

CONCEPT NOTE

Effective response to HIV in Moldova

Investing for impact against HIV, tuberculosis or malaria

SUMMARY INFORMATION			
Applicant Information			
Country	Republic of Moldova	Component	HIV
Funding Request Start Date	01 Jan 2015	Funding Request End Date	31 Dec 2017
Principal Recipient(s)	Center for Health Policies and Studies (PAS Center) Health System Restructuring Project - Coordination, Implementation, Monitoring Unit (PCIMU)		

FUNDING REQUEST SUMMARY TABLES

By Principal Recipient	2015	2016	2017	TOTAL
PAS Center	2,839,156	2,780,692	2,683,931	8,303,780
UCIMP	1,542,750	1,204,067	446,908	3,193,725
TOTAL	4,381,907	3,984,759	3,130,839	11,497,505

By Objectives and Modules	Share	2015	2016	2017	TOTAL
Objective 1. To increase access to evidence-based HIV prevention	43.1%	1,726,896	1,595,276	1,636,697	4,958,869
Module 1.1.: Prevention programs for people who inject drugs (PWID) and their partners	70.9%	1,224,270	1,121,442	1,151,612	3,497,323
Module 1.2.: Prevention programs for sex workers and their clients	19.0%	328,270	302,982	302,982	934,233
Module 1.3.: Prevention programs for MSM and TGs	7.8%	135,234	131,693	139,143	406,070
Module 1.4.: Preventing mother-to-child transmission	3.2%	39,123	39,159	42,961	121,244
Objective 2. To ensure universal access to comprehensive HIV treatment, care and support	38.4%	1,910,444	1,683,382	824,919	4,418,745
Module 2.1.: Treatment, care and support	95.0%	1,828,524	1,547,359	820,719	4,196,602
Module 2.2.: Health Information System and M&E	5.0%	81,920	136,023	4,200	222,143
Objective 3. To strengthen communities capacity and to ensure program sustainability	9.5%	402,328	363,862	326,984	1,093,174
Module 3.1.: Community systems strengthening	66.1%	269,206	244,896	208,018	722,120
Module 3.2.: Removing legal barriers to access	26.0%	94,766	94,766	94,766	284,298
Module 3.3.: Program management (NAP capacity building component)	7.9%	38,356	24,200	24,200	86,756
Grant management	8.9%	342,239	342,239	342,239	1,026,716
TOTAL	100%	4,381,907	3,984,759	3,130,839	11,497,505

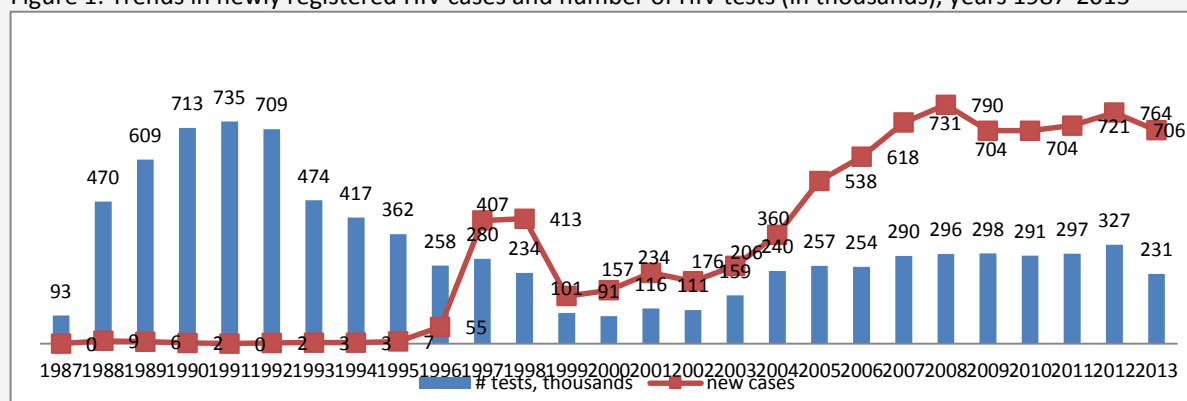
By Year and Allocation	2015	2016	2017	TOTAL
Allocation	4,381,907	3,984,759	3,130,839	11,497,505
Above	581,514	507,569	282,596	1,371,679
TOTAL	4,963,421	4,492,328	3,413,435	12,869,184

SECTION 1: COUNTRY CONTEXT

1.1 Country Disease, Health and Community Systems Context

The Republic of Moldova is a country in transition, which gained independence after the breakdown of the Soviet Union in 1991. Since gaining independence, Moldova has experienced sweeping political changes and instituted a number of economic reforms, which have resulted in relative stability in more recent years. The total population of the Republic of Moldova is 4.1 million, including the frozen conflict area region of Transnistria, with a population of 520,000 people. By the end of 2013, some 8,557 new HIV cases have been cumulatively registered (including Transnistria), with stable number of newly registered HIV cases in the past three years around 700 cases per year on average (Figure 1). The cumulative incidence was 129.9 per 100,000 inhabitants in Moldova (excluding Transnistria) and 463.3 in Transnistria at the beginning of 2014. The most affected sites are the city of Balti (cumulative incidence 704/100,000) and three towns in Transnistria: Slobozia (1,970/100,000), Ribnita (1,238/100,000) and Tiraspol (838/100,000) (DCDH: Annual Epidemic Update 2014).

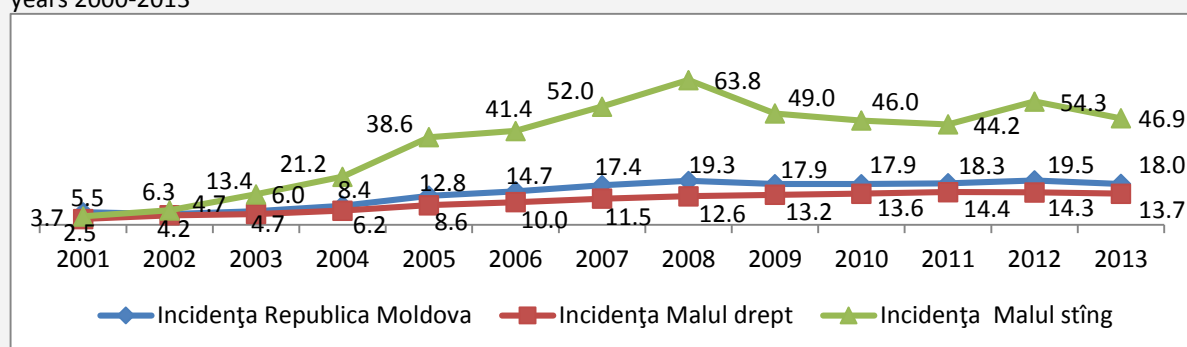
Figure 1: Trends in newly registered HIV cases and number of HIV tests (in thousands), years 1987-2013



Source: DCDH: Annual Epidemic Update, 2014

Trends in new HIV cases in the routine statistics (yearly incidence) show stabilization, at 18/100,000 on average, but still large discrepancy between Transnistria and the rest of the country (13.7/100,000 in Moldova excluding Transnistria compared to 46.9 in Transnistria). The data is presented in Figure 2.

Figure 2: Number of new HIV cases to 100,000 population, Transnistria and Moldova excluding Transnistria, years 2000-2013



Source: DCDH Epidemic Update, 2014

The gender distribution ratio has changed over time, with an increase of share of women reported HIV cases per year from 26.5% in 2001 to 46.3% in year 2013, probably due to a larger number of tests conducted among women than men. The prevalence in the general population is still well below 1% (DCDH Annual Epidemic Update, 2014).

The HIV epidemic in Moldova continues to be concentrated among key populations, mostly people

who inject drugs in civilian and prison sectors, with an increasing contribution of SWs and MSM. The newest size estimations show a population of 30,200 PWID (19,400 in Moldova excluding Transnistria, 10,800 - Transnistria, 12,000 SWs (Moldova excluding Transnistria - 10,000 and Transnistria - 2,000) and 13,500 MSM (9,700 - Moldova excluding Transnistria and 3,800 - Transnistria) (TB/HIV/STI Country Coordination Mechanism. Republic of Moldova Progress Report on HIV/AIDS 2010-2011).

Table 1: Size estimation of key populations, 2009 to 2013 Republic of Moldova

PWID		SW		MSM	
2009	2013	2009	2013	2009	2013
31,600	30,200	14,800	12,000	22,300	13,500

Several key affected populations face particular challenges in access to prevention, care and treatment, that is underage people who inject drugs below legal age of 18 years, due to legal limitations and the need of parental consent, men having sex with men overall and the youngest 15-24 years, especially due to internal and outside widespread homophobia, documented as a barrier in accessing MSM-friendly health services.¹ A segment of people who inject drugs have low levels of health-seeking behavior and they get to HIV physicians late in disease progression, when clinical outcomes suffer and call for strengthened case-management and better linkages between HIV prevention and PLHIV support NGOs with health services. Although the legal framework in the area of HIV has been revised and any legal barriers have been removed, the practice still shows cases of discrimination and refusing care based on vulnerabilities and HIV status. The current grant addresses this by providing legal aid and identifying and moving forward strategic litigation cases, a practices needed to be continued to effect the change in the public service provision.

Moldova's health system has significantly evolved from the model inherited from the Soviet Union, which in 1990s has disintegrated after severe economic downturn faced by the country. The years 2000 have brought economy recovery, creating conditions for rebuilding the health system. There were notable improvements in the health system's performance over the recent years but several constraints still affect negatively the effectiveness of HIV control. Moldova is still a lower-middle income country with a total per capita health spending of roughly \$150/year, which limits the possibilities to cover all needs of NAP from central and local budgets. It is particularly acute in regard to the community involvement of NGO sector in HIV prevention efforts.

Ensuring an appropriate level of human resources is also a challenge for the entirety of the health system and is particularly a problem for HIV services. Remuneration in the health sector is very low, leading to poor motivation and high turnover rates, resulting shortages of medical personnel in many territories and specialties such as HIV. Despite steps to expand the number of treatment facilities and decentralization of services to primary health care level, the fragmented, vertically structured nature of the health care system causes services to be inaccessible for many individuals. The state health institutions are unable to provide full coverage and enough flexibility in work with vulnerable and most-at-risk populations, therefore there is a need to provide prevention services through non-governmental service organizations in a more flexible and user-friendly manner.

These systemic weaknesses have a direct effect on HIV prevention, treatment and care. Each of these gaps will define the specific challenges for the national HIV program. As the weaknesses and disparities are addressed the overall performance of the health system will be strengthened and contribute to improved outcomes of HIV interventions. The national coordination of the HIV program has been greatly enhanced in the past decade. The National Coordination Council (NCC) for the National Programmes for the Prevention and Control of HIV/AIDS/STIs and TB was established in 2002. Since 2005 NCC has functioned as a national level inter-sectoral entity that

¹ COWI, Danish Institute for Human Rights (2011). Study on homophobia, transphobia and discrimination on grounds of sexual orientation and gender identity. Sociological report: Moldova. Kongens Lynby, Consultancy within Engineering, environmental Science and Economics& The Danish Institute for Human Rights: http://www.coe.int/t/Commissioner/Source/LGBT/MoldovaSociological_E.pdf

reflects Moldova's priorities and commitment to control HIV and TB. NCC performs the role of CCM as part of its overall mandate as the 'one' body for coordinating the national response to HIV.

As in other former Soviet Union countries, the health and social service delivery in Moldova were state-centered and community groups had little role to play. Starting early 1990s, community systems and community-based organizations have started to develop in Moldova, with international donor support, initially of Open Society Foundations, then of additional donors. As a response to the outbreak of HIV epidemic, a large group of population started to be increasingly affected by drug use and HIV and NGO service organizations started to appear. In years 2000, with support from international donors, the new NGOs initiated harm reduction projects with participation PWID as outreach workers and volunteers in providing peer-to-peer support, increasing coverage with services and providing non-medical care. Currently, there are several organizations nationally representing the interests of most-at-risk populations and PLHIV: the Union for HIV/AIDS Prevention and Harm Reduction in Moldova (UORN) represents interests of PWID and SWs, Gender-Doc represents interests of the LGBT community and several community-based organizations represent interests of PLHIV: National League of PLHIV, Positive Initiative and others.

The weaknesses of the community systems are: (1) lack of sustainable funding, as the majority of community organizations thus far have relied exclusively on international donor funding with earmarked funds for service activities for target groups; (2) organizational management, as given the narrow scope and short-term funding, the newly developed community based-organizations did not have enough resources to allocate to organizational strengthening; and (3) lack of sustainable contracting by the state: although NGOs are the main providers of HIV prevention in KAP, there is insufficient coordination with the public sector, and a lack of mechanism to contract out HIV prevention services to NGOs by the government that needs costing of services, certification and accreditation of NGOs. Despite the acknowledged role in service provision in HIV prevention, undertaken costing of harm reduction services, there has still no precedent of contracting out harm reduction service by NGOs through the National Health Insurance Fund. However, Ministry of Health planned to pilot one contract with harm reduction service NGO by the end of 2014.

Some progress has been made in integration of community-provided social services by NGOs and CBO to PLHIV in the public system. The Ministry of Labor, Social Protection and Family is at the last stage of developing accreditation standards that would allow contracting out such service by the state to NGOs.

1.2 National Disease Strategic Plans

The legal framework and health policies demonstrate country's political commitment in responding to the HIV epidemic, including those related to general health policy and HIV/AIDS issues. HIV prevention is an integral part of the National Strategy for Health System Development for 2008 – 2017, which foresees consolidation of actions in area to stop the increase in HIV incidence. The legislative tools include a set of laws which have been adopted to ensure sustainability of actions: Law on Health Protection (1995), Law on Reproductive Health and Family Planning (2001), Law on Migration (2003), Law on Equal Opportunities (2006), Law on AIDS Prevention and Control (2007, amended in 2011), Law on Combating Domestic Violence (2008), Law on Social Assistance (2008).

The National AIDS Programme (NAP) for years 2011-2015 was endorsed through the Government Decision of 24 December 2010 (see Annex 1). It had the following objectives: (1) HIV incidence will not exceed 20.0 cases per 100,000 population within the age group 0-39 years; (2) Mortality of people living with HIV/AIDS of the total number of persons estimated will be reduced by 10% by 2015. In June 2011 the National Programme on Prevention and Control of HIV/AIDS and STI underwent a Joint AIDS National Strategy (JANS) assessment performed by a team of national and international experts with recommendations to change its focus and reprioritize its goals to better match the epidemic profile. As a result of the assessment, a series of recommendations have been

developed and programme objectives have been reformulated. It has the following objectives:

Objective 1. To prevent the transmission of HIV, particularly among key populations. This objective focuses on preventing further transmission of HIV within key population (PWID, SWs, MSM, prisoners) through providing access to harm reduction programs, which will cover at least 60% of the estimated number of beneficiaries and also on preventing transmission of infection from these populations to the general population. The impact targets: prevalence of HIV among PWID not higher than 20%, among SWs – not higher than 11%, among MSM – not higher than 5%, among prisoners – not higher than 3.5% and among general population not higher than 0.44%. The following are the outputs per the objective:

- Output 1. By 2015, at least 60% of key populations (PWID, SW and MSM) have been tested for HIV and know their results (baseline 18%).
- Output 2. By 2015, 17 penitentiaries covered with HIV and STI prevention programs, including in the eastern territories (baseline 9).
- Output 3. By 2015, substitution treatment will be provided in 4 administrative territories to at least 1500 people.
- Output 4. By 2015, at least 60% of PWID covered by harm reduction programs (baseline 45%) within 25 administrative territories (baseline 20).
- Output 5. By 2015, services to prevent HIV will be available for MSM in 3 administrative territories (baseline 1) and at least 40% of MSM will be covered by prevention services (baseline 3.9%).
- Output 6. By 2015, at least 60% of SW will be covered by HIV prevention services (baseline 26%) and services to prevent HIV will be available for sex workers in 6 administrative territories (baseline 4).

Objective 2. Reduce the negative impact of the HIV/AIDS epidemic, particularly by providing treatment, care and support for people living with HIV and members of key populations. The impact targets: percentage of adults and children with HIV still alive and known to be on treatment for 12 months after initiation of antiretroviral therapy not lower than 88%, after 24 months – not lower than 80%, after 60 months – not lower than 75% and percentage of infants born to HIV-infected mothers – not higher than 2%. The following are the outputs per the objective:

- Output 1. By 2015, to provide more than 4,000 people living with HIV with antiretroviral treatment.
- Output 2. By 2015, at least 80% of patients with HIV that require prophylaxis with Cotrimoxazole receive it (baseline 73%).
- Output 3. By 2015, the rate of people living with HIV under medical supervision in health facilities who take at least one CD4 and viral load test in the past year will be at least 70% (baseline 57%).
- Output 4. By 2015, palliative care will be provided to people living with HIV in their homes in 3 administrative territories and in one hospital through a specialized unit (baseline 0).
- Output 5. By 2015, provide psychosocial and legal support to 5,000 people living with HIV and members of their families (baseline 3,717).
- Output 6. By 2015, at least 95% of HIV positive pregnant women will be covered by antiretroviral prophylactic treatment (baseline 82%).
- Output 7. All individuals in situations in which they have been exposed to risk of HIV infection who apply for post-exposure prophylaxis continue to receive it (baseline 100%).

Objective 3. Promote synergies with other parts of the health system. The impact and outcome: prevalence of hepatitis B among PWID < 5.9%, SWs < 4.5%, MSM < 3.8%, prisoners < 11.3%; prevalence of hepatitis C among PWID < 63%, SWs < 11%, MSM < 3.0%, among prisoners < 10.7%; prevalence of syphilis among PWID < 2%, among SWs < 3.9%, among MSM < 7.7%, among prisoners < 8.5%. The following are the outputs per the objective:

- Output 1. By 2015, > 40% of members of key populations within HIV prevention programs

will be covered by hepatitis B vaccination (baseline 0).

- Output 2. Introduce free specific treatment of hepatitis C for people living with HIV who are eligible for treatment, raising coverage to at least 10% by 2015 (Baseline – 0).
- Output 3. By 2015, at least 95% of members of key populations (PWID and their partners, sex workers and their clients, MSM) diagnosed with syphilis receive appropriate free treatment in public institutions (baseline 95%).
- Output 4. Maintain blood safety by ensuring that 100% of blood samples are tested for HIV and syphilis according to national protocols (baseline 100%).

Objective 4. Create an efficient program management system. Impact and outcomes within this objective will be measured using the UNGASS National Composite Policy Index and through mid-term and end-of-project evaluations. The success of this objective will be measured by the extent to which objectives 1 and 2 of the program are achieved. The following are the outputs per the objective:

- Output 1. Improved coordination and operational management of the national program.
- Output 2. By 2015, the share of public funds in HIV/AIDS related costs should increase at least to 40% (baseline 26%).
- Output 3. Strong and effective monitoring and evaluation systems.
- Output 4. Strengthened capacities of communities involved in responding to HIV, particularly people living with HIV.
- Output 5. Conduct surveillance studies of second generation every two years focused on specific population groups.

The harm reduction program went through a thorough evaluation, including a separate focus on the opioid substitution therapy. The evaluation was conducted under the Global Fund on-going program with participation of WHO, UNAIDS and UNODC (Annex_2_HR_Evaluation_Report and Annex_3_OST_Evaluation_Report). The results of these evaluations, in combination with JANS assessment serve as basis for development of the next cycle of NAP for 2016 – 2020. The preliminary discussions to prepare the next NAP have been launched and the priorities and targets covered in the current request for funding for the Global Fund NFM are in line with the above.

The key objectives of the NAP are closely linked to priorities of the National Health Policy for 2007-2021, outlined in the section on Control of Communicable Diseases, where the main priorities in the area of HIV are listed as follow: (a) better surveillance effort and increased state responsibility in implementation of HIV activities; (b) improved capacities on information campaign in the general population, youth and vulnerable groups; (c) increased access of populations with increased behavioral risks to programs of HIV prevention; (d) support by local public authorities, rehabilitation and social integration for people at-risk need to be ensured, as well as the access of PWID to substitution therapy; (e) HIV treatment program financed out of public funds; (f) priority to the prevention of infection transmission from mother to fetus; (g) better conditions to diagnosing and treatment of sexually transmitted diseases on an outpatient basis; (h) AIDS patients and HIV-infected people must gain access to specific antiretroviral therapy; (i) measures of medical and social rehabilitation of HIV-infected people and of AIDS patients; (j) ensured safety of blood transfusions and medical interventions needs to be ensured, whereby the public medical institutions need to be provided with the equipment and materials required for the provision of such interventions (Annex 4).

To assess impact and outcome-level indicators of the objectives 1 and 3, two rounds of second generation sentinel surveillance in key populations using the same method, respondent-driven sample (RDS), have been conducted in 2009/2010 and 2012/2013 in the three largest cities. For PWID, comparative results show a decrease in HIV prevalence in Chisinau (from 16.4% to 8.5%), a small increase in Balti (from 39.0% to 41.8%) and an important increase in Tiraspol (from 12.6% to 23.9%). In 2012/2013 IBBS Ribnita (in Transnistria) was included for the first time and the HIV prevalence in PWID was the highest in the country, at 43.7%. The HIV prevalence in SWs shows a worsening situation in Chisinau (from 6.1% to 11.6%) and a stable prevalence in Balti (23.4% and

21.5%). Finally, the HIV prevalence in MSM was much higher in 2012/2013 in both sites Chisinau (increase from 1.7% to 5.4%) and Balti (from 0.2% to 8.2%). In Transnistria there was no surveillance exercise for SWs and MSM (Table 1).

Table 2: HIV prevalence among key populations, IBBS 2009/2010 and 2012/2013, Moldova

Site	PWID		SW		MSM	
	2009	2012	2009	2012	2009	2012
Chisinau	16.4	8.5	6.1	11.6	1.7	5.4
Balti	39	41.8	23.4	21.5	0.2	8.2
Tiraspol	12.6	23.9	...	...	...	...
Ribnita	...	43.7	...	...	...	...

A sign of optimism is that in the youngest age group of PWID of 15-24 years, the HIV prevalence shows a stable or a decreasing trend in all three sites. However, the situation is worrisome for youngest MSM in both Chisinau and Balti, with an important increase in HIV prevalence from virtually no HIV among MSMs in 2009 to 3.2% in Chisinau and 6.9% in Balti (Table 3).

Table 3: HIV prevalence in the age group 15-24 years of key populations), IBBS 2009 and 2012, Moldova

	Chisinau		Balti		Tiraspol	
	2009	2012	2009	2012	2009	2012
PWID	1.7 [0-30.8]	2.0 [0-5.2]	18.7 [7.4-34.4]	6.6 [0.0-16.0]	13.6 [3.2-24.9]	1.1 [0-3.4]
SWs	1.6 [0-5.4]	6.5 [1.3-13.5]	15.6 [9.0-21.5]	8.7 [2.2-14.9]	...	...
MSM	0.6 [0-1.1]	3.2 [0-5.1]	0	6.9 [1.3-13.4]	...	...

Although with limited comparability due to sampling difference (convenience sampling until 2007 and respondent-driven sampling in the last two rounds 2009), HIV prevalence in 2009 among total population of people who use drugs shows a stable HIV prevalence in Balti and a decreasing trend in Chisinau compared to previous rounds of BSS (with sampling among program beneficiaries until 2007).

Table 4: HIV prevalence in people who inject drugs, IBBS 2001, 2004, 2007, 2009, and 2012, Moldova

City	2001	2004	2007	2009	2012
Chisinau	15.8	14.4	17.5	16.4	8.5
Balti	60.3	39.7	44.8	39	41.8

The key behavioral indicators show that using sterile syringe has become the norm in PWID (98% used a clean syringe at last injection in 2012, but only 82.3% in Tiraspol), but the integrated indicator for indirect sharing is still high (37.3% in Balti, 58.1% in Chisinau and 81.0% in Tiraspol). Slower progress has been seen in adopting safer sexual behaviors and reversing trends in particular groups: condom use at last sex among PWID averaged 35.1% in Chisinau, 42.8% in Balti, 36.5% in Tiraspol. In SWs in Chisinau, the reported condom use with commercial partners at last sex was 87.5% in 2013 and 80.1% in Balti, and only 23.7% for consistent use during the past 30 days in Chisinau, 48.0% in Balti. Condom use MSMs at last anal sex as receiving partner was 44.0% in Chisinau and 90.2% in Balti.

Coverage with HIV testing was the following - PWID: 47.3% (Chisinau), 43.4% (Balti); 29.1% (Tiraspol), 4.6% (Ribnita); SWs: 22.1% (Chisinau), 29.1% (Balti) and MSM: 12.1% (Chisinau), 1.1% (Balti) (NCHM: Summary results of IBBS 2012/2013). In the general population, according to the Multiple Indicator Cluster Survey carried out in the general population in Moldova excluding Transnistria in 2012, 78.5% of female respondents and 64,6% of male respondents know about the possibility to take an HIV test in the locality where they live and 13.8% have undertaken an HIV test and knew the result in the past 12 months.

Impact and outcome assessment of Objective 2 are collected through the national statistics. Coverage of pregnant women with HIV testing exceeds 99.0% of being tested for HIV at least once. In 2013, 79 new HIV cases among pregnant women were identified and an additional 72 women

with a known HIV status became pregnant and kept their pregnancy. Of them, 95.4% received prophylactic or ARV treatment in 2013.² According to national statistics, the rate of mother-to-child transmission of HIV in 2013 was 1.99%, reaching the impact target of the NAP (DCDH: Annual Epidemic Update 2014).

The number of people who received ARV treatment is rapidly increasing. By the end of 2013, a total 2,493 were on ART. During 2013 alone, 569 people have been enrolled in treatment, which is 84% of 677 PLHIV estimated by DCDH to be in need of ART. However, Spectrum estimates show ART coverage to be at 16.8%.³ With the rapid scale-up and increased availability of treatment and decentralization of ART sites, a new issue emerged, decreasing rate of adherence to treatment after 12 months of enrolment, from 88% in 2010 to 81.2% in 2013, missing the national target. Of those newly enrolled in 2013, 8.4% have died, pointing to late start of ART. By the end of 2013, a cumulative number 1,752 people with HIV have died (20.5% of the total number of people ever registered with HIV), according to the DCDH data. Of the total number of people known to be living with HIV (6,805), 5,249 or 77.1% have seen a physician for their HIV at least once (DCDH: Annual Epidemic Update 2014).

TB/HIV co-infection continues to be the single most important cause of death among PLHIV. A recent operational research has looked in detail at the quality of care of TB/HIV co-infection cases and identified that was the outcome for 32.1% of TB/HIV cases identified and treated in the period 2007-2011.⁴ Less than half (41.5%) of TB cases among PLHIV in 2012 and a bit over half (51.3%) in 2013 have initiated TB treatment.

The work on developing the new NAP will start in 2015 to get the new plan for years 2016-2020 approved. Evaluation of the current NAP will be performed in second half of 2014 to early 2015 with support from UNAIDS. The process foresees large-scale consultations with all stakeholders involved, both public and non-state actors, through the use of technical working groups established under the National Coordination Council, using the same participatory processes as for development of GF grants.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

2.1 Overall Funding Landscape for Upcoming Implementation Period

According to the latest WHO estimates (source: Health For All Database, WHO/EURO, update April 2014), public expenditures on health in the Republic of Moldova in 2012 constituted 5,34% of GDP which is the highest level in the former USSR countries but is lower than the EU average (7,32%). The share of health spending in the total government expenditure (13,26%) is also the highest in the region (CIS average: 10,21%) and is a bit lower than the European Union countries (EU average: 15,17%). At the same time, due to the low level of national income, in absolute terms public health expenditure remained as low as 233 PPP\$ per capita in 2012 (EU: 2,567 PPP\$ per capita).

The main system of health financing and coverage in Moldova is based on national compulsory health insurance, introduced in January 2004. The funding channeled through the national insurance scheme currently comprises 90% of the total public health spending and covers all health care institutions and interventions at central and local level. The central health budget, administered by the Ministry of Health, accounts for about 10% of public health spending and is

² National Coordination Council 2014. Declaration of Commitment of the United Nations General Assembly Special Session on HIV/AIDS. Republic of Moldova Progress Report on HIV/AIDS 2012-2013

³ Ibid

⁴ Bivol et al, 2014. Chart audit of TB/HIV co-infection cases in the Republic of Moldova

used for funding of public health services (formerly sanitary-epidemiology services), several national programs and administration at central level. The contributions to health from local (rayon level) authorities, other than MOH central state bodies as well as that of private sources are not significant. While the HIV funding needs include Transnistria, the information on funding from Transnistrian authorities is not available and therefore was not included.

In regard to funding of HIV/AIDS control interventions, exact financial information is available for the central MOH budget (covering procurement of HIV tests, ART and treatment monitoring for Moldova civil sector, prophylactic ART and milk formulas for Moldova, OI, STIs testing and treatment), and, through the National Health Insurance Company (NHIC), for medical services covering various aspects of HIV control such as VCT, OI treatment, ART treatment at treatment centers, PMTCT and STI services. The total estimated amount of government for 3 years (2015-2017) funding from Ministry of Health is equivalent to EUR 9,9 million (over 35% are NHIC sources).

Activities described in the Concept Note will assist the NAP in the following:

- Uphold and scale-up needle and syringe programs (NSP) and opioid substitution therapy (OST) as part of programs for PWID and their partners
- Uphold and scale-up behavioral change as part of programs for sex workers and their clients
- Promote behavioral change as part of programs for MSM and TGs
- Ensure ART, treatment monitoring and prevention of vertical HIV transmission in Transnistria region and penitentiary sector
- Strengthen laboratory for surveillance and treatment monitoring and develop relevant HR capacity
- Provide treatment adherence and counseling and psycho-social support to people infected and affected by HIV
- Operationalize routine reporting including second generation surveillance
- Involve communities in HIV response and provide legal services to key affected populations
- Improve NAP management.

The funding request to the Global Fund aims at filling important gaps not funded by the Government (e.g. harm reduction activities in PWID, CW and MSM, ART and monitoring in penitentiary sector and Transnistria region, support for adherence, community involvement for social accountability) in order to obtain an effective national HIV response. Below there is a presentation of the interaction between TGF and Government supported activities.

Interventions	TGF	GOV
Prevention in PWIDs	Scale up NSP to reach 60% coverage (one additional grant per year), new innovative interventions (PDI, gender-specific activities, overdose prevention, pharmacies, mobile units). Scale up OST to 5 new sites, ensure adherence to OST through NGOs and develop capacities.	Scale up NSP through NGOs to reach 60% coverage (two additional grants per year).
Prevention in SWs	Scale up preventive programs through NGOs to reach 60% coverage (one additional grant per year), new intervention – PDI.	Not financed by the Government at this moment
Prevention in MSMs	Expand services to reach 45% coverage, new interventions (PDI, internal homophobia, etc.) Capacity building for service providers and education programs to beneficiaries.	Not financed by the Government at this moment
PMTCT	Testing pregnant women, including rapid tests, milk formula and prophylactic ART for Transnistria. Capacity building for PH staff.	Testing pregnant women, including rapid tests, and prophylactic ART and milk formula for Moldova (excluding Transnistria).

VCT	Not financed by the Global Fund in the current application	VCT country network is fully covered. Rapid tests (saliva based) for key affected populations to be used by NGOs.
ART treatment	ART and treatment monitoring for Transnistria and penitentiary sector of Moldova. Capacity building for PH staff. Laboratory and equipment (ELISA, PCR, CD4/CD8, etc.). Treatment adherence, counseling and psycho-social support. Capacity building for NGO service providers.	ART and treatment monitoring for Moldova civil sector (excluding Transnistria).
OI	Not financed by the Global Fund in the current application	Fully financed by the Government
STI diagnosis and treatment	Not financed by the Global Fund in the current application	Fully financed by the Government
M&E	SYME HIV software adjustments, maintenance and technical support (M&E, IT, operators, etc). Refurbishment of rooms hosting SYME HIV operators; monitoring visits; IBBS.	Partially financed (routine statistics, salaries of personnel, infrastructure)
Development in the community sector	Capacity building for community involvement (local trainings, international events, etc.); NGOs organizational development; PR-ship capacity development; development of Harm Reduction resource center.	Not financed by the Government at this moment
Advocacy for social accountability	Communication campaigns on human rights promotion, stigma reduction, and awareness. Lobby and advocacy activities; empowerment of PWID community.	Not financed by the Government at this moment
Legal aid and litigation	Legal aid to key affected populations and strategic litigation.	Not financed by the Government at this moment
NAP management	Evaluation of NAP management and development of capacity for PR-ship. International events; partial NAP coordination admin support	Partially financed (salaries of personnel, infrastructure, maintenance)

At the same time, part of the interventions previously supported solely through TGF grants - food support for the most vulnerable ART and OST patients, social support for children (food support, cloths, school supplies, summer camps) – are taken by the Government. Also, full operation of SRCs will be taken by the Ministry of Labor, Social Protection and Family starting Year 2 of the project, while the Global Fund will partially support them only in Year 1. In 2013, the HIV-positive children started to benefit from Governmental formal compensation and no additional support is included in the current request for funding to the Global Fund NFM.

Other donor's contribution to NAP is less significant compare to the Global Fund. Besides technical support and contribution of UN agencies (UNAIDS, WHO, UNICEF, UNODC), no other external funding for HIV/AIDS control is anticipated for the coming years. Estimates for UN agencies' contributions are based on current allocations for HIV in the current cooperation agreements with the country. UN agencies orient their support primarily to technical assistance for development and adjustment on national guidelines (treatment, surveillance and other), development of the next cycle of the National Strategy and do not duplicate the Global Fund support through this funding request.

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	☒ Yes ☐ No	n/a
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%)	☒ Yes ☐ No	n/a
iii. Increasing government contribution to disease program	☒ Yes ☐ No	n/a

This proposal has been developed in line with the counterpart financing requirements of the Global Fund, which are set forth in the Policy on Eligibility Criteria, Counterpart Financing Requirements, and Prioritization. The Government of Moldova is committed to uphold financial sustainability of priority public health interventions, as it is key to ensuring continuity of impact. Over the last decade, the Government has substantially increased financial allocations to the health sector, including HIV control interventions, while the contributions of external partners in this area have been decreasing substantially during this period of time. At the moment, the Global Fund is the main (and sole in many instances) external source of support to HIV control in the country.

The Financial Gap Analysis and Counterpart Financing Table have been completed (see Table 1 enclosed). The counterpart financing requirements have been met. As seen from Line N (and P) in the 'Financial Gap Analysis and Counterpart Financing' table, the government contribution share is higher than a minimum threshold set for lower-middle income countries (20%). There is an increasing government contribution to national disease program over the next implementation period (figures in Line B of the 'Financial Gap Analysis and Counterpart Financing' table increase over time). Also, there is an increasing government contribution to the overall health sector over the next implementation period (figures in Line J of the 'Financial Gap Analysis and Counterpart Financing' table increase over time).

Over the last years government investments for the HIV/AIDS control interventions were mostly oriented to procurement of HIV tests, OI, STIs testing and treatment, VCT, specific medical services, etc. Compared to previous years, over the next period the government contribution increased for essential services, namely ART and treatment monitoring (CD4, PCR), but also testing for key affected populations based on rapid saliva testing through NGOs, ART for PMTCT and milk formula, and preventing services for KAP (two projects for needle and syringes exchange for PWID planned over the funding period). Detailed Government contribution is presented in the p.2.1. above.

The information used to complete the financial gap analysis and counterpart financing table was obtained from the Ministry of Health and include central budget, National Health Insurance Company, and other governmental bodies (Ministry of Labor, Social Protection and Family, Ministry of Justice, Ministry of Education, Ministry of Youth and Sport, National Center for Health Management, Blood Service, HIV laboratories, etc.) – for domestic resources; country offices of UN agencies (UNAIDS, WHO, UNICEF, UNODC) and the League of PLHIV – for external sources. For the previous years (2012 - 2013), data on domestic resources correspond with data reported in the UNAIDS National AIDS Spending Matrix as part of the UNGASS Country Report for Monitoring the

Declaration of Commitment on HIV/AIDS.

Estimates for UN agencies' contributions are based on current allocations for HIV in the current cooperation agreements with the country. Calculations of financial needs for the National Strategy are based on the revised National AIDS Program for 2011-2015 (Joined Assessment conducted in the summer of 2011). For years 2016-2017, the funding needs are based on year 2015 planning process taking into account inflation impact (8%) and other factors. The development of the next National AIDS Programme for the years 2016-2020 started already in 2014 and the current request for funding for the Global Fund NFM is in line with the preliminary discussions on priorities and targets of the next NAP cycle for 2016-2020.

The financial data presented are considered to be largely complete and reliable; as mentioned above, the needs for years 2016-2017 are estimated based on last year from the current strategy and therefore this should be taken into account when assessing the overall reliability of data. The Government overall and the Ministry of Health work continuously on strengthening financial data collection, e.g. on introducing a national health accounts (NHA) system and conducting different analyses, supported by the World Bank project and WHO.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

3.1 Programmatic Gap Analysis

The programmatic gap tables are attached in Excel format (see Table 2 enclosed). The coverage levels for the priority modules selected are consistent with the coverage targets in the modular template. The following priority interventions have been identified in this section:

1. Prevention programs for PWID and their partners
2. Prevention programs for SW and their clients
3. Prevention programs for MSM and TG
4. Treatment, care and support

These interventions are considered of high priority and represent a major focus of the current funding request and are described in details in the Programmatic gap tables. Also, the Project addresses additional priority interventions as Community Systems Strengthening and Removing Legal Barriers to Access. The identified gaps of the community systems are related to the need to increase organizational capacities and leadership of community organizations to act as true resource centers for their networks as well as to intensify legal aid and strategic litigation to PWID, SW and MSM.

3.2 Applicant Funding Request

The Republic of Moldova was invited by the Global Fund to submit HIV proposal for the New Funding Model. The CCM considers that the Global Fund decision took account of the disease burden and, at the same time, was based on the recognition of the progress in HIV/AIDS control in the country. The recent national efforts are still not sufficient to fully address the needs and drivers of the epidemic, therefore the Government is committed to follow the international recommendations, apply evidence-based interventions and target the Global Fund support based on national priorities for effective fight against the disease.

The overall **Goal of the Effective Response to HIV in Moldova Project is to reduce prevalence among key affected populations and AIDS related mortality in the Republic of Moldova** through

improving access of key affected populations to essential HIV prevention, diagnostic, treatment, care and support services. The project principles and priorities are consistent with the international policies and guidance, including those laid in the European Action Plan for HIV/AIDS 2012-2015, the UNAIDS new framework "Treatment 2015" to accelerate action in reaching 15 million people with ARV treatment by 2015 as well as with the recently updated National HIV Programme. It is aligned with the Global Fund HIV and TB Strategy and Investment Framework for EECA 2014-2017.

The project is build on lessons learned during implementation of previous Global Fund grants and existing capacity to fully address programmatic and financial gaps, it is an integral element to the National AIDS Programme (NAP) and involves Governmental and non-governmental organizations (NGOs). The project is constructed around three main Objectives, listed below with the 9 key Modules as following:

Objective 1. To increase access to evidence-based HIV prevention

Module 1.1. Prevention programs for people who inject drugs (PWID) and their partners

Module 1.2. Prevention programs for sex workers and their clients

Module 1.3. Prevention programs for MSM and TGs

Module 1.4. Preventing mother-to-child transmission

Objective 2: To ensure universal access to comprehensive HIV treatment, care and support

Module 2.1. Treatment, care and support

Module 2.2. Health Information System and M&E

Objective 3. To strengthen communities capacity and ensure program sustainability

Module 3.1. Community systems strengthening

Module 3.2. Removing legal barriers to access

Module 3.3. Program management

The proposal requests to uphold and scale-up the existing interventions that have been supported by the Global Fund, such as needle and syringe exchange, opioid substitution therapy, preventive programs for SW and MSM, quality ARV treatment, community systems strengthening and key NAP interventions in terms of targeted capacity building, multidisciplinary approach, M&E, etc. It also initiate new interventions, such as peer driven interventions, and innovative approaches to increase the coverage of services by involvement of pharmacies in HIV prevention and mobile units for harm reduction. The proposal targets health system strengthening, by intensifying case finding and improving case management using multi-disciplinary teams, support to improving performance, and strengthening patient-centered approaches in HIV/AIDS care delivery.

The Project duration is three years starting 01 January 2015, the timeline has been aligned with the country financial cycle and it frames a logical continuation of existing grants supported by the Global Fund. The ongoing HIV grant will come to an end in December 2014, therefore there is no duplication or overlap of the activities between the previous round-based grants and the forthcoming grant. The current funding request will be complementary to substantial financial resources allocated by the Government to HIV control. For example, the needs in procurement of ARV drugs are covered gradually from domestic sources, as well as the substantial human resources and facility costs.

The project follows the Global Fund recommendations on dual-track financing. Two Principal Recipients (PRs) have been nominated by the CCM: the Center for Health Policies and Studies (PAS Center, non-governmental sector) and the Health System Restructuring Project - Coordination, Implementation, Monitoring Unit (PCIMU, government sector).

A brief description of proposed Interventions by each Objective is given below.

Objective 1. To increase access to evidence-based HIV prevention

The design of current prevention program is largely consistent with the needs of the key affected populations, but requires some revisions and improvements. Still, the HIV prevention services do not fully reach those most hidden and vulnerable populations and do not effectively address the needs of specific populations (e.g. most-at-risk adolescents and women). The activities under this objective are focused on the needs of the key affected populations from civilian and penitentiary sectors. The Project uses outreach workers to target the most vulnerable PWID who cannot afford syringes and condoms, street sex workers who are the most vulnerable, and MSM engaged in unsafe sex in cruising areas. The project will provide low-threshold range of harm reduction services, including community access to rapid VCT for HIV and will support prevention of mother-to-child transmission activities in Transnistria.

Module 1.1. Prevention programs for people who inject drugs (PWID) and their partners

Intervention 1.1.1. Needle and Syringe programs as part of programs for PWID and their partners. While sterile syringe use has become consistent, safer sexual behaviors have not been adopted fully by PWID in Moldova. At this stage, harm reduction services supported by the Global Fund offer a minimal set of syringe, condom and IEC provision, which is insufficient to address effectively all drivers of the epidemic and all needs associated to effective HIV prevention.⁵ In order to increase the coverage and make these measures more effective, the Project activities are centered on service provision of the comprehensive package that still are not covered fully by NAP (needle exchange, condom programming, IEC, VCT, Hepatitis, STI, ARV, OST) and put additional emphasis on gender and age-specific programming, peer-driven interventions, overdose prevention, legal aid, activities in prisons, and an important component of technical assistance and training to improve quality of care and institutionalize new services. The intervention includes also all activities implemented in penitentiary sector, which is a well-known best practice model in the region and beyond.

Through specific grants to NGOs, the Project will expand the current range of services to provide needle exchange, condom distribution and targeted information for PWID and their sexual partners, overdose prevention, specific services for females and adolescent PWID, counseling and referral to VCT, STI prevention, OST, legal advice and provision of on-site integrated services. The Project will support a total of 8 grants to NGOs per year. For the first time, the Government committed to cover additional two grants per year to boost preventive activities for PWID: as result the Project will expand to uncovered geographic areas in Transnistria and Southern region. Also, to increase the coverage of PWID with harm reduction services, the Project will introduce a new approach in boosting access of key affected populations through peer-driven interventions in three main cities of Moldova (Chisinau, Balti and Tiraspol). It is estimated that the PDI seeds will recruit additional 1500 new beneficiaries by providing them peer-to-peer educational session and link them to NSP sites to access services.

To address the perpetuation of unsafe sexual behaviors in PWID, the project will conduct informational campaigns and behavior change activities to increase condom acceptability and promote safer sex behavior. Activities will include production of new informational materials to be used in motivational activities and will focus on developing new skills in service providers and outreach work in counseling for behavior change in MARPs. Additional targeted grant allocations will be provided to NGOs to add specific targeting of female and young PWID to their current range of activities. In parallel, the Project will improve the quality of harm reduction services through training of service providers. Basic harm reduction training will cover a total 100 NGOs

⁵ Documented in Harm Reduction program external evaluation report, 2013.

and public service providers involved in service delivery, to ensure quality service provision and minimal standards of services.

To increase coverage of PWID with services and access to a continuum of care, “one-stop-shopping” integrated services will be piloted in three main cities (Chisinau, Balti and Tiraspol), which concentrate more than 50% of PWID. The grants will support multidisciplinary teams to provide comprehensive package of services on a daily basis, including at the OST clinics. Also, the project will pilot provision of harm reduction services through two pharmacies in Balti city and through additional three mobile units. The harm reduction sites will improve links with specialized TB and HIV health departments to improve crosscutting links and TB/HIV collaborative interventions. Technical assistance will be provided to improve harm reduction program sustainability and develop necessary Governmental mechanisms of contracting NGO services.

Overdose prevention is seen a major unmet need by most PWID. The project will provide earmarked funds to the harm reduction organizations to add informational and educational activities regarding overdose prevention to their current range of activities and will support Naloxone procurement. Naloxone will be distributed to PWID upon completion of overdose prevention module. Also, the NSPs will cover, as part of their comprehensive approach to behavior change communication additional issues regarding the STIs, HCV, HBV and will build additional links to these services. Regarding TB/HIV collaborative interventions, CCM agreed to include a specific module on this issue under the TB funding request which is to be submitted in August 2014.

The detailed activities of this intervention are described further in the Modular Template and the Workplan and Budget files attached to the Concept Note (Table 3 enclosed and Annex 5 attached).

Intervention 1.1.2. Opioid substitution therapy and other drug dependence treatment as part of programs for PWID and their partners. OST strategy has been endorsed by the Government in 2005 and has registered progress, especially in penitentiary sector. The project plans to further scale-up OST by geographic extension in additional five locations in the Southern, Central and Northern regions of the country. The project will provide operational support to 5 new and 3 existing OST sites supported by the Global Fund. The Project will support methadone procurement, tests and disposable glasses to ensure quality OST maintenance. To improve on-side coordination, monitoring and evaluation of provided services, the project will support necessary technical assistance. The intervention will be implemented in closed collaboration with the Republican Narcological Center.

Under previous Global Fund support, Moldova established four sites working with enrolling and maintaining PWID in OST located in Chisinau, Balti, Cahul, and penitentiary system. The activities under this intervention aim to ensure outreach to PWID and family members to improve enrolment for OST and adherence to treatment through self-support and psycho-social activities. The program will continue to provide support to 4 community-based OST support sites to increase access to OST by facilitation enrolment and OST adherence. The community-based sites establish their services on ‘one stop shopping’ approach and provide additional services to improve cost-efficiency, quality of services and coverage, e.g. outreach work, HIV testing and counseling, harm reduction, linking with other services (including TB/HIV collaborative), peer-to-peer consultation, psychological and legal consultations, self support and social support. These services contribute to further prevention of HIV, tuberculosis, hepatitis and STIs, and improve the quality of life.

A series of information/follow-up sessions are used as platform for regular workshops (once per year) to develop mechanisms to ensure the quality of service provision. As result, the Project will expand the coverage, provide timely access to OST and ARV treatment, contribute to early diagnosis of HIV, tuberculosis, hepatitis and sexually transmitted infections and integrate psychosocial support services with harm reduction services according to the one stop shopping

principle. The intervention will be implemented in closed collaboration with the NGO New Life.

Taking into account performance and developments under previous Global Fund grants implementation, the Project is led by programmatic achievements of 60% coverage of PWID with prevention services by 2017 and will cover up to 15,200 PWID with prevention services. Under OST program, in Year 1 the project will enroll 150 new people, Year 2 – 160 and Year 3 – 170 (in average, about 420 beneficiaries per day receive OST treatment). By the end of the application the total number of people ever enrolled in OST will reach 1,740 people overcoming 10% of the estimated opiate injectable drug users in Moldova. Transnistria is an exception because OST is not legally allowed in the region. The activities under this module will be implemented by the PAS Center (principal recipient) and the Soros Foundation – Moldova (sub-recipient).

Module 1.2. Prevention programs for sex workers and their clients

Intervention 1.2.1. Behavioral change as part of programs for sex workers and their clients. The project will continue support of service provision to SWs mainly in 2 regions: Centre (Chisinau and surrounding territories in Orhei and Ungheni) and North (Balti municipality) through 3 projects. In order to increase the coverage, additional project will be initiated in Transnistria starting with Year 1. A comprehensive range of well-coordinated and flexible services will be provided to SWs, using peer and community outreach and based on lessons learnt in the previous period. HIV prevention in sex work settings will be directed to ensure: increased condom use and safer sex; reduced STI burden. A comprehensive approach to be able to adapt to changing needs and circumstances will be maintained. The following approaches will be used: easy access to condoms; easy access to information, communication, and education; risk reduction counseling; peer education; referral system for health care, including HIV testing and counseling, as well as health services – VCT services provided within NGOs, management of sexually transmitted infections.

To increase the coverage of SWs with preventive services, the Project will introduce a new approach in boosting access of key affected populations through peer-driven interventions (PDI) in two main cities of Moldova (Chisinau and Balti). PDI seeds will recruit other new clients, by providing them peer-to-peer educational session and link them to sites to access preventive services. Around 1000 new beneficiaries are planned to be reached with prevention services in the first year in the above-mentioned territories, which will achieve coverage of 56% on the way to the target established to be fulfilled by the NAP (60%) in year 3. Targets include 3,600 SWs in Year 1, 3,750 in Year 2, 3,900 in Year 3. The activities under this module will be implemented by the PAS Center (principal recipient) and the Soros Foundation – Moldova (sub-recipient).

Module 1.3. Prevention programs for MSM and TGs

Intervention 1.3.1. Behavioral change as part of programs for MSM and TGs. The project will support continuation of service provision to MSMs in Chisinau Balti and Tiraspol municipalities, and will extend the coverage especially in Balti and Tiraspol (Transnistria) through a grant implemented by GenderDoc-M (local NGO). Service provision includes outreach work in cruising areas and discos, provision of IEC, condoms and lubricants, counseling services and peer support. Condoms with increased resistance and lubricant will be procured and distributed by outreach workers. A series of capacity building training for service providers, for LGBT parents and information/communication sessions with program staff will be implemented, including for penitentiary staff. To increase the coverage of MSM with preventive services, the Project will introduce a new approach in boosting access of key affected populations through peer-driven interventions in Chisinau city. PDI seeds will recruit other new clients, by providing them peer-to-peer educational session and link them to sites to access preventive services. About 500 new beneficiaries are planned to be reached with prevention services in the first year, totaling to 2,700 in Year 1, 2,950 in Year 2 and 3,195 in Year 3, which is equal to 45% (the target established to be fulfilled by the NAP). The activities under this module will be implemented by the PAS Center

(principal recipient) and the Soros Foundation – Moldova (sub-recipient).

Module 1.4. Preventing mother-to-child transmission

Intervention 1.4.1. Preventing vertical HIV transmission. PMTCT within the NAP is based on a comprehensive approach aimed at addressing a broad range of HIV – related prevention, care, treatment and support needs of pregnant women, mothers, their children and families. PMTCT remains one of the priorities of the national HIV response and is aligned to the new 2013 WHO recommendations. For 2015 – 2017, ARV drugs and HIV test kits for all patients (excluding Transnistria) will be covered by the Government. The Project will support HIV testing of pregnant women during pregnancy and before delivery; ARV treatment during pregnancy, delivery and postpartum, as well as HIV prophylaxis and feeding support for infants born from HIV infected mothers only for Transnistria region, associated with relevant capacity building of service providers. As result, more than 95% of HIV-positive pregnant women will receive ARV to reduce mother to child transmission and more than 90% of infants born to HIV-positive women receive HIV test within 2 months of birth. The activities under this module will be implemented by the PCIMU (principal recipient).

Objective 2: To ensure universal access to comprehensive HIV treatment, care and support

The project seeks to continue efforts aimed at ensuring universal access to ARV treatment of patients in need, including monitoring, treatment adherence and psycho-social support to improve the quality of life. In parallel, the Government is committed to gradually take over ARV treatment costs and committed gradual increase of its contribution to the NAP (excluding Transnistria). The table below illustrates the gradual Governmental commitment regarding the ARV treatment sustainability.

	2015			2016			2017		
	GOV	TGF	Total	GOV	TGF	Total	GOV	TGF	Total
Nr. patients under ARV, 1 line	2,413	1,281	3,694	2,528	1,356	3,884	2,853	1,506	4,359
Nr. patients under ARV, 2 line	0	300	300	219	523	742	607	280	887
Nr. patients under ARV, 3 line	0	42	42	0	25	25	0	30	30
Nr. Children in ARV	70	25	95	70	30	100	70	30	100
Total	2,483	1,648	4,131	2,817	1,934	4,751	3,530	1,846	5,376

Module 2.1. Treatment, care and support

Intervention 2.1.1. Antiretroviral therapy (ART). The Project activities under this intervention aim to increase access to comprehensive HIV treatment. The proposed coverage with ART includes the following estimates: in 2016 - 1,904 adult and 30 children HIV patients; in 2017 – 1,816 adult and 30 children HIV patients, primarily from Transnistria and penitentiary system. Calculations have been made based on latest 2013 WHO recommendations/clinical guidelines, an annual enrollment of 625 new patients nationally and in line with the NAP 2011-2015.

Intervention 2.1.2. Treatment monitoring. The Project will support procurement of necessary lab equipment in Chisinau to replace existing obsolete equipment (including ELISA line, freezers and centrifuge). The NAP plans regionalization of the lab services starting 2015. This would bring the services closer to the patient, contribute to the reduction of transportation costs to Chisinau laboratory, as well as reduce the patients' waiting time for their results. In this context the project will support procurement of PCR for Balti and three flowcytometers for Comrat, Ribnita and Cahul, and related capacity building (training to lab staff). The project will cover also the needs related to treatment monitoring: determining the viral load for patients, PCR and CD4 testing in patients for all those enrolled and also for HIV patients who are in pre-treatment phase, as following: in Year 1 - 3,583 patients, of which 1,333 - on ART; Year 2 - 3,906 patients, of which 1,656 - on ART; and Year 3 - 4,113 patients, of which 1,863 - on ART. Funds provided by the

Government cover additional substantial costs, such as staff remuneration, facility costs, opportunistic infections diagnosis and treatment, STI diagnosis and treatment. The table below illustrates the Governmental commitment for next 3 years to cover costs of tests and treatment of opportunistic infections.

	2015		2016		2017	
	GOV	TGF	GOV	TGF	GOV	TGF
Cost of HIV and STI tests and treatment of opportunistic infections, EUR	348,562	174,670	377,497	195,728	410,640	209,122

Intervention 2.1.3. Treatment adherence. Under this intervention, the project supports activities for intensive patient support and follow-up as a fundamental component for ensuring adherence to HIV treatment. During previous Global Fund support, four regional social centers (RSC) have been established in partnership with Ministry of Labor, Social Protection and Family and Public Local Authorities. The establishment of these services included developing the concept, selection, allocation and refurbishment of these centers, developing regulatory framework and quality standards. They are currently stand-alone legal entities with mixed subordination to local public authorities and Ministry of Labor, Social Protection and Family. The centers have been established in the same areas where ART has been decentralized and act as referral for each of the 4 regions (North, Center, South and East). The centers serve as locations to centralize and concentrate all services available in both public and NGO sectors. It is planned that the existing RSC will be fully supported through domestic funding starting Year 2.

In parallel, to ensure access of PLHIV community and improve collaboration between the centers and provide low-threshold services to PLHIV and key populations, each of RSC work jointly with local NGOs who provide additional support and implement community outreach activities around the four RSCs. In addition, the four RSTs will be connected to the wider network of 9 NGOs outside the four sites that will ensure linking services, including counseling and psycho-social support (described below).

Intervention 2.1.4. Counseling and psycho-social support. As identified by the PLHIV needs assessment, one of the main deterrents of accessing and care retention is that PLHIV continue to experience stigma and discrimination when contacting public services. Peer support and community-based self-support programs have proven successful in providing enhanced wraparound services to PLHIV, while other project activities work on improving quality of public services and non-discriminatory attitudes. The project will continue to provide support to NGOs and community-based organizations to outreach to PLHIV and their families with a comprehensive support package, including psycho-social support, mentoring, case-management and linking them to other services. A total 9 grants per year will be awarded during project implementation. The project will support capacity building for HIV case management to ensure quality of service provision. The activities under this module will be implemented by the PCIMU and PAS Center (principal recipients) and the Soros Foundation – Moldova (sub-recipient).

Module 2.2. Health Information System and M&E

Intervention 2.2.1. Routine reporting. The Project activities are directed to operationalization of the SYME HIV software. The concept of the software was developed, with the support of the World Bank, the GFTAM and UNAIDS in 2005 to ensure HIV case reporting and follow-up treatment. The SYME HIV is not operational yet due to implemented structural reforms and transfer of NAP responsibility to the Hospital of Dermatology and Communicable Diseases. The Law nr.133 on protection of the personalized data from 2011 introduced additional requirements regarding security and confidentiality. The project will adjust the software to meet the provision of the above-mentioned law and will cover monitoring and evaluation costs related to HIV administrative statistics, analyses, studies, SYME HIV implementation at central and regional levels. It is planned that the project will support costs for IT consultant to manage technical issues,

six operators to introduce retrospective data in SYME HIV, maintenance services and necessary infrastructure to ensure database security requirements. Routine M&E costs are budgeted to cover fuel costs for the M&E and coordination unit staff from the Hospital of Dermatology and Communicable Diseases.

Intervention 2.2.2. Surveys. Activities under this intervention are oriented to partially support the costs for second-generation surveillance study in key population groups (PWID, SW and MSM). The most recent exercise has been conducted in the period 2012/2013 with the final report to be produced by the mid of 2014. The next round is proposed for the years 2016/2017 based on the methodology used in 2009/2010 and 2012/2013 rounds to ensure data comparability, consistency and progress/trends monitoring. The activities under this module will be implemented by PCIMU and PAS Center (principal recipients).

Objective 3. To strengthen communities capacity and to ensure program sustainability

Module 3.1. Community systems strengthening

Intervention 3.1.1. Institutional capacity building, planning and leadership development in the community sector. The activities under this intervention are oriented to further development the roles and strengthening capacity of key affected populations and communities, community organizations and networks in the design, delivery, monitoring and evaluation of services and activities. Particularly, the activities are oriented to build PR-ship capacity of communities to take over activities related to community support and involvement. The Project will further sustain the network of PLHIV organizations to coordinate community involvement on local and central level. In this respect, a series of capacity building events are planned for civil society and PLHIV in service provision, advocacy, communication and social mobilization, organizational development, etc. Also, a national HIV conference will be organized once in three years.

In parallel, the project will further increase the capacity of the National Harm Reduction Network (Union of Harm Reduction Organizations – UORN). The activities under this intervention aim to empower and develop the activism of PWID and their families through building mechanisms and platforms for dialogue, exchange of views, involvement in the design and provision of services, and delegation for the participation at national level. The activities will culminate by development of local initiative groups and coordinated by a National Advisory Committee of PWID.

Intervention 3.1.2. Advocacy for social accountability. The project will support communities to develop effective action for accountability, sustainability and continuous improvement of responses to HIV, will empower communities and key affected populations to communicate their experiences and needs to decision-makers at all levels, including technical assistance to develop effective advocacy and communication methods. As a result, 4 communication campaigns per year will be implemented, including both ongoing campaigns and campaigns connected to commemorative dates such as World AIDS Day. In addition 10 lobby and advocacy meetings at central and local levels will be organized per year. To ensure engagement of KAP, a traditional civil society engagement bulletin will be printed and distributed and a grant will be provided to cover PWID community empowerment activities. A series of national workshops, seminars and trainings will be conducted to strengthen capacity and expertise to improve community involvement. The activities under this module will be implemented by the PAS Center (principal recipient) and the Positive Initiative NGO (sub-recipient).

Module 3.2. Removing legal barriers to access

Intervention 3.2.1. Legal aid services and legal literacy. Legal aid services will serve both to provide direct legal support and improve legal literacy of key affected populations. Five specialized lawyers will be contracted to ensure continued support to KAP. They will periodically visit four Regional Social Centers, day centers for psycho-social support to PWID, and harm reduction sites. The activity will cover Transnistria region as well. To further increase the

effectiveness of legal support the project will also cover operations, including transportation, communication, human resources and office supplies.

Intervention 3.2.2. Community-based monitoring of legal rights. To complement support to community based monitoring under module 3.1, the project will monitor legal rights through strategic litigation cases. A special litigation coordinator will be hired to ensure a proper selection and promotion of policy/strategic litigation cases related to violation of human rights of PLHIV. Technical assistance (by local experts) will be hired to support a continued expertise of selected litigation cases (2 local experts). The activities under this module will be implemented by the PAS Center (principal recipient) and the Positive Initiative NGO (sub-recipient).

Module 3.3. Program management

Intervention 3.3.1. Policy, planning, coordination and management. The Project will gradually build up the capacity of the NAP team to take over the PR-ship role by the next application cycle and strengthen coordination and leadership role. In this respect NAP will be assessed to identify governance bottlenecks, legal barriers, management needs and gaps, and review the NAP structure and responsibilities. The assessment will be conducted jointly by teams of international and national consultants, under the overall guidance of UNAIDS and WHO.

The project will focus its activities on providing a mix of regional and international training opportunities for the NAP team, providing technical assistance to develop a road map for capacity building (including clear timeframe and outcomes) as well as conducting joint supervisory visits for field work evaluation. Small financial support will be provided to ensure proper operations of the central NAP unit (including office equipment, furniture, stationery etc.) The activities under this module will be implemented by PCIMU (principal recipient).

3.3 Modular Template

This request for funding has been designed taking into account the epidemiological profile (described in details in p.1.1. and p.1.2. above) and the most important targets to be addressed in the next period: need to increase coverage of the key affected populations and increase effectiveness of prevention of sexual transmission from key populations to their sexual partners through consistent use of condoms, especially sex workers and MSM. This will be addressed through new strategies: peer-driven interventions, pharmacy-based syringe exchange, diversification of condoms and introduction of counseling to reduce risk sexual behaviors, including of the sexual partners.

To address the need to decrease mortality, improve adherence to ART, and improve clinical management of TB/HIV co-infection cases, the strategy will involve enhanced focus on improving capacities of case-management and multidisciplinary teams and to increase clinical competencies in regional centers. A particular focus emphasizes the role of NGOs and community-based organizations in community-based outreach with rapid HIV testing, timely clinical follow-up and start of ART and adherence and psycho-social support to maintain people in ART. It also takes into account the need for further work of strengthening the role and professionalization of community-based services as part of the process of service integration and institutionalization.

To address the need to improve TB/HIV collaborative activities, the HIV grant will provide support to harm reduction sites that will improve links with specialized TB and HIV health departments to improve crosscutting links and TB/HIV collaborative interventions. The community-based sites establish their services on 'one stop shopping' approach and provide additional services to improve cost-efficiency, quality of services and coverage, e.g. outreach work, HIV testing and counseling, harm reduction, linking with other services (including TB/HIV collaborative), peer-to-peer consultation, psychological and legal consultations, self support and social support. The

collaborative activities of that aim for health system changes and collaboration of public medical institutions are being addressed in the TB GF proposal to the GF. Taking all this into consideration, the following modules have been prioritized:

- Prevention programs for PWID and their partners
- Prevention programs for SW and their clients
- Prevention programs for MSM and TGs
- PMTCT
- Treatment, care and support
- Health Information Systems and M&E
- Community systems strengthening
- Removing legal barriers to access
- Program management

The Modular Template has been completed and attached to the application in Table 3 enclosed. The performance indicators and budget figures, presented in the Modular Template, are based on detailed estimates of programmatic and financial needs. These assumptions and calculations are to be found in the Workplan and Budget files for each Objective (See Annex 5) to this funding request).

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

Republic of Moldova is a lower-middle-income country; this is why the Project focuses absolute majority of the budget on underserved and key affected populations and highest-impact interventions. It is oriented to the needs of the key affected populations (PWID, SW, MSM) in the civilian and penitentiary sectors. Although PWID, SW and MSM are the main drivers of the epidemic, they are those who most often experience barriers to prevention measures, treatment and care. These populations are perceived as lower social classes, are especially vulnerable economically and often hesitate to seek treatment for fear of discrimination and potential legal ramifications.

The project aim at increasing coverage and targeting enhanced access to essential comprehensive packages of services for the most vulnerable, marginalized and discriminated sub-populations of KAP. Outreach workers will target the most vulnerable PWID who cannot afford syringes and condoms, SWs projects will target mostly street SW, which are the most vulnerable socially and simultaneously at highest risk of HIV transmission, as will MSM outreach work target MSM engaging in unsafe sex in cruising areas. The project will provide low-threshold range of harm reduction services, including community access to rapid VCT for HIV.

The project aims to improve the quality of services of the comprehensive package of services, increasing equal access of KAP to the same services regardless of location. The project also aims at providing priority access to services that are otherwise available by law to all population, but not accessible to marginalized groups due to various reasons, including because of stigma and discrimination, such as access to OST and overdose prevention programs. Populations most affected by HIV are also poor, as about two third of PLHIV are unemployed. The project will prioritize their access to services through free HIV prevention and OST programs, improving quality of care of PLHIV and PWID and meeting their non-medical needs through psychosocial and peer support through.

Inequities between civilian and penitentiary sectors are also addressed that aims at improving the access to OST and NSP, psychosocial support, and improve quality of services. Using an HIV client management methodology, prisoners will be able to access the health and social care system and receive quality care within prison and upon release. It is a process that includes outreach,

screening, comprehensive assessment, care planning, service arrangement and accompaniment, monitoring and reassessment.

In conclusion, the Project interventions target key populations who are at the most risk for HIV and include prevention, diagnosis, treatment, care, support and capacity building activities. Budget-wise (excluding project management and activities covering coordination of NGOs), the interventions above consume about 85% of the requested project funds. Therefore, overall the budget well exceeds the minimum share required by the Global Fund in this regard.

SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

4.1 Overview of Implementation Arrangements

The Country Coordination Mechanism oversees the overall implementation of the project and ensures proper coordination between different sectors as well as different programs implemented by other external partners. The CCM will monitor the project progress to ensure that the activities are carried out according to the work plan and indicators of programmatic and financial performance are accomplished. It will make the key financial and programmatic decisions and will have the responsibility to address the main problems and challenges related to the project.

The CCM meetings will be convened quarterly or more frequently as necessary. Technical working groups for each component will work with the stakeholders between the CCM meetings and prepare the documentation to be endorsed by the CCM. The CCM and the Ministry of Health will carry out the role of coordination with other programs and development initiatives. The CCM will ensure practical coordination and collaboration with all local partners involved.

On an annual basis (or more frequently as requested by the CCM), the Principal Recipients (PAS Center and PCIMU) will prepare the project progress reports for review by the CCM. These reports will present the current state of the epidemic, project implementation progress, financial expenditures and implementation challenges and problems. The CCM will use this information to approve the changes in the program setup and resource allocation when necessary. The CCM will negotiate the recommended changes with the Global Fund through the country's Fund Portfolio Manager (FPM) and the Country Team.

The two Principal Recipients will execute their functions and apply procedures in accordance to the Global Fund requirements and in compliance with the national legislation. The grant funds will be transferred to the special accounts of the PRs. The PRs will be responsible for all practical issues related to the project implementation including oversight of the Sub-recipients (SRs). The PRs will undertake the functions of procurement (of health and non-health products, equipment and services), financial management, project-related monitoring and evaluation and reporting to the Global Fund.

The PRs will develop the work plans for project implementation and will present project performance reports to the CCM. Financial and activity progress reports will be forwarded to the CCM members for review. On an annual basis, the CCM will review the project performance and proposed work plans for the upcoming year and will approve additional disbursements. The following SRs have been identified for this Project:

- The Soros Foundation – Moldova – to implement prevention programs for PWID and their partners, SW and their clients, MSM and TGs, treatment adherence, counseling and psycho-social support;

- NGO Positive Initiative – to implement community system strengthening activities, advocacy for social accountability, legal aid services and community-based monitoring of legal rights.

Before signing the SR agreements, the PRs will carry out the assessments of prospective SRs in terms of their correspondence to the Global Fund requirements vis-a-vis the capacities for financial management, procurement, M&E and other aspects. The activities of SRs will be continuously monitored on the basis of verification of programmatic and financial indicators towards project implementation progress, including visits to SR project sites. The CCM Secretariat and the PRs will communicate with the Global Fund on the project progress. Progress Updates and Disbursement Requests will be forwarded to TGF FPM on a semi-annual basis or as otherwise agreed; other documentation will be provided as requested by TGF.

The NAP central unit is the main technical partner of the project. It will ensure practical coordination and collaboration with all other partners involved. The Local Fund Agent (currently Price Waterhouse Coopers, PWC) will act within the Terms of Reference agreed upon with the Global Fund, including on-site verifications (OSV) of project performance. External audits evaluating the project performance and financial management are an integral part of the proposed management arrangements.

4.2 Ensuring Implementation Efficiencies

Currently there are two Global Funds HIV grants under implementation, valid until the end of 2014, namely: Grant MOL-H-PCIMU (PR 1: PI CIMU HSRP) and Grant MOL-H-PAS (PR 2: PAS Center). There is also an interim funding application submitted to GFATM to cover ARV treatment needs for 2015, approved on May 5th, 2014 (PR: PI CIMU HSRP). The application has been built to uphold the goal, scope and key directions of the ongoing TGF-financed HIV program through supporting the key priorities of the National HIV Control Program 2011-2015 (NAP), namely prevention in key populations, treatment, care and support for patients and communities and consolidating health service's capacities for successful HIV case management, with special focus on groups at high risk.

Implementation of the NAP, as well as development of external funding applications in support of NAP implementation, are coordinated by the Country Coordination Mechanism for HIV and TB, an interministerial and intersectorial decision-making body that has under its auspices 8 functional working groups enhancing coordination and capitalizing upon the value added of joint efforts of all key stakeholders from different sectors. It is already a wise-implemented approach to discuss any type of new or additional intervention in HIV through the CCM structures and Moldova succeeded to avoid overlapping over the past decade. Actually, the CCM Bylaws and Operational Manual provide clear recommendations to all interested stakeholders to invest or contribute to national HIV response through CCM structures. For the non-CCM member development partners, there are several more platforms to ensure there is no duplication – UN Joint team on HIV/AIDS, Donors in Health Platform (at the level of Ministry of Health) and Official Development Assistance Platform (at the level of State Chancellery, Government of Republic of Moldova).

Interventions proposed under current application have been designed following a thorough analysis of program needs for 2015-2017 and their coverage under existing and planned funding from both governmental and external sources. The process has been carried in a transparent, cooperative and participatory manner, through a country dialogue involving relevant governmental entities, international agencies, and civil society, with the aim to avoid any overlapping of activities, as well as to ensure that all priority interventions are covered, from either local, or external resources.

4.3 Minimum Standards for Principal Recipients and Program Delivery			
PR 1 Name	Center for Health Policies and Studies (PAS Center)	Sector	CSO
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?		☒ Yes ☐ No	
Minimum Standards		CCM assessment	
1. The Principal Recipient demonstrates effective management structures and planning	The PAS Center staff members have substantial experience in the implementation HIV programs and projects. The key experts have extensive technical knowledge on HIV and many years in the management of HIV programs. Decision-making procedures concerning the operation of the PAS Center include regulations that cover three main areas: human resources, financial management and program execution. The Board of Directors endorses the operational manual. Coordination and approval by the Director is conducted according to the procedures of the PAS Center. The Procurement Specialist of the PAS Center has extensive experience in international health procurement including procurements within the projects funded by the World Bank, WHO and the Global Fund, and has the necessary competence and skills in procurement procedures.		
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	The experience in the implementation of grants is based on the close collaboration with the national partners and established procedures for selection of applications and grant management. The procedures are carried out in several stages and include the establishment of clear selection criteria. The selection of grantees is subject to the general policies and procedures aimed at ensuring the full transparency of the process. The PAS Center provides technical assistance to the grantees to strengthen their capacity to carry out grant activities according to the Terms of Reference and implementation schedule. The PAS Center has an extensive portfolio of projects financed by the World Bank, WHO/TB REACH, Soros Foundation – Moldova and others.		
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	The internal audit is carried out by the treasurer of the PAS Center. The purpose, authority and responsibility of the internal audit are defined in the PAS Center charter, approved by the Board of Directors of the organization. As per request of donors, the PAS Center conducts annual financial audits and annual state audits in accordance with the international audit standards.		
4. The financial management system of the Principal Recipient is effective and accurate	Financial management at the PAS Center is carried out in accordance with the financial policies of the organization. The financial policy of the organization is developed and systematically reviewed in order to comply with the best international practices in the field of financial management and accounting. As an organization legally registered in Moldova, PAS Center follows the financial management requirements and practices on accounting and financial reporting in accordance to		

	the country legislation. The office accounting uses an automated system '1C: Enterprise Version' adapted to grant management for reporting to the tax authorities. The possibility of opening additional accounts and sub-accounts in the PAS Center programs allows separate accounting of revenues and expenditures for projects of different donors, so the inclusion of the same expenses in reports to various donors is excluded. The payments for services are largely cashless payments. The organization's expenditures are made according to the approved program budget. Tax accounting in the organization is based on the accounting data. Fixed assets are subject to the systematic inventory of the organization. The transfer of funds to suppliers follows the PAS Center policies on procurement and financial management. Cash transactions in the organization are very limited. The transfers of funds to the suppliers are made only after verification of the presence of the stated budget to procure goods or services and compliance to the approved annual procurement plan, as well as to the required authorization by the relevant program management level.
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	Reception, custom clearance, storage and distribution of medical supplies is carried out in strict compliance with the provisions of the law on medical devices (#92 published on 20.07, 2012) and law on pharmaceutical activity (#1456 published on 15.04.2005) and on sub-law acts (Instructions on transportation, storage of medicines, health products endorsed through the MoH order #28 of 16/01/2006) that define precisely the requirements on transportation, receipt, storage, etc. Only licensed and accredited central warehouses are used for storage and stock management.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	The distribution system for medical devices is "pull" type and generally made on a quarterly bases and in emergency cases, based on reports from service providers. Recording and reporting will be based on two types of info systems: computerized and paper-based. At central level the information system is computerized and at local – service provider – level, it is mainly paper based. At the same time, PAS Center has the established systems for procurement and supply management of medicines, medical and non-medical products, which are set forth in the relevant PAS Center documents.
7. Data-collection capacity and tools are in place to monitor program performance	PAS Center is committed not to use parallel data collection systems and use the data of the national systems as appropriate. In order to ensure proper monitoring and evaluation of interventions to be implemented within the Project, PAS Center will define the target indicators for program implementation; prepare regular reports (quarterly, annual) with defined frequency of data collection and quality assurance; perform routine checks; perform initial and follow-

	up assessments; implement capacity building interventions for the program staff and grantees for effective data management. Regular reporting forms will be used for follow up the progress of indicators. In addition, relevant information will be collected and analyzed during monitoring visits in order to ensure the quality and reliability of the reported data. PAS Center program staff was trained on data quality control, which includes ensuring the confidentiality and security of storage of registration documentation by restricting access to the data source, use of passwords to protect electronic data storage and data catalogs. The staff engaged to surveys has been trained to ensure the protection of privacy and confidentiality of data belonging to the study participants.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	One of the key elements of M&E is an integrated data system and quarterly reporting. The indicators, activities and progress in achieving the goals and objectives of the program are tracked in order to identify problems and gaps, and make recommendations for their solution. The M&E officer develop M&E plan and implement the program, and regularly provides technical advice and oversees the implementation of the program activities. During the program, reporting is completed on a semiannual basis by the program coordinator and submitted for the review and approval. Based on these reports, the progress of the program implementation, achievements and problems / challenges are discussed with the participation of the key technical specialists and executive staff.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Assurance and quality monitoring is based on normative acts that provides for the quality assurance requirements across all stages of product movement, including storage and transportation conditions. Storage of medicines has to comply with the Instructions on transportation, storage of medicines, health products endorsed through the MoH order #28 of 16/01/2006.

PR 2 Name	Health System Restructuring Project - Coordination, Implementation, Monitoring Unit (PCIMU)	Sector	GOV
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?		☒ Yes ☐ No	
Minimum Standards	CCM assessment		
1. The Principal Recipient demonstrates effective management structures and	PCIMU is an autonomous, non-commercial and non-profit, self-financing organization, registered through Government's Decision No. 391 from 19 April 2000. The unit implements its activities following the national legislation in force, the World Bank guidelines, the requirements of the Global Fund to Fight AIDS, Tuberculosis and		

planning	Malaria and the unit's Regulation and Operational Manual of the unit. PCIMU has extensive experience in implementing grants and loans from different donors, as the World Bank, Swedish and Japanese Governments, European Bank of the Council of Europe, aimed to improve of the health status of the Moldovan Population, increase the quality and efficiency of the public health sector by improving access of the poor to essential services; blood safety, and strengthening of the control of HIV/AIDS and Tuberculosis in Republic of Moldova. Since 2003 the PI "CIMU HSRP" is a PR of the Global Fund grants (Round 1, 6, 8 and 9), both for TB and HIV/AIDS Components. PCIMU team has 15 positions filled out of the 16 ones as per unit's "Organizational Chart" (Executive Director, two Project Directors, two Project Coordinators, Financial Specialist, Accountant, two Procurement Specialists, two Monitoring and Evaluation Specialists, Drug Management Specialist, General Assistant, IT Specialist, Driver, and Customs Clearance Specialist). Out of 15 persons, 6 persons are directly involved in implementation of the consolidated TB Grant (MOL-T-PCIMU). PCIMU staff has higher education in medical field, economy and financial studies, philology, informational technologies, including master degrees in public health and PhD in medicine. The members of the team attended much international trainings on: project management, financial management, procurement management, drug management, M&E, results based management, etc. and participated to international conferences and seminars on HIV/AIDS and TB with presentations on implemented activities. PCIMU team has extensive knowledge on: establishment of project objectives, risk assessment and control, budgeting, project activities planning and management, monitoring and evaluation, progress tracing and reporting, defining final project results, procurement management, resource management, quality management etc. Evaluation of PR programmatic performance has shown that the HIV grant (MOL-H-PCIMU) has met its targets at a satisfactory level. Latest quantitative indicator rating by Global Fund for grant is B1 (for Semester I 2013).
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	PCIMU has extensive experience, as well as high capacity to effectively manage and oversee sub-recipients since 2003. During previous HIV grants many entities acted as Sub-recipients and Sub-sub-recipients of PCIMU, including non-governmental and governmental ones.
3. The internal control system of the Principal Recipient is	The internal control system is considered effective to detect misuse and fraud. As described in the unit's Operations Manual, PCIMU was established to implement the World Bank's funded projects procedures, as they are fully in line with the requirements of

effective to prevent and detect misuse or fraud	transparency, competitiveness, quality and efficiency, and are built based on the principles of (i) usage of funds only for intended purposes, (ii) economy and efficiency, (iii) competitive selection, (iv) appropriate evaluation criteria, (iv) appropriate technical specifications / terms of reference, (v) openness and transparency, (vi) highest standard of ethics – no fraud or corrupt practices, (v) avoidance of situations of conflict of interest. The system is implemented through mechanisms including: a code of conduct which all personnel subscribe; clear delegations of authority that limit an individual from processing incompatible transactions; regular reports and reconciliations to GFATM; a financial management system (1C) with strong and proven controls and periodic reviews and audits by Local Fund Agent and external audits for PR operations and PR compliance reviews for SRs operations.
4. The financial management system of the Principal Recipient is effective and accurate	The PR's financial management system is considered effective and accurate. PCIMU maintains a financial management system, including records and accounts, and prepares financial statements in a format acceptable to GFATM, adequate to reflect the operations, resources and expenditures related to project implementation and to meet the financial management requirements of the Republic of Moldova. A Project Operations Manual and a Project Information System that manages technical and financial data have been developed by PCIMU and approved by GFATM to be used as main tools in the PCIMU financial management. ZIP-based backup copies for the financial info are produced on a regular basis, depending on the nature of the documentation. Accounting records are maintained in a way that prevents any unauthorized and improper corrections (unauthorized subsequent amendments of transactions). The Local Fund Agent performs external semi-annual audits of the PCIMU financial management practices. In addition, annual external audits are performed by independent auditors on terms of reference acceptable to the GFATM. The Moldovan Court of Accounts, the country's supreme audit institution may perform as hoc external audits of the PCIMU.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	The stock management is built following general national regulations on management of medicines supply and special regulations developed for ARV medicines. National regulations include provisions regarding terms and procedures for medicines transportation, receipt and storage. Provisions in force define precisely the key stakeholders involved in ARV drugs supply management, including management of stock at central and regional levels, as well as their specific responsibilities. ARV drugs stocks are managed with involvement of central warehouse, regional warehouse from Transnistria (ARV treatment provided on the left bank of the river) and pharmacies of health facilities involved in providing ARV treatment. ARV drugs circulation recording and reporting systems are made based on standardized forms. Data management is both computerized and paper based. The software designed for managing data on ARV drugs has been developed to be part of SYME HIV (software developed to manage data on HIV) and shall be launched once the SYME HIV becomes functional. The data management information system is keeping information on: stock at the beginning of reporting period,

	received and distributed quantities and stock at the end of reported period; shelf life, batch number, producer and country of origin; supplier's data; date of supply movement, recalled back products. Every batch is recorded separately. Data at the level of warehouse and pharmacies are recorded in computerized system. Hospital pharmacies involved in dispensing ARV medicines at rayon level are organized according to regulation on activity of hospital pharmacy which defines separate terms for every responsibility of the hospital pharmacy, including structure and management' responsibility.
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	Drugs distribution and transportation are made following regulations endorsed by the executive order of the MoH # 763 of 18/10/2010 "Concerning decentralization of medical supervision and antiretroviral treatment" determines. The distribution system of "pull" type. Distribution is made on a quarterly basis and in emergency cases, based on quarterly reports and orders on behalf of local health facilities, which are to be presented according to a defined schedule. Quarterly reports are evaluated and approved by the Drug coordinator of the SDMC. The information system at the dispensing point is mainly paper based, following the de-facto dispensed medicines by patients. Patients are recorded ensuring personal data protection. Receipt of ARV medicines is made following observance of a set of criteria, including: physical characteristics; integrity of packages; conformity of medicines by name, pharmaceutical formulation, strength, shelf life, batch, supplier and quantity to provided documents (invoices, certificate of conformity etc.). Regulations also specify requirements with respect to supplied/distributed medicines supporting documents, aiming at ensuring recording and supply cycle follow-up. Drug distribution is performed by specialists with pharmaceutical background, trained on the matter. Dispensing of medicines to patients is performed by medical staff trained medicine dispensing management.
7. Data-collection capacity and tools are in place to monitor program performance	The PR uses the national systems to avoid creating parallel systems while gathering data and reports for reporting to GFATM. Data collection and quality assurance is undertaken by the M&E Unit of the Hospital of Dermatology and Communicable Diseases, which continuously oversees information flows for different HIV/AIDS/STIs management interventions, monitors data transmission, undertakes verification of data. Process data quality assurance is undertaken by PCIMU through quarterly verification of Sub-recipient's activity and financial reports and list of relevant indicators with achieved results. Semiannual reviews of Progress Updates, visits to beneficiaries, as well as on site data verification (if applicable) are undertaken by the LFA. The PR ensures that all project activities are documented and that the collected data are properly stored and archived. However, the PR documented several concerns: (1) the data management system (SIME HIV) is not completely functional as the software is still to be registered with the national authority for personal data protection, (2) the data management system continues to be paper-based at both state and region levels. PR receives quarterly reports from all its PRs against the agreed indicators and reports them to GFATM six-monthly.

8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	A functional reporting system has been developed to report program performance in a timely and accurate manner. The progress updates/reports produced under previous grant included: (a) Quarterly progress reports to the Ministry of Health, to the Ministry of Finance, to the Ministry of Economy and Commerce, CCM, covering among others, programmatic, financial, procurement issues; (b) Semi-annual progress update reports to the GFATM and to the National Committee of Experts of the Country Coordination Mechanism; (c) End-of-grant reports/Grant Completion Reports to the GFATM and to the Ministry of Health.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Meets standards. Drug quality is ensured via a complex system being composed by following implemented procedures mainly by the Medicines and Medical Devices Agency (MMDA) with some exception for licensing and accreditation: • Medicines' Authorization; • Surveillance of medicines quality and quality control of medicines imported or produced locally; • Pharmacovigilance activity and rational use of medicines; • Licensing and accreditation of pharmaceutical activity; • Supervision and control over the pharmaceutical activity; • Information on medicines; According to provisions of national law only medicines with marketing authorization can be placed on the market. All authorized medicines are input in the State Drugs Register. The legislation also regulates the cases when drugs not registered in the Moldova may be authorized for import from other countries and issued to population and health facilities. The regulation on marketing authorization has been revised and adjusted to the international provisions. Starting with January 2013, the CTD format has been introduced for the registration of medicines. Surveillance of quality of medicines and quality control of medicines: an active drug product testing system is implemented following provisions of Ministry of Health order # 521 of 01.06.2013, "Concerning the State Control over drugs' quality". All medicines, either imported for commercial purpose or as humanitarian aid or manufactured locally, are subject to compulsory state quality control, which is of three types: Preventive control; Post-marketing random control; Arbitration control. Drugs manufactured according with GMP rules and registered by companies from EU, Australia, Japan, Canada, US are tested randomly at the post-marketing stage. Medicines produced by manufactures from countries other than EU, Australia, Japan, Canada, US but compliant with national GMP, are to pass the first five tests. Should this be the case, further testing is made on a random basis. For manufacturers not compliant with GMP, all batches are to be tested. Regulations are defining terms for sampling; samples transportation to the laboratory; quality control testing results and reports: records and documentation. Information about the results on the quality testing of drugs is published on the website of the MMDA. Drugs' quality control by the state is ensured by the Drugs Control

	Quality Laboratory (DCQL) of the Medicine and Medical Devices Agency. In addition, ARV medicines quality control is ensured following the GF Quality Assurance Policy. Prequalified Medicines Quality Control Laboratory or ISO-certified Laboratory, ISO 17025 are contracted to perform quality control of medicines from different supply chain points. Regulations have been developed with regard to management drugs that failed the quality control, either at the import stage, or in case of post-marketing identification of quality issues. These are prohibited for sale and distribution on the territory of the Republic of Moldova and are to be returned to the manufacturer/supplier or destroyed accordingly. The safety of non-qualitative drugs destroying is ensured by a specialized department established within MMDA. With a view to ensuring procurement of high quality drugs, these are to comply with a set of quality provisions, i.e.: must be pre-qualified by the WHO, or; be registered by the stringent regulatory authorities; must be produced by a manufacturer complying with GMP according to WHO, or EMA, or FDA standards; the minimum shelf life shall be not less than 75% from the whole one. ARV medicines are part of the National Essential Drugs List. Supervision of quality of medicines is also ensured through the pharmacovigilance system, as described in the Law “Regarding medicines” by a separate department within MMDA. Reporting tools as standardized forms developed for physicians and patients to report adverse reactions are available in the system, inclusively on the website of MMDA. Starting with 2003, Moldova is member of WHO Programme for international drug monitoring, UPSALA. The legal provisions require healthcare professionals to report any adverse events/reactions. Additionally to the MoH general order for side effects management, the MoH order on management ARV treatment provides regulation on registration, collecting and reporting side effects. PR monitors stock management according to a defined programme. Storage of medicines has to comply with the Instructions on transportation, storage of medicines, health products endorsed through the MoH order #28 of 16/01/2006.
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4.4 Current or Anticipated Risks to Program Delivery and Principal Recipient(s) Performance

No major external risks are anticipated that may negatively affect the implementation of the proposed interventions. Still, there are some issues that have to be raised as factors to contribute to risk appearance. It is linked to the insurance of continuous supply of ARV drugs for 2018. To be in time and ensure there is no stock out, the procurement procedure has to be initiated in 2017 to have the advance payment performed to the suppliers. This issue has been discussed by the CCM and a thorough planning will be applied during the Project implementation, including development of necessary buffer.

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