

TB AND HIV

CONCEPT NOTE

Investing for impact against tuberculosis and HIV

Countries with overlapping high burden of tuberculosis (TB) and HIV must submit a single concept note that presents each specific program in addition to any integrated and joint programming for the two diseases.

In requiring that the funding requests be presented together in a single concept note, the Global Fund aims at maximizing the impact of its investments to make an even greater contribution towards the vision of a world free of the burden of TB and HIV. Enhanced joint HIV and TB programming will allow to better target resources, to scale-up services and to increase their effectiveness and efficiency, quality and sustainability.

All concept notes should articulate an ambitious, strategically focused and technically sound investment, informed by the national health strategy and the national disease strategic plans (NSPs).

The concept note for TB and HIV is divided into the following sections:

Section 1: The description of the country's epidemiological and health systems context including barriers to access, the national response to date, country processes for reviewing and revising the response, and plans for further alignment of the NSPs, policies and interventions for both diseases.

Section 2: Information on the national funding landscape, additionality and sustainability

Section 3: The funding request to the Global Fund, including a programmatic gap analysis, rationale and description of the funding request, as presented in the modular template.

Section 4: Implementation arrangements and risk assessment.

IMPORTANT NOTE: Applicants should refer to the TB and HIV Concept Note Instructions to complete this template.

Applicant Information			
Country	Ukraine		
Funding Request Start Date	01.01.2015	Funding Request End Date	31.12.2017
Principle Recipient(s)	PR 1: Ukrainian Center for Socially Dangerous Disease Control of the Ministry of Health of Ukraine (UCDC); PR 2: International HIV/AIDS Alliance in Ukraine (Alliance); PR 3: All-Ukrainian Network of People Living with HIV/AIDS (Network).		
<i>If the programs are to be managed as separate grants:</i>			
Funding Request Start Date for HIV		Funding Request End Date for HIV	
Principal Recipient(s) for HIV			
Funding Request Start Date for TB		Funding Request End Date for TB	
Principal Recipient(s) for TB			

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.

1.1 Country Disease, Health Systems and Community Systems Context

a. Epidemiological situation

HIV epidemic The current status of the HIV epidemic in Ukraine is associated with i) the stabilization of the epidemic and the wide spread of HIV among various populations most at risk of infection, ii) the uneven spread of HIV infection in different regions of the country, iii) the shift in dominant routes of HIV transmission, and iv) HIV affecting mainly population at working age. During 1987-2013 Ukraine officially registered 245,216 HIV infection cases among Ukrainian citizens of the 27 regions of Ukraine (Crimea, Kyiv, Sevastopol and 24 regions), including 65,733 AIDS cases and 31,999 AIDS-related deaths.

Ukraine has achieved significant progress in the fight against HIV/AIDS. This can *inter alia* be ascribed to the provision of comprehensive, focused prevention and harm-reduction services to the most vulnerable groups over the last few years, which led to a continuous decrease of HIV transmission among people who inject drugs and the stabilization of the HIV epidemic in Ukraine. From 1999 to 2011 there has been an annual increase in the number of officially registered cases of HIV infection (from 3,827 to 21,177¹, but a decline in the growth rate of new HIV infections by 7 times since 2005. While in 2012 Ukraine officially registered 20,743 new cases of HIV infection (45.5 per 100 thousand population), this was slightly more in 2013 with 21,631 new cases of HIV infection (47.6 per 100 thousand population).

As the level of HIV prevalence among pregnant women reflects the tendency of HIV infection among the general population, there is evidence of stabilization of the epidemic among the population of Ukraine. Sero-epidemiological monitoring data² show a steady reduction in HIV-infection levels among pregnant women in recent years, according to primary testing results (code 109.1), from 0.55% in 2009 to 0.39% in 2013. The figures correspond with registration data of new cases of HIV-infection among pregnant women. Similarly, the gradual decrease of the number of women with newly diagnosed HIV-positive status among the total number of HIV-positive pregnant women - from 74.4% in 2009 to 49.4% in 2013, underscores the finding.

HIV prevalence in the age group of 15-49 years is 0.62% and remains to be one of the highest among countries of Europe and Central Asia. At the beginning of 2014, 233,922 HIV-infected people³ were living in the country. The figure differs from the official statistics on the number of HIV-positive people who have been under medical supervision at specialized health care facilities (as of 01.01.2014, 139 573 thousand people were under medical supervision of whom 74.9% are active dispensary group)⁴.

The HIV epidemic can be sub-divided into 3 regional epidemics with the highest prevalence in 9 regions (including Crimea and Sevastopol in the estimations) with 40% of estimated PLHIV (100,000). Highest rates were registered in the south-eastern regions of Ukraine, including Odessa region (687.6 per 100 thousand populations), Dnipropetrovsk region (697.9), Nikolayev region (612.1), Donetsk region (644.5), Kherson region (333.2), Sevastopol (480.0) and Crimea (422.5). Western regions are areas with low and medium levels of HIV infection. See Annex 1 for maps and tables indicating the geographical distribution of the epidemic.

¹ UCDC statistics - people with a first-time diagnosis of HIV infection, including children in the stage of confirming the diagnosis of HIV. The numbers are different from those in the WHO/ECDC HIV surveillance network report in which HIV cases do not include children with confirmed diagnosis of HIV.

² MoH of Ukraine, Ukrainian CDC, SI "Institute of Epidemiology and Infectious Diseases named after L.V. Gromashevsky", at AMS Ukraine (2014). HIV Infection in Ukraine. Information Bulletin № 41. Kyiv.

³ National HIV/AIDS estimates in Ukraine as of beginning of 2013, September 2013, Kyiv, Ukraine

⁴ MoH of Ukraine, Ukrainian CDC, SI "Institute of Epidemiology and Infectious Diseases named after L.V. Gromashevsky", at AMS Ukraine (2014). HIV Infection in Ukraine. Information Bulletin № 41. Kyiv (Table 9 and 11, pages 52, 53).

The HIV/AIDS epidemic in Ukraine is concentrated in cities. In 2013 77 percent of the new cases of HIV infection were registered among the urban population, while the proportion of newly registered cases of HIV-infection among the rural population has been increasing rather slowly (from 21.0% in 2009 to 23.0% in 2013).

It is important to note that the figures of officially registered new cases of HIV infection reflect the efforts to increase access to HIV diagnosis and medical observation, rather than that they reveal the actual HIV incidence. The coverage rate of clinical examination of newly registered people with HIV infection during the period 2009-2013 in Ukraine increased from 54,5% to 68,3%, but is still regarded insufficient (i.e. below 70%).

With respect to age and gender, new cases of HIV-infection are mostly present in the age group 25-49 years; it's proportion has been gradually increasing from 63.8% in 2009 to 67.0% in 2013. In addition, the male to female ratio of reported new HIV cases has remained unchanged at 55 : 45 since 2009. The proportion of young people aged 15-24 years among the newly reported cases of HIV has gradually been decreasing in the recent years, from 12% in 2009 to 7% in 2013. This also indicates a certain stabilization of the HIV epidemic in general, as a result of a reduction in risk behavior by young people.

From 1995 to 2007 HIV transmission through drug injection had dominated in Ukraine, typically through injecting drug use. In 2008 this shifted towards a domination through sexual contact, mainly heterosexual. In 2013 the proportion of HIV transmission through sexual contacts (including mother-to-child HIV transmission) reached 65.7%, while the proportion of parenteral transmission of HIV through injecting drugs was 32.7%. Besides the key affected groups of sex workers and injecting drug users, men who have sex with men is the group that is becoming more epidemically significant. From 2005 to 2013 the number of officially registered new cases of HIV-infection among representatives of this group rose to 262. The number is assumed to be significantly underestimated, as these men tend to keep their sexual orientation secret.

Whereas previous to 2013 AIDS incidence increased annually, it decreased in 2013. In 2012 the incidence was 22.1 per 100 thousand population, and declined to 20.6 in 2013; in total, in 2013 3,514 AIDS-related deaths were registered (7.7 per 100 thousand population). In 2013, 6,769 HIV-infected people died because of different reasons, including the lack access to ART, lack of treatment/prevention of opportunistic infections and delayed treatment. The overall mortality rate went down to 14,0 per 100 thousand population, as compared to 14.8 in 2012.

As of 2008, the Government of Ukraine has significantly increased resource allocations to anti-retroviral procurement and treatment services. Most remarkable, resources allocated for Antiretroviral Therapy (ART) in the central state budget were covering 43,790 patients at the end of 2013, which is an impressive and much-needed increase compared to the 12,751 patients as at 1 January 2010. The total number of people receiving ART as of January 2014 in Ukraine reached 55,784, which is 23.8% of all PLWHA (including 2,621 prisoners), while 109,367 PLWHA would require ART using the criteria for ART CD 4 \leq 350⁵. Clearly, despite increased access, the expansion of ART still remains insufficient. Late application for medical care still contributes to the detection of newly registered HIV infections in the AIDS stage in 40-45% of the cases.

TB epidemic The current situation with TB in Ukraine is characterized by i) a modest reduction of the TB notification rate from 69.9 in 2012 to 69.2 per 100 thousand population in 2013 (including relapses from 83.8 to 80.5 per 100 thousand population), ii) the presumed growth of MDR TB rates among new and retreatment cases (18.7% MDR TB among new patients, 42.5% among relapses and 35% among other previously treated cases⁶); iii) a high

⁵ Source: MoH of Ukraine "Ukraine harmonized AIDS response progress report. Reporting period: January, 2012 – December, 2013", Kyiv, 2013, p. 45-46.

⁶ Source: National Statistics 2013. A drug-resistance survey (DRS) is currently implemented in the country, results will be available at the end of 2014.

mortality rate (14.1 per 100 thousands), and iv) a high and presumably increasing TB/HIV co-infection incidence rate (10.5 per 100 thousand)⁷.

An important component in the fight against TB is the application of a rational diagnostic strategy. In 2013 an upgrade of the laboratories at level III have been accomplished. Currently, all regions are equipped with automatic analyzers BACTEC and systems for rapid diagnosis of tuberculosis by GeneXpert. Due to CRT case detection as a modern method of diagnosis, the number of cases increased from 3,329 in 2009 to 7,149 during 9 months in 2013. According to the on-line database 8,386 people were registered on category IV in 2013.

In 2013 MDR treatment started for 8,944 patients. Second line drugs procured through the Global Fund to fight AIDS, Tuberculosis and Malaria (hereafter referred to as the Global Fund) supply during Phase 1, coupled with more stable financing and better procurement under the NTP allowed to provide nonstop treatment for MDR TB patients in 2013. Even with an increased treatment success rate of MDR TB in the 2011 cohort to 48.8% from 37.6% in 2010, the level of successful treatment remains too low.

Co-infection TB/HIV The tendency of increasing morbidity due to HIV and TB infection is spread over wider segments of the population of Ukraine, in particular, children and young people. Current TB control programs are characterized by the rapidly increasing numbers of patients with HIV-associated TB and drug-resistant TB, which is recognized as a serious social and medical problem requiring an integrated approach.

During the last ten years in Ukraine we observe an increase in morbidity from TB/HIV co-infection, from 2.4 per 100 thousand population in 2004 to 10.5 in 2013. TB remains the main cause of AIDS-related deaths. Among the total number of deaths of HIV-infected people, the proportion of persons diagnosed with TB is almost 60%. The mortality rate associated to TB/HIV co-infection is high and reached 5.6 persons per 100 thousand population in 2013.

The TB/HIV co-infection rate significantly varies by region, ranging from 1.1 per 100 thousand in Chernivtsy region to 24.7 in Odessa region, reflecting the general pattern of a higher epidemiological TB and HIV burden in the South-Eastern part of Ukraine. In fact, the highest TB incidence rate is reported in 4 regions, which overlap with the regions with the highest HIV burden: Kherson, Nikolayev, Dnipropetrovsk, and Odessa.

One of the reasons for the late diagnosis of TB among HIV-infected and AIDS patients is the atypical course of TB and the clinical features of associated diseases. The effectiveness of treatment of TB of PLWHA is significantly lower than among HIV-negative people. One of the reasons is the high resistance to first line anti-TB drugs and multi-drug resistance. Thus, the optimal path to improve effectiveness of TB treatment associated with HIV-infection is ART.

A high level of ART coverage and TB treatment of HIV-infected people significantly reduces mortality and increases their quality of life. According to the clinical protocol of ART for HIV infection in adults and adolescents, approved by the MoH on 12.07.2010 (N^o 551), the diagnosis of TB is an initiation of ART 2-8 weeks after the beginning of TB treatment.

Due to the implementation of a number of measures the “percent of HIV-infected people with TB, who received treatment for TB and HIV-infection” increased from 21.0% in 2008 to 35.7% in 2010. In 2013, due to the further expansion of access to ART, the indicator significantly increased again to 62.9%. The number of new TB cases (I-III categories) with TB/HIV co-infection in 2013 was 4,584 people, including 2,882 people who were already on ART. Analysis of the indicator by region demonstrates different degrees of access for patients with dual diagnosis of HIV-infection and TB to the appropriate treatment of both diseases and timeliness of its prescription. Highest levels are observed in regions including Volyn (86.7%), Vinnitsa (86.3%), Lviv (85.6%), Zaporizhia (80.1%), Ternopil (80.0%), whereas the lowest levels are in Donetsk (43.1%), Cherkassy (51.1%), Zhytomyr (54.6%).

b. Key affected populations

Ukraine is still in the category of countries with a HIV epidemic concentrated in specific high risk populations. According to sentinel surveillance data people who inject drugs injecting

⁷ Source: National Statistics, MoH of Ukraine, 2013 <http://ucdc.gov.ua/uk/statystyka/informatsijni-byulleteni/tuberkuloz>

drug users (PWID) are the most affected group by HIV. A positive downward trend in HIV is observed among commercial sex workers (CSW) who do not inject drugs.

Commercial sex workers (CSW) In 2013 HIV prevalence among CSW was 7.3%, showing a steady decrease from 9.0% in 2011 and 12.9% in 2009. Similar to previous years in 2013 the age group 25 years and older (9.5%) remains more vulnerable to HIV infection than the younger group under 25 (2.3%). The group with dual risk behavior i.e. FSW who inject drugs, is most affected (27.6 %), but decreased since 2009 (42.2%; in 2011 - 45.5%). Among CSW who report not using injecting drugs, HIV prevalence is substantially lower (5.8%; 2.0% among CSW under 25 years old and 7.6% among CSW 25 years and above). The most affected area's in terms of HIV prevalence among CSW are in the Southern and Eastern, Central and Western regions. In cities including Lugansk, Chernivtsy and Uzhhorod no HIV cases were registered among CSW.

Men having sex with men (MSM). In 2013 HIV prevalence among MSM was 5.9% (25 years and above 7.7%; under 25 years 3.0%), compared to 6.4% in 2011 and 8.6% in 2009 indicating a gradual decrease in the proportion of HIV-infected people among MSM (according to survey data⁸). The regions with higher HIV prevalence among MSM are traditionally the Eastern and some Southern regions. However, on the basis of modeling data⁹, new HIV infection cases (incidence) in this group are expected to increase in the forecasted period. According to these modeling experts, this is due to the fact that this risk group continues to have a number of barriers to HIV prevention, treatment, care and support services (mainly - due to the stigmatization of this group).

It is important to note that these official statistics data on HIV infection among MSM differ from research data¹⁰. Sentinel surveillance data show a high rate of infection among MSM in the regions, including those regions with traditionally low levels of HIV prevalence. In view of the fact that the results of sentinel surveillance don't coincide with the official data, a significant mis-accounting of HIV cases related to sexual relations among men is assumed. The differences are primarily connected to the fact that the MSM group is still stigmatized and doesn't report themselves as belonging to the group of MSM in AIDS centers. Therefore, the epidemic situation in the MSM group requires more careful and regular monitoring.

People who inject drugs (PWID) In 2013 HIV prevalence among PWID was 19.7%; in 2008/2009 this figure was 22.9%, indicating a gradual decrease in the prevalence of HIV among PWID. The highest prevalence of HIV among PWID is in Dnipropetrovsk, Mykolaiv and Odessa. The group under 25 years is less affected (6.4%) compared to the group 25 years and above (21.7%), while women are more vulnerable to HIV (22.4%) than men (18.8%).

The 17 year dominance of parenteral transmission resulted in 57,000 HIV-positive people who were infected through injecting drug, which is 43% of all registered HIV-infected adults. Due to the effective strategy of prevention interventions implemented among PWID from early 2000, the HIV epidemic is characterized by a clear tendency of decrease in both the absolute numbers of newly registered HIV cases among PWID and the proportion of PWID among new cases of HIV-infection. In 2013 5,847 IDUs were diagnosed with HIV, accounting for 27.0% of new cases of HIV infection¹¹ (2011 – 6,588 (31.0%), 2012 – 5,933 (29.0%)). The highest proportion of HIV-positive PWID is observed in Lviv, Kharkiv, Dnipropetrovsk regions (45.0%, 42.3%, 31.4% respectively) and the cities of Sevastopol and Kyiv (35.2%, 33.5% respectively).

⁸ 'Monitoring the behavior and HIV-infection prevalence among men who have sex with men as a component of HIV second generation surveillance'. The survey was carried out by the Centre of Social Expertize of the Institute of Sociology NAS of Ukraine in cooperation with UCDC on request of the ICF "International HIV/AIDS Alliance in Ukraine" during the period from April, 27 to October, 01, 2013.

⁹ National HIV/AIDS estimates in Ukraine as of beginning of 2013, September 2013, Kyiv, Ukraine.

¹⁰ Berleva G, Dumchev K, Kasianchuk M, M. Nikolko M, Saliuk TO et al. Analytical report based on the results of the 2011 survey: Estimation of the size of populations most-at-risk for HIV infection in Ukraine. Kyiv, Ukraine: ICF International HIV/AIDS Alliance in Ukraine, 2012.

¹¹ In addition to the specified indicators to identify new HIV cases among IDUs it is recommended to calculate HIV rate among persons having injected drugs for 3 years. According to the bio-behavioral survey 2013 HIV prevalence is 3.5% in this group.

Key affected populations for tuberculosis are PLWHA - for whom TB represents the first cause of mortality, prisoners and ex-prisoners (affected both with TB and HIV), contacts of TB/MDR TB cases, and populations particularly vulnerable to TB.

Prisoners Comparing 2013 with 2012, the prevalence and incidence rates of TB have increased, although absolute numbers of new TB patients decreased (from 1737 in 2012 to 1544 in 2013), the latter likely being due to a decrease in the overall number of prisoners. Out of the 125,918 people detained in prisons in 2013, 3,326 people registered as TB patients (all forms), i.e. a prevalence rate of 2641.4 per 100 thousand. In 2012, out of the 147,145 people detained in prisons in 2012, 3,534 people were registered as TB patients (all forms), i.e. a prevalence rate of 2401.7 per 100 thousand. The incidence rate increased from 1180.5 in 2012 to 1226.2 per 100 thousand in 2013 (UCDC data, 2013). The low success rate of 59% (all forms combined) is mainly due to treatment failure (13%) and a high number of prisoners who were released during their treatment and for whom the outcome is not known (23%).

Contacts of TB/MDR-TB cases In 2013 32,924 contacts of smear-positive patients were investigated (UCDC 2014), and among them 286 cases of tuberculosis were detected, i.e. a prevalence rate of 869 (per 100,000), showing that 'contacts of TB/MDR-TB cases represent an important risk group.

Other populations vulnerable to TB, including PWID, FSW, Roma minority population, and homeless people. In 2013 1,374 PWID were identified among new TB cases (4.4%). This is twice as higher as in 2012 (702 PWID, i.e. 2.2%)¹². For homeless people only partial information exists, as the denominator is not known (913 homeless people were diagnosed with active TB in 2013 nationwide). According to targeted screening of one group of homeless people, 13% was diagnosed with TB (UCDC 2014). Recent project data¹³ indicate that TB was detected in 16% cases of diagnosed Roma. Unhygienic and crowded living conditions and a culture of delayed health care seeking and distrust in health workers are given as reasons for their risk for TB.

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

Addressing human rights barriers and gender inequalities is crucial in the national response to HIV/AIDS and TB. HIV and TB-related discrimination is a pervasive and multi-faceted issue in Ukraine, and combined with gender inequality, a strong driver of the HIV and TB epidemics. The intersection of several forms of discrimination (HIV-status, gender, sexual orientation etc.) deepens social inequalities and increases the burden of HIV and TB on vulnerable groups and dramatically impacts the trajectory of the epidemics.

Human rights barriers Although significant improvements of the legal framework were achieved during implementation of Global Fund Round 10, the following *legal barriers with respect to HIV* remain unresolved (see Annex 2 for a full explanation on each item):

- criminalization of unintentional HIV-transmission, with risk of long imprisonment; criminalization of IDUs; punitive legislation towards sex workers;
- inefficient anti-discrimination legislation, but initialization of homophobia and transphobia into Ukrainian legislation on its way; discriminatory provisions for HIV-positive migrants; prohibition for PLWH to adopt children;
- inaccessibility of HIV-positive women to assisted reproductive technologies; inefficient SMT regulation, against international and national practices of effective SMT implementation; barriers that limit client access (affordability) to medicines; barriers in reach out to PLWH due to obligatory client's consent in writing; application of diagnostics and registration procedures cause high thresholds;
- regulations on the circulation of narcotic drugs are obsolete and hamper OST scale up; simplification of VCT procedures are required; regulations on the utilization of medical instruments, particularly needles and syringes used in HIV prevention programs, are obsolete;

¹² Source: Analytic and Statistical Bulletin "Tuberculosis in Ukraine", 2013. Table 30.

¹³ Source: TBD

- centrally planned social policy creates unbalanced local social services provision; barriers in receiving state funding by HIV-service NGOs; legal barriers for the use of Global Fund funds by UCDC and transfer funds to sub recipients (SR); lack of financing and inefficient use of national and local budget funds allocated to HIV/AIDS prevention, treatment, care and support services

Human rights barriers with respect to TB include the following:

- legal barriers for TB diagnostics and registration that limit access to prevention and treatment services for key populations.
- generally accepted and legalized lack of confidentiality and related stigma for all TB (and also HIV) patients. A suspected and then diagnosed TB patient is seen as a direct threat to the society and would need to be isolated. Often coercive treatment is proposed (too soon), after the patient failed to comply with very restrictive, non-patient-friendly ways of drugs administration. Consequently, it happens that patients with still a curable form of TB will be isolated in palliative care wards, thus increasing the risk of being exposed to MDR and XDR cross-infection. Patient's data is not privacy protected.

Human rights issues and TB in penitentiary institutes and after release :

- in prisons a dual loyalty of medical staff is observed, medical ethics are overshadowed by hierarchical military order; and often security reasoning takes over medically driven one; TB patients in prisons can be transferred from peripheral colonies to TB hospitals without necessity (just to check CD4, or to complete diagnosis, etc.), thus potentially non-TB patients are exposed for contracting TB or cross-infection; TB patients are not treated during prolonged stay in so called "Quarantine" zone of TB prison-hospitals (up to 14 days); moreover, in prisons the concept of "preterm release" for patients with TB stimulates them to have TB, not to treat TB;
- for arrested people under investigation the Court does not consider or does not have (not require) the TB status of the patient, thus often the patient remains in unsuitable settings for a long time; ex-prisoners suffering from TB are not prepared well, not transferred, not accompanied, often not encouraged to continue their treatment in a civil TB institution;
- double and triple stigma; patients suffering from TB and HIV are often the subject of discrimination in health care facilities once released from detention; having the status of ex-prisoner very often means triple stigma, pushing patient to hide his status and avoid health care settings.

Gender inequalities Fear of stigma, discrimination and violence prevent many members of marginalized groups from accessing health care and other services, in particular women and in rural areas. Among the main barriers to service access of women are time consuming housework, absence of specific services for women (in governmental facilities), and fear of status disclosure. HIV-positive women are more likely to become victims of various forms of violence due to their HIV-positive status. Also, women who use drugs and sex workers are more likely to suffer from violence, including unlawful acts of the police. This happens in a context in which crisis centers are often inaccessible due to documentation difficulties and drug using, and rehabilitation centers do not accommodate women with children.

Yet unexplored is the problem of transgender women. In general, they are left unattended, have low access to health services and medical care, and it is difficult for them to get counseling on gender identity issues related to hormone therapy and gender reassignment. Also seeking routine health care is often problematic due to their uncertain status and prejudice on the part of medical personnel. In addition, prejudice towards lesbians creates barriers in obtaining gynecologist care that might require disclosure of their homosexual orientation.

Upon efforts undertaken at the national level, awareness of key national players on gender inequalities treatment, care and support of PLWH has increased significantly. At the same time, at grass roots level, the sex of a client is still an impeding a factor in access to services in governmental facilities. However, the majority of the services provided by NGOs and state are gender neutral and overall positively influence the quality of these services.

Following the development of an informal gender strategy and its incorporation in the National AIDS Programme for 2014-2018, relevant steps have to be undertaken at regional level, because awareness of local managers on gender issues is quite poor.

d. Context of health systems and community systems

Health systems

Health systems support the HIV and TB responses in Ukraine. The following section addresses the six building blocks (WHO health systems framework): leadership/governance, health care financing, health workforce, medical products & technologies, information & research, service delivery.

Leadership & governance To ensure stronger leadership and governance of the HIV and TB response at the national level, implementation and monitoring of HIV and TB activities are instituted in two main government structures – the State Service of Ukraine on HIV/AIDS and Other Socially Dangerous Diseases (hereafter named State Service of Ukraine for Social Diseases) and the Ukrainian Centre for Socially Dangerous Disease Control of the Ministry of Health of Ukraine (UCDC). The State Service of Ukraine for Social Diseases is the central executive body responsible for implementation of the government policy in the areas of HIV and TB and ensures coordination between other relevant state bodies. UCDC is responsible for actual implementation of HIV and TB activities, inventory management of pharmaceuticals and health products, surveillance, monitoring and evaluation. (For more information see *section 1.3 on HIV/TB alignment: ‘Political leadership and governance for HIV/TB’*)

Less integration and coordination is observed at regional and local levels. TB and HIV services are provided by two separate vertical systems, which leads to HIV and TB services being highly disintegrated for the patient. The level of integration and coordination differs from region to region and mostly depends on the political will of health departments of regional/district/city state administrations as well as the initiatives of local communities and health services providers. Thus, only some TB hospitals distribute ARVs and provide CD4 and viral load testing. At the regional level (mostly in large cities) TB hospital staff includes infectious disease doctors and AIDS centers hire TB doctors. However, many patients still have to visit two or more different facilities for HIV and TB diagnostics and treatment¹⁴. Health care reform pilots implemented since 2010 have not included solutions yet. (see section 1.2 and 1.3 for a discussion on health care reform)

To ensure highest government support of implementation of the Global Fund supported programs the Law of Ukraine “On the Implementation of Programs of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine” entered into force in June 2012¹⁵. The law states that activities implemented within the Global Fund programs are to be incorporated in National HIV and TB programs.

Health care financing Total health expenditure in Ukraine was 7.7 % of GDP in 2012 (EU average of 9.8%), or approximately US\$299.3 per capita (2012 avg. exchange rate). Government health expenditure accounted for 12.7% of total consolidated budget expenditures, or approximately 4.4% of GDP, while the rest is mainly out-of-pocket expenditures (over 3.3% of GDP).

Activities aimed to strengthen the public financial management system and initiate health care reform have always been a challenge in Ukraine. The long-term objectives to switch to a social insurance-based health care were set in early 1990s, although very minimal legislative or structural changes were made to make it happen. Consequently, insurance revenues are minimal and most state health financing comes from general taxation. Eighty percent of the state budget is spent by local government administrations on the country’s public health care system. Allocations for health care are vertically organized at national, regional and district/city level. Although central ministries support some activities directly (in the framework of national-level state programs), expenditures are relatively low.

The need for the health care reform has been brought up by the new management of the Ministry of Health and The World Bank, which provides funding to support its implementation

¹⁴ Dr. Bonita Mangura et al. Analysis of gaps in TB/HIV co-infection service provision system. Analytical report .

¹⁵ <http://zakon2.rada.gov.ua/laws/show/4999-17>

in the aspects of the in-patient care financing reform. In mid May 2014 the Ministry of Health has announced the key concept principles of the health sector reform¹⁶ which aim to abandon the existing line-item and capacity-based budgeting (based on staffing norms and beds) towards planning of volumes of services to be delivered along with the output and quality-related indicators. These include the introduction of the performance-based budgeting at all levels of care, introduction of the contractual relationship between providers and purchaser, risk-adjusted capitation as a financing scheme for the primary health care, “per case” payment system for the in-patient care with the gradual implementation of DRGs, global budget holding at the secondary and tertiary levels. The Ministry of Health has announced the long-term plans to switch from the tax-funded to mandatory health insurance scheme, however, this may be possible after the abovementioned tasks are accomplished. (For more information on health care financing and health care reform, barriers and requirements and the relationship with HIV/TB integrated services can be found in the following sections: *section 1.2 ‘Linkage of the programs with the national health strategy’* and *section 1.3b ‘Key barriers to TB and HIV alignment’*).

Health workforce Currently, the human resources for health (HRH) policy is being addressed and regulated by a number of different legislative and regulatory documents. However, none of them provides an integrated strategic HRH approach and methods to implement a HRH policy in health care. The main weaknesses in HRH, relevant for both the HIV and the TB sectors, are as follows:

- lack of government’s strategic vision, which leads to poor planning and budgeting at national and local levels;
- weak sustainability of HRH training programs (most activities are funded by external donors);
- training on many HIV/AIDS and TB issues is not institutionalized in the state system of medical education, leading to low motivation of medical specialists to participate in such trainings;
- extremely high number of secondary and tertiary health specialist and an acute need of personnel in primary health care, which makes health care services high-threshold, thus contributing to low HIV and TB detection rates.

Medical products, technologies The supply of medical products is the responsibility of PRs, and is accompanied by a clear division of tasks and responsibility at the different tiers of the Procurement and Supply Management (PSM) cycle: forecasting, procurement, distribution, quality control etc. The detailed description of the supply process is reflected in the PSM plan. Key players of PSM coordination are PRs and the National TB Program (NTP) together with government officials, experts and other stakeholders.

Coordination between all partners is ensured through regular meetings with other projects in the field of TB/HIV, supported by the Ministry of Health, USAID, PATH and other partners at the CCM meetings. At regional level local authorities are responsible for PSM coordination in health care, except for ARV and TB drugs that are supplied from central level.

Selection of drugs takes into consideration the existing national treatment guidelines and WHO recommendations. In general, first-line drugs (FLD) for TB are financed by the state budget and procured through a competitive bidding mechanism. Fixed-dose combination products are available only if FLD is supplied/granted by the Global TB Drug Facility. The use of fixed-dose combinations of ARV drugs are becoming more common. However, due to the pricing differences (such drugs are mostly produced by brand companies and patent protected) it is not possible to significantly expand access to them. All procurement activities related to pharmaceuticals and medical products within the Global Fund program are in full compliance with the requirements of the Global Fund and National legislation. Thus, all TB and ARV drugs are WHO pre-qualified (or ERP approved) and produced on GMP certified facilities.

PRs control the stock level and forecast needs in pharmaceuticals and laboratory consumables on a regular basis. Additionally, regular monitoring visits to different facilities are

¹⁶ http://moz.gov.ua/ua/portal/Pro_20140527_0.html

conducted (PR, MoH). The accounting and reporting system on drugs and medical goods enables the control of consumption, deficit and stock level at the central level and at the level of facilities. At the central level modern private facilities are assigned to receive, store and distribute medical products, as they are responsible for distribution to retail outlets nationwide.

Potential risks and challenges in the PSM system are linked to inadequate financing, lengthy tender procedures and bureaucracy at each stage of the process, and cause frequent supply interruptions. Interruptions often occur in supplying a full set of first- and second-line TB medicines to TB patients at all levels of care, in addition to the lack of a sound monitoring mechanism on their use. The process of registration and re-registration is complicated and may lead to delays in importing registered medical supplies and drugs. Unregistered drugs are allowed to be imported in exceptional cases only, and this procedure (prescribed by MoH) is rather complicated and unpredictable. In order to mitigate the risk the accelerated registration procedure was adopted for the products procured within Global Fund projects. Furthermore, clearance and submission of registration documents in MoH is relative slow and time-consuming, and likely causes delays in the supply chain.

According to the legislation, the state supplies are to be conducted once per year with 100% annual stock+100% annual reserve for TB drugs and with 100% annual stock for ARV. The delivery is made to the facilities at once. National regulations do not allow for the formation of a buffer stock neither for TB nor for ARV, or for bridging the availability gap through the use of oblast funds. Oblasts experience stock-outs of essential TB medicines, including Rifampicin and lack of specific SLD for many diagnosed patients. In addition, interruption in the supply of laboratory consumables is still a bottleneck. In sum, the supply system does not allow for adequately reacting on arising issues, as it is not flexible enough to fill in the gaps rapidly.

Information and research With Global Fund grants PRs have established systems for quality data collection and reporting on prevention, treatment, care and support services. The PRs have built their capacity in conducting quality analysis of gathered information, which is used to inform and improve program activities.

However, neither a general health management information system (HMIS) nor a specific HIV MIS exists in Ukraine, except in some pilot areas¹⁷. It appears that the future of HMIS initiatives will be determined by decisions related to the development of HIS as part of the planned health care restructuring. Therefore, at present, in most cases epidemiology, counseling and testing, screening, diagnostics, treatment, PPHP inventory as well as care and support data are contained in different information flows with different responsible entities, which does not allow tracking patients throughout the various service providers. The data collection system is mostly paper-based, increasing the work load of health care personnel, thus leading to lower data quality and complicating data analysis.

Under the USAID-supported SIAPS project a country-wide electronic system for TB (e-TB manager) was introduced. A fully fledged HIV MIS will be developed in the next few years under the ACCESS project implemented by the Network with CDC funds under the PEPFAR program. It will ensure compatibility with other systems like the e-TB manager.

Service delivery HIV-related health services for PLWH and MARPs are mainly provided by health care facilities (AIDS centers, Trust Cabinets, ART sites). Some services (i.e. HIV testing) are provided by health staff employed by NGOs. However, licensing for these services by non state providers remains an issue to be solved still.

Social services on HIV prevention, care and support for PLWH are provided by regional NGOs and CBOs. Close cooperation between local NGOs and health care facilities allows the provision of effective medical and social services in the area of HIV/AIDS and increases the adherence of patients to particular services.

Services related to the organization of prevention, detection, confirmation of the diagnosis and treatment of TB are primarily provided by TB facilities and TB cabinets; the detection of patients with suspected TB is conducted in the facilities of primary health care (PHC). The detection of cases of active TB among populations particularly vulnerable to TB and social support to improve adherence to treatment, is also carried out with the participation of NGOs.

¹⁷ See 'Ukraine Health System Assessment 2011' (USAID)

Close cooperation between local NGOs and medical facilities allows to provide for effective health care and social services in the field of TB, increase patient adherence to specific services and improve access to vulnerable populations.

Despite of the positive trend, insufficient capacity levels in some regions demonstrate the necessity to strengthen cooperation between the governmental institutions working on AIDS and TB and non-governmental organizations to ensure timely access of patients with TB/HIV co-infection to health and social services, by improving on timely and complete diagnosis, prompt prescription of correct treatment and good adherence to ART and TB medication.

Community systems Involvement of HIV and TB affected communities remains a crucial component in carrying out prevention, treatment, care and support activities and achieving better health outcomes. Previous Global Fund grants provided unique support to ensure meaningful involvement of community representatives in the design, delivery and monitoring of HIV and TB programs. Community representatives have access to state policy development and the decision making process at the national level (as members of the National Council on issues of overcoming TB and HIV-infection/AIDS) and regional level (as members of regional TB and HIV/AIDS councils). At the level of service delivery representatives of affected communities are involved as direct service providers.

In spite of these significant achievements in ensuring meaningful involvement of communities to HIV/AIDS and TB response, the following challenges are still limiting participation of affected populations in the design and monitoring of HIV and TB programs, thus, limiting their access to essential services:

- inadequate or no involvement of communities in small towns and remote areas, due to a high level of stigma and isolation, absence of communication between representatives of different communities (PWID, MSM, CSW), lack of skills and readiness to cooperate with local authorities to ensure transparency of HIV and TB local programming and covering needs of affected populations;
- dependency of community initiatives from donor funding, with a low level of support from the government and private sectors;
- diversity of services provided by CBOs and NGOs – crucial need to develop standardized service delivery models that will be accepted by the government for institutionalization and ensuring social order for civil society organizations to provide HIV-related social services;
- limited possibilities of affected populations to participate in monitoring quality of services provided both by the state and NGO.

All of these bottlenecks will be addressed through the proposed activities, which foresee capacity building for community representatives, standardization of services, ensuring sustainability of community efforts through support from the state and private sector.

1.2 National Disease Strategic Plans

Separate National TB and HIV programs

The national HIV and TB responses in Ukraine are guided by two separate national programs that were adopted by the Parliament and have legal status. National programs are developed and adopted every five years with involvement of all relevant government bodies, international agencies, national NGOs and CBOs with involvement of KAP representatives. The planning cycles for HIV and TB do not match – the current TB program covers the period 2012-2016, while the new HIV programs covering the period 2014-2018. In spite of the institutional integration of HIV and TB responses at the national level, regional and local planning and implementation of HIV and TB national programs is carried out with minimal integration, which obviously undermines country's efforts in addressing TB/HIV co-infection, limits access of patients to care and contributes to TB-related mortality among HIV-positive people. So far there has been no official intention from the government to revise approaches to

HIV and TB planning in terms of synchronizing the timeframes of the two national programs or developing a joint TB/HIV program.

National HIV program

Goal and strategy The submission of the current Single TB and HIV Concept Note falls at the junction of the two National HIV/AIDS Programs (NAP). The NAP 2009-2013 has demonstrated significant progress in the HIV response, particularly in expanding ART coverage and increasing state spending for HIV programs. During NAP implementation a tendency for certain stabilization of the epidemic has been observed (see section 1.1a), namely, in decreasing the HIV growth rates, decreasing the share of new infections in 15-24 age group, mother-to-child transmission rates decreased six times. In spite of significant progress, the number of new infections continues to grow, while access to treatment and care, especially among KAPs, remains limited, thus, HIV mortality rates are still high.

The new NAP 2014-2018 has been developed through wide country dialogue involving key national players, international agencies, PLWH and representatives of key affected populations. Due to the current political crisis in Ukraine the submitted Program is still under consideration at the Cabinet of Ministers and is expected to be signed any time now (see Annex 3 for the draft NAP 2014-2018 submitted for approval). NAP 2014-2018 has been a basis for the HIV component of the current proposal in terms of suggested activities, service packages, coverage indicators and unit costs.

Overall goal of NAP 2014-2018¹⁸ is to decrease HIV/AIDS morbidity and mortality through ensuring sustainable and accessible service delivery in the field of prevention, diagnostics, treatment, care and support for PLWH. The priority areas include:

- HIV prevention with a focus on KAPs, which anticipates a transmission to state funding after Global Fund support would end (planned from 2017);
- significant increases in ART coverage having 118,000 patients on ART (compared to current 55,784) with government funding for the total ART need by 2018;
- strengthening the laboratory potential for HIV testing and ART monitoring (CD4, viral load tests, HIV drug resistance);
- care and support services for PLWH with an anticipated transmission to state funding in 2017.

The NAP 2014-2018 does not contain specific activities regarding TB/HIV co-infection. Co-infection is only addressed as a part of the care and support service package, which contains social worker's consultations on TB/HIV issues, referral to medical institution, and assistance in receiving access to medical services.

Limitation and lessons learned The NAP 2014-2018 has been based on the main outcomes and lessons learnt from NAP 2009-2013 that are reflected in the assessment of the implementation of the National AIDS Program 2009-2013¹⁹ (see Annex 4). The assessment defined the following achievements/strengths:

- significant increase of government funding, primarily for ARVs and diagnostics (HIV test, CD4 and VL tests) ;
- strong and outspoken civil society organizations, inclusion of civil society and KAPs to planning and implementation of HIV-related activities;
- substantial treatment scale-up;
- strong coordination of efforts – functioning CCM, single national disease strategic plan (NAP), single M&E system;
- considerable progress in PMTCT with integration of HIV and natal service provision systems;

¹⁸ NAP 2014-2018

¹⁹ "Assessment of the Implementation of the National AIDS Programme (NAP) in Ukraine: Synthesis Report (English original, December 2012)", Kyiv, 2012

- largest OST program in EECA region;
- effective approaches of working with PLWH and KAPs.

In spite of these significant achievements a number of weaknesses were defined, to be addressed in the next NAP 2014 - 2018:

- deficit of state funding –funds guaranteed under NAP are never provided in full by the state budget;
- lack of political will to ensure adequate HIV/AIDS response;
- high level of stigma and discrimination that hamper access of PLWH and KAPs to medical and social services;
- legal barriers that hinder planning and provision of services, i.e. inability to conduct international tenders; criminalization of HIV transmission, sex work and drug use, etc.
- ineffective approaches to planning which are based on available funding rather than actual needs and outcomes;
- absence of human resources development strategy;
- insufficient coverage of essential services (OST, care and support);
- low access to both medical and social services in prison settings;
- no guarantees for quality of services, absence of standards and monitoring mechanisms;
- lack of coordination between HIV and TB services, thus, low capacity to address the needs of co-infected patients;
- low level of service integration.

National TB program

Goal and strategy The National TB Program 2012-2016 (NTP)²⁰ has the overall goal to mitigate the TB epidemic situation focusing on TB morbidity and mortality, TB/HIV co-infection, MDR TB through ensuring high-quality TB prevention, diagnostics and treatment services (see Annex 5). The implementation of the program is presently at mid-term. The NTP prioritizes on improving the quality of laboratory services for TB diagnostics, the provision of up-to-date treatment of MDR-TB cases with appropriate patient support to ensure adherence, strengthening the links between civilian and penitentiary TB services, intensifying case finding and DOT support, and strengthening capacities for program management, coordination, monitoring and evaluation.

Limitation and lessons learned Ukraine faces a serious MDR-TB problem, together with a range of challenges that hinder the control of the spread of TB and MDR-TB. A review of the previous NTP (2007-2011) was conducted in 2010 by WHO²¹, calling for an urgent need for action, particularly including attention to M/XDR TB, ensuring uninterrupted supply of TB drugs, focusing on risk groups in case-finding, and promoting outpatient care.

In spite of significant efforts to address the challenges, the joint Global Fund-USAID-WHO-World Bank²² assessment mission in 2013 (see Annex 6) concluded that not much progress was made in implementing the WHO 2010 recommendations. Case-finding is still focused on easy-to-reach groups rather than attracting those who are at most risk of TB (homeless people, migrants, IDUs). The quality of laboratory services is not ensured, and of the use of new tools such as rapid molecular diagnosis of TB is limited. Prolonged and unnecessary hospital care, even for patients without severe conditions, is still a common practise.

Furthermore, the assessment mission in 2013 found that effective models of outpatient TB case management are absent, and the involvement of primary health care is not sufficient.

²⁰ State Targeted Social Program to Fight TB for 2012-2016.

²¹ Review of the National Tuberculosis Program in Ukraine, edited by Pierpaolo de Colombani and Jaap Veen, WHO, 2011.

²² Key recommendations from the Joint Global Fund-USAID-WHO-World Bank Mission. Phase II TB grant negotiation in Ukraine. May 2013. Report attached in Annex.

Apart from several pilot projects, direct observation of treatment (DOT) and patient support mechanism are not fully in place. Most of the hospitals²³ do not segregate patients based on infectiousness or drug resistance. While MDR-TB is common, resistance is not detected for several months since the country relies primarily on solid media culture methods. Among known MDR-TB patients, shortages of second line drugs result in inadequate treatment regimens for MDR-TB patients, contributing to prolonged infectiousness. The quality of MDR-TB treatment remains poor, the cure rates are low. HIV-positive patients suspected to have TB are often admitted to TB hospitals for a diagnostic work up, a practice that is not medically necessary and exposes them to the risk of TB exposure and or cross-infection.

In sum, the following challenges would need to be addressed for effective implementation of the current NTP and ensuring adequate TB response overall:

- low access of groups most at risk of having TB (homeless people, migrants, IDUs) to TB screening;
- prolonged and unnecessary hospital care even for patients without severe conditions;
- insufficient involvement of primary health care;
- lack of DOT initiatives;
- low quality and coverage of MDR TB treatment;
- lack of qualified personnel;
- PSM difficulties leading to interrupted supply of a full set of first- and second-line TB medicines to TB patients at all levels of care
- lack of coordination between penitentiary and civil TB control programs
- fragmented responsibilities for TB and MDDR-TB services among central government, oblast administration down to the lowest levels.

Linkage of the programs with the national health strategy

In the absence of a comprehensive national health strategy in Ukraine, diseases are usually addressed within the framework of separate national programs, like the programs on TB and HIV. In general, health care in Ukraine is much focused on treatment, while prevention – an important component in HIV and TB programs - is hardly addressed, thus causing a high financial burden on the health care system due to the use of relative expensive secondary and tertiary levels of care, and causing a fragmentation that prevents services to become integrated and client-centred.

The government acknowledges the need for reforming the health sector. Implementation of health sector reforms started in 2011, though cautiously, with the approval of a new law on reform pilots, the separation of the budget for secondary care at oblast (regional) level and primary care at district level, and other proposed legislative changes. The reform process²⁴ started in three regions and in Kyiv. Due to the recent political changes the temporary government stalled all on-going reforms. Nevertheless, an action plan for next steps in the reform process is expected to be approved in December 2014. The plan is oriented towards output and needs based financing for selected oblasts, away from input-based financing approaches.

Key concept principles of the reform could aim at abandoning the existing line-item and capacity-based budgeting (based on staffing norms and beds) towards planning of volumes of

²³ For a discussion on relative expensive hospital care versus primary health care, see the next section on program links to national health strategies.

²⁴ The reform process was supported by the World Bank through an Institutional Development Fund (IDF) grant and through advisory services, both at the central as well as oblast levels in the areas of health financing, primary care, and hospital reforms, and in the establishment of a new strategy to develop a modern health management information system. In 2014 preparations started for a new Oblast Health Reform Project, requested by the Government and supported by the World Bank, which will include selected oblasts and allow them to deepen their health sector reforms.

services to be delivered along with output and quality-related indicators. This would include the introduction of performance-based budgeting at all levels of care, introduction of a contractual relationship between providers and purchaser, capitation as a financing scheme for primary health care, a 'per case' payment system for in-patient care with the gradual implementation of diagnosis related groups (DRGs), and global budget holding at the secondary and tertiary levels.

However, the normative approach towards planning of the health providers' capacity has not been given up entirely, as the concept still prescribes to have a certain number of beds for various levels of the in-patient care. This may become a significant challenge for health care system optimization – one of the Global Fund's key preconditions of the grant. If these input-based norms will remain as the core mechanism of planning and resourcing, it will make the performance-based approach to planning and budgeting impossible.

Input-based planning of human resources is likewise setting barriers in the way – making needs-based resourcing difficult. To change this, specific rule-changes are required into the legislation related to abolishing of the Order #33, which regulates population-based staffing norms or addressing a set of the fiscal rules which forbid the re-allocation or saving of funds at the facility level.

Coordination inside the Government and among donors will become a major challenge in the health reform process. The supporting roles and positive attitudes of involved key ministries (Ministry of Finance, Ministry of Justice and Ministry of Health) towards health financing and changing from input-based and per bed financing of hospitals to service-output as base for resourcing, would, for example, be crucial for establishing new perspective for the reduction of TB hospital beds and re-funnel savings to primary care for outpatient DOTS service delivery. Likewise, political will on the part of the Cabinet of Ministers and the Office of the recently elected President is regarded essential for any success in health reform and introduction of performance based financing mechanisms.

In addition, an upcoming administrative-territorial reform may turn into a risk for the successful health reform if these two initiatives are not harmonized conceptually and time-wise. If these processes are aligned they are expected to create a supportive environment for introducing better long-, mid- and short-term planning, budgeting and resource handling at the sub-national level, where even within the current financing framework most of the health-related spending is being executed. Local government administrations, rather than the line ministries, are already the key players in the country's public healthcare system, spending over 80% of the public budget .

The Ministry of Health has had long-term plans to switch from the tax-funded to a mandatory health insurance scheme, however, its introduction might be more successful upon the gradual introduction of performance based financing.

Ukraine now looks for the potential solutions to arrange an uptake, optimization and increased cost effectiveness of the certain services after the Global Fund phase-out. More services related to HIV and TB are expected to be provided at the primary health care level in an integrated manner under public funding. The Ministry of Health and the Ministry of Finance should be working together to address this issue through the introduction a financing scheme, which not only allows but also promotes the delivery of these services in the general public health system at the primary level and prevention services through social contracting. Concerted efforts should be put into the promotion and advocacy of strengthening the health system in this way. Lack of well-thought communication on the reform-related issues with various parties – especially at the sub-national level and with the health care facilities' management – is a serious threat to the successful implementation and its political support at the service organization and service delivery level.

In addition, the government will need technical support to create the basis and further deepen health reform strategies, including the resource-optimization strategy (suggested by the USAID-funded project – "HIV Reform in Action", see Annex 7) for a full service primary health care (PHC) package that integrates the delivery of HIV-AIDS-, TB- and associated services

through the risk-adjusted capitation - a mechanism to optimize the allocation of resources across health facilities in Ukraine using population data weighted by relevant risk factors. This financing and budgeting approach for the health care facilities, unlike flat capitation, may take into account various health and demographic specifics of the catchment territory of the facility. Adding “per case payment” elements related to specific HIV and TB services for MARPs to the capitation-based budget will motivate providers to provide more of these services. Additionally, a capitation formula may be modified (e.g. based on HIV or MARP prevalence in the served catchment area) in a way to allow a conditional budget line for outsourcing an NGO to conduct an outreach prevention work aimed at recruiting new clients for testing and providing adherence support is required. Such mechanisms as well as new service packages for the outpatient and primary health care level require testing and feasibility and economic analysis.

The approach can also be applied to prevention among MARPs and TB/HIV high burden regions. Using evidence from a variety of international settings including post-Soviet nations, it allows to achieve efficient integrated PHC. In most nations, risk-adjusted capitation is used to provide an unbiased estimate of the expected costs of the citizen to the health care system over a given period.

Country process for development of National Disease Strategic Plans

National disease strategic plans are developed based on situation analysis including reviews provided by international organizations. Working groups are formed including main national stakeholders (MoH and other ministries, leading national institutions, international and NGO organizations working, technical assistance partners, representatives from key affected populations). The procedure and framework of the national programmes development are regulated by the Law on the State Targeted Programmes dated 18.03.2004 № 1621 <http://zakon4.rada.gov.ua/laws/show/1621-15> and the Regulations of the Cabinet of Ministers On Approval of the Procedures on development and Implementation of the State Targeted Programmes dated 31.01.2007 #106 <http://zakon1.rada.gov.ua/laws/show/106-2007-%D0%BF>. Draft documents of the programmes are discussed by the National Council and final documents are endorsed by the Parliament.

1.3 Joint planning and alignment of TB and HIV Strategies, Policies and Interventions

a. Plans for further alignment HIV and TB

Present TB and HIV strategies, policies and interventions lack the alignment necessary to generate tangible cost-effective results and impact on the diseases burden. It is recognised that alignment of TB and HIV in terms of planning, support systems and integrated services, has potential for efficiency gains, improved impact and sustainability. The Single TB and HIV Concept Note 2015-2017 (hereafter referred to as Concept Note) focuses on the further alignment of HIV and TB in relation to leadership and governance, financing, information systems, the health workforce, service delivery, as well as community systems.

Political leadership and governance for HIV/TB

In accordance with the Decree of the President of Ukraine No. 441/2011 dated 08.04.2011 the State Service of Ukraine on HIV-infection/AIDS and Other Socially Dangerous Diseases (hereinafter referred to as the State Service of Ukraine for Social Diseases) is a central executive authority, the activities of which are guided and coordinated by the Cabinet of Ministers of Ukraine through the Minister of Health of Ukraine. Its mandate includes developing and implementing the state policy on HIV-infection/AIDS, tuberculosis and other socially dangerous diseases, arranging the implementation of national and other programs, and coordinating other state bodies on HIV-infection/AIDS and other socially dangerous diseases (according to cl. 4.5 of the Rules and Regulations of the State Service of Ukraine on HIV-infection/AIDS and Other Socially Dangerous Diseases).

To streamline expenditures and government management in the domain of HIV-

infection/AIDS and tuberculosis, in 2012 the existing two separate state entities ('Ukrainian Centre to Prevent and Fight AIDS of MoH of Ukraine' and the 'All-Ukrainian Centre to Control Tuberculosis of MoH of Ukraine') were united into the 'Ukrainian Centre for Socially Dangerous Disease Control of MoH of Ukraine' (UCDC, Order of MoH dated 17 October 2012). There are plans to move UCDC under the management of the State Service of Ukraine for Social Diseases, to further ensure efficient coordination of HIV-infection/AIDS and tuberculosis interventions in Ukraine and avoid overlaps in functions.

In addition, in view of effectively coordinating the activities of key partners, which are the central executive authorities and non-governmental organizations, national and regional advisory bodies have been established, i.e. the National Council to Fight Tuberculosis and HIV-infection/AIDS (chaired by the Vice Prime Minister), and regional HIV and TB councils (chaired by deputy chairmen of regional administrations). State Service of Ukraine for Social Diseases holds the Secretariat of the National Council to Fight Tuberculosis and HIV-infection/AIDS.

It is recognised that political leadership and governance for HIV/TB extends beyond above mentioned institutions and should involve major other players, like the Ministry of Finance, Ministry of Justice, parliamentary health committee and others as well. Their full and collaborative engagement is necessary to realise breakthroughs in health reform, which are seen as a condition for optimal integration of HIV and TB services.

In terms of programming, as per the decision of the Cabinet of Ministers of Ukraine dated 2013 'On Approval of the National Target Social HIV-infection/AIDS Program for 2014-2018' the State Service of Ukraine for Social Diseases is the state contracting authority of the National HIV/AIDS Program 2014-2018 (NAP). This program mainly addresses HIV/AIDS interventions, whereas crossing HIV/TB interventions are included in the National Tuberculosis Program for 2012-2016 (NTP). These interventions contain 1) TB prevention among HIV patients with the help of isoniazid; prevention of pneumocystis pneumonia with the help of co-trimoxazole; 2) TB infection control measures at all medical establishments; 3) diagnostics of tuberculosis among HIV-positive patients and HIV testing among TB patients (orders of MoH No. 415 and No. 338); 4) early beginning of ART for TB patients in accordance with the HIV/TB treatment protocol; 5) integration of TB and HIV services; 6) case management programs for HIV/TB patients run by public organizations.

Further alignment and collaborative programming will take into account the scope and critical areas of the epidemiology of TB and HIV, priority regions for joint interventions, the maturity and capacity of TB and HIV programs at the national and regional levels, the health infrastructure, management and coordination capacity and readiness, as well as client needs. Efforts will concentrate on synergized programme management for improved efficiency; harmonization and coordination of national guidelines, tools and processes; engagement of representatives of key populations in joint planning for equal representation in TB and HIV proponent groups. In particular, joint planning and programming will be addressed at the level of oblast and municipalities (HIV and TB Councils), on the prevention of TB and HIV for overlapping risk groups (e.g. PWID and prisoners), an on governance (including M&E) of TB and HIV programmes in prisons.

Health care financing and equity for HIV/TB

HIV and TB programs are financed from the state budget of Ukraine and have separate budget programs at the national, regional and local levels. At the national level there is a joint budget HIV and TB program.

Restructuring financial flows in the system of health care as well as decentralization will help mobilize national funds for investments into the public health care system. TB and HIV service delivery are expected to become more efficient, effective and prompt. Though the current proposal is not focused on reforming health care financing, support will be based on several pilot initiatives related to efficient service delivery models and make contributions to future strategies, including the following:

- introduction of financial reform mechanisms as described in section 1.2 '*Linkage of the*

programs with the national health strategy' and section 1.3b '*Key barriers to TB and HIV alignment*'.

- release of the funds upon revising approaches to running TB hospitals (revision of grounds for hospitalization) and improvement of ambulatory assistance to TB patients;
- transition from financing medical establishments as such to the model of payment, which is based directly on services delivered– this will contribute to delivery of patient-focused services, including HIV/TB services;
- implementation of a social service procurement mechanism (access of NGOs to state financing for delivery of prevention/treatment, care and support services to high-risk groups);
- raising efficiency of the health care system during a transition period, ensuring sustainability of TB and HIV programs and relevant follow up activities;
- contribution to creating equal conditions for state, private and non-governmental organizations.

The *condition of co-funding* of prevention activities among PWID, MSM, CSW by local authorities would boost the implementation of social contracting, promote partnership of NGOs and local authorities in programming and monitoring and would enable cost-effective intervention models. Applying an ambulatory model of service delivery in TB programmes (starting with pilots²⁵) would reduce the demand for hospital care, thus generating savings that could serve the more efficient and result oriented models of service delivery, while shifting tasks to the civil society (adherence, care and support) through aforementioned social contracting. On the basis of a social order mechanism at national level, this social contracting of NGOs and community representatives for TB and HIV services are meant to be established.

Information systems for HIV/TB

The HIV and TB information systems run in parallel throughout the health system. The potential for alignment of these systems is recognized and strengthening is envisaged through a) harmonizing indicators and reporting mechanisms for HIV/TB collaborative interventions (at the local and national level); b) harmonization with national health information systems; c) HIV and TB (joint) sentinel surveillance (TB among HIV+ and HIV among TB); d) overcoming identified gaps in availability of data, consistency, exchange between data systems; e) investment in longitudinal electronic data system, for TB and HIV.

Health and community workforce

Alignment of health workers (working at primary, secondary and tertiary levels) in TB and HIV will be regulated through the TB/HIV protocol. Further alignment can be built through capacity building of service providers (e.g. family doctors and outreach nurses) in relation to the functions in the TB/HIV service protocol; and creating a more flexible workforce to ensure the decentralization of standard procedures from the level of doctor to nurses for both TB and HIV programmes (task shifting).

Service delivery and HIV/TB

Integrated service delivery has been modestly practiced in Ukraine and requires improvement and expansion. TB/HIV, TB/HIV/OST, NSP/HIV/TB joint points of delivery would need to be scaled up. This further alignment of TB and HIV in service delivery is proposed in the present Concept Note, thus ensuring a) a minimum package for HIV and TB prevention available to PWID and prisoners (TB prevention package included into the harm reduction package for overlapping risk groups), based on internationally recognized best practices; this would scale-up case detection for both TB and HIV; b) the application of cost-effective models for the prevention package for HIV and TB; and c) TB infectious control in HIV prevention programmes, including penitentiary institutes. See also the section 3.3. on integrated HIV/OST/TB services.

²⁵ Six pilot sites for the implementation of the ambulatory treatment model of TB patients are identified by MoH (Donetsk, Dnipropetrovsk, Vinnitsia, Kherson, Poltava, Kyiv).

Case detection and diagnostics is regulated through the TB/HIV protocol and would target 100% screening of TB for HIV+ and 100% screening of HIV for TB patients. Further alignment of TB and HIV for case detection and diagnostics will be developed by integrated services at the primary level through the One Stop TB/HIV Point of Care in polyclinics or/and Trust Offices. Also, alignment will take place in MDR-TB prevention among PLHIV and prisons.

TB and HIV treatment and care services are regulated by protocols on ART, TB and HIV/TB. The protocols aim at contributing to universal access to a continuum of testing, treatment, care and adherence services in HIV treatment and all forms of TB, including M/XDR-TB. The potential for further alignment will be developed through decentralization of ART (task shifting), a focus on the continuum of TB/HIV care (case detection, treatment, adherence) for key affected populations, multi-disciplinary/functional teams for TB and HIV treatment and care, integration of TB and HIV treatment at primary health care level and for family doctors.

A shift to an ambulatory model in TB treatment is expected to generate potential for joint planning and efficiency gains in HIV and TB programming, while the involvement of community based organization in services in TB (community DOT capacity) and HIV care can be planned jointly and integrated into One Stop TB/HIV Point of Care.

Regarding laboratory and diagnostic services for HIV and TB, joint planning is envisaged as well as alignment with existing national laboratory strategic plans and capacity building of the laboratory services.

Alignment care for HIV and TB at community level will be promoted through development of the delivery of integrated community based TB/HIV services (for MARPS), along with the delivery of other priority programs like MNCH if appropriate, especially in remote areas.

b. Key barriers to TB and HIV alignment

Among the key barriers to the successful implementation of the TB and HIV programs and achievement of the MDG targets the following constraints²⁶ are critical on the way to alignment of TB and HIV for more effective and impactful response for both diseases.

Lack of engaged leadership and cooperation prevent aligned programming One of the main obstacles to an adequate response to the epidemic is the lack of political will to appropriately tackle HIV and TB issues in the country. This is apparent within central and local governments. The political commitment of the central government to HIV/AIDS has been declarative for its largest part. The lack of political will of the government is not only specific to HIV/AIDS and TB, but to the health sector in general, because central government budget allocations for the health sector declined from 3.6% of GDP in 2007 down to 2.9% in 2011. In addition, while close to 91% of public funding for the NAP 2009-2013 was planned to come from the central budget (and 96 % of these funds were allocated to the Ministry of Health), actual spending from the state budget was far behind the NAP plans (about one third less in 2010) and this financial gap is also forecasted for the new NAP 2014-2018. As per the NAP 2009-2013 Assessment “political will and/or power within the MoH is not adequate to counteract this inner opposition within the sector and integrate and deliver the services needed to the PLWH”. The integration of TB and HIV services is well known to be one of the most effective ways of concurrently responding to HIV and TB problems, and this issue is purely health sector specific, however this has not occurred yet. Similar challenges are seen with the introduction, scale-up and integration of OST with HIV and TB services. The absence of government ownership and leadership has translated into gaps and low sustainability of response in countrywide, community-level prevention programs for MARPs.

Financial reform is an absolute condition for alignment, health reform and performance based financing Government funding is input-based and mainly linked to

²⁶ See the Consolidated Report on the ‘Assessment of the Implementation of the National AIDS Programme 2009-2013’ (2012).

beds and staff associated with those beds according to national “staffing norms,” and therefore, the majority of public resources are reserved to maintain the existing infrastructure²⁷. Experience from past years on the reduction of hospital beds shows that the current fiscal rule-set does not enable that savings made on hospital level can be transferred to enable delivery of out-patient services. This seriously hampers the development of the Ukraine health system and prevents healthcare to follow the same path as other countries in task-shifting from in-patient service delivery towards a more cost effective out-patient service model.

In modern evidence-based medicine, including TB services, out-patient primary care based service delivery has proven to be both effective and efficient world-wide. Results from the TB program in Ukraine however show a low compliance with treatment as well as a rising problem with MDR TB. The problems are linked. If development of MDR TB shall be prevented, the first priority is to emphasise compliance with prescribed DOTS treatment, for which a close-to-the-patient, counseling, treatment and monitoring is needed. This is not served well by forcing patients away from home, to spend long time in hospital beds. Instead, a close-to-home service, with a strong role of primary care allows the patients to maintain their daily life while being monitored and supported in their TB medication DOTS compliance.

However, presently existing fiscal-rule barriers prevent the transfer of saved funds from hospital level to primary care. These restrictive fiscal rules demand that funds saved as a result of optimization and rational restructuring on hospital level, are returned to the Treasury by the end of year. With the objective to facilitate overall cost-efficacy optimization in the healthcare system, this root cause would need to be further identified and analysed, the rule-set needs to be changed and a new financing mechanisms would need to be approved. Undertakings with analysis of fiscal rule restrictions and development of a modernized rule-set, needs to involve Ministry of Finance, Ministry of Health and Ministry of Justice, as well as the Treasury and possibly the Ministry of Economic Affairs. It is recommended that this is linked to donor coordination and collaboration efforts (*see also section 1.2 ‘Linkages of programs to the national health strategy’*).

Besides conditional financial reform, other determining factors will need to be addressed simultaneously. They include the lack of self-governance and decision-making on the level of health facilities, the lack of motivation for quality of work, overlapping of services at different levels of the health system, and the absence of a system of patients flow management throughout the levels of service provision²⁸.

At this stage a significant advocacy effort is required also to enable this health reform. Lack of well-thought communication on the reform-related issues with various parties – especially at the sub-national level and with the health care facilities’ management – is a serious threat to the successful implementation and its political support at the service organization and service delivery level.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

2.1 Overall Funding Landscape for Upcoming Implementation Period [2-3 pages]

Over the implementation period, total costs of the National AIDS Programme (NAP)—based on the targets established by the State Service and partners—are estimated at close to \$660 million for 2014-2017. This represents a financing gap of \$212 million. Costs of the NAP are expected to increase on average nine percent annually at the beginning of the period with a three percent decline in 2017. Total costs to implement the National TB Programme (NTP) are estimated at even higher at over \$1.1 billion with a corresponding funding gap of \$599 million.

²⁷ Source: World Bank Group – Ukraine Partnership: Country Program Snapshot April 2014
<http://www.worldbank.org/content/dam/Worldbank/document/Ukraine-Snapshot.pdf>

²⁸ Source: Presentation by USAID funded project “HIV Reform in Action” (2014)

The donor landscape for HIV/AIDS is varied in Ukraine. NASA findings indicate that over 20 donors provide aid for these programmes. Between 2012 and 2014, donors provided over \$188 million in support. Despite the large number of donors in this space, the actual amount of funding provided for HIV/AIDS is concentrated among a small number of donors, with just two—the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the United States Government (USG) —accounting together for approximately 90 percent of available international funding to-date (based on NASA 2012 preliminary results). The large number of donors suggests that ensuring adequate communication with and coordination among multiple donors is important in reducing administrative and opportunity costs, achieving additional efficiencies and helping to foster country ownership by partner countries. At the same time, the concentration of donor funding for HIV among only two donors suggests potential vulnerability as we expect the scope and magnitude of the GFATM funding commitments to change. The international donor landscape for TB is limited to only the USG and Global Fund. The two donors collectively provided close to \$60 million in support between 2012 and 2014.

Preliminary 2012 National AIDS Spending Assessment (NASA) results revealed that donor funding comprises only 31 percent of the country's spending on HIV and AIDS. The majority of funding – two-thirds— is from public sources, namely state (43 percent of the overall spending) and local budgets (23 percent of overall spending). In 2012, almost 70 percent of domestic public funds were spent on treatment (including human resources) and 20 percent on prevention. Focused prevention (among most-at-risk populations [MARPS] including prisoners) accounts for nine percent of the overall country's spending on HIV. This absorbs almost one-third of total spending on prevention. Although significant government funding is allocated towards prevention, only four percent this amount supported focused prevention in 2012. The remainder was funded from the external sources, notably The Global Fund. The absence of publicly-funded focused prevention interventions and ways to address this remain a priority. Sustainability discussions within the country remain ongoing at this time. In the future it is expected that the funding landscape in Ukraine will move towards supporting effective prevention services for MARPS.

For HIV/AIDS, anticipated funding from donors (excluding the Global Fund) for the upcoming implementation period is about \$73 million. The USG is expected to shoulder about 90 percent of this amount. Planned government expenditure on HIV/AIDS activities during the implementation period is expected to average \$89 million annually. This may be insufficient to cover treatment let alone other program expenses. For TB, anticipated funding from the USG is almost \$12 million.

At this time, USG support is primarily dedicated towards technical assistance and does not support almost any actual service delivery. The USG is also supporting implementation of proven practices in TB control and prevention in selected areas and working to improve access to HIV/TB co-infection diagnosis and treatment, but again – primarily in a form of the technical assistance.

On the other hand, NAP and NTP estimates—in line with programme objectives—include significant costs related to service delivery. More than 50 percent of HIV costs are expected to derive from ART and opportunistic infection (OI) treatment. Laboratory support for both diseases—including quality control, research, and surveillance—make up roughly 20 percent of costs.

Planned government expenditure on TB activities during the implementation period is expected to just nearly \$373 million. Combined with USG planned spending, this is less than half of required funding needs. As USG funds are primarily directed towards technical assistance and institutional capacity building, a large proportion of focused prevention and care and support services may be left unfunded. Anticipated funding at this time is inadequate to cover costs related to hospitalisation. The WHO STOP TB Budgeting and Costing Tool (used to calculate overall TB funding needs) projects that hospitalisation will equal over 40 percent of total costs. The tool also projects that almost one-third of costs will be tied to multi-drug resistant (MDR) TB and another 10 percent to improving diagnosis.

Unlike in HIV where the national spending is monitored through the NASA, TB expenditures are monitored mainly by the routine reporting of expenditures through the State Treasury. Some information on the TB funding landscape of is available in one of Ukraine's most affected, Donetsk oblast. According to the results of the TB sub-analysis of the National Health Accounts (NHA/SHA) exercise, almost 90 percent of TB spending in 2011 in the oblast came from domestic public sources (state and local budgets). Three percent came from private sources (private insurance and payment schemes, private corporations) and eight percent was paid out-of-pocket. The Multi-Drug Resistant (MDR)-TB share of the total expenditures was 11 percent. Given the high burden of MDR-TB in the oblast, we can assume a considerable funding gap. Almost 70 percent of all TB services in Donetsk are delivered through the in-patient care providers. This is representative of the situation at the national level.

The HIV Financial Gap Analysis and Counterpart Financing Table presents an overall funding gap in HIV of 32 percent of total expected program cost in 2014-2017. This financing gap will be reduced to almost 19 percent if the Global Fund grants the requested budget to Ukraine. Allocations to HIV include community systems strengthening; health and community workforce; monitoring and evaluation; policy and governance; prevention programs for men-having-sex-with-men (MSM), transgender groups (TG), people who inject drugs (PWID) and their partners, sex workers and their clients and other vulnerable populations; procurement; removing legal barriers to access; TB/HIV; and treatment, care and support.

The overall funding gap in TB is expected to reach 48 percent of total expected program costs, even when investing in the most cost-effective interventions. Allocations to TB include TB care and prevention and MDR-TB.

2.2 Counterpart Financing Requirements

Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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%)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
iii. Increasing government contribution to disease program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Despite the economic downturn and considerable budget cuts within the health sector in recent years, the Government of Ukraine (GoU) has been able to consistently increase coverage of the key HIV treatment interventions. Between 2012 and 2014, the number of patients receiving ART almost doubled, from 27,542 to 55,784. However, GoU contributions to

prevention are limited mainly to testing and PMTCT. Focused prevention among most-at-risk populations remain is largely funded by the Global Fund.

Total funding needs requirements for HIV/AIDS activities were obtained from the first iteration of the NAP 2014-2018. Funding was later reduced due to lack of resources. Total funding needs requirements for TB activities were obtained from the WHO STOP TB Budgeting and Costing Tool.

For HIV/AIDS, data on government revenues was obtained from preliminary NASA estimates (2012 only) whereas data from remaining years was obtained from the NAP draft budget. For TB, data on government revenues was obtained from the NTP. Data on HIV domestic private sector contribution is estimated from the 2012 NASA data.

Data on donor expenses were obtained directly from donors. Certain figures, particularly for 2014-2015, were provided specifically for this application. Other figures were obtained from the Phase II HIV/AIDS and TB applications.

USG provides bilateral support through the PEPFAR program and, in Ukraine, the PEPFAR program includes four USG agencies: CDC, DoD, Peace Corps and USAID. The USG is the largest external funding source after the GFATM but USG support is not directed towards HIV service provision. Rather, USG support in Ukraine focuses on the provision of technical assistance while GFATM funding supports prevention, care and support services as well as the procurement of ARV drugs. USG funding focuses on HIV and HIV/TB integration and USAID also has separate funding that is focused on TB only. We estimate that the PEPFAR/Ukraine program will have an annual budget of 25 million USD. However, we must emphasize PEPFAR's FY 2015, FY 2016 and FY2017 funding is planned and subject to the availability of appropriations and approval by the Global AIDS Coordinator. Additionally, we estimate that USAID will have about 2.5 million USD funding annually for TB services only.

The final counterpart contribution for HIV is 63 percent. This is in line with Global Fund requirements (minimum threshold of 40%). For TB, this figure is relatively higher and comprises 89 percent of the total expected contribution (see Annex 8.1 for supporting documents and Annex 42).

The GoU has confirmed its financial obligations towards NAP by approving the draft budget estimates in all interested ministries, including the Ministry of Finance.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

3.1 Programmatic Gap Analysis

The quantifiable programmatic analysis was done for the number of interventions in the priority 'service' and 'enabling' modules, which contribute mostly to the objectives and goal of the Concept Note. The following interventions were selected for programmatic gap analysis: provision of the defined service packages for PWID, CSW, MSM, prisoners, HIV testing and counselling, condom programme, HIV treatment, HIV care and support, MDR-TB treatment.

The size of the population in need as well as the country targets in the programmatic analysis refer to the National HIV/AIDS Programme 2014-2018 and the National TB Programme 2012-2016 and includes Crimea. The National HIV/AIDS Programme 2014-2018 has not yet been approved and when approved it will still include the targets for Crimea. The planned programmatic coverage for Crimea in 5 service Modules is included in the Concept Note to be considered for funding above allocation.

The concept of the programmatic table does not allow showing the share of the Global Fund grant in the estimated programmatic gap as per the nationally set targets. Instead the programmatic table formulas assess the programmatic gap as a percentage of the total size of the estimated population (key groups) without its relation to the nationally set targets for the programmatic coverage of the target groups. This assumption of the programmatic gap might

not be an approach to the programmatic gap analysis as applied in the country.

The 100% programmatic gap of the **HIV prevention programme for PWID** in 2015 and 2016 of the NAP 2014-2018 will be up to 60% (2015 -56%, 2016 -57%) covered by the Global Fund grant providing for reaching the 60% coverage targets of the National HIV/AIDS Programme, including Crimea (4% of the total estimated number of PWID in Ukraine including Crimea).

The 100% programmatic gap of the **HIV prevention programme for CSW** in 2015 and 2016 of the NAP 2014-2018 will be up to 37% covered by the Global Fund grant providing for reaching the national coverage targets of the National HIV/AIDS Programme, including Crimea (4% of the total estimated number of CSW in Ukraine including Crimea). The programmatic gap of 57% in 2017 (estimated as per cent from the total number of CSW and not the national targets of the planned coverage) is planned to be co-funded by the GF – 39%.

The 100% programmatic gap of the **HIV prevention programme for MSM** in 2015 and 2016 and 2017 of the NAP 2014-2018 will be up to 17%, 20% and 23% respectively covered by the Global Fund grant providing for reaching the national coverage targets of the National HIV/AIDS Programme, including Crimea (1% of the total estimated number of MSM in Ukraine including Crimea).

The 100% donation of condoms to the prevention packages for the MARPs will be done by the US Government for 2015-2017 (Annex 9). The programmatic gap analysis was done separately for the condom programme for MARPs as this is a part of the NAP 2014-2018 target and covered by donor contribution (see the programmatic gap analysis tables).

HIV prevention programme for prisoners within NAP 2014-2018 targeting above 80% of the target group will be covered partially by the domestic sources (25% in 2015, 16% in 2016 and 78% in 2017) and co-funded by the Global Fund grant at the level of 53%, 55% and 56% of the prison population annually as per the Programmatic Gap analysis. The prison population might reduce by up to 10,000 due to the expected amnesty.

The **opioid substitution therapy (OST)** programmatic gap is increasingly planned to be covered by the NAP 2014-2018: from 18% in 2015 up to 30% and 40% by 2016 and 2017 respectively, while the Global Fund funding will gradually be phasing out from 20% in 2015 down to 11% and 5% in 2016 and 2017 respectively. The financial incentives for the medical staff in the OST programme are planned for above allocation funding and considered as a prerequisite for sustainability of the programme in a phasing out strategy.

The programmatic gap in **HIV testing and counselling** for MARPs includes laboratory screening in the health facilities and rapid testing provided through NGOs within the prevention services. The Global Fund allocation for VCT (rapid testing) for **MSM** will cover 10%, 12% and 14% in 2015, 2016 and 2017 respectively, with the government funding for laboratory testing increasing from 6% in 2015 to 17% planned coverage of MSM by 2017. 1% of the total MSM population in Ukraine is planned to be covered by VCT as above allocation in Crimea.

For 2015-2016 22% of the total estimated **CSW** will be offered **VCT** through the Global Fund grant and 2% coverage of the total estimated CSW group with VCT is planned as above allocation for Crimea.

The laboratory **testing for IDUs** is increasingly planned in the NAP 2014-2018 from 22% to 41% coverage. The Global Fund grant will contribute to about 35% of the size group coverage with rapid tests for 2015-2017 and 2% of the total group of IDUs will be targeted in Crimea as planned for above allocation.

The Global Fund allocation for the **ARV treatment programme** will cover 9% in 2015 and 11% in 2016 and 2017 of the estimated number of PLHIV as per the latest Spectrum estimates, contributing to the national targets. Ukraine is included in the regional initiative on re-targeting and the new targets will be defined for the NAP 2014-2018 based on the methodology of percentage of PLHIV on treatment from the estimated number of PLHIV to gradually shift to the WHO guidelines 2013 and towards "Treatment as Prevention". The ART as well as other targets will be reviewed based on the revised methodologies of the indicators.

To meet the requirements of the indicators methodology in the Concept Note - harmonized with the GARPR indicators (Annex 10) , as well as to meet the requirements of the gap analysts template that refers to the national targets and indicators yet built with the previous methodology of estimation of people in need of treatment, a decision was made to apply the county targeted number of people planned for ART combined with the total estimated number of PLHIV (which was not a part of the target setting process for NAP 2014-2018) (see Annex 11 and Annex 12). With the GF funding complementing the nationally planned resource the national treatment targets might be overcome.

The targeting for **HIV care and support** in the NAP 2014-2018 was based on the number of PLHIV who are registered and get treatment (dispensary ART group) in need of care and support, while for the Concept Note programmatic analysis the total estimated number of PLHIV is used as denominator (total estimated population in need/at risk). The Global Fund is the unique donor in covering the 100% programmatic gap for HIV care and treatment in 2015 and 2016 and 64% gap in 2017. The Global Fund grant allocation provides for 28% (2015), 30% (2016) and 33% (2017) of coverage. The above allocation coverage is planned for Crimea (2% of the total estimated PLHIV in Ukraine).

As per the 2013 mid-programme review of the National TB programme 2012-2016 the total estimated number of people in need of MDR-TB treatment remains constant for 2015 and 2016 with 100% programmatic gap. The Global Fund grant will cover 31% of the population in need of treatment.

As per the Investment Case scenarios, up-dated by the Futures group to inform the Global Fund Concept Note application the Global Fund grant Ukraine will avert almost 3.5 times more new HIV infections (17,900 versus 4,770 if without Global Fund grant) and 58,630 premature death due to HIV-related complications (see Annex 13 and Annex 14) .

The programmatic gap analysis for the ‘enabling modules’, such as ‘Policy and Governance’, ‘Health and community workforce’, ‘Health information systems and M&E’, ‘Removing legal barriers’ included other donors involved in the areas of capacity building, advocacy and policy changes, complementary to the Global Fund grant interventions.

The Global Fund allocation planned for the module ‘**Health and community workforce**’ covers only a small part of the gap in the development of the workforce. Alongside with the activities requested to be funded as above allocation and complementary to the Global Fund Concept Note intervention in the ‘Health and community workforce’ module USAID provides assistance to the capacity building of the national and community workforce, covering partially a gap in the workforce development need for the qualitative ART programme. The module was developed based on the latest available assessments of the workforce (see Annex 15 and Annex 4) and with a perspective of the initiative to develop the ‘HIV and TB workforce capacity building plan’ (UCDC) , which should become a part of the overall national health system strategy of the workforce development based on the Strategy of WHO Human Resources for Health 2010-2015.

USAID funded Project ‘HIV Reform in Action’ also contributes to the joint advocacy of donors and national partners and creation of the policy dialogue around the health reform, financial management, fiscal rule barrier removal for efficient funding in HIV and TB (see also section 1.2 ‘*Linkage of the programs with the national health strategy*’ and section 1.3b ‘*Key barriers to TB and HIV alignment*’, which are also interventions under the modules ‘**Policy and Governance**’ and ‘**Removing legal barriers**’ of the Concept Note (Annex 7)

3.2 Applicant Funding Request

The programmatic and financial gap analysis address the present needs and constraints of the national response to both the TB and HIV epidemic. The State-funded National AIDS Program 2014 -2018 and the National Tuberculosis Plan 2012-2016 together with the current

Global Fund Round 9 and 10 Programs and other donor-funded projects can only partly address the identified weaknesses and gaps.

The proposed Concept Note is expected to partially fill the gaps. The goal of the three-year program is to contain the TB and HIV epidemics and reduce TB and HIV-related morbidity and mortality in Ukraine. Given the concentrated character of the epidemics, the focus is on people who inject drugs (PWID), commercial sex workers (CSW), men having sex with men (MSM) and the transgender population, TB infected people and their contacts, PLWHA and the sexual partners of MARPs and PLWHA, and the prison population.

While building on the achievements and lessons learned in Global Fund Round 6, 9 and 10, and within the framework of the National Programs on TB and HIV and existing programmatic and financial gaps and constraints, the vision for the Concept Note is to foster a long-term sustainable public health care system with continued and sustained TB and HIV prevention, treatment, care and support services increasingly integrated, institutionalised and client-centred, and scaled up through high-impact interventions in the most affected populations and epidemiological hot-spots of the country, while providing quality services that are gender sensitive and can be equitably accessed by key at risk populations.

In response to the challenges in the health sector, and in particular for TB and HIV programs, in terms of financing, institutionalisation, governance, political leadership, and other building blocks of the health system, the National Council has identified five strategic priorities to which this program described in the Concept Note will contribute:

Strategies

I. Guarantee continued/sustained care while phasing-out

The program focus will remain on important investment pillars:

a) the promotion and sustenance of *scaling up access to antiretroviral treatment*, ensuring that the most vulnerable people have access to a continuum of testing, treatment, care and adherence services. Hence responding to the fact that, despite efforts to improve treatment coverage, only half of HIV+ patients in need are currently receiving ART, of which less than 10% are for people who inject drugs. The main focus will be on identification and *early treatment* of HIV/TB patients, PWID, MSM and CSW in the 5 most affected regions (Donetsk, Dnepropetrovsk, Nikolayev, Odessa regions and Kyiv) where there will be nearly 50% of all the patients receiving ART on account of the Global Fund. Through the NAP 2014-2018 state funding will take over by means of a defined patient transfer plan. Penitentiary institutions and remote decentralized ART sites are included;

b) the promotion and enhancement of *access to comprehensive harm reduction, prevention, treatment and care services for people who inject drugs* and prevention, treatment and care services for other key affected populations;

c) strengthening the links and referrals between testing and treatment facilities and address losses in referrals of PWID between NGOs and AIDS Centres and the penal system through a *case management approach*.

For any impact to be achieved, the pillars are regarded complementary and will be coordinated and integrated to the extent possible.

Ukraine will need to anticipate a drop in funding of one of the two main external donors for HIV and TB interventions, namely the Global Fund. At the same time it is realised that gains made in the fight against HIV/AIDS in Ukraine will not be sustained without a continued increase in public resource allocation. Therefore, a phasing out strategy will ensure that government funding will gradually replace a selection of Global Fund funded activities, while seeking support from other donors and the private sector. It is envisaged that the proposed phasing out strategy for TB and HIV interventions will decrease the share of Global Fund supported services by 50% by the end of 2017 without a risk of interruption of interventions and with equal quality.

The phasing out strategy will be supported by program approaches that aim at optimal use of the scarce resources. They include the regional prioritization approach and the service

diversification approach, described below. The phasing out strategy will become a part of the Transition Plan and its success will be contingent of national leadership in sustainability and continuity of the response beyond 2017 as a component of the national TB and HIV programmes.

With the view to the phasing out strategy and equity for financing and using some of the recommendation of the “Ukraine HIV Programme Efficiency Study” (Annex 16) optimization tools were applied for unit costing methodologies, unification and standardization of service packages of all types of services (prevention, care and support in HIV and TB), what is a step on a way to phasing out strategy and up-take of the services by the government within the NAP 2014-2018 or by other donors. This is a basis for the systematic approach in the phasing out strategy from PRs to the Government, allowing unified programming of needs for services and workforce development based on the need in services, development of the social contracting (requiring standard approach to costing of services, their marketing) and etc.

II. Decentralise towards primary and ambulant health care

Responding to the relative high financial burden of secondary and tertiary health care, the program, following NAP 2014-2018, supports decentralization of services emphasising primary health care, greater responsibility of the local (regional and district) authorities in programming, implementation and monitoring. In general, the Concept Note will promote and contribute to health system changes to make them more efficient and effective. Conditional to the changes are financial reform acts that enable a system of performance based financing, promoting autonomy and ultimately the integration of services at the lower tiers of the system.

In particular, the necessary shift from hospital based care to primary and ambulant health care will be subject of attention. For HIV and especially TB this will include initiating at the local level the application of the ambulatory model of TB service delivery, first on a pilot basis. The ambulatory model will encourage the reduction of demand for hospital care and bring services closer to the target group. In addition, saved expenses at secondary level could be mobilized for up-scaling of this more efficient and impactful/result oriented service delivery model. Furthermore, the ambulatory care model would enable tasks (adherence, care and support) to be continued and carried out by other providers in addition to those of the government through social contracting. The shift to an ambulatory model in TB treatment has also potential efficiencies in combination with HIV care: community based organization’s involvement in services in TB (community DOT capacity) and HIV care can be planned jointly and integrated into One Stop TB/HIV Point of Care.

III. Regionalization and diversification according to KAP level

In order to economize on the use of scarce resources and aim at a higher impact on the HIV and TB epidemic and disease burdens in Ukraine (see section 1.1.), a regionalization and a service diversification approach will be adopted. They both refer to the specific local needs and characteristics of the target population.

a) *Regionalisation approach* The approach prioritizes on regions according to disease characteristics. It is based on the assumption that if HIV and TB transmission is reduced in the regions with the highest burden the epidemic situation of HIV, TB and TB/HIV in the whole country will improve. Global Fund support will be concentrated in the regions with the highest mortality and disease burden for HIV and TB/HIV (see Annex 1 for the geographic basis on the epidemics for the regionalisation approach and Annex 2). In practice, the Global Fund would cover 100% of needed prevention and care and support services in the regions with the highest disease burden for HIV and TB (5 overlapping regions). As per the methodology, developed for regionalization of prevention services (see Annex 17 for regionalization discussion paper), the regions are sub-divided into the groups based on several criteria including the size of key affected populations, health seeking and risk behaviour practices (as per the indicators), new cases dynamics, and the number of PLWH. The proposed sub-division of the regions as per the criteria should be linked to the choice of the best suitable prevention models as well as their prioritization, phasing out and integration.

Under this approach all groups of regions benefiting from the Global Fund will develop their local plans for phasing out of the Global Fund beyond 2017.

b) *Services diversification approach* The service diversification approach is based on prioritizing different service delivery packages (or models) for different target groups in the regions (see Annex 18). For example, currently NSP services for IDUs are provided through 4 main service models: 1) outreach; 2) community centres/NGO based; 3) through mobile clinics, and 4) drug stores. On the basis of a set of criteria, the service diversification approach applies up-scaling or down-scaling to service delivery models by region and by group of key affected people. The criteria may include the share of parenteral transmission in new cases, the level of access to the target group, the specificity of drug use and characteristics of drug users, the effectiveness of the model for HIV and TB testing, and its sustainability (criteria are to be further elaborated).

IV. Equality in public-private service provision for TB and HIV

Equity of health care financing is an element of the phasing out strategy and is regarded one of the major enablers for sustainability. With the adoption of principles and practices of equitable financing (first on a pilot basis), the non-governmental and private service providers should be equally recognized by the public health sector as integral elements of the system. Equitable access to public resources through social contracting is a part of the NAP 2014-2018, which aims at launching social contracting in all regions by 2018. Similar mechanisms have been piloted and analysed. Scale up of these mechanisms by 2018 will depend on the attainment of political and legal recognition of the private and non-governmental institutions (and their services) as part of health care for equitable funding. Equitable provision of healthcare financial resources to public, private and non-government institutions for effective delivery of services and disease control programs will be addressed through advocacy, interventions on removing legal barriers and interventions in policy and governance as part of the proposed Concept Note.

V. Alignment TB and HIV

Present TB and HIV strategies, policies and interventions lack the alignment necessary to generate tangible cost-effective results and impact on the diseases burden. It is recognised that alignment of TB and HIV in terms of planning, support systems and integrated services has potential for efficiency gains, improved impact and sustainability. The Concept Note focuses on the further alignment of HIV and TB in relation to leadership and governance, financing, information systems, the health workforce, service delivery, community support as well as the prison systems. The penitentiary system can serve as an example on how TB and HIV services can be aligned.

Alignment cannot be accomplished overnight. Therefore a stepwise (phased) approach will be adopted to prevent the disruption of on-going activities. Such an alignment plan for which technical assistance will be required, concerns the review and adaptation of organizational and management structures and standardisation of disease program management across regions and at the local level where possible, the promotion of integrated planning, programming, budgeting and supervision, the application of 'standard' service models, the testing of the level of efficiency gains and up scaling if efficient, the monitoring of sustained and efficient client-centred programs, and the promotion and enhancement of integrating standardized services across institutions, levels and sectors of the health system with involvement of other sectors for care and support.

Objectives

Provided these five key strategic priorities, the following three objectives with fourteen modules with specific interventions have been identified for the proposed program:

1. To scale up and ensure equitable access to high quality TB and HIV prevention, treatment, care and support with a focus on key affected populations (MARPs, PLWHA and other people most affected by the HIV and TB epidemic);

2. To strengthen the health systems towards sustainable and integrated solutions for key populations mostly affected by the HIV and TB epidemic;
3. To strengthen community systems that enable needs-based, cost-effective and integrated interventions for key populations mostly affected by the HIV and TB epidemic;

In section 3.3 the applicant funding request is further elaborated, whereby the rationale for the selection of the modules and their expected results are specified, together with further detailing the strategies and objectives as provided in the present section.

3.3 Modular Template

With reference to the identified strategic priorities of sustained and continued care and quality services for TB and HIV key affected populations (KAP), seeking service efficiency and optimal use of resources while aiming at handing over selected activities to the government (see section 3.2), and in response to the three objectives of the proposal, fourteen modules were selected (within budget). They can be divided into two main groups, i.e. *service delivery modules* (8) and *enabling environment modules* (6).

The choice of the service delivery and enabling modules has been determined by the programmatic gap analysis for the 15 key areas of response of the NAP 2014-2016 as well as for MDR-TB as per the programmatic gap analysis of the National TB Programme 2012-2016. The biggest programmatic gaps (e.g. 100% gap for 2015-2016) were identified for prevention among MARPs, as well as for HIV care and support. The programmatic gap in opioid substitution therapy (OST) is planned to be gradually covered by the state, while the Global Fund funded coverage will be down sized. The programmatic gap in ART, calculated upon the new methodology as percentage of estimated PLWH receiving ART, will be covered 11% by the Global Fund, while the rest is covered by the state to reach up to 48% and above (exceeding the nationally set target for the NAP 2014-2018 as per the programmatic gap analysis) of estimated PLWH, as such moving towards “treatment as prevention strategy”. The National HIV and TB strategies presented in the National Programmes stipulate the national phasing-in with national and local budgets from 2017, which influenced the prioritization of the interventions to be supported by the Global Fund.

The political changes in the country as well as the health reform dialogue, the piloting of its elements (e.g. within the World Bank loan) and other donors (USAID funded project “HIV Reform in Action”) influenced the choice and prioritization of the “enabling” modules and interventions. They are complementary to health reform advocacy activities in the country and/or leveraging the national policy dialogue on sustainability of prevention services, elimination of fiscal barrier rules, hindering the efficient investments into the HIV and TB, restructuring services provision and moving towards the public health approach. The programmatic gap analysis defined several interventions that have additional funding from the donors (UN, USAID) (trainings, capacity building, monitoring, advocacy) The priority modules were selected to synergize these efforts and leverage better articulated and impactful actions of all partners.

Linkage of vertical results chain of the modules towards impact

The interventions, both in the service and enabling modules of the Concept Note, aim at improving the continuum of care and treatment cascade to guarantee reduction of the incidents and mortality from HIV and TB. Currently, as per the data of the Information Bulletin #41, 2014 (Annex 12) the HIV treatment cascade starts with almost 3 million people tested annually (routine screening and MARPs testing) and 31,678 diagnosed as positive, of which 68.3% register, or are included into the dispensary group. Almost 54% of them were taken under medical supervision in III-IV clinical stages of HIV infection in 2013. Seventy five per cent of the dispensary group belongs to the active group, thus getting medical supervision at least once a year. 80,000 PLWH (76.5 % of the active dispensary group) are included into the care and support programme. 12,813 PLWH started ART in 2013 and 87 % of the people were receiving ART in the 12 months after initiation of therapy (cohort patients who started ART in 2012). Virological efficacy of ART in 2013 was 78,1 %.

The interventions of the service modules will ensure access of PWID (from 34% to 35%), CSW (from 22% to 23%) and MSM (from 10% to 14%) to testing on HIV and TB (primary screening as a part of the prevention package) and will be followed by better referral services to the health system for earlier initiation of HIV and TB treatment. The new indicator is introduced to monitor the effectiveness of the referral system. The share of PWIDs on treatment is increasing and is currently 11% (01.01.2014) and will increase as a result of

improved access to testing and referral (see Annex 19 for the services cascade for PWID proposed by Alliance). The share of PLHIV on OST is currently 42% (3591 clients) (Annex 12) and the share of those HIV positive PWID in OST programme receiving ART is 49% (1766 clients) (<http://ucdc.gov.ua/uk/statystyka/profilaktyka/zamisna-pidtrimuvalna-terapiya>). More OST positive clients will get ART by the end 2017 and the majority of OST clients will get HIV/TB and OST services at the integrated sites for the benefit of better outcomes of HIV and TB treatment.

The interventions under the enabling modules will contribute to the legislative and policy changes, allowing more effective work of the civil society as equal partners of the state organizations in service provision, the treatment cascade, building platforms for sustainability of services and phasing-in of the local budgets (prevention among MARPs) as well as increasing human rights perspectives for key populations, reaching better prices for drugs and reducing stigma and discrimination that may impact negatively on the success of the treatment cascade.

Service delivery modules

The following eight service delivery modules are selected: 1. Treatment, care and support; 2. MDR-TB; 3. Prevention programs for people who inject drugs (PWID); 4. Prevention programs for sex workers and their clients; 5. Prevention programs for MSM and TGs; 6. Prevention programs for other vulnerable populations (prisoners); 7. TB/HIV; and 8. TB care and prevention.

The general focus of the interventions in these modules is to ensure the continuum of care through the delivery of effective services for KAPs filling the gaps of the national HIV and TB Programs as per the programmatic gap analysis. All together these modules will spend over 90% of the 3-year Global Fund budget, with three modules (Treatment, care and support; MDR-TB; Prevention programs for PWID) containing more than 80% of the total funding for the modules and have the highest impact on both epidemics.

All interventions on **HIV treatment, care and support** will focus on KAPs (PWID, CSW, MSM, patients with TB/HIV co-infection, and prisoners) and will be concentrated in the five regions (Dnipropetrovsk, Donetsk, Nikolaevs, Odessa regions and Kyiv city) with the highest disease burden of HIV (where over 50% of all HIV-infected people live). However, other regions will not be excluded from interventions. In total, 26,033 patients, including prisoners, will be receiving ART under the Global Fund program (2 years funding with 9 months buffer) and is planned to be financed by the State Program in 2017. The number represents 20% of the total number of patients estimated to be on treatment in 2017. With Global Fund support a strong social component in community-based ART adherence is meant to reach this target in 2017. Hereby the focus is on applying models of active case finding (e.g. community initiated treatment intervention (CITI)) and case management that will enhance enrolment of the most marginalized patients to treatment and will improve the treatment cascade. However, it is yet uncertain what mechanisms will be applied so that community based ART adherence and out-patient services under Global Fund support will have a follow-up after funding ends and how the indicated target for community care in the NAP 2014-2018 can be reached. Nonetheless, to ensure achievement of the treatment retention target of 87% in 2017²⁹, adherence support services will also be provided to patients receiving ART under the State Program, including Crimea (planned as above allocation).

Interventions on **HIV prevention among PWID** will cover up to 193,290 most at risk PWID in 2017 (63% of the estimated population size) in all regions of Ukraine³⁰, with most resources allocated to high burden regions (high HIV prevalence and high risk of outbreaks). This level of coverage should sustain the impact on the epidemic, which the HIV prevention program had during last years, in reducing HIV incidence among PWIDs and in general

²⁹ This national target included in the National M&E Plan, to be approved after approval of the NAP 2014-2018.

³⁰ Crimea is included above allocation (both budget and target).

population.

Four service provision models, i.e. outreach, mobile clinics, stationary and pharmacy points of care will be applied in different combinations, allowing for HIV risk reduction communication and information-educational materials (IEM); distribution of syringes/needles, condoms; case detection by screening for HIV, HCV, and integrated primary TB screening; and linkage to care through CITI, which is a short-term rapid linkage to care intervention and thus facilitates early treatment access for active drug users.

Depending on the region different combinations of the 4 models will be applied for reaching the highest possible coverage and rationalising the cost of interventions (see Annex 16). In high and medium priority regions the proportion of outreach and mobile clinics will be increased, including screening for HIV during outreach, to maximize case finding and increase program sensitivity in terms of locating new outbreaks. In the lower priority regions pharmacy sites with referrals to stationary sites for HIV screening will be applied. For reaching new and remote areas with high HIV prevalence and high concentration of risk groups the mobile clinics and outreach models will also be used in lower priority sites.

In 2014 Alliance will conduct a *mobile clinic pilot* on the usage of this model to become a structural unit of healthcare facilities in several regions of Ukraine. The mobile clinic should facilitate timely detection of HIV infection, registering for medical supervision, and expanding timely access to ART for HIV positive representatives of risk groups. The model should allow common usage of the mobile clinic by NGOs and AIDS Centres, allow AIDS Centre staff to be involved in the mobile clinics operations at no additional cost for NGOs, allow NGOs to support clinics, define mobile clinics schedule and route of operation as well as allow the use of PIMA CD4 and other portable laboratory equipment in mobile clinics to conduct the full range of counselling and testing for HIV, CD4, STI screening, primary TB screening. Based on the results of the pilot, the model may be implemented in all projects.

Harm reduction through opioid substitution therapy (OST) for PWID is implemented through a range of healthcare facilities, i.e. narcological dispensaries, TB dispensaries, AIDS Centers, and general hospitals. Medical and psychosocial support for the patients receiving OST under the program will be provided through case management in OST sites. Above allocation funding is requested for incentive payments to staff in order to ensure achieving OST targets. OST patients under the Global Fund grant will be gradually handed over to state funding. Treatment starts with 9,600 patients in 2015 and gradually hand over will take place by transferring 4,300 in 2016 and 3,000 in 2017. Procurement for the OST drugs will be carried out with these schemes in mind.

The OST programme has also been a *catalyser for the integrated services approach* in the country. Overall there are 86 OST integrated care sites (out of total 161 OST sites) providing services to more than 5,500 clients (i.e. 67% of total clients on OST, 2013). Thirty one sites are located at narcology settings, 11 sites at TB clinics, 8 sites at the AIDS Centres and 36 sites are located in general hospitals. The HIV/TB integration model has progressed at 19 sites offering OST: TB clinics (11 sites, 2.5% of all clients of the integrated sites) and AIDS Centres (8 sites, 9% of all clients of the integrated sites). Further integration of TB/HIV as well as STI and hepatitis services are planned at 67 sites at the narcology settings and general hospitals, offering OST (Annex 20 for types of HCIs where ICC are planned by Alliance 2014). These 4 models of integration should be further scaled up and sustained with the planned growing Government's share of OST co-funding from 2015.

Similar to prevention among PWID, a combination of service provision models will be used for **prevention activities among sex workers (SW)** and **men having sex with men (MSM)**. Services will be provided via outreach, mobile clinics and stationary points. Regarding regionalization strategy the same approach of using mostly outreach and mobile clinics in high and medium burden regions will be used.

Prevention interventions for prisoners include informational campaigns, educational and motivational counselling, provision of condoms, lubricants and disinfectants, distribution of audio and video educational materials, pre and post test counselling IFA and

rapid HIV testing, all with the support of the Global Fund grant. Starting with 2014 additional funding will be provided from the state budget. Ultimately, 80% of prisoners will be covered by prevention activities (average 54% coverage with the Global Fund co-funding). Full funding from the state budget will start from 2018. Testing and counselling services will be provided by the medical personnel of penitentiary institutions.

Following the NAP 2014-2018 that indicates the **gradual transfer to funding prevention programs** by regional/local budgets per 2017, the proposal assumes that 50% of the budget needed to support HIV prevention programs among MARPs will come from National funding sources (central or regional budgets) by 2017 (except for prevention among prisoners; including Crimea). This means that from the beginning of 2017 increasing numbers of regions should start funding HIV prevention projects partially or fully and increase the proportion of funds in these programs through 2017. This 'phase-out assumption' of the proposal is based on successful examples in the recent past in Poltava and Cherkassy regions that provide evidence for local budget allocations to social projects for *inter alia* HIV prevention among PWID. Although the program foresees in advocacy efforts that should encourage replication of the examples, full coverage by the end of 2017 cannot be ensured and should be regarded a sustainability risk. It will be important to safeguard funding from the Global Fund to avoid interruption of services till the end of 2017 budget year and allow time for necessary legal, regulatory and procedural changes regarding the forming, approval, endorsement and implementation of the local budgets in 2017. The sustainability risk will remain however, if necessary changes have not been finalised by that time.

MDR-TB, TB and HIV/TB care and prevention The TB related modules are developed in response to the TB and HIV epidemic, taking into account the National TB Program 2012-2016 (NTP), the Operational Plan to Counter MDR-TB in Ukraine 2013-2014, and existing TB programs (Global Fund Round 9) and on-going other projects in Ukraine. The interventions all critically address timeliness, quality and comprehensiveness of case finding and treatment services in order to effectively reduce TB morbidity and mortality. Hereby, key affected populations (PLWH, prisoners, direct contact, and other vulnerable groups like homeless people and Roma minority groups) are the major target, either having sensitive or drug resistant TB or having a TB/HIV co-infection. The interventions in the current proposal are aligned with the scope, priorities and key directions of NTP and are focused on strengthening the programmatic management of TB and drug resistant TB, supporting patients and communities and consolidating health system's capacities for successful TB case management.

MDR-TB interventions propose a comprehensive approach to adequate MDR-TB management, tackling both provision of medications and initiating support for structural changes.

The structural changes are meant to gradually transform the TB care model, now largely based on hospitals towards an ambulatory mode of care delivery. The search for a new financial mechanism will be part of piloting projects in selected regions, in which ambulatory care models will be tested. The experience obtained will be documented and promoted for larger replication throughout Ukraine. Whereas the Global Fund will fund advocacy for the ambulatory model and lobby for change models, other donors finance the testing and implementation of the models. See also under 'policy and governance' of this section 3.3.

MDR-TB interventions aim at covering acute shortage of second-line drugs (SLD) for MDR-TB patients (NTP has budget to supply first line drugs (FLD)), contributing to MDR-TB treatment quality and building capacity in the area of MDR-TB programmatic management. Global Fund procurement will cover 42% of all patients estimated to receive MDR-TB treatment, focusing on patients, who were not treated with second-line drugs before (new, relapses and failures of 1st course), patients with Rif positive GeneXpert's results, MDR contacts (adults and children). The state budget will cover patients who have second-line treatment history. Interventions will also target patients of penitentiary institutions. Treatment provision will be accompanied with relevant social services for patients and their

families to ensure active case finding, adherence to care and better treatment outcomes.

Besides provision of treatment the MDR-TB interventions foresees activities to tackle operational aspects related to building up sustainable patient-centred TB services based on outpatient case management and appropriate patient support. For this purpose it is planned to revise national guidelines, operational policies, develop referral protocols, standardize staffing regulations based on internationally recognized principles.

As for some of these activities, Global Fund funding for this module will phase out in 2017, however plans for take over by the government would need to be worked out and agreed upon.

TB/HIV interventions require close collaboration between the two vertically organized service delivery systems, as well as close cooperation of NGOs and state organisations, enabling services that area as close to the patient as possible with minimal referral to different levels of service provision. Interventions will work towards the creation of a new model 'One Stop TB/HIV units of care'. The 'Protocol on the Collaboration between TB and HIV services' has been drafted and will become the guiding tool, once approved and adapted at regional and rayon levels. Furthermore, a range of other activities support TB and HIV collaboration, including outreach workers who will apply a questionnaire for better and timely TB detection at each contact with KAP, sputum collection and testing by Rapid Diagnostic Tests (GeneXpert) at HIV sites, developing and implementing IPT for HIV + patients at HIV sites with involvement of NGOs and communities, implementing minimal standards for TB Infection Control at sites where HIV+ patients gather, and providing counselling and psycho-social support to TB/HIV patients.

TB care and prevention interventions support the aims of above mentioned TB/HV and MDR-TB interventions. It furthermore strengthens and is complementary to on-going TB Control components in Ukraine. Particularly, the Global Fund supports fully or in a co-funding arrangement with the State rapid TB diagnostic and sensitivity testing techniques (DST), penitentiary TB services, and NGO's involvement in case finding, adherence and DOT provision. In 2017 these activities are subject to the phasing out strategy and initiation of social contracting and will be funded by the State. As mentioned above, there are risks associated in terms of continuity of care. If arrangements for social contracting or not ready in time or local budget cannot be made available sustainability is in jeopardy in 2017 and beyond.

Enabling environment modules

The following six modules are selected: 1. policy and governance; 2. health and community workforce; 3. removing legal barriers to access; 4. community systems strengthening; 5. procurement and supply chain management (PSCM); 6. monitoring and evaluation. They contain interventions regarded as **critical enablers** for health care and community system strengthening, and support necessary changes in TB, HIV and TB/HIV integrated service delivery, decentralisation and health care reform, thus aiming at a more sustainable environment for the delivery of services by the end of the programme.

Recognised as a central driver for supporting health care reform the **policy and governance** module is designed to help create an environment in which HIV and TB services can be better integrated, services can be more patient-centred, and a focus can be put on primary health care at the expense of costly secondary care. The interventions aim at supporting government leadership in developing a clear and feasible transition plan to enable the government to take over Global Fund supported services and better guarantee program continuation and sustainability. Interventions focus on

- 1) establishing a policy dialogue on financial and programmatic aspects of health reform and its implications for TB and HIV efficiency gains, including fiscal rule barriers to the efficient performance and allocation of funds and enforcement of effective social order mechanisms, involving also the Ministry of Finance and other key stakeholders and donors (WB, USAID, PEPFAR, CDC, D&T, UNAIDS, WHO);

2) recommending on HIV/TB service integration in treatment facilities and the role of primary health care in HIV-related service provision. Existing financing models of service provision were analysed and further optimized when developing the Concept Note budgets and unit costs of service packages. The applied optimization methodology allowed to develop standard and unified costing packages of prevention and care and support services, which will be easier to phase out for the domestic funding. The transparency and optimization of the unit costing will be further applied in formulating the costs of services in social contracting.

Taking into consideration the disease burden and socio-demographic characteristics, subsequent actions will be taken to develop necessary legislation to enforce the selected model/models and remove fiscal rule barriers.

In close relation, the module that contains interventions on **removing legal barriers to access to TB and HIV services** supports the activities under the policy and governance module, and ultimately aims at institutional changes for the further provision of comprehensive services for KAPs, PLWH, TB and co-infected HIV/TB patients, thus creating a national HIV and TB response that is independent from donor funding in the end.

Implemented by national and regional level NGOs, the interventions target i. change/adoption of legislation to ensure equal rights to health and social services for KAPs and PLWH, i.e. decriminalization of HIV transmission, antidiscrimination laws, removing of legal barriers in receiving reproductive health services and adopting children for PLWH, pharmaceutical policy reforms; ii. monitoring of state budgeting process and procurement at the national and regional level ensuring transparency and expanded access to services through rational use of government resources; iii. social contracting mechanism to enable NGOs and CBOs to receive funds from the government; iv. improving access to justice for PLWH through providing legal advice, representation in court; and v. human rights and access to HIV and TB care of prisoners via community-based monitoring of rights' violations.

Development of the national health care human resources strategy is on the agenda of the government and is expected to come in force during grant implementation. Other donors will contribute to this strategy, which will set government standards for workforce needs assessment, quality control of education/trainings, staff distribution, task shifting, etc. Meanwhile, the **health and community workforce** module under this proposal will focus on institutionalisation of existing HIV and TB training for physicians, nurses and other members of multidisciplinary teams that provide care services for HIV and TB patients. Special focus will be put on training of trainers to expand the pool of national trainers on HIV and TB treatment and care issues. To ensure value for money, most of the training will be done on a regional basis, only highly specialized/new courses will be provided at national level. The workforce capacity building intervention will be carried out in close cooperation with state training facilities, such as medical universities and post-graduate education institutions. Additional training needs will be covered via a number of technical assistance projects currently functioning in Ukraine with the support of other donors. Three-year implementation of this module will end with full transition of HIV and TB related training to the state system of medical education. The training activities, supported by other donors, as well as activities planned for the above allocation in this module would allow to fill in the entire programmatic gap in HIV and TB workforce development.

Building on previous Global Fund Rounds the further **strengthening of community systems** in the five most affected regions is regarded a cornerstone in support to continued and equitable access to HIV and TB health and social services of KAPs. The voice of the community will be stimulated and enhanced to provide knowledgeable and balanced feedback to service providers, policymakers and politicians at local, regional and also national level. Capacity building will take place in monitoring barriers to service access (stigma, gender) by communities themselves, in taking part in coordination mechanisms and policy dialogue at regional and national level, and establishing partnerships between NGOs and government bodies, resulting in stronger linkages and collaboration between communities, providers and policymakers concerned with the HIV and TB response. The interventions are expected to

contribute to the higher goal of sustainable governmental and non-governmental partnership promoting a standardized model for social services provision.

The **procurement and supply chain management** module responds to the country's commitment to change the state procurement system using international best practises and standards. It foresees in on going consultancy support for legislation change and is complementary to other in-country activities and state PSCM capacity. A significant number of activities, e.g. the development of legislative documents, standard operational procedures, standard templates, etc., will be performed to build an effective and transparent system of state procurement. Most of these activities either do not need funding allocation or will be supported by other donors.

Besides routine programmatic monitoring, the **monitoring and evaluation (M&E)** module will focus on the integration of HIV and TB monitoring systems and alignment of HIV and TB reporting. In a co-funding arrangement with the US Government special attention will be paid to development and improvement of national electronic management information systems (MIS HIV-infection in Ukraine, e-TB manager). Budget constraints have limited surveys to the most necessary ones. Most of the research activities in the framework of the proposal will be performed by the State PR, encouraging government leadership in the national M&E system and further transition of these activities to the State in the future. The module includes implementation and support of M&E in the State Penitentiary Service of Ukraine (SPSU).

3.4 Focus on Key Populations and/or Highest Impact Interventions [1 page]

This question is not applicable for Low Income Countries.

For TB and HIV, 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% of the budget on underserved and most-at-risk populations and/or highest-impact interventions.
- b. If the applicant is an upper-middle income country, describe how the funding request focuses 100% of the budget on underserved and most-at-risk populations and/or highest-impact interventions.

By means of the present Concept Note the funding request for Ukraine, categorized as a lower-middle income country, focuses at least 50% of the budget on underserved and most at risk populations and/or higher impact interventions. The request is structured around fourteen modules encompassing eight service delivery modules and six enabling environment modules.

The general focus of the interventions in the modules is to ensure the continuum of care through the delivery of effective services for most at risk populations filling the gaps of the national HIV and TB Programs as per the programmatic gap analysis. All together the service modules will spend over 90% of the 3-year Global Fund budget, with three modules (Treatment, care and support; MDR-TB; Prevention programs for PWID) containing more than 80% of the total funding for the modules and have the highest impact on both epidemics.

The service interventions are all focused on most-at-risk populations. Hundred per cent of the HIV prevention activities are targeted for PWID, MSM, FSW and prisoners and are provided through a choice of highest impact prevention models applied through the regionalization and diversification strategy. The prevention packages are supplemented with TB screening to increase early case detection and treatment among newly diagnosed PLWH as well as among MARPs.

The ART care and support interventions cover the PWID in need of care and support when on treatment. The phasing out strategy provides for keeping the focus on PWID in the programme, while shifting the intervention activities to the state ownership.

The TB care and support intervention as well as TB/HIV and MDR-TB interventions focus on TB patients in the regions with a high burden both of TB and HIV and a high burden of TB and HIV co-infections. PWID, FSW, PLWH, TB contacts, Roma, homeless and prisoners are the key groups for interventions.

The enabling environment modules (community systems strengthening, policy and governance, removing legal barriers, and workforce) are aiming at protecting the human rights of the most-at-risk groups and provide for advocacy for access to high quality services for those groups. The expected outcomes from the interventions under these modules would enable the scale-up of sustainable services for these most-at-risk groups

The proposal is based on Strategic Investment Guidance from Technical Partners and focuses on interventions that have been previously implemented in the country. These interventions proved to be effective in addressing the needs of MARPs and PLWH and bringing the HIV/AIDS epidemic under control.

4.1 Overview of Implementation Arrangements

Ukraine has a national health system that is mainly financed by general revenues from the budget. Local budget funds account for 70 - 80% of total budget spending; the remaining 20 - 30% is provided by the central budget. However, local budgets also receive subventions from the central budget to support healthcare financing mainly through program-based transfers which are given for specific purposes, e.g. to acquire ambulance vehicles for villages, to combat the A/H1N1 epidemic, etc. Wages and salaries constitute the largest share (close to 60%) of public health expenditures and drive overall spending trends in this sector. Recurrent spending for materials, services, etc. is the second largest share. Capital expenditures such as new construction, capital goods acquisition, and renovations are less than 10% of the entire health budget.

Local budgets are mainly responsible for financing the wages and salaries of health workers while recurrent spending on materials and capital expenditures are the shared responsibility of both the central and the local budgets. Research and development is financed by the central budget, including by means of these “programs”. Based on the World Bank estimates, the government finances close to 60% of total health spending, while the remainder comes from private/out-of-pocket household payments. This estimate is based on the analysis of the National Health Accounts. Some estimates consider out-of-pocket spending to be as high as total public spending. Most in-patient care is funded by the government, while the majority of out-patient care is financed by out-of-pocket payments. This occurs because a large share of out-patient care involves the purchase of pharmaceuticals. The World Bank estimates based on household surveys and other surveys for formal and informal out-of-pocket expenditures in health suggest that they may have been as high as 2.8 % of GDP for 2005.

All activities and funds request under Global Fund project are complementary to the National tuberculosis and HIV/AIDS programs, therefore implementation approach and unit cost are unified.

The proposed implementation arrangement between implementations agencies is based on the dual-track funding approach in includes three principal recipient – one governmental organization (Ukrainian center for decease control), and two non-governmental organizations (Alliance and PLWH Network). All three organizations are involved in the current grants, implemented in 2014, namely UCDC is PR for Global Fund Round 9 TB grant, and co-PR for Global Fund Round 10 on HIV, along with Alliance and the Network. At the same time the current implementation arrangement will bring the coordination at new level.

In particular, the coordination aimed at mainstreaming two major business processes relevant to all three PRs: procurement and sub-granting. The key goals of the new arrangement are

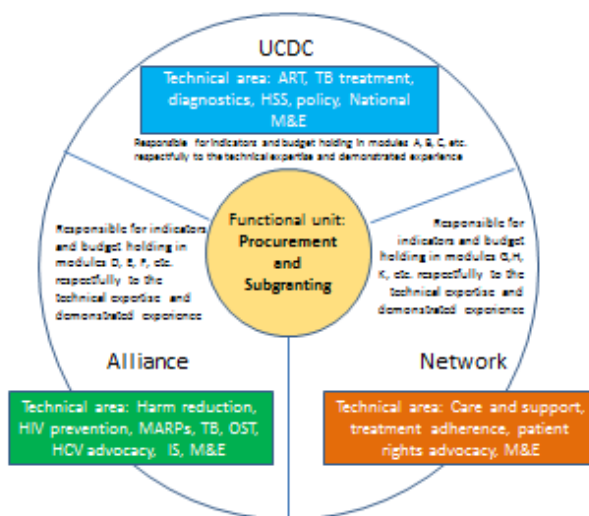
- Streamline sub-granting and procurement processes
- Optimize financial and human resources
- Maintain responsibility of each PR for programmatic and technical expertise, budget and performance

The two processes (procurement and sub-granting) are present in the scope of all PRs, at the same time coordination will be ensured by several innovative approaches:

- a) Establishment of joint functional unit focusing on procurement and sub-granting;
- b) Minimizing risks the most harmful nowadays, particularly a risk of blocking of the payments by state treasury
- c) Acknowledging strategic leadership in TB and HIV, led by UCDC

Thus, the proposed optimization scheme combines PRs’ organizational strengths and

programmatic expertise with streamlining business processes:



Advantages of the functional unit includes:

- Unification of sub-granting and procurement procedures
- One national call for proposals for all sub-granting activities within GFATM grant
- One window for sub grantees and one grant agreement
- No risk of double funding
- Full alignment of financial and program monitoring and audit for all GFATM funding
- Optimization of human resources of all PRs
- Easy to hand over to the government at the end of the project as fully functional project implementation unit

Please, note that representatives of women's organizations, people living with the two diseases and other key populations will actively participate in the implementation of this funding request, at the first place as sub-recipients working on the ground, but also taking part at the governance through CCM representation.

4.2 Ensuring Implementation Efficiencies

Complete this question only if the CCM is overseeing other Global Fund grants.

The Procedure on oversight activities regulates the planning and implementation of National Council oversight in the development of proposals, negotiating the conclusion of Agreements with TGF and implementation of GF-funded grants. The Procedure defines the responsibilities of the National Council, PR, SR and other third parties providing the oversight as well as the mechanism for their implementation through the Plan of Oversight. The annual oversight plan describes the directions and the measures regarding development of proposals, grant negotiations monitoring, program implementation (including achievements, use of funds, procurement and distribution of medicines, medical products and other consumables, provision of services, coverage of target groups, the PRs/SRs reporting documentation).

In order to ensure the implementation of the plan and to support the National Council decisions, the Oversight Commission was formed consisting of nine members from the National Council and other constituencies (stakeholders). The Commission makes onsite visits

to monitor the program implementation, checks the program and financial records by programs, reviews the OIG reports, participates in tender processes as observers, and participates in working meetings and documents exchange related to TGF programs implementation. The results of the Oversight Commission are presented to the National Council for its monitoring and reviewing. Based on the results of the review, the National Council makes decisions on the compliance or non-compliance of PR/SR programs implementation with respect to key indicators, provides recommendations to PRs and, if necessary, technical assistance for PRs to ensure the achievement of program objectives. The information on the Oversight Commission activities is available on the National Council Secretariat Website (<http://dssz.gov.ua>) and the latest Detail Report for activities carried out in 2012 by the Oversight Commission is present in Annex 21.

Implementation arrangement allows to keep running costs as low as 8%. All three principal recipients will have a quota in procurement and sub-granting functional units. Optimization will be achieved by streamlining the process, unification of the procedures, reducing the staff joining the unit, optimization of the employment arrangements through the “private entrepreneur” scheme reducing taxation.

In particular the implementation efficiencies will be achieved due to the following streamlining of the business processes and the division of responsibilities:

Sub-granting stage	Activity Description	Responsibility
Procedures, joint SR strategy	Review the existing grant management procedures of PRs, development of a single algorithm of grant management	PR(s) within respective modules
	Finalize the joint SR strategy	PR(s) within respective modules
	Assessment of resources (staff, premises) necessary to organize proper SG activities	PRs within respective modules; AU is leading
	Conducting set of trainings for PRs and FU's staff involved to in the process	FU
Call for proposal	Prepare unified documents needed for the subgranting process, such as approval management forms, amendments, payment orders	PR(s) within respective modules
	Develop unique sub granting SOP	FU
	Prepare joint call for proposal, agree all terms and conditions and technical requirements, expected outcomes, program indicators, etc.	FU
	Conduct the process in accordance with unique sub granting SOP	FU with PR(s) substantial involvement
	Conduct expert committee to select the winner	FU
	SR-to-be assessment if needed	FU
	Preparation of sub-granting documents for signing by PRs	PR(s) within respective modules

Sub-granting stage	Activity Description	Responsibility
Procedures, joint SR strategy	Review the existing grant management procedures of PRs, development of a single algorithm of grant management	PR(s) within respective modules
	Finalize the joint SR strategy	PR(s) within respective modules
	Assessment of resources (staff, premises) necessary to organize proper SG activities	PRs within respective modules; AU is leading
	Conducting set of trainings for PRs and FU's staff involved to in the process	FU
Call for proposal	Prepare unified documents needed for the sub-granting process, such as approval management forms, amendments, payment orders	PR(s) within respective modules
	Develop unique sub granting SOP	FU
	Prepare joint call for proposal, agree all terms and conditions and technical requirements, expected outcomes, program indicators, etc.	FU
	Conduct the process in accordance with unique sub granting SOP	FU with PR(s) substantial involvement
	Conduct expert committee to select the winner	FU
	SR-to-be assessment if needed	FU
	Preparation of sub-granting documents for signing by PRs	PR(s) within respective modules

Sub-granting stage	Activity Description	Responsibility
Procedures, joint SR strategy	Review the existing grant management procedures of PRs, development of a single algorithm of grant management	PR(s) within respective modules
	Finalize the joint SR strategy	PR(s) within respective modules
	Assessment of resources (staff, premises) necessary to organize proper SG activities	PRs within respective modules; AU is leading
	Conducting set of trainings for PRs and FU's staff involved to in the process	FU
Call for proposal	Prepare unified documents needed for the sub granting process, such as approval management forms, amendments, payment orders	PR(s) within respective modules
	Develop unique sub granting SOP	FU

	Prepare joint call for proposal, agree all terms and conditions and technical requirements, expected outcomes, program indicators, etc.	FU
	Conduct the process in accordance with unique sub-granting SOP	FU with PR(s) substantial involvement
	Conduct expert committee to select the winner	FU
	SR-to-be assessment if needed	FU
	Preparation of sub-granting documents for signing by PRs	PR(s) within respective modules

4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery			
PR Name	PR 1: Ukrainian Center for Socially Dangerous Disease Control of the Ministry of Health of Ukraine (UCDC)	Sector	Government
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		X Yes <input type="checkbox"/> No	
Minimum Standards		CCM assessment	
1. The Principal Recipient demonstrates effective management structures and planning		The management structure of UCDC includes staffing and approved by the Ministry of Health.	
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)		UCDC realizes Sub-Recipients management according to the following documents: a) «Sub-Recipients selection and management manual» b) «Sub-Recipients management manual»	
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud		UCDC's internal control system is based on the Manual «Global Fund to Fight AIDS, Tuberculosis and Malaria grant implementation»	
4. The financial management system of the Principal Recipient is effective and accurate		Financial management in UCDC is carried out for help the software «1C-Enterprise» (8.2 version for budgetary organizations of Ukraine).	
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products		Not applicable for UCDC	
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end		Not applicable for UCDC	

users to avoid treatment / program disruptions	
7. Data-collection capacity and tools are in place to monitor program performance	<p>UCDC uses the following tools for data collection and analysis:</p> <p>a) «ARVs movement and using electronic monitoring tool» – is filled monthly in electronic form;</p> <p>b) «Reporting forms concerning the balance and using of TB drugs and consumables» – are collected, generalized and analysed monthly in electronic form;</p> <p>c) Module «Cases» in e-TB manager system – is filled in electronic form;</p> <p>d) Module «Drugs» in e-TB manager system – is in the implementation process, will be filled in electronic form.</p>
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	<p>UCDC applies sustainable reporting practices on Global Fund program performance, such as:</p> <p>a) to the Global Fund (by established forms in accordance with the grant agreements);</p> <p>b) to the State Service of Ukraine on AIDS and Other Socially Dangerous Diseases (programs implementation monitoring cards by established forms).</p>
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	<p>UCDC follows in its activities the guidelines:</p> <p>a) «Guidance for procurement in Global Fund programs» – certified copy is attached;</p> <p>b) «Guidance for procurement and supply of goods and services with a view to realize programs implemented by the Global Fund to Fight AIDS, Tuberculosis and Malaria» (guidance project is developed for UCDC within the framework of USAID technical assistance and it is awaiting for approval by the Global Fund).</p>

4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery			
PR Name	PR 2: ICF “International HIV/AIDS Alliance in Ukraine”	Sector	Non-for-profit
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?	X Yes <input type="checkbox"/> No		
Minimum Standards	CCM assessment		

<p>1. The Principal Recipient demonstrates effective management structures and planning</p>	<p>Current structure and management system of the Alliance are aimed at effective and efficient implementation of complex national level programs on HIV/AIDS, TB and other socially dangerous infections. Alliance Governing Bodies consist of General Meeting (strategic body), Board (executive body) and Supervisory Committee (controlling body). Governing Bodies activity is regulated by particular Regulations developed in accordance with the Alliance Bye-Laws, which ensure sound, transparent and effective work of Governing Bodies. Executive Director is the highest official in the organization. Senior Management Team ensures openness and transparency of decision-making process. There is an independent mechanism (staff) for ensuring risk management, compliance and an internal audit, as well as for resolving disputable issues. Organizational structure consists of five departments and independent advisory unit and determines the modes in which the Alliance operates and performs. The Alliance 2013-2010 strategy is based on the organization mission, vision and values, developed into five strategic objectives, which are operationalized in work plans. Alliance has been marked by the Global Fund with the highest rating: A1.</p>
<p>2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)</p>	<p>Alliance has sufficient capacity and system required for effective management and supervision of sub-recipients activity. In 2013 145 organizations were Alliance sub-recipients (implementing partners) which performed HIV/TB programs. 371 projects were funded for the total sum of 102,337,139 UAH. Alliance ensures continuity of project activities of sub-recipients in all regions of Ukraine by their timely funding. Proper use of the sub-recipients Alliance is regularly confirmed during the annual independent audit. Capacity building of sub-recipients is an integral part of the function of the organization.</p>
<p>3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</p>	<p>Policies and procedures on governing of the internal control system are implemented in the Alliance. In order to strengthen internal controls over the proper use of funds and fraud prevention Special Policies on risk management and anti-fraud were introduced in Alliance in 2009: Anti-fraud Policy, Conflict of Interests Policy, and Whistle Blowing Policy. The Alliance's internal control system fosters proper and effective implementation the terms of the grant agreement. The effectiveness of the internal control system is subject of the external and internal audits. By providing positive audit reports the independent auditors regularly confirm that the financial accounting, financial reporting, and internal control systems of the Alliance are developed in accordance with international quality standards and are in full compliance with the regulations and requirements of donors, including the Global Fund. The audit of the Alliance's financial statements is carried out by company Deloitte, which was approved by the Global Fund.</p>
<p>4. The financial management system of the Principal Recipient is effective and accurate</p>	<p>Alliance employees demonstrated professionalism and ability to manage large volumes of funds and grants from various donors, including such as the Global Fund (Round 1, Round 6, first phase of Rounds 9 and 10); European Union; USAID, UN agencies; Foundation Open Society Institute; International HIV/AIDS Alliance (UK) and others. For the last 5 years the average amount, which was under Alliance management exceeded 27 million dollars per year. The financial activities of the year are</p>

	<p>verified by independent audit that regularly confirms that the financial statements and internal control systems in the Alliance are built in accordance with international quality standards and are fully compliant with the rules and donors, including Global Fund. The correctness of the calculation, tax payments and contributions to different social funds that were made by Alliance and their compliance with the legislation of Ukraine has been repeatedly inspected by state regulatory agencies; no violations were found .All Alliance payments are maintained by Crédit Agricole bank, which has a high rating. This ensures minimum risk for the donor. The system of financial management was highly appreciated by the Global Fund Secretariat.</p>
<p>5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>All central and regional warehouses engaged into Alliance’s implementation of Grant activities fully comply with requirements on square of facilities and provision of necessary storage conditions. All logistics providers are selected through the bidding process only. Each of 3 groups of logistics providers store cargoes of particular group of medical products procured by the Alliance:</p> <ul style="list-style-type: none"> • Liky Ukrainy SJSC – narcotic drugs for OST (2 warehouses of 547 and 1,295 square m). The company is fully licensed by Ukrainian NRA for full-cycle operations with pharmaceuticals, including narcotic drugs; • BaDM (6,150.7 sq.m) and Falbi (9,825.0 sq.m) handles medical products that need special temperature conditions. Both companies are the only GDP certified facilities of this kind in Ukraine. <p>Diana Luxe Logistics stores cargoes of mass health products, such as condoms, syringes, spirit swabs. The company operates with class A complex of warehouses of 15,000 sq.m total square.</p> <p>All providers ensure provisions of proper temperature and security control, as well as up-to-date stock management. Alliance’s staff provides regular monitoring of compliance of regional warehousing at partnering NGOs’ with requirements on necessary square and conditions of storage.</p>
<p>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</p>	<p>Alliance fully monitors and controls all operations with turn-over of any goods on the chain central warehouse-final recipient through its management information system (MIS). Among other features, MIS allows constant online tracking of stocks at each link and creating reports on potential deficit. Any charge-off of any goods at regional level is impossible without reported their distribution to final recipients. Plans for distribution of goods are made in advance and given to logistics providers for performing of proper delivery of cargoes. To ensure full responsibility and proper control of movements of all goods, Alliance engages its logistics providers for provision of the whole complex of operations on the way from acceptance of cargoes to central warehouses to delivery to regional recipients. All movements are made in safe, closed and clean vehicles only.</p>
<p>7. Data-collection capacity and tools are in place to monitor program performance</p>	<p>The Alliance system of programmatic monitoring includes all elements for getting qualitative data of program performance: unified system of indicators, primary forms, reporting forms, unique identified clients coding, on-line SyrEx database, projects’ rating system. Alliance monitors program performance on regular basis: monitors the data of SyrEx database (on-line), checks the reports (every quarter), monitors the primary</p>

	documents data, carry out the site visits (twice a year). There are practical manuals on programmatic monitoring system. Every year Alliance provides trainings on programmatic monitoring for sub-recipients. Reliability of program monitoring system of Alliance and data quality was confirmed by independent audits, provided by various donors and their local agents.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	The routine reporting system of Alliance ensures 239,637 people (58.94% of IDUs, 39.92% of CSW, 14.20% of MSM) - the year 2014 coverage of vulnerable groups reached by prevention programs in Ukraine. Alliance is able to report the qualitative data in such scales timely due to standardized system of projects accounting and reporting. The reporting system includes such mechanisms to ensure data quality: unified system of indicators with their description, standard reporting forms, automatized indicators calculation, control of data entry quality, monitoring of the indicator fulfillment and performance, projects monitoring.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Alliance takes all required measures to control procured medical product quality throughout the in-country supply chain. There is a dedicated staff member responsible for warehouse logistics and coordination of all parties involved. Respected laboratories have been selected on a competitive basis to do the laboratory analysis of procured products (prima facie pharmaceutical products and test-systems). Peculiarities of control over SMT products procured by the Alliance are testing on the entrance point for all qualitative parameters based on approved analytic-normative documentation. Respective tests are done by SE "Central laboratory on medication analysis" which is licensed to work with narcotic drugs. Following requests of WHO "Model of quality assurance system for procurement organizations" and Global FundTAM on pharmaceuticals quality monitoring, Alliance developed and agreed standard operations procedures on products quality control.

4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery			
PR Name	PR 3: All-Ukrainian Network of PLWH	Sector	Non-for-profit
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?	X Yes <input type="checkbox"/> No		
Minimum Standards	CCM assessment		
1. The Principal Recipient demonstrates effective management structures and planning	Being the Principal Recipient in Rd 6 and 10 the Network has built all the necessary management and planning structures and procedures that have been numerously assessed by the LFA and Global Fund Country Team. Strategic management of the Network is carried out by the General assembly and Coordination Council which form the mission, strategic goals and objectives of the organization. Operational management and planning is the		

	<p>responsibility of the Central office (CO) which is the administrative structure. CO as a structural unit of the Network carries the responsibility for implementation of the grants. Functioning of the CO is regulated by the Staff Manual which is updated upon need and contains provisions on general administrative issues, decision making, financial and grant management, M&E, procurement of goods and services, fundraising. Planning and decision making at the level of the CO is the responsibility of the Senior Management Team (SMT). Besides administrative decisions regarding CO structure and general management, SMT approves results of tenders and grant competitions. CO is divided into three departments (Program; Communication, Policy and Advocacy; Operations and Administration) with some separate teams (PSM, M&E, analytical) subordinated directly to the Executive director/Deputy executive director. Separate teams are responsible for different components of the Global Fund Program implementation with overall supervision from the SMT. Regular reporting to Global Fund (PU/DR) is developed by analytical team based on contributions from all structural units involved in the Program implementation. Existing structure ensures effective and transparent management, planning and decision making which is a solid basis for achieving best results of the Global Fund Program with rational use of resources.</p>
<p>2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)</p>	<p>Network's system of management and oversight of Sub-Recipients include units of program grant management and unit of financial grant management with significant role of M&E unit. The system is based on a number of the prescribed procedures and algorithms, regulated in the Staff Manual. Each SR's has its program and financial curators who are responsible for coordinating, monitoring and management of project implementation. Curators coordinate the process and all changes that occur during grant implementation, according to grant agreement and its annexes. They also provide oversight and monitoring of their Sub-Recipients through:</p> <ul style="list-style-type: none"> • Periodic program and financial reporting to the Network; • Monitoring visits to Sub-Recipients by Network's program, financial and M&E specialists, including recommendations for SR's after visits <p>Technical support is the important part of the Network's activities for the development of organizational and program capacity of Sub-Recipients. It is provided through counseling and technical support visits by Network's program, financial and M&E specialists, specialists of procurement unit, policy and advocacy unit etc.</p>
<p>3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</p>	<p>The system of internal control was introduced at Network starting from 2004. Sub-grants' control and audit is effectively performed by Network's financial and M&E officers in order to timely detect and prevent misuse of grant funds. The internal SOPs are developed for major organizational activities and their compliance is supervised by Senior Management Team. The positive audit opinions for the last 10 years prove that Network performs in accordance with its statute, signed agreements and donors' requirements; and that charitable donations are used reasonably, accurately and accountably. Recently policies on Anti-Fraud and Conflict of Interest were developed and put into force to provide working mechanism for the third parties to monitor and control Network's efficiency.</p>
<p>4. The financial management system of the Principal Recipient is effective and accurate</p>	<p>The Network's financial system was tailor-made to serve for the needs of not-for-profit accounting and provide accurate and detailed financial information both for the managerial and reporting purposes. The senior financial staff has full capacity to control the financial information flow within organization and to organize the process in the most effective ways. Being funds' recipient from a number of international donors with different reporting requirements (Global Fund Round 1, 6, 10; USAID; European Commission, CDC,</p>

	<p>UNAIDS, number of private foundations) the organization has full capacity to produce accurate and timely reports to ensure effective use of funds. The external audit every year confirms that information provided by Network's financial system is compliant both with the terms of donors' contracts and agreements, and with international financial reporting standards. The organization uses 1C Accounting system, electronic bank channels, 1C Document Flow software to produce financial reports.</p>
<p>5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</p>	<p>The Network's logistic partner LLC "Farmasoft" is acknowledged as GDP certified company with sufficient storage, distribution and human resources capacity. Upon importing to the country, the distribution of the medicines and other health products is performed to the regional AIDS centers and State Penitentiary Service institution. The recipient's storage conditions are aligned with an Order of MoH "On approval of rules of storage and quality control of drugs in health care facilities". The shelf life and consumption data of the medicines is the subject for monitoring by electronic tool at the recipient's and central level.</p>
<p>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</p>	<p>The distribution systems are represented by the logistic partner's electronic system of accounting, which is allow to gather information on medicines and health products turnover at the central level and by the reports of recipients on receipt, utilization etc. – on the regional level. The distribution covers all the territory of the country and is made once per year for the most of the products nomenclature. The products with lessen shelf life are distributed primarily.</p>
<p>7. Data-collection capacity and tools are in place to monitor program performance</p>	<p>All-Ukrainian Network(AUN) has established M&E unit, which is responsible for routine program and projects monitoring, evaluation, data verification and data quality. M&E unit consists of qualified personnel with sociology, epidemiology, IT and grant management backgrounds. AUN has in place:</p> <ul style="list-style-type: none"> • standard procedures for monitoring and reporting, standard forms for data input and reporting with relevant guidelines for sub-grantees(SRs) and AUN staff; • standard approaches in development of project-level indicators (output, coverage); • standard approaches to measure outcome and impact-level indicators (IBBS, sociological researches, surveys etc.); • standard procedures on reporting and reporting periods are set for SRs; • standard and specific(when needed) requirements to field project monitoring, data collection process, data quality assurance, data verification are developed for SRs and AUN staff; <p>for SRs which implement service-based projects for PLWH, unified electronic instrument is developed – Case++ database, a client-server application which is used to store, aggregate project data, build various reports and report routinely to AUN. AUN also uses data from Case++ database to report on National level and conduct national and sub-national analysis of coverage, clients` structure, enrollment of MARPs etc.</p> <p>To monitor projects implementation and verify reported data at field level, monitoring visits of relevant AUN officers are being conducted to SRs. Routine reporting with defined deadlines and procedures for report verification are used to monitor progress of SRs in project implementation during program year. In order to evaluate impact of program and projects results, behavioral and other sociological researches are used.</p> <p>Data-collection capacity and tools, integrity of program and project data of AUN was assessed by the Global Fund representatives during OSDV visits. Also, LFA verifies data and tools during routing data verification. AUN's M&E capacity received high regards for its</p>

	functional and effectiveness.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	<p>AUNs routine reporting system for Global Fund-funded projects is tailored to Global Fund requirements and currently serving to nearly 100 SRs in every region of Ukraine (which cover with services more than 65 000 of adults and 6 000 of children). Routine reporting systems consists of:</p> <ul style="list-style-type: none"> • standard data collection documentation and reporting forms, which are obligatory to use by every SR; • defined reporting periods, which are unified for every SR in order to ensure timeliness of the reporting; • internal regulations, timelines and guides for reports verification, developed for AUN staff; • specific guidelines on project monitoring, developed for SRs by AUN M&E officers; • guidelines on field level monitoring visits (program monitoring, financial monitoring, data verification and data quality visits); • Case++ database, which is used by SRs for data collection and reporting and by AUN staff for analysis of data, reporting verification, reporting to Global Fund and on National level (and Country reports such as GARP). <p>At SR level, project monitoring officer is responsible for data collection, verification and report submission to AUN, where program officers check the reports and forward them to M&E unit. M&E officers aggregate data, double-check it, process and prepare for report to Global Fund and on National level. Case++ database with support of MS Excel and other tools produce accurate and clean data, which is also subject to verification during routine field visits by AUN officers, LFA, OSDV missions. Data verification and data quality visits are used to verify reported data at SR level, assess quality of SR reporting system and internal M&E procedures and provide relevant recommendations for improvements.</p>
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	<p>All the purchased medicines are, at least, registered for use on the territory of the country and produced on GMP certified facilities and should pass the manufacturer's out coming quality check. Moreover, all the ARVs are WHO prequalified. The quality control of the medicines is the responsibility of the contracted WHO prequalified laboratory. The transportation of the medicines is carried out by the professional vehicle fleet with a capacity, in the case of need, to provide special storage conditions (e.g. cold-chain). The process of monitoring of the medicines quality at the regional level is stipulated by the number of the orders and decrees of the government.</p>

4.4 Current or Anticipated Risks to Program Delivery and PR(s) Performance [1-2 pages]

- 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, PR(s) and key implementers' capacity, past and current performance issues.
- b. Describe the proposed risk mitigation measures (including technical assistance) included in the funding request.

In this section the several identified programmatic and implementation risks will be elaborated, as well as mitigating plans. Internal risks have been analysed throughout the Concept Note, external risks that could jeopardize the operations and outcome of the programme are highlighted here. Apart from risks stemming from major political and

economic changes, also risks are described related to the diminishing availability of Global Fund allocations and the gradual handover to state ownership.

Political Instability Foremost, political instability has been affecting and likely will continue to influence the programme, particularly in the Southern and Eastern regions, where the HIV and TB epidemic have one of the highest prevalence in the country. Implementation of care-and-support services and procurement supply management are dependent on the regional stability.

Crimea As far as Crimea is concerned, it will remain part of the overall Global Fund Concept Note in the “above allocation” budget provision. Regarding the supply and procurement of commodities for the Crimea region, uncertainty exists on differences in laws and regulations between the Ukrainian and Russian governments. The banking system in Crimea is hand-operated by the Central Bank of Russia and there is an official prohibition to conduct payments to Crimean banks from the National Bank of Ukraine. This situation causes obstacles in transferring funds to sub recipients in Crimea.

The program in Crimea might be implemented through direct funds transfer to Crimean implementing partners, most probably selecting an implementing partner in Crimea serving as a hub/coordinating center. Meanwhile, the same programmatic role of PRs will be maintained, particularly in program design, monitoring, technical support, reporting and evaluation.

Other instable regions Similarly, the rather complicated political and war-like situation in Donetsk and Lugansk regions may cause operational obstacles to provision of care-and-support service and make it unpredictable whether health products in these regions can be delivered in the short run. However, the implementation arrangement will be flexible in these special areas.

Distracted attention The war crisis, but also the economic situation in Ukraine, is distracting attention of decision-making bodies, i.e. Cabinet of Ministers and ministries. This will likely hamper the advocacy process on removing legal barriers and ensuring sufficient funding of national HIV and TB treatment programs. The implementation of activities on removing legal barriers is seen as being strongly connected to the current political and economic instability. Appropriate measures that are adapted to the situation will lead the intervention process and will be closely monitored and shared with the Global Fund.

Additionally, the complicated political situation may cause abolition or redesign of the act on Social Reform initiated in 2012, in which the Network cooperates with the government. Nonetheless, the new government confirms the urge to reform the national social sector and is intended to proceed in line with the Strategy, proposed in 2013. The Network will track governmental intentions and if needed influence them via the Ministry’s Public Council and its working groups as well as managers of the respective Ministry departments, responsible for the reform.

Inflation and other economic risk factors Caused by the political unstable situation the economic situation has worsened. Due to the devaluation of the local currency (Hryvna - 47% upon the political crisis <http://pfsoft.com.ua/services/kursy-valut-nbu/arhiv.html>) the real (in terms of currency) budget of the State HIV/AIDS programme 2014-2018 – though still to be approved - has reduced. This might have an effect on the quantity of the ARV drugs to be procured by the state tenders.

Moreover, as prevention, treatment, care-and-support services to KAPs provided within the Global Fund program are planned to be transferred for local and state funding by the end of 2017, the general economic situation in Ukraine will likely influence the decisions of local councils and appropriate Ministries on the approval of local and national budgets for these service.

Furthermore, the economic problems and currency devaluation may hamper the further lowering of prices on ARVs and expansion of the treatment program in Ukraine. The devaluation on the national currency had resulted in problems with payments by MoH to the suppliers on delivered ARVs in the last year competitive bidding. The announcement of the new tender by MoH in the year 2014 is still underway.

Unit costs optimized The reduction of Global Fund support over the coming years and fall of the local currency have had its effect on the re-estimation of unit costs of services for HIV prevention as well as fore care and support in HIV and TB to achieve the best optimum solution for efficient minimum investments for optimum result. Thus, already in the NAP 2014-2018 the packages of prevention services for MARPs were sub-divided to a standard package (optimal, with a potential to be funded by the government after the GF phasing out) and additional services (planned to be funded exclusively by GF within round 10 phase 2) The optimization of the unit costs for prevention services for the CN application was informed by the Ukraine HIV Programme Efficiency Study as well as global strategies for better value for money.

The optimal prevention package of services planned in the NAP 2014-2018 was calculated in Hryvnas by the exchange rate of 2013 (1 USD=8 Hryvnas), making the following costs of the “optimal” package to be provided as per the planned coverage (IDUs - \$34.84, CSW – 88.5\$, MSM – 28.4\$). If the current rate is applied to converting the cost of package in Hryvnas to USD (1 USD=11.5 Hryvnas) the following unit costs \$24.23 for IDUs, \$61.59 –for CSW, \$19.79 – for MSM are to be applied. The cost of the package planned for the CN NFM optimized with the view to the current situation with the local currency, list of services proposed by the PR as optimized, operational costs optimization as advised by the GF and upon consensus of the WG. The packages of the CN NFM equals to \$27.20 -IDUs, \$34.43 – FSW, \$21.98– MSM (not counting stocks) (see Annex 22). The assumption of the PR is however that the optimized unit cost is comparatively low what might risk the involvement of the SRs into the programme. As a risk mitigation strategy all sub recipients will be urged to actively fundraise additional resources from other sources including local budgets and donors. Request the higher unit costs for MARP as above allocation was an option proposed by the PR.

PSM other risk factors Apart from the earlier mentioned direct risk factors on PSM due to the economic and political situation, it is important to note some other factors.

The limited number of participants in the tenders for ARV procurement restricts the diversity of penalties that could be used against them in case of delaying the shipment. Thus, the Network applies the penalties to suppliers with some probability that these suppliers will not participate in the future tenders with regard to relatively small quantities of ARVs (compared to MoH) and incurred finance losses from penalties.

Some procured ARVs are patented (e.g. Abacavir, Lopinavir/Ritonavir and so on). These patented medicines accumulate most of the available funds for the Network for ARV procurement. Thus procurement of generic products has inherent patent-related risks. At the same time there are TRIPS compliant mechanisms (compulsory licenses, non-profitable usage) that may improve competition between generic and brand suppliers, however those are not used in practice by the MoH Ukraine.

The process of registration/re-registration of medicines is very slow and bureaucratic. This causes delays in re-registration, which makes procured medicines unusable for the period to renewal of revision.

Other programmatic risks

The implementation of the full mode of the OST model is much depended on whether the legal barriers can be mitigated and sufficient Government funding can be ensured. In 2014-2015 work will be undertaken in collaboration with UCDC, the State Service of Ukraine for Social Diseases, and the Ministry of Health of Ukraine to gradually transfer substitution therapy to public funding. This also includes the provision of funding for medical and psychosocial support of OST patients, which is allocated in the project of National Programme from local budgets. The transfer of OST patients to public funding starts from the beginning of 2016, when 4,300 OST patients will be transferred to the state budget almost simultaneously.

Medical staff (doctors and nurses) provides services daily, in the weekend and during public holidays that is currently not financed by the state. Additional payment for these health care staff is regarded crucial in achieving OST targets. Over the last years scaling up has been extremely challenging in the current legal environment thus additional incentives to boost

motivation of OST doctor and nurses who work during the weekends has been a helpful tool in achieving the target. However, it is acknowledged that this incentive scheme is not a structural and sustainable solution. When transferring to government funding such additional payments by the state, ensuring the transfer of all regions at the same time, would be difficult because of regional differences and specificity. Notwithstanding these facts, the financial incentive for the narcologist and nurses is now requested as above allocation in the present Concept Note.

In June 2013 WHO approved new HIV treatment guidelines setting the margin of CD4 count less than 500 cells/ml as the starting point for ART. There is no national process regarding approval of these guidelines yet. If the WHO recommendation of 500 cells will be adopted in Ukraine, the need in treatment will increase drastically and may impose an additional burden on the Global Fund program as well the state budget.

HIV prevention, treatment and care services in Ukraine are well-developed but there is not enough linkage between them making it difficult to ensure continuum of care for PLWH. There are differences between the number of performed HIV tests and number of HIV+ people under medical follow-up and people on ART. At the same time the ART retention rates are high, – 84% of adults and children remain on treatment 12 month after its initiation, – which allows concluding that ART programs and relevant social services such as adherence support are well-organized and effective. It is obvious that there is a gap between C&T, prevention and treatment programs causing a significant number of lost-to-follow-up patients. Coordinated actions between PRs will be taken to address this challenge.

In spite of significant efforts of the Network and SPSU, data quality in the penal system remains problematic. The Network has developed M&E guidelines for SPSU, which include all the necessary procedures and tools for data collection, reporting and analysis. On-site data verification (OSDV) is conducted regularly and data quality issues are addressed during these monitoring visits. Capacity building in the penal system including M&E issues will be the responsibility of UCDC.

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 Attachments
- CCM Eligibility Requirements

CCM Endorsement of Concept Note