5
C	Minimum additional government investment per US$ GF CPF allocation for Upper LMICs = $1	1	1	1
D	Minimum additional government investment required to access total CPF allocation = B x C	5.1	3.4	8.5
E	Additional government investment committed	9.3	9.3	9.3

The counterpart financing share is 56%.The counterpart financing share meets the minimum threshold requirements for an Upper LMI country (40%). In addition, the WTP requirement has been met as $9.3 million is higher than required $8.5 million.

Between November 2014 and April 2015 the World Bank, UCL and UNSW with support from the World Bank, the Global Fund, UNAIDS and UNDP have conducted the National HIV Allocative Efficiency Analysis in Georgia. The analysis was performed using the Optimization & Analysis Tool (Optima). The report[23] suggests that the country has already allocated its HIV resources relatively well. However, it is recommended to explore the opportunities for further optimization of HIV investments, namely through increased investments in programs targeting the MSM population.

Aligning various related governmental programs may increase the effectiveness of funding utilization. Thus, close linkages of HIV NSP will be ensured with the **National Hepatitis C Elimination Program** for 2015-2020,[12] which the MoLHSA and the NCDC have initiated in close collaboration with CDC Atlanta. The Short Term/Urgent Measures of Hepatitis C Elimination Action Plan for Georgia has been submitted for the GOG's approval, the program will be launched on 21 April 2015. The long term HCV Elimination Strategy will be developed by NCDC and approved be the end of 2015. One of the main directions of the strategy is to enhance HCV surveillance through the expansion of HCV screening coverage of the key populations, including PWID, prisoners, PLWH, and MSM. Tandem PIT for HCV and HIV may become a cost-effective tool for early detection of both diseases.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

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

3.1 Programmatic Gap Analysis

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

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

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

1-2 PAGES SUGGESTED – ***only for modules that are difficult to quantify***

Information presented in Table 2 is sufficient for programmatic gap analysis for most of

the priority modules apart from the Module 6: Removing Legal Barriers to Access. This module unites all interventions related to policy development and advocacy, increased participation of the civil society in the development and delivery of essential HIV interventions, as well as ensuring smooth transition of essential intervention from external to domestic funding sources.

The current state of implementation of these activities is characterized by unclear responsibilities, lack of a single management and advisory authority, poorly developed priorities and work-plans. The proposed program includes setting specific policy development and advocacy tasks associated with specific HIV prevention and care priorities. These tasks will be elaborated in the national policy development and advocacy plan designed by the relevant stakeholders with support from the PR and technical guidance from the Policy and Advocacy Advisory Council consisting of representatives of the main stakeholders including KAPs, PLWH, and organizations representing their interests. Systematic monitoring of progress towards the main objectives of the policy and advocacy plan will ensure eventual attainment of the set priority targets.

The management center of the policy and advocacy area will be located in the PR. A dedicated position (Policy and Advocacy Specialist) has been budgeted for this purpose. The specialist will monitor and support the development and implementation of the national policy and advocacy plan, and will seek and coordinate necessary contributions from a range of stakeholders. The specialist will follow guidance of and report to the Policy and Advocacy Advisory Council. Most of the envisaged policy development and advocacy efforts will relate to:

- improvements in legislation, regulations, operational policies and practice standards related to HIV prevention and care interventions targeting PWID and their sexual partners, as well as SW and MSM;
- facilitation of more effective engagement of civil society in the delivery of care and support services for PLWH;
- ensuring smooth transition of the leadership and funding of the main HIV interventions (most importantly outreach and basic prevention targeting KAPs) from external sources to the state budget allocations.

3.2 Applicant Funding Request

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

4-5 PAGES SUGGESTED

The stakeholder consultations related to the revision of the National HIV strategic plan have taken place immediately prior to the concept note development. The NSP budget includes the indicative split by the sources of funding for various components of the national response. The NSP budget assumes phased decrease in the available external contribution (almost exclusively from the Global Fund), and balances this decrease with the growing contributions from the state budget. In line with this logic, the funding request to the Global Fund includes smaller funding amounts for each consecutive year covered by the concept note period. The requested Global Fund investment is expected to cover 37.6%, 28.2% and 22.6% of the total national HIV budget in 2016, 2017 and 2018 respectively. Contribution of the state grows significantly and in 2018 is expected to reach 62% of the total national response need.

Over the course of the NFM grant the government will be gradually taking over certain new components of the national response to HIV and develop the required capacities to exercise new functions. Thus over the course of 2016 - 2018 the government will incrementally take over the majority of OST related expenses, ART, laboratory monitoring,

and PMTCT costs, as well as the costs of community-based HIV testing among KAPs and IBBS studies. Several important areas of work will continue to be funded by external sources throughout this period. These include community-based outreach and basic prevention activities targeting PWID, MSM and SW, provision of community-based psychosocial care and support to PLWH, adherence support services provided by mobile service delivery units, advocacy activities, as well as operational studies.

Table below summarizes the funding request per modules indicating within allocation and above allocation requests.

Module name	Allocation		Above		Full request	
	USD	%	USD	%	USD	%
Prevention programs for MSM and TGs	1,780,825	11%	0	0%	1,780,825	10%
Prevention programs for sex workers and their clients	998,299	6%	0	0%	998,299	6%
Prevention programs for people who inject drugs (PWID) and their partners	6,440,351	39%	4,996	1%	6,445,347	38%
Prevention programs for other vulnerable populations (prisoners)	269,916	2%	0	0%	269,916	2%
Treatment, care and support	5,008,877	30%	2,728	0%	5,011,605	29%
HSS - Health information systems and M&E	684,526	4%	147,465	26%	831,990	5%
Removing legal barriers to access	292,736	2%	408,041	72%	700,777	4%
Program management	970,476	6%	0	0%	970,476	6%
Grand Total	**16,446,006**	**100%**	**563,230**	**100%**	**17,009,235**	**100%**

By 2017 the government in consultation with other stakeholders will develop a transition plan for handing these areas of work over to the government and other funding sources. The policy development and advocacy agenda of the proposed NFM grant will emphasize the significance of these elements of the national response and actively facilitate the required processes. It is expected that the current regional Global Fund supported program "*Harm Reduction Works – Fund It!"* will also facilitate allocations of state funding for HIV prevention work among PWID. The proposed program will be also aligned with any other pending regional initiative such as the regional program designed by the East European and Central Asian Union of PLWH Organizations (ECUO). Linking basic prevention services to the detection of HIV in key affected populations followed by facilitated access to ART is expected to position community-based outreach and prevention services within the context of the overall logic of the national response to the epidemic.

The concept of the prevention to care continuum has been adopted by the stakeholders, and the essential role of KAP outreach and prevention services in effective detection of HIV and ensuring access to care has been acknowledged. The tasks related to eliminating the loss at each of the cascade stages include:

- Accurate estimation of the key population sizes and realistic and accurate target setting;
- Maximizing the coverage of outreach efforts in order to establish contact with the majority of key populations;
- Effective promotion of universal testing for HIV among KAPs;
- Expedient progression of HIV positive clients to care and treatment services, and
- Ensuring access of patients to the required adherence and other support measures designed to ensure positive treatment outcomes.

The activities under the three objectives complement each other working towards achieving these tasks as follows:

Objective 1: Prevent HIV transmission, detect HIV, and ensure timely progression to care and treatment among the key affected populations

In line with the latest epidemiological trends, the program prioritizes significant increase in coverage and quality of HIV outreach and prevention interventions targeting KAPs (PWID,

MSM, SW, and prisoners) as well as improved detection of HIV in these populations followed by expedient progression to necessary HIV care and treatment services.

Effective outreach and community-based interventions among KAPs are essential elements of the national response to HIV epidemic. They enable behavioral changes that reduce the risk of HIV transmission. Community-based outreach allows for effective detection of HIV cases in KAPs. The program aims at significant scale-up of outreach and prevention activities targeting KAPs, primarily PWID and MSM. The existing outreach strategies and service combinations offered to KAPs will be optimized based on their role in HIV prevention and care. The coverage of KAP outreach and prevention programs will be expanded through:

- Segmentation of the target population and tailoring outreach mechanisms and service combinations to specific segments;
- Continued utilization of peer-based outreach and exploration of natural social networks of KAPs, which will allow accessing hidden and underserved segments of KAPs;
- Introduction of ICT-based communication;
- Regional target setting, as well as
- Mobile outreach and service delivery.

The appeal of services to clients and service retention will be strengthened through a range of quality improvements. These will include:

- Better tailoring of interventions to various segments of KAPs. This includes ensuring that the most relevant prevention commodities (such as certain types of needles depending on the drug of choice and distribution of sterile water to injecting users of powdered substances) are offered to clients;
- Significant revision of behavioral change communication (BCC) strategies. Ineffective Information, Education and Communication (IEC) delivery models (such as reproduction and distribution of printed materials containing basic and general information on HIV infection and associated matters) will be discontinued, but the overall BCC approach will be strengthened through the introduction of thorough regulations guiding the contents and delivery models of communication between front-line personnel and clients;
- More effective use of resources based on optimized budgeting in accordance with the demand for each specific service or commodity.

Late detection of HIV and late presentation for care and treatment represents one of the key challenges facing Georgian response to HIV epidemic. Timely detection of HIV improves the effectiveness of HIV prevention measures and ensures expedient access to care and support and timely initiation of vital HIV treatment, which in turn brings extra prevention benefits through the reduction of viral load in successfully treated HIV patients. HIV detection activities form an important part of the proposed program and will prioritize community-based testing of KAPs and their sexual partners. Observance of essential human rights, confidentiality principles and voluntary acceptance of the offered services will be ensured in all settings. Regulated and formalized mechanisms will be introduced at outreach and basic prevention services to facilitate expedient progression to required HIV care and treatment for those who test HIV positive. HIV prevention service providers will develop and implement interventions targeting sexual partners of PWID and female sexual partners of MSM[vi], as well as clients and regular sexual partners of FSW. These interventions will aim at ensuring timely detection of HIV in these important bridge populations with follow-up access to vital care and treatment services.

Human resource capacity of organizations delivering outreach, prevention and detection services will be strengthened in line with the increasing workload related to involvement in

[vi] According to 2012 BBS among MSM, about half of MSM reported having sexual relationship with a female partner in the past year, which represents a significant risk of onward transmission to bridge populations given the increasing prevalence of HIV in the MSM population and insufficient use of condoms by MSM.

comprehensive case management facilitation of client progression along the continuum of care, more intensive behavior change communication, and better tailoring of services to various segments of the target population.

Objective 2: Improve HIV health outcomes through ensuring universal access to quality treatment, care and support

The proposed program will support further strengthening of HIV care and treatment. Measures will be taken to reduce loss of patients at each of the steps of the care cascade including better enrolment and better retention in care. These will be achieved through ensuring access to essential medical care, improved case management, greater involvement of PLWH organizations in the delivery of psychosocial care and support, as well as introduction of specific targets and activities aimed to improve treatment uptake, adherence and effectiveness among people with history of injecting drug use. Links to TB, HCV and OST services will be strengthened. The role of civil society organizations including PLWH support groups in the uptake and provision of HIV care will be strengthened and formalized in the national protocols and other relevant regulations and ToRs. The government will continue supporting access to vital care and treatment services on the occupied territories in collaboration with NGOs operating there. It is expected that by the end of 2018, 4,800 people will be receiving antiretroviral treatment. The target is based on the projected increase in the number of PLWH detected in the community and clinical settings.

Georgian PLWH organizations will continue performing a range of important functions related to ensuring the quality of care and treatment for PLWH, including necessary psychosocial support to patients and their relatives, advice on complex matters related to status disclosure, challenges faced by children and adolescents living with HIV, and participation in supply of ARV medicines to patients residing in remote areas of the country. Community-based organizations of PLWH will further engage in facilitating timely progression of PLWH to community-based support and clinical care. The role of community-based organizations in service development and delivery, quality assurance, and patients' monitoring will be formalized, and the delivery of social support and other essential services will be included in the revised official treatment protocols.

Clinical care services will be also adjusted to address specific needs of people with history of IDU. Community monitoring of service quality will be introduced in clinical care settings.

Particular attention will be paid to strengthening crucial linkages that allow clients and patients to progress along the components of prevention and care continuum. Case management approach will be applied to achieve this at various levels including the level of outreach and primary detection of HIV, as well as the level of clinical facilities. The outreach-based case management will aim at detecting HIV cases in the community and ensuring effective linking of PLWH to community-based care and support services. The latter will ensure linking the clients to the required clinical follow-up including confirmation of diagnosis and establishment of the treatment need. Clinical case management of ART patients will also be linked to community support in order to address psychosocial support needs of the patients and ensure treatment retention and adherence. The proposed approach will be implemented in a coordinated effort of organizations providing prevention services to KAP (reaching out to clients, detecting HIV and ensuring access to community-based PLWH support services), PLWH organizations (comprehensive psychosocial support and linking clients to the required social and clinical services including ART), as well as clinical facilities providing treatment of HIV infection, HCV, STI, OST and other required health services. The outreach arm of the case management will also have a direct connection to the clinical arm, e.g. through the active promotion and linking of clients of needle and syringe programs to OST services.

Objective 3: Ensure sustainably strong response to the epidemic through enhanced government commitment, enabling legislative and operational environment, and greater involvement of civil society

In addition to essential outreach, prevention and care efforts targeting KAPs, structured policy development is an important component of the proposed program. The policy and advocacy agenda will be implemented in accordance with a plan outlining specific targets

and assigning clear responsibilities for the leadership and management of policy development and advocacy action. The stakeholders will establish an oversight mechanism (the Policy and Advocacy Advisory Council) to guide and monitor the advocacy and policy development activities. The mechanism will be supported by the Principal Recipient, will consist of representatives of key civil society and governmental players involved in the design and delivery of policy development and advocacy activities, and will lead on the development and implementation of policy and advocacy plan focusing on a range of essential areas including:

- Balanced allocation of state funding to support all branches of comprehensive response to HIV including care and treatment services and community-based outreach and prevention services for KAPs;
- Alignment of legislative and regulatory environment with HIV prevention and care objectives - regular policy reviews and analyses to verify compliance of legislation related to HIV and drug use with the practical tasks of HIV response, human rights imperatives, and regulations related to EU Accession Agreement, development and endorsement of legislative revisions, operational policies, and guidelines addressing issues affecting access to the essential HIV services;
- Development and promotion of specific mechanisms for increased involvement of PLWH and KAPs, as well as civil society organizations and networks in the development and delivery of essential HIV services including community-based outreach and detection of HIV, facilitation of timely progression to care and treatment, delivery of adherence and other support required to ensure the effectiveness of treatment and care, participation in service quality monitoring and assurance, as well as contributing to the elimination of HIV related stigma and discrimination;
- Involving PLWH and KAP networks in the oversight of the national response to HIV focusing on the most critical areas such as community control by PLWH and KAP representatives over the development and application of procurement and supply regulations related to essential medicines and other health products used in HIV prevention and treatment. The specific activities will be designed as part of the policy and advocacy planning process and monitored and guided by the Policy and Advocacy Advisory Council.

The proposed interventions are described in more detail in the following section as well as in the modular template.

The requested financial support from the Global Fund will allow for optimizing and scaling-up the national response to HIV with specific focus on the key affected populations. Integration, quality improvements and standardization of the key interventions will lead to the establishment of a sustainable national approach to addressing the challenges posed by HIV, which will be increasingly funded by the state over the course of the program implementation.

A range of the activities is included in the above allocation amount. Following the suggestion presented in the country portfolio analysis, the CCM is requesting the Global Fund to release a portion of funding refunded by the previous PR (the total amount of the refund is EUR 1,479,931) in addition to the NFM allocation. Release of this funding would allow covering the activities included in the above allocation portion of the concept note budget. These activities are classified as follows:

- Activities, which are expected to be funded by the government in course of implementation of the proposed program, but are not fully confirmed for governmental support. Given the significant increase in the planned state funding allocations during 2016-2018, it is proposed to utilize additional Global Fund funding to support the implementation of several activities, which are less likely to be picked up by the government within the timeframe of the proposed program;
- Some of the policy development and advocacy activities planned for 2017 and 2018. Depending of the progress in policy development and advocacy some of the planned activities in this area may become redundant at the later stages of the program implementation. However, there exists a risk of delays in achieving outcomes of policy development and advocacy interventions. Allocation of additional funding to continue policy development and advocacy efforts would eliminate this risk;

- Studies designed to monitor the progress of proposed interventions. The above allocation would allow for more optimal regularity of such studies;
- Improved supply of HIV prevention commodities (condoms and injecting equipment) per client per year.

3.3 Modular Template

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

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

b. Describe the expected impact and outcomes, referring to evidence of effectiveness of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

3-4 PAGES SUGGESTED

The proposed program includes six key modules embracing the essential priorities, and 3 technical modules of complementary nature. Four of the key modules relate to the prevention objective, one – to treatment and care, and one – to policy development and advocacy. Technical modules include Health information systems and M&E (operational studies and epidemiological research to verify the directions of national response), and the administrative module (Program Management). The six key modules are presented below.

Objective 1: Prevent HIV transmission, detect HIV, and ensure timely progression to care and treatment among the key affected populations

HIV prevention outreach, basic prevention and detection of HIV among people who use drugs (**Module 1**) will prioritize people who currently inject drugs but will also take into account the specific needs of people with history of injecting drug use and those at heightened risk of transition to injecting. Combinations of services offered to PWUD will be tailored to these and other sub-populations including users of powdered opiates, liquid solutions, and stimulants[vii].

Module 1 includes all standard interventions for PWIDs:

• Outreach and delivery of basic prevention services (including VCT, HCV and syphilis testing and questionnaire-based screening for TB) from stationary and mobile service delivery units;

• Delivery of gender sensitive services for women who inject drugs;

• Introduction of detailed BCC protocols regulating verbal communication between front-line service providers and clients;

• Finalization and endorsement of outreach and service delivery standards (also part of the Objective 3);

Along with communication messages regarding the risks involved in preparation, transportation, and distribution and injecting use of psychoactive substances, distribution of sterile injecting equipment is one of the most essential elements of the basic combination of HIV prevention services. The types of injecting instruments procured and distributed by the program will be based on historical records of client demand as well as the findings of ethnographic explorations of the drug scene, which will be regularly conducted. The program BCC strategy includes promotion of low dead space (LDS) injecting equipment and a specific module on LDS will be included in BCC protocols regulating communication of front-line service providers and PWID.

As a part of needle and syringe intervention, the PWIDs will receive syringes, needles, and other related commodities. On average 100 (Y1), 125 (Y2) and 150 (Y3) syringes will be distributed per one PWID-client per year.

It is assumed that 90% of PWIDs will accept the community-based VCT services provided by the program.

The coverage targets for community-based VCT among PWID are 23085 or 51% of the

vii. According to the recent study among the clients of harm reduction programs (data supplied by GHRN), the majority of clients use heroin (53%) and other opiates, but the share of stimulant users is also significant. 23% of respondents reported injecting *vint* or *jeff* – home produced stimulants. Liquid opiates use is common, e.g. 35% reported use of desomorphine (*crocodile*).

estimated number of PWID in Georgia in 2016, 25110 (56%) in 2017 and 27135 (60%) in 2018.

Given the high coverage of VCT services, they will be incorporated in BCC agenda and become part of the basic outreach and prevention service combination offered to clients.

The activities will also include the development of interventions targeting sexual partners of PWID. This includes strategies to reach out to sexual partners of PWID and introduction of basic services to attract them into programs (personal hygiene, sexual and reproductive health services). The program will perform routine analysis of effective strategies leading to the improved uptake of VCT by PWID and their sexual partners. Standard community-based VCT protocols will be revised based on the result of these analyses.

Outreach and delivery of HIV testing and counselling from mobile service delivery units and stationary points are the key activities under this intervention. 8 mobile units (including 4 new) will provide HIV testing and counselling as well as other prevention activities ensuring access to NSP programs for PWIDs in 25 cities of Georgia.

STI testing (on syphilis) will be offered to clients based on the results of initial outreach screening at the service uptake. For budgeting purposes it is assumed that on average 60% from reached PWIDs and 50% of sexual partners of PWIDs will be tested annually, 5% of reached PWIDs will test positive and require confirmation, 4% of reached PWIDs will receive treatment. All PWIDs screened positive on syphilis will be referred to “healthy cabinets” for follow up confirmation testing and treatment.

The HCV testing of PWIDs will be coordinated with the Georgia national Hepatitis C Elimination Program. Front line service providers will offer tandem testing for HIV and HCV as a standard option. Clients who tested HCV positive will be referred for further confirmation and initiation of treatment if required.

Greater utilization of HIV prevention benefits offered by opioid substitution maintenance and other treatment and rehabilitation options will be achieved through gradual increase in the capacity of service delivery system, improvements in service quality (including revision of the current dosing and other regulations), targeted promotion of OST services, strengthened psychosocial support of OST patients, improved accessibility of services for disadvantaged patients, accommodating the needs of women, and introduction of OST in penitentiary institutions. The capacity of GF supported OST is 700 in the civil sector and 100 in the prisons.

The OST intervention will be a focus of attention of the policy development and advocacy component of the proposed program. The actual costs of OST services will be increasingly funded by the government with the government assuming full responsibility for this intervention starting from 2017. The organizations involved in the delivery of harm reduction services and representing interests of PWID will monitor the development of OST services and support the introduction of a range of quality improvements planning within the National HIV Strategic Plan. The following activities are included in the proposed program in order to improve the quality and increase uptake and retention of clients in OST services:

- Development of OST promotion contents for standard BCC protocols and ToR of OST personnel;
- Supporting the development and delivery of gender sensitive psychosocial support services to OST patients;
- Promotion of and participation in the revision of OST protocols to accommodate the needs of women, enable effective take-home options, and update policies related to the use of illicit substances by OST patients;
- Monitoring the structural improvements designed to meet the needs of women on OST;
- Facilitating structured collaboration between the OST facilities, needle and syringe programs, and local law enforcement structures on issues affecting access to and effectiveness of OST utilization; and
- Supporting the revision of methadone use in penitentiary institutions.

Greater emphasis is placed on the effectiveness of outreach and prevention services targeting MSM (**Module 2**) in line with the growing epidemiologic significance of this population (13% HIV prevalence in 2012).

Better regulation of behavior change communication, innovative outreach techniques (including expanded utilization of Internet to deliver prevention messages and market services), and involvement of community-based organizations are among the strategies to increase the coverage and improve the quality of interventions. Emphasis is placed on the involvement of peers to explore the social networks of MSM and deliver essential communication. Pre-exposure prophylaxis (PrEP) option will be introduced and tested in 2017. The option will be made known and available to clients based on behavioral indications (sero-discordant relationship, multiple partners, and recent STI infection). Relevant protocols will be elaborated by the National AIDS Center. Initial testing on HIV will be started in 2016 in order to select the appropriate candidates. Prevention program delivery sites will be responsible for pre-selection process based on the designed selection criteria. Treatment initiation will be conducted by the National and regional AIDS Centers. The Centers will be responsible for PrEP laboratory and clinical monitoring also. Necessary follow ups will be conducted by the prevention sites that will include counselling, case management and adherence monitoring.

In order to increase number of MSMs reached by HIV prevention program it is planned to increase involvement of CBOs in HIV prevention activities. Three community resource centers run by CBOs (established in 2015) and established 2 more new service delivery units in 2016 that will improve linkages of MSM communities to HIV prevention and treatment services. HIV VCT, STI testing and treatment services will be provided by stationary and also mobile service delivery units.

An interactive web site will be developed to MSM community that will be used for increasing the knowledge regarding HIV and STI prevention among MSM, risk reduction communication and promoting condom use; three members of MSM community will be recruited and trained for on-line communication with MSM, including the chat room communications. The site will be widely used for referral of MSM to HIV prevention, ART and STI diagnostic and treatment services and popularization of PrPE.

MSM is population with the highest HIV prevalence among all KAPs. At the same time, 51.4% of MSM report having female partners as well. Due to high risk of transmission to the general population, during 2016, a qualitative study is planned for identifying possible ways of reaching female partners of MSM. After the conduction of study, some focused interventions will be designed and included in the BCC guidelines. The main focus of the BCC will be increasing of safe sexual practices among MSM.

Module 3 focuses on prevention programs for sex workers and their clients and includes all standard interventions (excluding harm reduction due to very low prevalence of injecting drug use among SW[viii]) as well as counselling on gender-based violence, internet-based outreach, BCC and referrals, facilitated progression to care and treatment through case management for HIV positive clients, and questionnaire-based screening of clients for tuberculosis (TB).

Prevention interventions will be conducted in the five big cities of Georgia: Tbilisi (the capital), Batumi (Adjara region), Kutaisi (Imereti region), Zugdidi (Samegrelo region) and Telavi (Kakheti region). Beside stationary service delivery units mobile labs will operate to bring testing service at the FSW gathering/working places and cruising areas. The list of STIs services include: syphilis, chlamydia and trichomoniasis.

The coverage targets for basic outreach and prevention among SW are: 2610 or 40% of the estimated SW population size in 2016, 3263 (50%) in 2017 and 3915 (60%) in 2018.

Key activities to be implemented includes:

- Outreach and delivery of basic prevention services (including VCT, HCV and syphilis testing and questionnaire-based screening for TB) from stationary service delivery units;
- Outreach and delivery of basic prevention services (including VCT, HCV and syphilis testing and questionnaire-based screening for TB) from mobile service delivery units;
- Development of a case management protocol to facilitate expedient progression to required HIV care and treatment;

[viii] Only 4 out 280 SW who participated in 2014 IBBSS – 3 out of 160 in Tbilisi and 1 out of 120 in Batumi reported injecting drugs in the past 12 months.

- Delivery of case management by outreach and prevention service providers in collaboration with PLWH support organisations and clinical facilities;
- Development of interventions targeting clients and regular partners of FSW;
- Peer Education training – these trainings are conducted regularly to recruit new or retrain old peer educators.
- Distribution of condoms and lubricants; and
- Distribution of printed materials – 1 copy per person per year – mainly for new clients or for providing information about new harm reduction or HIV prevention services.

During 2016, a qualitative study is planned for identifying possible ways of reaching partners/clients of FSWs. After the study is conducted, some focused interventions will be designed and included in the BCC guidelines targeting FSWs. It is also planned to design and print a booklet for FSWs partners (could include split in two types – one for partners and another – for clients, e.g. truck drivers).

Module 4 focuses on prevention programs among prisoners and includes BCC including distribution of IEC materials, ensuring availability of condoms and lubricants, and HIV testing and counselling. Preparatory work will be initiated and completed for introduction of the OST option in prisons in addition to currently available long-term detoxification with methadone. The prevention interventions will be implemented in 12 prisons countrywide, while OST option will be piloted in one or two prisons.

Observance of essential human rights, confidentiality principles and voluntary acceptance of the offered services will be ensured in all settings.

Human resource capacity of organizations delivering outreach, prevention and detection services will be strengthened through hiring additional personnel (mainly social and outreach workers) and training activities in line with the increasing workload related to involvement in comprehensive case management facilitation of client progression along the continuum of care, more intensive behavior change communication, and better tailoring of services to various segments of the target population.

Objective 2: Improve HIV health outcomes through ensuring universal access to quality treatment, care and support

The proposed program is expected to support further strengthening of HIV care and treatment (**Module 5**). Measures will be taken to reduce loss of patients at each of the steps of the care cascade including better enrolment and better retention in care. These will be achieved through ensuring access to essential medical care, improved case management, greater involvement of PLWH organizations in the delivery of psychosocial care and support, as well as introduction of specific targets and activities aimed to improve treatment uptake, adherence and effectiveness among people with history of injecting drug use. Outpatient and Mobile units of the AIDS Treatment Centers and self-support centers of PLWH will be in charge of establishment of the linkages between all AIDS treatment and care services, including ART adherence monitoring, TB, HCV and OST services. Relevant protocols for appropriate referrals will be developed for each service type that will be widely utilized by case managers across the program. The same individuals will be responsible to follow up calls to clients to ensure presentation of them to the relevant service sites.

The government will continue supporting access to vital care and treatment services on the occupied territories in collaboration with NGOs operating there. It is expected that by the end of 2018, 4,800 people will be receiving antiretroviral treatment. The target is based on the projected increase in the number of PLWH detected in the community and clinical settings.

Georgian PLWH organizations will continue performing a range of important functions related to ensuring the quality of care and treatment for PLWH, including necessary psychosocial support to patients and their relatives, advice on complex matters related to status disclosure, challenges faced by children and adolescents living with HIV, and participation in supply of ARV medicines to patients residing in remote areas of the country. Community-based organizations of PLWH will further engage in facilitating timely progression of PLWH to community-based support and clinical care. The role of community-based organizations in service development and delivery, quality assurance,

and patients' monitoring will be formalized, and the delivery of social support and other essential services will be included in the revised official treatment protocols.
The requested Global Fund support will contribute towards implementation of the following interventions:

- Provision of essential clinical care for all people living with HIV (PLWH) including access of patients to the required outpatient care and necessary laboratory diagnostics, in-patient care services, laboratory analyses to monitor disease progression and treatment progress (including CD4 cell count, HIV plasma viral load, and HIV drug resistance testing), as well as provision of quality adherence support services in collaboration with CBOs and patients' associations;
- Continued capacity development of the involved logistics and technical personnel, maintenance of means of transportation, health and communication equipment;
- Maintenance of the AIDS Health Information System including data quality control measures and field monitoring visits, regular revisions of clinical practice guidelines, implementation of quality control/clinical audit for clinical care, ART, and laboratory services;
- Intensification of collaborative activities between HIV and TB programs in order to ensure effective TB detection among HIV patients, provision of VCT for HIV for all TB patients, provision of both TB and HIV treatment for patients with co-infection, as well as administration of Isoniazid preventive therapy. Treatment and care for viral hepatitis to all PLWH in need is also ensured;
- In line with the new NSP, the program envisages a range of measures to reduce the negative influence of injecting drug use on treatment prospects. These include better collaboration with OST and addiction services; provision of additional adherence support to PLWH with history of IDU; and collaboration with outreach and prevention services on HIV detection and case management. NSP service sites case managers will be in charge of establishing relevant contacts and follow up protocols. The essential treatment targets in the monitoring framework are disaggregated by the history of IDU;
- Ensure provision of care and support services for PLWH. These services include the delivery of psychosocial support, peer support to strengthen treatment adherence, advice on coping with complicated issues facing PLWH, engagement of relatives of PLWH in care and support as well as in stigma elimination work, mutual support and awareness raising activities for PLWH, and a telephone hotline for PLWH, their relatives, and KAP representatives;
- Palliative care for chronically ill patients.

Objective 3: Ensure sustainably strong response to the epidemic through enhanced government commitment, enabling legislative and operational environment, and greater involvement of civil society

Module 6 (Removing Legal Barriers to Access) focuses on strengthening governance, improving policy environment and coordination of national response. The government is committed to sustaining the essential HIV prevention and care services previously funded from external sources including the Global Fund. The state budget allocations will be gradually increasing to ensure all essential interventions are sufficiently funded. However, the implementation of this transition will require thorough planning, changes in legislation and operational policies, as well as continuous involvement of the civil society and people affected by the epidemic in the development, implementation and monitoring of HIV policy development and application. The proposed program includes support to specific measures aimed at legislative changes and development of regulations and operational policies required to ensure uninterrupted delivery of essential HIV prevention and care services with special focus on the key affected populations.
The proposed funding transition planning will be achieved through the implementation of the following activities:
- Establishment of MoLHSA working group of relevant stakeholders for development of the Transition Plan; The draft Plan will be developed and submitted for approval to the CCM

be the end of 2016; The planning will include assessment/revision of operational policies required for smooth transition to governmental funding of activity areas currently funded from external sources.
- Development State procurement mechanisms and alternative procurement mechanisms with a focus on price optimization options;
- Development of effective mechanisms (standards of service, pricing, regulations) for transitioning of HIV prevention activities to the state funding;

Removing the legal barriers will be achieved through development and enforcements of legislative revisions, operational policies, regulations and guidelines to address issues affecting access to HIV services. Specific areas for legislative and policy initiatives are decriminalization of drug use, street testing for illicit substances, and access to rehabilitation services, prevention and management of overdose in community settings.
Greater participation of PLWH/KAPs/CSOs will be achieved through introducing effective constituency consultation mechanisms and supporting thematic policy development, advisory and advocacy activities implemented by national key population networks.
Collaboration of CSOs will be strengthened with associations of lawyers and human rights protection organizations on addressing discrimination: The joint plans of action will be developed through regular meetings to address the issue.
About 900 health care workers and 100 representatives of police and other law enforcement agencies will be trained annually to reduce HIV related stigma and improve their attitude and practice for HIV case management. Annual mass media campaigns will be implemented to address the issues of HIV and KAP related stigma and promote HIV prevention and treatment services.
The advocacy campaigns will also include:

- Annual drug policy conference (incorporating policy development and advocacy planning workshop);
- Advocacy campaigns devoted to relevant events such as AIDS Memorial Day, International Day Against Drug Abuse and Illicit Trafficking, International Hepatitis Day, International Overdose Awareness Day, and World AIDS Day (including printed materials);
- Strengthening of LGBT community capacity on HIV prevention and advocacy effort through training activities.

The development of effective policies and interventions requires up-to-date knowledge of epidemiology and response implementation data. The program includes essential epidemiologic and operational studies to ensure adequate intervention design. Improved knowledge of specific needs and vulnerability factors affecting various segments of KAPs will enable the development of effective and tailored interventions.
The results of the epidemiological studies and operational researches will be utilized for critical analysis of the interventions and development of adequate changes in the program designs and activities as well as targeting the right segments of the KAPs.
The existing program monitoring system will be further strengthened. An unified HIV Prevention database to be created by the end of 2015 within the GF Program will serve as an effective platform for M&E activities and analysis. The database institutionalization includes consistent utilization of Unique Identification Codes;
Next revision and adjustments in the essential monitoring and evaluation definitions is planned in 2017; The difference between the IBSS and programmatic data call for conducting the triangulation of available sources of data; This activity will be conducted through procurement of the relevant technical assistances. The unified HIV prevention database will enable service providers with tools for disaggregation of program monitoring data by the most epidemiologically significant segments of KAPs.
Collection and analysis of regional level data will allow for setting appropriate targets at the regional/municipal level. Participatory quality assessments of the drug scene and other essential contextual characteristics will allow for better understanding of changes affecting KAPs and the risk of HIV transmission, and for timely adjustment of the interventions.
Expected Impact, Outcomes and Coverage targets by end 2018
1. Increased funding of HIV response from state budget from 32% (2013) to 70% (2018);

2. By 2018 HIV prevalence among PWID, SW and prisoners is contained under 5% each[ix];
3. By 2018 HIV prevalence among MSM is contained under 15%;
4. Rate of late HIV detection is reduced from 62% to 30% by 2018;
5. AIDS related mortality is reduced below 2.0 deaths per 100,000 population

Taking into account the limitations of prevalence indicator in the context of effective prevention and care interventions leading to decreasing incidence of HIV transmission and decreasing mortality, it is important to collect data that may serve as proxy indication of incidence. This will be achieved through disaggregation of prevalence data by age (below 25 and 25 and more), as well as the length of injecting career (less than 3 years and 3 years and more). Combined and triangulated with the SPECTRUM estimates as well as with planned HIV incidence estimation study using recent infection testing algorithm (RITA), these disaggregated prevalence indicators will allow for establishing whether the expected reversal of the HIV epidemic is being achieved.
Targets for coverage by essential prevention services and HIV testing by the end of 2018 are as follows:

	2016	2017	2018
PWID coverage	25650 (57%)	27900 (62%)	30150 (67%)
PWID testing	23085 (51%)	25110 (56%)	27135 (60%)
OST capacity	800		
MSM coverage	4250 (25%)	5950 (35%)	8500 (50%)
MSM testing	3060 (18%)	4250 (25%)	6800 (40%)
FSW coverage	2610 (40%)	3263 (50%)	3915 (60%)
FSWs testing	1958 (30%)	2610 (40%)	3263 (50%)
Prison testing	5500 (55%)	6000 (60%)	6500 (65%)

Essential treatment coverage targets for 2018 are as follows:

Percentage of adults and children with HIV known to be on treatment 12 months after initiating treatment among patients initiating antiretroviral therapy	90%
Percentage of newly diagnosed persons who are enrolled in care	>90%
Percentage of people on ART tested for viral load (VL) with VL level ≤ 1000 copies/ml after 12 months of therapy	85%
Number of adults and children currently receiving antiretroviral therapy in accordance with the nationally approved treatment protocol at the end of the reporting period	4800 (59%[x])

ix. HIV prevalence data will be disaggregated by age (below 25 and more) and the length of drug using career (less than 3 years and more) in order to obtain proxy incidence data;
x. Denominator is based on the Spectrum estimates and will be changed in line with the regular Spectrum updates.

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

This question is <u>not</u> applicable for low-income countries.

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

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

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

½ PAGE SUGGESTED

The request to the Global Fund is centered on strengthening the continuum of HIV prevention and care services targeting the most affected populations including PWID, MSM, SW and prisoners, as well as people living with HIV. Four of the included modules are fully devoted to outreach and basic prevention services (including detection of HIV infection) among KAPs. The HIV care and treatment module including the PMTCT part (representing a marginal share of the requested funding) enable gradual transition of ART and associated activities from external to the state funding over the course of the proposed program. It should also be noted that PLWH with history of injecting drug use form a special segment within the population of ART patients, and will be provided with additional counseling and home-based monitoring services designed to improve treatment retention, adherence and outcomes. The studies included under the monitoring module support further development and improvement of interventions targeting KAPs and PLWH. Legislation, regulations, operational policies and patterns of practice affecting KAPs are the major focus of activities included under the module 'Removing legal barriers to access'. This module also concerns the promotion of essential HIV prevention services for KAPs. All included interventions are high impact interventions, which constitute essential parts of HIV service continuum.

SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

4.1 Overview of Implementation Arrangements

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

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

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

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

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

e. How representatives of women's organizations, people living with the three diseases, and other key populations will actively participate in the implementation of this funding request.

1-2 PAGES SUGGESTED

a) The proposed Principal Recipient has been nominated by the CCM for continuation of

the role as a successful PR with B1 rating. The PR, National Centre for Disease Control and Public Health, is a relatively young governmental organization, which actively explores new and more effective business models and open to creation of productive partnerships, including cross-sectorial ones. Over the course of its PR career the organization gained considerable authority among the civil society organizations involved in the development and delivery of HIV responses in Georgia. Introduction of a second PR would significantly increase the administrative burden of the proposed program and decrease the return on investment. A large proportion of the proposed program will be implemented by trusted non-governmental organizations at the SR level, which will represent the interests of PLWH and the key affected populations. The substantial policy development and advocacy component of the proposed program is an additional warranty for the essential engagement of civil society in the development of solutions to key challenges facing the national response to HIV epidemic, including those related to the response architecture. Combined with the increasing leadership and commitment of the government of Georgia, substantive involvement of civil society in the development and implementation of the program will offer a well-balanced implementation arrangement.

b) The proposed program involves only one Principal Recipient.

c) Most of the civil society SRs involved in the implementation of the current grant are expected to continue their engagement. In addition to this existing implementation workforce, several new organizations, notably, community-based organizations representing the interests of MSM and other KAPs are expected to get engaged and contribute to further expansion of intervention coverage and service quality improvements. These will be provided with necessary support to develop the required technical and administrative functions.

d) NCDC has established effective platform for coordination of services delivered by SRs and SSRs within the GF grants. SRs undergo pre-contracting assessment by PR, which identifies the strengths and weaknesses in their management systems and develops relevant risk-reduction recommendations. Implementation of the recommendations is subject to close monitoring by PR. Implementation schedules of each component of the program are agreed with SRs in advance and are incorporated in the contracts signed with SRs. The schedules also include activities to be implemented by SSRs.

M&E officers/coordinators responsible for different areas of work together with the Program Manager conduct monthly and quarterly meetings to review the achievements, drawbacks and in coordination with SRs initiate necessary actions and re-programming when appropriate. Coordination functions performed by the M&E officers are technically strengthened by advisory functions performed by dedicated cross-organizational bodies to improve the governance and technical strength of specific components such as the policy development and advocacy work.

SSRs are required to report to SRs on implementation progress on a regular basis. SRs generate consolidated monthly reports and submit them to PR. The report includes programmatic, financial and M&E information relevant to the implementation periods. Three M&E officers/coordinators of PIU HIV program team are responsible for regular coordination and monitoring of SRs and SSRs work. HIV program team's weekly meetings contribute to the effective coordination of cross-component activities, especially in case of procurement of supplies that are utilized by several SRs or training activities organized on subjects of common interests.

The CCM through its oversight committee is assessing the effectiveness of coordination arrangements established by PR and SRs. Dashboard review is an additional process that provides CCM members with the information regarding the program achievements and pending issues, including those that need better coordination for positive resolution.

e) Representatives of women's organizations, people living with HIV, and key affected populations will actively participate in the implementation of this funding request through the following mechanisms:

- CCM will include gender sensitivity dimension in the implementation of its oversight

function following the recent capacity development support provided to CCM members on the matter;

- Policy and Advocacy Advisory Council, which will provide essential guidance and govern the development and implementation of the program policy development and advocacy efforts will include representatives of PLWH community and KAPs. The Council will also involve representatives of women's organizations, human right protection organizations and other structures as appropriate in order to ensure the inclusiveness of intervention development and implementation processes;
- Women will be actively involved in the development of gender sensitive solutions such as design and implementation of measures to make OST services more attractive to women who inject drugs, as well as design of the interventions targeting sexual partners of PWID and female sexual partners of MSM.

4.2 Ensuring Implementation Efficiencies

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

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

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

1 PAGE SUGGESTED

The proposed program is a continuation of the existing HIV grant and will not overlap with it. It will be implemented in parallel with the Global Fund supported TB related activities. Stakeholders involved in the implementation of HIV and TB activities are engaged in the dialogue regarding the linkages between the programs, common challenges and required solutions. There is no overlap between the areas of work associated with HIV and TB grants, and no overlap between the implementation partners. The technical personnel directly involved in HIV program implementation are not involved in the implementation of TB program. Neither they perform overlapping functions.

The management system of the HIV and TB Program Implementation Units of the PR is based on the programmatic needs of the two Global Fund supported programs: HIV and TB Programs. HIV Program personnel, who were selected through a transparent process based on thorough assessment of their competencies, include the Program Manager and three M&E officers/coordinators. For cost-effective management of the unit, the rest of the staff is shared and are operating in full compliance with the donor regulations and requirements of the local regulating authorities regarding financial, procurement management, and logistical support. The shared management and administrative staff include the following:

- Financial team including one Financial Manager and three Financial Specialists;
- Procurement team including one Procurement Manager, three Procurement Specialists (one of them with PP procurement background), and one Logistics Specialist;
- One administrative assistant and one driver.

The two programs share administrative costs proportionately to the number of staff involved and their level of effort in the implementation of each of the programs.

4.3 Minimum Standards for Principal Recipients and Program Delivery			
Complete this table for each nominated Principal Recipient. For more information on minimum standards, please refer to the concept note instructions.			
PR 1 Name	**National Center for Disease Control and Public Health (NCDC)**	**Sector**	**Governmental**
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?		☒ Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		NCDC is a relatively new PR of TB and HIV grants. The organization has taken over the management of both grants from previous PR in April 2014. For this purpose NCDC has created dedicated PIUs to ensure effective implementation in compliance with donor and national regulations. The NCDC is a legal entity of public law accountable to MoLHSA, is largely funded from the State budget, and implements a number of projects funded by international donors. It is the country's lead organization at the national level for the prevention and control of communicable and non-communicable diseases. The NCDC collates health statistics for policy and decision makers with an aim of monitoring the public health conditions and facilitating the relevant policy development processes. The NCDC implements the following State Programs: HIV/AIDS, Tuberculosis, Immunization, Occupational Diseases, Safe Blood, Early detection and screening of diseases, Maternal and Child health and Epidemiological Surveillance. NCDC has experience of implementing programs financed by the state budget as well as by international donor organizations such as: US Centers for Disease Control and Prevention (CDC), Global Alliance of Vaccination and Immunization (GAVI), North-Atlantic Alliance (NATO) "Science for Peace", International Union against Tuberculosis and Lung Diseases, Defense Threat Reduction Agency (DTRA), European Union, WB, WHO, UNICEF. NCDC's main expenditure categories are: pharmaceutical products, lab materials, reagents, medical equipment etc. The total value of services and products procured by NCDC during the past 12 months is estimated at 10,115,000 USD. For the management of the Global Fund programs	

	NCDC has created a dedicated PIU to ensure smooth implementation of the grants in full compliance with the Global Fund requirements and the Georgian regulations. PIU has all 17 key positions filled as per unit's Organizational Chart[xi] (Global Fund Programs Director, two Program managers, 2 M&E officers for HIV and TB Programs, and M&E specialists (2 for HIV Program), financial Manager, three financial specialists, Procurement manager, three procurement specialists, logistics specialist, PSM specialist, and administrator). 15 out of the 17 staff are involved in the implementation of HIV Program. The PR unit is well integrated with the rest of NCDC management. Three staff members of NCDC are providing technical and management support to the PIU unit ensuring the effective linkages in accounting, administrative and programmatic areas. PIU staff has been selected through transparent and competitive process observed by LFA and the Global Fund portfolio manager. The Program team is comprised of highly skillful and experienced professionals in the field of public health, health management, and program management, including procurement and financial management with good knowledge of the state regulations. During the last 12 months of the program implementation the PIU staff has gained extensive experience of working under the Global Fund framework of program management, including establishment of project objectives, risk assessment and control, budgeting, project activities planning and management, monitoring and evaluation, progress tracking and reporting, defining final project results, procurement management, resource management, quality management etc. Evaluation of PR programmatic performance has shown that the HIV grant has met its targets at a satisfactory level. Within the first three months of acting as a PR (April-June, 2014) NCDC received B1 rating from the Global Fund for GEO-H-NCDC Program.
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	NCDC possesses high capacity and has gained sufficient experience in the effective management and oversight of sub-recipients during the last 12 months of acting as the Global Fund PR. Within the current Global Fund HIV program NCDC is managing 8 SRs and 24 SSRs that represent a mixture of state institutions, NGOs and CBOs. The principles of the SRs and SSRs oversight and control are regulated by the relevant SOPs. The PIU is established as an effective team for management and oversight of SRs and SSRs, for accurate, effective and transparent financial management and control, well defined set of programmatic indicators,

[xi] Please refer to Annex with organizational chart.

	and accurate data collection and validation systems. The SRs are provided with the regular programmatic and financial management feedback.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	NCDC's internal control system is considered effective to detect misuse of funds and/or fraud. As described in the PIU Operations Manual, the management system is fully in line with the requirements of transparency, competitiveness, quality and efficiency, and is built based on the principles of (i) usage of funds only for intended purposes, (ii) economy and efficiency, (iii) competitive selection, (iv) appropriate evaluation criteria, (iv) appropriate technical specifications / terms of reference, (v) openness and transparency, (vi) highest standard of ethics excluding fraud or corrupt practices, (v) avoidance of situations of conflict of interest. The internal control system is implemented through mechanisms including: a code of conduct which all personnel subscribe to; clear delegation of authority that prevents individuals from processing incompatible transactions; regular reports and reconciliations to the Global Fund; a financial management system with strong and proven controls and periodic reviews and audits by the LFA and external audits of PR operations and PR compliance reviews for SRs operations. For the last fiscal year the external audit was completed by KPMG during February-March 2015 and the PR was found to be fully compliant.
4. The financial management system of the Principal Recipient is effective and accurate	The PR's financial management system is considered effective and accurate. PIU maintains a financial management system, including records and accounts, and prepares financial statements in a format acceptable to the Global Fund, adequate to reflect the operations, resources and expenditures related to project implementation and to meet the financial management requirements of Georgia. A Project Operations Manual, that includes a chapter on financial management, has been developed by PIU with assistance of GMS and has been shared with the Global Fund and used as the main tool in the PIU's financial management. Accounting records are maintained in a way that prevents any unauthorized and improper corrections (unauthorized subsequent amendments of transactions). The LFA performs external semi-annual audits of the PIU's financial management practices. In addition, annual external audits are performed by independent auditors on terms of reference acceptable to the Global Fund.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health	In relation to the Global Fund programs, the overall responsibility for Pharmaceuticals and Health Products Management (PHPM) related activities, as outlined in the "Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2012)" stays with NCDC as the PR. The PR assumes the overall responsibility for

products	implementation of grant PHPM activities in line with applicable policies and principles (including compliance with the Global Fund Principles on Procurement, and their Quality Assurance Policies). At NCDC the Central warehousing and logistics/distribution are performed for specific diseases and/or type of products. Laboratory supplies and vaccines are warehoused in the premises of the NCDC. HIV and TB products (including prevention, diagnostics, and treatment) are warehoused in SRs storage rooms: IDACIRC, the National TB Center, the National Center for Narcology, and NGOs such as Tanadgoma and GHRN. The Global Fund PIU runs procurement and inbound logistics with three staff, separately from the state-funded programs, which are run by six other staff. Customs clearance is outsourced to a broker company. IDACIRC serves as central warehouse for ARV medicines and other health products delivered through the Global Fund support. IDACIRC has adequate space to appropriately store high volumes of ARV drugs, although it is spread over several separate rooms within the pharmacy. Information on central stock, including all receipts and issues are documented on paper-based forms and also entered in AIDS HIS. On a quarterly basis, the HIV/AIDS Treatment and Care Component manager monitors the management of stock of all pharmaceuticals and health products supplied under the Global Fund programs at the central, regional and district levels. In relation to medicines the main aspects that are looked into are: storage, record keeping and reporting, stock balance, prescribing and adherence to treatment regimens. Storage and distribution of methadone is regulated by a decree of the minister of LHSA (decree #212/N, 2008). As soon as PR receives the methadone stock, it is stored in main storage at the Ministry of Internal Affairs (MIA) and is transferred to SR. After that SR takes responsibility for storage and distribution of the regulated substances. The main stock is placed in special facility of MIA to ensure the highest degree of security. The specially authorized representative of SR is responsible for the main stock and its distribution to SSRs. The distribution of methadone to the treatment program is carried out once in 4 months at the request of SSRs. In OST program facility the stock is stored in a special room – storage that is organized according to the above-mentioned decree with high level of security. Relevant institutional SOPs are in place that guide the storage and dispensing of the drug at the OST centers. Storage at the central level is in secure areas

	protected from unauthorized access and free from pests, direct sunlight, extremes of temperature, water or leaks. Items requiring cold chain are stored in walk-in coolers or upright refrigerators with thermometers and full time power. Receipt and distribution of goods to and from the central level are recorded using various inventory control tools. The warehouses are equipped with measure tools for monitoring temperature and tool for recording mentioned parameters. The goal of the Logistics Management Information System (LMIS), developed within the USAID HSSP program is currently in the final phase of piloting, is to manage the receipt, issue, expenditure and decommission of stock across multiple public health programs. Different transactions can be performed, including receipt and issue of stock as well as generating statistical data, reports and conducting analysis. The HIV commodities will be managed using this system once it is up and running. The standardized recording and reporting forms for drug management (consumption, ordering) are in use by all AIDS treatment centers in the country. Regional Centers provide reports to the IDACIRC on a monthly basis. The reports include individualized patient specific data and summary reports for the particular month for FLDs and SLDs. The summary reports provide information on the balance of the stock at the beginning and the end of month, quantities received and consumed; expiry dates of drugs; these reports that are collated by IDACIRC for submission to NCDC each month. Also, it is planned that all of the NCDC's PSM activities will by unified and centralized for the supply chain's successful transition to the refrigerated and non-refrigerated warehouse at one of its main facilities - Lugar Center. PR will be able to utilize this state-of-the-art warehouse for the Global Fund Program PSCM purposes. NCDC is planning to improve its capacity and the process of delivering goods to its regional public health units and PR will be reviewing the options for utilizing the same mechanisms for transportation of prevention commodities to its regional sites.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	The secure and continued supply of health products is ensured in operations based on the relevant SOPs for forecasting, development of specifications, market search, procurement and distribution. After the necessary port and customs formalities are completed, the drugs and health products are delivered to the storage facility of the SRs where goods are inspected, received and stored before being distributed to the treatment and prevention services' sites. Storage capacity at all treatment facilities is considered sufficient for the expected quantities.

	Regular monitoring of inventory management activities are undertaken by the PR through visits to SRs and SSRs' facilities. The monitoring includes review of storage practices, relevant documentation, physical presence of assets and purchased goods, as well report validation. 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, monitor use of the products and manage expiry dates. As mentioned above, IDACIRC serves as a central warehouse of the treatment and care component of the Global Fund program. All drugs and other health products procured through the program are delivered to IDACIRC's central pharmacy, from where drugs are distributed to service provider sites. ARV drugs are dispensed to patients at 5 treatment sites countrywide – IDACIRC AIDS outpatient clinic and 4 regional treatment facilities who act as SSRs. Product dispatch from IDACIRC is based on SSR's formal order request, which is screened by IDACIRC by reviewing information on stock level and number of patients at the treatment site. Drug pick-up by the patient at the various treatment sites is documented in the medication log-book and the data from the log-book is entered into the AIDS-HIS within 2 working days. The distribution of Methadone follows very strict rules regulated by the Ministerial decrees. The Drug is stored at the special storage site with high security standards and is distributed upon formal request of OST program manager. The state security personnel accompanying the courier safeguard the delivery. The OST program manager receives and counts the drug, adds the amount to the stock register and hands to the OST pharmacist who is in charge of the methadone storage and dispensing. The drug stock information at all OST program sites is updated on a daily basis. Distribution of HIV screening test-systems, syringes and condoms follows different principles from the distribution of ARV drugs. They are delivered directly to SRs and SSRs storages according to the plan PR indicates in the tender announcement for procurement of syringes. Local sub-managers inspect the goods and sign the delivery forms. The delivery to the regional sites of VCT program is conducted by vehicles and authorized personnel. In this case three different SRs are in charge of distribution: GHRN, Tanadgoma and IMHPA. Total number of regional and district sites is 21. The travel time to the most remote site by car is 6 hrs. The same principles of procurement and distribution are applied to prevention commodities. Procurement

	of syringes, condoms and lubricants will be conducted through IDA, while all other prevention commodities, including screening tests will be procured locally. Suppliers will be responsible for delivery of the goods to SRs. SRs will distribute supplies among SSRs and relevant amounts will be budgeted in the program. SRs and SSRs will be reporting utilization of prevention commodities through LMIS of PR. PR and SRs will monitor consumption online and also through monitoring visits. SRs and SSRs mostly utilize rented storage rooms with poor conditions. During 2015 PR is planning to provide technical support to either improve the conditions of the rented storage rooms or make SRs and SSRs to find better facilities with adequate storage conditions.
7. Data-collection capacity and tools are in place to monitor program performance	The initial stage of data management at the PR level is data collection from sub-recipients. Sub-recipients of HIV program are implementing programmatic activities based on grant agreements signed with NCDC. The agreements include sub-recipients' scope of work, implementation work-plan and budget, performance indicators and targets, relevant procedures for grant management, reporting procedures and other clauses. PIU HIV program M&E activities are conducted by the M&E officer and two M&E specialists. They conduct the sub-recipient's assessment to determine whether the nominated SR meets requirements in terms of institutional and programmatic capacity, financial management, supply management, and monitoring and evaluation capacity. To ensure the quality and integrity of the programmatic and financial data reported by the SRs, the following elements and procedures are in place: • Standard procedure for review and reconciliation of SRs' reports; • Onsite data validation and coaching of SRs; • Annual financial audit by independent auditor of projects implemented by the SRs. Generally, the periodic reporting and disbursement schedule is monthly, In accordance with the terms of the grant agreements with the sub-recipients, the SRs provide to the NCDC periodic programmatic and financial reports along with the next disbursement request, which is submitted not later than 15 days after the end of each period. The HIV Program M&E team reviews and verifies SR's periodic reports to determine whether the reported activities are in compliance with the grant agreement between the PR and the SR, the agreed upon performance framework. Data analyses are conducted comparing planned targets versus actual achievements monthly, quarterly, semi-annually and

	a detailed review of underlying reasons for observed variances are provided. Semi-annually consolidated progress reports are generated and discussed by the PIU Program Manager and relevant stakeholders in joint review meeting and prior to completing of the PU/DR. Hard copies of reports submitted by Sub-Recipients are stored at PIU. IDACIRC operates its web-based database for collecting and analyzing the close to real time data regarding monitoring of ART. At present SRs working on prevention programs use excel databases that contain all relevant data, but relatively time-consuming for the analytical work. However, In 2015 PR has budgeted and is planning to procure services for the development and implementation of the unified National HIV Prevention Service database that will be also web-based real time software applicable to all HIV programs and fully satisfy the Global Fund M&E reporting needs. The piloting of the database will be completed by the end of 2015. The monitoring and evaluation information (including external evaluation reports) is 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 feeds into the reports on the National HIV/AIDS Program, international reports, such as GARPR report, and is channeled to respond to other data collection obligations / purposes, as well as used for continuous improving of Program implementation.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	As it was indicated above, the PR is using the SRs existing capacity for routine data reporting systems. The databases (both the web-based for ART and excel database for prevention programs) have analytical capacity and the routine reports can be provided regarding all performance indicators. However, the new web-based unified HIV prevention services database to be institutionalized by the end of 2015, will considerably strengthen this capacity and will provide options for real-time data analysis. All SRs and SSRs have sufficient technical capacity to get enrolled in the new software system, enter the data and generate monthly, quarterly and semi-annual coverage data. M&E indicators are well defined in the updated M&E framework of the HIV NSP. The final agreement regarding the definitions of performance indicators was reached in January 2015 when the last amendments were made for coverage indicators for PWIDs, MSM and FSWs.

9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	It is the responsibility of the NCDC/PIU to ensure that all HIV health products (pharmaceuticals, as well as diagnostics) being purchased with Global Fund financing, meet the requirements of the National Drug Regulatory Authority and of the Global Fund's quality assurance policies. The procurement of all first and second-line ARV drugs is conducted through the Global Fund Pooled Procurement Mechanism (PPM). All ARV and HCV treatment drugs that are purchased under the Global Fund grant comply with the Global Fund QA policy requirements and meet the following criteria: i) Prequalified by the WHO Prequalification Program or authorized for use by a Stringent Drug Regulatory Authority (SRA); or ii) Recommended for use by an Expert Review Panel (ERP). All diagnostic products purchased are in strict adherence to the Global Fund QA policy requirements: i) The PR ensures that all medical equipment procured under the grant, are manufactured at a site compliant with the requirements of ISO 13485:2003 or an equivalent quality management system recognized by a regulatory authority which is a member of GHTF; and ii) Any Diagnostic Products, for which the above does not apply, should be manufactured at a site compliant with all applicable requirements of the ISO 9000 series. One out of the three procurement specialists is a physician with extensive experience of working on sales and procurement of health products, The PR ensures that bidding documents prepared for procurement of diagnostic products include the following provisions: On arrival, goods received are inspected for compliance with stated requirements such as packaging and labeling and quantities are verified before confirmation of receipt is provided. The State Regulation Agency for Medical Activities (SRA) of MoLHSA is a national drug regulatory authority responsible for market authorization of pharmaceutical products, licensing of pharmacies and pharmaceutical manufacturing, inspection of pharmaceutical premises, quality control, rational use and pharmaco-vigilance. But it has no capacity for GMP inspection and no role in procurement. SRA does not have its own laboratory and these services are currently outsourced to the laboratory of the National Forensics Bureau of the Ministry of Justice of Georgia. This laboratory has ISO 17025:2010 certification. SRA conducts pharmacy inspections and carries out random sample purchases at pharmacies, which afterwards are sent

	to the laboratory for testing. In case of failing QC test SRA organizes a product recall. Currently, samples of the pharmaceutical products from public health service providers are not taken. The PR in collaboration with IDACIRC and SRA plans to utilize SRA's expertise in QA. The relevant sampling plan is developed on a risk-based approach. Pharmaceutical samples are drawn from various points of the supply chain and tested in the Laboratory of National Forensics Bureau of the Ministry of Justice of Georgia (laboratory has ISO 17025:2010 and therefore meets the Global Fund requirements). The PR is currently negotiating with the Lab for QC of selected medicines from the stock procured of previous PR. The medicines procured by the NCDC For the QC of HIV diagnostic test-systems the Serology and Virology Laboratories of the IDACIRC is used. The Serology and Virology Laboratory of the IDACIRC participates in annual external proficiency testing and has the 2013 certificate from Oneworld Accuracy. The laboratory undertakes regular equipment maintenance and calibration is done as scheduled. Other HIV diagnostic laboratories countrywide monitor the performance of screening test systems through the observation and documentation of false positive results of HIV screening. In case of receiving excess number of false positive results, the regional Lab would alert the IDACIRC Lab experts and will request the Quality Check of the test-system. Unfortunately, there is no mechanism or practice in place to assess if the specificity of the test-systems purchased and distributed is satisfactory. The IDACIRC Laboratory for all VCT sites performs all confirmation testing of reactive samples. Management of medicines that failed quality control is performed in accordance with the following general provisions: (a) The national regulation describes management procedure in case of failing quality at the import stage or in case of post – marketing identification of the quality issue. (b) The drugs, whose quality does not correspond to the provisions of the analytical-normative documentation, are prohibited for sale and distribution in Georgia. These drugs must be returned to the manufacturer/supplier or destroyed in accordance with the current legislation. From the procurement perspective, the minimum shelf life shall be not less than 60% from the total term in case of medicine with 2 years or more shelf life; In case of product with total shelf life up to 2 years, the minimum shelf life at the delivery should be 80%.

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

a. With reference to the portfolio analysis, describe any major risks in the country and implementation environment that might negatively affect the performance of the proposed interventions including external risks, Principal Recipient and key implementers' capacity, and past and current performance issues.

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

1-2 PAGES SUGGESTED

HIV prevention, treatment and care interventions to be implemented within the GF NFM CN program are complex, multi-sectorial, and require strong and effective coordination of efforts among different stakeholders to ensure that the major risks are identified from the beginning and all necessary measures are taken to guarantee reasonable assurances regarding the achievements of the goal and the objectives set within the program.

Sustainability of the national response to HIV and fulfillment of commitments regarding increasing domestic allocations for HIV programs by the state is the most critical task where the main focus of the risk reduction and management efforts needs to be located during 2016-2018. The commitment of the relevant government departments and other stakeholders to sustainable funding of the National HIV program is confirmed through the endorsement of the NSP document by the CCM and will be further strengthened with the pending approval by the Cabinet of the Ministers.

The CCM will closely monitor and strongly advocate for the fulfillment of the state obligations guaranteeing uninterrupted implementation of ART, OST and other key interventions to be funded from the state budget.

In order to ensure smooth transition from the Global Fund to the state funding of the HIV programs, by mid 2017 the CCM will develop and present to the Global Fund the sustainability plan for the transition period for National HIV Program that will provide detailed framework for handover of all activities supported by the Global Fund to the state emphasizing and addressing the greater needs for making necessary regulatory changes for developing an effective platform for state funding of HIV prevention activities among the key affected populations. Among the other topics, the transition plan will include thorough analysis of subcontracting mechanisms allowing civil society organizations to deliver essential outreach, prevention, and care services to PLWH and KAPs[xii].

Lack of experience and adequate mechanisms for local procurement of ARV medicines is another risk that CCM draws its attention to. In 2015 the country is obliged to procure the first line ARV drugs with the state funds. PR is exploring different procurement options, including local distributors and PPM, for placing timely orders and achieving best quality and price. Based on the initial market search both locally and internationally, the CCM and PR are confident that through this challenging process the country will be able to establish a solid foundation and develop effective mechanisms for addressing this risk and procure quality ARV medicines at reasonable prices. Once the local procurement mechanism is fully tested, the following shift from external funding source to state budget will not present significant challenges, as the procurement function will be exercised by the same governmental agency – NCDC. This will greatly facilitate harmonization of quantification, supply and other aspects of the transition. Uninterrupted provision of ART will remain a top priority issue in the risk management agenda of CCM and PR.

[xii] Although this represents an important area in the design of operational mechanisms for the national response to HIV epidemic, the required amendments are of limited magnitude. NGOs are currently contracted by a governmental agency (NCDC) to implement HIV prevention and care interventions. There are no legal barriers to subcontracting civil society organizations. Most of the technical difficulties faced by some NGOs, such as those associated with the bank guarantee requirement for advanced payments for services, can be resolved at operational level.

With regard to the programmatic and performance risks, poor quality of data is a risk for effective M&E and reporting within the program. Unified web-based HIV prevention database that has to be developed within the current GF HIV grant by the end of 2015 will resolve the issue and provide integrated M&E framework and relevant analytical tools for tracking the programmatic achievements and simplified reporting for the State, the Global Fund, and GARPR.

From financial and fiduciary risks maintaining adequate absorption rates was in the past one of the challenges the PR was facing. During the past implementation period PR has identified considerable inefficiencies, as well as generated savings due to rationalization of the ART regimens.

In order to address this risk PR has established average monthly consumption monitoring process for HPHE products and is going to utilize this experience during budgeting and procurement planning processes that will improve the absorption rate as the budgeting will better reflect the actual needs of SRs and SSRs.

High inflation rate currently observed in the country is one of the most critical and difficult to manage risks. CN budget includes 5% inflation adjustment rate per year to address this risk. If this arrangement will not be sufficient, the CCM and PR will conduct prioritization of the interventions and will make relevant re-programing to ensure balanced funding of all key activities.

Addressing the challenges related to access to essential HIV prevention and care services by the key populations, including legislative and regulatory amendments, stigma reduction measures, and community monitoring of service delivery and human rights violations will require constant monitoring and stakeholder support. The CCM is going to effectively utilize its oversight function, and the PR will rely on strategic guidance from the Program Advocacy Council in its management of the policy and advocacy component of the program (Module 6 – Removing Legal Barriers of Access). The Council will effectively engage and include representatives of the affected communities and human rights protection organizations. External technical assistance will be thought where required and feasible. The CCM will develop and monitor implementation of relevant actions to address issues identified during oversight or technical assessments.

For governance and oversight the CCM and PR do not envisage any major risks. Both, the LFA and external audit found the PR compliant with the Global Fund and local regulations. PR's organizational structure, leadership and internal controls are well tailored to the program needs. The senior management has been instrumental in ensuring smooth transition from the previous PR in April 2014. PR is working on further improvements in its management and oversight capacities as well as on improvement of SRs and SSRs' capacities.

In 2015 PR is taking major actions for improvement of its PSCM system. Logistics Management Information System (LMIS) is currently being piloted and will be fully institutionalized by PR by the end of 2015. The system will allow full tracking of all assets and consumables at PR, SR and SSR levels.

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

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

References:

1. Global AIDS Response Progress Report, Georgia, January 2012 - December 2013, National Centre for Disease Control and Public Health, Tbilisi, 2014.

http://www.unaids.org/sites/default/files/country/documents//GEO_narrative_report_2014.pdf

2. Population Size Estimation of Men Who Have Sex with Men in Georgia, 2014. Curatio International Foundation, Tanadgoma. August, 2014. http://www.curatiofoundation.org/uploads/other/0/255.pdf

3. Tsertsvadze T, Chkhartishvili N, Dvali N, Karchava M, Chokoshvili O, Tavadze L*, et al.* Estimating HIV incidence in eastern European country of Georgia: 2010-2012. *Intl J STD AIDS* 2014,25:913-920.http://std.sagepub.com/content/25/13/913

4. Estimating the prevalence of injecting drug use in Georgia. 2012.

5. HIV risk and prevention behaviours among People Who Inject Drugs in six cities of Georgia, Bio-behavioral surveillance survey in Tbilisi, Batumi, Zugdidi, Telavi, Gori, Kutaisi in 2012 , Study report Prepared by: Curatio International Foundation Public Union Bemoni February 2013

6. Population Size Estimation of Female Sex Workers In Tbilisi and Batumi, Georgia 2014

7. HIV risk and prevention behaviors among Female Sex Workers in two cities of Georgia Bio-behavioral surveillance survey in Tbilisi and Batumi. Curatio International Foundation, Tanadgoma. August, 2014. http://www.curatiofoundation.org/uploads/other/0/292.pdf

8. HIV/AIDS treatment and care in Georgia. Evaluation report. WHO 2014. Pages 1, 4.

9. Global Tuberculosis Report 2014, World Health Organization

http://www.who.int/tb/publications/global_report/en/

10. National Center for Tuberculosis and Lung Diseases, TB National Database, Tbilisi, Georgia, July 2014

11. Chkhartishvili N, Sharvadze L, Chokoshvili O, Bolokadze N, Rukhadze N, Kempker RR*, et al.* Mortality and causes of death among HIV-infected individuals in the country of Georgia: 1989-2012. *AIDS Res Hum Retroviruses* 2014,30:560-566

12. Short term/urgent measures of Hepatitis C elimination, Action Plan for Georgia, National Center

for Disease Control and Public Health, 2015

13. Chkhartishvili N, Sharavdze L, Chokoshvili O, DeHovitz JA, del Rio C, Tsertsvadze T. The cascade of care in the Eastern European country of Georgia. *HIV Med* 2015,16:62-66.

http://www.ncbi.nlm.nih.gov/pubmed/24919923

14. The situation of human rights and freedoms in Georgia. Annual report of the public defender of Georgia, 2012. Page 346 on HIV related stigma http://www.ombudsman.ge/uploads/other/1/1350.pdf

15. E.g. N.Gulua, et al. HIV related knowledge, attitude, practice and stigma among dentists in Georgia. : 6th IAS Conference on HIV Pathogenesis and Treatment: Abstract no. CDC135. Accessed at www.iasociety.org/Abstracts/A200741366.aspx on 10 April 2015.

16. HIV risk and prevention behavior among Men who have Sex with Men in Tbilisi, Georgia. Bio-behavioral surveillance survey in 2012. Curatio International Foundation, Tanadgoma. February, 2013. http://new.tanadgomaweb.ge/upfiles/dfltcontent/3/123.pdf

17. The Georgian Healthcare System State Concept 2014 – 2020 “Universal Healthcare and Quality Management for Protection of Patients Rights”, GoG Ordinance No 724, December 26, 2014

18. Government of Georgia Ordinance No 400, June 17, 2014. Accessed 29/12/2014 at http://www.government.gov.ge/files/382_42948_789793_400170614.pdf

19. HIV risk and prevention behaviors among Prison Inmates in Georgia Bio-behavioral surveillance survey in 2012. Curatio International Foundation, Tanadgoma. February, 2013. http://new.tanadgomaweb.ge/upfiles/dfltcontent/3/124.pdf

20. The Joint United Nations Program on HIV/AIDS, The Gap Report. Geneva: UNAIDS; 2014.

http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2014/UNAIDS_Gap_report_en.pdf

21. Chkhartishvili N, Sharvadze L, Chokoshvili O, et al. Mortality and causes of death among HIV-infected individuals in the country of Georgia: 1989-2012. *AIDS Res Hum Retroviruses.* Jun 2014;30(6):560-566.

22. Badridze N, Chkhartishvili N, Abutidze A, Gatserelia L, Sharvadze L. Prevalence of hepatitis B and C among HIV positive patients in Georgia and its associated risk factors. *Georgian Med News.* Dec 2008(165):54-60.

23. Clemens Benedikt(World Bank); Hassan Haghparast Bidgoli,JasminaPanovska Griffiths, Laura Grobicki and Jolene Skordis Worrall,(UCL); David Wilson, Cliff Kerr and Robyn Stuart (UNSW). Report on Optima Modelling Results, April, 2015