

# STANDARD CONCEPT NOTE CUBA

# Investing for impact against HIV, tuberculosis or malaria

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

A concept note is divided into the following sections:

- **Section 1:** A description of the country's epidemiological situation, including health systems and barriers to access, as well as the national response.
- **Section 2:** Information on the national funding landscape and sustainability.
- **Section 3:** A funding request to the Global Fund, including a programmatic gap analysis, rationale and description, and modular template.
- **Section 4:** Implementation arrangements and risk assessment.

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

SUMMARY INFORMATION				
Applicant Information				
Country	Cuba	Component	HIV	
Funding Request Start Date	1-January-2015	Funding Request End Date	31-December-2017	
Principal Recipient(s) UNDP - United Nations Development Programme				

# **Funding Request Summary Table**

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

Module	Allocated/ Above	2015	2016	2017	Total
Drayantian programs for MCM and TCa	Allocated	724,007	711,324	711,824	2,147,155
Prevention programs for MSM and TGs	Above allocation	0	0	0	0
Prevention programs for other vulnerable	Allocated	581,757	537,089	512,921	1,631,767
populations (please specify)	Above allocation	0	0	0	0
Dragram management	Allocated	977,501	1,004,912	1,069,690	3,052,103
Program management	Above allocation	0	0	0	0
Treatment, care and support	Allocated	3,887,370	4,340,968	4,773,041	13,001,379
Treatment, care and support	Above allocation	1,578,747	1,877,464	1,427,977	4,884,188
Total	Allocated	6,170,635	6,594,293	7,067,476	19,832,404
Total	Above allocation	1,578,747	1,877,464	1,427,977	4,884,188

#### **SECTION 1: COUNTRY CONTEXT**

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

# 1.1 Country Disease, Health and Community Systems Context

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

- a. The current and evolving epidemiology of the disease(s) and any significant geographic variations in disease risk or prevalence.
- b. Key populations that may have disproportionately low access to prevention and treatment services (and for HIV and TB, the availability of care and support services), and the contributing factors to this inequality.
- c. Key human rights barriers and gender inequalities that may impede access to health services.
- d. The health systems and community systems context in the country, including any constraints.

# National and regional context

Cuba is officially known as the Republic of Cuba, its official language is Spanish and its capital is Havana. Following a reorganization in 2010, the country is now divided into 15 provinces, 167 municipalities and the special municipality of Isla de la Juventud. To the west of Isla de la Juventud lie the provinces of Pinar del Río; Artemisa; Havana; Mayabeque; Matanzas; Villa Clara; Cienfuegos; Sancti Spíritus; Ciego de Ávila; Camagüey; Las Tunas; Holguín; Granma; Santiago de Cuba and Guantanamo. The special municipality of Isla de la Juventud is located to the south of the provinces of Artemisa and Mayabeque.

At the end of 2012, Cuba had an estimated population of 11,163,934,1 with a population density of 101.6 inhabitants/km<sup>2</sup>. Of the total number of inhabitants, 19 percent live in the capital.

Cuba is situated in the Caribbean, the region that is the second most affected by the AIDS epidemic. However, in the regional context, Cuba has the lowest prevalence among adults (0.2 percent), and together with Barbados, has the lowest AIDS mortality rate.<sup>2</sup> The epidemic has grown at a slow but steady rate, however, with the slight peculiarity that the prevalence seen in the 15 to 49 year age group of the general population is not reflected in all population groups on the island. Amongst men who have sex with men (MSM), the group most affected by the epidemic, the national prevalence rate is 3.7 percent, however in the capital some 8.05 percent of MSM are living with HIV. The prevalence rate amongst persons who have transactional sex is 1 percent, whereas the prevalence rate is twice the national average among young people in the 20 to 29 year age group living within the 26 municipalities in the country.

# Current epidemiology of the diseases and trends

The first cases of HIV/AIDS in Cuba were diagnosed in 1986, and by December 2013 some 19,781 cases had been reported, of which 16,479 sufferers were still alive on that date.

<sup>1</sup> National Office of Statistics (ONEI) [Oficina Nacional de Estadísticas] Anuario Estadístico de Cuba, 2012 [Statistical Yearbook of Cuba]

<sup>2</sup> UNAIDS World Report 2013.

The principal mode of HIV transmission is sexual (99.6%), with very low rates of transmission through blood and through mother-to-child transmission (MTCT). Action taken in the latter case has seen the rate of transmission fall from 21 percent in 2002 to 1.79 percent in 2013. Based on these results, WHO is set to begin the process of certifying the eradication of MTCT in the third quarter of 2014.

In the last few years, the prevalence rate has increased slightly in the 15 to 49 year age group (0.1 percent a 0.2 percent in the period 2011-2013). This is linked to a decrease in mortality, a sustained increase in access to antiretroviral therapy (ART) and retention rates at 12, 24 and 36 months (93.6 percent, 92.4 percent and 90 percent, respectively), and an increase in the diagnosis of new HIV cases among MSM in the 20 to 34 year age group.<sup>3</sup> Data from 2013 shows that AIDS mortality fell 7.5 percent in that year, compared with the figure for 2012 (2.33 per 100,000 in 2013 v 2.5 per 100,000 in 2012).

The estimated prevalence among MSM in the 15 to 49 year age group is 17 times higher than the prevalence rate in the general male population in the same age bracket (3.7 percent vs. 0.2 percent), and it is higher in the country's capital (8.05 percent).4

In the last six years the most affected age group has continued to be the 20 to 29 year age group and, in terms of gender, eight out of every ten persons diagnosed with HIV are men. The ratio of men to women is 4.4:1.

#### Geographical variation

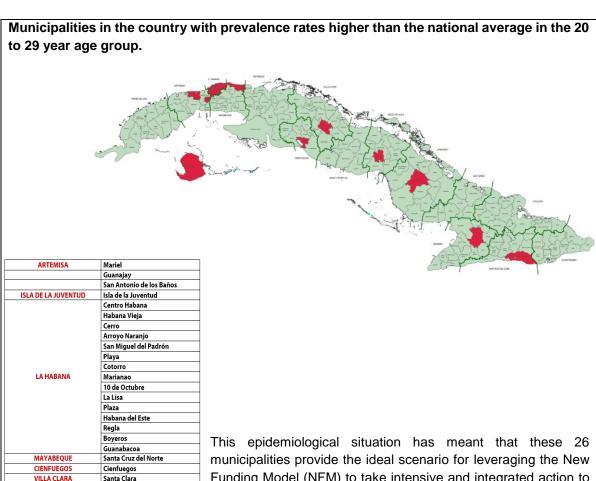
The epidemiological investigation of each case of HIV and the stratification of the data obtained down to the local level has allowed us to ascertain the locations and populations most affected by HIV, according to different epidemiological variables. As a result, more is now known about the different sub-epidemics, and preventive action can be better targeted, which facilitates the identification of the resources that are required in order to broaden the scope of the program.<sup>5</sup>

The risk of contracting HIV is 3 times higher in the capital, and at the end of 2013 three strata were identified based on the number of people living with HIV (PLHIV) in the 15 to 49 year age group. These are 109 municipalities with a prevalence rate below the national rate, 33 with a prevalence rate similar to that of the country as a whole, and 26 municipalities with higher prevalence. Monitoring of PLHIV in recent years has shown that approximately 63.4 percent are concentrated in these 26 municipalities. These municipalities also have the highest prevalence rate among young people and young adults (20 to 29 years). (See graph)

<sup>&</sup>lt;sup>3</sup> Cuba, GARPR 2014.

<sup>&</sup>lt;sup>4</sup> [Numerator: No. of MSM who have tested positive for HIV, according to data from the Cuban Ministry of Health's (MINSAP) National HIV/AIDS database. Denominator: No. of MSM, according to data from the survey on HIV prevention indicators issued by ONEI.

<sup>&</sup>lt;sup>5</sup> Plan estratégico nacional 2014-2018 [National Strategic Plan 2014-2018], p. 21



Funding Model (NFM) to take intensive and integrated action to contain transmission in key groups and slow the course of the epidemic.

#### **TB/HIV** co-infection

CAMAGUEY

GRANMA

SANTIAGO DE CUBA

Ciego de Ávila

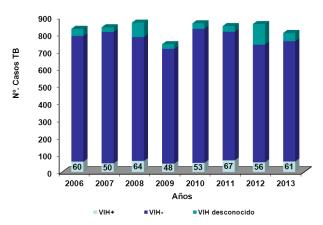
Santiago de Cuba

Camagüey

Bavamo

The annual incidence of TB/HIV co-infection (incidence plus relapse) has varied little in recent years. HIV-negative TB cases are predominant, and the number of persons of unknown HIV serostatus has fallen. In 2013, HIV was ruled out in 93 percent of reported cases of tuberculosis and by the end of that year 76.4 percent of PLHIV had been tested for TB<sup>6</sup> and 69 percent had started receiving Isoniazid prophylaxis.

No. of cases of TB by serological condition in relation to HIV: Cuba 2006-2013

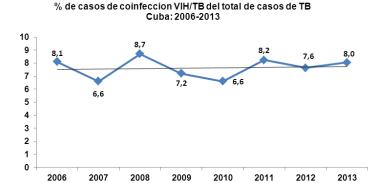


Source: program data from the National Program for the Control of Tuberculosis (PNC-TB)

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<sup>6</sup> Informe de monitoreo del proyecto [RCC project monitoring report]

In 2013, 61 cases of co-infection were diagnosed. Treatment for HIV and TB was received in 86 percent of those cases.<sup>7</sup> The percentage representing co-infection in the total number of TB cases has fluctuated between 6.6 and 8.7 percent in the last eight years, and in the last 3 years it has stayed at approximately 8 percent.



Source: program data from the PNC-TB

The national TB and HIV programs are implementing the joint TB/HIV activities recommended by WHO. These are described in the national strategic plan, together with indicators that undergo regular monitoring and evaluation at the national and local level.8

The gaps identified in the handling of TB/HIV co-infection include insufficient compliance with antiretroviral treatment and isoniazid prophylaxis, as well as weaknesses in the immunological monitoring of PLHIV, due to the insufficient availability of reagents, which has a knock-on effect on early commencement of antiretroviral treatment.

Through this proposal, we hope to tackle these gaps by purchasing reagents and medicinal products that will, apart from allowing us to monitor all PLHIV properly, also allow ART to be started early in persons with <500 CD4/mm3. Another activity planned in this proposal is the implementation of prophylaxis in selected municipalities. This will also have a positive impact on the prevention of coinfection.

TB diagnosis will also be improved by using molecular tests and rapid tests that help to shorten the potential period of transmissibility of TB between persons with HIV and between persons with HIV and the community. To this end, a GenXpert machine will be made available, and there are plans to purchase reagents in order to study symptoms that are suggestive of TB.

The health care products required for these activities (rapid HIV tests, tuberculin and isoniazid) will be costed by the Cuban Ministry of Health.

# **Antiretroviral treatment**

Access to ART has been increasing, with 9,651 persons undergoing treatment at the end of 2013 (98 percent with <350 CD4 and 58.6 percent of all PLHIV).9

The national treatment guides recommend starting treatment in adults and children over 10 years with CD4 ≤ 500 cells/mm3, prioritizing cases of severe-advanced infection or with CD4 ≤350 cells/mm3. They also recommend starting treatment, irrespective of the clinical status of the patient

<sup>7</sup> Cuba, Global AIDS response progress reporting (GARPR) 2014

<sup>8</sup> National Strategic Plan 2014-2018 pp. 95, 178 and 179

<sup>9</sup> HIV/AIDS Database, MINSAP and Cuba GARPR 2014

and their CD4 count, in cases of TB/HIV co-infection, HBV/HCV co-infection, pregnant women and seronegative nursing mothers with male partners who are HIV positive. 10

Around 23 percent of persons undergoing treatment are taking some form of medicine that is not included in the current WHO protocols, and although there is an implementation plan in place for the gradual phasing out of those products, the available funding and local production are as yet insufficient.

For 2015, around 15,000 PLHIV will require ART. The challenge lies in standardizing and optimizing treatment regimens, implementing the initiation of treatment according to the national guidelines and in line with WHO recommendations, replacing medicines that are not recommended, improving compliance, reducing the cost of medicinal products, ensuring that the commitments made to the Office of the Inspector General of the Global Fund are met and in line with strategy 2.0.11

#### **Key Population Groups**

The National Strategic Plan 2014-2018 (PEN 2014-2018) identified key groups that are at greater risk of infection, based on the available epidemiological information. Specific preventive interventions have been planned for these groups. 12

This proposal will focus on PLHIV, MSM living in urban areas, transgender persons and young people in the 20 to 29 year age group living in the 26 municipalities in which the prevalence rate is double the national average.

In Cuba there are no formal or informal organizations that group together people who practice transactional sex (PPTS). As a result, this population group will be approached through crosscutting, peer-based strategies that include MSM and transgender groups and young people, since they are seen neither by themselves nor society as sex workers.

# Men who have sex with men:

- They represent 8.7 percent of Cuban men in the 15 to 49 year age group and 8.8 percent of residents in urban areas. Approximately half of these men are bisexual, their average age is 34 years and they display higher territorial mobility than the rest of the population.
- The prevalence of HIV in MSM is higher than the estimated figure for the adult population in the 15 to 49 year age group (3.7 percent for Cuba and 8.05 percent in Havana) and the incidence of other STIs is also comparatively higher in this group (4.9 percent in MSM vs 2 percent in heterosexual men).
- In 2013, 65 percent of PLHIV diagnosed with serious and/or advanced immunodeficiency were MSM, and this has an impact on the rates of early mortality caused by AIDS, whilst allowing silent transmission to continue. Mortality is higher than recorded in the rest of the population, and the extended life expectancy gained by MSM who started receiving ART in 2008 (4.6 years) is lower than in heterosexual men (5.0) and women (4.8)
- Some 51.5 percent of MSM used a condom the last time that they had anal sex.
- 16.3 percent of MSM who were tested for HIV in the last 12 months knew the results.
- There is evidence of stigmatization of and discrimination against MSM in 33.4 percent of the population.

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<sup>10</sup> Plan estratégico nacional 2014-2018 [National Strategic Plan 2014-2018], p. 140

<sup>11</sup> Plan estratégico Nacional 2014-2018, "Principales debilidades identificadas en el proceso de evaluación de la estrategia", [Principal weaknesses identified in the process of evaluating the strategy] p.47

<sup>12</sup> Plan estratégico Nacional 2014-2018, "Caracterización de las poblaciones clave de mayor riesgo", [Characterization of the key population groups at greater risk]p.15

In the process of updating the national strategy, gaps were identified in the indicators that measure knowledge of serological status, condom use and perception of risk. Preventive action needs to be more geared towards this population group.

#### Transgender population

- Diagnostic studies carried out by CENESEX (National Center for Sexual Education) have revealed that stigmatization and discrimination are limiting the social integration of transgender people.
- According to references from the transgender network, the estimated size of this population group is 3,002 for the whole country, and around 700 practice transactional sex (23 percent).
- There is insufficient knowledge within this group of the scale of the epidemic, and further study of this group is therefore required.
- Of those transgender persons who practice transactional sex, 42.6 percent said that they had used a condom with their last client.
- Transgender groups have reported having been victims of gender-based violence, demonstrating the need for intervention to reduce the harm and to respond effectively to this problem.
- From 2012, transgender persons diagnosed with HIV have been identified in the MINSAP HIV/AIDS Database. Prior to that they were classified as MSM, and this information is currently being updated. Even though the Cuban transgender network (Red Trans-Cuba) has estimated the size of the transgender population, there is no reliable figure on the level of prevalence within this group. This proposal will produce an estimate based on a sentinel study in conjunction with the Cuban transgender network.<sup>13</sup>

# **Persons living with HIV**

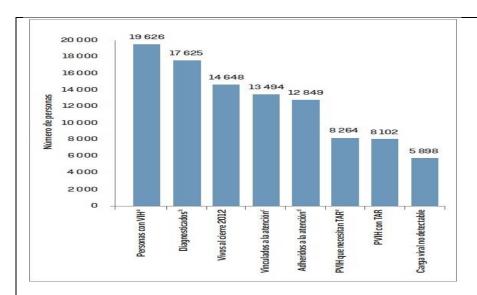
- In 2013, PLHIV represented 0.2 percent of the total population in the 15 to 49 year age group, 14 the average age of this group was 35 years, just over half were living in Havana and the rest were distributed chiefly in the provinces of Santiago de Cuba, Villa Clara, Granma, Camagüey and Holguín.
- Some 80.4 percent were men and 87.8 percent of these men were MSM.
- Some 10.8 percent of women with HIV had had a pregnancy in the last 5 years.
- The HIV care continuum at the end of 2012<sup>15</sup> is illustrated in the following graph. The bar marked as (a) represents the total number of PLHIV diagnosed, plus an estimate of those who are undiagnosed, based on the proportion of late diagnoses (13 percent).

Cuba's HIV Care Cascade: 1986-2012

<sup>&</sup>lt;sup>13</sup> Personal communication. Cuban transgender network

<sup>&</sup>lt;sup>14</sup> Spectrum results. 2013. Program data from the HIV/AIDS Database.

<sup>&</sup>lt;sup>15</sup> Antiretroviral Treatment in the Spotlight: A Public Health Analysis in Latin America and the Caribbean 2012. Washington, DC: OPS, 2013



Using qualitative studies and grass-roots education methodologies, attention is being paid to the specific requirements and vulnerability that are or might in the future affect women with HIV compared with their male counterparts. On the one hand, differences have been noted in relation to discrimination caused by sociocultural patterns and domestic overload. On the other hand, training groups and workshops have shown that although there are manifestations of gender-based violence in women and men living with HIV, women and homosexual men are the main victims. (These dimensions need to be studied in greater depth in order to respond to them and eliminate the problem).

# People who practice transactional sex

- This group represents 1.5 percent of the population in the 15 to 49 year age group, 2.0 percent of men and 1.1 percent of women between those ages.
- In the 15 to 39 year age group, PPTS are predominantly female and from 40 onwards they are predominantly men, in the proportion of 65 percent males to 35 percent females.
- The estimated prevalence of HIV in this group is 1.3 percent for both sexes, 6.5 times higher than the prevalence in the general population in the 15 to 49 year age group.
- In the MSM population group, PPTS represent 5.2 percent of people in the 15 to 49 year age group.
- Some 72.01 percent of PPTS in the 15 to 49 year age group said that they had used a condom with their last client.
- 24 percent of PPTS in the 15 to 49 year age group who were tested for HIV in the last 12 months knew the results.

#### Young people in the 20 to 29 year age group

In Cuba, for epidemiological, sociocultural and behavioral reasons, the key group "young people" goes beyond 224 years, as is the case in some other regions.<sup>16</sup>

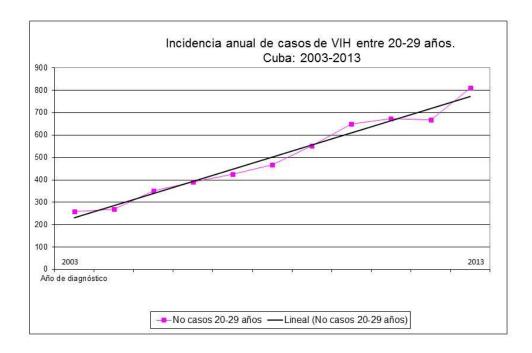
The epidemiological reasons include:

In the last 10 years, annual incidence has followed an upward trend, as shown in the graph below.17

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<sup>&</sup>lt;sup>16</sup> http://www.unesco.org/new/en/social-and-human-sciences/themes/youth/youth-definition/

<sup>&</sup>lt;sup>17</sup> HIV/AIDS Database, MINSAP 2013. Cuba



- Of all cases of HIV diagnosed in the country, 46 percent of sufferers were aged under 30 when they were diagnosed.
- Among young people in the 20 to 29 year age group, the highest number of new infections in the last 6 years has been reported.
- The proportion of female PLHIV in this group (24 percent) is higher than the national average (20 percent).

#### Behavioral reasons:

- Research has shown that young people are still relatively unaware of the risks.
- They continue to practice unprotected sex. Close to 45 percent said that they had not used a condom the first time they had had penetrative sex.
- Youth is the stage of life with the highest level of sexual activity, and reaffirming the importance of safe sex is a vital way of ensuring sexual and reproductive health in men and women.
- Young people switch partners frequently but condoms are not being used systematically.
   More than a third (34.7 percent) have unprotected sexual relations with occasional partners.
- 40 percent had mistaken beliefs or were unaware of the basic aspects of the infection.
- In the 20 to 29 year age group, 64 percent of males and females who had had more than one sexual partner in the last 12 months said that they had used a condom the last time they had sex.
- Only 17.56 percent of men and women in the 20 to 29 year age group had been tested for HIV in the last 12 months and knew the results.

In the last six years, the age groups most affected were still in the 20 to 29 year age bracket. It is vital that we invest strategically in this group in order to reap the maximum benefits, since the sexual behavior that young people adopt now and the behavior that they maintain throughout their sexual life will determine how the HIV epidemic develops in the decades to come. This proposed investment will help us to move one step closer to achieving the collective vision of a world free from the burden of HIV, making the Millennium Development Goals achievable.

# Access to services aimed at prevention, diagnosis and treatment and factors that contribute towards inequality

The National Health Policy is geared towards universal, free and equitable access by the population to these services. To this end, the Program of Comprehensive Care for the Family (Programa de Atención Integral a la Familia) has been developed and refined since the 1980s. In order to develop this program, general practitioners and family nurses have been engaging in activities aimed at promoting health, preventing disease and providing care and rehabilitation in the population that they treat.

The national response to the HIV epidemic is based on social, community and cross-sector intervention. The Operative Group to Tackle and Fight AIDS (Grupo Operativo para el Enfrentamiento y Lucha contra el sida - GOPELS), set up in the 1980s, provides the required crosssector decision-making forum. This group operates at the national, provincial and municipal level. It is presided over at the national level by the Minister of Health and in the provinces and municipalities by the appointed President or Vice-President of the Government. Its members are representatives from all sectors of society, state bodies and civil society organizations, which include representatives of the key population groups.

Universal coverage by primary care health care services ensures that the population has access to diagnostic testing, prevention and treatment for other STIs, advice, family planning and care for PLHIV, among other things.

Being tested for HIV is now culturally acceptable. It is prescribed, subject to consent and counselling before and after, as part of the minimum health care package for the following groups: pregnant women and their partners, persons with other STIs, sexual partners of PLHIV, persons diagnosed with tuberculosis, on request (this includes anonymous tests) and the sexually active population in general.

Between 2.2 and 2.5 million tests are carried out each year, however, there is a problem in that the number of tests reported in one year does not correspond to the number of people who say that they "know their results", which must be related to gaps in post-test counselling. This proposal includes action aimed at improving this statistic.

Citizens of both sexes do not have to pay for health care; it is provided according to peoples' needs and irrespective of their income. The area in which people live, their gender, the color of their skin and other conditions have no bearing on their access to health care, since this is a country of equal rights.

However, in spite of the political will and advances made in terms of legislation, traditional social representations, stereotypes and sociocultural and symbolic constructs do exist in relation to sex and gender (and in terms of what is accepted as and assumed by the concept of "male and female"), and this could limit access to health care services by key population groups.

Pressure and taboos associated with constructs of hegemonic masculinity mean that men are less likely to use health care services, and they frequently report having experienced (or being afraid of experiencing) discrimination or differential treatment because of their sexual orientation or gender identity. In women, domestic overload and their role as carers together with feelings linked to stigmatization and low self-esteem can also prevent them from getting the most out of the health care services that are on offer.

Transgender and PPTS groups may also be paying less attention to their health and using services less because they do not share the gender constructs that society values and recognizes in the most positive light.

It is vital that we continue to work on these subjective aspects, whilst continuing to improve the training for health care personnel, so as to ensure a more effective response to gender-based sociocultural barriers, which also resonate in other social dimensions or structures, such as age, sexual orientation or skin color. The area in which people live also has an impact on how services are used in certain cases.

In the last three years, the focus has been on approaching and eliminating gender inequality. Noteworthy here is the planning and implementation of the gender strategy in support of the educational component of the National Response to STIs-HIV/AIDS, <sup>18</sup> demonstrating the need to pay particular attention to the creation of a theoretical, methodological framework relating to gender, sexual diversity and STIs-HIV/AIDS, whilst improving education, training and communication on topics related to gender and STIs-HIV/AIDS, designing and implementing a monitoring and evaluation system that is mindful of these issues, and creating environments that are conducive to gender equality in the prevention of STIs-HIV/AIDS.

# The health systems and community systems context

The first level of health care is the point of entry to the National Health System. There are more than 11,000 medical practices in the country, located within the community and run by one or more general practitioners and family nurses, and covering 100 percent of the population, including the most remote areas.

The Family Medicine Program is applied in all medical practices, including special sub-programs focusing on areas that are prioritized in the country's health policy, such as the prevention and control of STIs-HIV/AIDS. GP practices are overseen and supported by 451 polyclinics considered as the bedrock of the national system, focusing as they do on comprehensive health care for men and women, the family and the community, in a sociological, geographical and demographic space known as an Area Health Centre, which incorporates a range of institutions operating under the auspices of the polyclinic and caring for 25,000 to 30,000 inhabitants on average. The institutions integrated in the Polyclinic include community pharmacies in which condoms and distributed and antiretroviral drugs are dispensed free of charge.

Comprehensive care for persons living with HIV is part of the family medicine program, thereby ensuring access to services and guaranteeing that these people are cared for at every level of the health care system. This is achieved through the work of doctors and nurses working in medical practices and staff providing other services at polyclinics (psychology, social work, dermatology, family planning and stomatology, among others), to which all persons living with HIV have access.

Special staff (STI nurses) have been trained to provide direct care for STIs. These STI nurses are in every polyclinic in the country, and they are trained in communication, interview and epidemiological analysis techniques and how to draw up regular reports, patient care and guidance, locating and analyzing contacts, health care education in the community, how to administer treatments, counselling, techniques aimed at monitoring compliance with treatments in the community and support for PLHIV.

Specialist care and monitoring is also offered to persons living with HIV by medical staff with suitable training from other municipal and provincial health care services and from the network of hospitals.

#### Monitoring ART Optimization

All persons diagnosed as being HIV positive will be referred as quickly as possible for Comprehensive Care. They will be informed of their diagnosis at the polyclinic at the corresponding

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<sup>18</sup> Estrategia de género en apoyo al componente educativo de la Respuesta Nacional a las ITS-VIH/sida [Gender strategy in support of the educational component of the National Response to STIs-HIV/AIDS], CNP, Havana, 2012

area health center and registered at their local medical practice within 30 days following confirmation of the diagnosis. The first consultation will take place immediately once the diagnosis has been confirmed, and from that point onwards their care will be addressed at the different levels of the health care system, according to the individual needs of each person.

At the first consultation, a clinical monitoring program will be established, applying the criteria of continuous assessment and risk evaluation established in the program for general practitioners, which includes immunization schemes, TB research, risks prior to conception (for women), the risk of other STIs, nutritional assessment and tests of CD4 levels and viral load, as well as the routine examinations and tests included in the Plan. The patient will also be referred for psychology consults and counselling, working in conjunction with mutual self-help teams.

Once all of the complementary care has been provided and the action that corresponds to the first consultation has been completed, the GP will present the patient's case to the Basic Working Group at the area health center (GBT), which corresponds to the specialist appointed by each territory to provide specialist evaluation, classification and monitoring.

The clinical monitoring plan, the procedures to be adopted (consisting essentially of criteria for the commencement of ART) and the process of monitoring compliance will be in accordance with the patient's classification, based on stages defined by WHO and CD4 levels which prioritize those PLHIV with CD4 of less than 500 cells per mm3.

There are STI/HIV/AIDS groups at the provincial and municipal level implementing activities at every level, aimed at the prevention and control of STIs/HIV/AIDS. A protocol has been developed for action to be taken under the program, and the necessary working relationships have been established between the national and local levels in order to ensure that the program's information, monitoring and evaluation systems function properly.

Community work is coordinated by provincial and municipal GOPELS, and technical support is provided by STI/HIV/AIDS groups. As a result of projects funded by The Global Fund, community centers dealing with HIV/AIDS have been strengthened. These include: guidance centers for women and the family, run by the Federation of Cuban Women (Federación de Mujeres Cubanas), territorial STI/HIV/AIDS centers, which have taken under their wing community organizations of all key groups, such as Self-Help Teams (EAM) and promoters of MSM, young people, women and PPTS.

Community projects with regional scope are being developed, and key population groups are being allowed to get involved in their design, implementation and monitoring. These include the Afrodita project (beauty salon and STI/HIV/AIDS prevention). The area health center provides a friendly environment for persons living with HIV, young people, MSM and PPTS, and it is there, through the GP and Family Nurse Program, that the country channels most of its efforts and resources aimed at improving the health of the population, by means of comprehensive action geared towards the individual, the family, the community and the surrounding area. This is also creating a favorable scenario, in support of the mission and vision of the Support Line for PLHIV, as well ensuring that projects geared towards MSM, young people and women have the desired impact. Through the alliance between GP practices, the Basic Working Groups at area health centers and Polyclinics working relationships geared towards care, support and prevention of STIs and other diseases are being established and included in local initiatives, community projects and the generation of independent projects and projects funded by the Global Fund (Carrito por la vida, mobile training units, Expovida, Callejón de la ceiba, Cursando el Barrio, Premios Esperanzas and Quisicuaba, among others).

The second level of care consists of the network of hospitals that are integrated into other institutions that provide staff training, service providers and institutions responsible for production.

The third level of care is represented by 13 national institutes and 3 hospitals that serve as a benchmark and cover care functions, staff training and high-level research in the country. These

include the Pedro Kouri Institute of Tropical Medicine (Instituto Pedro Kourí - IPK), which is a center of excellence for the clinical care of PLHIV.

# 1.2 National Disease Strategic Plans

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

- a. The key goals, objectives and priority program areas.
- b. Implementation to date, including the main outcomes and impact achieved.
- c. Limitations to implementation and any lessons learned that will inform future implementation. In particular, highlight how the inequalities and key constraints described in question 1.1 are being addressed.
- d. The main areas of linkage to the national health strategy, including how implementation of this strategy impacts relevant disease outcomes.
- e. For standard HIV or TB funding requests<sup>19</sup>, describe existing TB/HIV collaborative activities, including linkages between the respective national TB and HIV programs in areas such as: diagnostics, service delivery, information systems and monitoring and evaluation, capacity building, policy development and coordination processes.
- f. Country processes for reviewing and revising the national disease strategic plan(s) and results of these assessments. Explain the process and timeline for the development of a new plan (if current one is valid for 18 months or less from funding request start date), including how key populations will be meaningfully engaged.

Before this concept note was drafted, the national strategic plan (PEN) was reviewed and updated.

The aim of the national strategic plan for the prevention and control of STIs and HIV/AIDS for the period 2014-2018 is to reduce the incidence of sexually transmitted infections and HIV in Cuba, through universal access to health care, treatment and prevention services.

The specific objectives are:

- 1. Improving monitoring and epidemiological control of sexually transmitted infections and HIV.
- 2. Encouraging equal access to basic diagnostic, health care, treatment, monitoring and support services.
- 3. Promoting the strategic management of human resources and skill building.
- 4. Strengthening the response to the HIV epidemic by the different sectors of society and civil society, fostering gender equality and respect for the different sexual orientations and gender identities.
- 5. Promoting responsible sexual conduct in the key groups most at risk and in the general population, through information, education and communication-based activities.

The following key results areas will be developed as a means of approaching the specific goals:

- Monitoring and protecting the health of the general population, with an emphasis on the key most at risk population groups.
- Comprehensive health care for individuals, families and the community
- Management and training of human resources
- Clinical research

-

<sup>&</sup>lt;sup>19</sup> Countries with high co-infection rates of HIV and TB must submit a TB and HIV concept note. Countries with high burden of TB/HIV are considered to have a high estimated TB/HIV incidence (in numbers) as well as high HIV positivity rate among people infected with TB.

- Cross-sector management
- Information management and management

The national strategy was approved in December 2013 by the Executive Committee of the Cuban Ministry of Health, the national Operative Group to Tackle and Fight AIDS, and shared with the Country Coordinating Mechanism (CCM).

During the first months of 2014, the focus was on activities related to the implementation of the strategy: presentation at national program meetings, provincial boards, national meetings of key groups, networking with key actors and cross-sector exchanges, among others.

The principal changes that implementation of the national strategic plan will entail are as follows:

- Maximizing the benefits of antiretroviral treatment as a means of preventing new infections, adapting the national ART guidelines to bring them in line with the current recommendations from WHO, changing the criterion for commencing ART (fewer than 500 CD4 cells).
- Full withdrawal of ARVs that are not recommended by WHO (stavudine and indinavir).
- Scaling up STI-HIV/AIDS prevention in MSM and other groups as well as increasing the participation of that community.
- Consolidating the gender strategy, fostering respect for and non-discrimination for gender identities and promoting a change of attitude in the general population in relation to the models and roles that are contributing to risk behavior in relation to STIs and HIV/AIDS.
- Fostering better understanding of transactional sex among men and women and developing a suitable program to reduce the harm caused.
- Consolidating integration between health care teams and civil society groups, sharing leadership over the educational approach for key population groups.
- Increasing early diagnosis by improving the process of active case seeking, pre- and post-test counselling at all levels of the health care system.
- Informing health services of confirmed diagnoses, improving the network of laboratories and developing collaborative activities involving health services and key population groups to increase early diagnosis and to ensure that members of these key groups get the care and monitoring that they require.

Moving forward with these projects will mean improving the quality of care and the quality of life of persons living with HIV, offering medicinal products that are recommended by WHO and reducing the number of treatment regimens, with a smaller quantity of tablets to be consumed each day. It will also encourage participation by key groups at greater risk and promote a reduction in stigmatization and discrimination against MSM, transgender persons and PLHIV.

Specifically in the case of PLHIV, it will mean paying greater attention to the different requirements of men and women living with HIV and the gender inequality that is preventing a more effective response to the epidemic. It will also be important to test males (homosexual men and other men who have sex with men) and in particular young people, promoting gender equality and eliminating the gaps that exist in relation to sexual orientation and gender identity.

The national health strategy includes five strategic goals:

- 1. Improving the health of the population and increasing the level of satisfaction with the services on offer.
- 2. Consolidating action relating to hygiene, epidemiology and microbiology and strengthening health monitoring.
- 3. Regulating the health care sector.
- 4. Consolidating training and research.
- 5. Complying with the different procedures arising from international cooperation involving the Cuban Health System.

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The strategic objectives of the sector enhance the performance of the national strategic plan whilst outlining the policy that guides and drives the scaling up planned for the 2014-2018 period.

The transformations that are taking place in the health sector, aimed at improving the health of the population and increasing the level of satisfaction with the services on offer, are the driving force behind the national strategic plan's efforts relating to equal access to health care, treatment and support. The training of human resources is also being improved, as is the process of embedding the national strategy in national systems for planning, procurement and supplies, as well as monitoring and evaluation.

The national HIV/AIDS information system offers reliable data, almost in real time, and it is completely integrated into the national health care information system. The national strategy defines the reporting responsibilities and obligations of the national units and regions, which in turn ensures that they have access to the information required for the implementation of this proposal. The information will continue to be broken down according to sex and age, and that breakdown will be strengthened in the pertinent indicators and scales, so as to ensure an in-depth gender and generational analysis.

The Cuban Ministry of Health was responsible for coordinating the updating of the national strategy, through the national program for the prevention and control of STI-HIV/AIDS and the participation of civil society (persons living with HIV, men who have sex with men, projects for young people and women), the different sectors of society and other organizations involved in the cross-sector response include: the National Office of Statistics and Information, the Council of Churches, the academic sector and international organizations.

The process of updating the national strategic plan involved mobilizing and securing the participation of actors from different fields, who brought with them a wealth of experience from their spheres of influence, in the interests of planning a more effective response, in accordance with the country's economic and social policy and in conjunction with regional and international HIV/AIDS strategies.

The Estrategia de Género en apoyo al Componente Educativo de la respuesta nacional a las ITS-VIH/sida (Gender-based strategy in support of the educational component of the national response to STI-HIV/AIDS), as a public policy document, and the *Grupo Gestor para la Promoción de la Igualdad de Género en la prevención del VIH* (management group for the promotion of gender equality in the prevention of HIV) as a management and implementation mechanism, were vital to the process of updating the national strategic plan.

Participation took the form of meetings, according to a schedule for the preparation of information and bilateral and group consultations as the participants completed their respective sections. Video conferences were held with provincial groups, in addition to face-to-face meetings with representatives from the different areas, a presentation to the Operative Group to Tackle and Fight AIDS (GOPELS) and the CCM, and forums at which state bodies, the different sectors of society, multilateral organizations and civil society were represented.

An evaluation of the strategy is planned for the start of 2017.

# SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

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

# 2.1 Overall Funding Landscape for Upcoming Implementation Period

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

- a. The availability of funds for each program area and the source of such funding (government and/or donor). Highlight any program areas that are adequately resourced (and are therefore not included in the request to the Global Fund).
- b. How the proposed Global Fund investment has leveraged other donor resources.
- c. For program areas that have significant funding gaps, planned actions to address these gaps.

In line with economic policy, the following activities have been planned in the field of Public Health in the coming years:

- Raising the quality of service provision, and ensuring the satisfaction of the population and improving working conditions and the care offered to health care professionals. Guaranteeing that resources are used efficiently, making savings and preventing unnecessary spending.
- Reorganizing and rationalizing health care services and making them more regional, according
  to the needs of each province and municipality, including emergency care and the ambulance
  service. Guaranteeing that within the health system it is easy for every patient to receive the
  care that he/she needs and that it is of the required quality standard.
- Strengthening health-related promotion and prevention activities geared towards healthier lifestyles, contributing towards improving the health of the population, with cross-sector and community participation.

For that reason, this proposal does not contain any action that requires funding for clinical research and information and knowledge management, since those areas benefit from resources provided by the Government.

In monetary terms, the budget allocated by the Government covers the following costs:

- Salaries and other payments to health care personnel (specialist doctors, staff members with master's degrees in different fields and nursing and health technology graduates, as well as general technical staff, among others).
- Costs relating to premises and facilities used for treatment, prevention and care (GP and family nurse practices, polyclinics, local, territorial, regional and national laboratories, research facilities, rehabilitation centers, municipal and provincial hygiene, epidemiological and microbiology centers, hospital consulting rooms, admissions rooms, centers providing comprehensive care for persons living with HIV, maternity homes, among others).
- The cost of electrical energy, water, telephone and gas for all health care facilities.
- Costs relating to other personnel not linked to the health care sector but working on the epidemic (workers from other sectors with functions that include food distribution, the distribution chain for medicinal products and reagents, voluntary personnel in the field of prevention who receive their salaries through the organizations to which they belong, among others)
- The 100 percent state food subsidy for children and adults of both sexes who are living with HIV.
- Research into the epidemic, second generation monitoring surveys and specific studies, salaries of survey takers and technical personnel in charge of running thee surveys. This also includes the cost of research conducted by institutions in the country who share their results for the benefit of the national strategy.
- Medicinal products and technology produced in the country and offered free of charge to the population and to persons living with HIV: (the Ultra Micro Analytical System - SUMA, which sustains the program of research into HIV and ART, among others).

The global economic crisis and the economic and financial embargo imposed on Cuba for more than 50 years are affecting the availability of the resources required in order to implement the plan. The resources received from the Global Fund are having the greatest impact in terms of closing the gaps in State funding, compared with the contribution of other donors.

In the last 12 years, these funding gaps have been closed with the financial support of the Global Fund, accompanied by the national strategy, and in turn the country has increased its contribution as it moves towards greater sustainability. However, there are aspects within those program areas that require funding that is not totally covered and that form part of the activities to be prioritized in this proposal. These are outlined below.

Monitoring and protecting the health of the general population, with an emphasis on the key most at risk population groups.

- Acquiring antiretroviral drugs to cover the gap arising from persons who are not receiving treatment in accordance with WHO recommendations, maximizing the benefits of antiretroviral treatment as a means of preventing new infections and continuing with the plan for the gradual removal of medicinal products that are not recommended. PLHIV undergoing ART covered by the program represent between 26 and 29 percent, inasmuch as the proposal will cover those PLHIV who have in their treatment regimen at least one medicinal product acquired using the new funding, reaching between 46 and 49 percent. With this support, the program will be providing cover for between 75 and 78 percent by 2017. This corresponds to 100 percent of PLHIV who are estimated to need ART in the period 2015-2017.
- Acquiring new reagents in order to monitor a higher number of persons undergoing treatment and detect resistance to antiretroviral drugs. This is necessary in order to ensure the effectiveness of this treatment, which is being offered to a significantly higher number of people, whilst bringing the process of diagnosis closer to primary health care services, strengthening the network of health care services and its dealings with the key population groups, so as to increase early diagnosis, access to care, compliance and follow-up care. In order to ensure effective follow-up and availability of the necessary reagents in the necessary timeframe, and with a view to strengthening the network of health care services, the Government is making significant monetary resources available and the funding received down through the years from the Global Fund has also been of vital importance, however there are additional funding gaps of around US\$ 4,884,187, as detailed in the following tables:

Gaps in follow-up care and monitoring of PLHIV

Details		CD4		V	L (viral loa	d)	F	Resistance	
Details	2015	2016	2017	2015	2016	2017	2015	2016	2017
Requirement	32,53	36,11	39,80				600	630	650
	4	9	0	31,633	35,181	38,834	000	030	030
Covered by	12,00	12,80	13,80						
National	0	0	0	12,600	14,080	15,560	100	130	150
Program	U	0	0						
Covered by	15,00	18,60	23,00						
the Concept	0	0	20,00	14,224	16,240	20,800	300	300	300
Note	U	U	U						
Total	27,00	31,40	36,80						
coverage	0	0	0	26,824	30,320	36360	400	430	450
(*)									
Programmati	5,534	4,719	3,000	4,809	4,861	2,474	200	200	200
c gap									
(**) Funding	88,81	75,74	48,14	604,88	611,39	311,12	70,00	70,00	70,00
gap	5	5	4	5	5	9	0	0	0

<sup>(\*)</sup> Quantity of tests required to cover the gap

<sup>(\*\*)</sup> Total amount required in order to cover requirements per year.

# Gaps in terms of the strengthening of the network of health care services

Details	2015	2016	2017
		Medicinal products for the treatment of these diseases	Medicinal products for the treatment of these diseases
Opportunistic Diseases	Reagents for molecular diagnosis	1 Real time PCR machine (Rotor-Gene) and real time PCR reagent kits (Argene-MWS r-gene)	2 Vitek machines and 1 Bac/alert kit
Radiology	1 multislice CT scanner	1 C-arm device	1 Ultrasound machine
Cytometry		1 flow cytometry	2 flow cytometry
		device	devices
3 laboratories for the	Panels, reagents and	1 flow cytometry	
decentralization of	non-durable goods	device	
confirmation of HIV	for the new		
infection	laboratories		
Funding gap	815,047	849,879	998,704

# Gaps in the distribution chain and storage of health care products (equipment, supplies and others)

Details	2015	2016	2017
Distribution and storage of health care products		Refrigerated trucks and air conditioning equipment	Hoists, pallets, trolleys, shelves
Funding gap	-	270,445	86,492

# To summarize, the additional funding gaps are as follows:

Details	2015	2016	2017
CD4	88,815	75,745	48,144
VL (viral load)	604,885	611,395	311,129
Resistance	70,000	70,000	70,000
Opportunistic diseases	15.047	141,582	141,582
Opportunistic diseases	15,047	160,317	320,630
Radiology	800,000	200,000	250,000
Cytometry		100,000	200,000
Laboratories for the decentralization of HIV infection		247,980	
Distribution and storage of health care products		270,445	86,492
Total additional funding gap	1,578,747	1,877,464	1,427,977

# Comprehensive health care for individuals, families and the community

- Consolidating the educational activities aimed at key population groups, strengthening their awareness regarding serological status and condom use, whilst heightening their risk perception, increasing access to forums, supplying educational materials, condoms and lubricants and offering HIV tests with counselling.
- Broadening the preventive focus of compliance, improving the participation of health care teams in alliances with the support structure for persons living with HIV.
- Optimizing the tools available for the approach towards serodiscordant couples.
- Strengthening the focus on rights in relation to manifestations of stigmatization and discrimination towards PLHIV, MSM and transgender persons.
- Cultural instruments are being used to great effect in the strategy in order to promote a change in attitudes in terms of the general population's perception of gender. Non-formal education, popular consumption and cultural and creative industries are helping to propagate stereotypes based on inequality, which legitimize certain types of gender-based violence: property-related violence, psychological abuse, etc.
- Consolidating the gender strategy in the educational component by encouraging a change of attitudes in the general population towards behavior that carries a risk of STIs and HIV/AIDS, and the models and roles that are contributing towards a lack of respect and other vulnerabilities affecting men and women with different gender identities. Particular attention is being paid to: sexist stereotypes relating to sexuality, the dominance of hegemonic masculinity and associated behavior, the obstacles to achieving negotiating power when it comes to using condoms and manifestations of gender-based violence and its link to HIV/AIDS.
- Fostering better understanding of transactional sex among men and women, and developing a suitable harm reduction program.
- Strengthening strategies based on the local response and participatory models in which key population groups design, implement and evaluate suitable strategies.
- Consolidating integration between health care teams and civil society groups, enabling them to share leadership over the educational approach to key population groups.
- Ensuring that all areas of the program are involved in providing technical and professional training for working teams in prioritized provinces and municipalities, whilst improving procedures for identifying key population groups and ensuring that they are monitored and provided with follow-up care by basic health care teams.
- Developing the technical skills of STI-HIV/AIDS nurses at area health centers in prioritized municipalities, whilst improving the performance of these staff members as a central figure in the program within the Primary Health Care system.

All of these activities in the new proposal are geared towards supporting the national effort, and their contribution is shown in Table 2.

For Cuba, the sustainability of intervention proposed down through the years in relation to previous grants has been a major challenge, given the economic limitations that the country has been facing. However, we have made progress on matters relating to the planning, focus and prioritization of strategies that are having a greater impact on the epidemic.

Following the experience gleaned in the previous period the Cuban brand of condoms, "Vigor", was registered and introduced in the country with the help of the Global Fund and the Ministry of Health. At the end of the Round 6 project, the Government committed to purchasing these condoms in sufficient quantities for the rest of the country, taking into account the fact that the RCC (Rolling Continuation Channel for Global Fund grants) only covers three provinces. This proposal only provides for the acquisition of free sample condoms, and the Government's contribution will be used to continue purchasing Vigor condoms, in larger numbers each year.

One of the most important advances in terms of commitments established and part of the legal framework, is Ministerial Resolution 139/2011 of the Minister of Education, approving and implementing the Sex Education Program, focusing on gender and rights, which now forms part of the basic, special and elective teacher training curricula and the post-graduate development studies offered to management and all teaching staff. It is also included in educational and extracurricular activities for students and also in family education schools and guidance forums, with the support of other sectors and organizations. Likewise, progress has also been made in relation to planning tools, the cross-cutting expansion of activities, capacity-building aimed at the inclusion of new material in the curriculum, as well as the implementation and coordination of materials and activities, as a result of all of which this proposal requires less funding in this area.

Another aspect that has been left out of the proposal is the purchase of dietary supplements, which was included in all previous projects. The country's politicians have decided to continue helping PLHIV to achieve the required nutritional balance.

The same is true of the purchase of rapid HIV tests, which were at one point being purchased using funding from the Global Fund. For the last three years, they have been available in sufficient quantity to carry out testing throughout the country, and only a very small quantity are included in this proposal, for a one-off study of transgender groups.

A similar situation has arisen regarding the purchase of medicinal products for co-infected patients who are monoresistant or multiresistant. From now on these products will be covered in the national budget.

This proposal also excludes the Federación de Mujeres Cubanas (FMC) [Federation of Cuban Women] as part of its cross-sector response. This is an NGO that has in the past received financial support from the Global Fund as part of all previous projects. It is aimed at training female developers and building their skills, and today it designs and implements its activities according to the problems, interests and needs of Cuban women, with a focus on gender and taking into account the human capital that these women offer. It does not require additional funding.

Similarly, the National STI-HIV/AIDS Program has an IT system, implemented in 2009 with the financial support of the Global Fund. Since 2011, it has been sustained by domestic funding, including software improvements in the last two years aimed at ensuring optimum functionality and the efficient registration of PLHIV throughout the country. During its visit in November 2011, the OIG classified this system as very good.

Implementation of WHO recommendations began in 2012, with the withdrawal of indinavir and stavudine from the preferred first-line treatment regimens in the national guidelines. The number of PLHIV receiving this medicinal product has been reduced, and a plan has been established for its phased withdrawal, which is being monitored. Talks are also underway with the pharmaceutical industry in Cuba in order to increase the local production of antiretroviral drugs, and the output of drugs that are already in production, in response to the growing demand.

Likewise, CECMED (National drug regulatory authority) has been the focus of capacity-building activities aimed at complying with the Plan de Aseguramiento de la Calidad de los Medicamentos (Plan for the Quality Assurance of Medicinal Products) approved by the Global Fund, as a requirement for approval of the proposed purchase of antiretroviral drugs. For antiretroviral drugs in 2013-2014, this analysis was outsourced to an international laboratory, since there is no specialist laboratory of this type in the country. However, in 2015 it is due to be conducted by a Cuban laboratory which is currently undergoing certification.

In spite of all of these areas of progress, significant steps are still being made today towards ensuring the sustainability of the program's activities, prioritizing those that have the greatest impact and in which we intend to invest. As a result, we are expecting a greater contribution from the Government towards the purchase of reagents (CD4 and viral load tests) for the monitoring and care of PLHIV, gradually, until all requirements are covered, as well as considerable efforts by our national industry to cover more and more of the requirement for antiretroviral drugs, under the limitations imposed by our current economic situation and depending on external factors such as the embargo and the global economic crisis.

# 2.2 Counterpart Financing Requirements

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

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

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

- b. Compared to previous years, what additional government investments are committed to the national programs in the next implementation period that counts towards accessing the willingness-to-pay allocation from the Global Fund? Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.
- c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.

At the moment the country is investing around 58 million pesos in the procurement of medical equipment and maintenance (including spare parts) to improve the quality of health care at all levels, from primary care to tertiary care. This is helping to bring about an improvement in care for persons living with HIV and boosting the performance of the HIV/AIDS program. Since health care services in Cuba are offered free of charge and access is universal, any investment that is made or planned at any point brings better quality care for all persons, irrespective of their serological status.

During 2013 and so far in 2014, the Cuban Ministry of Health approved an investment of 11.6 million pesos for the technical development of CECMED (the national regulatory authority for medicinal products and medical equipment). From that figure, 2.5 million pesos were allocated for the setting up of a laboratory for quality control of medicinal products. The laboratory is now finished and awaiting accreditation by WHO. This strategy of monitoring the quality of medicinal products is

described in the Quality Assurance Plan approved in 2013 by the Global Fund. The laboratory has entered the certification phase and is expected to become operational in 2015. Therefore any costs incurred will be met by national funding.

This year, the ministry allocated 3 million pesos for the purchase of condoms and a further 200,000 will be used for the storage and distribution of condoms at the national level and to outlying areas. These contributions increase each year, according to the requirements provided for under the program.

In addition, a wage increase for health care workers has been approved, and this is affecting the budget allocated to the HIV program in the order of around 6 million pesos.

Each year the amount of funding allocated to the HIV program increases, and a large portion of those funds is used to ensure national production of antiretroviral drugs used in combined regimens with antiretrovirals purchased with funding from the Global Fund, according to the protocols approved in 2013 by the Cuban Ministry of Health with the endorsement of WHO.

With the standardization of Strategy 2.0 and the new treatment rules approved by UNAIDS and WHO, the following will be requested by the SNS (National Health System):

- 1. Greater investment in the Cuban pharmaceutical industry to ensure growing coverage by antiretroviral drugs produced domestically.
- 2. Increased human and financial resources to support the monitoring and treatment of new cases for which this strategy is requesting cover.
- 3. Increased coverage of reagents and the equipment required for the virological and immunological monitoring of all patients undergoing ART.

The organizational structure of the Ministry of Health includes a *Dirección Nacional de Economía* (National Directorate of Economics), from which health spending at the national level is controlled and validated, along budgetary lines, as established in the accounting rules issued by state bodies in their accounts classifier. This information is drawn up, checked and certified by the directorate and sent regularly to the National Office of Statistics and Information. In addition, pursuant to this proposal, that same information will be sent to the Global Fund on an annual basis, in the second fortnight of February each year, following the close of the financial year, as agreed between the parties following consultations with the Portfolio Management team.

# **SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND**

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

# 3.1 Programmatic Gap Analysis

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

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

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

The process of updating the national strategic plan was the subject of a programmatic gap analysis and provided a platform for identifying projections for the period 2014-2018 and for the identification of priorities to be taken into account for this concept note.

The process benefited from heavy involvement by civil society (PLHIV, MSM, youth projects and women), the various sectors of society and other organizations involved in the cross-sector response, such as the National Office of Statistics and Information, the Council of Churches, the academic sector and international organizations.

Taking as a focal point the programmatic gaps identified when designing the national strategic plan, the country selected three priority modules, two associated with preventative measures among key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities, in which prevalence in those age groups is double the figure for the country as a whole) and a third module to cover the gaps relating to the care, treatment and support provided to PLHIV.

Module 1: Prevention programs for MSM and transgender persons

Module 2: Prevention programs for other vulnerable groups (persons living with HIV and young people in the 20 to 29 year age group)

Module 3: Treatment, Care and Support. The work has been designed to include the following intervention:

The prioritization of these modules was the results of collective analysis carried out through meetings, workshops, work groups, circulating documents and gathering feedback. The program and partners of the national response took into account the available epidemiological information, the estimates produced and submitted to UNAIDS in 2014 during the Global AIDS Response Progress Reporting (GARPR) period, monitoring and evaluation reports relating to previous grants and from the national program, and an analysis of the results from research conducted. Technical support was also provided by certain areas within MINSAP, the national HIV/AIDS technical committee, different sectors of society, with the political endorsement of GOPELS and the contribution of other technical partners and resident United Nations agencies such as PAHO, UNFPA, UNICEF, WFP and UNESCO. At a meeting of the CCM on 28 March 2014, the selected modules were presented and approved by participating members.

The targets and estimates used to identify programmatic gaps in the prioritized modules stemmed from an analysis of the information compiled during the process of updating the national strategic plan, during the 2014 GARPR period and when drafting the country's report for the certification of the eradication of mother-to-child transmission of syphilis and HIV. The data used in the aforementioned reports was obtained from the HIV/AIDS Database, the 2013 statistical yearbook on health, projected figures for PLHIV requiring ART per treatment line and according to new national guidelines, the Spectrum projections system, the results of the 2013 survey on HIV prevention indicators and the PLHIV survey of 2013.

In the prevention modules, the principal gaps that were found to be preventing the goals of the national strategic plan from being reached and that are to be covered by the proposal are shown in Table 2. They relate to: key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the national figure) who are only being covered by a minimum package of services focused on behavior change, carrying out HIV testing and counselling which are being provided through programs targeting key population groups, and MSM, transgender persons and young people in the 20 to 29 year age group who practice transactional sex and who are covered by interventions aimed at reducing harm through programs for sex workers and their clients.

In module 3, "treatment, care and support for PLHIV", the main gap is associated with: the purchase of antiretroviral drugs that allow ART regimens to be standardized and optimized, the task of getting that process off the ground according to recent national guidelines issued in line with WHO recommendations, phasing out antiretrovirals that are not recommended, improving compliance, reducing the cost of medicinal products and complying with the commitments undertaken by the country with the Office of the Inspector General of the Global Fund, whilst adhering to strategy 2.0. The failure in reaching the goals of the national strategic plan and in being able to treat all PLHIV who require treatment is quantified in Table 2 of the proposal. This proposal aims to cover one hundred percent of patients who require ART each year.

In the "treatment, care and support for PLHIV" module, priority is also being given to other gaps that are reducing as a result of the proposal but that cannot yet be covered fully with the allocated budget. Gaps associated with TB/HIV co-infection and follow-up and monitoring for PLHIV have been identified as priorities for inclusion in the proposal.

Associated with these shortcomings, in the context of the TCS-2, TCS-3, TCS-4 and TB/HIV-2 indicators shown in Table 3, it is difficult to quantify how the grant from the Global Fund is contributing towards reaching the goals of the national strategic plan, which is why in Table 3 they are linked to the national program (national contribution and contribution from the Global Fund) and the established goals are those that the country has proposed reaching and that appear in the national strategic plan.

In the case of the indicator for TB/HIV-2 co-infection, in order to ensure ART for patients co-infected with HIV/TB, the contribution of the grant provided by the Global Fund towards reaching the goals of the national strategic plan (97 percent in 2015, 99 percent in 2016 and 99 percent in 2017) is associated with the purchase of antiretroviral drugs, in this particular case efavirenz, since the other antiretrovirals used in the regimen (AZT-LAM-EFV) are produced domestically.

The gaps in follow-up care for PLHIV included in the proposal are associated with the purchase of reagents and expendable supplies for CD4 and viral load testing. This grant will be used to purchase 56 percent in 2015, 59 percent in 2016 and 63 percent in 2017 of CD4 reagents required in order to perform 2 tests each year on PLHIV undergoing ART. In terms of the reagents required in order to perform 2 viral load tests each year on PLHIV who are on ART, this grant will be used to fund 53 percent of these purchases in 2015, 54 percent in 2016 and 57 percent in 2017. There are also plans to support the national program with resistance and hematological studies. The shortcomings covered by the proposal in relation to resistance studies are associated with the purchase of a class 2 biological safety cabinet, a thermal cycler for 96 samples, two electrophoresis chambers and accessories, and the reagents required in order to carry out 300 resistance studies each year. In order to ensure that the gaps relating to hematology are covered, there are plans to purchase an ABX Micros 60 hematology analyzer, two dehumidifiers, one pH meter, two OLYMPUS microscopes, one real time PCR machine (Rotor-Gene), one spectrophotometer (Zuzi 4211/50), as well as reagents and expendable supplies.

In addition to the three priority modules mentioned, it was deemed prudent to add a fourth module: "Program Management". The activities being implemented as part of this module include management and monitoring and evaluation of the grant. This work is being carried out jointly by the project management units included by recent principal coordinator UNDP, the National Office of Statistics (ONEI), the National Project Office (ONP) and MINSAP. Each of these organizations has its own part to play in the proposal. As Principal Recipient, UNDP oversees the system for monitoring capabilities and promotes its strengthening. It also ensures that project expenditure is in accordance with the annual work plans and the UNDP and Global Fund rules, and is responsible for general monitoring of the project, supervising activities that have a greater impact on the results and submitting regular reports to the Global Fund. ONEI is the body responsible for managing the flow of information pertaining to the results of the projects and carrying out regular studies. This includes assisting sub-recipients when drafting their M&E plans, gathering information and

evaluating indicators, drafting reports on progress made in the program, which it submits to UNDP and the Global Fund, and conducting probabilistic modelling at the national level, aimed at evaluating the projects. This includes designing, surveying, loading, validation, processing, analyzing and drafting a report on the results. The ONP represents and organizes project subrecipients in relation to the planned activities, striving continuously towards compliance with the expected outcomes, the stipulations set out for the different working processes and ensuring that funds are used properly. It also supervises and evaluates this entire process. It receives, revises and processes all documents in the flow of financial and program-related information, together with the PR. MINSAP is responsible for ensuring that all activities correspond to the national strategic plan. It proposes corrective action where necessary, according to the behavior of the epidemics and the interests that it is tasked with protecting. It provides guidance for regional program directors on cross-sector coordination with sub-recipients in its sphere of activity and on the supervision of activities and working processes, and it also provides technical advice. It is important to stress that the alliances and synergies achieved between these bodies have contributed towards the positive results obtained in relation to previous Global Fund grants in Cuba.

The additional gaps that are not covered by the proposal and for which additional funding of US\$ 4,884,187 will be requested are detailed in section 2.1. They are associated with requirements for reagents for viral load and CD4 testing that will cover the additional gap to ensure follow-up care for PLHIV, in accordance with the international recommendations and national guidelines, in an attempt to mitigate the migration of patients to second-line treatment and in order to comply with WHO treatment strategy 2.0. They are also associated with the purchase of reagents for resistance testing, which have an impact on the effectiveness of the treatment, the purchase of reagents for molecular diagnosis and medicinal products used to treat opportunistic diseases, which contribute towards the quality of life and survival of patients. Finally, the additional gaps in question are also associated with the strengthening of the network of health care services and laboratories that can confirm diagnoses, increasing the decentralization of care and access to care by PLHIV, and with the strengthening of the distribution chain and storage of health care products, to ensure an uninterrupted supply at delivery points for medicinal products.

# 3.2 Applicant Funding Request

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

Cuba is submitting this request based on the allocated amount of US\$ 21,820,228, of which US\$ 1,987,824 corresponds to the pending disbursement from the current grant, and the remaining US\$ 19,832,404 has only been scheduled for the period 2015-2017.

In the light of the funding that is available for this period and the programmatic gaps in the national strategic plan, and in order to strategically plan investments so as to maximize their effect, a collective analysis was carried out by the national program with a view to identifying the priority modules and interventions that will enable the achievement of the defined objectives.

The analysis was based on the available epidemiological information, estimates produced during the 2014 window for GARPR reporting to UNAIDS, an analysis of the results of previous research, and the monitoring and evaluation reports relating to previous grants and the national program. The process also benefited from the heavy involvement of civil society (PLHIV, MSM, youth projects and women) and other organizations involved in the cross-sector response, such as the National Office of Statistics and Information, the Council of Churches and the academic sector, with technical support from areas within MINSAP, the national HIV/AIDS technical committee and various sectors of society, as well as the political endorsement of the Operative Group to Tackle and Fight AIDS and contributions from other technical partners and resident United Nations agencies: PAHO, UNFPA,

UNICEF, WFP and UNESCO. At a meeting of the CCM on 28 March 2014, the modules selected were presented and approved by participating members.

Taking as a focal point the programmatic gaps identified when designing the national strategic plan, the country selected three priority modules, two associated with the work on prevention among key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities, in which prevalence in those age groups is double the figure for the country as a whole) and a third module chosen to tackle gaps relating to the care, treatment and support provided to PLHIV. In addition, it was decided that it would be a good idea to add a fourth module: "Program Management", which is to include funding requested by the Principal Recipient and the Management Units for the administration, monitoring and evaluation of the grant.

The gaps identified in the previous sections will be addressed through the selected modules and by means of regular intervention. The level of funding requested for each module is detailed below:

Module 1: Prevention programs for MSM and transgender persons (US\$ 2,147,156 required to cover the gaps in the national strategic plan)

Module 2: Prevention programs for other vulnerable groups (PLHIV, young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the figure for the country as a whole) (US\$ 1,631,766 required to cover the gaps in the national strategic plan))

Module 3: Treatment, care and support (US\$ 13,001,379 has been allocated and will be used to cover the gaps in medicinal products and to reduce shortcomings follow-up and support identified in the national strategic plan)

Module 4: Program management (US\$ 3,052,103 has been allocated, which includes 7 percent of the grant as GMS to the Principal Recipient)

Modules 1 and 2 were included with a view to working directly with the key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the figure for the country as a whole), through: interventions aimed at changing behavior, improving the performance of HIV testing and counselling as part of programs for key population groups and interventions aimed at harm reduction, through programs for sex workers and their clients.

The behavior change interventions will include activities geared towards encouraging responsible sexual conduct, based on the assumption that safe sexual practices and using condoms correctly and systematically will lead to a reduction in the number of new infections. There are plans to develop a series of activities in accordance with the behavior change strategy, including human resource training, the distribution of condoms and lubricants, providing tools for self-care, positive prevention, prevention of HIV and other STIs, the production of educational and promotional materials on matters such as sexual orientation, gender and violence, all with a rights-based approach. In terms of PLHIV, self-care and compliance with treatment will be encouraged through community and multidisciplinary educational activities, focusing on rights and gender and aimed at reducing the incidence of other STIs and the transmission of HIV and preventing reinfection, whilst achieving undetectable viral loads. Minimum service packages have been defined to assess the level of coverage achieved in each population group, and the budget required to support the intervention is US\$ 3,164,504.88. This is allocated amongst key population groups as follows: US\$ 1,521,850.82 for MSM, US\$ 318,692.55 for transgender persons, US\$ 869,152.40 for PLHIV and US\$ 454,809.11 for young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence is double the figure for the country as a whole.

In the intervention on HIV testing and counselling for key population groups, in order to achieve the target number of persons who have been tested for HIV and know their results, work will mostly involve activities aimed at encouraging MSM, transgender persons, people who practice transactional sex and young people to have a HIV test as a means of ensuring that they know their serological status, as the first step towards prevention and caring for their health. In order to achieve this, the proposal covers the promotion of counselling services and tests aimed at creating a demand in these population groups for health care related to their serological identity in respect of HIV and in order to encourage them to seek medical help early on. Counselling services will also be strengthened, through the training of peer counsellors, Hazte la Prueba (get tested) activities at places where the MSM and transgender populations meet, the activation of sentinel sites for rapid syphilis and HIV testing, and monitoring of testing among these population groups in the most

affected area health centers in the prioritized municipalities that have a level of prevalence equal to or higher than the national figure. Various different activities have been designed in the plans with a view to encouraging key population groups to have HIV tests, however the targets only include those indicators that are associated in each module with persons who are due to be tested and receive their results under the scope of this proposal. The requested budget for the development of this intervention is US\$ 181,849.08 which is broken down according to the key population groups as follows: US\$ 53,313.96 for MSM, US\$ 92,104.50 for transgender persons and US\$ 36,430.62 for young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the figure for the country as a whole.

The intervention aimed at harm reduction as part of the programs for sex workers and their clients has been included in modules 1 and 2 with a view to creating a mechanism that allows us to work directly with people who practice transactional sex. As indicated in the report produced by the Office of the Inspector General of the Global Fund following its visit to Cuba in 2011, this is very difficult in Cuba, since these persons do not identify themselves and are not identified by society as "sex workers". As a result, they do not form a cohesive, easily accessible group that can be directly approached. Thus, the approach taken in this proposal is to deploy a cross-cutting, peer-based strategy, to reach MSM, transgender persons and young people. The activities set out in the proposal are geared towards training MSM, transgender persons and young people in the 20 to 29 year age group who practice transactional sex as peer educators, so that once they are trained, they can carry out activities directly with their peers, in the interests of achieving the coverage sought under the project. The principal activities developed by trained peer educators, and for which funding is requested are, in the case of MSM, aimed at drawing attention towards sexual and reproductive rights, ending stigmatization and discrimination and reducing gender-based violence, producing educational materials, exchanging experiences with international NGOs working in the area of transactional sex, and conducting IEC activities put on display by the teatro callejero (street theatre) group at locations frequented by MSM who practice transactional sex. In addition, transgender persons are proposing working on this issue through the use of social image workshops for those who practice transactional sex. The aim is to ensure their integration in society, as well as training for family members. In turn, the groups of young people involved are proposing developing skills among young people who practice transactional sex, with an emphasis on self-care, assertiveness and responsibility when it comes to using condoms and negotiating for their use, as well as the systematic use of good practices aimed at HIV/AIDS prevention. The requested budget for the development of this intervention is US\$ 432,567.74 and it is broken down according to the key population groups as follows: US\$ 63,615.60 for MSM who practice transactional sex, US\$ 97,578.75 for transgender persons who practice transactional sex and US\$ 271,373.39 for young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which the level of prevalence doubles the national average.

Module 3 provides for investment in five intervention areas:

Intervention 1: Monitoring compliance (US\$ 53,892)

Intervention 2: Following up on treatment (US\$ 3,721,200)

Intervention 3: Antiretroviral treatment (US\$ 9,076,957)

Intervention 4: Prevention, diagnosis and treatment of opportunistic infections (US\$ 127,081)

Intervention 5: Counselling and psychosocial support (US\$ 22,250)

Through the intervention to monitor compliance we hope to promote the implementation of the compliance monitoring protocol included in the national strategic plan, with training activities for health care providers and by strengthening alliances with the Support Line for PLHIV, in order to create awareness in that sector of the community as one means of reaching the common goal of undetectable viral load. Most of the activities included in the proposal are national in scope and the "treatment as prevention" strategy is due to be implemented in municipalities selected by the extent to which they are affected. The funding requested for the development of these activities is US\$ 53,892.

In order to monitor treatment, once reagents have been purchased their coverage will be extended and improvements will be made to the quality of systematic follow-up care for PLHIV. In addition, there will be comprehensive regular check-ups for these people, including their clinical, immunological and virological status, and the national protocol for follow-up care will be observed, thus preventing complications. Thanks to previous grants, the country has laboratory capabilities and personnel trained to carry out these studies, and as such the requested funding of US\$ 3,721,200 is for the most part to be used for the purchase of reagents and consumable supplies for CD4 and viral load testing; although some of the money will also be used to provide support for the national program in the areas of resistance and hematological studies.

As part of the antiretroviral treatment intervention, once the quantities requested have been obtained, the project will work towards the standardization of ART regimens. Treatment in line with the current national protocol will begin (at fewer than 500 CD4 cells) as well as the gradual phasing out of stavudine and indinavir until they have been fully replaced. Through these activities the goal is to provide ART for around 75 percent of PLHIV, which corresponds to the total number of estimated PLHIV who need ART. In order to meet these goals, the updated ART protocols will be used. These are well-known by the doctors (who have already received training in them) who will be administering the treatment. In addition, an adequate system for the distribution of medicinal products will ensure that once they are received at the central warehouse they will be dispatched guickly to the pharmacies from where they will be dispensed. The funding requested with a view to ensuring that all PLHIV receive the requisite treatment is US\$ 9.076.957.

In order to implement the intervention aimed at the prevention, diagnosis and treatment of opportunistic diseases, the activities proposed are designed to close the diagnostic gaps that were not fully covered by the national program. The proposal focuses on strengthening molecular diagnosis at the Instituto Pedro Kourí, whilst supporting infection control in hospital admissions rooms for persons with TB/HIV and MDR-TB co-infection. Inter-program TB/HIV activities will be strengthened in the areas of monitoring and evaluation, and training personnel from both programs and health care providers on how to handle co-infection, with a view to improving the results that are achieved. Other activities related to TB/HIV co-infection (medication for MDR patients, ruling out latent tuberculosis infection in PLHIV, Intermittent Preventive Therapy in PLHIV and HIV testing in TB patients) are being implemented by the Ministry of Health. The funding requested for this intervention is US\$ 127,081.

The counselling and psychosocial support intervention included in the proposal is aimed at providing training on topics such as healthy eating and nutrition for health care providers involved in providing comprehensive care for PLHIV, as well as technical support for nutritional assistance groups that include PLHIV. The majority of these activities are taking place in the province of Havana, the country's capital, and funding of US\$ 22,250 is requested.

Module 4 includes activities for the management and monitoring and evaluation of the grant. This work is being carried out jointly by the project management units included by recent Principal Recipient UNDP, the National Office of Statistics (ONEI), the National Project Office (ONP) and MINSAP. The alliances and synergies achieved between these bodies have contributed towards the positive results obtained in relation to previous Global Fund grants in Cuba. The funding requested for this module is US\$ 3,052,103. The funding includes 7 percent of the grant as a GMS for the Principal Recipient, plus its human resources costs, audits of the sub-recipients and other administration costs. This figure also includes the costs of the National Office of Statistics (ONEI) associated with monitoring and evaluation activities for the project, as well as activities geared towards designing, implementing, typing and analyzing the results of the Survey on HIV Prevention Indicators and the Survey of Persons Living with HIV. Also included are the costs incurred by the National Project Office (ONP) as a result of follow-up activities and implementation by sub-recipients of the activities and tasks included in the action plans, as a necessary link between the sub-recipients and the principal recipient, and the cost of managing purchasing and supplies. The cost of purchasing and supplies are not associated with management units of the project, however they are required for the implementation of the grant.

The additional gaps that are not covered by the proposal, and for which additional funding of US\$ 4,884,187 is requested, are detailed in section 2.1. They are associated with the monitoring and treatment of PLHIV, strengthening the network of health care services and strengthening the distribution chain and storage of health care products. They are summarized as follows:

Identified funding gaps	2015	2016	2017
CD4	88,815	75,745	48,144
VL (viral load)	604,885	611,395	311,129
Resistance	70,000	70,000	70,000
Opportunistic diseases	15.047	141,582	141,582
Opportunistic diseases	15,047	160,317	320,630
Radiology	800,000	200,000	250,000

С	Cytometry	-	100,000	200,000
L	aboratories for the			
d	lecentralization of confirmation of		247,980	
Н	IIV infection			
D	Distribution and storage of health		270.445	86.492
С	are products	-	270,445	00,492
Α	Additional funding gap	1,578,747	1,877,464	1,427,977

With reference to the monitoring and treatment of PLHIV, the funding gaps are associated with requests for reagents for viral load and CD4 testing to ensure follow-up care for PLHIV, and in accordance with the international recommendations and national guidelines. This is designed to mitigate the migration of patients to second-line treatment and in order to comply with WHO's treatment strategy 2.0. They are also associated with the purchase of reagents for resistance tests, which have an impact on the effectiveness of the treatment, the purchase of reagents for molecular diagnosis, and medicinal products used to treat opportunistic diseases and which contribute towards the quality of life and survival of patients.

In terms of strengthening the network of health care services and laboratories, the principal gaps are associated with the purchase of assembly panel and cytometry equipment, which increases decentralization and access by PLHIV to treatment. The development of imaging at the Instituto Pedro Kourí, which constitutes the tertiary level of health care, will contribute towards improving the diagnosis and follow-up care offered to these patients, through the installation of the following equipment: Multislice CT, C-Arm and ultrasound.

The opportunistic infections that most frequently affect PLHIV are neurotoxoplasmosis, cerebral cryptococcosis, as well as the increasing incidence of opportunistic tumoral diseases, which require high-technology imaging for a quality early diagnosis and for the follow-up care of these patients.

Imaging studies allow results to be obtained in real time for the staging of patients with oncological/hematological diseases, offering them early diagnosis and proper treatment in order to improve their quality of life and prolong their life. Neurotoxoplasmosis is one of the most frequent neurological complications in AIDS, and the mass effect and cerebral edema that it causes need to be monitored by CT scan, since it cannot be diagnosed through clinical techniques alone until it has reached an advanced stage.

Early symptoms of tuberculosis of the central nervous system, and intracranial tuberculomas in HIV patients tend to be non-specific and diagnosed late. The most modern diagnostic imaging techniques allow primary diseases of the central nervous system to be diagnosed early without the need for invasive techniques such as stereotactic biopsy and anatomical pathology studies.

The fact that these technologies are not available at IPK (Instituto Pedro Kourí) means that patients need to be transported, which could cause their health to deteriorate further or result in loss of life. It also causes delayed diagnosis and may enable the illness to progress to a more advanced state, with the risk of hospital-acquired infections.

In order to strengthen the distribution chain and storage of health care products, two refrigerated trucks are required, as well as air conditioning equipment, hoists, pallets, trolleys and shelves to ensure the proper storage and uninterrupted supply to delivery points of medicinal products.

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# 3.3 Modular Template

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

- a. Explain the rationale for the selection and prioritization of modules and interventions.
- b. Describe the expected impact and outcomes, referring to evidence of effectiveness of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

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In accordance with the National Strategic Plan for 2014-2018, one of the goals of the project is "to reduce the incidence of STIs and HIV in key population groups, with an emphasis on MSM", since it is this group that is most affected by the epidemic in the country, but also because the low mortality rates, the downward trend of mortality rates and retention rates for treatment at 12, 24, 36 and 60 months point to the need to reduce the incidence of these infections in order to have a positive impact on the epidemic.

In order to reach that goal, the activities in this proposal are designed to support the national program to reach two key objectives:

- 1- Promoting responsible sexual behavior in the key groups at greatest risk, fostering gender equality and respect for the different sexual orientations.
- 2- Strengthening equal access to basic diagnostic, health care, treatment, monitoring and support services.

Four indicators, related to an increase in condom use and a reduction in stigmatization and discrimination, will be used to assess whether the first objective has been reached. The indicators are:

- 1. The percentage of men who used a condom the last time they had anal sex with a male partner.
- 2. The percentage of people who practice transactional sex who used a condom with their last client.
- 3. The percentage of MSM who used a condom the last time they had sex with an occasional partner.
- 4. The percentage of people in the 12 to 49 year age group who show attitudes of acceptance towards PLHIV and MSM.

The treatment retention indicator will be used to ascertain whether the second objective has been reached:

1. The percentage of adults and children who are known to be continuing with their treatment 12 months after they started it.

Given the funding that is available for the years 2015-2017 and the programmatic gaps in the national strategic plan, once the objectives of the proposal were defined and strategically planned in order to maximize the investment impact, a collective analysis was carried out by the national program to identify the priority modules that would enable the objectives to be met.

The exercise was conducted through meetings, workshops, working groups, the circulation of documents and gathering of feedback. The analysis took into account: the available epidemiological information, the gaps identified during the assessment of the national strategy, estimates produced during the 2014 window for GARPR reporting to UNAIDS, trends in the results reported by the surveys of HIV prevention indicators that have been conducted in the country since 1996 and surveys of persons living with HIV carried out as part of Cuba's Global Fund projects, the results of other research and monitoring and evaluation reports relating to previous grants and the national program. The exercise also benefited from heavy involvement by civil society (PLHIV, MSM, youth projects and women), various sectors of society, organizations involved in the cross-sector response, such as the National Office of Statistics and Information, the academic sector and the Council of Churches, with technical support from areas within MINSAP, the national HIV/AIDS technical committee and various sectors of society, as well as the political endorsement of the Operative Group to Tackle and Fight AIDS and contributions from other technical partners and resident United Nations agencies: PAHO, UNFPA, UNICEF, WFP and UNESCO.

As a result of this analysis, three priority modules were selected, two associated with the work on prevention among key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities, in which prevalence in those age groups is double the figure for the country as a whole) and a third module chosen for the purpose of covering gaps relating to the care, treatment and support provided to PLHIV. In addition, it was decided that it would be a good idea to add a fourth module to the proposal: "Program Management", which is to include funding requested by the Principal Recipient and the Management Units for the administration, monitoring and evaluation of the grant. At a meeting of the CCM on 28 March 2014, the selected modules were presented and approved by participating members. The modules are as follows:

Module 1: Prevention programs for MSM and transgender persons

Module 2: Prevention programs for other vulnerable groups (PLHIV, young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the figure for the country as a whole)

Module 3: Treatment, Care and Support

Module 4: Program Management

Modules 1 and 2 were included with a view to working directly with the key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group residing in the 26 prioritized municipalities in which prevalence in that age group is double the figure for the country as a whole), through behavior change interventions, HIV testing and counselling for key population groups, and harm reduction interventions as part of programs for sex workers and their clients.

The behavior change interventions will include activities geared towards encouraging responsible sexual conduct, based on the assumption that safe sexual practices and using condoms correctly and systematically will lead to a reduction in the number of new infections. The activities include training of human capital, distribution of condoms and lubricants, social marketing of condoms, training and educational activities aimed at providing tools for self-care, positive prevention, prevention of HIV and other STIs, the production of educational and promotional materials on matters such as sexual orientation, gender, violence and prevention of HIV and other STIs, all with a rightsbased approach. In the particular case of PLHIV, self-care and compliance with treatment will be encouraged through community and multidisciplinary educational activities, focusing on rights and gender and aimed at reducing the incidence of other STIs and the transmission of HIV and preventing reinfection, whilst achieving undetectable viral load in PLHIV. Training meetings with PLHIV will also be organized, aimed at developing skills that encourage them to care for their health and also geared towards seeking synergies and the exchange of good practices at different territorial levels. We will work towards strengthening the role of the seropositive woman in the implementation of activities that promote quality of life, and activities involving orphaned children and adolescents affected by and/or infected with HIV will also be promoted. In addition, training activities at different levels have been planned, as a means of increasing social commitment and leadership and promoting forums that foster gender equality and respect for sexual diversity, with a view to reducing stigmatization, discrimination and opting out of society. The funding requested for the development of this intervention is US\$ 3,164,504.88.

In the intervention aimed at HIV testing and offering counselling as part of programs for key population groups in order to influence the indicator of the number of persons belonging to key groups who have been tested for HIV and know their results, work will mostly involve activities aimed at encouraging MSM, transgender persons, people who practice transactional sex and young people to have a HIV test as a means of guaranteeing that they know their serological status, as the first step towards prevention and caring for their health. In order to achieve this, the proposal makes provision for the strengthening of counselling services, through the training of peer counsellors, activities related to the "Hazte la Prueba" (get tested) campaign at places where the MSM and transgender populations meet, the activation of sentinel sites for fast syphilis and HIV testing, monitoring of HIV testing among these population groups at area health centers, as well as the promotion of pre- and post-test counselling. Various different activities have been designed in the plans with a view to mobilizing key population groups to have HIV tests, however the targets only include those indicators that are associated in each module with persons who are due to be tested and receive their results under the scope of this proposal. The budget requested for the development of this intervention is US\$ 181.849.08.

The intervention aimed at harm reduction as part of the programs for sex workers and their clients has been included in modules 1 and 2 with a view to creating a mechanism that allows us to work directly with people who practice transactional sex. As indicated in the report produced by the Office of the Inspector General at the Global Fund after its visit to Cuba in 2011, this is very difficult in Cuba, since these persons do not identify themselves and are not identified by society as "sex workers", and as a result they do not form a particular group and it is difficult to get access to them in order to work with them directly. As part of this proposal, it was decided to approach this population group in a cross-cutting, peer-based strategy, that encompasses MSM, transgender persons and young people. The activities set out in the proposal are geared towards training MSM, transgender persons and young people in the 20 to 29 year age group who practice transactional sex as peer educators, so that once they are trained, they can carry out activities directly with their peers, in the interests of achieving the coverage sought under the project. The principal activities developed by trained peer educators, and for which funding is requested are, in the case of MSM, aimed at drawing attention towards sexual and reproductive rights, ending stigmatization and discrimination and reducing gender-based violence. Activities include: producing educational materials, exchanging experiences with international NGOs working in the area of transactional sex, and conducting IEC activities through events put on by groups such as the teatro callejero (street theatre) at locations frequented by MSM who practice transactional sex. In addition, transgender persons are proposing working on the topic through Social Image workshops for people who practice transactional sex, aimed at guaranteeing their integration in society, as well as training for family members. In turn, the youth groups involved are proposing developing skills among young people who practice transactional sex, with an emphasis on self-care, assertiveness and responsibility when it comes to using condoms and negotiating for their use, as well as the systematic use of good practices aimed at HIV/AIDS prevention. The budget requested for the development of this intervention is US\$ 432,567.74.

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Through a cross-cutting approach, the three interventions will take into account the fact that certain sexual behaviors and culturally transmitted beliefs that remain are perpetuating inequality and constituting a barrier to the efforts being made in terms of sex education and sexual health. These include: the continued evidence of stigmatization and discrimination of sexual diversity; that control over sexual relations is still mostly in the hands of men; that the rights of men and women do not always prevail in acts of prevention; that many families are not assuming their role in the sex education of daughters/sons or in accepting homosexual or bisexual relationships and continue to consider them to be inappropriate; and that women do not always negotiate for condom use as a means of protecting themselves in their sexual relations out of fear of their partner. In addition, we will take into account the fact that it is not enough simply to provide useful and protective information, but rather that it is fundamental that we appeal to peoples' consciences, generating emotions and getting many men and women involved so that they might do some soul searching and change their behavior, in order to bring about a change in attitude and to achieve the expected and required outcomes in terms of reducing HIV infection and achieving equality for diverse men and women with multiple identities.

These population groups will be targeted through a minimum package of services, which, in the case of MSM, young people and transgender persons, will include condoms, information on the prevention of STIs/HIV and knowing where they can have an HIV test. In the particular case of PLHIV, the scope of the intervention depends on their having received condoms and literature on compliance with their treatment, and their knowledge of where to go to receive medical care.

To facilitate working with these population groups a prior estimate of their size was made. The figure for the total number of persons living with HIV was provided by the HIV/AIDS Database of the STI/HIV/AIDS Department at the Cuban Ministry of Health's National Directorate of Epidemiology. Data from the HIV/AIDS Database and the Spectrum projections system was used for the projections. A breakdown of the Cuban population by gender, age and residential municipality is based on data from the Centro de Estudios de Población y Desarrollo (Center for Population and Development Studies) at the National Office of Statistics and Information (CEPDE-ONEI). The MSM population is estimated using the survey on HIV prevention indicators conducted by ONEI, which since 1996 has included a module of questions that are asked in a differentiated manner and that were designed with a view to ascertaining the size of this population group in Cuba and its provinces and ascertaining and evaluating trends in behavior, knowledge, attitudes, beliefs, perceptions and motivations in the general population and specifically in this group. This survey also provides the basis for estimating the number of people who practice transactional sex. Transgender persons have been one of the least studied of the groups proposed. To date the exact number in this group has not been ascertained, however Red-Trans Cuba (a Cuban transgender network), which conducts its activities with the technical assistance of the National Center for Sex Education, conducted a national survey that indicates that there are 3,002 transgender persons, and this is the figure that will be used in the program.<sup>20</sup>

The annual targets for monitoring the indicators entered in each of these modules do not have a cumulative scope, even if an increase is expected from one year to the next. People will be reached as part of the project through the activities that are planned, avoiding double counting, and arriving each year at a figure for the number of MSM, transgender persons, young people in the 20 to 29 year age group residing in the 26 prioritized municipalities where prevalence is twice the national level and PLHIV registered as a target through the minimum package of services that has been defined. The sources for reports will be data from quarterly reports issued by the sub-recipients of the project, and they will also be validated through the surveys carried out by ONEI.

Module 3: Treatment, Care and Support. The work has been designed to include the following intervention:

Intervention 1: Monitoring compliance (US\$ 53,892)

Intervention 2: Following up on treatment (US\$ 3,721,200)

Intervention 3: Antiretroviral treatment (US\$ 9,076,957)

Intervention 4: Prevention, diagnosis and treatment of opportunistic infections (US\$ 127,081)

Intervention 5: Counselling and psychosocial support (US\$ 22,250)

<sup>20</sup> The survey on HIV prevention indicators conducted by ONEI estimates the number of transgender persons at 3,512, however the percentage standard deviation associated with this figure means that the confidence interval for the parameter is very large [457-6566]. As a result a decision was taken to work with the number reported by the Cuban transgender network, which is within the range of that interval.

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This module includes activities geared towards strengthening the care, treatment and support given to PLHIV.

The task of monitoring compliance with treatment will be driven by the implementation of a monitoring protocol contained in the national strategic plan. As part of the proposal, we intend to use training activities for health care providers and the strengthening of alliances with the Support Line for PLHIV to improve monitoring by health care personnel and to create awareness among persons living with HIV, with a view to reaching the common goal of undetectable viral loads. Levels of compliance will be boosted by the completion of training activities on topics such as healthy eating and nutrition for health care providers involved in providing comprehensive care for PLHIV, as well as technical support for nutritional assistance groups that include this community. Most of the activities included in the proposal are national in scope and the "treatment as prevention" strategy is due to be implemented in municipalities selected by virtue of the extent to which they are affected. The funding requested for the development of these activities is US\$ 53,892.

The strategy for monitoring treatment is based on systematic follow-up of PLHIV undergoing ART and regular comprehensive assessment of their clinical, immunological and virological status, ensuring that the right medical decisions are made in order to prevent complications. This grant will also provide for gaps in supplies of reagents for CD4 and viral load testing requested by the National Program for the follow-up care to be offered to patients in accordance with the national protocols. The country has laboratory capabilities and personnel trained to carry out these studies, set up using previous grants, and as such the requested funding of US\$ 3,721,200 is for the most part to be used for the purchase of reagents and consumable supplies for CD4 and viral load testing, although some of the money will also be used to provide support for the national program, with resistance and hematological studies.

As part of the antiretroviral treatment intervention, access to antiretroviral treatment will be increased and the project will work towards the standardization of ART regimens, treatment in accordance with the current national protocol will begin (at fewer than 500 CD4 cells) and the gradual phasing out of stavudine and indinavir will begin, until such point as they have been fully replaced. With these activities it is hoped to provide ART for around 75 percent of PLHIV, this figure represents the total number of estimated PLHIV who need ART. In order to meet these goals, the updated ART protocols will be used. These are well-known by the doctors (who have already received training in them) who will be administering the treatment. In addition, an adequate system for the distribution of medicinal products will ensure that once they are received at the central warehouse they will be dispatched quickly to the pharmacies where they are dispensed. The funding requested with a view to ensuring that all PLHIV receive the requisite treatment is US\$ 9,076,957.

The intervention for the prevention, diagnosis and treatment of opportunistic diseases is geared towards implementing activities that contribute towards closing the diagnostic gaps that are not fully guaranteed under the national program, focusing on strengthening molecular diagnosis at the Instituto Pedro Kourí, whilst supporting infection control in hospital admissions rooms for persons with TB/HIV and MDR-TB co-infection. Inter-program TB/HIV activities will be strengthened in the areas of monitoring and evaluation, and when training personnel from both programs and health care providers on how to handle co-infection, with a view to improving the results that are achieved. Other activities related to TB/HIV co-infection (medication for MDR patients, ruling out latent tuberculosis infection in PLHIV, Intermittent Preventive Therapy in PLHIV and HIV testing in TB patients) are being implemented by the Ministry of Health. The funding requested for this intervention is US\$ 127,081.

The counselling and psychosocial support intervention included in the proposal is aimed at providing training on topics such as healthy eating and nutrition for health care providers involved in providing comprehensive care for PLHIV, as well as technical support for nutritional assistance groups that include PLHIV. The majority of these activities are taking place in the province of Havana, the country's capital, and funding of US\$ 22,250 has been requested.

Module 4: Program Management. The work will be completed through the Grant Management intervention, which includes activities relating to the administration and monitoring and evaluation of the proposal.

The grant management team will work in conjunction with UNDP, ONEI, ONP and MINSAP. These bodies form the grant management units, and even though each one has its own part to play in the proposal, the alliances and synergies created between them have contributed to the positive results yielded from previous grants involving Cuba and the Global Fund. Funding of US\$ 3,052,103 has been requested for this module, which figure includes 7 percent of the grant as a GMS for the Principal Recipient.

UNDP. As Principal Recipient, UNDP oversees the system for monitoring capabilities and promotes their reinforcement. It also ensures that project expenditure is in accordance with the annual work plans and the UNDP and Global Fund rules and is responsible for general monitoring of the project, supervising activities that have a greater impact on the results and submitting regular reports to the Global Fund.

National Project Office (ONP). It represents and organizes project sub-recipients in relation to the planned activities, striving continuously towards compliance with the expected results, the stipulations set out for the different working processes and ensuring that funds are used properly. It also supervises and evaluates this entire process. It receives, revises and processes all documents in the flow of financial and program-related information, together with the PR.

MINSAP. It is responsible for ensuring that all activities correspond to the national strategic plan. It proposes corrective action where necessary, according to the behavior of the epidemic and the interests that it is tasked with protecting. It provides guidance for territorial program directors on cross-sector coordination with sub-recipients in its sphere of activity and on the supervision of activities and working processes, and it also provides technical advice.

National Office of Statistics (ONEI). It is the body responsible for managing the flow of information pertaining to the results of the projects and carrying out regular studies. This includes assisting sub-recipients when drafting their M&E plans, gathering information and evaluating indicators, drafting reports on progress made in the program, which it submits to UNDP and the Global Fund, and conducting probabilistic modelling at national level, aimed at evaluating the projects. This includes designing, surveying, loading, validation, processing, analyzing results and issuing publications.

All of the management units work together on the following: the M&E Action Plan, visits to national and territorial sub-recipients, annual regional M&E workshops, a quarterly meeting of the Coordinating Committee and systematic informal coordination sessions. They also work together on the integration of reports to the Global Fund.

#### Sustainability

For Cuba, the sustainability of interventions proposed through the years in relation to previous grants has been a major challenge, given the economic limitations that the country has been facing. However, we have made progress on matters relating to the planning, focus and prioritization of strategies that are having a greater impact on the epidemic.

In the previous grant period the Cuban brand of condoms, "Vigor", was registered and introduced in the country with the help of the Global Fund and the Ministry of Health. At the end of the Round 6 project, the government committed to purchasing these condoms in sufficient quantities for the rest of the country, taking into account the fact that RCC only covers three provinces. This proposal only provides for the acquisition of free sample condoms, and the government's contribution will be used to continue purchasing Vigor condoms, in larger numbers each year.

One of the most important advances in terms of commitments established, and which forms part of the legal framework, is the Minister of Education's Ministerial Resolution 139/2011, which approved and implemented the Sex Education Program. This focuses on gender and rights and now forms part of the basic, special and elective teacher training curricula and the post-graduate development studies offered to management and all teaching staff. It is also included in educational and extracurricular activities for students and also in family education schools and guidance forums, with the support of other sectors and organizations. Likewise, progress has also been made in relation to planning tools, the cross-cutting expansion of activities, capacity-building aimed at the inclusion of new material in the curriculum, as well as the implementation and coordination of materials and activities. As a result of all of the above this proposal requires less funding in this area.

The purchase of dietary supplements has been left out of the proposal. It was included in all of the previous projects, however the country's politicians have decided to continue helping PLHIV to achieve the required nutritional balance.

In terms of the purchase of rapid HIV tests, though they were at one time purchased using funding from the Global Fund, in the last three years they have been in sufficient quantity to ensure testing throughout the whole country. Only a very small quantity has been included in this proposal, for a one-off study on transgender groups.

Medicinal products for co-infected patients with monoresistance or multiresistance will be covered by the national contribution.

This proposal also excludes the Federación de Mujeres Cubanas (FMC) [Federation of Cuban Women] as part of its cross-sector response. This is an NGO that has in the past received financial support from the Global Fund as part of all previous projects. It is aimed at training female developers and building their skills, and today it designs and implements its activities according to the problems, interests and needs of Cuban women, with a focus on gender and taking into account the human capital that these women offer. It does not require additional funding.

The National STI-HIV/AIDS Program has an IT system, implemented in 2009 with the financial support of the Global Fund. Since 2011, it has been sustained by domestic funding, including software improvements in the last two years aimed at ensuring optimum functionality and the efficient registration of PLHIV throughout the country. During its visit in November 2011, the OIG classified this system as very good.

In terms of progress on the implementation of WHO recommendations, this began in 2012 with the withdrawal of indinavir and stavudine from the preferred first-line treatment regimens in the national guidelines. The number of PLHIV receiving this medicinal product has been reduced, and a plan has been established for its phased withdrawal, which is being monitored. In response to growing demand, talks are also underway with the pharmaceutical industry in Cuba, to increase the number of antiretroviral drugs produced in the country, and to increase the output of drugs that are already in production here.

CECMED has been the focus of capacity-building activities aimed at complying with the Plan for the Quality Assurance of Medicinal Products, approved by the Global Fund, as a requirement for approval of the proposed purchase of antiretroviral drugs. For antiretroviral drugs in 2013-2014, this analysis was outsourced to an international laboratory, since there is no specialist laboratory of this type in the country. However, in 2015 it is due to be conducted by a Cuban laboratory which is currently undergoing certification.

In spite of all of these areas of progress, significant steps are still being made today towards ensuring the sustainability of the program's activities, prioritizing those that have the greatest impact and in which we intend to invest. As a result, we are expecting a greater contribution from the Government towards the purchase of reagents (CD4 and viral load tests) for the monitoring and care of PLHIV, gradually, until all requirements are covered, as well as considerable efforts by our national industry to cover more and more of the requirement for antiretroviral drugs, under the limitations imposed by our current economic situation and depending on external factors such as the embargo and the global economic crisis.

# Additional gains expected from the funding requested above the amount allocated

The additional gaps that are not covered by the proposal, and for which additional funding of US\$ 4,884,187 is requested, are detailed in section 2.1. They are associated with the monitoring and treatment of PLHIV, strengthening the network of health care and laboratory services, and strengthening the distribution chain and storage of health care products. They are summarized as follows:

Identified funding gaps	2015	2016	2017
CD4	88,815	75,745	48,144
VL (viral load)	604,885	611,395	311,129
Resistance	70,000	70,000	70,000
Opportunistic discoses	15,047	141,582	141,582
Opportunistic diseases	15,047	160,317	320,630
Radiology	800,000	200,000	250,000
Cytometry	-	100,000	200,000
Laboratories for the decentralization of confirmation of HIV infection		247,980	
Distribution and storage of health care products	-	270,445	86,492
Additional funding gap	1,578,747	1,877,464	1,427,977

With reference to the monitoring and treatment of PLHIV, the gaps in funding are associated with requests for reagents for viral load and CD4 testing to ensure follow-up care for PLHIV, in accordance with the international recommendations and national guidelines, in an attempt to mitigate the migration of patients to second-line treatment and in order to comply with WHO treatment strategy 2.0. They are also associated with the purchase of reagents for resistance tests, which have an impact on the effectiveness of the treatment, the purchase of reagents for molecular diagnosis and medicinal products used to treat opportunistic diseases, which contribute towards the quality of life and survival of patients.

In terms of strengthening the network of health care services and confirmation laboratories, the principal gaps are associated with the purchase of assembly panel and cytometry equipment, which increases decentralization and access by PLHIV to treatment. The development of imaging at the Instituto Pedro Kourí, which constitutes the tertiary level of health care, will contribute towards improving the diagnosis and follow-up care offered to these patients, through the installation of the following equipment: Multislice CT, C-Arm and ultrasound.

The opportunistic infections that most frequently affect PLHIV are neurotoxoplasmosis, cerebral cryptococcosis, as well as the increasing incidence of opportunistic tumoural diseases, which require high-technology imaging for a quality early diagnosis and for the follow-up care of these patients.

Imaging studies allow results to be obtained in real time for the staging of patients with oncological/hematological diseases, offering them early diagnosis and proper treatment in order to improve their quality of life and prolong their life. Neurotoxoplasmosis is one of the most frequent neurological complications in AIDS, and the mass effect and cerebral edema that it causes need to be monitored by CT scan, since it cannot be diagnosed through clinical techniques alone until it has reached an advanced stage.

Early symptoms of tuberculosis of the central nervous system, and intracranial tuberculomas in HIV patients tend to be non-specific and diagnosed late. The most modern diagnostic imaging techniques allow primary diseases of the central nervous system to be diagnosed early without the need for invasive techniques such as stereotactic biopsy and anatomical pathology studies.

The fact that these technologies are not available at IPK (Instituto Pedro Kourí) means that patients need to be mobilized, which could cause their health to deteriorate further or result in loss of life. It also causes delayed diagnosis and allows patients to progress to a more advanced state, with the risk of hospital-acquired infections.

In order to strengthen the distribution chain and storage of health care products, two refrigerated trucks are required, as well as air conditioning equipment, hoists, pallets, trolleys and shelves to ensure proper storage and uninterrupted supply to delivery points for medicinal product.

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

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

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

- a. If the applicant is a lower-middle-income country, describe how the funding request focuses at least 50 percent of the budget on underserved and key populations and/or highest-impact interventions.
- b. If the applicant is an upper-middle-income country, describe how the funding request focuses 100 percent of the budget on underserved and key populations and/or highest-impact interventions.

Cuba's application is focused on strengthening those areas of the program in which gaps were identified during the analyses carried out, based on the resources that are required in accordance with the operative framework for the national strategic plan and the State's contribution to meet this demand.

For this reason, in our proposal the resources requested to cover the interventions of the modules for prevention in key population groups (MSM, transgender persons, PLHIV and young people in the 20 to 29 year age group with a cross-cutting focus on PPTS in all of those groups - Module 1 and 2) represent 19 percent of the total budget allocated, whilst 66 percent corresponds to interventions for treatment, care and support (Module 3), in which the final beneficiaries are PLHIV and the other key groups identified throughout the country. As such, the interventions proposed in the 3 modules cover 85 percent of the total budget for the allocation.

The project management activities of UNDP (Principal Recipient), ONP and ONEI and the procurement unit will account for 8 percent of the funding executed, whilst the remaining 7 percent corresponds to the GMS of the Principal Recipient, as per current implementation arrangements.

## **SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT**

## 4.1 Overview of Implementation Arrangements

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

- a. If applicable, the reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement (i.e. both government and non-government sector principal recipient(s).
- b. If more than one principal recipient is nominated, how coordination will occur

between principal recipients.

- c. The type of sub-recipient management arrangements likely to be put into place and whether sub-recipients have been identified.
- d. How coordination will occur between each nominated principal recipient and its respective sub-recipients.
- e. How representatives of women's organizations, people living with the three diseases, and other key populations will actively participate in the implementation of this funding request.

4.1.a. What are the implementation arrangements for the project and the UNDP-Government of Cuba National Legal Framework.

In 2003, the CCM appointed UNDP as the Principal Recipient (PR) of the Global Fund projects for Cuba. The legal framework for this association is set out in various framework documents signed with the country, [and] the central agreement signed with the Cuban Government in May 1975. This agreement describes important points relating to this Concept Note, as follows:

- Article III, clause 1 establishes the need to appoint a Cooperation Organization and an Implementation Organization for each development project agreed between UNDP and the national government. In the case of Global Fund projects, the ministries of Foreign Trade and International Cooperation (MINCEX) were appointed as the Cooperation Organization, and MINSAP (Cuban Ministry of Health) as the body in charge of implementation. In addition, it was established that a working plan and project document (PRODOC) should be drawn up jointly by UNDP and the Implementation and Coordination Organizations.
- Article VII describes the mechanisms established for assistance from other sources, establishing the possibility of receiving funding from third parties, as is the case of the Global Fund.
- Article IX refers to the privileges and immunities granted to organizations from the United Nations system. These include tax breaks and exemptions for purchases relating to the project.

Since 2003, UNDP, MINCEX and MINSAP have been drafting the respective project documents, and their respective amendments, in accordance with the Grant Agreements signed with the Global Fund.

Likewise, the Global Fund Grant Agreements for Cuba are signed by the legal representative of the Coordination Organization (MINCEX), the chairwoman of the CCM and the legal representative of UNDP.

The Legal Framework for the CCM.

Article 44 of the CCM by-laws - Cuba states that "according to the CCM's decision, the responsibilities of the Principal Recipient are assumed by a multilateral organization with a permanent representation in the country". Since Project Round 2 was approved for Cuba in 2003, to date, the Global Fund has approved 4 projects. Only one of these projects is currently being implemented (Round 2 RCC), and another one is being wrapped up (Round 7 for Tuberculosis).

At the time of allocating the resources for the New Funding Mechanism and after having received notification from the Global Fund of the awarding of the budget, the Chairwoman of the CCM circulated a request for expressions of interest among United Nations agencies resident in the country, for the nomination of the Principal Recipient for Global Fund projects.

The CCM received written responses from FAO, UNICEF, WFP, UNFPA, PAHO and UNESCO, turning down the invitation and supporting the appointment of UNDP to continue in its role as principal recipient of the funds from the grant, from which point, at the meeting of the CCM on

28 March 2014, the appointment of UNDP was approved by the members of the CCM, who voted at a plenary, public session.

Notwithstanding the above, in light of the Global Fund requirements relating to the need to ensure secret ballots, the CCM met again on 21 April 2014 to conduct a secret ballot, and UNDP's nomination as principal recipient was ratified.

- 4.1 b. The current grant and the proposal for the New Funding Model is based on the work carried out with a single PR (UNDP), and as such coordination between several PRs does not apply here.
- 4.1 c Describe the coordination between the SRs and the PR. What are the management arrangements?

The CCM selects the sub-recipients according to the mechanisms established in its management arrangements. This selection mechanism is shared with UNDP, which sends each SR a standard letter of agreement based on the standards established by the legal office of UNDP in New York and in accordance with the criteria established in the grant agreement signed with the Global Fund, in part B, Special Terms and Conditions. These standard letters of agreement with the SRs are accompanied by the project document (PRODOC) drafted by UNDP and the Cuban cooperation and implementation organizations, as well as a work plan approved by the project management units.

The letters of agreement also establish the legal conditions for implementing the project and the control and monitoring mechanisms. These documents need to be signed by three parties: the legal representative of UNDP, the Chairwoman of the CCM and the legal representative of the SR. The period of execution of the letter covers the same period as the agreement signed by UNDP and the Global Fund, and it is backed up legally by the framework agreements established by the national government, UNDP and the Global Fund.

Mechanisms for coordination between the SRs and the PR.

PRODOC establishes two principal coordination mechanisms:

Program Coordination Mechanism:

The Coordination Committee is in charge of the program management mechanism. It is formed by the three project management units, which are (i) the National Project Office (ONP) and other implementation bodies at MINSAP, (ii) ONEI and (iii) UNDP. This Committee meets at least once a quarter to examine how the project indicators are developing and to propose modification to the action plans, where necessary.

Financial Monitoring Mechanism:

Quarterly financial monitoring meetings (referred to jokingly as Marathons). These meetings are convened by the coordination organization (MINCEX), and the SRs and other MINSAP bodies are invited. The focus is on identifying bottlenecks in the implementation of the financial aspects of the project, and studying mechanisms to ensure that the budget is put to better use.

4.1.d. How will representatives of women's organizations, people living with HIV/AIDS and other key populations participate in the implementation of this funding request?

From the start of the project, the importance of the participation of the key population groups in its implementation has been emphasized. At the end of the four-year period of the previous national strategic plan, a process of continuous dialogue was instigated. It continues today and will end once the preparation of the Concept Note is complete.

Process of National Dialogue.

The national dialogue is being executed in Cuba in three phases, based on the new methodology of the Global Fund, in order to mitigate the risk of presenting a project that is not participatory and suited to the needs of the key population groups in the country.

The first phase concluded in November with the approval of the national strategic plan. In October 2013 the PR presented the new funding model at an extraordinary meeting of the CCM, and from that point discussions on the second phase began.

The second phase commenced once the budget allocation established by the Global Fund for the country was revealed. The first step during this phase was the creation of the Committee for the Drafting of the Methodological Note by the CCM (ad-hoc group). The Committee is made up of management units from MINSAP, ONEI and UNDP, the Federation of Cuban Women (FMC), key groups and ONP.

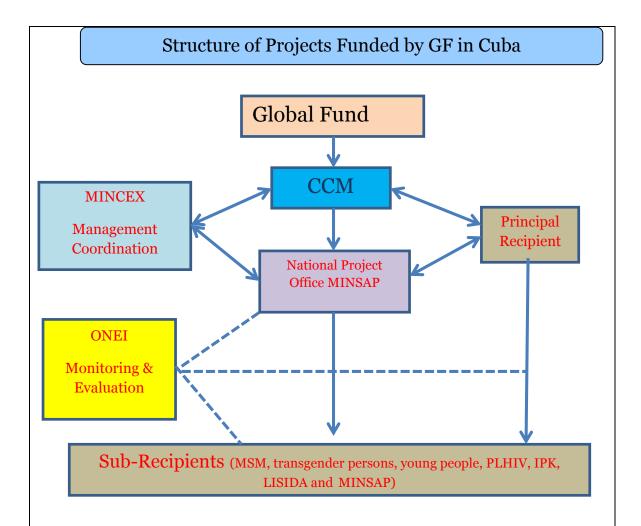
In December the national strategic plan was presented for discussion at the CCM. In March the central group was formed from the ad-hoc group. One sub-group was formed as a drafting team for the concept note, and another group was set up to evaluate the eligibility of the CCM.

The central group is headed up by UNDP, and UNICEF is in charge of the eligibility group (see details in the minutes of the CCM).

This mandate granted by the CCM was executed during the month of April of this year, with a study and analysis of eight drafts presented by the following actors: Young people, MSM, PLHIV, PPTS, MINSAP, CENESEX, IPK and the AIDS Research Laboratory (LISIDA).

The third phase will commence after the Concept Note is approved, and the participation process will be the same as in the previous phases.

The structure of the Global Fund project in Cuba has been designed in such a way as to ensure that there is a mutual division of tasks and controls, in terms of the implementation of the program and the financial aspects of the project. It is expressed in the following chart:



#### Key processes in the project.

According to section B of the Grant Agreement signed by the Global Fund and the Principal Recipient, on the Special Terms and Conditions, the Principal Recipient is responsible for purchasing. In the case of Cuba and due to the nature of the national implementation of the project (NIM), as explained above, purchases are made in accordance with the national purchasing procedures and the frameworks established by the Global Fund and UNDP.

## Purchasing Procedures

The process for acquiring goods and services starts with the sub-recipients, who, based on the approved Purchasing Plan, present the procurement request to the National Project Office (ONP), with the corresponding technical specifications or terms of reference, as well as details of the budget allocation for the goods or services in question. Following a detailed review of the request from the sub-recipient, which includes but is not limited to an assessment of whether the goods or services meet the terms approved in the plan, whether they correspond to the funds allocated in the budget and whether the description of the goods or services is adequate, the ONP prepares a file for referral to the government entity responsible for procurement for grant programs (EMED) in order for the tendering phase to commence. To date, the use of EMED is in response to the possibilities in the relevant legislation of an exemption on customs duty for goods and services received as donations and in relation to projects. The processes differ according to the goods or services involved, but the fundamentals are as follows:

Purchases of Medicinal Products: The request is submitted by IPK, generally 3 to 4 months prior to the start of the planned period, so as to ensure that the products arrive on time. Once the referral has been by the ONP to EMED, the latter sends the call for proposals to UNDP and to those manufacturers or distributors of the medicinal products that are represented in the

country and included in the list of suppliers. According to the established procedure, UNDP asks UNICEF for an estimate of costs (from the Supply Division in Copenhagen) and quotes from the signatories of the Long-Term Agreements, which in the case of antiretroviral drugs are IDA, IMRES, MEG and GIZ. Once the estimated costs have been received from UNICEF, as well as the different quotes, they are sent to EMED, which prepares the tender document, which includes all of the bids received from the suppliers on its list.

ONP and EMED together convene a Procurement Committee, which, with the assistance of the sub-recipient, analyses all of the bids received, always awarding the contract to the bid with the best price, provided that the delivery time is adequate, the medicinal product has been pre-qualified by WHO, Global Fund and/or a renowned regulatory body for medicinal products.

Once a supplier from EMED's list of suppliers has been awarded the contract, it draws up the contract, including deadlines for delivery, according to the needs of the sub-recipient and in order to ensure that when the medicinal products arrive they have a long enough shelf life to meet demand and provide reserve stocks.

Tenders awarded to UNICEF and other LTAs require the presentation of the Request for Direct Payment by the sub-recipient in order to issue the corresponding purchase order using request details from the sub-recipient that are identical to those used in the case of the contracts. Only in the case of UNICEF are goods paid for in advance, and the amount due is settled with a statement of account upon receipt of the last shipment.

In the case of EMED contracts and purchase orders for all remaining commercial LTAs, payment is made once each medicinal product has been received, with the approval of the sub-recipient and using the established documents.

Once the contract has been signed and the purchase order confirmed, the estimated date of arrival of the different medicinal products is ascertained from the date on which each batch is produced by the manufacturers, most of which are generics originating in India. 21 days before the products are shipped, each supplier who does not have its products registered in the country (in our case, only Roche, as a direct producer, has its medicinal products registered) submits the documents requested by CECMED, the national regulatory authority for medicinal products and medical equipment, for timely registration and so that the import permit can be issued. Only EMED can complete this registration process, subject to appointment. Once the required permits have been reviewed, approved and confirmed, the supplier is instructed to proceed with the shipment.

The supplier sends the shipment documents through its forwarding agent, arriving approximately 10 days later, depending on the availability of space for the shipment. EMED is responsible for the customs clearance process, which should take no more than 7 days to complete, submitting to the government entity that manages imported medicinal products (Unidad Empresarial Básica de Medicamentos Importados - UEBMI) at EMCOMED the documents that are required in order to collect the products from the airport, insofar as this is the only body with properly certified means of transport for the transportation of medicinal products. UEBMI distributes the medicinal products to the provincial drug stores, based on the number of patients in each province.

There are established maximum and minimum systems. The provincial drug stores need to have coverage for 90 days, whilst pharmacies require maximum coverage of 60 days and patients need to be able to get their hands on a 1-month supply.

This prevents stockouts from happening when a new patient is registered.

Pharmacies have a weekly ordering system (they order items for which there is less than 30 days' cover.

Drug stores have a monthly reconciliation system. This reconciliation report reaches UEBMI. The national program validates this information, comparing the details that appear on the HIV/AIDS database against the reconciliation carried out by provincial HIV/AIDS groups with their drug stores, carrying out a cross-referenced reconciliation between the number of patients registered in the distribution system and checks of patients undergoing treatment, by the surgeries that are treating them.

Purchase of condoms for distribution free of charge: The procurement request is submitted by each key group, based on the quantity and budget approved for this item, in their procurement and working plans, generally 3 to 4 months prior to the start of the planned period, to ensure that the goods arrive on time. The ONP revises each request and consolidates them into a single remittance, which it sends to EMED in order to group everything together into a single shipment, thereby reducing freight and handling costs. For the purchase of condoms, EMED alone asks UNDP for supplies, and the latter, through its agreements with the UNFPA procurement and supplies division in Copenhagen, asks that agency for a pro-forma invoice for the requested items. This division of UNFPA has Long-Term Agreements with the principal manufacturers of contraceptives worldwide, thereby guaranteeing the quality and certification of the products that are received.

Once the pro-forma invoice has been received at UNDP, generally 21 days after it is requested, it is forwarded to EMED to be added at the Procurement Committee 5 days later, at which point it is analyzed by the sub-recipients, according to their needs and budgetary capacity.

Once UNFPA has been instructed to make the purchase, the order is confirmed, requests for direct payment are received from the sub-recipients and the purchase order is issued to UNFPA. After 5 to 7 weeks the shipment documents are received. This is approximately 10 weeks from the date on which the order was issued.

EMED processes the customs documents and the condoms should arrive within 15 days once the shipment is received at the EMSUME (Storage and distribution company for medical consumables) warehouses. It takes 21 days for EMSUME to distribute all of the condoms to its provincial warehouses, which then deliver them to the Provincial Hygiene and Epidemiology Centres (CPHE), where they are used by each of the programs for key population groups in their promotion and prevention activities. The CPHE issue requests to EMSUME's provincial warehouse according to the quantity of condoms that they require for their activities with key population groups, based on stock rotation in such a way that there is always enough stock to reach those persons during the activities.

Purchase of reagents and consumables: The sub-recipients MINSAP, LISIDA and IPK are responsible for submitting to the ONP the procurement request for reagents and their corresponding consumables. As in the processes described above, the ONP checks that the request corresponds with the procurement plan and the supplier's action plan. It then issues the remittance to EMED, which launches the bidding process for its list of suppliers of that type of product. In approximately 21 days the bids are received from the different suppliers and forwarded to the sub-recipients for technical validation and approval, which can take up to 15 days. The tender document is then drawn up with the bids that were deemed to be technically compliant and the evaluation process is conducted in accordance with the universal principle of best value for money.

The delivery times for these contracts vary according to inventories and available stocks, and therefore the contracts are generally signed for partial deliveries, in order to prevent products with a short shelf life from expiring and to ensure a continuous supply.

According to the established schedule, EMED receives the shipment documents and completes the customs formalities in order for the UEBMI at EMCOMED to take delivery of the shipped goods. UEBMI distributes the products to the selected laboratories in the country, including IPK and LISIDA facilities.

Purchase of other health care consumables, equipment for printing forms and other materials: This starts with the sub-recipient, who, at the start of the period in the Action Plan, based on the approved Purchasing Plan, submits the procurement request to the ONP, with the corresponding technical specifications or terms of reference, as well as details of the budget allocation for the goods or services in question. Following a detailed review of the request from the sub-recipient, which includes but is not limited to an assessment of whether the goods or services meet the terms approved in the plan, whether they correspond to the funds allocated in the budget and whether the description of the goods or services is adequate, the ONP prepares a file for referral to EMED in order for the tendering phase to begin and to allow it to approach its list of approved suppliers for the goods or products in question.

In approximately 21 days the bids are received from the different suppliers and forwarded to the sub-recipients for technical validation and approval, which can take up to 15 days. The tender document is then drawn up with the bids that were deemed to be technically compliant and the adjudication process is conducted in accordance with the universal principle of best value for money, including a heavy weighting for delivery time if this is vital for the completion of a task or activity aimed at reaching a given indicator.

According to the agreed delivery date, EMED receives the shipment documents and completes the customs formalities in order for the goods received to be dispatched to EMSUME warehouses. It takes 21 days for EMSUME to distribute all of the products to its provincial warehouses, and the warehouses in turn distribute them to the Provincial Hygiene and Epidemiology Centers or selected laboratories, as applicable. The CPHE issue requests to EMSUME's provincial warehouse according to the quantity of condoms that they require for their activities with key population groups, based on stock rotation in such a way that there is always enough stock to reach those persons during the activities. In the case of the selected laboratories, they receive all of the allocated products in a single shipment.

#### Financial Procedures

All of the *financial resources* are received by UNDP. UNDP administers the funds allocated to all of the recipients in the project, paying the suppliers of goods or services directly using the request for direct payment submitted and backed up by the required supporting documentation. The supporting documentation varies according to what is agreed in each contract or purchase order. If partial payment is made and in order for the final payment to be executed, Acknowledgement of Receipt or a Certificate of Conformity are required in order to certify that the goods and/or products were to the complete satisfaction of the end user. Payment for workshops and other activities that are not subject to a procurement process is in accordance with the request for direct payment submitted by the sub-recipient involved, and in addition to the invoice, notification of the task to which the payment in question corresponds is required.

All requests for payment are signed by the sub-recipient and reviewed and certified by the ONP, which checks and reviews all of the information and data included.

On a monthly basis, UNDP and the ONP cross-check the details of payments made and the availability of funds in the budget, including any outstanding payments from all parties. Irrespective of the fact that information is sent to the Global Fund on a half-yearly basis, the parties cross-check and reconcile their details with the sub-recipients on a quarterly basis.

#### Monitoring and Evaluation Procedures.

Like the reconciliation process, the *Monitoring and Evaluation* process for the project (M&E) is also quarterly, irrespective of the fact that reports are submitted to the Global Fund on a halfyearly basis. The Management Units described above carry out individual visits to each subrecipient, checking the supporting documentation for each activity reported. This information is compiled and included in the report submitted in advance to each sub-recipient, and only once it has been verified is it included in the reports to be submitted to the Global Fund.

Also as part of the M&E process for the project, surveys of HIV prevention indicators and persons living with HIV (PLHIV) are carried out. Both studies are based on probabilistic samples collected countrywide, and these form the basis for following up on the results indicators included in this proposal, which are part of the National Health Care Information System. The studies are also used to determine the size of population groups that form the key groups (MSM and PPTS) and to ratify or correct the figures reported in relation to the number of persons reached in the different indicators.

The Progress Report for the project is submitted at the first meeting of the CCM following the close of each quarter, in order to allow each representative from member organizations, including key population groups and decision makers, to form a critical judgment, and so that action plans can be drawn up with a view to resolving and/or overcoming any difficulties encountered when managing the program or in its financial aspects.

## 4.2 Ensuring Implementation Efficiencies

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

Describe how the funding requested links to existing Global Fund grants or other funding

requests being submitted by the CCM.

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

The funding has been requested in order to ensure the continuity of the current project relating to the HIV epidemic. There is no duplication, since we are not receiving any other grant and this request is aimed at completing the current project.

As explained above, the country is funding the vast majority of the budget for the national strategic plan in Cuba.

#### Human resources:

All human resources for the project will be funded by the national government. Payments to the project will not be used for salaries, with the exception of the management units.

#### Training

National trainers will be used when training human resources, according to the established action plans. Salaries for training staff will not be paid in a specific manner. The budgets allocated for training workshops will focus on the cost of logistics, accommodation and the purchase of supplies for their activities. There is no additional or complementary funding apart from the funding from the Global Fund.

Follow-up, Supervision and Evaluation

Activities are planned in conjunction with MINSAP and ONEI, and all spending is covered by the project in accordance with the action plans. There is no additional funding, apart from the funding granted by the Global Fund.

4.3 Minimum Standards for Principal Recipients and Program Delivery					
	for each nominated Principal Recipier ords, please refer to the concept note in		formation		
PR 1 Name	United Nations Development Programme (UNDP)	Sector			
•	ecipient currently manage a Global Fund use component or a cross-cutting health g grant(s)?	□XYes □1	No		
Minimum Standards	3	CCM assessi	ment		
The Principal management structure	Yes, UNDP has PR since 2003, evaluations hav satisfactory	and its			
2. The Principal Rec effective manage (and relevant sub-	Yes, the Pl specialist teal reliable ERP sy	m and a			
	rol system of the Principal Recipient is and detect misuse or fraud	Yes, evaluations h received for conducted	ave been		

4. The financial management system of the Principal Recipient is effective and accurate	Yes, it is a global integrated system
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 implementation process is conducted in accordance with national standards that are integrated.
<b>6.</b> 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	There is a distribution system for health care products.
7. Data-collection capacity and tools are in place to monitor program performance	Yes, support is also provided by the National Office of Statistics and Information and the Health Care Information System.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Yes. See point 7.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	The country has the necessary capacities.

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

- a. With reference to the portfolio analysis, describe any major risks in the country and implementation environment that might negatively affect the performance of the proposed interventions including external risks, Principal Recipient and key implementers' capacity, and past and current performance issues.
- b. Describe the proposed risk-mitigation measures (including technical assistance) included in the funding request.

## 1. Risks to program delivery and performance

# 1.1. Risks to program delivery and performance.

As mentioned above, during the first phase of the National Dialogue process, weaknesses were identified, from which risks could be determined. The teams responsible for analyzing the situation with regard to the program and the project identified 16 weaknesses (see the approved national strategic plan), the majority of which related to the planning aspect of the project.

Weakness	Degre e of risk	Risk	Mitigation
Weaknesses in the comprehensive approach towards STIs, problems with the syndromic management of	Low	Poor knowledge by medical teams of the treatment protocols.	The treatment protocols for STI are included in the national strategic plan.

cases, and in the application of the correct treatment protocols and in monitoring the etiology of STI syndromes.			Training is being designed for health care personnel.
Stigmatization and discrimination towards PLHIV is still evident, particularly towards MSM and transgender persons in health care services.	Mediu m	Stigmatization and discrimination increase the risk of limiting access to health care services by the key population groups.	Training for health care personnel on how to provide adequate care for the key population groups. Implementation of the gender strategy with an educational component.
Research on monitoring of and resistance to antiretroviral drugs is insufficient.	Low	The lack of research on resistance to antiretroviral drugs is increasing the risk of infective treatments and increased morbidity and mortality among PLHIV undergoing ART.	We are seeking to close the gap identified in relation to resistance studies, and acquiring the necessary products.
Representatives of key population groups have not been fully integrated into the health care team, and this is limiting their participation in the planning and implementation of educational activities and in the analysis of the health situation at the local level, as a basic means of improving the health of that community.	Low	The lack of exchanges between the key groups and health teams means that the work being done by these groups is not reaching the community level, and this could increase the risk of resources being concentrated on non-essential activities rather than being geared towards the problems of those groups.	The decentralization of care at the community level and its incorporation for exchanges with the health authorities.

# 1.2. Limited relevance of the program.

The greatest risk of limited relevance of the program lies in the dilution of the impact of the project's activities.

Weaknesses	Degre e of risk	Risk	Mitigation
Consolidating integration between health care teams and civil society groups, sharing leadership over the educational approach for key population groups.	Low	The lack of exchanges between key groups and health teams means that the work being done by these groups is not reaching the community level, and this could increase the risk of resources being concentrated on non-essential activities rather than being geared towards the problems of those groups.	Integrating the work of health care teams with activities implemented by the key population groups to achieve greater impact.
Confirmatory diagnosis is centralized and relatively lengthy.	Mediu m	The time that elapses between requesting an HIV test and confirming the diagnosis can mean that there are delays in providing care, treatment	Diagnosis is being decentralized and the confirmation process strengthened in order to shorten the times involved and to ensure that new

		and follow-up for HIV positive patients, increasing the risk of exclusion of these key groups.	cases are included in the system as quickly as possible.
Low technical quality of leaflets and other promotional items.	Low / mediu m	The risk of educational or training messages not achieving the desired result	A directorate has been set up to review and validate media in order to achieve the desired effect
Low technical quality at workshops and meetings: It is not uncommon for these events to lack properly qualified teachers or personnel to transmit key knowledge aimed at bringing about change	Mediu m	Insufficient training of promoters, peer promoters and other actors who have a direct bearing on changes in the behavior of key population groups	Raising the bar when it comes to preparing training activities, requiring more highly qualified personnel to provide training.
Cross-sector activities in the most affected people's councils are still weak, and the management of the Basic Health Care Team needs to be improved.	Low	A lack of coordination among basic teams, which could lessen the impact of their activities.	Establishing the right vertical flow from the basic to the central level and vice-versa.

# 1.3 Inadequate quality of M&E

Throughout its history the project has strengthened and used the structure provided by the national monitoring and evaluation system, avoiding the creation of parallel evaluation systems.

Possible weakness	Degre e of risk	Risk	Mitigation
Frequent delays, submitting incomplete or low-quality reports (half-yearly progress reports on the project - PUDR).	Low	A lack of information in the Global Fund portfolio that might allow corrective action to be taken.	PUDR, EFR and other reports have been submitted on-time throughout the project's history.
A high degree of complexity in the implementation of projects, owing to the number of subrecipients, access to implementation sites for project activities, oversized projects.	Mediu m	The project has had a high number of sub-recipients. The large number of SRs could mean that the work of the PR is overloaded, diluting the impact of the project.	Adjusting the number of SRs to include only those that are in charge of the key population groups and the care, follow-up and treatment of the epidemic, establishing technical alliances where possible with other partners such as WHO/PAHO.
A lack of human resources, knowledge and experience of the Global Fund reporting requirements.	Low	A lack of quality in the information sent to the Global Fund, which is preventing corrective action from being taken when implementing the project.	MINSAP and the PR have sufficient human resources with vast experience of the implementation of Global Fund projects.
A lack of information systems.	Low	Information that is not verifiable, and poor reliability of data.	MINSAP, ONEI and the PR have adequate information systems.
A history of a failure to comply with the terms and conditions of Global Fund Agreements.	Low	Delays in disbursements required for the	The PR does not have a history of non-compliance with the terms and

		implementation of the project.	agreements with the Global Fund.
Collection of inadequate data and low quality information, which tends to have a knock-on effect on other risks such as treatment and even including the risk of financial fraud.	Low	A lack of reliable data that would allow the impact of the grant to be measured.	Both ONEI and the PR have been working on the project for more than five years, and this has allowed them to accumulate knowledge and experience. The teams of ONEI, the PR and MINSAP have sufficient personnel.
Weaknesses in planning mechanisms and in the manner in which information is used, including M&E policies and guidelines, and in the distribution of roles to ensure the quality of information at every level.	Low	Failures in terms of data collection mechanisms, their use and the bodies responsible for managing them, all of which is preventing the progress of the project from being measured.	The project document signed at the beginning of the grant process established the coordination unit responsible for overseeing the project's M&E activities and guaranteeing adequate liaison between the different actors involved in M&E.

# 1.4 Risk of not reaching the objectives relating to impact and output

Possible weakness	Degre e of risk	Risk	Mitigation
Limited work in proximity to people who practice transactional sex (PPTS), for which group the cross-sector activities have not yet provided the integration required in order to respond to the strategy aimed at preventing STIs and HIV in men and women who practice transactional sex within priority municipalities.	High	Limited contact with the population group that practices transactional sex, limiting the possibility of behavior change. This limited work could have a direct influence on the impact indicator associated with PPTS interventions.	Inclusion of peer-based work with PPTS among young people, MSM and transgender persons to reduce the harm to this population group for which a working group has not been formed.
A low capacity for the distribution of health care materials and products.	Mediu m	A direct negative impact on the intervention associated with prevention activities and service packages.	Improvement of the distribution flow, to incorporate materials and products from the project in the distribution network for the national system.

# 2. Fiduciary and financial risks

The project has established a series of controls to prevent money from being wasted and to mitigate the risks in this area.

Possible weakness	Degre e of risk	Risk	Mitigation
Delays in the project's payment mechanisms.	Low	Loss of credibility and a lack of trust in dealings with suppliers, which is limiting the capacity of procurement processes.	The project has established fast payment mechanisms that allow activities to be implemented in accordance with the action plans.
A lack of control mechanisms for the projects, which could facilitate fraud or corruption.	Low	The deviation of funds, which is affecting the expected outcomes of the	Thanks to the way in which it is structured, the project has counterbalance and

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		grant and giving rise to a loss of confidence in the PR, the Government and the donor.	mutual control mechanisms. Apart from that, the PR carries out annual audits that are shared with the Global Fund. Throughout the 11 years implementing the Global Fund projects no weaknesses have been detected in the control mechanisms for the project.
Low capacity for financial absorption	Low	Evidence of poor planning or deficiencies in the implementation of planned activities	There has been no poor usage of the financial resources provided by the grants, and the planned activities have been executed satisfactorily.
Poor financial efficiency	Low	Poor control of resources, encouraging deviations and improper use.	In line with the International Public Sector Accounting Standards, the project has established a policy of zero cash advances. The PR is using the ATLAS Enterprise Resource Planning system for global financial monitoring and control, which facilitates the separation of duties. There is no history of deviations of funds during the project.
Market and macroeconomic losses	Low	Use of resources to cover losses, limiting the implementation of planned activities.	The PR has established the mechanisms that allow it to minimize potential financial losses. Throughout the project's history there have been no macroeconomic losses.
Poor financial reporting	Low	A lack of knowledge regarding how the grant is progressing and of the causes for any delays, which would allow corrective measures to be taken.	The use of the ATLAS system mitigates the possibility of financial inefficiency, allowing payments and the costs associated with the project to be monitored and tracked. These are regularly supervised during Global Fund audits. Financial reports, including EFR, have been submitted on-time and have been of the required quality.

3. Risks associated with the procurement, distribution and storage chain (Procurement and Supply Management -PSM)

Weaknesses	Degre e of risk	Risks	Mitigation
Fluctuations in condom supplies, leading to stockouts	High	There may be delays in the PSM distribution chain for	Improvement of the distribution flow, to

and non-compliance with indicators for sales completed, as well as quality control difficulties for each of the points in the distribution chain.		condoms and teaching materials. There is a history of shortcomings in the distribution of the supplies required in order for the project to function properly.	incorporate materials and products from the project in the distribution network for the national system.
Around 23 percent of persons who are undergoing treatment are consuming one or other of the antiretroviral drugs that are not recommended today by WHO, and the procurement plans approved by Global Fund are not sufficient to ensure that they are phased out completely.	Mediu m	There may be delays in the procurement and supply management chain, including the purchase of medicinal products.  There is a history of stockouts of antiretroviral drugs purchased by the project.  The economic blockade by the United States against the country complicates the purchase of medicinal products, equipment and reagents.	Seeking out new alternatives to ensure the availability, quality, timely supply and stability of supplies and the best prices to maximize the procurement of antiretroviral drugs, looking into the possibilities offered by Strategic Funds or Reimbursable Aid. Increasing the coverage "buffer" to 6 additional months of stocks.
Around 72 percent of the PLHIV require ART. We do not have all of the medicinal products and reagents required for the treatment and follow-up care that they need, according to the new WHO guidelines for treating PLHIV under 500 CD4/mm3. The economic impact of this update will reduce the number of persons with access to antiretroviral drugs and follow-up tests.	Mediu m	The lack of a significant buffer poses a permanent risk to the implementation of the project.  There is a history of stockouts of antiretroviral drugs purchased by the project.  The economic blockade by the United States against the country means that the purchase of medicinal products, equipment and reagents is difficult.	An increase in the volume of antiretroviral drugs purchased, according to the new ART strategy (regimen 2.0), increasing the buffer from 3 to 6 months' cover.
A lack of adequate procedures for the storage and distribution of health care products, including managing high temperatures. Failure to monitor the quality of products or poor quality control.	Low	Loss of health care products caused by poor handling, which could have a negative impact on the outcomes of the project.	The storage procedures for health care products have been assessed repeatedly by LFA. There is an adequate quality control system for these products, as explained in the Quality Assurance Plan.
Low technical capacity, low levels of quality testing, or a limited capacity on the part of bodies responsible for regulating the quality of medicinal products.	Low	Poor use of grant resources destined for the purchase of medicinal products.	Medicinal products are purchased in accordance with the Global Fund and UNDP procedures and subject to WHO quality criteria. Medicinal products are regulated by the regulatory authorities in the country, in accordance with domestic regulation criteria.
A lack of planning or budgetary allocation for activities aimed at monitoring the quality of products included in the country's proposal, including adequate quality control of pharmaceutical products throughout the supply chain.	Low	The development of resistance to medicinal products as a result of the purchase of low quality antiretroviral drugs or poor handling of those drugs throughout the supply chain.	The Quality Assurance Plan has been approved by the Global Fund and it has adequate budgetary support.

A history of a large quantity of expired, contaminated or counterfeit health care products to be found throughout the supply chain.	Low	Decreased compliance and the development of resistance to treatments caused by the repeated suspension of treatment as a result of a lack of adequate medicinal products.	Throughout the project there has been no history, either on the part of the PR or the ALF, of expired, contaminated or counterfeit products purchased using funds from the project.
A history of a lack of compliance with the criteria established by the Global Fund in its quality assurance policy for products purchased for the projects, including the purchase of health care products that do not meet the quality criteria established by the Global Fund, the use of laboratories that do not meet the Fund's quality criteria, or the introduction of low quality products throughout the supply chain.	Low	A lack of quality products that allow proper treatment to be offered to PLHIV.	There is no history of a failure to comply with the quality criteria established by the Global Fund in relation to its quality assurance policies applicable to medicinal products.

## 4. Governance risk

Weaknesses	Degre e of risk	Risk	Mitigation
A lack of supervision by the CCM	Low	A lack of awareness among the key population groups and other members of the CCM of the financial and programmatic progress made in relation to the project, preventing corrective action from being taken as required.	The CCM is functioning correctly, in accordance with the criteria established by the Global Fund. There is no history of noncompliance on the part of the CCM in Cuba.
A lack of supervision by the Principal Recipient.	Low	Mismanagement of the grant and haphazard task implementation.	The PR is functioning correctly, in accordance with the criteria established by the Global Fund. There is no history of noncompliance on the part of the PR in Cuba.
Inadequate reporting and non-fulfilment of commitments to the Global Fund.	Low	A lack of awareness when managing the Global Fund portfolio of the actual state of implementation of the project, giving rise to mistaken interpretations of the realities facing the country.	The CCM and the PR have sent all necessary documentation to the Global Fund in order to comply with all of the criteria established by that organization. There is no history of non-compliance on the part of the CCM or the PR.

# CORE TABLES, CCM ELIGIBILITY AND ENDORSEMENT OF THE CONCEPT NOTE

Before submitting the concept note, ensure that all the core tables, CCM eligibility and endorsement of the concept note shown below have been filled in using the online grant

management platform or, in exceptional cases, attached to the application using the offline templates provided. These documents can only be submitted by email if the applicant receives Secretariat permission to do so.

- ☐ Table 1: Financial Gap Analysis and Counterpart Financing Table

- □ Table 4: List of Abbreviations and Annexes
- □ CCM Eligibility Requirements
- □ CCM Endorsement of Concept Note